

CervicalCheck Steering Committee

Weekly report to the Minister

16 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, over €1 million has been reimbursed in respect of various health and social care costs, approximately €815,000 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 last 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. The HSE has reported that the average time to deliver slides to independent experts is 23 days. Release of some slides has been delayed. Legal representatives for the HSE are contacting all solicitors to check if they are encountering any delays and to address any issues.

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. Of the 856 who have so far consented to take part in the review, 1,455 slides will be transferred. Reminder letters will issue next week to those who have not yet responded.
- In relation to media reports this week which suggested the HSE is carrying out a separate audit in relation to the 221 affected women, this is not correct. There is an assessment of the current position being carried out by the HSE, as part of its ongoing work, to ensure an understanding of the overall situation. This has no bearing on the progress or outcome of the RCOG review.

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 with a market engagement seminar planned for end of 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.

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 94,096 with 813 consultations in the week ending 9 November. 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.

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	<p>Current position, issues & challenges</p> <p>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. The average time to deliver slides to the independent expert is 23 days. There have been some delays. In light of public concern our legal representatives are contacting all solicitors to check if they are encountering any delays and to address any issues.</p>

Interface with RCOG Review	
Project Management	<p>Project Manager in Place</p> <p>Assistant National Director (HSE) commenced working as the Programme Lead on the RCOG Review on Wednesday the 1st of August.</p>

CervicalCheck Steering Committee Weekly Report from HSE

	Project Manager (HSE) commenced working as the Project Manager on Wednesday the 1 st of August.												
Project Governance	<p>Programme Governance</p> <ul style="list-style-type: none">Project Team holds daily meetings and teleconferences to progress deliverables, identify critical actions / timeframes, areas for escalation, risks, issues, and dependencies.Weekly Teleconference with RCOG and Dept. of Health to progress interagency logistics and communication <p>Next steps</p> <ul style="list-style-type: none">Continue weekly teleconference with Dept. of Health and Expert Review Panel (scheduled for Thurs 15th Nov)												
Project Plan													
Workstream	Actions Progressed (w/e 9 th Nov)												
Patient Support Services	<ul style="list-style-type: none">Next of Kin details for deceased women comprehended by review in process of validation with acute services, due to be complete this week.As of Friday 09th November:<ul style="list-style-type: none">1,591 letters issued to individuals.1,531 invited to participate who are contactable and comprehended by the RCOG Review. <i>60 women removed from overall cohort as either not within scope of review or not contactable despite repeated attempts.</i>853 (56%) have consented to participate in the Review												
Information Services	<ul style="list-style-type: none">As volume of calls has decreased to avg. 1 per day, opening hours of call centre reduced from 7 to to 5 days a week 9am – 6pm. To be revisited when more letters issue.As of Friday 9th Nov, there have been 106 calls to the information line these are detailed as follows;<table><tr><td>Total Calls to Information Line</td><td>106</td></tr><tr><td>Total Calls (general)</td><td>34</td></tr><tr><td>Total Calls (clinical)</td><td>72</td></tr><tr><td>Calls (clinical) resolved at initial contact</td><td>49</td></tr><tr><td>Calls (clinical) escalated to acute hospitals, following SOP</td><td>23</td></tr><tr><td>Calls (clinical) resolved by acute hospitals</td><td>23</td></tr></table>	Total Calls to Information Line	106	Total Calls (general)	34	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
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Case Management System (CMS)	<ul style="list-style-type: none"> Completed application to NCRI submitted for RCOG's access to relevant data. 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	<ul style="list-style-type: none"> SOP sent forward to CervicalCheck Labs for further technical input and consultation. Engaging with CervicalCheck ICT to facilitate Expert Review Panel with access to electronic records where required. Data analysis undertaken to develop database of slides for each laboratory, related to women consenting to participate in Review to date
Communications	<ul style="list-style-type: none"> To support distribution of letters to women: Liaising with HSE Comms / HSE Digital to coordinate approach and issuing proactive communications as appropriate/agreed. Stakeholder engagement and communications plan related to the RCOG review circulated to Dept. of Health and Expert Review Panel for consideration.
Acute & Community Services	<ul style="list-style-type: none"> Weekly briefing sent to Acute Operations for onward circulation to relevant hospitals and clinical services, to Lead Colposcopists through CervicalCheck Weekly teleconference with Acute Operations Progressing validation of 'Next of Kin' details with Acute services as per agreed SOP, where women are deceased. 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	<ul style="list-style-type: none"> 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. Queries arose as to the validity of certain identified cases included in consent process for RCOG Review. Concerns were raised with NSS and ICT Data Quality, which provided the datasets used for undertaking the consent process. NSS and ICT Data Quality investigating further against NCRI data provided to them. Expert Panel and Dept. Of Health have been advised. Undertaking continuous process of review and revalidation of data provided to date.

