CervicalCheck Steering Committee

Weekly report to the Minister

9 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, €972,975 has been reimbursed in respect of various health and social care costs, of which approximately €800,000 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 this week.

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.

- Next of kin details are being provided by the relevant acute hospital and the HSE reports that this validation process is over 70% 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 893 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 104 calls have been received, of which 7 2 related to clinical questions. The HSE has advised that all 72 of these calls have now been resolved. The average daily volume of calls has fallen now to one.

- 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.

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. Work is ongoing to finalise the laboratory strategy for the HPV test, following agreement to extend existing contracts for cytology services (and subject to finalisation of the extended contracts). In tandem, work on development and testing of necessary ICT changes is underway and colposcopy capacity planning is being scoped out.

6. 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 92,290 with 663 consultations in the week ending 2 November, compared with 1,554 in the previous week. 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.

7. 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 this month.

8. 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. A revised implementation plan was discussed by the CervicalCheck Steering Committee at its meeting of 8 November. Comments on the plan raised at the meeting will now be incorporated.

The next meeting of the CervicalCheck Steering Committee is scheduled for 29 November, with a further meeting to follow on 18 December.

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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. 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.

Interface with RCOG Review	
Project Management	**Project Manager in Place**

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	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. • Thurs 1st Nov: Weekly Teleconference with RCOG and DOH to progress interagency logistics and communication **Next steps** • Continue weekly teleconference with DOH and Expert Review Panel (scheduled for Thurs 8th Nov)

Project Plan

Workstream	**Actions Progressed (w/e 5th Nov)**
Patient Support Services	• NOK details for deceased women comprehended by review in process of validation with acute services, due to be complete this week. As of Friday 2nd November • 1,591 letters have issued to individuals requesting consent to participate in Review • Consent forms returned by 893 individuals (56%), of which 858 have consented to participate. 96% of returns are consents.
Information Services	• As volume of calls has decreased to avg 1 per day, opening hours of call centre reduced from 7 days to 5 days a week 9am – 6pm. To be revisited when more letters issue. • An Post returns being contacted and details updated if contact made and letters reissued • As of Friday 02nd Nov, there have been 104 calls to the information line. Detailed as follows;

Total Calls to Information Line	**104**
Total Calls (general)	32
Total Calls (clinical)	72
Calls (clinical) resolved at initial contact	49

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	Calls (clinical) escalated to acute hospitals, following SOP 23 Calls (clinical) resolved by acute hospitals 23
Case Management System (CMS)	• 2nd Nov: Expert Review Panel feedback returned on application to NCRI for access to data for purpose of the Review • CMS updated to include new information provided by NSS/NCRI/GRO. • Working to incorporate additional requirements for slides transfers who are also involved in legal proceedings.
Laboratory Logistics	• 30th Oct: Received and incorporated feedback from Expert Review Panel on draft SOP to facilitate safe and secure transport of slides between the CervicalCheck laboratories and RCOG lab in Bristol. • Engaging with CervicalCheck ICT to facilitate Expert Review Panel 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. • Thurs 1st Nov: SOP for the interagency management of public/non patient queries (i.e. press, FOIs, PQs, public representations) related to the RCOG review circulated to DOH and Expert Review Panel for consideration.
Acute & Community Services	• Weekly briefing sent to Acute Operations for onward circulation to relevant hospitals and clinical services • Weekly briefing sent to CervicalCheck for onward circulation to lead colposcopists through the Programme Manager of Cervical Check. • Weekly teleconference with Acute Operations GM • Progressing validation of NOK details with Acute services as per agreed SOP, providing contact information for NOK where women identified as deceased in database provided by NSS. As of Friday 02nd Nov, 237 issued to Acute Services, and 175 (74%) returned. • 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	• SOP for laboratory logistics, communication and slide transportation: awaiting feedback from RCOG Expert Review Panel. Delay in circulating SOP to laboratories, pending completion of NSS contract negotiations with labs. • Acute Services to follow-up on outstanding confirmation of NOK details for women identified as deceased, so that letters can issue to those individuals inviting them to participate in RCOG Review. Where NOK details cannot be

	ascertained through acute services, additional measures to be taken to follow-up and establish details. For discussion with community services. • Queries arose as to the validity of certain identified cases included in the consent process for the RCOG Review through the NCRI. These are being investigated.

Next Steps

Workstream	**Actions Planned** (w/c 5th Nov)
Patient Support Services	• Issue cohort of letters to Next of Kin where details validated by acute services • The issue of reminder letters to women pending confirmation from DOH and Expert Review Panel • 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)	• Submit completed application to NCRI for access to data • 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 gave feedback on Tues 30th Oct on the SOP for slide transfers. This has been incorporated into the SOP, which is ready for review by the CervicalCheck labs, pending advancement of lab negotiations. • 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.

	• Engage with legal services (Philip Lee) and NSS Client services on approach and correspondence to women in legal process.
Communications	• Stakeholder / Comms plan to be circulated to the DOH and Expert Review Panel for feedback • Managing feedback and queries from women/NOK, clinicians, media and public as remaining cohorts of women or 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. • Where NOK details cannot be ascertained through acute services, additional measures to be taken to follow-up and establish details. For discussion with community services.

