CervicalCheck Steering Committee

Monthly report to the Minister

July 2019

1.	**Independent Expert Panel Review**	Following the Government decision in May 2018, an Independent Clinical Expert Panel Review is being carried out by the Royal College of Obstetricians and Gynaecologists (RCOG) with expertise also sourced through the British Society for Colposcopy and Cervical Pathology. The purpose of this Review is to provide women with independent clinical assurance about the timing of diagnosis and treatment. A total of 1,074 women consented to be included in the review, or about 63% of those eligible to participate. There have been ongoing approximately weekly interactions between the Department, the HSE and the RCOG Expert Panel throughout July, the purpose of which has been to discuss the progress of the Review at an operational level, particularly relating to the process of receiving consent from women or their next of kin, as well as the transfer of slides for all consenting participants. This intensive engagement has also served to ensure that there is a consistent channel through which any issues arising could be raised and discussed by all parties. Detailed logistical planning has been carried out by the HSE to put the necessary arrangements in place. The HSE has held continuing engagement with clinicians in relation to the communication of the individual report, and a central resource of clinicians is also in place to support the communications process. The Department has had ongoing regular communication with the RCOG Lead Assessor throughout 2019 and members of the RCOG Expert Review Panel visited Dublin from 16-18 May. Officials from the Department and the HSE met again with RCOG in Dublin on 24 July, with the assessors participating by telecon, with a focus on the communications process.
2.	**Implementation of the recommendations of Dr Scally's Scoping Inquiry into CervicalCheck**	The Implementation Plan for the recommendations of the First and Final Reports of the Scoping Inquiry was developed between September and November 2019 and approved by Government on 12 December 2018. The Plan provides the necessary foundation to ensure a highly effective and well managed cervical screening programme. Dr Scally provided a formal assessment of this Plan and progress against it in late February. Dr Scally is clear that significant effort and resources are being committed to addressing the problems he identified, and that the appropriate resourcing and project management structures are in place. Following Dr Scally's assessment, a revised Implementation Plan, overseen by the Department, was approved by the Minister on 21 May and is published on the Department's website, along with a Progress Report for Quarter 1 2019. A Q2 2019 progress report was approved by the Minister in July, for publication on the website of the Department. As of the end of Q2 2019, there were 161 actions arising from the 56 recommendations. The number of completed actions has increased significantly from Q1 with 91 actions now complete and 36 actions in progress.

		Within July, further progress includes: • work on the establishment of a Women's Health Taskforce within the Department of Health, which is planned to start its work in September (Recommendation 2). • a notice seeking expressions of interest for membership of the National Screening Committee was advertised in July, with a closing date of 30 August 2019 for receipt of applications (Recommendation 5) • an organisational and governance review of the NSS was completed, with the report setting out a series of recommendations for implementation. It is expected that the process of implementation will commence in Q3 2019 following approval of the report (Recommendation 6) • HSE training programmes for open disclosure were updated and briefing sessions for open disclosure leads and trainers is continuing. Workshops for open disclosure leads were organised across all divisions to ensure effective implementation approaches to the open disclosure policy and programme at community, hospital group, National Ambulance Service and screening services level (Recommendation 28) • project improvement plan developed by the NSS for all quality assurance programmes based on international best practice. Revised principles of operation for all screening programme QA committees have been reviewed and provided to all committees for consultation & feedback (Recommendation 45) Actions are being identified to address the additional two recommendations identified in Dr Scally's Supplementary Report, to be incorporated in a revised Implementation Plan. These are expected to include further actions relating to procurement of laboratory services and monitoring of compliance.
3.	**Laboratory capacity**	Continued progress has been made in reducing the backlog of smear tests and in reducing smear test turnaround times in July. Since the 1st of May, MedLab Pathology Ltd has no longer been accepting new samples and is focused on clearing its backlog. The HSE has agreed with Medlab that it process its backlog of tests based on a HPV (human papillomavirus) initial testing model i.e. HPV testing will be carried out on samples prior to cytology. It is expected that approximately 15% of the total samples will be HPV positive. These samples are being prioritised for cytology by the laboratory. Where the HPV test is positive, the test will be prioritised by the laboratory for cytology because these women are considered to have the higher clinical risk. Samples that are HPV negative are at a much lower risk of developing cervical cancer. If the HPV test is negative, the test will go through cytology, but at a later stage because these women are considered less at risk. As of 21 July, the HSE has reported that the MedLab backlog was at 6,841, down from 55,000 on the 1st of May. The HSE has reported that average turnaround times for the Coombe and Quest labs are 4 weeks and 10 weeks respectively, although it should be noted that the turnaround times can fluctuate week to week.

