DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE

JOINT COMMITTEE ON HEALTH

Dé Céadaoin, 3 Aibreán 2019

Wednesday, 3 April 2019

The Joint Committee met at 9 a.m.

MEMBERS PRESENT:

Deputy Stephen Donnelly,	Senator Colm Burke.
Deputy Bernard J. Durkan,	
Deputy Kate O'Connell,	
Deputy Margaret Murphy O'Mahony,	
Deputy Louise O'Reilly,	

In attendance: Deputy Lisa Chambers and Deputy Bríd Smith.

DEPUTY MICHAEL HARTY IN THE CHAIR.

The joint committee met in private session until 9.12 a.m.

CervicalCheck Screening Programme Update: Discussion (Resumed)

Chairman: This morning, the committee is meeting with representatives of the HSE and CervicalCheck to receive an update on the CervicalCheck programme. The committee has expressed a particular interest in hearing about the proposed introduction of HPV testing for cervical screening and in discussing delayed smear reporting.

On behalf of the committee, I welcome Mr. Damien McCallion, national director of screening services, Dr. Colm Henry, chief clinical officer, and Ms Michele Tait, HSE implementation lead for the Scally report, and Dr. Lorraine Doherty, the new clinical director of CervicalCheck.

I draw the attention of witnesses to the fact that by virtue of section 17(2)(*l*) of the Defamation Act 2009, witnesses are protected by absolute privilege in respect of the evidence they give to the joint committee. If, however, they are directed by it to cease giving evidence on a particular matter and continue to do so, they are entitled thereafter only to qualified privilege in respect of their evidence. They are directed that only evidence connected with the subject matter of these proceedings is to be given and asked to respect the parliamentary practice to the effect that, where possible, they should not criticise or make charges against any person or an entity by name or in such a way as to make him, her or it identifiable. I advise witnesses that any opening statements they make to the committee may be published on its website after the meeting. Members are reminded of the long-standing parliamentary practice to the effect that they should not comment on, criticise or make charges against a person outside the House or an official either by name or in such a way as to make him or her identifiable.

I invite Mr. McCallion to make his opening statement.

Mr. Damien McCallion: Good morning Chairman and members of the committee. I thank the committee for the invitation to attend this meeting. I am joined by my colleagues, Dr. Colm Henry, chief clinical officer, HSE, Dr. Lorraine Doherty, clinical director, CervicalCheck, and Ms Michele Tait, implementation lead for the Scally report, HSE.

The HSE remains extremely conscious of women's concerns regarding cervical screening over the past year and, in particular, many women's anxieties due to the delays in reporting on smear test results. The HSE is doing its utmost in order to find solutions to these waiting times and we apologise to the women for these delays and for the upset caused. We continue to address and manage a vast range of issues that have emerged as a result of the crisis in the CervicalCheck programme last April. Our priority areas include stabilising and strengthening our cervical screening programme; continuing to support women and families who were directly impacted by the CervicalCheck crisis; implementing Dr. Scally's recommendations; strengthening governance arrangements; enhancing the quality assurance of the programme and advancing the implementation of HPV primary screening. This report, previously circulated to the committee, updates on these key areas of priority.

In the area of supports to women and families, our information line continues to provide information to women who are understandably anxious at delays in accessing their results. We also support women and their families in the provision of access to their records and ensuring women get their slides from laboratories where required for legal review. The client services

unit in our national screening service continues to support this process and, to date, 118 out of 125 slide requests have been dealt with, on average, within 27.5 days while seven requests are currently work in progress.

We continue to support the women impacted through the 221+ group through our community liaison officers. The community liaison officers support women and their families in provision of the support packages provided to government. We are also developing a public and patient inclusion plan for our screening services. We have established a patient panel for cervical screening that has already provided critical input into aspects such as communication and Dr. Scally's recommendations. We have also brought patient representatives on to a number of key project groups within our screening services. We are very grateful to the many patient representatives who voluntarily give up their time to support our screening programmes. We have made a start in this area and remain committed to bringing patients to the centre of our screening programmes.

We are continuing to support the independent international expert panel review being undertaken by the Royal College of Obstetrics and Gynaecology, RCOG, which was established by the Minister for Health, for women who were diagnosed with cervical cancer. The HSE supported the consent process, established a national helpdesk, developed an eligible dataset with the National Cancer Registry and implemented a client management system to support the RCOG. In recent weeks the laboratories have commenced the transfer of slides and the RCOG estimates that it will take six months for the process to conclude.

On programme turnaround times, in 2018 around 370,000 women presented to the programme, an increase from 280,000 in 2017, or approximately 90,000 in total. We remain concerned at the length of time being taken for reporting of cervical smears. Over half of samples received are being processed within 15 weeks, although it can take up to 33 weeks for the report to be provided. There is currently a backlog of some 79,500 slides.

We have worked with existing private providers, other private providers and public service providers in other countries to try to grow our laboratory capacity. Some of our existing providers have managed to reduce the wait times and we continue to work with others to try to find additional capacity. While we continue to pursue active leads, this has proved very challenging due to the global shortage in cytology. This has been caused by a reduced cytology requirement as countries implement HPV primary screening, which sees a reduction of approximately 80% for cytology requirements. We are actively trying to identify possible solutions that will help reduce the wait times which we know are causing a lot of anxiety for women. While this is very undesirable, our clinical advice is that this poses a very low risk to women. Notwithstanding this, we recognise that these delays are extremely difficult for women and we are making every effort to improve this situation. We have made significant improvements in the turnaround times with two of our three laboratories and are working closely on an improvement plan with the third laboratory. We are absolutely focused on reducing waiting times for results as quickly as possible.

A key risk to enable cervical screening to continue in Ireland was the extension of the laboratory contracts. The HSE signed agreements with both providers to enable continuity of the programme. The HSE also made a decision to expand the public laboratory capacity and an agreement was reached with the Coombe Women and Infants University Hospital to do so. This will provide a better balance between public and private laboratory capacity provision.

An initial capital allocation was made to develop a national cervical screening laboratory

at the Coombe. A project steering group and project team are now in place with building and workforce plans being developed. While we are planning for a rapid building programme through a modular development, it will still take a number of years to implement, primarily due to the workforce challenges.

We are progressing plans to introduce HPV primary screening. A project team is in place and is progressing the seven work streams involved in the project. We have completed a review of international HPV primary screening implementations. The review informs us that our critical path will be the availability of a provider and the timescales to implement the ICT systems to support HPV primary screening. Furthermore, ICT testing is under way, development of education and training materials has commenced and our procurement team has started the tender process for laboratory services with a pre-tender market engagement session held before Christmas.

A contract notice is about to issue, which will seek formal bids from laboratory service providers. Our market engagement has identified significant challenges and concerns in the provider community that we are addressing as we move into the tendering process, to ensure that we are successful in acquiring a laboratory service provider. We remain committed to implementing HPV primary screening as soon as possible, with the critical path to be determined by the tender process that is under way.

The HSE has contributed significantly to the development of an implementation plan, in collaboration with other State agencies, in response to the Scally review recommendations. We have appointed a senior manager, Ms Tait, to oversee the implementation and established a HSE implementation oversight group, jointly chaired by our chief clinical officer and deputy director general of operations. We have now developed a set of 101 actions arising from recommendations that are the responsibility of the HSE to implement and we are reviewing appropriate actions against each recommendation as the implementation progresses. Examples of progress to date include key appointments and governance changes. An organisational review of risk management structures has also been commissioned by the HSE in addition to the establishment of an expert group within the national screening service to review clinical audit processes across all screening programmes.

An interim revision of the HSE open disclosure policy has been completed and approved by the HSE directorate and the process of communicating this and ensuring its implementation throughout the system will commence in the coming weeks pending a more detailed review in late 2019. The HSE has also reviewed and updated its national financial regulations policy on procurement documentation. All six recommendations from Dr. Scally's interim report have now been fully implemented, resulting in significant improvements in the information and supports provided to women and other service users on our cervical screening programme. The HSE has maintained open communication with patient representatives on the implementation plan and will continue to work collaboratively with them throughout 2019.

