

CervicalCheck Steering Committee

Weekly report to the Minister

26 October 2018

1. Update on support package

The provision of supports to women and families is continuing. The HSE reports that Liaison Officers are working towards advising clients of the 221+ support group, and that a meeting has been arranged with the co-ordinator of this group. The HSE advises that Liaison Officers have met in order to better coordinate supports and to assist in future planning for the service. A structured questionnaire has been issued to Liaison Officers for their assistance in planning possible supports to be made available to women and their families.

Dr Scally intends to hold meetings in Dublin, Cork and Galway, in line with the meetings which he has held already, to inform women of his findings. The first meeting took place in Dublin on Tuesday 9 October.

The Government decision of 11 May provided that where women had been prescribed a medicine by their treating clinician, any out-of-pocket costs would be met. Arrangements are in place to reimburse, on receipt of claims, a range of costs that the women and their families incur from 11 May including travel costs, childcare costs and medical appointment costs among others. Reimbursement of retrospective costs is taking place, and an automatic review system is in place to simplify and streamline the process to ensure prompt payment of all items covered by the Government decision. To date, over €846,000 has been reimbursed in respect of various health and social care costs, some €690,000 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, and no issues are arising in this regard. 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.

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.
- Almost 1,600 letters have now issued providing information in relation to consent and the consent form for participation in the review, which is the total number of letters issuing directly to women affected. The remaining letters are all those issuing to next of kin of women who have, sadly, died. The HSE has reported that next of kin details are being provided by the relevant acute hospital. The Department will continue to engage with the HSE to ensure that validation is completed and remaining letters issue as expeditiously as possible.
- Approximately 827 consent forms are reported to have been returned up to end of last week, with 96% of women who have responded agreeing to take part in the review.

- The HSE is continuing to make every effort to ensure clear information is provided that addresses any queries, issues or concerns raised by women about the review or the consent process. The HSE established a dedicated phone line at the outset of the consent process, to answer any questions women may have arising from the process. Additional clinical and administrative resources have been identified to enable swift response to clinical queries from women who are part of the consent process, including those with microinvasive cancer. To date 98 calls have been received of which 72 related to clinical questions. Opening hours have been extended to weekends and the HSE is ensuring that women's queries are being fully and appropriately addressed.
- Dr Scally's report, published 12 September, includes two recommendations in relation to clinical audit by CervicalCheck, including the development of robust and externally validated audit processes, and the inclusion of patient advocates in the oversight of clinical audits. These will be implemented in full along with the other recommendations in the report. The Minister committed to returning to Government within three months with an implementation plan for the 50 recommendations, and Dr Scally has agreed to provide a review of the implementation plan in advance of this.

4. Introduction of HPV as the primary method of testing

The introduction of HPV testing as the primary screening mechanism for CervicalCheck, with cytology as a reflex test, will involve a reconfiguration of the laboratory work involved. Detailed capacity planning is ongoing and introduction will be subject to a tendering process for work carried out outside the public sector.

Heads of Agreement have been signed with the contracted labs to extend their contracts for cytology services pending the introduction of HPV testing as the primary screening test. This allows for the continuation of the service without interruption. Work is now required to finalise the laboratory strategy for the introduction of the HPV test.

The Clinical Advisory Group established to advise on the project has made a decision in relation to the choice of HPV assay, required before tender documents can be finalised, as well as the final age range and intervals and genotyping. Dr Marc Arbyn, who was a member of the HIQA HTA panel, is also providing support and expertise to this Group. HSE officials have advised that all necessary clinical decisions which are required for drafting of procurement documents have now been made and procurement market analysis is progressing.

5. Clinical Director

Interviews for a Clinical Director for CervicalCheck took place on 22 August and the HSE advises that the contract is currently being finalised.

