CervicalCheck Steering Committee

Weekly report to the Minister

30 November 2018

1. Update on support package

The provision of supports to women and families is continuing and the HSE reports that Liaison Officers are working actively to better coordinate supports and to assist in future planning for the service. It is hoped that this work will be concluded in the coming weeks.

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. 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. To date, €1.04m has been reimbursed in respect of various health and social care costs, almost €833,000 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.

A note in relation to financial support for patient advocates was submitted to the Minister for consideration in recent weeks, and the Department is now in contact with the Cervical Check Patient Support Group in relation to how best to facilitate the necessary arrangements.

2. Release of records

The HSE remains focused on responding to all requests for records as soon as possible. To aid this process external legal advisors are liaising with women and their solicitors on the release of slides. The protocol in place ensures the integrity and traceability of slides being transferred; 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. The HSE has reported that the average time to deliver slides to independent experts is 25 days.

Release of some slides has been delayed. Legal representatives for the HSE have contacted solicitors to check if they are encountering any delays and to address any issues. Arising from this exercise, a number of cases have been identified where the HSE had not been informed of the requestor's name and/or the designated lab expert to whom the slides are to be sent. As a result, the HSE are working with these solicitors to ensure that all required details are sent to the labs.

3. Independent Expert Panel Review

The protocol for the International Clinical Expert Review led by the Royal College of Obstetricians and Gynaecologists (RCOG) has been published on the Department of Health website.

Over 1,700 letters have now issued providing information in relation to consent and the consent form for participation in the review, which is the total number of letters issuing directly to women affected. The remaining letters are all those issuing to next of kin of women who have, sadly, died.

Next of kin details are being provided by the relevant acute hospital. Where next of kin details could not be ascertained through acute services, the RCOG Support team in the HSE is seeking to establish details with primary care. 161 of these letters have been issued this week. 498 reminder letters have now issued to those who have not yet responded. Approximately 900 women have consented to take part in the review, with around 50 of these received this week.

The transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review has encountered some external challenges. These are being addressed as a matter of priority.

4. Validation exercise in relation to the 221 affected women

The HSE has advised it has commenced a validation exercise on the data held on the 221 affected women. This is to ensure the National Screening Service has the most up to date information, which will be used to help with planning support needs for patients, for example.

5. Laboratory contracts

Heads of Agreement have been signed with the contracted labs to extend their contracts for cytology services pending the introduction of HPV testing as the primary screening test. This allows for the continuation of the service without interruption and includes efforts to secure additional laboratory capacity to help address the backlog of smears being part of these negotiations. The HSE has confirmed that one of the contracts was formally signed this week.

6. 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. The Clinical Advisory Group established to advise on the project has made a decision in relation to the choice of HPV assay, required before tender documents can be finalised, as well as the final age range and intervals and genotyping. Dr Marc Arbyn, who was a member of the HIQA HTA panel, is also providing support and expertise to this Group. HSE officials have advised that all necessary clinical decisions which are required for drafting of procurement documents have now been made and procurement market analysis is progressing.

A pre-market engagement session took place on 27 November. Work is ongoing to finalise the laboratory strategy for the HPV test, taking account of options and the futureproofing of the service. In tandem, work on development and testing of necessary ICT changes is underway and colposcopy capacity planning is being scoped out.

7. Smeartaking activity

Continuity of supply arrangements are in place with the existing laboratories to ensure the continued provision of cytology services until the introduction of the HPV testing regime. The increased demand has undoubtedly put immense pressure on lab capacity and the HSE has been working actively with the labs to manage this. The total number of additional GP consultations to date is now over 98,000. The issue of the backlog of smear tests remains a priority concern for the HSE. As outlined above, efforts to secure additional laboratory capacity to help address the backlog of smears form part of the finalisation of laboratory contract extensions.

8. Alternative resolution mechanisms

Judge Meenan's report on alternative mechanisms to avoid adversarial court proceedings for women and their families affected by CervicalCheck was approved by Government on 16 October. Consideration of Judge Meenan's report is ongoing.

9. 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, and planning for the implementation of the 50 recommendations contained in the final report of the Scoping Inquiry has begun.

Work on the Implementation Plan for the recommendations of the CervicalCheck Scoping Inquiry is continuing, with the aim of finalising the Plan to allow for submission to Government within the three-month timeframe set out by Dr Scally. The plan was submitted to Dr Scally for his independent review on 23 November.

The next meeting of the CervicalCheck Steering Committee is scheduled for 18 December.

CervicalCheck Steering Committee
Weekly Report from HSE

Oversight and engagement with the HSE on modules of their work as follows:

- Management of supports to patients/families
- Provision of documents to patients
- Interface with RCOG Review
- Management of laboratory capacity issues
- Introduction of HPV Screening

Management of supports to patients/families	
Significant Issues	There are no exceptional items to report in relation to Community Supports.