We have continued to strengthen the governance and management of our screening services. We have established an interim management team in the national screening service, with the reassignment of senior people to key positions while we fill these positions on a permanent basis. We recently appointed a director of public health and CervicalCheck clinical director, Dr. Doherty, and a CervicalCheck laboratory quality assurance lead. In addition, a risk committee for our screening services, which is independently chaired, was put in place in the third quarter of 2018. An interim quality and risk manager was also appointed in the third quarter of 2018 and implementation of Dr. Scally's recommendations on strengthening our quality assurance

processes has commenced. We have also identified a number of priority positions for implementation, which are currently going through the approval process.

I assure members that the HSE is absolutely focused on stabilising the cervical screening programme to enable us to progress the introduction of a new enhanced HPV primary screening testing methodology. All possible resources are being directed at this challenge.

Following the recent untimely death of Laura Brennan, I want to take this opportunity to acknowledge Laura's work in promoting the HPV vaccine and the importance of cervical screening in the most difficult of personal circumstances. I had the privilege of meeting her and I know that she was an inspiration to us all through her dedication, bravery and humour. We all have a responsibility to take up her crusade to eliminate cervical cancer in Ireland. Our thoughts are with her family and friends at this most difficult time.

This concludes my opening statement and, together with my colleagues, we will endeavour to answer any questions committee members may have.

Chairman: I propose that committee members have ten minutes each for questions and answers and non-committee members have five minutes each. Everyone will get an opportunity to speak.

Deputy Stephen Donnelly: I thank the witnesses for their time and their detailed submission. I know they are all working very hard on trying to clear up some of the damage being done to what appears to have been one of the most successful screening programmes of its kind anywhere in the world. I will start with accountability and move into some of the waiting times and what is being done. I would also like to look at the waiting times for colposcopy. While there has been a lot of focus on the number of women waiting for test results and the amount of time they are waiting, there has not been as much focus on women waiting for access to colposcopy because these referrals have also increased. Approximately 80,000 women are waiting for test results. Some have been waiting for more than eight months. Waiting times for referral for colposcopy have also increased. The HPV test, which was due to launch last September, appears to have been delayed indefinitely. We do not have dates. "As soon as possible" is the language being used. We know this is largely due to the offer of the free out of cycle test because there were 90,000 additional tests that overloaded the system.

We know that on Wednesday, 24 April 2018, the story broke from the steps of the High Court. We know that two days later, in spite of having never met the senior management of CervicalCheck, the Minister said publicly he had no confidence in them. We know this was interpreted by many as there being a problem with the programme itself. We know that at approximately 4 p.m. the following day the Minister tweeted the offer of a free out of cycle smear test. To this day, the Minister maintains that before the offer of the test was made there was no clinical advice not to do so. He has stated this categorically. In response to a parliamentary question three weeks ago, he told me neither he nor his officials received advice that recommended against the tests in advance of the decision. He went further in the Dáil and said that those who persisted in stating he acted against official advice were incorrect and had misled the Dáil. That is a pretty strong position from the Minister.

Yesterday, we received a submission from Dr. Gráinne Flannelly, who was the clinical lead at the time. Dr. Henry is referenced in her submission. What she states directly contradicts the Minister's position. What she states suggests the Minister has misled the Dáil for the second time. He misled the Dáil on the children's hospital and has apologised for doing so.

We now know that at lunchtime on that Saturday, the Department of Health called the national screening service after a meeting attended by Dr. Henry. He is in no way implicated in the advice, he is just referenced as having been there. Dr. Flannelly stated Mr. Charles O'Hanlon, who was running the national screening service, received a call from the Department of Health regarding the offer of the out of cycle test. She goes on to detail she met Mr. O'Hanlon and, in the strongest possible terms, advised against the tests. Not only this, but she predicted what would come to pass. She predicted what we are all dealing with here today. She stated the laboratories would not have sufficient capacity for cytology if the offer was made and that this would lead to longer waiting times. She predicted that the colposcopy service would not have the capacity to deal with the additional referrals and this has come to pass. She also stated that most importantly it would fundamentally undermine the screening programme, which is exactly what this ill-advised offer did. Critically, she states Mr. O'Hanlon called the Department of Health back within the hour, which was before the Minister tweeted his offer, which happened at 4.13 p.m. We have very detailed evidence from Dr. Flannelly stating the Minister and-or his officials at the Department were advised by experts at the national screening service not to proceed and this offer was made before any announcement. We have a timeline to back this up. We also have evidence that the advice predicted the fundamental undermining of the programme, which is exactly what has happened.

At an official level, and I am not asking the witnesses a political question or asking them to peer inside the mind of the Minister, do the witnesses accept that expert clinical advice was given to the Department of Health before the decision was made to offer the free out of cycle smear test?

Mr. Damien McCallion: I will ask my colleague, Dr. Henry, to respond but before I do I will make a general point. With regard to the pressure on the programme, approximately two thirds of the cases are out of cycle smear tests and one third are women who have re-engaged with the programme or new women, and this is positive. Unfortunately, in the circumstances we are in, it has created pressure. This is an important point of context with regard to overall pressure and positioning the out of cycle smears relative to the other impacts that have come on the programme as a result of the crisis. Dr. Henry will comment on the other aspects.

Dr. Colm Henry: I became aware of Dr. Flannelly's advice last night when I received her statement. Like most people I became aware of the announcement of the out-of-hours smear when it was announced publicly. As a doctor, I understand screening and its rationale, the balance between risks and benefits and that the addition of out-of-cycle smears tilts the relative worth or value of the screening programme in one direction more than another. I also recall significant public anxiety at the time. When we set up our phone line around the same time, we were inundated with calls and could not keep up. GPs were inundated with inquiries from women who were anxious about screening. There was a great deal of misinformation and misunderstanding, reflected not only in women's engagements with their GPs and calls to helplines but also in reporting and at the political level. I understand screening and the justification for in-cycle and out-of-cycle smears and what that means. However, when looking back it is reasonable to judge any decisions in the context of the time, that is, the great anxiety that prevailed among women in Ireland and the misinformation and misunderstanding.

Deputy Stephen Donnelly: The context is certainly important. Nonetheless, it is important to be led by clinical and expert advice on these issues. As noted by Dr. Flannelly, overtesting has no medical benefit and can tilt into harm. Is that fair?

Dr. Colm Henry: I recently visited Public Health England. That agency asks questions

about British screening programmes and new proposed screening programmes. When subjecting a healthy population to a test, the fundamental question is always whether it will do more good than harm. All screening programmes which involve populations, as opposed to people who are unwell, involve that balance between creating value, reducing harm and avoiding inflicting harm. The balance of interest is calculated-----

Deputy Stephen Donnelly: I appreciate that. This may be a question for Dr. Doherty as the clinical lead. Is there a medical benefit to offering the out-of-cycle test?

Dr. Lorraine Doherty: I thank the Deputy for his question. As he knows I have recently arrived in the CervicalCheck service. I was not involved in the decision-making on this at the time. Nevertheless, at the time we were dealing with a very difficult situation concerning confidence in the programme and anxiety among the population of women in Ireland, who were concerned about the result of their cervical smear and what that might mean for them. When one is working in a crisis situation one often has to take decisions that one would not take in the cold light of day-----

Deputy Stephen Donnelly: I understand the political context. I am asking a medical question of the clinical lead. Is there a medical benefit to a shorter interval?

Dr. Lorraine Doherty: The medical benefit can include a range of benefits, including psychological benefit. Where stress or distress is caused to a patient by a perceived lack of intervention it behoves medical practitioners to decide what is the most appropriate intervention to undertake. In this scenario the decision to offer women the opportunity to avail of a free smear was taken collectively by the Government. This was particularly important for women who were anxious and could not afford to pay for an additional smear. A decision was taken at a point in time that the service was in crisis. Ordinarily we would not advise women to have out-of-cycle smears unless there was a good reason to do so.

Deputy Stephen Donnelly: I thank Dr. Doherty. As the national director of services, does Mr. McCallion accept, given the submission we now have, that the decision to offer the out-of-cycle test was taken contrary to clinical advice provided by the national screening service?

Mr. Damien McCallion: As the Deputy said, I was not there at the time. We only had sight of the submission the Deputy refers to late last night. I do not have a copy here. I think it was tweeted somewhere. Dr. Henry and Dr. Doherty have set out the programme's perspective. We are not focusing on the timing. To be blunt, my focus is on restoring the programme's credibility, finding capacity to deal with the backlog and resolving the many issues in front of us.

Deputy Stephen Donnelly: I thank Mr. McCallion. I have a final question on colposcopy. A lot of data have been provided about women waiting to hear their test results. What are the waiting times and how many are waiting who have been referred for colposcopy as part of the care pathway of the screening service, as opposed to for other reasons?

