CervicalCheck Steering Committee

Weekly report to the Minister

2 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.

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, over €908,000 has been reimbursed in respect of various health and social care costs, almost €742,500 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.

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. Release of some slides has been delayed due to legal issues and the laboratories' focus on the contract extension and operational backlog. The HSE advises these are being escalated as a priority.

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.

- Almost 1,600 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.

- The HSE has reported that next of kin details are being provided by the relevant acute hospital. As of Friday 26th of October, this validation process is over 60% complete. The Department will continue to engage with the HSE to ensure that validation is completed and remaining letters issue as expeditiously as possible.

- Approximately 882 consent forms are reported to have been returned up to end of last week, with 96% of women who have responded agreeing to take part in the review.

- 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 HSE established a dedicated phone line at the outset of the consent process, to answer any questions women may have arising from the process. To date 100 calls have been received, of which 72 related to clinical questions. The HSE has advised that all 72 of these calls have now been resolved.

- Dr Scally's report, published 12 September, includes two recommendations in relation to clinical audit by CervicalCheck, including the development of robust and externally validated audit processes, and the inclusion of patient advocates in the oversight of clinical audits. These will be implemented in full along with the other recommendations in the report. The Minister committed to returning to Government within three months with an implementation plan for the 50 recommendations, and Dr Scally has agreed to provide a review of the implementation plan in advance of this.

4. 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. The HSE is now in the process of concluding final contracts and operating arrangements, with efforts to secure additional laboratory capacity to help address the backlog of smears being part of these negotiations.

5. Introduction of HPV as the primary method of testing

The introduction of HPV testing as the primary screening mechanism for CervicalCheck, with cytology as a reflex test, will involve a reconfiguration of the laboratory work involved. Detailed capacity planning is ongoing and introduction will be subject to a tendering process for work carried out outside the public sector. Following agreement to extend existing contracts for cytology services pending the introduction of HPV testing as the primary screening test, work is now required to finalise the laboratory strategy for the introduction of the HPV test.

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.

6. Clinical Director

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

7. Smeartaking activity

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. It has reported that lab activity remains above normal levels up to last week. The total number of additional consultations to date is over 90,000. 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, and the Minister has committed to returning to Government with proposals next month.

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.

The CervicalCheck Steering Committee will oversee the implementation of these recommendations. A draft implementation plan has been previously discussed by the Steering Committee at its meeting of 4 October. A further draft has been circulated to the Committee ahead of its next meeting on Thursday 8 November.

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 records 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. Release of some slides has been delayed due to legal issues and the laboratories focus on the contract extension and operational backlog. These are being escalated as a priority.

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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** • Project Team holds daily meetings and teleconferences to progress deliverables, identify critical actions / timeframes, areas for escalation, risks, issues, and dependencies. • Wed 24th Oct: Weekly Teleconference with RCOG and DOH to progress interagency logistics and communication **Next steps** • Further consultation on stakeholder engagement and communication plan with RCOG and Dept. of Health planned • Continue weekly teleconference with DOH and RCOG (scheduled for Thurs 1st Nov)

Project Plan

Workstream	Actions Progressed (w/e 26th Oct)
Patient Support Services	• Letters ready to issue to next of kin pending validated data provided by NSS/NCRI to RCOG support team. • Tues 23rd Oct: Participated in weekly teleconference with Patient Liaison Officers. • 1,591 letters have issued to individuals requesting consent to participate in RCOG Review • Consent forms returned by 882 individuals (55%), of which 848 have consented to participate. 96% of returns are consents.
Information Services	• Opening hours of call centre reduced to 5 days a week (down from 7) 9am – 6pm • An Post returns being contacted and details updated if contact made and letters reissued • As of Friday 26th Oct, there have been 100 calls to the information line.