Provision of documents to patients	
Significant Issues	**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. In some cases there have been delays with the laboratories due to operational pressures and we are ensuring that we continue to focus on reducing the time taken - the average time to deliver slides to the independent expert is 25 days. In relation to access to slides: some concerns were expressed in relation to significant numbers of women not getting access to slides, as a result we contacted all solicitors to establish if there were indeed people waiting on slides. As a result we have identified a significant number of cases where the HSE have not been informed of the requestor's name or/and their designated lab expert where the slides are to be sent to – as a result we are working with those solicitors to ensure that all required details are being sent to the labs.

CervicalCheck Steering Committee
Weekly Report from HSE

Interface with RCOG Review	
Project Management	**Project Manager in Place** Assistant National Director (HSE) commenced working as the Programme Lead on the RCOG Review on Wednesday the 1st of August. Project Manager (HSE) commenced working as the Project Manager on Wednesday the 1st of August.
Project Governance	**Programme Governance** • Support Team holds daily meetings and teleconferences to progress deliverables, identify critical actions / timeframes, areas for escalation, and project RAIDS. • Teleconference with RCOG and Dept. of Health to progress interagency logistics and communication, and discuss timeframes **Next steps** • Continue weekly teleconference with Dept. of Health and Expert Review Panel

Project Plan

Workstream	Actions Progressed (w/e 23rd Nov)

Patient Support Services	• As of Friday 23rd November:
	  ○ 1,542 invited to participate in Expert Panel Review, who are contactable and comprehended by the Review.
	  ○ 860 (56%) have consented to participate in the Review *(an increase of 2 from previous week*)
	• This week, reminder letters issued to 476 women comprehended by the Review.
	• Where Next of Kin details could not be ascertained through acute services, RCOG Support team is seeking to establish details with primary care.

Information Services	• Further to issue of reminder letters, opening hours of call centre increased to 7 days a week 9am – 6pm. • As of COB Fri 23rd Nov, there have been 119 calls to the information line (*an increase of 7 from previous week*). There was no increase in calls related to clinical diagnosis. Details as follows:

	Total Calls to Information Line — **119** Total Calls (general) — 47 Total Calls (clinical) — 72 Calls (clinical) resolved at initial contact — 49 Calls (clinical) escalated to acute hospitals, following SOP — 23 Calls (clinical) resolved by acute hospitals — 23
Case Management System (CMS)	• RCOG provided with colposcopy data and failsafe data from CervicalCheck ICT • CMS updated to include new information provided by NSS, NCRI, and GRO. • Met CMS developers to progress design improvements
Laboratory Logistics	• Responses received from laboratories in respect of slide transfer/communication SOP on 20th and 22nd Nov. • Response letters issued to labs Fri 23rd Nov offering solutions to their challenges . Meetings with labs requested for w/c 26th Nov
Communications	No update to report
Acute & Community Services	• Weekly briefing sent to hospital groups through Acute Operations, and to Lead Colposcopists through CervicalCheck • Weekly teleconference with Acute Operations • Responses provided to individual clinicians who have contacted the Programme with queries on the RCOG Support Programme and the Expert Panel Review.
Current Position, Significant Issues	• The transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review has encountered some external challenges. The Support Team has addressed those within its scope as a matter of priority, and has escalated those which are outside of its authority. • Ascertaining Next of Kin details for deceased women through acute and primary care services – taking more time than expected as requires review of medical records for this information. • After consent letters issued, the RCOG Support Team was made aware that a number of women written to were not within the scope of the Review. This issue was raised with NSS ICT and the Office of the CIO (Data Quality), which

	provided the datasets used for undertaking the consent process, and they are investigating against NCRI data provided to them. The RCOG Team is undertaking a continuous process of review and revalidation of data provided to date.

Next Steps

Workstream	Actions Planned (w/c 26th Nov)
Patient Support Services	• Issue cohort of letters to Next of Kin where details validated. Continue to ascertain outstanding contact details with primary care. • Continue scanning and logging consent returns on Case Management System, as they are received. • Continue regular engagement with Patient Liaison Officers and other stakeholders.
Information Services	• Continue follow-up on calls to information line and to dedicated email address for health professionals • Employ regular quality checks to ensure capacity meets demand. Where required, identify and assign further additional clinical & administrative resources to the call centre in line with the project plan timelines.
Case Management System (CMS)	• As letters issue, continue to update CMS with validated data • Incorporate additional requirements for slides transfers who are also involved in legal proceedings.
Laboratory Logistics	• Continue work to facilitate transfer of slides from CervicalCheck laboratories to RCOG laboratory (Bristol, UK).
Communications	• Manage feedback and queries from women/Next of Kin, clinicians, media and public as remaining cohorts of women of next of kin receive letters.
Acute & Community Services	• Continue weekly briefings and teleconferences with Acute Operations and CervicalCheck. • Continue developing protocol to support Expert Review Panel with relevant medical records from acute and community services where requested.

