

CervicalCheck Steering Committee
Weekly report to the Minister
28 September 2018

1. Update on support package

The HSE reports that Liaison Officers have held 325 face-to-face meetings with women and families to discuss their needs. This includes 178 initial meetings and 147 follow-up meetings, together with other regular interactions between women, families and Liaison Officers.

An event for the 221 women and families involved in the CervicalCheck audit was held on Sunday 16th of September. Approximately 140 women and family members attended. The event was very well received.

Structured feedback from this event is awaited with a view to using this information to provide more targeted support to those who need it.

Delivery of supports

- The HSE has now issued 685 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 GP visit cards in 94 cases to recategorise these as medical cards under the terms of the CervicalCheck support package. Numbers of medical cards issued in total now appears stable.
- Alongside the provision of medical cards, supports, including counselling, physiotherapy, occupational therapy, dental, ophthalmic and nursing services have been made available to those requesting them. Guidance is also provided regarding grants and services available from local authorities.
- Women have been contacted by their Liaison Officers to ensure that everyone is aware of and has access to the report of the Scoping Inquiry, following its publication on Wednesday 12th September. The Department understands that 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 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. The HSE has developed a simplified claim process for women and their families to minimise the burden involved while providing the required assurance from a public finance perspective. To date, over €563,000 has been reimbursed in respect of various health and social care costs, some €412,000 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.
- 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.

2. Release of records

The HSE remains focused on responding to all requests for records as soon as possible. The HSE reports that:

- 124 legal requests have been received to date, of which 106 have been processed
- 298 FOI or data access requests have been made, of which 292 have received a response

The HSE's protocol for providing women with access to their physical smears aims to provide women with access while preserving the integrity of the slides. The protocol also provides a tracing mechanism for slides. Information in relation to the protocol continues to be issued to women with their records to facilitate them in accessing smears should they wish to do so. The HSE advises that solicitors are using this protocol to access smears when required.

- 23 slide requests have been made in accordance with the protocol; 11 have been processed.

3. Independent Expert Panel Review

A senior and experienced HSE Project Manager is in place, together with key project leads and support staff, to ensure all possible support is provided for the RCOG review. Progress to date is as follows:

- Information in relation to consent together with consent form issued to 216 women and families in mid-August. Five women of the initial 221 elected not to receive any further correspondence from the HSE and so did not receive this pack. Over 1,300 letters have now issued and the HSE has reported that it expects the vast majority of remaining letters to be either completed or issued by end of last week, excluding those involving next-of-kin. The Department will continue to engage with HSE to ensure remaining letters issue as expeditiously as possible.
- Approximately 330 consent forms are reported to have been returned up to end of last week, with 94% 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. A dedicated information line is available to answer queries people may have when they receive their letter. Additional clinical and administrative resources have been identified to support calltaking where women have queries, with opening hours extended to weekends
- The Department is committed to continuing to support and facilitate RCOG and the HSE in progressing this review as expeditiously as possible, and to do so in a way that ensures quality, comprehensiveness and integrity of the results.

4. 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. Communications and information materials have been shared with the Committee for comment.

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. A Steering Group, chaired by the Deputy Director General Operations, has also been set up within the HSE to oversee the implementation of the recommendations from the final report of the Scoping Inquiry.

5. 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. A project steering group comprising all key stakeholders is in place and a project manager has been appointed.

A key decision is the choice of HPV assay, required before finalisation of tender documentation. This requires clinical input and a Clinical Advisory Group has been identified. The second meeting of this group was due to take place on the 27th of September.

Negotiations on the extension of existing lab contracts are currently ongoing, to maintain the programme pending introduction of the new test and related procurement.

6. 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.

7. Smear-taking activity

The HSE has reported that lab activity remains above normal levels up to last week. The total number of additional consultations to date is over 77,000. The issue of the backlog of smear tests is a priority concern for the HSE as the current average processing time is 61 days. The National Screening Service and HSE Procurement are engaging with laboratory service providers to address capacity issues.

