CervicalCheck Steering Committee Weekly report to the Minister 19 July 2018

1. Overview

The Steering Committee met on Thursday 19 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

The HSE reported that Liaison Officers have to date held 215 face-to-face meetings with women and families to discuss their needs. This includes 166 initial meetings and 49 follow-up meetings.

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. 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 (20 July) it was expected that 193 payments would have been made. Remaining payments will be completed once individuals' banking details have been received.

Delivery of supports

- As of 19 July, the HSE had issued 590 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 has developed a simplified claim process for women and their families to minimise the burden involved while providing required assurance from a public finance perspective.
- Agreement has been reached in relation to the payment of retrospective expenses. The
 Department will write to the HSE requesting that arrangements be put in place to enable

retrospective financial assistance to be provided in respect of the full period since the date of diagnosis and in respect of the categories of costs covered by the Government decision of 11 May.

4. Release of records

A significant team is in place in CervicalCheck to deal with requests for records. The HSE has confirmed that the majority of documents are now being provided within agreed timelines. 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.

- 119 legal requests have been received to date, of which 2 were received within the past week; 86 have been processed, of which 15 were within the past week
- 188 FOI or data access requests have been made and 180 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.

The HSE have confirmed that as of next week there will be a single point of contact in place within the HSE to assist women and families in retrieving their records, which may be kept in multiple locations.

5. International Clinical Expert Panel Review

Representatives from the Royal College of Obstetricians and Gynaecologists (RCOG) visited Dublin on Tuesday 17 July and met with the Minister, Department officials, the HSE, a patient representative and the medical colleges. RCOG emphasised the importance of their independence throughout the process.

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 HSE is finalising an overall resource plan for the review and priority tasks have been identified and are being advanced. It has been agreed that consent will be required from all women or their next of kin before their slides are included in the review. The approach for obtaining consent will be tailored to the different cohorts of women and families involved, recognising the very sensitive nature of this issue. A letter will be drafted to be used as part of the consent process. 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, is in place.

The HSE has reported that work has begun on implementing the plan, 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. 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, and it is working to secure further specialist expertise to support the project. 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.

8. 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. However, there is a significant backlog of smear tests which remain to be analysed. The HSE is monitoring this through weekly calls and meetings with the labs to manage the situation. Any available lab capacity is being used to process the tests as quickly as possible, while having regard to the rigorous testing requirements. With regard to GP consultations and smeartaking activity, the HSE has advised that claims for 50,194 GP consultations have been submitted in the past eleven weeks.

9. Communications

As agreed at the meeting of 12 July, a draft letter to the 221 women involved in the original audit has been prepared. This was submitted to the Steering Committee at this week's meeting for feedback, with a view to issuing the letter early next week.

20 July 2018

Oversight and engagement with the HSE on modules of their work as follows			Deadline	Status
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 Liaison Officers in each of (Community Healthcare Organisations)				
Project Plan				
	This week	To date		
Number of meetings held with affected women & families (Liaison Officers)	15	166 initial meetings 49 additional meetings.		
Number of medical cards issued	33	590		
Number of ex gratia payments made	20	186		
Number of supports requested	27	415		
Number of supports provided	42	162		

1	Oversight and engagement with the HSE on modules of their work as follows			Deadline	Status
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.	٧			
	Operational Team Composition				
	While this process was not in place prior to the cervical check crisis a significant team has been put in pace to ensure that women and their legal representatives receive their records in the most timely manner possible. The team comprises of:				
	 Operations manager responsible for overall coordination Four legal personnel with three in Dublin and one part time in Limerick Administrative support 				
	Initially the operations manager was reassigned within screening given the priority attached to the release of records. A new operations manager is starting next Monday to increase capacity.				
	Project Plan	٧			
	There is a defined operational process for the release of records.				
		This	То		
	Number of legal requests made	week 2	date 119		
	Number of legal requests responded to	15	86		
	Transact of legal requests responded to	1.0	50		L

1	Oversight and engagement with the HSE on modules of their work as follows			Deadline	Status
1.b	Provision of documents to patients				
	0 - 30 days		84		
	30 days +		2		
	Number of requests on hold, awaiting clarification from solicitor		4		
	Number of FOI / Data access Requests made	10	188		
	Number of FOI / Data access Requests responded to	13	180		
	0 - 30 days		170		
	30 days +		10		
	Current position, issues & challenges				
	Daily workshops continue to assess progress being made, with a focus on responding to all requests as soon	as poss	ible.		
	Update Action				
	One patient expressed concern at the level of redaction in her document. These redactions were necessary as there was some data which related to other patients. A letter is being issued to explain this to the patient in question.				