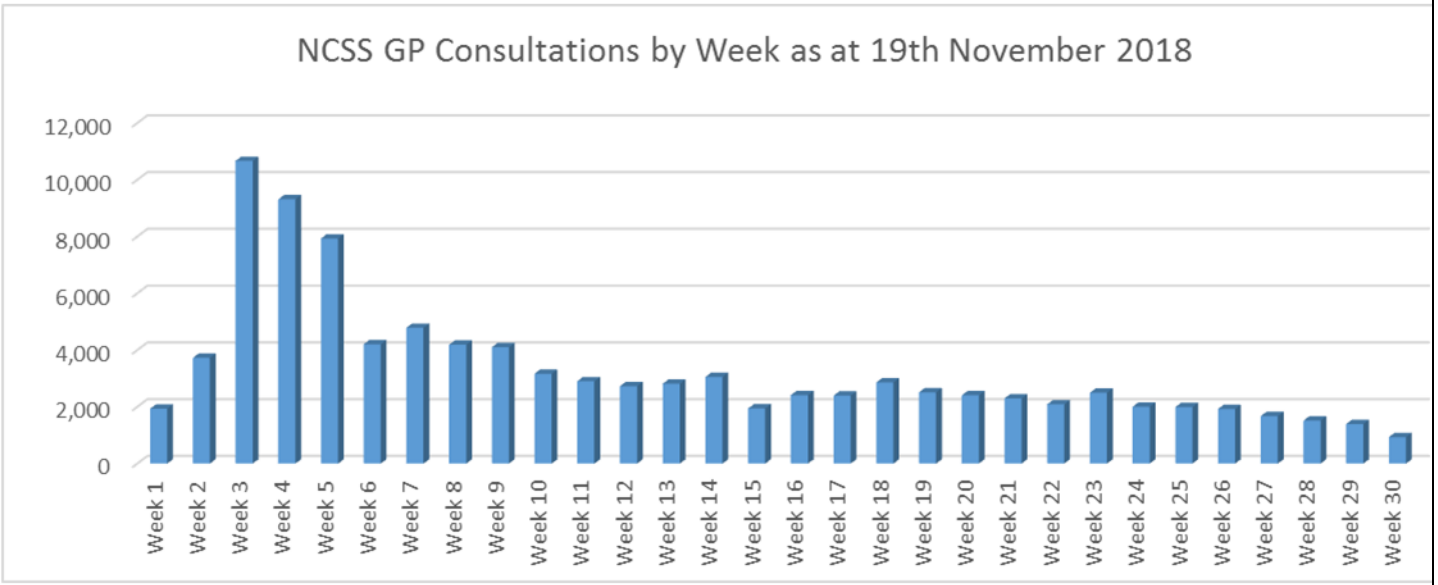
Management of Laboratory Capacity Issues	
Project Management	Project Manager in Place **Project Team Composition**

	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 group is focused on a) extension of lab contracts and b) managing the demand due to 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. Because of the skilled nature of cytology screening and the difficulty in recruiting trained staff, lab turnaround time issues can be slow to resolve. Laboratories are required to capture the smear on a slide within 6 weeks. This has been resolved with the laboratory so we do not foresee future issues. The lab working group continues to work closely with the three labs to understand and manage current capacity issues. Weekly reports are being provided and ongoing engagements to identify further actions to mitigate this risk. We are happy to say that we agreed continuity of supply arrangements with both existing cytology laboratories so that they continue to provide cytology services to CervicalCheck beyond the end date of the contract on Sunday 14th October. We are now concluding final contracts and operating arrangements with both Quest and Medlab pathology over the coming weeks. We are also trying to secure additional laboratory capacity as part of these negotiations.
Uptake of Smear Tests	*Out of cycle smears* Total number of additional GP consultations to date is more than 98,000. The knock on effect of this has been 1) the estimated number of early repeat smear tests to take place in the period of 1st May to 31st October 2018 is in the region of 48,088 2) a Global trend with respect to decreases in the availability of cytology staff has also exacerbated the ability of the contracted labs to increase their throughput through this time 3) as a result this has increased the reporting times to women up to 20 weeks and more in some cases. The table below sets out the increased number of GP consultations.
Average Time for Processing Results	The average processing time is currently 80 days.