8. 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 is undertaking a specific review regarding the claims arising out of the issues surrounding CervicalCheck. He has confirmed that this work is underway and will be completed in October.

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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)				
	Project Plan				
		This week	To date		
	Number of meetings held with affected women & families (Liaison Officers)	14	178 initial meetings 147 and additional meetings.		
	Number of medical cards issued	0	685		
	Number of ex gratia payments made	0	208		

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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																								
	Number of supports requested	23	508 Top ten supports requested to date; <table><tr><td>Counselling</td><td>125</td></tr><tr><td>Complimentary Therapy</td><td>57</td></tr><tr><td>Transport costs</td><td>42</td></tr><tr><td>Medical appointment expenses</td><td>38</td></tr><tr><td>Medical Notes</td><td>34</td></tr><tr><td>Childcare Costs</td><td>28</td></tr><tr><td>Diagnostic</td><td>22</td></tr><tr><td>HCP</td><td>21</td></tr><tr><td>Physio</td><td>19</td></tr><tr><td>Medication</td><td>19</td></tr></table>	Counselling	125	Complimentary Therapy	57	Transport costs	42	Medical appointment expenses	38	Medical Notes	34	Childcare Costs	28	Diagnostic	22	HCP	21	Physio	19	Medication	19		
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	Number of supports provided	18	356 Top ten supports provided to date; <table><tr><td>Counselling</td><td>83</td></tr><tr><td>Complimentary Therapy</td><td>42</td></tr><tr><td>Transport costs</td><td>33</td></tr><tr><td>Medical appointment expenses</td><td>31</td></tr><tr><td>Medical Notes</td><td>29</td></tr><tr><td>Childcare Costs</td><td>22</td></tr><tr><td>Medication</td><td>16</td></tr><tr><td>Diagnostic</td><td>16</td></tr><tr><td>HCP</td><td>15</td></tr><tr><td>Nursing</td><td>10</td></tr></table>	Counselling	83	Complimentary Therapy	42	Transport costs	33	Medical appointment expenses	31	Medical Notes	29	Childcare Costs	22	Medication	16	Diagnostic	16	HCP	15	Nursing	10		
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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				
	<p>Current position, issues & challenges</p> <ul style="list-style-type: none"> • In some cases retrospective claims are delayed as women/families seek information from hospitals in relation to previous appointments. Clients also find this task psychologically difficult. Liaison Officers are assisting in this process. • Structured feedback from the Athlone meeting is awaited with a view to using this information to provide more targeted support to those who need it. • Liaison Officers continue to engage to support with both urgent and routine issues that have arisen for those affected. 				

Oversight and engagement with the HSE on modules of their work as follows			
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 team has been created and work is progressing to expand the team 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"> - PM for overall coordination. - Two legal personnel in Dublin. 	√	

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	- Four Administrative support personnel.		
	Project Plan There is a defined operational process for the release of records.	√	
		This week	To date
	Number of legal requests made	1	124
	Number of legal requests responded to	3	106
	0 - 30 days	-	93
	*30 days +	-	13
	Number of requests on hold, awaiting clarification from solicitor	-	2
	Number of FOI / Data access Requests made	4	298
	Number of FOI / Data access Requests responded to	15	292
	0 - 30 days	-	253
	**30 days +	-	39
	Number of slide requests made (per protocol)	0	23
	Number of slide requests processed (per protocol)	0	11
	Current position, issues & challenges 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.		
	Update Action *During the setup of the client services team in April/May in the early part of the crisis there were 10 requests which extended over the 30 days. 6 of the 10 were pre-GDPR requirement for 40 days but resourcing was a constraint at the start of this process. **During the setup of the client services team in April/May in the early part of the crisis there were requests which extended over the 30 days, many of these were during the setup period and others have occurred due to waiting for hospital medical records, verification of patient or next-of-kin details and screening queries.		

