CervicalCheck Steering Committee

Weekly report to the Minister

7 December 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. 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, €1.05m 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 31 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 is 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, including letters to next-of-kin of women who have, sadly, died, have now issued providing information in relation to consent and the consent form for participation in the review, and 924 women so far have consented to take part in the review. A small number of letters remain to issue to next-of-kin. The transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review has encountered some external challenges which are being addressed as a matter of priority.

4. Validation exercise in relation to the 221 affected women

The HSE has advised it is undertaking 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 has now been formally signed.

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 and submissions from those companies which attended are due to be submitted by 6 December. 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 101,000. 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.

While there is no time limit or expiry for slides in relation to cytology, there is a requirement to perform secondary HPV testing (provided where low grade abnormalities are identified in cytology, around 7-8% of all slides) within three to six months, depending on which test is used, and this is being monitored. As part of looking forward to next year, the HSE is developing a capacity plan to take account of available capacity and expected demand, with the aim of bringing the programme into stabilisation in 2019.

Following the Minister's announcement in April that any woman who was concerned about her health could have a free GP consultation and, if necessary, a repeat smear test, it has been agreed that this service will cease from 31 December. Letters issued to GPs on

Wednesday 5 December to advise them of the current position and the CervicalCheck website has also been updated.

8. Implementation of recommendations of the Scally Inquiry

The Implementation Plan, the development of which was overseen by the CervicalCheck Steering Committee has overseen the development of the Implementation Plan for Dr Scally's recommendations, and agreed the plan on 4 December last. The plan has now been independently reviewed by Dr Scally, and the Minister intends to bring a Memorandum on the Plan to Government on Tuesday 11 December.

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 31 days. The HSE continues to engage directly with the laboratories to try to make sure that slides are imaged and prepared for release as quickly as possible, and to maintain ongoing pressure on the labs to improve this element of their performance. To this end, weekly operational meetings are taking place to identify, assess and deal with blockages in the process as a matter of urgency 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 requestors 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.

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 30th Nov)**
Patient Support Services	• As of COB Fri 30th November: o 1,703 invited to participate in Expert Panel Review, who are contactable and comprehended by the Review *(increase of 161 from previous week*) o 924 (54%) have consented to participate in the Review *(increase of 64 from previous week*) • This week, letters issued to 161 next of kin in relation to deceased women comprehended by the Review. • Next of kin details for 15 women outstanding from one HG, Programme Team following up with HG through Acute Operations.

CervicalCheck Steering Committee
Weekly Report from HSE

<table>
<tr><td>Information Services</td><td>

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 128 calls to the information line (an increase of 9 from previous week). There was no increase in calls related to clinical diagnosis. Details as follows:

<table>
<tr><th>Total Calls to Information Line</th><th>#</th><th>Change from Previous Week</th></tr>
<tr><td>Total Calls (general)</td><td>128</td><td>↑ 9</td></tr>
<tr><td>Total Calls (clinical)</td><td>47</td><td>No change</td></tr>
<tr><td>Calls (clinical) resolved at initial contact</td><td>72</td><td>No change</td></tr>
<tr><td>Calls (clinical) escalated to acute hospitals, following SOP</td><td>49</td><td>No change</td></tr>
<tr><td>Calls (clinical) resolved by acute hospitals</td><td>23</td><td>No change</td></tr>
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</td></tr>
<tr><td>Case Management System (CMS)</td><td>

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

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<tr><td>Laboratory Logistics</td><td>

CervicalCheck held extended meetings with two laboratories on 30th Nov – RCOG Programme included on agenda for discussion.

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<tr><td>Communications</td><td>No update to report</td></tr>
<tr><td>Acute & Community Services</td><td>

Weekly briefing sent to HGs 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.

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<tr><td>Current Position, Significant Issues</td><td>

The transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review has encountered some challenges. These have been escalated.

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	• One HG has not yet returned NOK details for deceased women comprehended by the review. Following up with HG through Acute Operations GM. • 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 3rd Dec)**
Patient Support Services	• 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	• Meeting with a CC lab, CC Interim Programme Manager, and, RCOG Programme Lead scheduled for Tues 4th Dec to progress solutions to laboratory challenges in transferring slides. • Continue to develop database of required slides in relation to new consents, by lab.
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

CervicalCheck Steering Committee
Weekly Report from HSE

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 comprises 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 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 101,000. The knock on effect of this has been 1) the estimated number of early repeat smear test 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. In April, the Minister for Health announced that any woman of screening age with concerns about her cervical screening could avail of a free consultation, and if necessary, a free repeat smear test with any GP registered with CervicalCheck. These services will, as scheduled, cease on 31st December 2018. HSE has today (5th December) written to GPs registered with CervicalCheck to advise them of this process.

