

CervicalCheck Steering Committee

Weekly report to the Minister

22 March 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. Most recent figures show that approximately €1.3m has been reimbursed in respect of various health and social care costs, approximately €1m 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.

The HSE completed an exercise on the data held on the 221 affected women, with the aim of ensuring the National Screening Service has up to date information to support planning support needs for patients, for example. The report was shared with the 221+ Patient Support Group and is 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 27 days.

The HSE has reported that 118 slides have been provided out of a total of 123. There are 5 currently being processed. A total of 551 records have been provided, from 562 requests to date. There are 11 outstanding requests which are being processed.

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. 1,075 (63%) women have consented to take part; the final closing date for consents to be received was Friday 15 February.

The Expert Review Panel has been provided with colposcopy and other data from CervicalCheck in respect of women who have consented to participate, and the transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review is ongoing. The most recent position, as of 22 March, is that approximately 811 slides have transferred. The HSE reports it is continuing to work closely with laboratories to facilitate the transfer. The Information Line remains in service and integrated with the larger helpline, with a low level of calls being received (one in the last week).

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. CervicalCheck confirms it has completed validation and identification of women impacted, and all letters have now issued. The HSE SIMT is monitoring the number of women who do not take up the offer of a re-test.

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. Smear taking activity and laboratory capacity

The total number of additional GP consultations was around 112,000. 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 the number of 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 it has 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 has 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.

6. Introduction of HPV as the primary method of testing

A pre-tender market engagement seminar has taken place, and feedback is completed. This, together with laboratory capacity planning, will inform the laboratory configuration strategy and a lab subgroup for the project is in place to assess constraints and opportunities within the ecosystem of lab service providers. The lab subgroup has begun a review of QA guidelines, while a Clinical Advisory Group is reviewing the cohort of acceptable assays. A Prior Indicative Notice has been published in the OJEU, putting the market on notice of the intention to procure a suitably qualified laboratory provider to provide HPV primary screening and secondary screening by way of liquid based cytology. A contract notice is due to issue in March to commence the procurement process.

Colposcopy capacity planning is underway by the National Women and Infants Health Programme, which is required to support the introduction of the HPV test. Fourteen 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.

7. Colposcopy waiting times

The most recently reported data is January 2019. 90% of women with high grade abnormalities were seen within 4 weeks of referral (against target of 90%). 89% of women with low grade abnormalities were seen within 8 weeks of referral (against target of 90%). Currently, time taken in a clinical setting is reported to be considerably longer to facilitate answering questions and putting women at ease, and efforts to manage any impact on waiting times include extra clinical sessions and a focus on waiting list management through appropriate categorisation of referrals.

8. Ex-gratia scheme for non-disclosure

The terms of the CervicalCheck non-disclosure ex-gratia scheme were approved by Government on 11 March 2019, including an Independent Assessment Panel comprising a retired High Court Judge (who will act as Chair), an independent clinician and a person of good standing. The Chair of the Independent Assessment Panel is retired High Court Judge, Aindrias Ó'Caoimh.

CervicalCheck Steering Committee

Weekly Report from HSE 20/03/19

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 slide requests as soon as possible - the average time to deliver slides to the independent expert is 27 days. Weekly operational meetings continue to monitor the laboratories.</p> <p>The HSE has provided 118 slides out of a total number of 123. There are 5 currently being processed which were received between Dec – Jan 31st.</p> <p>A total number of 551 records have been provided, out of a total number of 562 requests. There are 11 outstanding which are being processed.</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>

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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	<ul style="list-style-type: none">1,075 (63%) women have consented to participate in the Expert Panel Review. The closing date for consent forms was 15th Feb.																				
Laboratory Logistics	<table><thead><tr><th>Lab</th><th>Number of slides requested to date</th><th>Number of slides sent to RCOG¹ <i>(including troubleshooting)</i></th></tr></thead><tbody><tr><td>SONIC Medlab</td><td>341</td><td>0</td></tr><tr><td>SONIC CPL</td><td>275</td><td>232 ↑87</td></tr><tr><td>QUEST</td><td>1,088</td><td>376</td></tr><tr><td>Coombe</td><td>62</td><td>75</td></tr><tr><td>Total</td><td>1,766</td><td>683</td></tr></tbody></table> <ul style="list-style-type: none">Quest shipped 93 slides to the UK on Friday 15 March.SONIC Medlab does not have equipment to image slides at specification required. Medlab is exploring options for having the slides imaged at another lab.	Lab	Number of slides requested to date	Number of slides sent to RCOG ¹ <i>(including troubleshooting)</i>	SONIC Medlab	341	0	SONIC CPL	275	232 ↑87	QUEST	1,088	376	Coombe	62	75	Total	1,766	683	<ul style="list-style-type: none">Quest laboratories have advised that they are shipping 100 slides W/C March 18th.Meeting scheduled for 19th March with NSS Client Services and legal counsel to agree process where slides requested for RCOG Expert Panel Review are currently under legal review and therefore unavailable.	
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Information Services	<ul style="list-style-type: none">There was 1 call to the information line in the last week (159 total calls to the information line since it opened in August 2018). An RCOG Support Team member (registered nurse) follows-up on calls to discuss any queries directly with the women.																				
Case Management System (CMS)	<ul style="list-style-type: none">Daily updates to CMS to reflect updates to consent information, slide tracking, contact notes, and other relevant information.																				
Acute & Community Services	<ul style="list-style-type: none">Responses provided to individual clinicians who contact the Programme with queries on the RCOG Support Programme and the Expert Panel Review.SOP established to support provision of medical records from acute services to the Expert Review Panel where requested.Structures and processes are being established to support disclosure of results with reference to existing processes already documented e.g. HSE Open Disclosure Policy, Safety Incident Management Policy, Lookback Review Guidance, etc. <ul style="list-style-type: none">Continue work in preparing for disclosure process.																				
Current position, significant issues	<ul style="list-style-type: none">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.The UK lab (North Bristol NHS Hospital) has advised that they can only process receipt of up to 200 slides per week, although they can accept larger quantities of slides and store them until they can be processed. The RCOG Support Team is working with all labs to ensure a steady but manageable transfer of slides from the USA and Ireland to Bristol.SONIC Medlab do not have the equipment to digitally image slides to the specifications required. Medlab is urgently seeking alternatives to have slides imaged at 2 other labs so that they may be sent to the Expert Review Panel as soon as possible.The Coombe has one remaining slide for transport to the UK, however there has been a delay in the delivery of equipment required to digitally image the slides to agreed specifications. It is not expected that the equipment will be deliver on 26th March, and the slide can be imaged and transported subsequently.																				

