

## **CervicalCheck Steering Committee**

### **Weekly report to the Minister**

**22 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, approximately €1.23m has been reimbursed in respect of various health and social care costs, approximately €923,000 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 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 26 days.

The HSE has reported that 112 slides have been provided out of a total of 121. There are 9 outstanding requests, which were received between December and January. A total of 546 records have been provided, from 549 requests to date.

#### **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 15 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 1,075 (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 February, is that approximately 590 slides have transferred. All slides from the Coombe have now been transferred, with transfer from the other labs continuing in batches. The HSE reports it is continuing to work closely with labs to facilitate and track the transfer. The HSE RCOG Support Team is holding weekly briefings

with HSE Acute Operations to support the review, and 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. Letters have now issued to all women affected, save for a very small number where contact details are still being sought. Retests arising from this issue will be prioritised for testing.

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. Smeartaking activity and laboratory capacity**

The total number of additional GP consultations was around 111,000. The estimated number of early repeat smear tests which took place between May 1<sup>st</sup> and December 31<sup>st</sup> is approximately 57,810, or just over half the number of consultations.

The average processing time for smear tests is currently 27 weeks. 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. A Periodic 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.

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 it is intended to have all site visits complete by early March.

#### **7. Colposcopy waiting times**

The most recently reported data is November 2018. 93% of women with high grade abnormalities were seen within 4 weeks of referral (against target of 90%). 90% 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.

# CervicalCheck Steering Committee

## Weekly Report from HSE 20/02/19

### 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	
<b>Significant Issues</b>	There are no exceptional items to report in relation to Community Supports.

2. Provision of documents to patients	
<b>Significant Issues</b>	<p><b>Current position, issues &amp; challenges</b></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 26 days. Weekly operational meetings continue to monitor the laboratories.</p> <p>The HSE has provided 112 slides out of a total number of 121. There are 9 currently being processed which were received between Dec – Jan 31<sup>st</sup>.</p> <p>A total number of 546 records have been provided, out of a total number of 549 requests. There are 3 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>

# CervicalCheck Steering Committee

## Weekly Report from HSE 20/02/19

3. Interface with RCOG Review																							
<b>Project Governance</b>	<ul style="list-style-type: none"> <li>Support Team continues to hold daily meetings and teleconferences to progress deliverables, identify critical actions / timeframes, areas for escalation, and project RAIDS.</li> </ul>																						
	<b>Actions Progressed</b>	<b>Activities Planned</b>																					
<b>Patient Support Services</b>	<ul style="list-style-type: none"> <li>As of COB Friday 15<sup>th</sup> Feb, there are 1,702 women or their next of kin invited to participate in Expert Panel Review, who are contactable and comprehended by the Review. 1,075 (63%) have consented to participate, and the final closing date for consents was 15<sup>th</sup> Feb.</li> </ul>																						
<b>Laboratory Logistics</b>	<table border="1"> <thead> <tr> <th>Lab</th><th>Number of slides requested to date</th><th>Number of slides sent to RCOG<sup>+</sup> (Total slides including troubleshooting)</th></tr> </thead> <tbody> <tr> <td>SONIC Medlab</td><td>402</td><td>0</td></tr> <tr> <td>SONIC CPL</td><td>254</td><td>83 (84)</td></tr> <tr> <td>QUEST</td><td>1,072</td><td>100 (100)</td></tr> <tr> <td>Coombe</td><td>70</td><td>70 (75)</td></tr> <tr> <td><b>Total</b></td><td><b>1,798</b></td><td><b>253 (259)</b></td></tr> </tbody> </table> <ul style="list-style-type: none"> <li>Next week (w/c 18<sup>th</sup> Feb): CPL has advised they will ship 50 slides and Quest has advised they will ship 290 slides</li> <li>SONIC Medlab does not have equipment to image slides at specification required. The Coombe has offered support in imaging slides. Discussions are on-going with the Coombe to implement this.</li> </ul>	Lab	Number of slides requested to date	Number of slides sent to RCOG <sup>+</sup> (Total slides including troubleshooting)	SONIC Medlab	402	0	SONIC CPL	254	83 (84)	QUEST	1,072	100 (100)	Coombe	70	70 (75)	<b>Total</b>	<b>1,798</b>	<b>253 (259)</b>	<ul style="list-style-type: none"> <li>Continue to work with Quest and SONIC to facilitate and track the transfer of slides.</li> <li>CC Interim Programme Manager and CEO of the Coombe to progress agreement re imaging Medlab slides.</li> <li>Continue working with Client Services to establish process to correlate slides requested for legal proceedings with slides requested for RCOG Expert Panel Review.</li> </ul>			
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<b>Information Services</b>	<p>RCOG Support Team member (registered nurse) assigned to follow-up on calls with women to discuss any queries or concerns.</p> <table border="1"> <thead> <tr> <th></th><th>#</th><th>Change from Previous Week</th></tr> </thead> <tbody> <tr> <td><b>Total Calls to Information Line</b></td><td>152</td><td>↑ 1</td></tr> <tr> <td>Total Calls (general)</td><td>80</td><td>↑ 1</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	<b>Total Calls to Information Line</b>	152	↑ 1	Total Calls (general)	80	↑ 1	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	
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<b>Case Management System (CMS)</b>	<ul style="list-style-type: none"> <li>Making required infrastructural amendments to CMS to align data capture/display fields in respect of slide transfers.</li> <li>Daily updates to CMS to reflect updates to consent information, slide tracking, contact notes, and other relevant information.</li> </ul>	<ul style="list-style-type: none"> <li>As letters issue, continue to update CMS with validated data.</li> <li>Continue QA process of validation of new consents received against CMS.</li> </ul>																					
<b>Acute &amp; Community Services</b>	<ul style="list-style-type: none"> <li>Weekly briefing sent to Hospital Groups and to Lead Colposcopists</li> <li>Weekly teleconference with Acute Operations and CervicalCheck.</li> <li>Responses provided to individual clinicians who contact the Programme with queries on the RCOG Support Programme and the Expert Panel Review.</li> <li>Drafting protocol to support provision of medical records from acute services to the Expert Review Panel where requested – feedback received from hospital groups on SOP.</li> <li>Planning approach to disclosure process with RCOG and DOH, with reference to existing processes already documented e.g. HSE Safety Incident Management Policy.</li> </ul>	<ul style="list-style-type: none"> <li>Continue weekly briefings and teleconferences with Acute Operations and CervicalCheck.</li> <li>Continue developing protocol to support Expert Review Panel with relevant medical records.</li> </ul>																					

