

CervicalCheck Steering Committee
Weekly report to the Minister
26 July 2018

1. Overview

The Steering Committee met on Thursday 26 July. The meeting chair was Ms Tracey Conroy, Assistant Secretary, Acute Hospitals Policy Division.

2. Update on support package and *ex gratia* payment

The HSE reported that Liaison Officers have to date held 221 face-to-face meetings with women and families to discuss their needs. This includes 171 initial meetings and 50 follow-up meetings. There have also been a substantial number of less formal interactions between women, families and Liaison Officers.

With Liaison Officers engagement with women now well established, it is not expected that numbers of meetings held will change significantly from week to week. It is important to note that every individual's circumstances will be unique to them and thus the HSE has taken care to respect the wishes of the women and their families regarding the timing of contacts and subsequent meetings. Where meetings have not yet been held, this reflects the wishes of the individuals concerned either to meet at a future date that suits them or, in some instances not to take up the offer of support.

The HSE also reported that it is anticipated that the two remaining women of the 221 who have not yet been contacted will be reached shortly. An email address for the woman who lives overseas has been identified and the final woman of the 12 recently identified cases is due to meet with her consultant this week.

***Ex gratia* payment as recommended by Dr Scally**

Arrangements to make the ex-gratia payment of €2,000 to each of the women affected or, where a woman has died, to their next-of-kin are being coordinated through the Liaison Officers. The HSE reported that by the end of this week (27 July) it was expected that 192 payments would have been made. Remaining payments will be completed once individuals' banking details have been received.

Delivery of supports

- As of 26 July, the HSE had issued 604 new medical cards to women and family members or next-of-kin where the woman has, sadly, died. This includes the amendments that have been made to the terms of existing medical cards or G.P visit cards in 87 cases to recategorise these as medical cards under the terms of the CervicalCheck support package.
- Alongside the provision of medical cards, primary care supports, including counselling, have been made available to those requesting them. This is very much a client-driven process and requests for supports will differ from individual to individual. A range of other health supports is being provided in response to requests for physiotherapy, occupational therapy, dental, ophthalmic and nursing services among others.
- 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. This includes medicines not officially approved for reimbursement and any other non-standard therapies, once prescribed for the patient by their doctor. Arrangements are in place to reimburse 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. These will be reimbursed upon receipt of claims from individuals. The HSE has developed a simplified claim process

for women and their families to minimise the burden involved while providing required assurance from a public finance perspective.

- The Department has written to the HSE requesting that arrangements be put in place to enable retrospective financial assistance to be provided. The HSE is making good progress in relation to developing the necessary administrative supports and structures. The Department is also engaging with DPER on the issue of retrospective payments.

4. Release of records

A significant team is in place in CervicalCheck to deal with requests for records. The HSE is fully committed to providing any requested documents in line with the Minister's expressed expectation that all patient information, including documents, files and audits related to patients, will be made available to patients or their representatives without delay, and that the provision of information will be streamlined to the fullest extent possible to avoid unnecessary bureaucracy.

- 128 legal requests have been received to date, of which 12 were received within the past week; 95 have been processed, of which 9 were within the past week
- 200 FOI or data access requests have been made and 197 of these have been responded to.

The HSE has advised that a protocol for providing women with access to their physical smears is now in place, aimed at preserving the integrity of the smears for women who may wish to take legal action. Information in relation to the protocol is now being issued to women with their records, to facilitate them in receiving smears should they wish to do so. The HSE advises that solicitors are now using this protocol to access smears when required.

The HSE has confirmed arrangements for a single point of contact within the HSE to assist women and families in retrieving their records, which may be kept in multiple locations.

5. International Clinical Expert Panel Review

The HSE now has a senior and experienced Project Manager in place, together with key project leads and support staff, to ensure all possible support is provided for the RCOG review. The initial focus is on validation of the details of the 1850 women within the cohort for the review (other than the 221 already known), in order to seek consent. Consent documents including an introduction letter, patient information sheet (provided by RCOG), consent form and FAQs have now been drafted, and are being reviewed by NALA before issue to the 221 women next week. The approach for obtaining consent will be tailored to the different cohorts of women and families involved, recognising the very sensitive nature of this issue.