1	Oversight and engagement with the HSE on modules of their work as follows		Deadline	Status
1.b	Provision of documents to patients			

1	Oversight and engagement with the HSE on modules of their work as follows			Deadline	Status
1.c	Interface with Scally Inquiry				
		Yes	No		
	Project Manager in Place	٧			
	Yes – A senior manager is assigned to oversee the timely release of documents to Dr Scally's review.				
	Project Team Composition				
	There is a legal services partner with a significant number of solicitors to support the release of documents. In addition we have another 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 for Dr Scally.				
	Current position, issues & challenges				

1	Oversight and engagement with the HSE on modules of their work as follows		Deadline	Status
1.c	Interface with Scally Inquiry			
	 Issues regarding searchability have been addressed. Continuing to supply documents as requested by Dr Scally. DG is linking with Dr Scally on a regular basis to ensure that the review is supported 			
	Update Action			

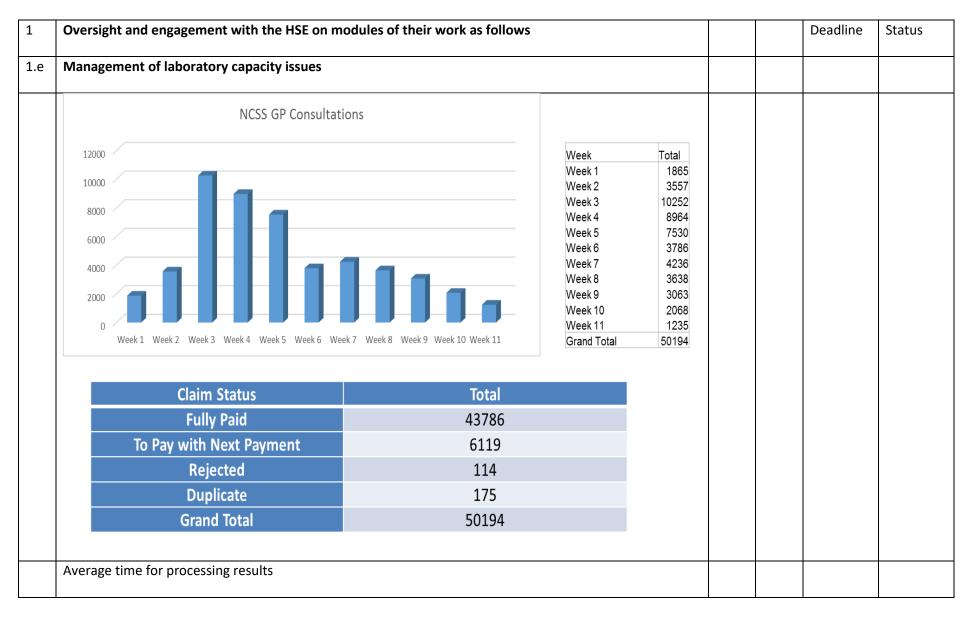
1	Oversight and engagement with the HSE on modules of their work as follows			Deadline	Status
1.d	Interface with RCOG Review				
		Yes	No		
	Project Manager in Place	٧			
	A Senior manager is being recruited to head up the HSE response and we expect to have this person in place in the next two weeks. In the interim the NSS Head of Operations and CervicalCheck programme manager are covering the project.				
	Project Team Composition				
	There are four main sections for the team required to support RCOG. These are:				