6. Smeartaking activity

Heads of Agreement in place with the laboratories in relation to extension of contracts also include arrangements to address the backlog in testing that has arisen as a result of the significantly increased demand for smears we have seen in recent months. This increased demand has undoubtedly put immense pressure on lab capacity and the HSE has been working actively with the labs to manage this. It has reported that lab activity remains above normal levels up to last week. The total number of additional consultations to date is over 87,000. The issue of the backlog of smear tests remains a priority concern for the HSE.

7. Alternative resolution mechanisms

Mr. Justice Charles Meenan is currently the Chairperson of an Expert Group established to consider an alternative mechanism to the court process for resolving clinical negligence claims. In addition to this work, Justice Meenan has undertaken a specific review regarding the claims arising out of the issues surrounding CervicalCheck. This work is now complete and his report was published on the 16th of October.

The Judge's report proposes that a Tribunal be established under legislation to hear and determine claims arising out of CervicalCheck. Hearings in a Tribunal would be heard in private and be less formal than a court process. This alternative system will take into account the issue of liability, each person's Constitutional right of access to the courts and all parties' Constitutional rights to fair procedures. For these reasons he notes that the system must be voluntary. Judge Meenan's report requires consideration by a number of Government Departments and the Minister has committed to returning to Government with proposals next month.

8. Implementation of recommendations of the Scally Inquiry

The HSE working group which is addressing the recommendations of the First Report on information about screening for women has continued its work, and planning for the implementation of the 50 recommendations contained in the final report of the Scoping Inquiry has begun.

The CervicalCheck Steering Committee will oversee the implementation of these recommendations. The Minister met with Dr Scally on Wednesday 10 October. The Minister has asked Dr Scally to provide an independent review of the implementation plan recommended in his report. Dr Scally will also be carrying out further work in relation to the laboratories, and the Terms of Reference for this work were today published on the Department's website.

A draft implementation plan has been previously discussed by the Steering Committee at its meeting of 4 October. It is intended that a further draft will be circulated to the Committee ahead of its next meeting on Thursday 8 November.

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Oversight and engagement with the HSE on modules of their work as follows:

- Management of supports to patients/families
- Provision of documents to patients
- Interface with RCOG Review
- Management of laboratory capacity issues
- Introduction of HPV Screening

Management of supports to patients/families	
Significant Issues	No significant issues to note. Meeting of Liaison Officers took place to better coordinate supports and to assist in future planning for the service.

Provision of documents to patients	
Significant Issues	The team remains focused on responding to all requests as soon as possible. External legal advisors are liaising with women and their solicitors on the release of slides. 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. There have been some teething problems in this process with the labs but these are being addressed.

Interface with RCOG Review	
Project Management	<p>Project Manager in Place Assistant National Director (HSE) commenced working as the Programme Lead on the RCOG Review on Wednesday the 1st of August.</p> <p>Project Manager (HSE) commenced working as the Project Manager on Wednesday the 1st of August.</p>
Project Governance	<p>Programme Governance</p> <ul style="list-style-type: none"> • Project Team holds daily meetings and teleconferences to progress deliverables, identify critical actions / timeframes,