The Department of Health is committed to continuing to support and facilitate RCOG and the HSE in progressing this review as expediently as possible, and to do so in a way that ensures quality, comprehensiveness and integrity of the results.

6. Implementation of recommendations of the Scally Inquiry

An implementation plan outlining the key actions to be undertaken by the HSE to address the four recommendations contained in the First Report from Dr Scally, on information for women, is in place. The HSE has reported that work is continuing on implementing the plan, with working groups coordinating the various streams of work. Subject matter experts have been identified who will support the work.

7. 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 and will

be subject to a tendering process for any work carried out outside the public sector. The HSE has advised that a Project Steering Group is in place for this work, recognising that this is a policy and operational priority, and it is working to secure further specialist expertise to support the project. The Department is continuing to engage with the HSE, within the Steering Committee, to ensure the switch to HPV testing progresses as quickly as possible.

8. Smeartaking activity

The HSE has reported that lab activity, which had risen as a consequence both of out-of-cycle smears and increased uptake generally, has begun to diminish to more normal levels. However, it still remains significantly above baseline levels of activity and there is a backlog of smear tests now which remain to be analysed. The HSE is monitoring this through weekly calls and meetings with the labs to manage the situation and engaging with the labs to identify all possible solutions to manage the backlog. The HSE has advised that claims for 53,613 additional GP consultations have been submitted in the past twelve weeks.

9. Communications

A letter and update for the 221 women involved in the original audit has been prepared, providing a range of details including on the two reviews, the package of supports, and how to request records. This will issue on 27 July.

26 July 2018

CervicalCheck Steering Committee
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| | | | | | |
|-----|---|------------------|--|-----------------|---------------|
| 1 | Oversight and engagement with the HSE on modules of their work as follows | | | Deadline | Status |
| 1.a | Management of supports to patients/families | | | | |
| | | Yes | No | | |
| | Project Manager in Place: David Walsh/Mary Walshe | Yes | | | |
| | Project Team Composition David Walsh ND, Mary Walshe Chief Officer Maria Kavanagh Liaison Officers in each of (Community Healthcare Organisations) CHO 1 C Walsh CHO 2 B Austin CHO 3 B Carroll CHO 4 H Sweeney CHO 5 S Murphy CHO 6 D Healy CHO 7 C Hanley CHO 8 J Bourke CHO 9 B Horgan | | | | |
| | Project Plan | | | | |
| | | This week | To date | | |
| | Number of meetings held with affected women & families (Liaison Officers) | 6 | 171 initial meetings and 50 additional meetings. | | |
| | Number of medical cards issued | 14 | 604 | | |
| | Number of ex gratia payments made | 6 | 192 | | |

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|------------------------------|--|-----|---|--|----|-----------------------|----|-----------------|----|------------------------------|----|-----|----|-----------------|----|---------------|----|------------|----|------------|----|--------------|---|--|--|
| | Number of supports requested | 16 | 431 Top ten supports requested this week. | | | | | | | | | | | | | | | | | | | | | | |
| | Number of supports provided | 156 | 318 Top ten supports provided <table><tr><td>Counselling</td><td>74</td></tr><tr><td>Complimentary Therapy</td><td>47</td></tr><tr><td>Transport costs</td><td>30</td></tr><tr><td>Medical appointment expenses</td><td>25</td></tr><tr><td>HCP</td><td>22</td></tr><tr><td>Childcare Costs</td><td>20</td></tr><tr><td>Medical Notes</td><td>13</td></tr><tr><td>Medication</td><td>11</td></tr><tr><td>Diagnostic</td><td>10</td></tr><tr><td>Disabilities</td><td>9</td></tr></table> | Counselling | 74 | Complimentary Therapy | 47 | Transport costs | 30 | Medical appointment expenses | 25 | HCP | 22 | Childcare Costs | 20 | Medical Notes | 13 | Medication | 11 | Diagnostic | 10 | Disabilities | 9 | | |
| Counselling | 74 | | | | | | | | | | | | | | | | | | | | | | | | |
| Complimentary Therapy | 47 | | | | | | | | | | | | | | | | | | | | | | | | |
| Transport costs | 30 | | | | | | | | | | | | | | | | | | | | | | | | |
| Medical appointment expenses | 25 | | | | | | | | | | | | | | | | | | | | | | | | |
| HCP | 22 | | | | | | | | | | | | | | | | | | | | | | | | |
| Childcare Costs | 20 | | | | | | | | | | | | | | | | | | | | | | | | |
| Medical Notes | 13 | | | | | | | | | | | | | | | | | | | | | | | | |
| Medication | 11 | | | | | | | | | | | | | | | | | | | | | | | | |
| Diagnostic | 10 | | | | | | | | | | | | | | | | | | | | | | | | |
| Disabilities | 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| | Current position, issues & challenges <ul style="list-style-type: none">Updated support guidance will issue to clients later this week outlining retrospectionContact with clients regarding RCOG review must be clear and managed closely in order to avoid undue upset and provide continued assurances. | | | | | | | | | | | | | | | | | | | | | | | | |
| | Update Action 04/24 A written communication to be developed within the next week, to issue to the 221 women as soon as possible Update Action 04/25 Preliminary work to begin within the HSE in relation to the holding of workshops for the 221 women. An update on this is to be provided at next week’s meeting Update Action 04/26 A solution in relation to the simplification of the claims process is to be identified and reported on at the meeting next week | | | 19/07/18 19/07/18 19/07/18 | | | | | | | | | | | | | | | | | | | | | |