4.	**Laboratory IT issue**	The HSE announced on 12 July that it was putting in place a rapid review, led by Professor Brian MacCraith, as a result of an issue which meant that test results were not issued or were delayed for some women and their GPs.
5.	**Introduction of HPV as the primary method of testing**	Work continues within the HSE on the significant volume of work underway to support the introduction of primary HPV screening. The HSE submitted a draft HPV Project Plan to the Department on 15 July, which has since been approved by the Minister.
6.	**Colposcopy waiting times**	The most recently reported data is valid to end June 2019. 81% of women with high grade abnormalities were seen within 4 weeks of referral (against target of 90%). 76% of women with low grade abnormalities were seen within 8 weeks of referral (against target of 90%). The data reflect the fact that, 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. The HSE has recently completed a Colposcopy Unit Impact Assessment Report, based on site visits to all colposcopy units, focused on identifying short, medium and long-term requirements. The Department engaged closely with the HSE in July in relation to implementation of that report's recommendations.
7.	**Establishment of CervicalCheck Tribunal**	The Cervical Check Tribunal Bill passed all stages of both houses and was signed into law by the President on 23 July 2019. The Tribunal, once established, will be open to individuals who are part of the '221' group, along with individuals who are identified during the Independent Expert Panel Review currently being undertaken by the Royal College of Obstetrics and Gynaecology (RCOG) in the UK, where this review presents findings discordant with those of the original cytology examination. It will also be open to individuals who are participating in the Review of Cervical Screening (the 'RCOG audit') whose slides have been lost. Suitable premises for the Tribunal have been identified. OPW has advised that its target is to hand over the premises in December 2019. In setting out her initial requirements for the Tribunal, Judge Irvine stressed the importance of having a set of rules in place when the Tribunal is established in order that claimants/potential claimants can make an informed decision on having their case heard before the Tribunal or the High Court. Legal advisors have been engaged to draft the Rules and have produced an initial draft. Judge Irvine is currently considering a further draft of the Tribunal's rules and is aware of the considerations that were raised in the Oireachtas during the passage of the legislation.

		It is intended that that Tribunal will be staffed with a combination of legal and administrative staff. The staffing requirements for the Tribunal will stem from the Rules and procedures for the Tribunal. Clinical Indemnity Unit are engaging with Judge Irvine, the Courts Service and the Department's HR team to progress this. The Courts Service have indicated willingness to release a court registrar to the Tribunal. The first preference is that the three members of the Tribunal should be serving or retired judges of the Superior Courts. The Department is engaging with the Attorney General and consulting with Judge Irvine and the Department of Justice to identify suitable candidates.
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. The Independent Assessment Panel has determined that €20,000 is the appropriate amount for the ex gratia payment. So far, approximately 150 applications have been received, which shows a good level of engagement with the scheme. To date 140 payments have been made and the Assessment Panel is continuing to examine remaining applications on hand.

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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 29 days. Weekly operational meetings continue to monitor the laboratories. The HSE has provided 141 slides out of a total number of 150 independent requests. There are 9 currently being processed.

No.	Laboratory?	Date made?	How many Calendar days outstanding?
1	Quest	16/01/2019	196
2	Quest	18/02/2019	163
3	Quest	11/06/2019	50
4	Quest*	24/06/2019	37
5	Quest**	27/06/2019	34
6	Quest and CPL	03/07/2019	28
7	Quest and Coombe	17/07/2019	14
8	Quest and Coombe	18/07/2019	13
9	Quest, CPL, Medlab	19/07/2019	12

* All 3 slides were released to RCOG for review. Not yet returned to go to client.