CervicalCheck Steering Committee Weekly Report from HSE

Next Steps

Workstream	Actions Planned (w/c 12 th Nov)
Patient Support Services	<ul style="list-style-type: none"> • Issue cohort of letters to Next of Kin where details validated by acute services • Follow up to ascertain outstanding Next of Kin contact details with primary care • The issue of reminder letters to women pending confirmation from Dept. of Health 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	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Updated list of women to be provided to labs to facilitate transfer of slides following completion of data validation for the specific cohort.
Communications	<ul style="list-style-type: none"> • Finalise SOP for the interagency management of public/non patient queries (i.e. press, FOIs, PQs, public representations) related to the RCOG review with feedback from Dept. of Health and Expert Review Panel. • Manage 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	<ul style="list-style-type: none"> • 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 'Next of Kin' details cannot be ascertained through acute services, additional measures to be taken to follow-up and establish details with primary care services.

CervicalCheck Steering Committee Weekly Report from HSE

Management of Laboratory Capacity Issues	
Project Management	<p>Project Manager in Place</p> <p>Project Team Composition</p> <p>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.</p>
Project Plan	<p>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.</p> <p>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.</p>
Uptake of Smear Tests	<p><i>Out of cycle smears</i></p> <p>Total number of additional GP consultations to date is more than 94,000. 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 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.</p>
Average Time for Processing	<p>The average processing time is currently 79 days.</p>

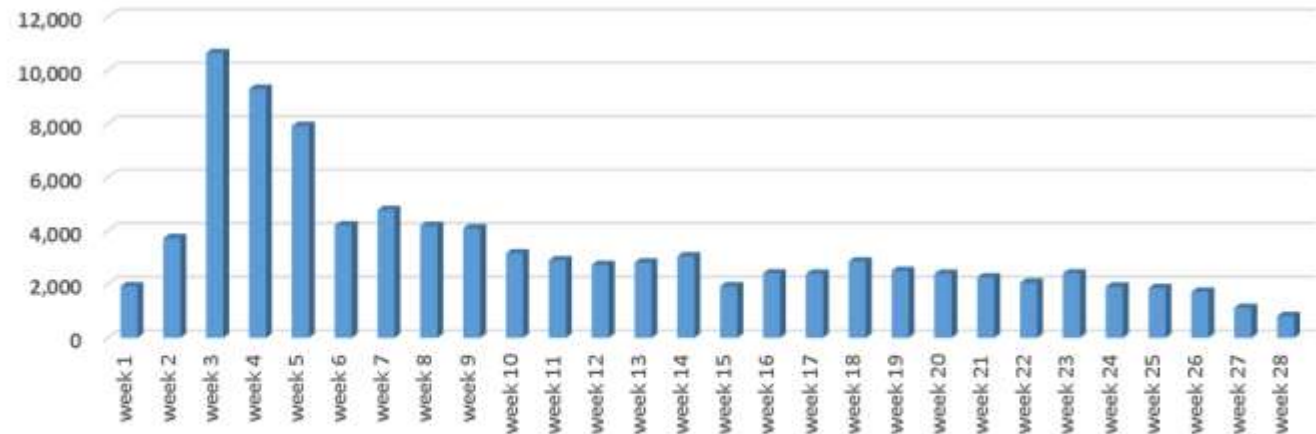
CervicalCheck Steering Committee Weekly Report from HSE