Mr. Damien McCallion: I will make a general comment and I will ask Dr. Doherty to speak on more specific details. She met with the colposcopists as recently as yesterday. In broad terms, colposcopy services are under pressure. The turnaround times achieved are still good. That is because extra sessions were provided for in anticipation of needs arising from human papillomavirus, HPV, screening. That is not to say the service is not under very significant pressure. It has seen a significant increase in referrals from GPs. Women are anxious and are going to general practice, which has led to an increase. During our previous appearance before

the committee, Dr. McKenna discussed some of the solutions we are considering. I will ask Dr. Doherty to speak about that based on her experience yesterday.

Dr. Lorraine Doherty: I thank the Deputy for the question. I had a meeting with the colposcopy community yesterday, which was the first time I have met with them since I took up the post. I heard from my colleagues about their commitment to delivering a first-class service to the women of Ireland. However, they are under pressure from the increased number of referrals to the programme from primary care and elsewhere. I have seen from the data that colleagues have worked to increase the number of clinics available in most of the centres across Ireland, particularly those that generally have many patients referred for colposcopy. In some cases they have doubled the number of sessions or added at least one or two sessions a week. The data show that waiting times are not abnormally high at the moment. We need to look at how we are going to support this going forward. The additional capacity is being delivered in the context of goodwill and support for delivering this programme within hospitals. We need to continue to support our colleagues in delivering that service.

Deputy Stephen Donnelly: If I understand Dr. Doherty correctly, the waiting times to see a colposcopist have not increased in the past year. Is that correct?

Dr. Lorraine Doherty: The target calls for 90% of women to be seen within four weeks of referral. The data show that the majority of centres achieve numbers like 100% or 86%. There is a reasonably good rate of achievement of that target. The percentage seen after 12 weeks is much higher. In terms of performance, the service is sustaining quite intense pressure but nevertheless seems to be coping reasonably well for now.

Mr. Damien McCallion: I would like to add a point that is quite important for Deputy Donnelly and others. Notwithstanding that, as Dr. Doherty said, there is significant pressure on the service. There is a lot of work to be done with GPs. As Dr. McKenna said during our previous appearance, gynaecological and other services and the model of working must also be examined. Moreover, we have commissioned impact assessments through Dr. McKenna, who is the clinical director of the national women and infants health programme, to prepare ourselves for HPV screening. That will result in a spike in colposcopy referrals on a phased basis over several years. That will involve visiting each unit, looking at the short-term and long-term issues and identifying the resources needed to address them. In particular, this will include re-engineering some of the pathways for patients for GPs. That process is fairly well advanced. That team has now visited approximately 75% of the units and will provide a set of recommendations on how we can strengthen that service.

Deputy Louise O'Reilly: I thank all our witnesses. I join Mr. McCallion in expressing sympathy to the family and friends of Ms Laura Brennan. She did absolutely fantastic campaigning work at a time in her life most of us would not have been at all able to do so. She took on the mantle and will always be remembered for the great work she did.

I am struggling with this. I wish to discuss the pathway of communication between the HSE and the Department of Health. I fully appreciate that the witnesses only saw this announcement last night, as did we. It is very clear that advice was given which should have made its way to the Minister. Despite that, at a meeting of this committee on 13 February, Mr. Breslin was happy to confirm that the advice did not get to the Minister. The Tánaiste doubled down on that the very next day. My question is directed at Mr. McCallion. When clinical advice of the nature communicated by Dr. Flannelly makes its way from the HSE to the Department of Health, is there an expectation that action will be taken? According to her submission, she

strongly advised against it. Incidentally, it turns out that she was right about all the things we are discussing here, such as that GPs were not organised, laboratories would not have capacity, the colposcopy services would not have capacity and, worryingly, that it would fundamentally undermine the screening programme. That advice came from senior people in the HSE to the Department. When communicating advice of that nature, can Mr. McCallion outline how he ensures it gets to the right person? It clearly did not on this occasion, or it did and we were misled. I need to understand that.

Mr. Damien McCallion: The challenge for us is that we cannot account for what happened at that time in detail. The detail of that issue is probably one the Department can clarify. What we can talk about is, broadly speaking, what has brought the pressure into the programme in terms of both the out-of-cycle testing and those women who have re-engaged-----

Deputy Louise O'Reilly: It is very clear that what brought the pressure into the programme was the tweet from the Minister, notwithstanding the fact that no homework was done and no effort was made to address any of these concerns, that all women were offered an out-of-cycle test to reassure them. Clearly, he was acting against advice given to people in his Department. As the senior person in the HSE, what does Mr. McCallion understand happens to advice given by the HSE to the Department of Health? If nobody in the Department of Health is listening or the advice is being ignored, there is a serious issue.

Mr. Damien McCallion: It is difficult for me in this instance. First, we were not there at the time. In general terms, it depends on the circumstances of that advice. If it is on policy matters, they are matters for the Department. If it is on operational matters, they are matters for the HSE. We offer advice and we have dialogue with the Department across many settings, both formally and informally. The Department will always consider that advice. As I said, it depends on the context of whether it is an operational matter or a policy matter. All I am flagging in this case is that Dr. Flannelly sent in her submission and set out her understanding at that time. We have set out how we saw the decision at the time and the context for it, but we were not aware of how that dialogue happened from there. The Department has set that out to the committee previously. It is not something we can clarify here today.

Deputy Louise O'Reilly: Mr. McCallion would not have a view about that advice being ignored.

Mr. Damien McCallion: No. We have set out the context in terms of-----

Deputy Louise O'Reilly: We all understand the context but now we are dealing with a massive backlog. Women are waiting because of a decision that was taken to offer repeat smear tests without doing any homework whatsoever. We now find that, contrary to what the Minister said, advice was given. I am trying to understand how that advice would make its way from the HSE to the Department of Health. Mr. McCallion is saying there are effective lines of communication but I am saying that they are not working.

Mr. Damien McCallion: Again, we saw this last night with Dr. Flannelly's note. In general, where advice is given the decision-making rests on whether it is a policy matter or a matter for ourselves. We are trying to focus on solving the issues we have with the backlog and the capacity. Generally, we have a great deal of dialogue with the Department on all sorts of issues daily, and the decision making rests in terms of either policy or operational matters. Obviously, Dr. Flannelly set out her understanding of it at that time. I cannot comment on that with regard to the sequence or timing, as I was not there. As Deputy Donnelly said, there have been re-

sponses already from the Department about how that operated so I am not in a position to give the specifics of that.

Deputy Louise O'Reilly: Would Mr. McCallion be happy that the advice given in the submission was relayed to the Department in any event? Dr. Flannelly clearly says that Mr. O'Hanlon relayed it. Would Mr. McCallion be happy that the advice made its way there?

Mr. Damien McCallion: I cannot confirm it. I was not there. I will obviously take Dr. Flannelly at her word on it but I cannot comment on it as we were not there at the time.

Deputy Louise O'Reilly: Okay. What is the current backlog rate? Can Mr. McCallion provide us with information on the difference in wait times for those who are paying for it privately and public patients?

Mr. Damien McCallion: The backlog is often quantified in total slides, which is approximately 79,000 or close to 80,000. We always have approximately 20,000 slides that are working through the system if things are on an even keel. In some ways the critical determination is the turnaround times for women to get their results, what is known as the TAT. We have made significant improvements with two of the laboratories, in the Coombe and Quest Diagnostics. They are now down to three weeks and seven weeks, respectively. That can vary a little week to week-----

Deputy Louise O'Reilly: Three for the Coombe and seven for Quest Diagnostics.

Mr. Damien McCallion: Yes. They can vary a little week to week based on demand or because the system is so sensitive at present that if one or two staff are on leave that can affect it. We have got additional resources into those laboratories and we are working on a solution with the third laboratory, MedLab Pathology, which is up at 33 weeks. Clearly, that is a major concern and it has deteriorated. Notwithstanding that the clinical advice on this is that it still presents a low risk, as I mentioned in my opening statement, from the experience of this crisis this is very worrying for women. We see it coming through on our information line. I met the staff who work on the information line last Thursday and, understandably, there is a great deal of anxiety about it.