* The total number of slides sent to the UK may be greater than total number of slides requested from labs due to troubleshooting process whereby 2 slides (original and treated) are prepared from one sample

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4. Management of Laboratory Capacity Issues	
Uptake of Smear Tests	<p>Out of Cycle Smears</p> <p>The total number of additional GP consultations between May 1st to December 31st was more than 112,000. 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>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. On our latest figures the maximum processing time is 27 weeks, this remains a serious concern & lab capacity is a challenge with both existing providers and in other jurisdictions.</p> <p>The CervicalCheck team has completed validation & identification of each woman impacted by the Quest HPV expiry issue which the programme was notified of in November. The programme has issued letters to each of the women impacted in the period of 28th January to date. We have agreed with Quest that the 4,600 results will be turned around in 4 weeks.</p> <p><u>Measures taken</u></p> <ul style="list-style-type: none"> • 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. <p>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.</p>

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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 Project Vision managed by PMO team	
Project Team Composition	<ul style="list-style-type: none">Project team established with identified project manager and work stream leadsCervicalCheck Clinical Director commenced 4/02National laboratory QA lead appointed. Commenced 14/1Colposcopy lead still outstanding. There is colposcopy representation on the Clinical Advisory Group (CAG). Meeting with colposcopists held.	
Current Position, Significant Issues	<ul style="list-style-type: none">Stabilisation of current programme and capacity planning- 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. Tender notice is expected to issue in June and there is a risk that no laboratory will provide a response.	
Project Plan		
	Actions Progressed	Activities Planned
Clinical	<ul style="list-style-type: none">Engagement with the Institute of Obs&Gynae and Colposcopy nurses continued.The CAG subgroup has begun their review of the cohort of acceptable assays.The Lab Subgroup has started their review of the QA guidelines.	<ul style="list-style-type: none">Review colposcopies impact assessment progressA CAG subgroup will complete their review of the cohort of acceptable assays.The QA guidelines review by the working group of the CAG committee will continue.
Procurement	<ul style="list-style-type: none">Periodic Indicative Notice published to the OJEU putting the market on notice of the intention to procure a suitably qualified laboratory provider to provide HPV primary screening and secondary screening by way of liquid based cytology.	<ul style="list-style-type: none">A Contract Notice will issue in March to commence the procurement processThe team will work to fill the membership of the Procurement Evaluation Group by way of invitations to external experts.
Labs	<ul style="list-style-type: none">No work progressed on project plan due to on going operational issuesLab Capacity subgroup was formed to inform the CervicalCheck programme of options available to manage the lab capacity going forward.	<ul style="list-style-type: none">A new Lab subgroup to form in order to assess capacity constraints & opportunities across the ecosystem of lab service providers.Subgroup now awaits a decision re the options presented.
Communications	<ul style="list-style-type: none">No work progressed on project plan due to on going operational issues	<ul style="list-style-type: none">Dedicated comms lead to commence ASAPWorking group to be established and include member from NIO to align approach with HPV vaccination
ICT	<ul style="list-style-type: none">No work progressed on project plan due to on going operational issues	
Resources for Health Professionals	<ul style="list-style-type: none">Updating of the clinical information for the HCP guide has progressed.Current draft of the guide has been circulated for further input in prep for group review on 26th	<ul style="list-style-type: none">Team are compiling new content, images, references etc. on ongoing basis for the new guidebook and online resources.Team meeting for review of new guidebook scheduled for end of March
Hospitals (Colposcopy)	<ul style="list-style-type: none">14 site visits have taken place. Scope of work includes reviewing current operational pressures for all units, impact of the introduction of HPV and RCOG.Team is validating the data being gathered with colposcopy system data to track alignment continuously.	<ul style="list-style-type: none">Continue with site visits, all completed by March 31st; had to be extended due to local hospital availability to meet.Remodelling of colposcopy referral rates to be undertaken to take into account current operational challenges.

CervicalCheck Steering Committee Weekly Report from HSE 20/03/19

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

January Data					January Data	
	Monthly		Annual YTD		Month Year Colposcopy Clinic (& associated histology laboratory)	Average (Combined)
	Projected	Actual	Projected	Actual	*Waiting time HG end month - Target 90% to be seen within 4 weeks of referral	90%
Referrals	1,625	1,471	1,625	1607	*Waiting time LG end month - Target 90% to be seen within 8 weeks of referral	89%
					*HG - High Grade, LG - Low Grade	
					**Figures for the Coombe not available this month	