** 2 of 3 slides were released to RCOG for review (1 x CPL and 1 x Medlab). Outstanding slide is with Quest.

A total number of 593 records consisting only of GDPR Data Subject Access Requests and Freedom of Information (FOI) Requests have been provided, out of a total number of 600 requests. There are 7 outstanding which are being processed.

Issues: The HSE has identified a 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 (as of 19th July)

Project Governance	• Weekly interagency telecon with Expert Review Panel and Department of Health as regards project planning & matters for review/decision. • Fortnightly meetings with DoH and HSE regarding RCOG Support Programme accelerated to weekly meetings for July. Last meeting held Thursday 18 July.

	Actions Progressed	Activities Planned
Patient Support Services	• 1,053 women or next of kin are participating in the RCOG Expert Panel Review. • Second update letter drafted, to issue to review participants Tuesday 23 July with more details on how meetings will be arranged to communicate review results to them.	• Continue to ascertain next of kin details for women identified as deceased since consenting to participate in the review, where relevant.
Laboratory Logistics	• A total of **1,738 slides** were transported from CervicalCheck labs to the RCOG-contracted lab in Bristol (NBHT) to be included in the RCOG Review. o 7 slides were returned to labs of origin mid-review at client request o 302 slides were returned by courier from NBHT to 3 labs (Quest, Coombe and CPL) on Fri 19 July. o 1,429 sides remain to be transported back to their labs of origin. • A schedule and timeframes for transport of remaining slides has been provided by the RCOG. It is expected it will take approximately 6 weeks to return all slides. • Weekly teleconference with NBHT held on Wed 17 July.	• Shipment of 3 outstanding partial clinical records transported to RCOG on 11th July
Information Services	• Call centre hours 5 days per week, 9am-6pm. An RCOG Support Team member (registered nurse) follows-up to discuss queries directly with women. • There were no calls to the information line in the last two weeks (217 total calls to the information line since it opened in August 2018).	
Case Management System (CMS)	• Met with external CMS developers on 17 July to progress CMS updates to support communication of results to women.	
Acute & Community Services	• Coordinating provision of clinical records for RCOG Expert Panel to review, as requested by the Panel. To date: o RCOG Expert Panel has now received full clinical records in respect of **129 women.** o On 12 July, the RCOG requested clinical records to be sourced for **5 additional women**. These records have been requested from treating hospitals through agreed process with Acute Operations. They are expected for return by Tues 30 July	• It is expected the final shipment of 5 medical records will be transported to RCOG w/c 29 July.
Clinical Open Disclosure	• Engaged with NSS in relation to the Colposcopy Unit assessment report to finalise the business case for 2019/2020 funding requirements. • Engagement with Colposcopy Units around the country is ongoing to achieve final confirmation as to the Units participating in the communication of review results. • Acute operations engaged with all hospital group CEOs to seek to maximise local participation for communication of results and logistics of same. • Finalising plan / logistics for Central Team training scheduled for 22 July. • Commenced indemnification process and HR set up for central team (clinical). • Submitted high-level indicative cost estimate for central team to communicate results.	• Plan content / logistics for workshops for local teams on 7 and 14 August. • Provide training on communication of results for Central Team on Monday 22 July. • Seek indicative requirements from hospital groups and their associated cost estimates for local teams to communicate results.
Current position, significant issues	• While hospitals have identified the treating clinician(s) for the consented cohort, many women attended more than one colposcopy clinic and identifying the appropriate treating clinician to deliver review results 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 Issues

Average Time for Processing Results

Following an extensive review of public and private laboratory capacity, in a number of countries, we can confirm that two of our existing providers have managed to reduce the wait times; it is worth noting that over half of samples received by the labs are being processed within 10 weeks.

We have been working particularly closely with Medlab Pathology Ltd, which is the laboratory with the largest number of smear tests waiting to be processed, to process outstanding tests as a matter of priority. Since 1st May 2019, the laboratory has ceased receiving new samples and is focused on processing its backlog. We have agreed that it employs HPV (human papillomavirus) initial testing, followed by cytology, to process these tests. 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.

