CervicalCheck Steering Committee

Weekly report to the Minister

17 May 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. As of end-April, €1.42m has been reimbursed in respect of various health and social care costs, €966,000 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.

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 the average time to deliver slides to independent experts is 27 days. To date, 125 slides out of a total number of 132 have been provided to women and families. A further 7 requests are currently 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. 1,074 (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 HSE reports it is continuing to work closely with laboratories to facilitate the transfer. The most recent position, is that as of 17 May approximately 1,371 slides have transferred. Imaging of the remaining slides began on 13 May and is expected to take approximately three and a half weeks to complete. Work is ongoing by the HSE in relation to communicating results of the RCOG review to women. 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 advised that about 4,500 women would require a retest and arrangements were made for retests for these women, which were to be processed within a four-to-six-week timeframe.

The HSE has advised that, despite an initial delay, Quest Diagnostics is confident that future samples received will have results issued within the stated four-to-six-week timeframe. As of 3 May, 2,929 repeat smear test samples have been received by Quest, 2,758 results have been processed/results notified to CervicalCheck and 171 tests are currently awaiting results. The HSE advises that the SIMT established in relation to this issue 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 identified.

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 reports that tests are currently being reported between 3 weeks and 33 weeks of the test being taken. In some cases, this is taking longer. Over half of samples received by the labs are being processed within 8 weeks.

The lab with the largest backlog has ceased accepting new tests from 1 May and will now focus solely on tests in the backlog. The HSE has agreed with the lab that it carry out a HPV test on smear test samples, prior to cytology, as a means of prioritising slides appropriately. It is expected that approximately 15% of the total samples taken will be HPV positive. These samples will be prioritised for cytology by the laboratory.

The HSE has advised that it has sourced additional capacity internationally and it is currently working to agree commercial arrangements, and complete quality assurance processes, in order to enable it to incorporate this capacity into the CervicalCheck programme.

6. Introduction of HPV as the primary method of testing

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.

A significant volume of work is underway within the HSE to support the introduction of primary HPV screening. A Steering Group is in place to oversee the project, chaired by the Clinical Director of CervicalCheck, with a dedicated project team in place in the National Screening Service to support this work. The negotiations which are underway in relation to the additional laboratory capacity will have an impact on this project. The outcome of these negotiations is awaited.

7. Colposcopy waiting times

The most recently reported data is valid to end March 2019. 89% 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.

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, Mr Justice Aindrias Ó'Caoimh, was appointed on 5 March 2019, and the remaining two members were appointed by the Minister on 23 April. On 8 May letters issued to women in the 221 cohort, or their next of kin, inviting them to participate in the scheme.

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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 125 slides out of a total number of 132. There are 7 currently being processed. A total number of 573 records have been provided, out of a total number of 581 requests. There are 8 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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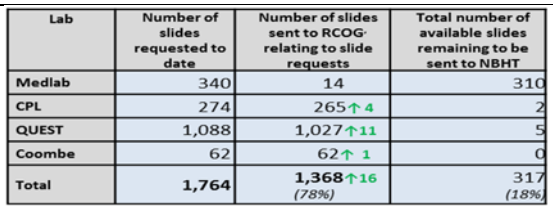
3. Interface with RCOG Review

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	• 1,074 (63%) women have consented to participate in the Expert Panel Review.	
Laboratory Logistics	 • 16 slides transferred from 3 labs in the last week. The Coombe has transferred all requested slides to the RCOG , with 0 outstanding. • Proposal received from Medlab on Tuesday 8th May on the imaging of requested slides at the Coombe, to commence May 13th. It is expected to take at least 3 ½ weeks to image all requested slides. Proposal agreed by the Coombe, and shared with RCOG and DOH.	• Maintain regular contact to Medlab and the Coombe on imaging of Medlab slides, to ensure slides are imaged and transferred as per proposal agreed.
Information Services	• There were 4 calls to the information line in the last week (189 total calls to the information line since it opened in August 2018).	
Case Management System (CMS)	• A Project Manager has been assigned from Office of the CIO to oversee the maintenance and development of the CMS – met members of the HSE RCOG Support Team on 8th May to discuss planning and requirements for CMS.	
Acute & Community Services	• The Expert Review Panel identified a list of women for whom clinical records are required for review when they are in Dublin on Saturday 18th May. In line with the agreed SOP with acute services, this list has been separated by hospital and circulated to the appropriate hospital group for retrieving the relevant files. Files are due for receipt W/C May 13th. • A panel of women (or their next of kin) consenting to participate in the Review has been formed to meet with members of the RCOG Expert Review team on Friday 17th May. The Expert Review team will request the group's views on RCOG correspondence relating to issuance of results, with the aim of enhancing the person-centredness of the reporting process.	
Clinical Open Disclosure	• Structures and processes are being established to support disclosure of results with reference to existing processes already documented e.g. HSE Open Disclosure Policy • The CCO, as commissioner of the Open Disclosure Working Group, sent letter of invitation and Terms of Reference to the group. Meeting held on Wednesday 15th May.	
Current position, significant issues	• The CervicalCheck contracted laboratories have identified a number of slides that are currently unavailable for the RCOG Review, as they were previously released to an independent expert reviewer and have not yet been returned to the originating laboratory as yet. Letters are issuing from the NSS to these women and their solicitors where relevant. Unfortunately, for those slides not received by the expert panel by 30th April, they are unable to review those cases. • The CervicalCheck contracted laboratories have also identified a number of slides that are proving difficult to locate. The labs are making every effort to retrieve these slides.	