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	<p>areas for escalation, risks, issues, and dependencies.</p> <ul style="list-style-type: none"> Thurs 18th Oct: Weekly Teleconference with RCOG and Dept. of Health to progress interagency logistics and communication <p>Next steps</p> <ul style="list-style-type: none"> Further consultation on stakeholder engagement and communication plan with RCOG and Dept. of Health planned for w/c 22nd Oct Continue weekly teleconference with DOH and RCOG (scheduled for Tues 23rd Oct) 												
Project Plan													
Workstream	Actions Progressed (w/e 19 th Oct)												
Patient Support Services	<ul style="list-style-type: none"> Mon 15th Oct: Feedback received from PPI Group and changes made to next of kin letters to encompass some of the suggestions made. Tues 16th Oct: Participated in weekly teleconference with Patient Liaison Officers. As of Friday 19th October <ul style="list-style-type: none"> 1,591 letters have issued to individuals requesting consent to participate in RCOG Review Consent forms returned by 871 individuals (55%), of which 827 have consented to participate. 96% of returns are consents. 												
Information Services	<ul style="list-style-type: none"> Opening hours of call centre 7 days a week 9am – 6pm An Post returns being contacted and details updated if contact made and letters reissued As of Friday 19th Oct, there have been 98 calls to the information line. 26 were general queries and 72 were clinical queries. Acute Operations provides a daily report at COB on the status of all calls escalated, and confirms when they have been resolved. <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td>Total Calls to Information Line</td><td>98</td></tr> <tr> <td>Total Calls (general)</td><td>26</td></tr> <tr> <td>Total Calls (clinical)</td><td>72</td></tr> <tr> <td>Calls (clinical) resolved at initial contact</td><td>49</td></tr> <tr> <td>Calls (clinical) escalated to acute hospitals, following SOP</td><td>23</td></tr> <tr> <td>• Closed</td><td>20</td></tr> </table>	Total Calls to Information Line	98	Total Calls (general)	26	Total Calls (clinical)	72	Calls (clinical) resolved at initial contact	49	Calls (clinical) escalated to acute hospitals, following SOP	23	• Closed	20
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Case Management System (CMS)	<ul style="list-style-type: none"> • New workstream lead has been assigned by Data Quality Team to support development of Case Management System. • CMS updated to include information provided by NSS/NCRI. • Working to incorporate additional requirements for slides transfers who are also involved in legal proceedings. 	
Laboratory Logistics	<ul style="list-style-type: none"> • SOP draft progressed to facilitate safe and secure transport of slides between the CervicalCheck laboratories and RCOG lab in Bristol. Currently under clinical review with RCOG. Circulation to laboratories pending completion of NSS contract negotiations. • Engaging with CervicalCheck ICT and RCOG to facilitate RCOG with access to electronic records where required. 	
Communications	<ul style="list-style-type: none"> • To support distribution of letters to women: Liaising with HSE Comms / HSE Digital to coordinate approach and issuing proactive communications as appropriate/agreed. 	
Acute & Community Services	<ul style="list-style-type: none"> • Sat 13th Oct: National Director NSS, RCOG Programme Lead and Patient Support Services Coordinator met with Hospital Group CEOs and Lead Colposcopists. • Mon 15th Oct: Weekly briefing sent to Acute Operations for onward circulation to relevant hospitals and clinical services • Wed 17th Aug: Weekly teleconference with key stakeholders, including Acute Operations GM and CervicalCheck Interim Programme Manager. • Thurs 18th Oct: Letters issued to registered CervicalCheck smertakers (5,500) • Progressing validation of Next of Kin details with Acute services as per agreed SOP, providing contact information for NOK where women identified as deceased in database provided by NSS. As of Friday 19thOct, 237 issued to Acute Services, and 150 (63%) returned. 	
Current Position, Significant Issues	<ul style="list-style-type: none"> • SOP for laboratory logistics, communication and slide transportation: awaiting feedback from RCOG Expert Review Panel. • Acute Services to follow-up on outstanding confirmation of NOK details for women identified as deceased, so that letters can issue to those individuals inviting them to participate in RCOG Review. • Queries raised as to validity of certain identified cases included in consent process for RCOG Review. NSS and Data Quality investigating further against NCRI data provided to them. 	