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|-----|---|------------|-----------|-----------------|---------------|
| 1 | Oversight and engagement with the HSE on modules of their work as follows | | | Deadline | Status |
| 1.b | Provision of documents to patients | | | | |
| | | Yes | No | | |
| | Project Manager in Place There is an operational manager assigned to oversee access to records and smear results. | √ | | | |
| | Operational Team Composition While this process was not in place prior to the cervical check crisis a significant team has been put in place to ensure that women and their legal representatives receive their records in the most timely manner possible. The team comprises of: <ul style="list-style-type: none"> - Operations manager responsible for overall coordination. - Four legal personnel with three in Dublin and one part time in Limerick. - Administrative support. Initially the operations manager was reassigned within screening, given the priority attached to the release of records. However a dedicated project manager has been appointed to increase capacity and coordinate all data access activity. This PM started on July 24 th . | | | | |
| | Project Plan There is a defined operational process for the release of records. The newly appointment project manager will maintain oversight of and report on the number of open requests, turnaround time etc. | √ | | | |

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| | | This week | To date | | |
| | Number of legal requests made | 12 | 128 | | |
| | Number of legal requests responded to | 9 | 95 | | |
| | 0 - 30 days | TBC | TBC | | |
| | 30 days + | TBC | TBC | | |
| | Number of requests on hold, awaiting clarification from solicitor | | 4 | | |
| | Number of FOI / Data access Requests made | 12 | 200 | | |
| | Number of FOI / Data access Requests responded to | 17 | 197 | | |
| | 0 - 30 days | | 187 | | |
| | 30 days + | | 10 | | Initial resourcing challenges meant that these cases were not processed within the expected 30 day turnaround time. |
| | Current position, issues & challenges | | | | |
| | The team remains focused on responding to all requests as soon as possible. | | | | |
| | Update Action | | | | |
| | External legal advisors continue to liaise with women and their solicitors on the release of slides. All pending court cases have been prioritised. Each solicitor is required to confirm they will need the smears and provide their laboratory details. The HSE will request that the labs send the slides directly to the nominated lab. There have been some teething problems in this process with the labs but these are being addressed. | | | | |

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|-----|--|------------|-----------|-----------------|---------------|
| 1 | Oversight and engagement with the HSE on modules of their work as follows | | | Deadline | Status |
| 1.c | Interface with Scally Inquiry | | | | |
| | | Yes | No | | |
| | Project Manager in Place Yes. A senior manager is assigned to oversee the timely release of documents to facilitate Dr Scallys review. | √ | | | |
| | Project Team Composition There is an external legal services partner with a team of solicitors to support the release of documents. In addition we have a HSE senior manager assigned to support the legal team in the provision of documents. HSE divisions have also assigned lead personnel to support the provision of documents to the central team. | | | | |
| | Project Plan We are working to the timeframes as outlined by Dr Scally. | | | | |
| | Current position, issues & challenges 1. Issues regarding searchability have been addressed. Closed. 2. We continue to supply documents as requested by Dr Scally. 3. NSS team members are attending meetings with Dr Scally as requested. 4. The HSE DG has continued to link with Dr Scally on a regular basis to ensure that the review is supported by HSE leadership. | | | | |

