

CervicalCheck Steering Committee

Weekly report to the Minister

11 January 2019

1. Update on support package

The provision of supports to women and families is continuing and the HSE reports that Liaison Officers are working actively to better coordinate supports and to assist in future planning for the service. 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, €1.17m has been reimbursed in respect of various health and social care costs, over €906,000 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. The HSE has advised it is undertaking a validation exercise on the data held on the 221 affected women. This is to ensure the National Screening Service has the most up to date information, which will be used to help with planning support needs for patients, for example.

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 35 days.

Legal representatives for the HSE have contacted solicitors to check if they are encountering any delays and to address any issues. Arising from this exercise, a significant number of cases have been identified where the HSE had not been informed of the requestor's name and/or the designated lab expert to whom the slides are to be sent. As a result, the HSE is working with these solicitors to ensure that all required details are sent to the labs. The HSE provided a detailed report on the release of slides to the Public Accounts Committee in December.

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. As of Friday 4 January, 1,714 letters, including letters to next-of-kin of women who have, sadly, died, have issued providing information in relation to consent and the consent form for participation in the review, and 1,072 women have consented to take part in the review (62%). The final date for consents to be received was 28 December 2018. The Expert Review Panel has now been provided with colposcopy and other data from CervicalCheck in respect of women who have consented to participate.

The transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review has encountered some external challenges which are being addressed as a matter of priority.

There are on-going discussions between HSE and the laboratories to arrange for the transfer of slides as soon as possible. Further engagement with two of the labs took place this week, with a teleconference with the third lab scheduled for early next week. Slide retrieval is underway, with one laboratory expecting to begin the transfer of slides very shortly.

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. Dr Marc Arbyn, who was a member of the HIQA HTA panel, is also providing support and expertise to the Clinical Advisory Group established to advise on the project. 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.

Colposcopy capacity planning is underway by the National Women and Infants Health Programme, which is required to support the introduction of the HPV test. A pre-market engagement seminar took place on 27 November and assessment of submissions from eight companies which participated in the pre-market seminar is underway currently. This, together with laboratory capacity planning, will inform the laboratory configuration strategy, taking account of options and the futureproofing of the service. In tandem, work on development and testing of necessary ICT changes is underway.

5. Clinical Director and filling of key posts

The HSE has advised that the new Clinical Director has been appointed and is due to commence work on 5 February 2019. A pathology lead and a quality assurance lead have been appointed, both on a two day per week basis. An interim public health advisor has also been appointed and took up post last month.

6. Smeartaking activity

The increased demand for smear tests has put pressure on lab capacity and the HSE has been working actively with the labs to manage this. The total number of additional GP consultations to date is over 108,000. The issue of the backlog of smear tests remains a priority concern for the HSE. Efforts to secure additional laboratory capacity to help address the backlog of smears form part of the finalisation of laboratory contract extensions. These efforts include additional recruitment by the laboratories, provision of overtime and management of annual leave. However, it is clear that the backlog will take some time to resolve and the HSE is focused on capacity planning to take account of available capacity and expected demand, with the aim of bringing the programme into stabilisation.

The provision of free GP consultations and out-of-cycle smear test has now ceased, as planned, as of 31 December. Letters issued to GPs on Wednesday 5 December to advise them of the current position and the CervicalCheck website has also been updated.

7. Implementation of recommendations of the Scally Inquiry

The CervicalCheck Steering Committee has overseen the development of the Implementation Plan for Dr Scally's recommendations, and agreed the plan on 4 December last. The plan has now been independently reviewed by Dr Scally, and was approved by Government on Tuesday 11 December. The Plan was subsequently published on the Department's website. It is expected that Dr Scally will provide further detailed observations formally to the Minister shortly.

The next meeting of the CervicalCheck Steering Committee is scheduled for 22 January.

