CervicalCheck Steering Committee Weekly report to the Minister 7 September 2018

1. Update on support package and ex gratia payment

The HSE reports that Liaison Officers have held 293 face-to-face meetings with women and families to discuss their needs. This includes 176 initial meetings and 117 follow-up meetings, together with other regular interactions between women, families and Liaison Officers.

Delivery of supports

- The HSE has now issued 680 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 fertility treatments and adoption. The decision has now been made to fund IVF, both
 retrospectively and prospectively, and Liaison Officers are engaging with relevant patients
 to advise them that this decision has been made. The Department intends to engage
 further with DCYA to further progress contact between patients and Tusla.

Ex gratia payment as recommended by Dr Scally

Liaison Officers have been 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 207 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:

- 123 legal requests have been received to date, of which 3 were received within the past week; 102 have been processed, of which 1 was within the past week
- 281 FOI or data access requests have been made and 256 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. Representatives from CervicalCheck met with one solicitor who had raised concerns in relation to the protocol for the provision of slides and reported that the issues raised have been addressed.

• 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. Five 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 issuing of consent letters to the remaining ~1,600 women and families has begun. The first 100 of these issued on Thursday 6th of September and it is intended that the majority of the remaining consent letters will have issued by the 14th of September.
- The HSE has advised that letters to next of kin in cases where women are deceased will take longer as the process of validating the details of the next of kin is more complex. An update on the envisaged timelines for this has been requested for next week.
- Of the letters already issued, 49 have consented and 10 have refused consent.
- There was some concern among women with pending legal cases or those considering taking legal action in relation to the length of time that their slides would be unavailable to them during the RCOG process. 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.

- 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.

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. The Group received research findings on 24 August which have been used to update draft materials, that are now 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. A key decision for the Clinical Advisory Group is the choice of HPV assay, required before finalisation of tender documentation.

A site visit to the Netherlands took place on the 6th of September, with a further visit to the UK planned in the coming weeks, which will inform the procurement process. Procurement of market analysis to inform specification and market model is to be completed by 11 September. Department officials met with the HPV project team this week for a detailed discussion on the project plan, and a further meeting will follow.

Interviews for a Clinical Director for CervicalCheck took place on 22 August. Negotiations with the successful candidate are underway and it is hoped that the appointment will be finalised shortly.

6. Smeartaking activity

The HSE has reported that lab activity remains approximately 20% above normal levels. The total number of additional consultations to date is over 70,000. The issue of the backlog of smear tests is a priority concern for the HSE as the current average processing time is 52 days.

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.

The current contracts with the labs are due to expire in mid-October. Negotiations with the labs in relation to contract extensions to cover the period until the roll out of HPV testing are underway.

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.

7 September 2018

.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)	9	176 initial meetings and	117 additional
	3		meetings.	
	Number of medical cards issued	12	680	
	Number of ex gratia payments made	4	207	
	Number of supports requested	5	481	
			Top ten supports request	ed to date:
			Counselling	141
			Complimentary Therapy	41
			Transport costs	41
			Medical appointment	
			expenses	30.00
			Medical Notes	25
			Diagnostic HCP	24
			Childcare Costs	23
			Fertility	19
			Physio	18
	Number of supports provided	5	357	1
			Top ten supports provide	d to date:
			Counselling	105
			Transport costs	33
			Complimentary Therapy	29
			Medical appointment	
			expenses	26
			HCP Childcare Costs	21.00

Current position, issues & challenges			
	Disabilities	11	
	Medication	13	
	Medical Notes	19	
	Diagnostic	20	

- Clients have expressed concern with regard to the RCOG process.
- Clients continue to advise of their infertility issues and their desire for support on these matters. Following a discussion with the DoH the patient representatives have been advised of the decision to fund IVF treatment. Liaison Officers will now engage with relevant patients.

t Manager in Place is an operational manager assigned to oversee access to records and smear results. tional Team Composition this process was not in place prior to the cervical check crisis a team has been d and work is progressing to expand the team to ensure that women and their legal entatives receive their records in the most timely manner possible. am comprises of:	Ves V	No
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am comprises of:		1
- PM for overall coordination.		
- Three legal personnel in Dublin.		
- Two Administrative support personnel.		
 Additional two admin resource's required. 		
t Plan	V	
is a defined operational process for the release of records.		
	This week	To date
er of legal requests made (reclassified)	3	123
er of legal requests responded to (reclassified)	1	102
0 - 30 days	-	91
*30 days +	-	11
er of requests on hold, awaiting clarification from solicitor	-	2
er of FOI / Data access Requests made	2	281
	5	256
er of FOI / Data access Requests responded to	-	238
er of FOI / Data access Requests responded to 0 - 30 days		18
0 - 30 days	3	19
0 -	•	·

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 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 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.