1	Oversight and engagement with the HSE on modules of their work as follows		Deadline	Status
1.d	Interface with RCOG Review			
	- Patient services			
	- Logistics (to support laboratories transfer process)			
	- Hospital co-ordination and delivery			
	- Communications			
	An overall resource plan is being finalised following the meeting with RCOG this week while priority positions are being filled. A Patient Services manager has been assigned to lead the patient services team.			
	Project Plan			
	HSE are developing a plan alongside the overall RCOG plan. Priority tasks have been identified and these are being advanced while the full project plan is being worked through with RCOG. The HSE Interim Lead is scheduling a meeting with the RCOG Project Manager following this week's meeting with the RCOG team.			
	Current position, issues & challenges			
	There was a very useful meeting held with the RCOG team this week to set out the overall process and consider what is required. In addition RCOG are developing a clear communication on the RCOG process that will facilitate the rollout of the consent process to women.			
	Following the meeting with RCOG it is clear that significant resource is now required by the HSE to support the RCOG review. A resource plan is developed to support the review and priority positions are being filled to mitigate the risk.			
	The HSE and Department of Health will work together to agree the consent process which is the critical next step. This will then enable the consent process to commence with the women impacted.			

1	Oversight and engagement with the HSE on modules of their work as follows		Deadline	Status
1.d	Interface with RCOG Review			
	Update Action			

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	٧			
	Yes. Cervical Check Programme Manager is leading this response.				
	Project Team Composition	Υ			
	Given the nature of the issues presenting a working group is in place to support the project manager comprising of HSE procurement, HSE Legal and Cervical Check Operations team. This ensures a coordinated response to the operational issues presenting as a result of the demand arising from the out of cycle smear test.				
	Project Plan				
	The labs have seen an increase in demand as a result of the decision to provide free out of cycle smears to women plus the return of many women to the programme, which is a positive outcome. This demand is far in excess of normal levels, which is resulting in processing delays at the labs for patient smears. This remains a priority concern for the HSE.				
	The working group members are working closely with the three labs to understand and manage current capacity issues. The labs are reporting to the CervicalCheck team on a weekly basis providing status updates on the number of samples received, processing times etc.				
	Laboratory action plans are being monitored to ensure that they address the problem in the shortest possible timeframes.				
	Uptake of smear tests:				

1	Oversight and engagement with the HSE on modules of their work as follows		Deadline	Status
1.e	Management of laboratory capacity issues			
	Out of cycle smears Total number of additional consultations to date is more than 50,000. Weekly totals are still running at more than 1,000 consultations. Note the normal capacity for a laboratory as part of the programme is circa 5000 per week so we still have a 20% increase in uptake as a result on the free smear test. This is presenting serious patient safety issues for the HSE and the laboratories. Laboratories 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 consultations:			



	Oversight and engagement wit	h the HSE on modules of their work	as follows	Deadline	Status
.e	Management of laboratory cap	acity issues			
	The target cycle time is 17 days last week is:	and the average time is currently 40	days. The current reporting time for		
	<u>Lab</u>	Average Reporting Time	7		
	The Coombe	55 days			
	Medlab	47 days			
	Quest	17 days			
	Current position, issues & challe	enges			
	Our primary concern remains th	ne backlog of samples to be processe	d. We are satisfied that two of the labs		
	have addressed the backlog or he third lab but it is a concern.	nave a plan in place to mitigate this.	Ne are continuing to work with the		
	third lab but it is a concern. Weekly calls and meetings cont additional shifts have been incluwork has been undertaken with	nave a plan in place to mitigate this. I inue with the labs in order to managuded (where possible) to help ease the	e the situation. Extra resources and ne backlog and delays. While a lot of ces serious challenges in addressing		
	third lab but it is a concern. Weekly calls and meetings cont additional shifts have been incluwork has been undertaken with	nave a plan in place to mitigate this. I inue with the labs in order to managuded (where possible) to help ease the labs it is clear that one of the labs fa	e the situation. Extra resources and ne backlog and delays. While a lot of ces serious challenges in addressing		
	third lab but it is a concern. Weekly calls and meetings cont additional shifts have been incluwork has been undertaken with the backlog. A number of altern	nave a plan in place to mitigate this. I inue with the labs in order to managuded (where possible) to help ease the labs it is clear that one of the labs fa	e the situation. Extra resources and ne backlog and delays. While a lot of ces serious challenges in addressing		