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1.c	Interface with RCOG Review	Yes	No
	Project Manager in Place Assistant National Director (HSE) commenced working as the Programme Lead on the RCOG Review on Wednesday the 1 st of August. Project Manager (HSE) commenced working as the Project Manager on Wednesday the 1 st of August.		
	Programme Governance Daily meetings and teleconference calls with the Project Team to identify critical actions, timeframes, and areas for escalation, risks, issues, and dependencies are taking place.	√	
	Project Plan Communication to/from Women <ul style="list-style-type: none"> 1,329 letters have been issued. The balance of letters, excluding the next-of-kin letters, have either issued or will be completed by Thursday 27th. Consent forms returned by 328 individuals, of which 309 consent to be part of the review. Acute hospitals supporting validation of next-of-kin where PCRS has confirmed the women have deceased. RCOG have participated in weekly teleconferences with Patient Liaison Officers. Call Centre: <ul style="list-style-type: none"> Additional resources have been identified (clinical and administrative) to support call centre. Opening hours extended to weekends 9am – 6pm to support anticipated volume of calls. A protocol has been established with the NSS, NCRI and Acute Hospital Operations to manage and follow up on queries which require escalation for follow-up. 	√	

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	<p>Laboratory Logistics:</p> <ul style="list-style-type: none">• Process of engagement with NSS, RCOG and the labs has commenced with the view to transferring slides as quickly as possible. Bristol Lab (RCOG UK) has confirmed they can commence receiving slides from w/c 24th Sept.• Case Management System updated to identify laboratory locations for relevant slides, and keep a log of supply chain management processes for slide transfers• Tues 18th Sept: Workshop held with key stakeholders to review process map for slide transfer protocol. Draft SOP developed, awaiting technical input from RCOG and labs.• Thurs 20th Sept: Teleconferences held with the CervicalCheck laboratories to discuss requirements and establish points of contact to commence process. <p>Acute & Community Services</p> <ul style="list-style-type: none">• Developing process with acute hospitals to expedite validation of Next-of-Kin where a woman is known to be deceased.• Developing protocol to supply RCOG with relevant medical records from acute and community services where requested.		
	<p>Case Management System</p> <ul style="list-style-type: none">• Further CMS development in progress to support labs transport process• Training on CMS has commenced for all relevant staff.• Data is being uploaded on CMS as validated data received is from NSS. <p>Communications</p> <ul style="list-style-type: none">• To support the distribution of letters to women: Liaising with HSE Comms / HSE Digital to coordinate approach; issuing proactive communications as appropriate/agreed; and developing a draft press statement and media FAQ.• Communications plan and stakeholder map drafted and is in consultation. <p>Current Position, Issues and Challenges</p> <ul style="list-style-type: none">• Hospitals will need to develop plans for the RCOG at local level which will present significant operational challenges to rollout.• Managing feedback and queries from women/Next-Of-Kin, clinicians, media and public as remaining cohorts of women or next of kin receive letters.		

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	Next Steps <ul style="list-style-type: none"> Continue plan to issue remaining letters. Continue regular engagement with Patient Liaison Officers and other stakeholders. As letters issue, continue to update CMS. Training on CMS to continue for relevant staff. Design of CMS to be updated in line with agreement on labs transport process. Finalise agreement on slide transfer Standard Operating Procedure with NSS, laboratories, and RCOG. Identify timelines to commence slide transfer process w/c 24th Sept. Continue to follow up on calls received through information line. As remaining letters issue, identify and assign further additional clinical & administrative resources to the call centre in line with the project plan timelines. Complete Communication Plan and Stakeholder Map, progress engagement with stakeholders as planned.
	Update Action

	Oversight and engagement with the HSE on modules of their work as follows		
1.d	Management of laboratory capacity issues	Yes	No
	Project Manager in Place Yes.	√	
	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.	√	
	Project Plan 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. 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 and the potential introduction of overtime for screeners from September. Negotiations continue with existing labs and they are at a critical point. This is the most significant risk to		

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the programme. Contingency plans are being developed and it should be noted that there are limited alternatives to sustain the programme at current levels.