Our focus is on trying to put in place some of the solutions we have identified over the last number of months to get capacity. I mentioned in the opening statement that we have had to trawl the world, from Australia to America to Europe, to try to find capacity. We also have to take that on in a way, given the experience from Dr. Scally's report, that we go through a full quality assurance process for any laboratory that we connect into the system. We are also developing a public laboratory at the Coombe. There is a commitment to that and we received funding this year to do it. We have set up a couple of project teams. One is to build the laboratory - there is a construction project involved - and one is to staff it.

We have limited medical manpower in cytopathology in this country, which is an issue for us. We must grow the medical workforce and the screening workforce. Getting screeners is very difficult when a country moves to HPV primary screening. The UK is under massive pressure with backlogs as well. Part of the reason in the UK is that as it switches laboratories over and consolidates from the old testing model to the new one, the requirement for cytology reduces so people who have made careers in that are leaving. That presents challenges. We are trying to pick up some of those people from the UK and to come up with all sorts of propositions to get them to come and work here, even temporarily, to help alleviate and reduce

the time. At present, we are in the middle of quite complex negotiations which I do not wish to compromise. Some of them are going on as we speak today and were taking place over the last week or two to nail this down, but I am more optimistic than I would have been when we were last before the committee about getting extra capacity on board that will help to address it.

In the longer term, our aim would be to rebalance the current model where we have approximately 9% in the public system and 81% in the private system. The commitment to build the laboratory at the Coombe will help that, but it will take time. In the short term we must avail of capacity in other jurisdictions to help get us out of the problem we are in at present and to ensure women get the results.

Deputy Louise O'Reilly: However, if one pays privately one can get it turned around in three weeks, but if one is a public patient one can wait up to 33 weeks. It is very worrying that the capacity seems to exist for those who have the money. With regard to the extensive efforts being made to source capacity overseas, Mr. McCallion referred to quality assurance. Does that involve on-site visits?

Mr. Damien McCallion: It does. In one of the laboratories where we have a number of prospective laboratories, we have a team assembled. Dr. Doherty can perhaps speak about the quality assurance process which follows on from Dr. Scally's report. We have tried to strengthen the quality assurance. A number of steps have been taken and I will ask Dr. Doherty to speak on those.

Dr. Lorraine Doherty: Since I took up the post I have been looking at the governance arrangements within the service, which includes the quality standards for aspects of the programme. The first priority was to look at the laboratory quality assurance, QA, standards to ensure they were fit for purpose. We have undertaken a complete review of those. Alongside that, we have planned for on-site visits to laboratories that will be providing this service to Ireland and the programme-----

Deputy Louise O'Reilly: I am sorry to interrupt, but will those on-site visits take place before or after the contracts are signed?

Dr. Lorraine Doherty: There are on-site visits to start now with the laboratories currently working with us. They are to start next week, when a team of us will visit some of those laboratories.

Deputy Louise O'Reilly: I am talking about the additional capacity. We can go back over the-----

Dr. Lorraine Doherty: I am sorry. I misunderstood the question.

Deputy Louise O'Reilly: Will the contracts be signed first and then the QA will happen, as is clearly happening with the on-site visits at present because these people are under contract? My question was in reference to the efforts to source additional capacity. Mr. McCallion referred to the ongoing negotiations. Will there be an on-site visit before contracts are signed?

Dr. Lorraine Doherty: My understanding is the contracts have not been signed yet and the on-site visits are starting on Monday.

Mr. Damien McCallion: The intention is that the quality assurance visits will be completed before we start to move on the final contract. The contract will be subject to quality assurance

and we will be able to address that in a number of legal ways. We want to tie down capacity but we will not do that unless the quality assurance is in place.

Deputy Louise O'Reilly: This scandal is evolving and there is a drip feed of information to the media. We now know that samples are expiring and that patients will have to be recalled, in connection to which 1,000 women received letters recently. Does Mr. McCallion anticipate that there will be more recalls of that nature or is he on top of the situation?

Mr. Damien McCallion: I think what the Deputy is referring to is misinformation. There is always a percentage of samples that will, for a variety of reasons, expire. We monitor this very closely. There was an issue in October or November last year but it was addressed with the laboratories. The rate is within the norms we have always had. This was old information that might have been misrepresented over the past number of days. There has been no change from the normal screening programme.

Deputy Louise O'Reilly: Given the size of the backlog, the numbers are going to be high.

Mr. Damien McCallion: It is still a very small number as a proportion of the total within the programme.

Deputy Louise O'Reilly: Can Mr. McCallion give me an idea of the number?

Mr. Damien McCallion: Expired samples and vials would be between 40 and 50 in a typical month and, over a year, there would be between 500 and 600. We had a spike for a period but that was addressed with the labs.

Senator Colm Burke: I wish Dr. Doherty every success in her new role. Last year, the credibility of the people in charge of CervicalCheck changed overnight. In many cases it arose because of a misunderstanding of information. It is a very serious issue and it is important to ensure that the correct information about the programme is given at all times. Can Dr. Doherty envisage a controversy like this arising again? Continuous information was not being given out by CervicalCheck over the years and the information was kept very low-key. Is there a plan to make sure all relevant information is made available to the media on an ongoing basis? Will Dr. Doherty ensure there is no misinterpretation of information as it becomes available?

Dr. Lorraine Doherty: I will answer the question about communication in the context of public information and professional information. My background is in the NHS and whenever I have had to deal with a loss of confidence or another crisis in a service, communications have always been one of the learning elements that need to be addressed. It is fundamentally important that we get this right.

As I have only recently joined the service, I have not been involved in the most recent update of our public and patient information, which is very impressive and can be seen on our website. Ms Tait will speak about this a bit more in a few minutes. Communication is fundamentally important to the programme. Everything needs to be open and the professional communication needs to be well informed and well developed with professionals. A programme of work is ongoing to enhance the communication arrangements within the service for members of the public, patients and the health professionals involved in the programme. We are working on redeveloping the information for health professionals in the context of the move to HPV primary screening and we are developing new educational resources for health professionals. We are also establishing new lines of communication with our consultant colleagues, whom I met yesterday, to ensure they are kept fully up to date with guidelines and information on the

programme.

Ms Tait will speak about the new information being made available to the public.

Senator Colm Burke: I wish to go back to one issue. Over a 48-hour or 72-hour period, the credibility of the whole CervicalCheck programme changed. Is Dr. Doherty satisfied that the structure that is now in place will prevent such a situation arising again?

Dr. Lorraine Doherty: Yes. I am satisfied. We have put in place enhanced governance arrangements and enhanced staffing around all aspects of the programme. Communication has been a strong focus within the service since I arrived and there is a communications working group which works with us on all aspects of our programme. We pay good attention to the communication aspects of our programme and we are working very hard to ensure we never have a crisis of confidence in the service again.

Ms Michele Tait: Dr. Scally made a number of recommendations across lots of areas. Since the report was published last year, the HSE has made significant changes in the information it gives to women and service users of CervicalCheck. The information is unrecognisable from the information we used to give people. This was done in consultation with patients at every step of the way since last September. There have been almost 200,000 visits to the website since we brought in the changes, all on foot of Dr. Scally's recommendations which have relevance across information, governance, quality assurance, etc. A huge body of work has already been done on the information we give to the public and we have also worked hard to improve the information we share with clinical colleagues. All Dr. Scally's recommendations are being fully implemented by the HSE.

Mr. Damien McCallion: This was a crisis of the most significant proportions and there is a lot of learning to be had by the system as a whole. We have tried to see how it may apply to other settings too. There remain significant challenges and we need to address the backlog because communication is important to a woman who has been waiting for a long time and wants to know when she will see her results. We still have work to do. Many of the ingredients have been put in place but I cannot say we can give clarity to all the people who are waiting as of yet and this is because we have yet to nail down the question of capacity. People want certainty and they want specific things. We have a long way to go to get the service on to a stable footing. Screening is a process involving the GP, the laboratory, colposcopy and treatment.

We feel we have learned a lot from patients and the many patient advocates who have stepped up have brought about huge change. Patients are at the centre of this and, as we have brought patients into the various aspects of the programme and its structures, it has brought about a unique change in how we approach our work.

