CervicalCheck Steering Committee

Monthly report to the Minister

October 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 1,038 women are participating in the review.

The Department has had ongoing regular communication with the RCOG Lead Assessor throughout 2019, and there has been intensive engagement between the Department, the HSE and the RCOG as the process nears its conclusion, with a particular focus on the operational level. The HSE has held continuing engagement with clinicians in relation to the communication of the individual reports to women and families, and a central resource of clinicians is also in place to support the communications process. Training has been provided for all clinicians taking part in this process, as well as for associated support staff. The priority is to ensure that reports are communicated to individual participants sensitively and appropriately.

This is a large scale process and will take some time to complete, and so the intention is to communicate first with certain priority groups. These will of course include those where the Review has found a result that disagrees with the original CervicalCheck result, as is expected for a proportion of cases, in line with international experience. Meetings commenced in early October and are ongoing. Where the RCOG assessors find a result that disagrees with the original result, Liaison Officers are in place in the HSE to offer support as required to women or their next of kin, and to facilitate women and their families to access the package of measures.

On 9 September, the HSE sent a letter to all participants in the review to provide an update about the process, and to advise participants of when they may expect to receive their individual reports. This letter also provided women with options about how they may choose to receive their report. The feedback from participants has been positive, both in relation to the information pack and the options for receiving results. The communication of results to priority groups has now commenced. The transfer of individual reports from RCOG to the HSE is nearing completion and is subject to a detailed verification process carried out by the HSE which is designed to ensure that each participant receives the right report. The Department is continuing to engage with the HSE and with RCOG to support the resolution of any issues arising, with daily interaction throughout October. The lead assessors travelled to Dublin on October 30 to meet with patient representatives, as well as officials from the Department of Health and the HSE.

In addition to the individual reports, the RCOG will also produce an aggregate report for the Minister, which will make recommendations, where appropriate, with the aim of improving care for women. RCOG have advised that this report is now complete. However, the

		Department will not receive the report until all participants in the priority group have had an opportunity chosen method.	to receive their results by their
		While the aggregate report is yet to be received, the RCOG has advised that, based on the provisional finding characteristics of the CervicalCheck Screening Programme that fall within the scope of the Review appearance in the UK.	
2.	Implementation of the recommendations of Dr Scally's Scoping Inquiry into CervicalCheck	The Scoping Inquiry led by Dr Gabriel Scally produced three reports; a First, Final and Supplementary report on the Department of Health website, following Government approval. In total, the Scoping Inquiry made improvement of our screening and wider health services. The Implementation Plan for the original 56 recommendations of the Scoping Inquiry was approved by Gov Dr Scally has been clear that significant effort and resources are being committed to addressing the prob	de 58 recommendations for the ernment on 12 December 2018.
		appropriate resourcing and project management structures are in place. Following the publication of the Supplementary Report in June 2019, the HSE developed eight actions recommendations Dr Scally made in the report. These were submitted to the Department for inclusion in the Commendation of the Supplementary Report in June 2019, the HSE developed eight actions recommendations Dr Scally made in the report. These were submitted to the Department for inclusion in the Commendation of the Supplementary Report in June 2019, the HSE developed eight actions recommendations Dr Scally made in the report. These were submitted to the Department for inclusion in the Commendation of the Supplementary Report in June 2019, the HSE developed eight actions recommendations Dr Scally made in the report. These were submitted to the Department for inclusion in the Commendation of the Supplementary Report in June 2019, the HSE developed eight actions recommendations Dr Scally made in the report. These were submitted to the Department for inclusion in the Commendation of the Supplementary Report in June 2019, the HSE developed eight actions recommendations Dr Scally made in the report.	
		Total = 170	expected to be published in November, subject to
		■ Completed	approval from the Minister. Quarterly Reports for Q1 and
		112 ■ In Progress	Q2 have been published.
		■ Not Due to Start	As of the end of Q3 2019,
		Overdue to Finish	there were 170 actions that were developed to meet the 58 recommendations. There
		has been an increase in actions completed, and 112 actions are now complete. A further 27 actions are in p and 5 are overdue to start. 7 of the actions are not yet due to start.	