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Oversight and engagement with the HSE on modules of its 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 | |
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| Significant Issues | There are no exceptional items to report in relation to Community Supports. |

| Provision of documents to patients | |
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| Significant Issues | <p>Current position, issues & challenges</p> <p>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. In some cases there have been delays with the laboratories due to operational pressures and we are ensuring that we continue to focus on reducing the time taken - the average time to deliver slides to the independent expert is 35 days. The HSE continues to engage directly with the laboratories to try to make sure that slides are imaged and prepared for release as quickly as possible, and to maintain ongoing pressure on the labs to improve this element of their performance. To this end, weekly operational meetings are taking place to identify, assess and deal with blockages in the process as a matter of urgency.</p> <p>In relation to access to slides: some concerns were expressed in relation to significant numbers of women not getting access to slides, as a result we contacted all solicitors to establish if there were indeed people waiting for slides. As a result we have identified a significant number of cases where the HSE has not been informed of the requestors name or/and their designated</p> |

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| | 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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| Interface with RCOG Review | |
| Project Management | <p>Project Manager in Place Assistant National Director (HSE) is in place since August.</p> <p>Project Management activities are on-going lead by the Project Manager (HSE) .</p> |
| Project Governance | <p>Programme Governance</p> <ul style="list-style-type: none"> Support Team continues to hold daily meetings and teleconferences to progress deliverables, identify critical actions / timeframes, areas for escalation, and project RAIDS. <p>Next steps</p> <ul style="list-style-type: none"> Continue engagement with Dept. of Health and Expert Review Panel via weekly teleconference. |
| Project Plan | |
| Workstream | Actions Progressed (w/e 4th January) |
| Patient Support Services | <p>As of COB Friday 4th January:</p> <ul style="list-style-type: none"> 1,714 invited to participate in Expert Panel Review, who are contactable and comprehended by the Review . 1,072 (62%) have consented to participate in the Review. |
| Information Services | <ul style="list-style-type: none"> Opening hours of the call centre are 5 days per week, 9am – 6pm. As of COB Friday 4th January, there have been a total of 140 calls to the information line . Details as follows: |

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| | | <table> <tr> <th></th><th>#</th><th>Change from Previous Week</th></tr> <tr> <td>Total Calls to Information Line</td><td>140</td><td>↑ 4</td></tr> <tr> <td>Total Calls (general)</td><td>68</td><td>↑ 4</td></tr> <tr> <td>Total Calls (clinical)</td><td>72</td><td>No change</td></tr> <tr> <td> Calls (clinical) resolved at initial contact</td><td>49</td><td>No change</td></tr> <tr> <td> Calls (clinical) escalated to acute services</td><td>23</td><td>No change</td></tr> <tr> <td> Calls (clinical) resolved by acute services</td><td>23</td><td>No change</td></tr> </table> | | # | Change from Previous Week | Total Calls to Information Line | 140 | ↑ 4 | Total Calls (general) | 68 | ↑ 4 | Total Calls (clinical) | 72 | No change | Calls (clinical) resolved at initial contact | 49 | No change | Calls (clinical) escalated to acute services | 23 | No change | Calls (clinical) resolved by acute services | 23 | No change |
|--|---|---|--|---|---------------------------|--|------------|------------|-----------------------|----|-----|------------------------|----|-----------|--|----|-----------|--|----|-----------|---|----|-----------|
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| Total Calls to Information Line | 140 | ↑ 4 | | | | | | | | | | | | | | | | | | | | | |
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| Calls (clinical) resolved by acute services | 23 | No change | | | | | | | | | | | | | | | | | | | | | |
| Case Management System (CMS) | <ul style="list-style-type: none"> Expert Review Panel provided with colposcopy data and failsafe data from CervicalCheck ICT in respect of 800+ women who have consented to the Review. CervicalCheck ICT working with NCRI to progress sharing of data between NCRI and Expert Review Panel. Letter sent to NCRI confirming the number of consents received for the Review. | | | | | | | | | | | | | | | | | | | | | | |
| Laboratory Logistics | <ul style="list-style-type: none"> Continuing to develop database of required slides in relation to new consents, by laboratory. Teleconferences held with two CC laboratories (SONIC/MedLab and Quest), CC Interim Programme Manager, and RCOG Programme Lead prior to the Christmas period to progress solutions to laboratory challenges in transferring slides . Working with Client Services to establish process to correlate slides requested for legal proceedings with slides requested for RCOG Expert Panel Review. | | | | | | | | | | | | | | | | | | | | | | |
| Communications | <ul style="list-style-type: none"> Weekly teleconference with Expert Review Panel and DOH re project planning & matters for interagency review. | | | | | | | | | | | | | | | | | | | | | | |
| Acute & Community Services | <ul style="list-style-type: none"> Weekly briefing sent to HGs through Acute Operations and to Lead Colposcopists through CervicalCheck Weekly teleconference with Acute Operations Responses provided to individual clinicians who have contacted the Programme with queries on the RCOG Support Programme and the Expert Panel Review. | | | | | | | | | | | | | | | | | | | | | | |
| Current Position, Significant Issues | <ul style="list-style-type: none"> The transfer of slides from CervicalCheck labs for the purpose of the Expert Panel Review has encountered some challenges. These have been escalated. The Support Team has addressed those within its scope as a matter of priority, and has escalated those which are outside of its authority. (see above) | | | | | | | | | | | | | | | | | | | | | | |
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Next Steps