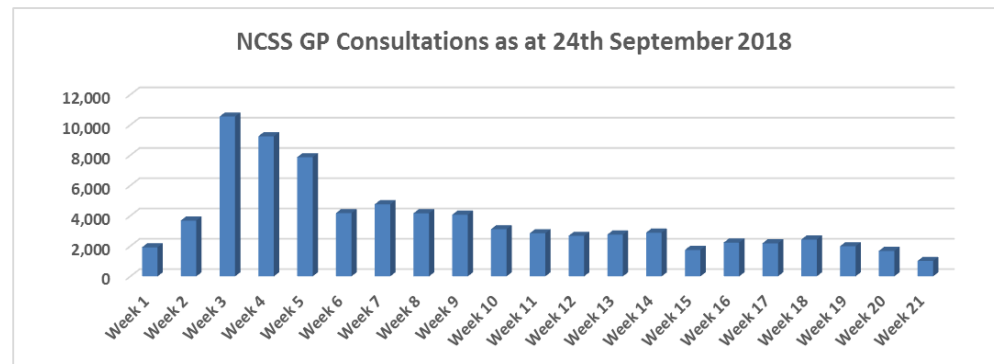
Uptake of smear tests:

Out of cycle smears

Total number of additional consultations to date is more than 77,000. The normal capacity for the labs 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 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.

Claim Status	Total
Fully Paid	66,511
To Pay with Next Payment	10,801
Rejected	334
Duplicate	330
Grand Total	77,976

Week	Total
Week 1	1,916
Week 2	3,684
Week 3	10,549
Week 4	9,248
Week 5	7,863
Week 6	4,174
Week 7	4,757
Week 8	4,162
Week 9	4,071
Week 10	3,113
Week 11	2,846
Week 12	2,673
Week 13	2,759
Week 14	2,886
Week 15	1,747
Week 16	2,230
Week 17	2,184
Week 18	2,431
Week 19	1,988
Week 20	1,677
Week 21	1,018
Grand Total	77,976



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	Average time for processing results The average processing time is currently 61 days.		
	Update Action The National Screening Service and HSE Procurement along with Legal Representation are engaging directly with the Laboratory Service Providers in order to address capacity issues i.e. contingency labs, performance, and other contract related issues. More intensive contract meetings are scheduled to take place again this week. We are now at a critical point on extending the laboratory contracts and it is clear that to address the backlogs in some labs will require clarity on future extensions.		

1.e	Introduction of HPV Screening	Yes	No
	Project Manager in Place Yes. A Project Manager is in place and the expression of interest is still open for the appointment of a Clinical Lead for the HPV primary screening project. Also, an expression of interest is currently open for a lead cytopathologist and lead colposcopist to join the project team.	√	
	Project Team Composition <ul style="list-style-type: none"> Clinical Advisory Group: chaired by interim Clinical Director: next meeting is on 27th Sept. Some workstream resources to be filled (Communications, Hospitals/Colposcopy, ICT). Project Plan <i>Update on the key workstreams</i> Clinical <ul style="list-style-type: none"> Clinical Advisory Group – initial members identified and invited. Meeting held on 13th Sept. Proposals on key clinical decisions were drafted and discussed on the 13th Sept further work needed, e.g. the allowable HPV test assay(s) Procurement <ul style="list-style-type: none"> Market analysis to inform specification and market model is still in progress and is awaiting the clinical decisions to move forward. ICT <ul style="list-style-type: none"> Development and testing on changes to the Cervical Screening Register were progressed Still addressing the availability of testers in terms of resourcing Lab Configuration	√	

