

CervicalCheck Steering Committee

Weekly report to the Minister

1 February 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. 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 €1.19m 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 a validation 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. It is intended that this report will be issued to the members of the 221+ Patient Support Group prior to publication.

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.

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.

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 1,079 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 transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review has now commenced.

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 issued to the vast majority of affected women this week. 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 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 in December. A colposcopy lead is still being sought.

6. Smear-taking activity and laboratory capacity

The average processing time for smear tests is currently 96 days.

The total number of additional GP consultations was over 110,000. The estimated number of early repeat smear tests which took place between May 1st and December 31st is approximately 57,810. 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.

Smear test samples must be sent to the laboratory and made into slides within six weeks of the smear test date. After six weeks, the sample is deemed expired and cannot be processed. Transferring slides to samples in this timeframe was being achieved by the laboratories used by CervicalCheck until they experienced a high demand on resources following the announcement of free repeat smear tests in April. In the period April to December 2018, a

proportion of overall cervical screening samples were not transferred to slides within the six-week timeframe. Repeat testing was required in 550 cases or 0.25% of total samples. This compares with a rate of 0.23% for the same period in 2017.

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. 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.

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. Colposcopy waiting times

As requested by Steering Committee members, the HSE weekly report now includes details on colposcopy waiting times, with the acknowledgement that these are collected on a monthly basis and are reported two months in arrears.

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.

CervicalCheck Steering Committee

Weekly Report from HSE

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	<p>Current position, issues & challenges</p> <p>The team remains focused on responding to all requests as soon as possible - the average time to deliver slides to the independent expert is 32 days. Weekly operational meetings continue to monitor the laboratories.</p> <p>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.</p>

CervicalCheck Steering Committee Weekly Report from HSE

3. Interface with RCOG Review																							
Project Governance	<ul style="list-style-type: none"> 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	<p>As of COB Friday 25th January:</p> <ul style="list-style-type: none"> ➤ 1,716 invited to participate in Expert Panel Review, who are contactable and comprehended by the Review . ➤ 1,079 (63%) have consented to participate in the Review. 																						
Laboratory Logistics	<ul style="list-style-type: none"> Continuing to develop database of required slides in relation to new consents, by laboratory. Labs sent updated slide request for new consents, as of 18th Jan 2019. On-going communication with the CC-contracted laboratories (QUEST, SONIC/MedLab and Coombe). SOP for transport of slides amended following legal input, re-issued to labs 22 Jan 2019 along with request for schedule for slide transport Letter issued from RCOG Support Programme Lead to SONIC/MedLab on 23 Jan 2019 directing release of slides. The Coombe has commenced retrieval and imaging of slides. 	<ul style="list-style-type: none"> Quest advised they would commence transfer of slides by Fri 25 Jan 2019 – RCOG Support team following up with Quest on progress. Continue to negotiate with SONIC/Medlab to agree on the transfer of slides. Coombe to have slides transferred by 01/02 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. 																					
Information Services	<p>As of COB Friday 25th January, there have been a total of 144 calls to the information line. Details as follows:</p> <table border="1"> <thead> <tr> <th></th><th>#</th><th>Change from Previous Week</th></tr> </thead> <tbody> <tr> <td>Total Calls to Information Line</td><td>144</td><td>↑ 3</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> </tbody> </table>		#	Change from Previous Week	Total Calls to Information Line	144	↑ 3	Total Calls (general)	69	No change	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	<ul style="list-style-type: none"> 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.
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Case Management System (CMS)	<ul style="list-style-type: none"> Making required infrastructural amendments to CMS to align data capture/display fields in respect of slide transfers with updated SOP sent to labs 22 Jan 2019. 	<ul style="list-style-type: none"> As letters issue, continue to update CMS with validated data. Continue QA process of validation of new consents received against CMS. 																					
Acute & Community Services	<ul style="list-style-type: none"> Weekly briefing sent to HGs through Acute Operations and to Lead Colposcopists through CervicalCheck. Responses provided to individual clinicians who have contacted the Programme with queries on the RCOG Support Programme and the Expert Panel Review. 	<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. 																					
Current position, significant issues	<p>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. Coombe commenced slide transport W/C 28/01/19.</p>																						

CervicalCheck Steering Committee Weekly Report from HSE

4. Management of Laboratory Capacity Issues	
Uptake of Smear Tests	Out of Cycle Smears <p>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.</p>
Average Time for Processing Results	<p>The average processing time is currently 96 days, with some taking longer. This remains a serious concern & lab capacity is a challenge with both existing providers and in other jurisdictions.</p> <p>Last week the CervicalCheck team continued 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.</p>

CervicalCheck Steering Committee Weekly Report from HSE

5. Introduction of HPV Screening		
Governance	<ul style="list-style-type: none">HPV Steering Group established with NSS, HSE and service user representativesProject team established with CervicalCheck, NSS and HSE membershipDetailed project plan on ProjectVision managed by PMO team	
Project Team Composition	<ul style="list-style-type: none">Project team established with identified project manager and workstream leadsCervicalCheck Clinical Director commencing on 4th FebNational laboratory QA lead appointed. Commenced 14/1Colposcopy lead still outstanding. There is colposcopy representation on the Clinical Advisory Group (CAG)	
Current Position, Significant Issues	<ul style="list-style-type: none">Stabilisation of current programme- increase in laboratory test volumes in 2018 (32% increase) 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	<ul style="list-style-type: none">Recently published data on the use of mRNA to be reviewed. Public Health and Performance Evaluation Unit (PEU) leading out on this.	<ul style="list-style-type: none">Update to be provided to the CAG for final decisions on preferred assay
Procurement	<ul style="list-style-type: none">Market trawl commencedPre tender market engagement seminar feedback completed.	<ul style="list-style-type: none">Finalise membership of Procurement Evaluation team
ICT	<ul style="list-style-type: none">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	<ul style="list-style-type: none">Finalise unit testing by the end of Feb
Resources for HP's	<ul style="list-style-type: none">Workshop planned with workstream team Jan 31stGP advisor is updating clinical information on the HCP guide	<ul style="list-style-type: none">GP advisor will liaise with E-learning company with changes3rd draft finalised and agreed by 12th March
Hospitals (Colposcopy)	<ul style="list-style-type: none">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.	<ul style="list-style-type: none">Continue with site visits, all completed by March 1st; had to be extended.Meeting with Colposcopy leads in Feb

CervicalCheck Steering Committee Weekly Report from HSE

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.

Colposcopy data

November Data				
	Monthly		Annual YTD	
	<i>Projected</i>	<i>Actual</i>	<i>Projected</i>	<i>Actual</i>
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