| Workstream | Actions Planned (w/c 7 th Jan) |
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| Patient Support Services | <ul style="list-style-type: none"> 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 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. Commence QA process of revalidation of all consents against CMS. Incorporate additional requirements for slides transfers which are also involved in legal proceedings. |
| Laboratory Logistics | <ul style="list-style-type: none"> Quest Diagnostics has advised it will be in a position to commence moving early in the New Year. Working with Quest to strengthen communication and logistics to support process, as per SOP. Further teleconferences/ meetings with laboratories to progress slide transfers will be held week commencing January 7th 2019. |
| Communications | <ul style="list-style-type: none"> Manage feedback and queries from women/NOK, clinicians, media and public as remaining cohorts of women's next of kin receive letters. |
| Acute & Community Services | <ul style="list-style-type: none"> Continue weekly briefings and teleconferences with Acute Operations and CervicalCheck. Continue developing protocol to support Expert Review Panel with relevant medical records from acute and community services where requested. |

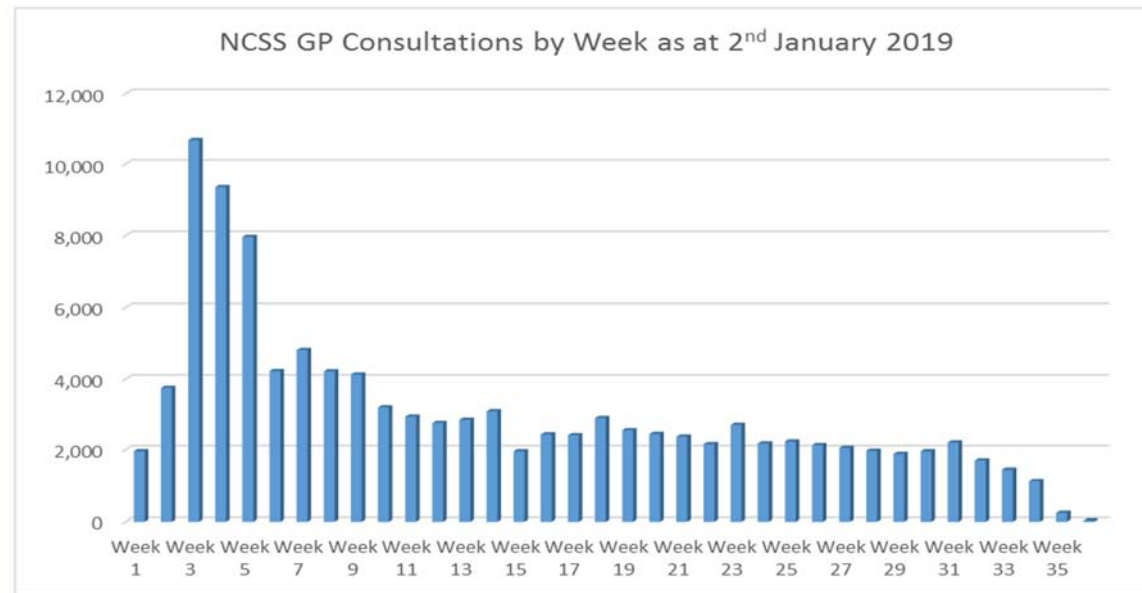
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| Management of Laboratory Capacity Issues | |
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| Project Management | <p>Project Manager in Place</p> <p>Project Team Composition</p> <p>Given the nature of the issues presenting, a working group was put in place to support the project manager. This group comprises HSE procurement, HSE Legal and the CervicalCheck Operations team. This group has been focused on a) extension of lab contracts and b) managing the demand due to 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. Because of the skilled nature of cytology screening and the difficulty in recruiting trained staff, lab turnaround time issues can be slow to resolve. Laboratories are required to capture the smear on a slide within 6 weeks. This has been resolved with the laboratory so we do not foresee future issues. The lab working group continues to work closely with the three labs to understand and manage current capacity issues. Weekly reports are being provided and ongoing engagements to identify further actions to mitigate this risk.</p> <p>Continuity of supply arrangements with both existing cytology laboratories is agreed so that they continue to provide cytology services to CervicalCheck beyond the end date of the contract on Sunday 14th October. Concluding final contracts and operating arrangements with both Quest and Medlab pathology is ongoing.</p> |