# CervicalCheck Steering Committee

## Weekly Report from HSE 20/02/19

<b>Current position, significant issues</b>	<ul style="list-style-type: none"> <li>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.</li> <li>As SONIC Medlab do not have the equipment to digitally image slides to the specifications required, agreement is progressing between the NSS, the Coombe and SONIC Medlab to have the slides imaged in the Coombe.</li> </ul>
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*\* 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.*

### 4. Management of Laboratory Capacity Issues

<b>Uptake of Smear Tests</b>	<p><b>Out of Cycle Smears</b></p> <p>The total number of additional GP consultations between May 1<sup>st</sup> to December 31<sup>st</sup> was more than 111,000. The estimated number of early repeat smear tests to take place in the period of May 1<sup>st</sup> to December 31<sup>st</sup> is in the region of 57,810.</p>
<b>Average Time for Processing Results</b>	<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. The average processing time is currently 27 weeks, with some taking longer. This remains a serious concern &amp; lab capacity is a challenge with both existing providers and in other jurisdictions.</p> <p>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. We have agreed with Quest that the 4,400 results will be turned around in 4 weeks.</p> <p><u>Measures taken</u></p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> </ul> <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>

## CervicalCheck Steering Committee Weekly Report from HSE 20/02/19

5. Introduction of HPV Screening		
Governance	<ul style="list-style-type: none"><li>HPV Steering Group established with NSS, HSE and service user representatives</li><li>Project team established with CervicalCheck, NSS and HSE membership</li><li>Detailed project plan on Project Vision managed by PMO team</li></ul>	
Project Team Composition	<ul style="list-style-type: none"><li>Project team established with identified project manager and work stream leads</li><li>CervicalCheck Clinical Director has commenced 4/02</li><li>National laboratory QA lead appointed. Commenced 14/1</li><li>Colposcopy lead still outstanding. There is colposcopy representation on the Clinical Advisory Group (CAG). Meeting with colposcopists scheduled on Friday, 22<sup>nd</sup> Feb.</li></ul>	
Current Position, Significant Issues	<ul style="list-style-type: none"><li><b>Stabilisation of current programme and capacity planning</b>- 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.</li><li><b>Public confidence</b>- reporting times and retests are impacting on confidence in the cervical screening service.</li><li><b>Procurement</b>- 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.</li></ul>	
Project Plan		
	Actions Progressed	Activities Planned
Clinical	<ul style="list-style-type: none"><li>Next Clinical Advisory Group (CAG) meeting scheduled for 28<sup>th</sup> Feb</li><li>Colposcopy forum meeting scheduled for 22<sup>nd</sup> Feb</li></ul>	<ul style="list-style-type: none"><li>CAG meeting on 28<sup>th</sup> Feb</li></ul>
Procurement	<ul style="list-style-type: none"><li>Revised approach based on advise from SCA &amp; legal team</li><li>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.</li></ul>	<ul style="list-style-type: none"><li>A Contract Notice will issue in March to commence the procurement process</li></ul>
ICT	<ul style="list-style-type: none"><li>Unit testing for CSR at NSS site underway (80%)</li><li>Discussions underway with Practice Management System vendors for 2<sup>nd</sup> version of referral form to be uploaded</li></ul>	<ul style="list-style-type: none"><li>Finalise unit testing for CSR by the end of Feb</li></ul>
Resources for Health Professionals	<ul style="list-style-type: none"><li>Workshop with workstream team Jan 31st</li><li>GP advisor is updating clinical information on the HCP guide</li></ul>	<ul style="list-style-type: none"><li>GP advisor will liaise with E-learning company with changes</li><li>3<sup>rd</sup> draft of HCP guide finalised and agreed by 12th March</li></ul>
Hospitals (Colposcopy)	<ul style="list-style-type: none"><li>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.</li></ul>	<ul style="list-style-type: none"><li>Continue with site visits, all completed by March 1<sup>st</sup>; had to be extended due to local hospital availability to meet.</li></ul>

## CervicalCheck Steering Committee Weekly Report from HSE 20/02/19

### 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

November Data				
	Monthly		Annual YTD	
	<i>Projected</i>	<i>Actual</i>	<i>Projected</i>	<i>Actual</i>
New referrals	1,625	1,110	17,875	16,876

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	**93%
*Waiting time LG end month - Target 90% to be seen within 8 weeks of referral	**90%
*HG - High Grade, LG - Low grade	
** Figures for the Coombe not available this month	