CervicalCheck Steering Committee

Weekly report to the Minister

8 February 2019

1. Update on support package

The provision of supports to women and families is continuing. 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, almost €1.2 has been reimbursed in respect of various health and social care costs, approximately €910,000 of which relates to retrospective payments.

The HSE has recently completed an exercise on the data held on the 221 affected women. This is to ensure the National Screening Service has the most up to date information, which will be used to help with planning support needs for patients, for example. The report was shared with the 221+ Patient Support Group and has now been published on the CervicalCheck website.

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 25 days.

The HSE has reported that 109 slides have been provided out of a total of 118. There are 9 outstanding requests, which were received between December and January 31st.

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 Friday 1 February, 1,702 have been invited to participate in the review, including next-of-kin of women who have, sadly, died. Letters have issued providing information in relation to consent and the consent form for participation in the review, and 1,072 (63%) women have consented to take part. 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 transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review has now commenced. All slides from the Coombe have now been transferred, with transfer from the other labs ongoing.

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. Letters have now issued to the vast majority of affected women. CervicalCheck will continue to work with Quest Diagnostics to ensure any retests arising from this issue are prioritised for testing by the lab.

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 have identified.

5. Clinical Director

The new Clinical Director commenced work on 4 February 2019.

6. Smeartaking activity and laboratory capacity

The HSE reports that the average processing time for smear tests is currently 27 weeks.

The total number of additional GP consultations as a result of the CervicalCheck issues was over 110,000, while the estimated number of early repeat smear tests which took place between May 1st and December 31st is approximately 57,810, or just over half of the total consultations.

The HSE has continued to focus on actively identifying solutions to the lengthening of smear test turnaround times. It is working with existing private providers, other private providers and public service providers in other countries to identify lab capacity. The HSE has advised that they have agreed with laboratories to prioritise those slides which originate from women who attended colposcopy as this cohort of women is considered to have the highest clinical risk. In addition, the HSE have agreed with the laboratory with the largest backlog that they carry out a HPV test on smear test samples, prior to cytology, as a means of prioritising slides appropriately.

7. Introduction of HPV as the primary method of testing

A Steering Group and project team are in place for the introduction of HPV testing as the primary screening mechanism for CervicalCheck, with cytology as a reflex test, and work on the project is continuing across seven workstreams. Finalisation of the decision on a preferred assay (DNA or mRNA) is ongoing. A pre-tender market engagement seminar has taken place, feedback is completed. This, together with laboratory capacity planning, will inform the laboratory configuration strategy. Finalisation of the strategy is also dependent on current discussions in relation to contractual arrangements with Medlab and the Coombe. ICT development and testing continues, along with work on resources for healthcare practitioners. Colposcopy capacity planning is underway by the National Women and Infants Health

Programme, which is required to support the introduction of the HPV test. Six site visits have taken place as part of this work, which includes reviewing current operational pressures for all units as well as the impact of the introduction of primary HPV testing and the RCOG review, and further site visits are planned.

8. Colposcopy waiting times

The most recently reported data is November 2018. 94% of women with high grade abnormalities were seen within 4 weeks of referral (against target of 90%). 96% of women with low grade abnormalities were seen within 8 weeks of referral (against target of 90%).

9. 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.

In addition, Dr Scally has informed the Department that his supplementary report will be completed in the coming weeks and will include assessment of further laboratories which were used to examine slides for CervicalCheck. His report is awaited.

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

10. Minister's meeting with 221+

On 31st January, the Minister met with members of the 221+ group. 221+ has since reported that the feedback from this meeting has been positive overall.

A report on the meeting is being prepared for circulation to members by the 221+ Group.

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Oversight and engagement with the HSE on modules of its work as follows:

1. Management of supports to patients/families
2. Provision of documents to patients
3. Interface with RCOG Review
4. Management of laboratory capacity issues
5. Introduction of HPV Screening
6. Colposcopy

1. Management of supports to patients/families	
Significant Issues	There are no exceptional items to report in relation to Community Supports.