| Uptake of Smear Tests | <p><i>Out of cycle smears</i></p> <p>Total number of additional GP consultations to date is more than 108,000. The knock on effect of this has been 1) the estimated number of early repeat smear test to take place in the period of 1st May to 31st October is in the region of 48,088 2) a Global trend with respect to decreases in the availability of cytology staff has also exacerbated the ability of the contracted labs to increase their throughput through this time 3) as a result this has increased the reporting times to women up to 20 weeks and more in some cases. The table below sets out the increased number of GP consultations.</p> <p>In April, the Minister for Health announced that any woman of screening age with concerns about her cervical screening could avail of a free consultation, and if necessary, a free repeat smear test with any GP registered with CervicalCheck. These services ceased, as scheduled, on 31st December 2018. HSE wrote, on the 5th December 2018, to GPs registered with CervicalCheck to advise them of this process.</p> |

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| Week | Total |
|-------------|---------|
| Week 1 | 1,954 |
| Week 2 | 3,747 |
| Week 3 | 10,697 |
| Week 4 | 9,354 |
| Week 5 | 7,958 |
| Week 6 | 4,220 |
| Week 7 | 4,807 |
| Week 8 | 4,210 |
| Week 9 | 4,124 |
| Week 10 | 3,177 |
| Week 11 | 2,917 |
| Week 12 | 2,739 |
| Week 13 | 2,831 |
| Week 14 | 3,065 |
| Week 15 | 1,952 |
| Week 16 | 2,425 |
| Week 17 | 2,399 |
| Week 18 | 2,879 |
| Week 19 | 2,539 |
| Week 20 | 2,435 |
| Week 21 | 2,359 |
| Week 22 | 2,152 |
| Week 23 | 2,689 |
| Week 24 | 2,173 |
| Week 25 | 2,227 |
| Week 26 | 2,125 |
| Week 27 | 2,047 |
| Week 28 | 1,969 |
| Week 29 | 1,878 |
| Week 30 | 1,953 |
| Week 31 | 2,196 |
| Week 32 | 1,697 |
| Week 33 | 1,438 |
| Week 34 | 1,119 |
| Week 35 | 240 |
| Week 36 | 26 |
| Grand Total | 108,717 |

| Claim Status | Total |
|--------------------------|---------|
| Fully Paid | 100,124 |
| To Pay with Next Payment | 7,560 |
| Rejected | 618 |
| Duplicate | 415 |
| Grand Total | 108,717 |



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| Average Time for Processing Results | <p>The average processing time is currently 92 days.</p> <p>We are continuing to monitor the expiration of smears for low grade HPV testing. This remains a challenge for laboratories. A laboratory capacity plan is being developed for the next 6 months to address the backlog. This is required to stabilise the programme in order for to address the backlog and HPV primary screening to be implemented.</p> |
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Introduction of HPV Screening