	Total Calls to Information Line — **100** Total Calls (general) — 28 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)	• New workstream lead has been assigned by Data Quality Team to support development of Case Management System. • CMS updated to include information provided by NSS/NCRI. • Working to incorporate additional requirements for slides transfers who are also involved in legal proceedings.
Laboratory Logistics	• SOP under review by RCOG to facilitate safe and secure transport of slides between the CervicalCheck laboratories and RCOG lab in Bristol. • Engaging with CervicalCheck ICT and RCOG to facilitate RCOG with access to electronic records where required.
Communications	• To support distribution of letters to women: Liaising with HSE Comms / HSE Digital to coordinate approach and issuing proactive communications as appropriate/agreed.
Acute & Community Services	• Weekly briefing sent to Acute Operations and Cervical Checl for distribution. • Weekly teleconference with key stakeholders, including Acute Operations GM and CervicalCheck Interim Programme Manager. • Progressing validation of next of kin details with Acute services as per agreed SOP, providing contact information for next of kin where women identified as deceased in database provided by NSS. As of Friday 26th Oct, 237 issued to Acute Services, and 153 (64%) returned.
Current Position, Significant Issues	• SOP for laboratory logistics, communication and slide transportation: awaiting feedback from RCOG Expert Review Panel. • Acute Services to follow-up on outstanding confirmation of next of kin details for women identified as deceased, so that letters can issue to those individuals inviting them to participate in RCOG Review. • Queries arose as to the validity of certain identified cases included in consent process for RCOG Review. NSS and Data Quality investigating further against NCRI data provided to them.

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Next Steps

Workstream	Actions Planned
Patient Support Services	• Continue plan to issue remaining letters to Next of Kin, as details received from acute 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 to 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 • Progress design of CMS to be updated further in line with agreement on labs transport process.
Laboratory Logistics	• We provided (Sept 20th) labs with an indicative list of women who had consented to participate in the RCOG Review to that date, for the purpose of transparency and to allow the labs plan foreseeable workloads in terms of slide transfers. • The lead consultant cytopathologist with the Expert review panel is due to give feedback on the SOP for slide transfers. • There have been some delays in finalising the SOP for slide transfers as the labs have been focused on contract extension and identifying solutions for the backlog.
Communications	• Managing feedback and queries from women/next of kin, clinicians, media and public as remaining cohorts of women or next of kin receive letters.
Acute & Community Services	• Weekly teleconference with RCOG Support Programme, Acute Operations, and CervicalCheck. • Continue developing protocol to support RCOG with relevant medical records from acute and community services where requested. • Escalate non returned data for next of kin with Acute Services.

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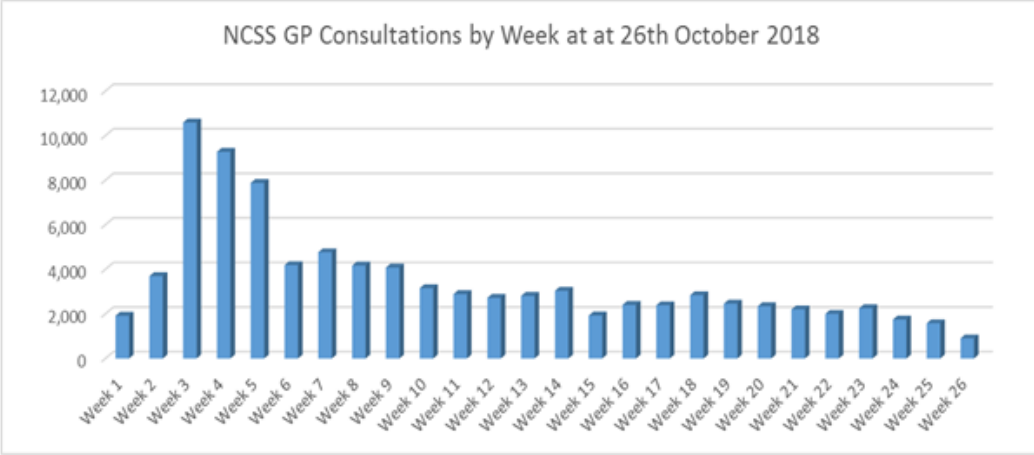
Management of Laboratory Capacity Issues	
Project Management	Project Manager in Place **Project Team Composition** Given the nature of the issues presenting a working group was put in place to support the project manager. This group comprise HSE procurement, HSE Legal and the CervicalCheck Operations 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 have agreed continuity of supply arrangements with both existing cytology laboratories so that they will 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 consultations to date is more than 90,000. The normal capacity for the labs is approximately 5,000 slides reviewed per week. This is delaying the reporting of smear results to women. The table below sets out the increased number of GP consultations.
Average Time for Processing Results	The average processing time is currently 77 days.

