CervicalCheck Steering Committee

Weekly report to the Minister

14 June 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-May, €1.46m has been reimbursed in respect of various health and social care costs, €973,000 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 28 days. To date, 131 slides out of a total number of 137 have been provided to women and families. A further 6 requests are currently being processed.

3. Independent Expert Panel Review

1,073 (63%) women have consented to take part from a total of 1,702 invited in the International Clinical Expert Review led by the Royal College of Obstetricians and Gynaecologists (RCOG).

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 concluded on 7 June 2019.

The HSE's RCOG Clinical Open Disclosure Group is continuing to meet regularly to plan for the communication of results. Strategic planning is required to minimise impact on current clinical services whilst maintaining the need to disclose review findings in a timely, considerate and patient centred manner.The RCOG Expert Review Panel visited Dublin on May 17-19 and met with a panel of women or their next-of-kin who are participating in the review. The purpose of this meeting was to enhance the person-centredness of the reporting process. In addition, the Panel viewed patient case files and held meetings with Officials from the Department of Health and the HSE during this visit.

While over 96% of requested slides have transferred, some difficulties have been encountered by labs in either locating slides or in retrieving slides which had been sent out for external independent review at the request of individuals concerned / solicitors acting on their behalf. This means that just under 4% of slides have unfortunately not been transferred to the review by the deadline of 7 June and cannot be therefore included.

As a result, 31 women whose slides are still being sought by the lab will now receive a partial report (if they have other slides included in the review) or no report (if the unavailable slide was the only one in the review). The first priority has been to contact these women and their

families whose slides are still being sought and the HSE has completed this communication, having received confirmation of the final position from the laboratories on 7 June. Calls were made to women and families by senior healthcare professionals and the HSE has apologised to those concerned. Follow-up letters will be subsequently issued week commencing 17 June. The HSE has also contacted 10 women and families whose slides are unavailable as they have been sent out for independent review on their behalf.

The Information Line remains in service and integrated with the larger helpline, and has been extended to 7 days a week. The HSE reports that a low level of calls is being received.

4. Smeartaking activity

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 30 weeks of the test being taken, taking longer in some cases, but that over half of samples received by the labs are being processed within 5 weeks.

The HSE reports that steady progress is being made in dealing with the backlog, with the overall number of outstanding tests reducing. The HSE reports that, as of 9 June 2019, the total number of outstanding smear tests was 54,474.

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 this 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.

5. Laboratory capacity

Following a global search for capacity, Quest Diagnostics was identified by the HSE as having the necessary capacity to sustain the national cervical screening programme and a contract for the provision of this additional capacity was signed on 7 June.

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.

7. Colposcopy waiting times

The most recently reported data is valid to end April 2019. 81% of women with high grade abnormalities were seen within 4 weeks of referral (against target of 90%). 84% 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.

9. Supplementary Report of the Scoping Inquiry into the CervicalCheck Screening Programme

The Supplementary Report of the Scoping Inquiry into the CervicalCheck Screening Programme, by Dr Gabriel Scally, was published on 11 June 2019, following Government approval. The Supplementary Report makes two further recommendations, which have been accepted. Actions to implement these recommendations will be incorporated into the existing Implementation Plan for all of the Scoping Inquiry recommendations.

A progress report on the Implementation for the recommendations of the Scoping Inquiry for Quarter 1 2019 is published on the Department of Health 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 131 slides out of a total number of 137. There are 6 currently being processed. A total number of 580 records have been provided, out of a total number of 588 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

- Weekly interagency telecon with Expert Review Panel and Department of Health as regards project planning & matters for review/decision – took place Fri 7th June.
- Meeting held between CCO, National Director NSS, HSE RCOG Programme Lead, AND Acute Operations and CD NWIHP to discuss appropriate governance arrangements.

	Actions Progressed	Activities Planned
Patient Support Services	• An update letter (to be signed by ND NSS) has been drafted to Review participants to inform them on current status and apologise for unforeseen delays. Approval received from the DOH. Letter is ready for issue, pending confirmation from ND NSS.	
Laboratory Logistics	<table><tr><th>Lab</th><th>Number of slides requested to date</th><th>Number of slides sent to RCOG relating to slide requests</th><th>Total number of available slides remaining to be sent to NBHT</th></tr><tr><td>Medlab</td><td>339</td><td>325</td><td>0</td></tr><tr><td>CPL</td><td>274</td><td>267 ↑2</td><td>0</td></tr><tr><td>QUEST</td><td>1,088</td><td>1,039 ↑4</td><td>1</td></tr><tr><td>Coombe</td><td>62</td><td>62</td><td>0</td></tr><tr><td>Total</td><td>1,763</td><td>1,693 ↑6 (96%)</td><td>1 (<1%)</td></tr></table> • All available slides (except 1) have now been sent to the RCOG for inclusion in the review. The one available outstanding is held on instruction from a woman's solicitor and pending direction from the solicitor. • 4% of slides (69) are either unavailable or still being sought by the labs, relating to 45 women. Have received further information and documentary evidence from labs in relation to missing slides.	• Where slides cannot be retrieved, commence contacting the women or next of kin to advise on status • Follow-up with RCOG Expert Panel on their proposed schedule and timeframes for the safe return of slides to labs of origin, so that HSE Programme can support this process.
Information Services	• There were 2 calls to the information line in the last week (202 total calls to the information line since it opened in August 2018).	• Call centre hours to be extended to 7 days per week from next week (w/c 10 June) to prepare for any calls related to unavailable slides and the update Letter to RCOG participants.
Case Management System (CMS)		
Acute & Community Services	• Weekly teleconference with Acute Operations and CervicalCheck – most recent took place Wed 29 May • Coordinating provision of clinical records for RCOG Expert Panel to review, as requested by the Panel: o Expert Panel has received clinical records in respect of **84 patients** to date. o A request for clinical records in relation to **an additional 27 patients** was circulated by Acute Operations to relevant hospitals on Fri 24th May, with records due for return 10th June. o A request for clinical records in relation to **an additional 20 patients** was received from RCOG on Tues 4 June and circulated by Acute Operations. The records are due for return 21st June.	• Mid-June: Remaining clinical records (due for return 10 June) to be transported to RCOG for review.
Clinical Open Disclosure	• Meeting took place on Thursday 6 June with Lead Clinician in Cork to progress discussion regarding open disclosure planning and process. • Responses received from 13 hospitals identifying treating clinician for consented cohort. Requested returns from outstanding hospitals.	• Convene meeting of the additional clinical support identified during week commencing 10 June 2019.
Current position, significant issues	• Identification of treating clinician for the consented cohort has commenced, a large proportion of the consented cohort have attended more than one colposcopy clinic and identifying the appropriate treating clinician may be challenging in these cases. • Strategic planning required to minimise impact on current clinical services whilst maintaining the need to disclose review findings in a timely, considerate and patient centred manner.	

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4. **Management of Laboratory Capacity**	
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 30 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 5 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. • Steering group meeting took place 23/05	• 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

April				
	Monthly		Annual YTD	
	Projected	Actual	Projected	Actual
Referrals	1,625	1,555	6,500	5,943

April Data	
Month Year Colposcopy Clinic (& associated histology laboratory)	Average (Combine
*Waiting time HG end month - Target 90% to be seen within 4 weeks of referral	81%
*Waiting time LG end month - Target 90% to be seen within 8 weeks of referral	84%
*HG - High Grade, LG - Low Grade **Figures for the Coombe not available this month	