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| Project Management | <p>Project Manager In place.</p> <p>Project Team Composition</p> <ul style="list-style-type: none"> • Cervical Check Clinical Director has been appointed and will commence in February 2019 • The expression of interest for the appointment of a Clinical Lead Colposcopist were unsuccessful. NSS are in discussion with a pathology lead and hope to confirm an appointment for mid-January. • 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 Colposcopy lead, Pathology lead. |
| Project Plan | |
| Workstream | Actions Progressed (w/e 4th January 2018) |
| Clinical | <ul style="list-style-type: none"> • Assessment of feedback to proposed screening pathway and eligibility framework continues. |
| Procurement | <ul style="list-style-type: none"> • Submissions from participants were received, the closing date was 6th December. • Assessment of submissions – 8 companies have submitted comments will conclude mid January |
| ICT | <ul style="list-style-type: none"> • CSR amendments - testing commenced. • Colposcopy IT – awaiting spec agreement, funding, and agreement of testing sites. • Laboratory IT - awaiting decisions on laboratory configuration and procurement. • GP IT – no specified changes yet. |

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| Lab Configuration | <ul style="list-style-type: none"> Configuration options - work limited until the market engagement seminar is completed and current programme stabilisation w.r.t. laboratories completed. |
| Communications | <ul style="list-style-type: none"> Communications lead identified for this project . To engage with team. |
| Resources for HPs | <ul style="list-style-type: none"> Continued work on: <ol style="list-style-type: none"> Developing training materials & the e-learning modules; and Guide for Primary Care which will be available in hardcopy and through the e-learning portal. |
| Hospitals (Colposcopy) | <ul style="list-style-type: none"> Colposcopy capacity planning and management of women referred to colposcopy has commenced by the women & infants programme. HG CEOs have officially been communicated to regarding this piece of work by National Hospital operation |
| Current Position, Significant Issues | <p>Current position, issues & challenges</p> <ol style="list-style-type: none"> 1) Stabilisation of the current programme remains a huge issue. Current backlogs from the 2 private providers will impact the transition to HPV primary screening. 2) Absence of a fulltime Clinical Director for the programme is impacting a number of key activities. A Clinical Advisory Group has been set up to address these decisions. 3) Failure to recruit a colposcopy or cytopathology lead for the program and project. There were no applicants. 4) Laboratory configuration strategy being reassessed by requirements to stabilise current programme and responses to market engagement seminar. 5) Market engagement seminar – assessment of responses. 6) Communications resources (external & internal) have been identified and work now will commence on a communications plan for the transition to HPV primary screening. Urgent. |
| Immediate Activities | |
| Workstream | Actions Planned |
| Clinical | <ul style="list-style-type: none"> Convene CAG to review clinical decisions to date and pending decisions. Circulate scope of work and arrange series of meetings with colposcopy leads. |

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| Procurement | <ul style="list-style-type: none">Finalise contract details with laboratories following agreement to continue.Assess outcome of market engagement seminar.Commence work on procurement strategy |
| ICT | <ul style="list-style-type: none">Continue testing of changes to Cervical Screening Register. (February 2019)Labs ICT development - awaiting nomination of labs to be contactedColposcopy IT - Funding approval to be sought. Testing sites (colposcopy services) to be identified (Urgent). |
| Lab Configuration | <ul style="list-style-type: none">Laboratory configuration strategy to be finalised looking at the options and future proofing services. |
| Communications | <ul style="list-style-type: none">Assess workshop (Comms, PMO) outcomes on communications planning. |
| Resources for HPs | <ul style="list-style-type: none">Progress materials development and the appointment of the elearning technologist. |
| Hospitals (Colposcopy) | <ul style="list-style-type: none">Identify lead for hospitals / colposcopy requirements.Complete capacity planning exercise and schedule meetings with lead colposcopists.Secure hospital commitments for 2019.Identify colposcopy lead (clinical). |
| Update Action | Cervical Check clinical director will commence 4/2/2019 |