CervicalCheck Steering Committee

Weekly report to the Minister

25 January 2019

1. Update on support package

The provision of supports to women and families is continuing, and the HSE reports that the number of supports being provided continues to increase on a weekly basis in response to requests. Arrangements are in place to reimburse, on receipt of claims, a range of costs that the women and their families may incur, including travel costs, childcare costs and medical appointment costs among others.

In addition, measures have been put in place to ensure that retrospective costs are reimbursed, while an automatic review system is in place to simplify and streamline the claims process to ensure prompt payment of all items covered by the Government decision. To date, just over €1.18m has been reimbursed in respect of various health and social care costs, almost €910,000 of which relates to retrospective payments.

The HSE has advised it is undertaking a validation exercise on the data held on the 221 affected women, which is expected to be available shortly. 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.

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 32 days.

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 significant 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. It is reported by the HSE that the process of agreeing slide transfer is continuing.

The HSE provided a detailed report on the release of slides to the Public Accounts Committee in December.

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.

The HSE project team is holding daily meetings and teleconferences to progress the project. As of Thursday 10 January, 1,714 letters, including letters to next-of-kin of women who have, sadly, died, have issued providing information in relation to consent and the consent form for participation in the review, and 1,077 women have consented to take part in the review (63%).

The final date for consents to be received was 28 December 2018. The Expert Review Panel has now been provided with colposcopy and other data from CervicalCheck in respect of women who have consented to participate.

The HSE has advised that Quest has appointed a laboratories lead to manage the distribution of slides to RCOG, and has indicated it will be in a position to commence the transfer of slides shortly.

4. Expiration of Tests - HPV Testing Outside Recommended Timeframe

In November 2018, the HSE became aware of an issue with Quest laboratories in relation to the usage, outside the manufacturers recommended timeframe, of a number of tests used for secondary HPV testing. This matter has recently been the subject of much media attention.

Where low-grade changes are detected on a cervical smear test, a second, so-called 'triage' test – which looks for the HPV virus – is carried out by laboratories. This test for HPV should be carried out within 30 days of the sample having been given by a woman.

This issue first came to light because of ongoing improvement work across the screening programme, including strengthening of the programme's quality assurance processes as recommended in the Scally Report. An expert clinical team was immediately convened to establish the facts with the laboratory and review the situation.

The HSE has received the final dataset from Quest and validation of this dataset is ongoing. This work is nearing completion and the HSE advises that its aim is to contact all women affected by the end of next week.

The HSE has advised that clinical research shows that HPV tests remain effective even when they are performed outside the recommended timeframe and that there is little risk of inaccuracy due to the issue that Quest has identified. Any retests will be processed by the laboratory as a priority. The priority of the HSE and the Department of Health at this point is to work to reassure women taking part in cervical screening.

5. Clinical Director and filling of key posts

The HSE has advised that the new Clinical Director has been appointed and is due to commence work on 4 February 2019. A pathology lead and a quality assurance lead have been appointed, both on a two day per week basis. The QA lead commenced work on 14 January. An interim public health advisor has also been appointed and took up post last month.

6. Smeartaking activity and laboratory capacity

The average processing time for smear tests is currently 89 days.

The total number of additional GP consultations was over 110,000. The HSE has been working actively with the labs to manage the backlog and to improve turnaround times for smear tests. The HSE reports that laboratories have agreed to undertake additional recruitment, provide for overtime and manage annual leave in an effort to minimise the backlog. In addition, the HSE is aiming to source additional screening capacity, which would improve the turnaround time of results. However, sourcing capacity and resources is a global challenge as countries start to move to primary HPV screening, which vastly reduces the requirement for cytology screening staff.

It is clear that the backlog will take some time to resolve. The HSE has advised that it is focused on capacity planning to take account of available capacity and expected demand, with the aim of bringing the programme into stabilisation this year.

7. 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. Dr Marc Arbyn, who was a member of the HIQA HTA panel, is also providing support and expertise to the Clinical Advisory Group established to advise on the project.

Colposcopy capacity planning is underway by the National Women and Infants Health Programme, which is required to support the introduction of the HPV test. A pre-market engagement seminar took place on 27 November and assessment of submissions from eight companies which participated in the pre-market seminar is underway currently. This, together with laboratory capacity planning, will inform the laboratory configuration strategy, taking account of options and the futureproofing of the service. Finalisation of the lab configuration strategy is also dependent on the conclusion of contractual arrangements with Medlab and the Coombe. In tandem, work on development and testing of necessary ICT changes is underway.

8. Implementation of recommendations of the Scally Inquiry

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 was approved by Government on Tuesday 11 December. The Plan was subsequently published on the Department's website. It is expected that Dr Scally will provide further detailed observations formally to the Minister shortly. It is intended that formal quarterly updates will be provided against each action, with informal updates on progress made to be provided to the Minister on a monthly basis.

The next meeting of the CervicalCheck Steering Committee is scheduled for 21 February.

CervicalCheck Steering Committee
Weekly Report from HSE

Oversight and engagement with the HSE on modules of its 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 32 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 on going 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 for slides. As a result we have identified a significant number of cases where the HSE has 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) is in place since August 1st. Project Management activities are on-going lead by the Project Manager (HSE).
Project Governance	**Programme Governance** • Support Team continues to hold daily meetings and teleconferences to progress deliverables, identify critical actions / timeframes, areas for escalation, and project RAIDS. **Next steps** • Continue engagement with Dept. of Health and Expert Review Panel via weekly teleconference.