CervicalCheck Steering Committee
Weekly Report from HSE

Week	Total
week 1	1,935
week 2	3,726
week 3	10,665
week 4	9,312
week 5	7,932
week 6	4,206
week 7	4,786
week 8	4,189
week 9	4,101
week 10	3,168
week 11	2,901
week 12	2,729
week 13	2,814
week 14	3,054
week 15	1,943
week 16	2,414
week 17	2,395
week 18	2,860
week 19	2,512
week 20	2,405
week 21	2,296
week 22	2,088
week 23	2,496
week 24	2,005
week 25	1,991
week 26	1,926
week 27	1,673
week 28	1,516
week 29	1,395
Week 30	935
Grand Total	98,368

Claim Status	Total
Fully Paid	90,934
To Pay with next Payment	6,473
Rejected	574
Duplicate	387
Grand Total	98,368



CervicalCheck Steering Committee
Weekly Report from HSE

Introduction of HPV Screening

Project Management	**Project Manager** In place. **Project Team Composition** • The expression of interests for the appointment of a Clinical Lead for the HPV primary screening project, a lead cytopathologist and a lead colposcopist were unsuccessful. NSS are currently reviewing options. • Clinical Advisory Group: international expert Dr. Marc Arbyn is supporting this group. Dr Arbyn was a member of the HIQA HTA panel and is a leading expert on HPV primary screening in Europe • Still awaiting Clinical lead, Colposcopy lead, Pathology lead.

Project Plan

Workstream	Actions Progressed (w/e 23rd November 2018)
Clinical	• Steering Group presented clinical work decisions made to date. • Assessment of feedback to proposed screening pathway and eligibility framework continues.
Procurement	• Pre- market engagement session scheduled for 27th November: preparations finalised. • Pre-registration of participants has taken place.
ICT	• CSR development - Complete and application delivered to NSS for testing. Commenced unit testing of the individual changes and testing of SSIS packages. Preparation for full system test underway. • Colposcopy IT- Changes required agreed and estimate provided by 1 of the 2 vendors. (€30k approx.) Testing sites being sought. • Laboratory IT development awaiting decisions on laboratory configuration and procurement. • GP practices – practice management IT – Healthlink: No specs for changes, if any, available yet.
Lab Configuration	• Configuration options - work limited until the market engagement seminar is completed and issues related to current programme and backolg are resolved.
Communications	• Communications lead identified for this project.

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Weekly Report from HSE

Resources for HPs	• Team continue to work on 2 pieces: 1. Developing training materials & the e-learning modules 2. Guide for Primary Care which will be available in hardcopy and through the e-learning portal.
Hospitals (Colposcopy)	• Colposcopy capacity planning and management of women referred to colposcopy continues to be scoped out. Hospital Group CEOs have officially been communicated to regarding this piece of work by ND Acute Operations.

Current Position, Significant Issues

Current position, issues & challenges

1) Continuing efforts to secure contract extensions with existing labs is critical to enable the programme to proceed.
2) Stabilisation of the current programme remains a huge issue. Current backlogs from the 2 private providers will impact the transition to HPV primary screening.
3) Absence of a fulltime Clinical Director for the programme is impacting a number of key activities.
   - ❖ Decision required on the cervical screening pathway

   A Clinical Advisory Group has been set up to address these decisions.
4) Failure to recruit a colposcopy or cytopathology lead for the program and project. There were no applicants. A letter of invite for a colposcopy lead will be re-issued to Dr Peter Boylan, Chair of the Institute for Gynaecologist and Obstetricians.
5) Laboratory configuration strategy being reassessed by requirements to stabilise current programme.
6) Market engagement seminar to assess laboratory interest in offering HPV primary screening (in November).
7) Communications resources (external & internal) have been identified and work now will commence on a communications plan for the transition to HPV primary screening.

Immediate Activities

Workstream	Actions Planned
Clinical	• Circulate scope of work and arrange series of meetings with colposcopy leads in November.
Procurement	• Finalise contract details with laboratories following agreement to continue. • Pre-tender Market engagement seminar on the 27th November in the NSS.

	• Assess outcome of market engagement seminar.
ICT	• Continued testing of changes to Cervical Screening Register. (February 2019) • Laboratories ICT development - Awaiting nomination of labs • Colposcopy IT - Awaiting feedback from the second vendor. Funding approval to be sought once we get the second estimate and a development and testing schedule can be agreed.
Lab Configuration	• Laboratory configuration strategy to be progressed following market engagement seminar and resolution of current programme issues with laboratories.
Communications	• Review workshop outcome (Comms, PMO). • Arrange a workshop with CervicalCheck staff and National Communications to deliver messages.
Resources for HPs	• Progress materials development and the appointment of the elearning technologist.
Hospitals (Colposcopy)	• Complete capacity planning exercise and schedule meetings with lead colposcopists • Secure hospital commitments for 2019. • Identify colposcopy lead for HPV project.
Update Action	**Update Action 04/28** Update on the possibility of appointing a clinical lead for the move to HPV testing. **Update on 02/10/18**-The expression of interest was extended to the 10th Oct. **Update 19/09/18** NRS are finalising the contract with the successful candidate for the post of clinical director.