Results

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
week 28	813
Grand Total	94,096

Claim Status	Total
Fully Paid	90,934
To Pay with next Payment	2,259
Rejected	516
Duplicate	387
Grand Total	94,096

NCSS GP Consultations by Week as at 9th November 2018



CervicalCheck Steering Committee Weekly Report from HSE

Introduction of HPV Screening	
Project Management	<p>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.</p> <p>Project Team Composition</p> <ul style="list-style-type: none"> 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 9 th November 2018)
Clinical	<ul style="list-style-type: none"> Steering Group presented clinical work decisions made to date Assessment of feedback to proposed screening pathway and eligibility framework continues.
Procurement	<ul style="list-style-type: none"> Procurement market analysis to inform specification and market model is progressing . The procurement lead has drafted a document that will be published on e-tenders when approved. Approach approved by Steering Group 7th Nov and proposed dates agreed
ICT	<ul style="list-style-type: none"> CSR development- Complete and application delivered to NSS for testing. All test resources are now in place and we have commenced Unit testing of the individual changes and testing of SSIS packages. Preparation for full system test has begun Colposcopy IT- Changes required agreed and estimate provided by 1 of the 2 vendors. (€30k approx.) Laboratory IT development awaiting decisions on laboratory configuration and procurement. New form has been made available to all practices in hardcopy and on the Programme website. The electronic copy has been delivered to Healthlink who are dealing with the accredited practice management system vendors. No delivery estimate available yet.
Lab Configuration	<ul style="list-style-type: none"> Configuration options paper continued to be developed but work is limited until the market engagement seminar is completed to understand the commercial interest.
Communications	<ul style="list-style-type: none"> Communications lead identified for this project

CervicalCheck Steering Committee Weekly Report from HSE

Resources for HPs	<ul style="list-style-type: none"> Team continue to work on 2 pieces: <ol style="list-style-type: none"> Developing training materials Guide for Primary Care which will be available in hardcopy and through the e-learning portal.
Hospitals (Colposcopy)	<ul style="list-style-type: none"> Colposcopy capacity planning and management of women referred to colposcopy continues to be scoped out. CEO have officially been communicated to regarding this piece of work by ND NAHD
Current Position, Significant Issues	<p>Current position, issues & challenges</p> <ol style="list-style-type: none"> Stabilisation of the current programme remains a huge issue. Current backlogs from the three providers will impact the transition to HPV primary screening. Absence of a fulltime Clinical Director for the programme is impacting a number of key activities. <ul style="list-style-type: none"> ❖ Decision required on the cervical screening pathway <p>A Clinical Advisory Group has been set up to address these decisions.</p> 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. Laboratory configuration strategy being reassessed by requirements to stabilise current programme. Market engagement seminar, originally planned to be completed in November to assess private lab interest in tendering for HPV primary screening, will now take place in November. 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	<ul style="list-style-type: none"> Circulate scope of work and arrange series of meetings with colposcopy leads in November. Commence planning for GP contract negotiations with CervicalCheck team
Procurement	<ul style="list-style-type: none"> Finalise contract details with labs following agreement to continue. Approval from Steering Group re market engagement approach, date and clinical participation agreed. Notification to be uploaded to e-tenders this week. Seminar is take place at the end of November Finalise slide deck, logistics and comms plan for market engagement seminar.

CervicalCheck Steering Committee Weekly Report from HSE

ICT	<ul style="list-style-type: none"> • Testing of changes to Cervical Screening Register. (February 2019) • Labs ICT development - Awaiting nomination of labs to be contacted • Colposcopy IT - Awaiting feedback from the second. Funding approval to be sought once we get the second estimate and a development and testing schedule can be agreed.
Lab Configuration	<ul style="list-style-type: none"> • Laboratory configuration strategy to be finalised looking at the options and future proofing services.
Communications	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • Complete capacity planning exercise and schedule meetings with lead colposcopists • Secure hospital commitments for 2019. • Identify colposcopy lead for HPV project.
Update Action	<p>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.</p> <p>Update 19/09/18 NRS are finalising the contract with the successful candidate for the post of clinical director.</p>