CervicalCheck Steering Committee

Weekly report to the Minister

29 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.

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 25 March, is that approximately 907 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.

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.

The HSE has advised that while the vast majority of women awaiting results for these repeat tests remain within the four to six week timeframe committed by the lab, a small number of women are regrettably waiting longer. This is due to an initial delay in the establishment of the ICT system for dealing with these tests, which took longer than anticipated. Despite this initial delay, the HSE has advised that Quest Diagnostics is confident that samples received to date will be processed within the next two weeks, while future samples received will have results issued within the stated four to six week timeframe.

5. Smeartaking 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. This work includes reviewing current operational pressures for all colposcopy units as well as the impact of the introduction of primary HPV testing and the RCOG review. The most recent update from the HSE advised that the majority of planned site visits have now taken place.

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.

All women, or their next of kin, in the 221 cohort identified from the clinical audit as having discordance in their smear test result will be invited to participate in the Scheme. The Department is currently engaging with the HSE in order to finalise arrangements for communicating invitations to the women. It is expected that the invitations will be issued shortly and following this, full details of the Scheme will be published on the Department's website.

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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 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. The HSE has provided 118 slides out of a total number of 125. There are 7 currently being processed which were received between Dec – Jan 31st. A total number of 554 records have been provided, out of a total number of 563 requests. There are 9 outstanding which are being processed. 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 (Risks, Actions, Issues, Decisions).
- 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.

	Actions Progressed	Activities Planned
Patient Support Services	• 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><tr><th>Lab</th><th>Number of slides requested to date</th><th>Number of slides sent to RCOG[1] (including troubleshoots)</th></tr><tr><td>SONIC Medlab</td><td>341</td><td>0</td></tr><tr><td>SONIC CPL</td><td>275</td><td>267</td></tr><tr><td>QUEST</td><td>1,088</td><td>565 ↑96</td></tr><tr><td>Coombe</td><td>62</td><td>75</td></tr><tr><td>Total</td><td>1,766</td><td>907</td></tr></table> • Quest shipped 96 slides to the UK w/c 18th March. They have been requested to transfer all remaining slides to the NBHT (RCOG contracted lab) by the end of March. • SONIC Medlab does not have machinery required to image slides at specification required; in the absence of this, they have manually digitally imaged a small number of slides, to the specifications outlined in SOP, to be transferred to the NBHT w/c 25 March. Agreement currently being negotiated with Coombe to have Medlab slides imaged there, after new equipment installed (w/c 25 March) and staff trained.	• W/C 25th March: Transfer slides to the NBHT.
Information Services	• There were no calls 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)	• Daily updates to CMS to reflect updates to consent information, slide tracking, contact notes, and other relevant information.	
Acute & Community Services	• 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.	• Continue work in preparing for disclosure process.
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. • 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. • 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	**Out of Cycle Smears** 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.
Average Time for Processing Results	We remain extremely concerned at the length of time being taken for reporting of cervical smear tests, which regrettably are being reported between 4 weeks and 33 weeks of the test being taken. In some cases this is taking longer. However, it is worth noting that over half of samples received by the labs are being processed within 15 weeks. 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. <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 work stream leads • CervicalCheck Clinical Director 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). Meeting with colposcopists held.
Current Position, Significant Issues	• **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	• 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.	• Review colposcopy impact assessment progress • A 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	• Work has been ongoing in preparing and getting legal signoff on the materials to support the contract notice being issued.	• A Contract Notice will issue in April to commence the procurement process • The team will work to fill the membership of the Procurement Evaluation Group by way of invitations to external experts.
Labs	• No work progressed on project plan due to on going operational issues • Lab Capacity subgroup was formed to inform the CervicalCheck programme of options available to manage the lab capacity going forward.	• Subgroup now awaits a decision re the options presented.
Communications	• No work progressed on project plan due to on going operational issues	• Dedicated comms lead to commence ASAP • Working group to be established and include member from NIO to align approach with HPV vaccination
ICT	• No work progressed on project plan due to on going operational issues	
Resources for Health Professionals	• 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	• 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)	• 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.	• 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.

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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

February Data				
	Monthly		Annual YTD	
	Projected	Actual	Projected	Actual
Referrals	1,625	1,377	3,250	2,985

February 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	89%
*Waiting time LG end month - Target 90% to be seen within 8 weeks of referral	95%
*HG - High Grade, LG - Low Grade **Figures for the Coombe not available this month	