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1.e	Introduction of HPV Screening	Yes	No
	<ul style="list-style-type: none"> Draft configuration options prepared, work is ongoing on detailing this further. <p>Resources for Health care Professionals</p> <ul style="list-style-type: none"> Resource Planning is still in progress <p>Immediate activities</p> <ul style="list-style-type: none"> Finalise clinical decisions. The Clinical Advisory Group's next meeting is scheduled for September 27th Market information session proposed to allow services required to be explored with a view to determining level of interest and potential contractual issues. (October 2018) Detailed capacity planning with the Coombe and NVRL to continue into September & October to review their capability to deliver HPV primary testing (i.e. adequate resources, IT requirements and timelines to deliver any changes to their systems). Work on the development and testing of changes to the Cervical screening register is continuing. <p>Current position, issues & challenges</p> <ol style="list-style-type: none"> Continuing efforts to secure contract extensions with existing laboratories is critical to enable the programme to proceed. Stabilisation of the current programme (increase in demand on the laboratories and colposcopy with repeat and additional workload) Intense negotiations continue with existing labs. Key issue for the laboratories are reputational and financial concerns. The Clinical Advisory Group was setup to mitigate the risk of the Clinical Director or lead for the programme. However, no final decisions have yet been made on the; <ul style="list-style-type: none"> Cervical screening pathway The HPV test assay Also, no colposcopist or public representative currently exist on the CAG at the moment There is a dependency to conclude the HPV test assay to allow the market information session to take place. 		
	<p>Update Action 04/28 Update on the possibility of appointing a clinical lead for the move to HPV testing will be provided next week.</p> <p>Update on 14/08/18: The negotiations with the possible candidate to take on the clinical lead role were unsuccessful. We are going to issue another</p>		

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1.e	Introduction of HPV Screening	Yes	No
	<p>expression of interest to the clinical community. Update on 05/09/18 A further expression of interest was issued again last week. Update on 12/09/18 this expression of interest has been extended for an additional fortnight.</p> <p>Update on 28/08/18 Interviews for a clinical director took place last week and an offer will be made to the identified candidate this week. Update on 05/09/18 The offer was made and final negotiations are concluding with the successful candidate. Update 19/09/18 NRS are finalising the contract.</p> <p>Update Action 04/29 A review meeting is being scheduled with DoH regarding the project plan. Update on 12/09/18 This meeting took place on 06/09/18</p>		
2	Implementation assurance on Scally Inquiry and RCOG recommendations		

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Members of the Scally Implementation working group with NSS

CervicalCheck Team:

- Smear taker Co-ordinator
- Senior Health Promotion Officer

National Screening Service team:

- Communications Information Manager
- Information and Communications Officer

Advocacy Team:

- Head of Open Disclosure
- Members of the Advocacy team on a needs basis

Communications Team:

- Client Services Director
- Senior Comms Manager
- Content Manager
- Content writer
- Communications Manager

Based on the phase of development different skill sets such as user testing, web development and social media management will be used.

The working 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.

Reference Group Membership

Invitations to join the Reference Group are currently with a number of national and international experts, drawn from the relevant fields and ensuring clinical, non-clinical input and patient representation alongside experience in screening programmes, communication, health literacy and behavioural economics.

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2.a	Scally Inquiry recommendations	Current position, issues & challenges	Deadline	Status
	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	The PPI panel meeting took place on 24 th September, 2018. The materials were endorsed by the group, with some minor edits needing to be implemented. The feedback was very positive and the members complimented the enhanced materials. The inclusion of the symptoms in the materials was deemed to be very valuable. The usability testing of the old cervicalcheck.ie website took place on 24 th September. Final edits to the materials, including feedback from the DoH Steering Committee will take place during this week. The migration of the website content is taking place this week. The video storyboard continues to be developed.	31.10.18	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	See above.	31.10.18	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	See above.	31.10.18	In progress
	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	See above.	31.10.18	In progress

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2.a	Scally Inquiry recommendations	Current position, issues & challenges	Deadline	Status
	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			