2. Provision of documents to patients	
Significant Issues	**Current position, issues & challenges** The team remains focused on responding to all requests as soon as possible - the average time to deliver slides to the independent expert is 25 days. Weekly operational meetings continue to monitor the laboratories. The HSE has provided 109 slides out of a total number of 118. There are 9 outstanding which were received between Dec – Jan 31st. A total number of 542 records have been provided, out of a total number of 548 requests. There are 6 outstanding which have been received. Issues: The HSE has identified a significant number of cases where it 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.

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3. Interface with RCOG Review

Project Governance

- Support Team continues to hold daily meetings and teleconferences to progress deliverables, identify critical actions / timeframes, areas for escalation, and project RAIDS.

	Actions Progressed	Activities Planned
Patient Support Services	• As of COB Friday 1st Feb: o 1,702 invited to participate in Expert Panel Review, who are contactable and comprehended by the Review o 1,072 (63%) have consented to participate in the Review	
Laboratory Logistics	• Transport of slides has commenced in respect of all labs (Coombe, SONIC, and Quest) ➢ All slides held in the Coombe transferred this week to the RCOG nominated lab in the UK (75 slides). ➢ Slides held by SONIC and Quest in the USA were ready for transit, but are delayed due to an additional requirement for higher resolute imager: ▪ SONIC: 100 slides ▪ Quest: 99 slides • SONIC and Quest have been asked to provide full schedule for transport of remaining slides.	• Continue to work with Quest and SONIC to facilitate and track the transfer of slides. • CC Interim Programme Manager and RCOG Programme Lead to progress solutions to laboratory challenges in transferring slides. • Continue working with Client Services to establish process to correlate slides requested for legal proceedings with slides requested for RCOG Expert Panel Review. • Transfer slides being held.
Information Services	RCOG Support Team member (registered nurse) assigned to follow-up on calls with women to discuss any queries or concerns. **Total Calls to Information Line**: 150 (↑ 6) Total Calls (general): 78 (↑ 6) Total Calls (clinical): 72 (*No change*) Calls (clinical) resolved at initial contact: 49 (*No change*) Calls (clinical) escalated to acute services: 23 (*No change*) Calls (clinical) resolved by acute services: 23 (*No change*)	• 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)	• Making required infrastructural amendments to CMS to align data capture/display fields in respect of slide transfers. • Daily updates to CMS to reflect updates to consent information, slide tracking, contact notes, and other relevant information.	• As letters issue, continue to update CMS with validated data. • Continue QA process of validation of new consents received against CMS.
Acute & Community Services	• Weekly briefing sent to Hospital Groups through Acute Operations, and to Lead Colposcopists through CervicalCheck Interim Programme Manager. • Weekly teleconference with Acute Operations and CervicalCheck. • Responses provided to individual clinicians who have contacted the Programme with queries on the RCOG Support Programme and the Expert Panel Review. • Drafting protocol to support Expert Review Panel with provision of medical records from acute and community services where requested.	• Continue weekly briefings and teleconferences with Acute Operations and CervicalCheck. • Continue developing protocol to support Expert Review Panel with relevant medical records.
Current position, significant issues	• The transfer of slides from Cervical Check labs for the purpose of the Expert Panel Review has commenced. Further engagement and on-going communication will continue with all laboratories to address any challenges that arise, in order to ensure the safe and quality transport of slides.	

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4. Management of Laboratory Capacity Issues	
Uptake of Smear Tests	**Out of Cycle Smears** The total number of additional GP consultations to date was more than 110,000. The estimated number of early repeat smear tests to take place in the period of May 1st to December 31st is in the region of 57,810.
Average Time for Processing Results	We remain extremely concerned at the length of time being taken for reporting of smear tests and apologise sincerely to women affected by these delays. The average processing time is currently 27 weeks, with some taking longer. This remains a serious concern & lab capacity is a challenge with both existing providers and in other jurisdictions. The CervicalCheck team continue to validate and identify each woman impacted by the Quest HPV expiry issue which the programme was notified of in November. The programme commenced issuing letters to each of the women impacted in the week of 28th January. The program team continue to work with Quest Diagnostics to ensure any retests (approx.6000) that result from this issue are prioritised for testing by the lab. <u>Measures taken</u> • We have worked with existing private providers, other private providers and public service providers in other countries to try and grow our laboratory capacity. Some of our existing providers have managed to reduce the wait times and we continue to work with others to try and find additional capacity. • We have agreed with laboratories to prioritise those slides which originate from women who attended colposcopy; as this cohort of women is considered to have the highest clinical risk. • We have agreed with the laboratory with the largest backlog that they carry out a HPV test on smear test samples, prior to cytology, as a means of prioritising slides appropriately. Since April 2015, CervicalCheck has used HPV testing as an additional test for any low grade changes detected through cytology. The additional information provided by this HPV test is used to determine the recall recommendation for women. • While we continue to pursue additional capacity, this has proved very challenging due to the global shortage in cytology. This has been caused as a result of the reduced cytology requirement as countries implement HPV primary screening - which sees a reduction of approximately 80% for cytology requirements. We are actively trying to identify solutions that will help reduce waiting times which we know are causing a lot of anxiety for women.