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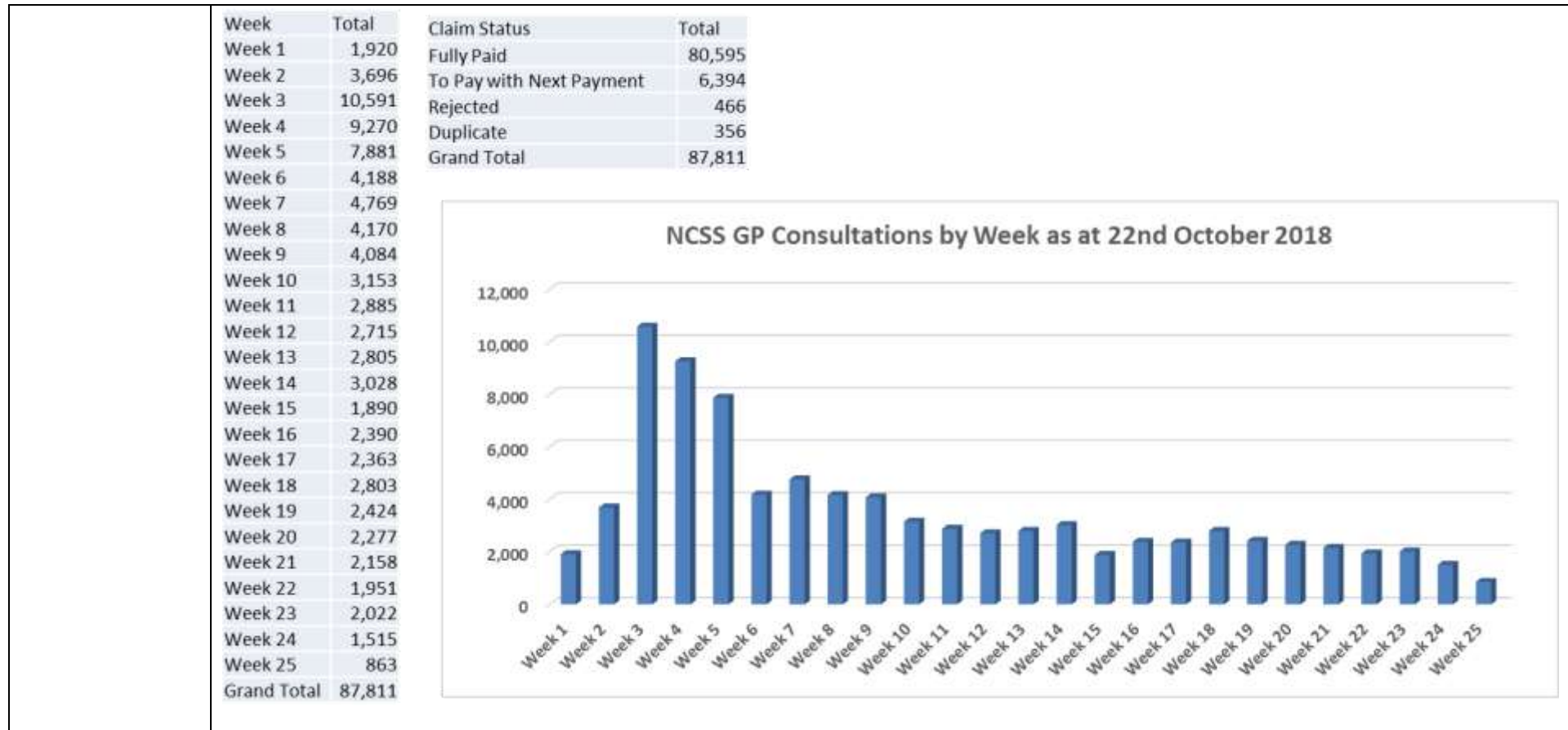
Next Steps