Week	Total
Week 1	1,921
Week 2	3,696
Week 3	10,591
Week 4	9,271
Week 5	7,882
Week 6	4,189
Week 7	4,769
Week 8	4,171
Week 9	4,085
Week 10	3,155
Week 11	2,892
Week 12	2,721
Week 13	2,810
Week 14	3,039
Week 15	1,927
Week 16	2,405
Week 17	2,389
Week 18	2,841
Week 19	2,465
Week 20	2,345
Week 21	2,206
Week 22	2,004
Week 23	2,255
Week 24	1,749
Week 25	1,582
Week 26	902
Grand Total	**90,262**

Claim Status	Total
Fully Paid	80,595
To Pay with Next Payment	8,827
Rejected	484
Duplicate	356
Grand Total	90,262



Introduction of HPV Screening

Project Management	**Project Manager** A Project Manager is in place. 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. **Project Team Composition** • 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	

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Workstream	Actions Progressed (w/e 26th October 2018)
Clinical	• Consideration of changes that may be required to QA guidelines for cytopathology. • Assessment of feedback to proposed screening pathway and eligibility framework commenced. • Colposcopy capacity planning and management of women referred to colposcopy continues to be scoped out.
Procurement	• Consideration of changes that may be required to QA guidelines for cytopathology. • Assessment of feedback to proposed screening pathway and eligibility framework commenced. • Colposcopy capacity planning and management of women referred to colposcopy continues to be scoped out
ICT	• Procurement market analysis to inform specification and market model is progressing . The procurement lead has drafted a document that will be published on etenders when approved.
Lab Configuration	• Work on development and testing of changes to Cervical Screening Register continued. • Addressing issue of testing capacity (resources). • Laboratory IT development awaiting decisions on laboratory configuration and procurement.
Communications	• No progress – awaiting dedicated resource / channel to form communications.
Resources for HPs	• Resource development – e-learning - commissioned. Resources cannot be finalised without clinical pathways (above) resolution.
Hospitals (Colposcopy)	• Continued assessment of capacity exercise with the hospitals. • HSE meeting with hospital colposcopists took place 13th Oct.
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 has been 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 analysis originally planned to be completed in October to assess private lab interest in tendering for HPV primary screening will now take place in November. 7) Communications resources (external & internal) for implementation of the project to be defined.

Immediate Activities

Workstream	Actions Planned
Clinical	• Finalise scope of work for impact assessment • Circulate scope of work and arrange series of meetings with colposcopy leads in November.
Procurement	• Finalise contract details with labs following agreement to continue. • Finalised market information session proposed to allow services required to be explored with a view to determining level of interest and potential contractual issues and publish notice on etenders.gov. • Laboratory configuration strategy to be finalised looking at the options and future proofing services.
ICT	• Testing of changes to Cervical Screening Register. (February 2019) • Further address issue of testing capacity (resources). • Colposcopy IT development to be initiated.(end October 2018)
Lab Configuration	• Finalise laboratory configuration strategy. Factor current laboratory continuation.
Communications	• Finalise stakeholder mapping exercise with workstream leads. • Start communications – messaging.
Resources for HPs	• Progress e-learning module to include recent clinical decisions.
Hospitals (Colposcopy)	• Complete capacity planning exercise. • Secure hospital commitments for 2019. • Identify colposcopy lead.

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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.