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5. Introduction of HPV Screening

Governance	• HPV Steering Group established with NSS, HSE and service user representatives • Project team established with CervicalCheck, NSS and HSE membership • Detailed project plan on Project Vision managed by PMO team
Project Team Composition	• Project team established with identified project manager and workstream leads • CervicalCheck Clinical Director has commenced 4/02 • National laboratory QA lead appointed. Commenced 14/1 • Colposcopy lead still outstanding. There is colposcopy representation on the Clinical Advisory Group (CAG)
Current Position, Significant Issues	• **Stabilisation of current programme-** increase in laboratory test volumes in 2018 has resulted in significant lengthening of the process and reporting timelines. • **Capacity planning-** is underway to address the backlog with a detailed planned impact assessment and options appraisal. • **Public confidence-** reporting times and retests are impacting on confidence in the cervical screening service. • **Procurement-** despite on-going work to develop services in the Coombe to maximise public provision in the future, this work is time dependent. Additional lab services will be required for the HPV primary screening transition as there is not sufficient capacity available in the public sector.

Project Plan

	Actions Progressed	Activities Planned
Clinical	• Recently published data on the use of mRNA to be reviewed. Public Health and Performance Evaluation Unit (PEU) leading out on this.	• Update to be provided to the CAG for final decisions on preferred assay . Next meeting scheduled for end of Feb.
Procurement	• Market trawl commenced • Pre tender market engagement seminar feedback completed.	• Finalise membership of Procurement Evaluation team
ICT	• Unit testing for CSR at NSS site underway (80%) • Discussions underway with Practice Management System vendors for 2nd version of referral form to be uploaded	• Finalise unit testing by the end of Feb
Resources for HP's	• Workshop with workstream team Jan 31st • GP advisor is updating clinical information on the HCP guide	• GP advisor will liasie with E-learning company with changes • 3rd draft finalised and agreed by 12th March
Hospitals (Colposcopy)	• 6 site visits have taken place. Scope of work includes reviewing current operational pressures for all units, impact of the introduction of HPV and RCOG.	• Continue with site visits, all completed by March 1st; had to be extended. • Meeting with Colposcopy leads in Feb

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6. Colposcopy

- CervicalCheck has established a network of quality assured colposcopy clinics for women requiring further investigation following a smear test. A woman can be referred to one of 15 colposcopy clinics located nationwide.
- Extra clinical sessions have been added to reduce waiting lists
- Within the current climate time taken in a clinical setting is considerably longer to facilitate answering queries and putting women at ease
- Extra efforts made when appointments are cancelled to fill the vacant slot to further reduce waiting lists.
- Extra efforts to ensure the increased referrals are categorised in a prompt manner to ensure high and low grade are seen within guidelines

Colposcopy data

November Data				
	Monthly		Annual YTD	
	Projected	*Actual*	*Projected*	*Actual*
New referrals	1,625	1,591	17,875	15,759

November Data	
Month Year Colposcopy Clinic (&associated histology laboratory)	Average (combined)
*Waiting time HG end month - Target 90% to be seen within 4 weeks of referral	**94%
*Waiting time LG end month - Target 90% to be seen within 8 weeks of referral	**96%
*HG - High Grade, LG - Low grade	
** Figures for the Coombe not available this month	