Lab	Number of slides requested to date	Number of slides sent to RCOG relating to slide requests	Total number of available slides remaining to be sent to NBHT
Medlab	340	14	310
CPL	274	265 ↑ 4	2
QUEST	1,088	1,027 ↑ 11	5
Coombe	62	62 ↑ 1	0
Total	1,764	1,368 ↑ 16 (78%)	317 (18%)

** 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 3 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 8 weeks. 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. While we continue to pursue active leads 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 c80% for cytology requirements. We are actively trying to identify possible solutions that will help reduce the wait times which we know are causing a lot of anxiety for women. Whilst this is very undesirable, our clinical advice is that this poses a very low risk to women. Notwithstanding this, we recognise that these delays are extremely difficult for women and we are making every effort to improve this situation. We have made significant improvements in the turnaround times with two of our three laboratories and are working closely on an improvement plan with the third laboratory. We are absolutely focused on reducing waiting times for results as quickly as possible. The HSE has been working closely with the lab with the largest number of tests waiting to be processed, MedLab Pathologies Ltd, to clear all outstanding smear tests as a matter of priority. This lab processes smear tests for women based mainly in the south and west of the country. We are making some progress in this regard; with the overall number of outstanding smear tests steadily reducing. This work with MedLab Pathologies Ltd is being done based on a HPV initial testing model; i.e. HPV testing will be carried out on smear test samples prior to cytology. While the human papillomavirus (HPV) is a very common virus and usually clears without treatment, some types can cause changes in the cells of the cervix that can later develop into cervical cancer. This HPV testing model was chosen as the most effective way for the lab to process all outstanding tests based on prioritising women most at risk. This means that: - All outstanding tests will have an initial HPV test carried out. - Tests which report as HPV positive will be prioritised for cytology, as these women are considered to have the highest clinical needs. - Tests which report as HPV negative will have cytology performed as a second priority, as these women are considered to have lower clinical needs. While this model this may result in an initial further delay for women with negative HPV results, it will ultimately allow women with HPV positive results, who are considered most at risk, to be prioritised and for those women to receive necessary follow-up care. We hope that this process will provide reassurance to women whose outstanding tests are with MedLab Pathologies Ltd that we are doing out utmost to expedite these tests.

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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). Meetings with colposcopists are held regularly.
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.

Project Plan

	Actions Progressed	Activities Planned
Clinical	• Engagement with the Institute of Obs & Gynae and Colposcopy nurses continued. • Additional part-time colposcopy participation has provisionally been obtained for the programme.	• The HPV steering group meeting is scheduled for next week. • The QA guidelines review by the working group of the CAG committee to continue.
Procurement	• Activities paused due to ongoing negotiations with existing laboratory service providers.	• No immediate activities planned at this stage pending the conclusion of current negotiations.
Labs	• Development of the laboratory monitoring metrics for primary screening HPV continues. • The laboratory strategy continues to be developed in line with existing and future procurement models.	• Finalise the long term lab strategy
Communications	• A dedicated Comms resource has been assigned to the project. • A review to provide baseline insights of all NSS screening campaigns' activity in 2018 is now complete. • The market research agency has been briefed on a programme of work to identify the relevant audience insights that will inform the HPV screening campaign • A creative agency has been briefed and tasked with carrying out a market review of HPV screening campaigns.	• The market research agency to revert with a proposal, including methodologies (qualitative/quantitative/other), costs and timeline/dates. • Detailed project plan to be developed, to include the operational activities required for the Comms work stream.
ICT	• Work continued on the IT testing components required for the GP practice management system and the colposcopy clinics systems links.	• Work to continue at the GP and Colposcopy units while the private lab provider is determined.
Resources for Health Professionals	• The team continue to update the content required for the e-learning training module and all materials required to inform all health professionals.	• Team are compiling new content, images, references etc. on an ongoing basis for the new resources.
Hospitals (Colposcopy)	• The team continue to compile data from their visits to the colposcopy units in Ireland. • In parallel, a report providing existing metrics and modelling data (for future scenarios) for the colposcopy units was progressed further.	• One final colposcopy unit visit is due to take place to conclude the visits. • Remodelling of colposcopy referral rates to be continued 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

March				
	Monthly		Annual YTD	
	Projected	Actual	Projected	Actual
Referrals	1,625	1,515	4,875	4,486

March 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	90%
*HG - High Grade, LG - Low Grade **Figures for the Coombe not available this month	