We are making progress in this regard, with a steady reduction in the laboratory's backlog.

The table below shows the number of smear test samples waiting to be resulted, as of July 21st , 2019.

Lab	Average Turnaround Time
Coombe	4 weeks
Quest	10 weeks*

Lab	Backlog
Medlab	6,841 (Down from 55,000 on May 1st)

In addition to this, following an extensive period of contract negotiations, the HSE has secured additional capacity from our remaining providers Quest Diagnostics & The Coombe, to provide the necessary capacity to allow the CervicalCheck programme continue until such time as the introduction of HPV primary screening. Both Quest Diagnostics and CWIUH are long term, accredited, strategic partners of the HSE who have supplied screening services to the cervical screening programme for eleven and seven years respectively.

*Note that Quest have taken on additional workload from Medlab which may have an adverse effect on the turnaround time.

Current HPV Issues

The HSE learned last week that Quest Diagnostics had failed to send test results to the GPs of around 800 women. The tests were on samples which were retested because their original mRNA HPV test was carried out outside the manufacturer's recommended timeframe.

These women had previously been found to have had low-grade cytological changes from their smear test. Since 2015 it has been the practice of CervicalCheck to test women with low grade abnormalities for the HPV virus. This allows the programme to decide the appropriate clinical pathway for each woman.

Quest retested these samples using a DNA HPV test, which has a longer expiration period. This avoided the woman having to get another smear test. Both of these tests are widely used in international screening programmes and are equally acceptable.

	The DNA HPV is a more sensitive test than the MRNA test, which has both advantages and disadvantages. o As we would have expected, there are a small number of women whose HPV status changed as a result of the retest using the more sensitive test. A total of 52 who previously tested negative tested positive. o The GPs of all of these 52 women, whose status had changed, received their test results in February of this year. o CervicalCheck records show that over half of these women have been referred on for further investigation, and we are currently confirming directly with GPs that all the women's results have been discussed in full with her in each case. Dr Colm Henry, Chief Clinical officer of the HSE said;"In terms of clinical risk the women affected had shown low-grade cytological changes which is at a very low risk of progression. That said, we want to apologise again to any woman that has been affected by this issue and we are continuing to keep in contact with them in relation to what has happened and any action that they need to take. The delays in results being forwarded are not acceptable, and the HSE's ongoing independent review into this incident will be investigating this in full detail."
McCraith Review Support	A lead from our Programme Management Office has been appointed to provide documentation to the review and ensure no difficulties with access to documents. In the region of 4,000 documents have been provided and staff are participating in interviews with Professor McCraith this week.

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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 4/02/19 • National laboratory QA lead appointed. Commenced 14/1/19 • Lead for 'Resources for Healthcare Professionals' workstream appointed June 2019. • 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. • **Public confidence**- reporting times and retests are impacting on confidence in the cervical screening service. • Recent issues have required team to focus on the incident impacting on HPV project.

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 & 03/07	• The QA guidelines review by the working group of the CAG committee to continue. • Review and approval of screening pathways and eligibility framework.
Procurement	•	• Full strategic procurement will take place in 2020.
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 is undertaking 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 in development, 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. • Testing of updated Cervical Screening Register almost complete.	• Work to continue at the GP and Colposcopy units while the private lab provider is determined. • Assessment of resource requirements to deliver Lab ICT is underway.
Resources for Health Professionals	• Workstream lead appointed. • 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. • Detailed project plan in development.
Hospitals (Colposcopy)	• Visits to colposcopy units completed • In parallel, a report providing existing metrics and modelling data (for future scenarios) for the colposcopy units was progressed further.	• Identify lead for colposcopy workstream • 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

June				
	Monthly		Annual YTD	
	Projected	Actual	Projected	Actual
Referrals	1,625	1,629	9,750	9,170

June 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	81%
*Waiting time LG end month - Target 90% to be seen within 8 weeks of referral	76%

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