		Following a request by the Minister, a further review of implementation planning and progress is underway by Dr Scally and his team. The Scoping Inquiry team has met with the HSE and is scheduled to meet with action owners in the Department and the NCRI in early November. Within October, further progress on Departmental actions includes: • The second meeting of the Women's Health Taskforce, which was established in the Department of Health in September, on 30 October. • The appointment of 18 members to the National Screening Advisory Committee by the Minister. This follows the previous appointment of Prof Niall O'Higgins as Chair. The Committee will hold its inaugural meeting on 18 November 2019. The accompanying HSE report outlines the ongoing work in relation to actions being led by the HSE.
3.	Laboratory capacity	Significant progress has been made in clearing the backlog of smear tests and reducing turnaround times. Medlab Pathology, which reported a backlog of 55,000 smear tests in May 2019, has now completed the processing of these tests, having ceased accepting new tests from 1 May this year. This marks a significant and welcome milestone for the programme. The HSE has reported that average turnaround times for the Coombe and Quest are now 7 and 4 weeks respectively. The HSE reports that it hopes to sustain these turnaround times going forward, which will ensure that women and their GPs get their results in a reasonable time period.
4.	Introduction of HPV as the primary method of testing	Work continues within the HSE on the significant volume of work to support the introduction of HPV primary screening. On 10 July, the HSE submitted a draft project plan for the HPV primary screening project, comprised of seven high level sub plans for each of the seven identified workstreams required to make the transition. The HSE identified 28 February 2020 as a realistic date for transition and of its intention to work to an earlier timeframe if possible. The Minister has now approved the plan as submitted, and the Secretary General has written to the HSE CEO to advise of same and to request the HSE to take all opportunities to deliver an earlier timeframe. The HSE will provide monthly reports to the Department, updating on progress in all seven workstreams. Some key areas of progress include: • Additional clinical resources have been identified for the colposcopy workstream, including a colposcopy lead, which will allow greater progress to be made in this area. • The Primary Screening Algorithm and Eligibility Framework for the majority of women have been approved by the Screening Pathways Review Group in the HSE. A review of screening pathways and eligibility framework for women with special circumstances is to be undertaken.

		Visits to the laboratories in the Coombe and in the USA are planned in November
		• The laboratory strategy continues to be developed and a contract has been signed with Quest and the Coombe for the first 12 months of HPV primary screening.
5.	Colposcopy waiting times	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. These colposcopy units remain under pressure in light of increased demand from both screening and direct referral by GPs.
		The HSE has advised that time taken in a clinical setting is considerably longer to facilitate answering queries and putting women at ease. The HSE advises that extra clinical sessions have been added to reduce waiting lists, and extra efforts are being made when appointments are cancelled to fill the vacant slot to further reduce waiting lists, and to ensure the increased referrals are categorised promptly. Women are provided with access to colposcopy services, subject to clinical judgement and prioritisation.
		The most recently reported data is valid to end September 2019. 64% of women with high grade abnormalities were seen within 4 weeks of referral (against target of 90%). 60% of women with low grade abnormalities were seen within 8 weeks of referral (against target of 90%). Funding of €2 million is being rolled out in Q4 2019 for the additional resource requirements identified in the assessment of capacity at colposcopy clinics undertaken by the National Women and Infants Programme, which should support improvement in these turnaround times.
6.	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. Progress had been made in respect of identifying the most appropriate way to amend the Act to facilitate eligibility for cohorts identified during the passage of the legislation through the Oireachtas. The chairperson has indicated her opposition to increasing the eligibility at this time. A proposal for the Minister to meet with the Tribunal Chair to discuss the matter was communicated to her by the Attorney General in a letter of 14 November 2019. Suitable premises have been identified for the Tribunal in the Infinity Building in Smithfield and a contractor has been contracted to carry out the works. It had been anticipated that the premise would be available by the end of December 2020, however OPW have now indicated that they are aiming to have the project delivered by 29 February 2020.

7.	Ex-gratia scheme for non- disclosure	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 a number of drafts have been produced. 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 seconded an experienced registrar, who ultimately be the Tribunal Registrar, to the Department of Health to assist with setting up the Tribunal. The Department has been engaging with the Attorney General's Office to identify two suitable persons for appointment as ordinary members of the CervicalCheck Tribunal. The Attorney General recommended two person for appointment as ordinary members of the Minister has given approval to proceed with the necessary arrangements for the appointments. On 11 March 2019, the Government agreed to the establishment of an ex-gratia scheme for those affected by the non-disclosure of the Cervical Check audit. The Scheme is designed to provide an alternative, non-adversarial and person-centred option for those affected by the CervicalCheck non-disclosure issue. The Independent Assessment Panel, chaired by Justice Aindrias Ó Caoimh, has determined that €20,000 is the appropriate amount for the ex gratia payment. All women, or their next of kin, in the 221-cohort identified from the clinical audit as having discordance in their smear test result are
		eligible to participate in the Scheme. The Scheme was developed following consideration of Mr Justice Meenan's Report on an alternative system for dealing with claims arising from CervicalCheck.
		So far, 161 applications have been received and payments of €20,000 have been made in all cases. The scheme remains open.