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 92,000. 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 80 days.

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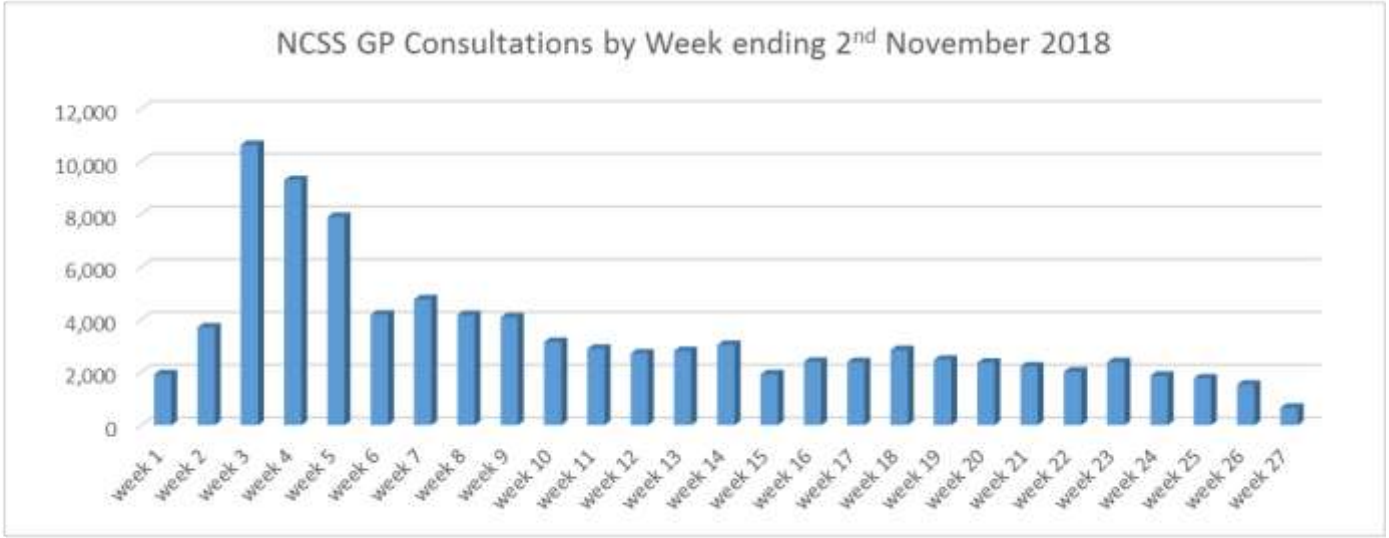
Week	Total
week 1	1,929
week 2	3,708
week 3	10,628
week 4	9,293
week 5	7,902
week 6	4,194
week 7	4,772
week 8	4,177
week 9	4,092
week 10	3,163
week 11	2,899
week 12	2,725
week 13	2,813
week 14	3,044
week 15	1,929
week 16	2,409
week 17	2,393
week 18	2,851
week 19	2,482
week 20	2,368
week 21	2,230
week 22	2,032
week 23	2,390
week 24	1,882
week 25	1,778
week 26	1,544
week 27	663
Total	92,290

Claim_Status	Total
Fully Paid	80,595
To Pay with next Payment	10,839
Rejected	500
Duplicate	356
Grand Total	92,290



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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

Workstream	Actions Progressed (w/e 2nd November 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.
Procurement	• 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.
ICT	• 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.
Lab Configuration	• Configuration options paper continued to be developed but work is limited until the market engagement seminar is completed to understand the commercial interest.
Communications	• No progress – awaiting dedicated resource / channel to form communications.
Resources for HPs	• Team continue to work on 2 pieces: o Develop materials o Guide for Primary Care which will be available in hardcopy and through the elearning portal

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Hospitals (Colposcopy)	• Colposcopy capacity planning and management of women referred to colposcopy continues to be scoped out. • 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	• Circulate scope of work and arrange series of meetings with colposcopy leads in November. • Commence planning for GP contract negotiations with CervicalCheck team
Procurement	• Finalise contract details with labs following agreement to continue. • Seek approval from Steering Group re market engagement approach, date and clinical participation. • Publish notice on etenders.gov.

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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	• Laboratory configuration strategy to be finalised looking at the options and future proofing services.
Communications	• Finalise stakeholder mapping exercise with workstream leads. • Arrange a workshop with CervicalCheck staff, National Comms, service user rep & smear takers to agree an approach to develop a Comms plan.
Resources for HPs	• Scope out work on mandatory training for the HPV roll out as indicated by Dr. Scally. Mandatory training to be discussed at QS &RM meeting and next QA Committee (23rd Nov) • Progress e-learning module to include recent clinical decisions.
Hospitals (Colposcopy)	• Complete capacity planning exercise. • Secure hospital commitments for 2019. • Identify colposcopy lead.
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.