Senator Colm Burke: When is the report of the Royal College of Obstetricians and Gynaecologists expected? At what stage will we be able to get 80% of the analysis done by laboratories in Ireland? I understand the figure is at less than 50% at the moment. My final question is on the recruitment of lead clinicians. As Mr. McCallion is aware, the recruitment of consultants presents a big challenge for the HSE. There are more than 500 consultant vacancies. I presume this is an area that also will be affected. I have raised the issue of long-term planning. For instance, we need to consider how many lead clinicians in this area will retire within the next five years and whether we are planning to make sure we have replacements for those lead clinicians. One aspect concerning the HSE I find frustrating is that jobs are advertised after the person in the post has retired and a locum can be filling in for anything up to two years before a new lead

clinician appointed. How much forward planning is being done in that area?

Mr. Damien McCallion: I will pick up on the Senator's first few questions and I will ask Dr. Henry to comment on the workforce planning from the medical side. On the report of the Royal College of Obstetricians and Gynaecologists, RCOG, the Senator will appreciate it is an independent review.

Senator Colm Burke: Absolutely.

Mr. Damien McCallion: Our role is simply to facilitate it and that still involves a substantial amount of work. We have a large team providing support through the consent process, the call centre and so on. My understanding is that its aim is still to finish within the six-month target. Regarding the slides, I think more than 60% have now moved to the RCOG in Bristol in the UK. With respect to further slides, they are all scheduled to move to completion within a matter of three to four weeks, and the RCOG is in that process. We have weekly calls with the RCOG. We are trying to plan ahead for the end point when it finishes its work because there will be a disclosure process and a process to feed back the report's findings at the end, which the HSE will have to support as well, and we have commenced that.

We made a commitment to develop the public laboratory at the Coombe Hospital, and we are grateful to the hospital and its board for working with us on that. The Coombe undertakes about 9% of the programme's work. There is a significant development task in terms of staffing to develop medical consultants who have the specialties that we need. There are 1.5 whole-time equivalents in the system and we need to build resilience into the system around that. The Coombe has been very supportive of the programme and has provided a great deal of advice and support to us on how to deal with many of the issues we face in it.

The other element is the infrastructure. We have made an initial allocation of funding for the development of a national cervical screening laboratory and we are going through the design process. While I do not have a detailed plan, we are using the fast-track modular build model to get there as quickly as we can and, hence, as I said in my opening statement, between the workforce side and the capital side I anticipate it will take us certainly up to two years to get there. The implication of that with respect to our HPV primary screening is that we will need to run a tender to ensure we get a partner to work with us both to maintain the programme as it is today and to deliver HPV primary screening as quickly as possible. My colleague, Dr. Doherty, can speak to that if Senator would like.

Senator Colm Burke: What percentage of the work will be done in the laboratories in Ireland?

Mr. Damien McCallion: We reckon within two years we could get it up to about 50% in terms of the work that is needed from the workforce side, the building side and the equipping side and so on, and that is taking a very aggressive approach. This is not simply a plug in and play model.

Senator Colm Burke: I accept that.

Mr. Damien McCallion: It is a challenge to get consultants who might want to work in this area. We have to examine merging specialties and we are looking at that with our medical manpower people to see how we could design that. The Royal College of Physicians of Ireland, RCPI, has been working very closely with us on all of this also. There is a major commitment by everyone to try to improve that. We need to be conscious that we need those partners to work

with us over the next number of years and beyond. In most countries the model used tries to have more than one laboratory to ensure there is some resilience in the service in the event of another crisis of any sort arising. To illustrate the point, people may remember the tragic death of a lady in the UK, Jade Goody, which caused a major spike in people coming forward for screening and the programme there ran into all sort of problems at the time, although nowhere near the circumstances we are in today. We need to have capacity to be able to increase the programme as required and to have the resources available.

Senator Colm Burke: For clarification purposes, what percentage of the laboratory work is being done in Ireland now?

Mr. Damien McCallion: The Coombe does 9% or, say, 10%, and 45% is done both in Quest and MedLab. That is the breakdown. I will ask one of my colleagues if they want to speak on the issue of HPV screening. Dr. Lorraine Doherty might want to touch on that.

Dr. Lorraine Doherty: As the Senator will note, the strategic intent for the programme is to move towards HPV primary screening, and we have established an active planning process for that. We have an overarching HPV steering group, a HPV project group and a clinical advisory group. We have also undertaken a programme of visits to other centres which have introduced HPV primary screening to learn from them the key things we need to consider within the planning and implementation phrases. We have established a number of work streams around laboratory issues, communication issues for patients and professionals, training and education for professionals, clinical pathways, colposcopy impact assessment and our IT system. All of those are factors within the work programme that need to be addressed.

What is critical to taking this forward is addressing the backlog to make sure that we have capacity to take forward this new part of the screening programme and to ensure we have a contract in place with a provider to provide this service. My colleagues have been working on developing the tender arrangements for a provider for HPV primary screening. There is a great deal of work to be done, but I must stress we must have stability within the programme before we can start moving to a completely new mode of screening. That is essential. We must make sure that those who will be called for screening are fully aware of what HPV primary screening means and that they receive all that information before the screening programme starts. Very importantly, we need to make sure that those who will be responsible for delivering the programme, that is, the smear takers, the GPs and the practice nurses, are fully supported with professional information and training. As the Senator will note from what I have described, a considerable body of work is to be undertaken to reach the end point at which we deliver this programme.

Chairman: The witnesses might deal with one further question and then I will move on.

Mr. Damien McCallion: Regarding the medical point concerning the development of medical leads-----

Senator Colm Burke: That is a concern I have as quite a number of clinicians are due to retire within the next five years.

Dr. Colm Henry: We face a problem not only with putting consultants in obstetric and gynaecology posts but also with putting them in across disciplines, particularly in model 3 hospitals and the mental health area, and model 3 hospitals have mostly unscheduled disciplines. Some of this relates clearly to changing conditions for consultants but also fewer trainees want to

work in smaller model 3 hospitals, in single-handed departments or small departments. Most trainees want to work in larger departments - we have surveys that confirm this - in urban centres where they can do more complex work.

Our approach to this, not just in obstetrics and gynaecology and colposcopy, is to consider it from a hospital group perspective in terms of how we can create a hospital group by departments. That, however, asks bigger questions of us as to the sustainability of providing so many unscheduled services in 27 unscheduled care hospitals. Clearly, these are questions we will have to address as part of manpower planning because these jobs simply are not as attractive as they used to be.

Senator Colm Burke: Quite a number of clinicians are due to retire in that area over the next five years.

Dr. Colm Henry: That is correct, both here and in other disciplines. It is not an issue that is confined to colposcopy. In some model 3 hospitals over 50% of the consultants are between 55 and 65 years of age.

Mr. Damien McCallion: To give the Deputy some reassurance, the impact assessment process on colposcopy, to which Dr. Doherty referred, is looking at the wider issues, not just the immediate crisis but also HPV screening and beyond. The question is how we can create a sustainable service. That does not mean there are magic answers but at least we can examine that and try to plan around it as best we can in the coming years. I think that is what the Deputy was referring to in terms of colposcopy.

Senator Colm Burke: I thank Mr. McCallion for that.

Deputy Margaret Murphy O'Mahony: I welcome the witnesses. I wish Dr. Doherty luck in her new role. I hope it all goes very well for her. Most of the questions I wanted to ask have been asked but I was not satisfied with some of the answers so I want to go over some old ground. A few months ago, the Minister sat where the witnesses are sitting now and I asked him the reason he went ahead with the out-of-cycle testing when it was clear it had been recommended that he should not do it. He looked at me and said that that recommendation had not reached him. With what came out last night, I believe it did reach him. He is not here to answer for himself but it is clear that officials in the HSE and in the Department of Health were told not to go ahead or it was recommended that they should not go ahead with it. Do the witnesses believe that advice did or did not reach the Minister?

Mr. Damien McCallion: As I said, we cannot answer that question for the Deputy in the sense that, first, we were not there at the time and, second, that is something the Department can probably address in terms of that issue. All we can do is try to explain the context for it at the time, the break-out in terms of the pressure on the programme, and how the figure of 90,000 splits between out-of-cycle cases and women re-engaging with the programme. The Deputy will appreciate that we are trying to look at how to resolve it going forward. In terms of the retrospective piece, I do not believe we can add any more to that.

Deputy Margaret Murphy O'Mahony: Does Ms Tait believe the smears that resulted from the out of cycle testing are still clogging up the system? If so, is it having an effect on the implementation of Dr. Scally's recommendations?