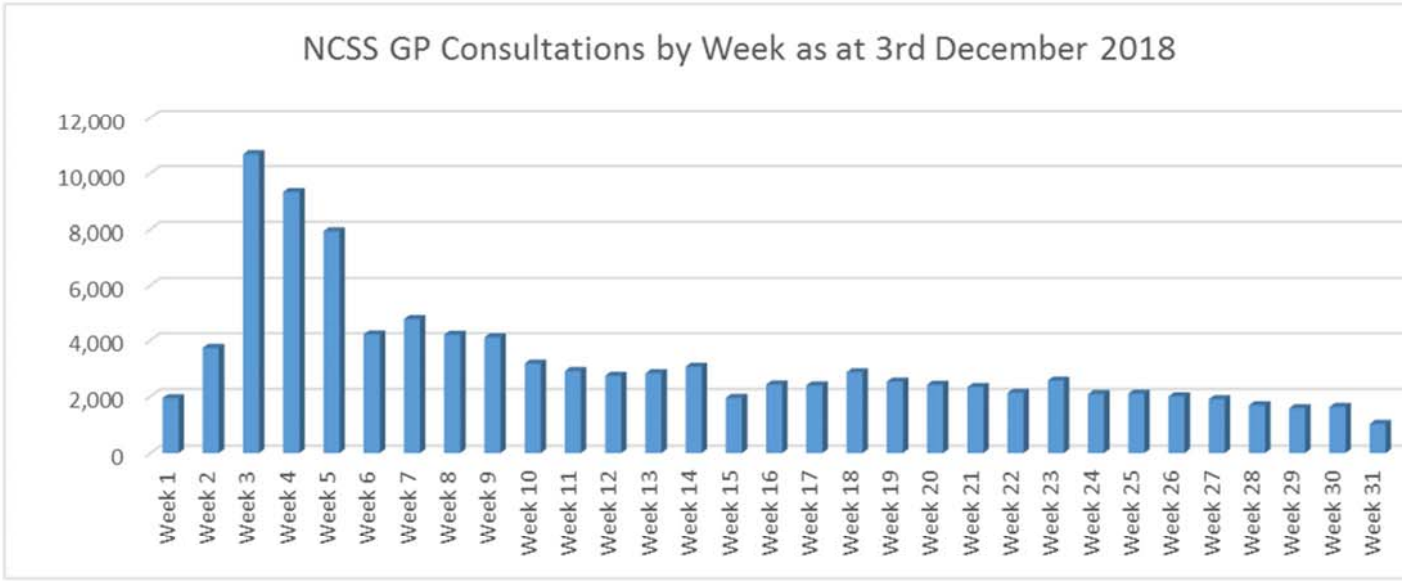
CervicalCheck Steering Committee
Weekly Report from HSE

Average Time for Processing Results	The average processing time is currently 79 days. We are monitoring the expiration of smears for low grade HPV testing. This is a challenge for laboratories. A laboratory capacity plan is being developed for the next 6 months. This is required to stabilise the programme in order for HPV primary screening to be implemented.

CervicalCheck Steering Committee
Weekly Report from HSE

Week	Total
week 1	1,938
week 2	3,730
week 3	10,675
week 4	9,325
week 5	7,940
week 6	4,212
week 7	4,791
week 8	4,197
week 9	4,105
week 10	3,171
week 11	2,905
week 12	2,735
week 13	2,820
week 14	3,058
week 15	1,949
week 16	2,421
week 17	2,395
week 18	2,862
week 19	2,525
week 20	2,419
week 21	2,328
week 22	2,124
week 23	2,561
week 24	2,079
week 25	2,095
week 26	1,997
week 27	1,896
week 28	1,685
week 29	1,577
week 30	1,622
Week 31	1,017
Grand Total	101,154

Claim Status	Total
Fully Paid	90,934
To Pay with next Payment	9,214
Rejected	619
Duplicate	387
Grand Total	101,154



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 pathologist and a lead colposcopist were unsuccessful. NSS are in discussion with a pathology lead. • 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 30th November 2018)
Clinical	• Assessment of feedback to proposed screening pathway and eligibility framework continues. • Discussion with Scottish National Cervical Screening Programme.
Procurement	• Market engagement seminar (Tuesday 27th November) completed. • Submissions from participants by 6th December.
ICT	• CSR amendments - testing commenced. • Colposcopy IT – awaiting spec agreement, funding, and agreement of testing sites. • Laboratory IT - awaiting decisions on laboratory configuration and procurement. • GP IT – no specified changes yet.
Lab Configuration	• Configuration options - work limited until the market engagement seminar is completed and current programme stabilisation w.r.t. laboratories completed. • Discussion with Scottish National Cervical Screening Programme.
Communications	• Communications lead identified for this project . To engage with team.

CervicalCheck Steering Committee
Weekly Report from HSE

Resources for HPs	• Continued work on: 1. Developing training materials & the e-learning modules; and 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 has commenced by the women & infants programme. HG CEOs have officially been communicated to regarding this piece of work by ND NAHD
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. 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. 5) Laboratory configuration strategy being reassessed by requirements to stabilise current programme and responses to market engagement seminar. 6) Market engagement seminar – assessment of responses. 7) Communications resources (external & internal) have been identified and work now will commence on a communications plan for the transition to HPV primary screening. Urgent.
Immediate Activities	

CervicalCheck Steering Committee
Weekly Report from HSE

Workstream	Actions Planned
Clinical	• Convene CAG to review clinical decisions to date and pending decisions. • Circulate scope of work and arrange series of meetings with colposcopy leads in November.
Procurement	• Finalise contract details with laboratories following agreement to continue. • Assess outcome of market engagement seminar.
ICT	• Continue testing of changes to Cervical Screening Register. (February 2019) • Labs ICT development - awaiting nomination of labs to be contacted • Colposcopy IT - Funding approval to be sought. Testing sites (colposcopy services) to be identified (Urgent).
Lab Configuration	• Laboratory configuration strategy to be finalised looking at the options and future proofing services.
Communications	• Assess workshop (Comms, PMO) outcomes on communications planning.
Resources for HPs	• Progress materials development and the appointment of the elearning technologist.
Hospitals (Colposcopy)	• Identify lead for hospitals / colposcopy requirements. • Complete capacity planning exercise and schedule meetings with lead colposcopists. • Secure hospital commitments for 2019. • Identify colposcopy lead (clinical) 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.