Workstream	Actions Planned
Patient Support Services	<ul style="list-style-type: none"> Continue plan to issue remaining letters to Next of Kin, as details received from acute services <i>-pending validated data provided by NSS/NCRI to RCOG support office.</i> Continue scanning and logging consent returns on Case Management System, as they are received. Continue regular engagement with Patient Liaison Officers and other stakeholders.
Information Services	<ul style="list-style-type: none"> Continue to follow-up on calls to information line and to dedicated email address for health professionals Employ regular quality checks to ensure capacity meets demand. Where required, identify and assign further additional clinical & administrative resources to the call centre in line with the project plan timelines.
Case Management System (CMS)	<ul style="list-style-type: none"> As letters issue, continue to update CMS with validated data Progress design of CMS to be updated further in line with agreement on labs transport process.
Laboratory Logistics	<ul style="list-style-type: none"> w/c 22nd Oct: Draft SOP to support slide transfers to be returned by RCOG and go to CervicalCheck Laboratory Coordinator and Labs for further technical input and consultation. Engage with laboratories to facilitate transport of slides to RCOG lab in Bristol.
Communications	<ul style="list-style-type: none"> Managing feedback and queries from women/NOK, clinicians, media and public as remaining cohorts of women or next of kin receive letters.
Acute & Community Services	<ul style="list-style-type: none"> Weekly teleconference with RCOG Support Programme, Acute Operations, and CervicalCheck. Continue developing protocol to support RCOG with relevant medical records from acute and community services where requested. From w/c 22nd Oct: Further strengthening communication and engagement with hospital services by sending weekly briefing to Colposcopy Units directly through the Programme Manager of Cervical Check.

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Management of Laboratory Capacity Issues	
Project Management	<p>Project Manager in Place</p> <p>Project Team Composition</p> <p>Given the nature of the issues presenting a working group was put in place to support the project manager. This group comprises HSE procurement, HSE Legal and the CervicalCheck Operations team. This will ensure a coordinated response to the operational issues presenting as a result of the demand arising from the out of cycle smear tests.</p>
Project Plan	<p>Since April any woman who is concerned can attend her GP for a free smear and this has resulted in a testing backlog in all three labs. These delays remain a priority concern for the HSE.</p> <p>Actions taken to address backlog include additional recruitment to assist on clerical support to free up screening staff, the streamlining of processes around release of reports and QA checks of same. One of the main contracted lab service providers has requested to use one of their other accredited sites that meet all the aspects of the contract. NSS have agreed and confirmed this as appropriate. This process has been initiated. The lab contractors continue to provide overtime, manage annual leave and schedules with their best efforts to address the backlog.</p> <p>We are happy to say that we have agreed continuity of supply arrangements with both existing cytology laboratories so that they will continue to provide cytology services to CervicalCheck beyond the end date of the contract on Sunday 14th October. We are now concluding final contracts and operating arrangements with both Quest and Medlab pathology over the coming weeks.</p>
Uptake of Smear Tests	<p><i>Out of cycle smears</i></p> <p>Total number of additional consultations to date is more than 87,000. The normal capacity for the labs is approximately 5,000 slides reviewed per week so we are still seeing a 20% increase in uptake as a result on the free smear test. This is delaying the reporting of smears to women. All the labs have expressed concern at the continuing extension of the free smears due to the serious impact on the normal reporting cycle. The table below sets out the increased number of GP consultations.</p>
Average Time for Processing Results	<p>The average processing time is currently 77 days.</p>

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Introduction of HPV Screening

Project Management

Project Manager

A Project Manager is in place. The expression of interests for the appointment of a Clinical Lead for the HPV primary screening