L.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	
	We are working to the timeframes as outlined by Dr Scally.		
	Current position, issues & challenges		
	 Issues regarding searchability have been addressed. Closed. 		
	2. Documentation has been provided to Dr Scally in line with his requirements.		
	3. The HSE DG has continued to link with Dr Scally on a regular basis to ensure that the review	is supported b	y HSE leadership.
	4. Dr Scally is now concluding his report and we are still proving any clarification necessary.		

1.d	Interface with RCOG Review	Yes	No
	Project Manager in Place	٧	
	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 1st of August.		
	Project Team Composition	٧	
	 Meeting of RCOG Programme Team held on the 30th Aug to progress RCOG Review Panel Support Programme Governance, Workstreams and Communications. Terms of Reference for Programme Team and Project Initiative Document (PID) progressed. Project plan for phased issue of letters to remaining cohort of women completed. Teleconference held on the 30th Aug between the RCOG support team, DOH and RCOG Expert Review Panel to progress key elements of the project. 		
	Workstreams currently: Patient Support Services Call Centre Coordination Case Management System (workstream to be closed when CMS design complete) Communications Acute and Community Services Laboratory Services Coordination A lead coordinator is in place for each workstream in order to oversee actions and workflow, and to ensure agreed deliverables are achieved within timeframes.		
	Progress against Project Plan	٧	

Workstream	Actions Progressed (w/e 31 Aug)
Patient Support Services	59 (27%) consent forms returned from the first cohort of women and next of kin. 49 have consented to take part in the review.
	Patient Support Services Liaison for RCOG Support Team participated on weekly teleconference with Patient Liaison Officers on Tuesday 28 th Aug, to keep them updated on process and get feedback.
	Detailed project plan for coordination and circulation of remaining letters is complete. The balance of letters will commence to be issued on the 6 th through to the 15 th Sept.
Call Centre Coordination	Manual for call centre staff updated as of 27 th Aug, including information on "slides tab" in Case Management System. There have been a very small number of calls from women to the RCOG call centre to date.
Case Management System	 Data validation is underway for the remaining cohort of women. Liaised with key stakeholders on audit process for definitive cohort identification.
Communications	Overseeing queries coming in through HSE Comms / HSE Digital.
HSE Services	 Acute Services: Telecon with acute services rescheduled for Wednesday 5th Sept. Colposcopy Units and Healthcare Service Providers: letters to be circulated. Commenced engagement process with stakeholders to supply relevant medical records from acute & community services to RCOG Review Panel, where requested.
Laboratory Services	 Queries on slides process, submitted to RCOG for confirmation - received feedback from RCOG. Call held with RCOG and DOH on 30th August to obtain clarity around slide review timelines. Meeting held to discuss slide transfer protocol and process for transfer of slides.

Current Position, Issues and Challenges

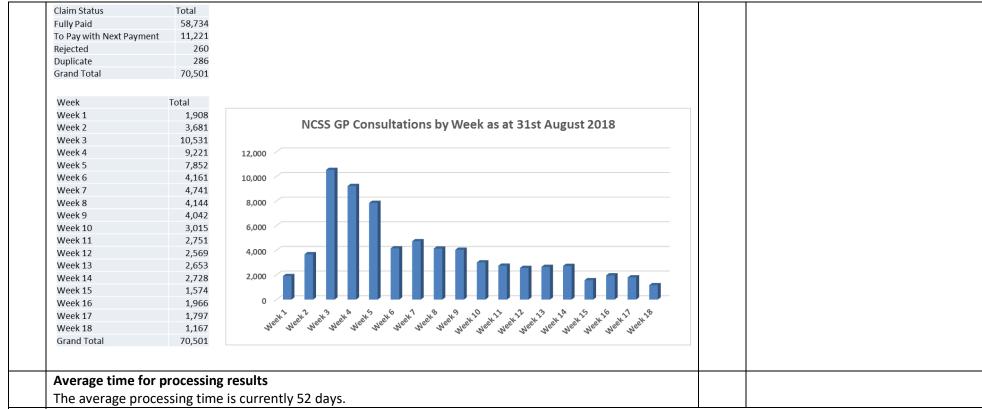
- Data management system being progressed.
- Letters for remaining cohort of women and next of kin in draft and will be updated to reflect information received from RCOG.
- Timeline for phased issue of letters of next cohort of letters agreed.