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|-----|--|--|--|-----------------|---------------|
| 1 | Oversight and engagement with the HSE on modules of their work as follows | | | Deadline | Status |
| 1.c | Interface with Scally Inquiry | | | | |
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| | Update Action | | | | |

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|-----|---|------------|-----------|--|--|
| 1.d | Interface with RCOG Review | | | | |
| | | Yes | No | | |
| | <p>Project Manager in Place</p> <p>A project lead has been recruited to head up the HSE response to the RCOG review. This person is a senior manager and will be in post this week.</p> <p>The project lead will be supported by a patient services manager who has been appointed to head up the patient validation and consent process. This person will start on Monday 30th. Six patient service officers are required to support the process and this hiring process is underway.</p> <p>IT are scoping out a database to support the RCOG process. A project office has been established in the NSS office on Parnell St and this office has been equipped to support the work.</p> | √ | | | |

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| | <p>Project Team Composition</p> <p>There are four main sections for the team required to support RCOG. These are:</p> <ol style="list-style-type: none"> 1. Patient services 2. Logistics (to support laboratories transfer process) 3. Hospital co-ordination and delivery 4. Communications <p>An overall resource plan has been finalised following the meeting with RCOG last week and priority positions, including the project lead and patient services manager, have been filled.</p> | | | | |
| | <p>Project Plan</p> <p>The HSE are developing a plan alongside the overall RCOG plan. Priority tasks have been identified and these are being advanced while the full project plan is being worked through with RCOG. The newly appointed project lead will work to finalise the plan when they start in w/c July 30th.</p> | | | | |
| | <p>Current position, issues & challenges</p> <p>Good progress has been made on the recruitment of a team to lead the HSE response to the RCOG review. This team will be mobilised over the coming weeks, with the project lead starting in w/c July 30th.</p> <p>The project lead will focus on the highest priority items and this will include agreement on the consent process with women / service users.</p> | | | | |

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| | Update Action | | | | |
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|-----|---|------------|-----------|-----------------|---------------|
| 1 | Oversight and engagement with the HSE on modules of their work as follows | | | Deadline | Status |
| 1.e | Management of laboratory capacity issues | | | | |
| | | Yes | No | | |
| | Project Manager in Place Yes. The CervicalCheck Programme Manager is leading this response. | √ | | | |
| | Project Team Composition Given the nature of the issues presenting a working group was put in place to support the project manager. This group comprise 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. | Y | | | |

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| | <p>Project Plan</p> <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 as they require the use of overtime for existing staff and there are workload limits set for quality assurance purposes. Staff leave at this time of year is also impacting the ability of the labs to address the backlog.</p> <p>The lab working group continues to work closely with the three labs to understand and manage current capacity issues. The labs are reporting to the CervicalCheck team on a weekly basis providing status updates on the number of samples received, processing times etc. Lab action plans are being monitored to ensure that they address the problem in the shortest possible timeframes without sacrificing patient safety.</p> | | | | |
| | <p>Uptake of smear tests:</p> <p><i>Out of cycle smears</i></p> <p>Total number of additional consultations to date is more than 53,000. Weekly totals continue to run at more than 1,000 consultations. The normal capacity for a lab is approximately 5,000 per week so we are still seeing a 20% increase in uptake as a result on the free smear test. This is presenting serious patient safety issues for the HSE and the laboratories. 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</p> | | | | |

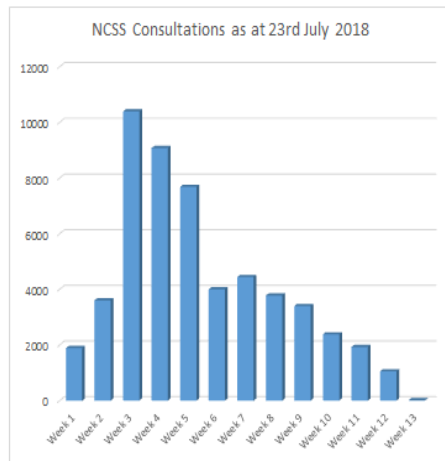
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out the increased number of GP consultations.