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	<p>project, a lead cytopathologist and a lead colposcopist were unsuccessful. NSS are currently reviewing options.</p> <p>Project Team Composition</p> <ul style="list-style-type: none"> Clinical Advisory Group: international expert Dr. Marc Arbyn is supporting this group. Dr Arbyn was a member of the HIQA HTA panel and is a leading expert on HPV primary screening in Europe Still awaiting Clinical lead, Colposcopy lead, Pathology lead.
Project Plan	
Workstream	Actions Progressed (w/e 19th October 2018)
Clinical	<ul style="list-style-type: none"> Consideration of changes that may be required to QA guidelines for cytopathology. Assessment of feedback to proposed screening pathway and eligibility framework commenced. Colposcopy capacity planning and management of women referred to colposcopy to be engaged
Procurement	<ul style="list-style-type: none"> Procurement market analysis to inform specification and market model can progress further now that some clinical decisions have been taken.
ICT	<ul style="list-style-type: none"> Work on development and testing of changes to Cervical Screening Register continued. Addressing issue of testing capacity (resources). Laboratory IT development awaiting decisions on laboratory configuration and procurement.
Lab Configuration	<ul style="list-style-type: none"> Draft configuration options – work on further detailing in progress to detail the capacity required through public vs private providers
Communications	<ul style="list-style-type: none"> No progress – awaiting dedicated resource / channel to form communications
Resources for HPs	<ul style="list-style-type: none"> Resource development – e-learning - commissioned. Resources cannot be finalised without clinical pathways (above) resolution
Hospitals (Colposcopy)	<ul style="list-style-type: none"> Continued assessment of capacity exercise with the hospitals. HSE meeting with hospital colposcopists took place 13th Oct.
Current Position, Significant Issues	<p>1) Continuing efforts to secure contract extensions with existing labs is critical to enable the programme to proceed. PMO team are reviewing the current project plan, critical path and milestones to incorporate the effects of the lab negotiations on the HPV project rollout.</p>

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	<ul style="list-style-type: none"> 2) Stabilisation of the current programme (increase in demand on the laboratories, backlog and colposcopy with repeat and additional workload) 3) Absence of a fulltime Clinical Director for the programme is impacting a number of key activities. <ul style="list-style-type: none"> ➤ Decision required on the cervical screening pathway ➤ A Clinical Advisory Group has been set up to address these decisions. 4) Failure to recruit a colposcopy or cytopathology lead for the program and project. There were no applicants. A letter of invite for a colposcopy lead has been issued to Dr. Peter Boylan, Chair of the Institute for Gynaecologist and Obstetricians. 5) Laboratory configuration strategy being reassessed by requirements to stabilise current programme. 6) Market analysis originally planned to be completed in October to assess private lab interest in tendering for HPV primary screening will now take place in November. 7) Communications resources (external & internal) for implementation of the project to be defined.
Immediate Activities	
Workstream	Actions Planned
Clinical	<ul style="list-style-type: none"> • Examine screening pathway options with respect to estimated number of referrals to colposcopy.
Procurement	<ul style="list-style-type: none"> • Finalise contract details with labs following agreement to continue. • Finalised market information session proposed to allow services required to be explored with a view to determining level of interest and potential contractual issues. (Oct 2018) • Laboratory configuration strategy to be finalised looking at future proofing services.
ICT	<ul style="list-style-type: none"> • Work on development and testing of changes to Cervical Screening Register. (February 2019) • Further address issue of testing capacity (resources). • Colposcopy IT development to be initiated.(end October 2018)
Lab Configuration	<ul style="list-style-type: none"> • Finalise laboratory configuration strategy. Factor current laboratory continuation. • Detailed capacity assessment with the Coombe and NVRL to continue in October to review their capability to deliver a proportion of HPV primary testing (i.e. adequate resources, IT requirements and timelines to deliver any changes to their systems) (November 2018) • Together with workshops with Coombe & NVRL, will inform the laboratory configuration and procurement processes for sufficient and appropriate capacity.

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Communications	<ul style="list-style-type: none">• Finalise stakeholder mapping exercise with workstream leads• Start communications- messaging	
Resources for HPs	<ul style="list-style-type: none">• Progress e-learning module to include recent clinical decisions	
Hospitals (Colposcopy)	<ul style="list-style-type: none">• Complete capacity planning exercise.• Secure hospital commitments for 2019.	
Update Action	<p>Update Action 04/28 Update on the possibility of appointing a clinical lead for the move to HPV testing. Update on 02/10/18-The expression of interest was extended to the 10th Oct.</p> <p>Update 19/09/18 NRS are finalising the contract with the successful candidate for the post of clinical director.</p>	