Project Plan

Workstream	**Actions Progressed (w/e 18th January)**
Patient Support Services	• As of COB Thursday 17th January: o 1,714 invited to participate in Expert Panel Review, who are contactable and comprehended by the Review . o 1,077 (63%) have consented to participate in the Review.
Information Services	• Opening hours of call centre are 5 days per week, 9am – 6pm. • As of COB Thursday 17th January, there have been a total of 141 calls to the information line . Details as follows:

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	<table><tr><th></th><th>#</th><th>Change from Previous Week</th></tr><tr><td>Total Calls to Information Line</td><td>141</td><td>No change</td></tr><tr><td>Total Calls (general)</td><td>69</td><td>No change</td></tr><tr><td>Total Calls (clinical)</td><td>72</td><td>No change</td></tr><tr><td>Calls (clinical) resolved at initial contact</td><td>49</td><td>No change</td></tr><tr><td>Calls (clinical) escalated to acute services</td><td>23</td><td>No change</td></tr><tr><td>Calls (clinical) resolved by acute services</td><td>23</td><td>No change</td></tr></table>
Case Management System (CMS)	• Expert Review Panel provided with colposcopy data and failsafe data from CervicalCheck ICT in respect of the 1077 women who have consented to the Review. • CervicalCheck ICT working with NCRI to progress sharing of data between NCRI and Expert Review Panel. Letter sent to NCRI confirming the number of consents received for the Review. • QA process of revalidation of 1035 consents against CMS completed. New consent forms validated once received.
Laboratory Logistics	• Continuing to develop database of required slides in relation to new consents, by laboratory. • Teleconferences held with the CC laboratories (SONIC/MedLab and Coombe) on Thursday 10th January 2019 and Quest on Monday 14th January 2019. • CC Interim Programme Manager, and RCOG Programme Lead to progress solutions to laboratory challenges in transferring slides. • Demo scanner received in Coombe Lab and 2 staff initially trained . Coombe has commenced retrieval of 35 slides and will progress remainder asap. • Quest have appointed a laboratory lead to manage the distribution of slides to RCOG. • Medlab has completed the slide retrieval process. • Working with Client Services to establish process to correlate slides requested for legal proceedings with slides requested for RCOG Expert Panel Review.
Communications	• Weekly teleconference with Expert Review Panel and DOH re project planning & matters for interagency review.
Acute & Community Services	• 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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Current Position, Significant Issues	The transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review has encountered some challenges. These have been escalated. Further engagement and on-going communication will continue with all laboratories to address issues and arrange for the transport of slides as soon as possible.

Next Steps

Workstream	**Actions Planned (w/c 21st Jan)**
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. Continue QA process of validation of new consents received against CMS. • Incorporate additional requirements for slides transfers who are also involved in legal proceedings.
Laboratory Logistics	• Quest Diagnostics have advised they will now be in a position to commence moving slides by January 18th 2019. • Further training required for staff on Demo scanner in Coombe Lab. Coombe to provide date for transfer of slides following a meeting with the Master of the Coombe scheduled for next week. • Continue to negotiate with MedLab to agree on the transfer of slides.
Communications	• Manage feedback and queries from women/NOK, clinicians, media and public as remaining cohorts of women's 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.

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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 comprises HSE procurement, HSE Legal and the CervicalCheck Operations team. This group has been 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. Continuity of supply arrangements with both existing cytology laboratories is agreed so that they continue to provide cytology services to CervicalCheck beyond the end date of the contract on Sunday 14th October. A final contract is in place with Quest and final contracts and operating arrangements with Medlab is on-going.
Uptake of Smear Tests	*Out of cycle smears* Total number of additional GP consultations was more than 110,000. 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. Free consultations and free repeat smear tests have ceased as scheduled.
Average Time for Processing Results	The average processing time is currently 89 days. With some taking longer.

	We are continuing to monitor the expiration of smears for low grade HPV testing. This remains a challenge for laboratories. A laboratory capacity plan is being developed for the next 6 months to address the backlog. This is required to stabilise the programme in order to address the backlog and for HPV primary screening to be implemented.

Introduction of HPV Screening

Project Management	**Project Manager** In place. **Project Team Composition** • Cervical Check Clinical Director has been appointed and will commence in February 2019 • The expression of interest for the appointment of a Clinical Lead Colposcopist were unsuccessful. NSS are in discussion with a pathology lead and hope to confirm an appointment in January. • National laboratory QA lead appointed. Commenced 14/1 • 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 Colposcopy lead, Pathology lead.

Project Plan

Workstream	**Actions Progressed (w/e 18th January)**
Clinical	• Assessment of feedback to proposed screening pathway and eligibility framework continues.
Procurement	• Submissions from participants were received, the closing date was 6th December. • Assessment of submissions – 8 companies have submitted comments - concluded mid January
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.

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Lab Configuration	• Configuration options - work limited until the market engagement seminar is completed and current programme stabilisation w.r.t. laboratories completed. • Completion is dependant on concluding Medlab/Coombe arrangement.
Communications	• Communications lead identified for this project . To engage with team.
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 National Hospital operation

Current Position, Significant Issues	**Current position, issues & challenges** 1) Stabilisation of the current programme remains a huge issue. Current backlogs from the 2 private providers will impact the transition to HPV primary screening. 2) Failure to recruit a colposcopy lead for the program and project. There were no applicants. 3) Laboratory configuration strategy being reassessed by requirements to stabilise current programme and responses to market engagement seminar. 4) 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

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.
Procurement	• Finalise contract details with laboratories following agreement to continue. • Assess outcome of market engagement seminar.

	• Commence work on procurement strategy
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).
Update Action	**Cervical Check Clinical Director will commence 4/2**