Ms Michele Tait: Everything is being done in parallel. The implementation of Dr. Scally's report covers many areas across the HSE. Clearly the work that is being undertaken to clear the

backlog is impacting on our ability to progress some of the recommendations in Dr. Scally's report. Everything is being managed in parallel. We have been able to make progress on many of the areas Dr. Scally examined and made recommendations on, despite the current backlog with some of the smear tests. There are many moving parts in all of this and everything is being done simultaneously, with teams of us working on different parts of it. There definitely is an impact but not across the whole of the implementation plan the Deputy will have seen recently. Dr. Scally spoke about the progress the HSE has made so far in delivering the implementation plan. Everything is being done in parallel and there are lots of moving parts in this. In some areas on which we want to move forward, particularly in developing the HPV screening programme, the impact of that, as Dr. Doherty noted, will be that we need to stabilise the programme and have the backlog significantly reduced. When we move to that part of Dr. Scally's plan in terms of what the screening services will look like in the future, that will be dependent on some of the issues that are causing the delays in the system being addressed.

Deputy Margaret Murphy O'Mahony: To tie in with that, what is being done to ensure people continue to have faith in the screening system and continue to be screened?

Ms Michele Tait: As Mr. McCallion stated, we have opened up communications with patients on this from the get-go. As the implementation lead for the Scally report, one of my objectives is to restore public confidence in the screening programmes, particularly in CervicalCheck. We have made great efforts to keep communications open with patients and encourage members of the public to continue to attend for their smear tests. This programme will continue to save lives and it is important that people continue to have confidence in it and attend for their smear tests when they are called. We are doing this work in parallel with everything else that is taking place in the organisation.

Deputy Margaret Murphy O'Mahony: I agree with Ms Tait. I never miss an opportunity to advise people to continue using the programme because, as Ms Tait said, it has saved lives.

Mr. Damien McCallion: Some of those who have been most affected by this crisis have become the greatest advocates for the programme. We spoke about Laura Brennan in a different context earlier. As I said, we still have a challenge to restore confidence and we need to address the backlog. If people are waiting for a long period, that is a challenge for us and we are working to address that. Hopefully, as we get through the backlog, that will also help. It is through some of those actions that confidence will begin to be restored. The numbers remain stable and increased rather than decreased last year. People also re-engaged with the programme, which was positive. That is ultimately where we want to be. HPV primary screening will, we hope, create another opportunity to rebuild confidence. As Dr. Doherty stated, we need to get all of those ingredients right. The professionals are very important as well and we all have great faith in them. General practitioners are probably the most trusted health professionals. We have a lot of work to do. There are 4,500 smear takers and GPs who engage with the programme daily and their confidence has also been impacted. We have to rebuild confidence among this group and among women and their families.

Deputy Margaret Murphy O'Mahony: I am concerned by the news that people who pay can get a smear test result faster. As a woman, I am concerned that women with enough money to pay for a test can have their minds put at ease, whereas those who do not have enough money are expected to wait for their results. How can the HSE stand over that awful system?

Mr. Damien McCallion: The public-private dynamic is a reality of our healthcare system as a whole. However, the number of private tests carried out in the two laboratories that under-

take a small amount of private work is very small. It is not significant in terms of the overall numbers. Having said that, every test is critical for us given the search that we have been doing around the world. We are continuing to make sure that none of the providers undertakes an extra element of that. That is outside our contract with those providers but the number is very small in the context of what we want. Our focus with the current providers is on ensuring that they give us the extra capacity we need to deal with the backlog and ensure we get the programme on to a stable footing.

Deputy Margaret Murphy O'Mahony: Everybody should be dealt with. The current practice is very unfair.

Mr. Damien McCallion: As I said, we are trying to focus on that. We need significant capacity to address this - there is no point in pretending otherwise - and we have been working on that. In recent weeks, we have started to make inroads into that. This has involved engaging with public and private laboratories throughout Europe and in Australia and the United States to try to find people who will work with us and help us to get through this.

Deputy Kate O'Connell: I thank the witnesses for attending. I add my voice to the tributes to Laura Brennan. What was so significant was her age. When people of my age tell teenagers what to do they may not listen but Ms Brennan's age and youth, which were the great tragedy of it all, had such an impact. It is not long ago that a few of us who, like the HSE and CervicalCheck, were battling to get the vaccination rate up had to deal with terrible abuse on social media, as did Laura Brennan. It is great to see how she was able to stand up in the face of such abuse. She saved lives and, to my mind, she saved the HPV programme because, to call a spade a spade, the HPV vaccination rate was heading below 50%, which would have rendered the programme unviable. Ms Brennan saved lives and we should all be forever grateful to her. We should treat a vaccination rate of 70% as a line in the sand. It would be a disservice to Laura Brennan's memory to allow it to fall below 70% again. I would like to see it increase to 95%.

To follow on from Deputy Murphy O'Mahony's comments on fairness, I want to address the issue of the additional free smear out of cycle. My understanding is that there was pressure on GP surgeries at the time because women of means who could afford an additional smear were asking for an additional test. The response was to provide the option of a free smear. I understand from discussions in previous meetings that women did not use a token to get a free smear but a clinical decision was made at the bedside with a GP. Perhaps Dr. Doherty will confirm that it was a clinical decision at the bedside and there were no tokens for a free smear. It is important to point out that not everyone was given a free smear out of cycle.

Dr. Lorraine Doherty: I thank the Deputy for her question. As she is aware, I was not involved in the service at that time. I am not aware of what information GPs were sharing at that time regarding the demand for services. The decision to undertake a cervical smear is between the GP or other doctor and his or her patient. It is a decision that is taken in a clinical consultation context and it is a clinical decision. What informs that decision is between the doctor and the patient and I cannot comment on what individual doctors would discuss with their patients. However, when an intervention such as a cervical smear is offered, the decision as to whether it is appropriate for the patient is taken by the GP and the patient.

Deputy Kate O'Connell: If my figures are correct, the number of women who presented increased from 280,000 in 2017 to 370,000 in 2018, an increase of 90,000 women. The backlog is 79,500 or the guts of 80,000. In that case, is the extra capacity in the system sufficient for only 10,500 additional presentations? According to the opening statement, the backlog is

79,500, which suggests the HSE has found additional capacity for only 10,500 tests.

Mr. Damien McCallion: There are peaks and troughs so unfortunately the numbers get more complex.

Deputy Kate O'Connell: I assume these numbers are true.

Mr. Damien McCallion: I am not doubting the numbers.

Deputy Kate O'Connell: They are taken from the Mr. McCallion's opening statement.

Mr. Damien McCallion: Yes, I would not doubt them. I am simply explaining that there have been peaks where there have been major gaps in capacity. As the figure has grown, we have acquired capacity, some of which is temporary which means we have it for a period. One of the key issues is to get the capacity in quickly. It needs to come through the existing providers so the process of connecting a new laboratory probably takes four or five months. It is not a simple plug and play process when one uses new laboratories, aside from the issues raised earlier on the quality side.

Deputy Kate O'Connell: In Dr. Scally's report we discovered that some of the labs in the US were not ISO accredited but were accredited to the American College. Is the HSE still using labs that do not have the accreditation that was in the contract?

Mr. Damien McCallion: Dr. Scally was satisfied that we could continue to work with Quest, MedLab and the Coombe.

Deputy Kate O'Connell: My understanding is that he wanted clarification on whether they were equal. I still do not have clarification and I do not think this committee has received clarification that the self-granted American standard is the same as what we requested in the contracts.

Mr. Damien McCallion: Dr. Scally was clear from his first report that we could continue to renew the contracts. He had no performance issues with Quest and MedLab. The point about accreditation is subject to his second report which is ongoing. I have maintained close contact with Dr. Scally to ensure that in any additional work or capacity we get from the existing laboratories he is satisfied that there is nothing he is uncovering that would lead to any concern about us doing that.

Deputy Kate O'Connell: He is happy enough for the contracts to be renewed but perhaps not to create new contracts if the accreditation was not equal.

Mr. Damien McCallion: I met with him last week and while he has not completed his second report on the laboratories he did complete his progress report on the implementation of his report. He is still satisfied that we can continue to negotiate with the laboratories to ensure we get additional capacity over and above-----

Deputy Kate O'Connell: Laboratories with what accreditation?

Mr. Damien McCallion: With existing providers.

Deputy Kate O'Connell: With existing accreditation.

Mr. Damien McCallion: Exactly yes.

Deputy Kate O'Connell: Of the extra people, the 90,000 plus who entered the system for smears between 2017 and 2018, what proportion were women engaging with the system for the first time, is a tenth, a third, half?