Next Steps

- RCOG Governance: Complete Project Plan.
- Patient Support Services: Issue reminder letters to 1st cohort of women and next of kin and complete draft of letter to remaining cohort following teleconference with RCOG and DOH on 30th August with a view to issue on a phased basis commencing 3/9/18. Continue regular communication with Patient Liaison Officers.
- Call Centre: Further training to call centre staff on slide tab in the CMS. Follow up on calls received through information line. Update call centre manual. As remaining letters are issued, assign additional resources to the call centre in line with the project plan timelines.
- HSE Services: Teleconference with Acute Hospital CEOs scheduled for Wed 05th Sept. Progress establishing process to supply relevant medical records from acute, primary and social care services to RCOG Review Panel, where requested.
- CMS: Progress design of CMS to required parameters, pending validation of data. Complete audit process for definitive cohort identification.
- Communications: Complete Communication Plan.
- Laboratory Services: Identify timelines for transfer of first batch of slides to RCOG.

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 in terms of financials 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.				
	Uptake of smear tests:				
	Out of cycle smears				
	Total number of additional consultations to date is more than 70,000. 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 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.				
	table below sets out the increased humber of or consultations.				
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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	٧	
	Yes. A Project Manager is in place and negotiations are continuing again this week with a possible		
	clinical Lead for the HPV primary screening project.		
	Project Team Composition	٧	
	 In the absence of a clinical lead for the project (Issue), a clinical advisory group is being 		
	formed, to be chaired by the interim Clinical Director of the programme. Key clinical		
	decisions and recommendations required for project advancement will be determined by		
	this group.		
	Immediate activities		
	 Detailed capacity planning with the Coombe and NVRL to continue in September to review 		
	their capability to deliver HPV primary testing (i.e. adequate resources, IT requirements		
	and timelines to deliver any changes to their systems)		
	 The Holland site visit to explore their approaches to HPV testing roll out is now scheduled 		
	to take place this week (6 th & 7 th Sept). 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		
	mid-late Sept.		
	 Interim Clinical Director has nominated representation for a Clinical Advisory Group. TORs and letters of invite to be issued this week. 		
	and letters of invite to be issued tills week.		
	Current position, issues & challenges		
	 Stabilisation of the current programme (increase in demand on the laboratories and colposcopy with repeat and additional workload) 		
	 Intense negotiations continue with existing labs. Key issue for the laboratories are reputational and financial concerns. 		

f	Introduction of HPV Screening	Yes	No
	3) Absence of a fulltime Clinical Director for the programme is impacting a number of	f	
	key activities.		
	 Decision required on the cervical screening pathway 		
	 Decision required on the HPV test assay 		
	A Clinical Advisory Group is being setup to mitigate the risk of no Clinical Director or		
	lead for the programme.		
	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 projec	t	
	to be defined.		
	Update Action 04/28 Update on the possibility of appointing a clinical lead for the move to HPV to	sting will be prov	ided next week.
Update on 14/08/18: The negotiations with the possible candidate to take on the clinical lead role were unsuccessful. We are go expression of interest to the clinical community. Update on 05/09/18 A further expression of interest was issued again last week			
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. Up			
	05/09/18 The offer was made and final negotiations are concluding with the successful candidate		
	Update Action 04/29 A review meeting is being scheduled with DoH regarding the project plan.		

3 Implementation assurance on Scally Inquiry and RCOG recommendations

Members of the Scally Implementation working group

CervicalCheck Team:

- Smear taker Co-ordinator
- Senior Health Promotion Officer

National Screening Service team:

- Communications Information Manager
- Information and Communications Officer

Advocacy Team:

- Head of Open Disclosure
- Members of the Advocacy team on a needs basis

Communications Team:

- Client Services Director
- Senior Comms Manager
- Content Manager
- Content writer
- Communications Manager

Based on the phase of development different skill sets such as user testing, web development and social media management will be used. 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.

Reference Group Membership

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.

3.a	Scally Inquiry recommendations	Current position, issues & challenges	Deadline	Status
	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	NALA has reviewed the documentation and suggested changes to content and to the format of the materials. These are in the process of being implemented. The ESRI has provided a paper on "Behavioural Principles of Good Risk Communication" that will be considered by the working group at workshop on 4 th of September, along with the feedback from NALA. Research update: PPI: 6 of the 9 evaluations have been returned. Professional Interviews: 5/6 complete, there is one outstanding interview due to annual leave. Fact checking on website continues and scoping out of additional UX research for the website is being progressed.	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

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			