1 Oversight and engagement with the HSE on modules of their work as follows				Deadline	
1.f	Introduction of HPV Screening				_
		Yes	No		
	Project Manager in Place	٧			
	Project Manager is in place and discussions are continuing with a possible clinical Lead for the HPV screening project.				
	Project Team Composition				
	The project was being led by the former Cervical Check clinical director While efforts are ongoing to secure a new clinical lead for the project a formal HPV screening project team has been established.				
	The project is being supported by the newly established Programme Management Office in the NSS. This is being led by the NSS Programme Management lead, given the priority of this project.				
	Further specialist resource is needed to support the project and given that HPV Screening has only been rolled out in a small number of countries we are searching in England, as one of those countries, for possible expertise as it does not exist in Ireland. Contact is continuing with a range of agencies to secure the required expertise.				
	A formal HPV Programme Steering group has been established to oversee the project comprising all the key stakeholders. A number of working groups are also being established to address specific aspects of the project.				
	Project Plan				

1 Oversight and engagement with the HSE on modules of their work as follows			Status
1.f	Introduction of HPV Screening		
	Planning for the introduction of HPV screening has been underway for the past 18 months but 3 months have been lost since it has been essential to prioritise the focus on managing the CervicalCheck audit incident. Further effort is required to stabilise the adverse impacts on programme delivery.		
	Five key workstreams have been identified; Clinical Pathways, Laboratories Reconfiguration; ICT; Communications and Resources for Health Professionals.		
	One of the most critical roles is the HPV Clinical Lead position and we are optimistic despite initial recruitment challenges that we can secure an appropriate candidate in the coming weeks. The critical path for the project is:		
	 Finalising the clinical model, clinical pathways and QA processes Finalising a Laboratory strategy Establishing MOUs with and between the Coombe and NVRL Public procurement tender and contact to a laboratory for the remainder of the caseload Development of IT system changes (CSR; GPs; Colposcopy; Laboratories) 		
	Current position, issues & challenges		
	A number of issues have been flagged for the HSE HPV Steering Group-		
	 Appointment of a clinical lead for the HPV screening project Decision required on the cervical screening pathway - clinical input required Decision required on the HPV test type – clinical input required Laboratory strategy Stabilisation of the current programme (increase in demand on the labs and colposcopy with repeat and additional workload) Difficulties in attracting appropriate skilled resources 		

1	Oversight and engagement with the HSE on modules of their work as follows			Deadline	Status
1.f	Introduction of HPV Screening				
	The next HPV steering meeting is scheduled for July 25 ^{th.}				
	Update Action 6/1207 An update on the possibility of appointing a clinical lead for the move to HPV testing will be provided next week			19/07/18	Ongoing
	Update Action 7/1207 A more detailed project plan is to be provided for next week's meeting			19/07/18	Ongoing

3	Implementation assurance on Scally Inquiry and RC	OG recommendations	Deadline	Status
3.a	Scally Inquiry recommendations	Current position, issues & challenges		
	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	Reviewed the existing content and analysed feedback from users from the past 12 months. Analysed google analytics to see what information that users required the most. Searched for content gaps. Content plan has been created and work is ongoing at drafting content. Assessing best approach to user testing.	31.07.18	In progress - Working group meeting taking place 19.07.2018
	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	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. Work is ongoing on logistical details on the dissemination of materials.	31.07.18	In progress - Working group meeting taking place 19.07.2018
	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	Scoping of work has commenced. Work is ongoing on logistical details on the dissemination of materials.	16.09.18	In progress - Working group meeting taking place 19.07.2018
	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	The HSE's Open Disclosure Lead has been invited to be part of the working group. There has been an initial meeting to scope out the details of open disclosure and how it relates to CervicalCheck.	16.09.18	In progress - Working group meeting taking place

3	Implementation assurance on Scally Inquiry and RCOG recommendations			Deadline	Status
3.a	Scally Inquiry recommendations	Current position, issues & challenges			
					19.07.2018pr ogress
	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 recommendations				
	Tbc				