Mr. Damien McCallion: Around a third is our estimate of that, approximately 26,000 or 27,000.

Deputy Kate O'Connell: In terms of the transition to HPV testing, did somebody say it would take two years to get it up and running and is that from now or then?

Mr. Damien McCallion: I will ask Dr. Doherty to answer that in a moment. The HPV date is one we all want to get to as quickly as possible and finding the critical path for that is why we have been holding off on the date.

Deputy Kate O'Connell: We heard from Dr. Denton, who came in with Dr. Scally, that it could be done within a year. That was six months ago.

Mr. Damien McCallion: I think Dr. Denton's comment was related to the time from start to finish. This is something that is being worked on. We have met many of those in other countries. Circumstances in every country are different.

Deputy Kate O'Connell: Mr. McCallion has talked about trawling the world, does that mean the witnesses are all physically going places?

Mr. Damien McCallion: Thankfully, we have conference calls and the like. People have gone to some places to speak to people, to Holland, France, the UK, Northern Ireland.

Deputy Kate O'Connell: To Australia?

Mr. Damien McCallion: Not to Australia. We did a conference with the Australians and have worked with them in terms of possibilities.

Deputy Kate O'Connell: Australia aims to eradicate cervical cancer in ten years.

Mr. Damien McCallion: It has, and it is more advanced in many ways. It has had screening for a lot longer than we and many other countries have. We work closely with Australia. There are two objectives: to try to find capacity to deal with the backlog and to try to identify laboratories that might work with us on HPV primary screening. There are big challenges when a company looks into Ireland at the moment and we have to make sure we can attract people to work with us. That is a risk we have to manage around this. There is not a normal tendering environment around HPV primary screening. I will ask Dr. Doherty to answer the timeline question.

Dr. Lorraine Doherty: As I have outlined in one of my previous answers there are several steps we have to go through before we can move to HPV primary screening. We have taken evidence from several countries about how they have led the development of their programme. While we have not visited Australia we have been in contact with colleagues there and have done a detailed review of some of the National Health Service, NHS, programmes, in particular the Scottish one.

A variety of approaches have been adopted to taking this forward. In some regions in Australia and New Zealand they stopped or suspended programmes for a while to allow for the introduction of the new programme. The laboratory issues are fundamentally important to having

a recognised service provider and plugging it into our existing call and recall systems and how we generate results. All of that takes time.

The planning and implementation phases take quite a bit of time to put together to ensure they are done in a safe and evidence-driven way to achieve a quality service at the end of that process. It is not a thing to be rushed in a couple of months. Getting a laboratory provider to contract with us is unlikely before later this year. We cannot give a definitive timescale for when this service will be introduced but the Deputy must recognise that we have a very robust work programme going on to move us towards that point.

Deputy Kate O'Connell: Dr. Doherty said the programme is suspended in other jurisdictions. I assume that is to draw a line in the sand in moving from one to the other. I imagine that in the Irish situation because of the complexities in the past two years, we would not want to see any suspension of the programme. We have had enough difficulty I would imagine. I just want to make sure this is not soft selling a suspension of the CervicalCheck programme.

Dr. Lorraine Doherty: If we go back to earlier conversations in this room we spoke about rebuilding confidence in the programme. We want people to know the screening service is available, that they can access it and will be called to screening when it is their turn to be screened. Stopping the programme would be a very difficult decision and not one we would want to take if we were to restore confidence in this programme for women.

Mr. Damien McCallion: Our sole focus, and we have made movement with two of the laboratories on their turnaround times, is to address the third lab so that we can get the programme back to an even keel. That allows us to move on with HPV primary screening. We would love to see it go in this year but whether we can do that will be contingent on the tender process. That will be the critical path, to identify a partner to work with us to get this in place, in as short a time as possible and, to echo Dr. Doherty's point, in a structured sensible safe way. That is our objective.

Deputy Bernard J. Durkan: To follow up on Deputy Murphy O'Mahony's question, who advised the Minister not to go ahead with the review programme?

Mr. Damien McCallion: The context for the discussion came from a document from Dr. Gráinne Flannelly, which we only saw overnight. I am not aware of what happened at the time. I need to be clear that I personally was not around at that stage and to be clear about how that was engaged. I cannot give any more information on the historical context. Our focus is to resolve this in the future and ensure we deal with the backlog.

Deputy Bernard J. Durkan: If senior officials or a body advises the Minister not to proceed in a particular fashion there has to be some reason because presumably the Minister erred on the side of safety to reassure the public, insofar as it can be done, which is a big issue as far as we are concerned because the public asks us questions. People do not always respond kindly if we cannot give adequate answers. It does not really sit well with them if we say we have not been able to get a straight answer to their question. The question of who gave the advice and on what basis remains. We need to be clear about that. It is our job to try to convey to the public that we know to some degree why this happened.

Dr. Colm Henry: Earlier we were asked similar questions. We became aware last night of Dr. Flannelly's written statement and advice. I am taking that at face value. To my knowledge no other advice was sought or given by the HSE apart from the advice Dr. Flannelly states she

gave last night. While we are correctly focusing on the backlog now, at that time there was a lot of public anxiety and it is easy to forget that. Women were very concerned. There was a great deal of misinformation and mischaracterisation of this crisis and there was a danger of a collapse in confidence in the screening programme, which has saved lives over the years. It is not for me to say how a decision was made because I do not know but I remember very well the concern that our phone lines were oversubscribed by people seeking advice and reassurance and general practitioners around the country were facing women who were similarly very concerned. This concern was reflected in the media and at political level, including the Committee of Public Accounts here where we faced questions about a crisis of confidence. It was in that context.

Deputy Bernard J. Durkan: That is not the business of the Committee of Public Accounts; that is the business of this committee.

Dr. Colm Henry: I understand that.

Deputy Bernard J. Durkan: The Committee of Public Accounts has a different function altogether. It reviews expenditure, not public policy. That is not its business at all and I would like to reiterate that.

Dr. Colm Henry: I am merely reflecting the fact that concern was expressed by different agencies or subcommittees and in the media. This reflected huge public concern over the programme. There was a huge volume of misinformation and misunderstanding over what the crisis meant and my understanding is that a decision was made in that context that measures had to be taken to alleviate public concern.

Deputy Bernard J. Durkan: I am not blaming the messenger, but a week or two ago the papers reported that almost 2,500 women were on a waiting list to be tested. Between the crisis first bursting on the scene and this week, how many of the women have been tested? I worry that we go from week to week where there is another announcement that something else has arisen or there is a pending problem and that erodes public confidence in the system. We need to get to the bottom of it. To what extent is capacity a problem? Would the State be better off investing in national capacity rather than subcontracting? Were the Government to invest in national capacity, that would represent a once-off capital expenditure where the other is repeated every day with each person who is tested. Has there been any cost-benefit analysis of that?

Mr. Damien McCallion: A total of 9% of the programme I mentioned earlier is in the public system in the Coombe. We aim to build that up to give greater resilience within the programme. Funding has been allocated on the capital programme to advance the development of a national cervical screening laboratory in the Coombe. We have a steering group in place with the Coombe, a joint group, and a project team and we are working on the designs for that. We are also working on the basis of a fast-track modular build to get it in place as quickly as possible. Equally critical is the need to develop the workforce, as I said earlier. There is a very small workforce for cervical screening cytology or cytopathology here in Ireland.

Deputy Bernard J. Durkan: How short of what is required is the service?

Mr. Damien McCallion: It is significant and the challenge is more in terms of it -----

Deputy Bernard J. Durkan: Is it 20% or 30%?

Mr. Damien McCallion: To illustrate the point on the medical side, there is a number of

roles. There is the logistics of being able to manage all the smears, which is relatively easy to develop, but, on the medical side, there are approximately 1.5 consultants in the public system. We need a number of other consultants but we must look at a model that allows them to operate in other aspects of pathology. One is unlikely to attract people into a role with that specialty on its own. We are looking at how we develop that. The other challenge, which I mentioned earlier, relates to the screeners themselves. Cytology is becoming a much reduced profession. The current model will reduce the requirement for cytoscreeners by approximately 80%. In some UK trusts at the moment, for instance, a significant backlog is emerging where screeners are leaving because of difficulties relating to their future career prospects, and laboratories are being closed. We are trying to capture some of that if we can to help us with our current problems, even in the short term.