Out of Cycle Smears - GP Consultations

| Claim Status | Total |
|--------------------------|---------------|
| Fully Paid | 43,786 |
| To Pay with Next Payment | 9,486 |
| Rejected | 166 |
| Duplicate | 175 |
| Grand Total | 53,613 |

| Week | Total |
|--------------------|--------------|
| Week 1 | 1886 |
| Week 2 | 3599 |
| Week 3 | 10388 |
| Week 4 | 9071 |
| Week 5 | 7679 |
| Week 6 | 4002 |
| Week 7 | 4439 |
| Week 8 | 3779 |
| Week 9 | 3397 |
| Week 10 | 2379 |
| Week 11 | 1928 |
| Week 12 | 1049 |
| Week 13 | 17 |
| Grand Total | 53613 |



Note: Week 13 is reporting as a low figure as the week starts on Monday 23rd July and reflects just a few hours of PCRS processing time.

Average time for processing results

The target cycle time for each lab is 17 days. One lab is operating very close to this target, at an average of 18 days. However two labs are outside of target, operating at an average reporting time of more than 50 days.

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|--|---|--|--|--|--|
| | Current position, issues & challenges <p>Our main concern remains the backlog of samples to be tested. Staff leave is an issue in each lab so overtime continues to help address the backlog. As long as numbers received remain steady and ideally start to reduce, the labs project that specimen reception and data entry backlog will take approx. 8 weeks to clear.</p> <p>Weekly calls and meetings continue with the lab in order to manage the situation.</p> | | | | |
| | Update Action | | | | |

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|-----|---|-----|----|--|--|
| 1.f | Introduction of HPV Screening | | | | |
| | | Yes | No | | |
| | Project Manager in Place <p>Yes. A Project Manager is in place and discussions are continuing with a possible clinical Lead for the HPV primary screening project.</p> | √ | | | |
| | Project Team Composition <p>Prior to April 2018 the project was being led by the former CervicalCheck clinical director While efforts are ongoing to secure a clinical lead for the project a formal HPV screening project team has been established.</p> <p>A number of working groups are being established to address specific aspects of the project. These groups are working on detailed tasks lists and estimated timelines which will, ultimately, be included in the project plan. Work stream leads have been appointed for all</p> | √ | | | |

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|-----|--|--|--|--|--|
| 1.f | Introduction of HPV Screening | | | | |
| | <p>work streams with the exception of the clinical lead.</p> <p>Further specialist resource will be required to deliver this project and given that HPV primary screening has only been rolled out in a small number of countries we are searching abroad for specialist advice.</p> <p>A formal HPV Primary Screening steering group has been established to oversee the project comprising all the key stakeholders. This steering group is meeting on July 25th.</p> | | | | |
| | <p>Project Plan</p> <p>Planning for the introduction of HPV screening has been underway for the past 18 months but 3 months were lost since when it became essential to prioritise management of issues arising out of the CervicalCheck audit incident. Further effort is required to stabilise the adverse impacts on programme delivery and this is a priority for the newly appointed Programme Director.</p> <p>Six key work streams have now been identified, up from five work streams in last week's report. Laboratories Reconfiguration has been split into two work streams; (i) Laboratories reconfiguration and (ii) Labs procurement. The other work streams remain; Clinical Pathways, ICT, Communications and Resources for Health Professionals.</p> <p>Critical path / dependencies:</p> <ul style="list-style-type: none"> • Finalise clinical pathway • Laboratories: finalise service specifications • Public procurement tender and contract to a laboratory for the remainder of capacity • IT system changes (CSR; Laboratories; Colposcopy; GPs – all largely in parallel, laboratory IT development on longest timescale) • Establish contracts and MOUs <p>A high level project roadmap and a detailed project plan for each work stream are still being developed.</p> | | | | |

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|--|--|--|--|--|---------|
| | <p>Current position, issues & challenges</p> <p>Implementation planning for the transition to HPV primary screening is ongoing. Work continuing on Gantt chart, risks and issues.</p> <p>A number of issues have been flagged for the HSE HPV Steering Group which met on the morning of July 25th-</p> <ul style="list-style-type: none">• Appointment of a clinical lead for the HPV screening project• Recruitment of a clinical director for CervicalCheck Programme• Decision required on the cervical screening pathway - clinical input required• Decision required on the HPV test type – clinical input required• Laboratory reconfiguration options• Tender for additional laboratory provider through EU tendering process• Stabilisation of the current programme (increase in demand on the laboratories and colposcopy with repeat and additional workload)• Capacity planning to scope the increased demand on labs and colposcopy clinics• Demand on CervicalCheck resources due to RCOG and Scally review <p>The HPV primary screening project team continues to meet weekly. The steering group met on the morning of July 25th.</p> | | | | |
| | <p>Update Action 04/28 An update on the possibility of appointing a clinical lead for the move to HPV testing will be provided next week</p> | | | | Ongoing |
| | <p>Update Action 04/29 A more detailed project plan is to be provided for next week’s meeting</p> | | | | Ongoing |

CervicalCheck Steering Committee
Weekly Report from HSE 26th July 2018

| 3 | Implementation assurance on Scally Inquiry and RCOG recommendations | | | Deadline | Status |
|-----|--|---|--|----------|-------------|
| 3.a | Scally Inquiry recommendations | Current position, issues & challenges | | | |
| | 1. A more comprehensive guide to the CervicalCheck screening programme should be provided online so that women who wish to learn more about the programme can obtain information easily | Content plan is being created. Content will be provided to subject matter experts in w/c July 30 th . Workshop to be held on August 9 th to discuss next steps. | | 01.10.18 | In progress |
| | 2. The information statements provided to women about the limitations of the tests should be more explicit about the possible reasons why screening might miss abnormalities that are present, as these can result in the development of cervical cancer. This information should be included in the leaflet sent to all women with their screening invitation, and in the information sheet accompanying their consent form | Scoping of work has commenced. Work is ongoing on logistical details on the dissemination of materials. | | 01.10.18 | In progress |
| | 3. The information for women accompanying the consent form should guarantee that they will have full and open access to their cervical screening record on request | Scoping of work has commenced. Work is ongoing on logistical details on the dissemination of materials. | | 16.09.18 | In progress |

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|-----|---|---|--|----------|-------------|
| 3 | Implementation assurance on Scally Inquiry and RCOG recommendations | | | Deadline | Status |
| 3.a | Scally Inquiry recommendations | Current position, issues & challenges | | | |
| | 4. The information for women accompanying the consent form should guarantee that should there be a problem or error of any significance with the screening or reporting process, open disclosure of all the details will take place in a timely, considerate and accurate manner | The HSE's Open Disclosure Lead has been invited to be part of the working group. There has been an initial meeting to scope out the details of open disclosure and how it relates to CervicalCheck. | | 16.09.18 | In progress |
| | 5. The provision of an immediate ex gratia payment of €2,000 to each woman involved and to the next of kin of the deceased, recognising that it is important that women do not encounter any financial obstacles to participating and making their voices heard in relation to both the Scoping Inquiry and any resulting Commission of Inquiry | N/A | | | |
| | 6. That a process be commenced to hold structured conversations with each of the women affected by the CervicalCheck issues who wish to have their experience documented, and with the relevant surviving family members of any affected woman who has died, if they so wish | N/A | | | |
| | Update Action | | | | |

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|-----|--|---------------------------------------|--|----------|--------|
| 3 | Implementation assurance on Scally Inquiry and RCOG recommendations | | | Deadline | Status |
| 3.a | Scally Inquiry recommendations | Current position, issues & challenges | | | |
| | <p>Members of the Scally Implementation working group: CervicalCheck Team: Smeartaker Co-ordinator and Senior Health Promotion Officer: Communications Team: Client Services Director, Senior Comms Manager, Programmes and Campaigns, Content Manager, Digital, Communications Manager; National Screening Service team: Communications Information Manager, Information and Communications Officer. Advocacy Team: Head of Open Disclosure and members of the Advocacy team on a needs basis.</p> <p>The group will be supported in their work by a research process and a reference group, which will provide expert advice at key points of the project.</p> | | | | |
| 3.b | RCOG recommendations | | | | |
| | Tbc | | | | |