Deputy Bernard J. Durkan: Are we capturing it on the basis of a better system or are we capturing the fall-off from the UK's system and applying it here?

Mr. Damien McCallion: No, there are two issues. One is that we are trying to capture some resources over the next period - both laboratories and individuals who are qualified to work in laboratories - to address the backlog. That is crucial. Our current pressure is that in some cases women are waiting excessive periods. That is one of the core issues we want to tackle. We have made some inroads. The times have reduced in the Coombe and Quest Diagnostics laboratories. We have challenges and we are working with our other partner to address those. We have found some solutions but we are trying to work them through in the coming weeks.

Deputy Bernard J. Durkan: From a health and safety perspective, what is an excessive waiting period for the return of results?

Mr. Damien McCallion: Our clinical advice is that the periods we have present a very low risk to women. That is fine but we are conscious that is little comfort to the women awaiting their results if they are sitting at home so our focus is still on trying to address that. Dr. Henry or Dr. Doherty may want to add to that.

Dr. Colm Henry: The main clinical risk is that of anxiety from waiting. Cervical cancer happens to be very slow growing. In many cases, it takes ten to 15 years to develop. My colleague, Dr. McKenna, gave evidence at another hearing and he described the exceedingly low chance, although not negligible, that harm would result as a consequence of the delay and that the intervention would have changed. That is not to take from the distress and anxiety that the delays cause for women.

Deputy Bernard J. Durkan: As the weeks go buy, how successfully has public confidence in the system been restored by way of overhauling the numbers? I acknowledge there is a long-term plan but that could take one, two or three years. Three years is a long time.

Mr. Damien McCallion: One laboratory is back to its pre-crisis turnaround times, the other is making significant inroads and we are working with the third laboratory. We have identified capacity with that third laboratory which we are currently trying to secure contractually, going through the relevant quality assurance steps to bring it on board. A lot of work is ongoing to bring those times down. Ultimately confidence will be restored for women who are waiting when they get their results. That is one aspect of the restoration of confidence. There is a range of other factors in restoring confidence in the programme generally which Dr. Doherty might speak to.

Dr. Lorraine Doherty: On restoring confidence, the clear strategy we have adopted is communicating in an enhanced way with patients. Earlier, we heard about the active engagement with patients who have been affected by this programme and women who are involved with it. We also overhauled all the information provided to the public and to women regarding the programme, some of which my colleague Ms Tait described earlier. There is a new website for CervicalCheck with new information for health professionals and patients. The information sent to patients and women in the screening programme has been enhanced and improved greatly to support women in the programme. We hope all of this will help to rebuild confidence in understanding the screening programme and that the programme is still there to provide a service for women. Ultimately, we are working to address the capacity issues around the laboratory and move towards HPV primary screening all of which will be further confidence-building measures for the programme.

Deputy Bernard J. Durkan: I have raised one issue on numerous occasions. We seem to be bedevilled by waiting lists in this country for almost everything. There is now a waiting list for everything. That should not be the case. As the new applicants come on stream, some of whom are more urgent than others, do they go onto a waiting list? Is it possible to attack the waiting list from both sides and is that happening? Are the new applicants for screening tests and slide tests added to the tail end of the waiting list that is there? If that is how waiting lists are eroded, it will never happen. There will be a ten-year waiting list before we know where we are. We have discussed this previously. Numerous public bodies have this same tendency towards waiting lists and it is a cushion. It does nothing for health and safety, it does not restore confidence in anybody or in the system, and it is not good for the morale of those working in the system because they are also bedevilled by the constant pressure from people who legitimately criticise the existence of waiting lists. Is the waiting list being controlled and is it being eroded from two sides rather than being extended and saying the service is up to speed?

Mr. Damien McCallion: Screening is slightly different in that we are screening a largely well population. A cohort of women who were identified have earlier recalls under the programme. For example, people are referred to colposcopy might have a priority. However, screening is different from, for instance, being on a waiting list for an acute hospital orthopaedic outpatient appointment. Dr. Doherty might comment further on that.

Dr. Lorraine Doherty: I assume the waiting list mentioned is the waiting time for results. All women have equitable access to the screening programme. They will be called in turn when it is their turn to be screened; that has not changed. In one particular laboratory we have a backlog of smears which have not yet been read. Changes were made to the screening programme some years ago where we introduced what is called HPV reflex testing, where some smears were tested with a HPV test. We are also aware, from previous experience in the system, that HPV testing can expire. We have to make sure that does not happen. Within the backlog we are prioritising the smears that are in danger of going out of date and applying the HPV test to them in an effort to manage risk. As was correctly pointed out there is a waiting time, and there is a risk that the smears will be out of date and cannot be read. Where a woman is HPV positive, namely, at higher risk, she is immediately prioritised for her cytology test. That is already in place to manage risk. We have also prioritised women who have having interventions such as colposcopy because they are also deemed to be at higher risk. We have adopted a risk-based approach to managing that backlog. However, we are as anxious as everyone else to find a solution to that backlog, and to put a provider and staff in place to deliver the results in a more timely way. Efforts continue to try to achieve that.

Deputy Kate O'Connell: I have a brief follow-on from that. If a woman in her mid-20s turns up with symptoms, for example bleeding, and a family history, is she prioritised? Those having a colposcopy are prioritised, as Dr. Doherty has outlined to Deputy Durkan, as are those who are HPV positive. Are women who turn up with symptoms also prioritised? For example, if two 30 year old women turn up, one with no symptoms and one with symptoms, does the woman with the symptoms jump the list? Is she prioritised?

Dr. Lorraine Doherty: A woman with symptoms does not have to wait to be called for screening before she can address that issue. If a woman with symptoms like those the Deputy has described presents at a GP surgery it is not appropriate to just take a smear and send it in to the screening programme. That patient requires a referral to a gynaecology clinic for urgent clinical assessment. They are prioritised in terms of addressing their needs given their symptomatic condition.

Deputy Kate O'Connell: They leapfrog the CervicalCheck programme and go to the clinical setting.

Dr. Lorraine Doherty: Those women would not have a smear taken at that time, but would be referred directly to gynaecology for-----

Deputy Kate O'Connell: For colposcopy.

Dr. Lorraine Doherty: Well, the gynaecologist would assess them to see what the most appropriate management programme is.

Deputy Kate O'Connell: What sort of timeframe is involved for that 30 year old symptomatic woman?

Dr. Lorraine Doherty: There is a process for prioritising those referrals on the referral forms. Where a GP indicates that there is a suspicion that a patient has a problem with her cervix it can be written on the form and a particular box can be ticked. Patients are then prioritised to be seen more rapidly in gynaecology clinics.

Deputy Kate O'Connell: What timeframe is involved in that? Is it two weeks, one month or six months?

Dr. Lorraine Doherty: I do not have that information. They are not part of the screening programme, and we do not deal with them.

Deputy Bernard J. Durkan: I am sorry to interrupt. The danger is that the referral is being referred on. The crucial question is how long it takes to deal with the referral. We do not know the answer.

Dr. Colm Henry: This is a very important communication message for us, and I know that the Deputy, among others, has been to the fore in highlighting the difference between a screening programme and a diagnostic programme. Screening is for a population of healthy people who are persuaded to undergo a test that might pick up a problem. When a person has symptoms it is not relevant to the screening programme. We have three cancer screening programmes, namely, breast, bowel and cervical cancer screening, and in each of those people who develop symptoms, whether rectal bleeding or vaginal bleeding, they enter a clinical pathway that brings them to an urgent referral to a relevant clinician and bypasses everything else. Screening would be a distraction from that.

Chairman: Before I bring in our non-members, the first of who will be Deputy Bríd Smith, I want to say that the issues that arose last April were caused by non-disclosure, in particular the non-disclosure of a look-back audit on women who had already been diagnosed with cancer and whose smears were being reviewed. That was the issue at the time, and it still is an issue. At the moment the issue is the backlog on smear results. It is important to say that 65,000 women have been identified through the screening programme as having varying grades of abnormality and who have been treated very successfully by the programme and are walking around today, almost oblivious to the fact that they had a brush with cancer and were treated at a pre-cancerous stage. It is important to point out that 65,000 women benefitted substantially from the programme. A small number of women did not.

As has been outlined, a screening programme is not the same as a diagnostic programme. No screening programme will identify every single cancer. In population health the population benefits, but the individual may not benefit. The majority of individuals do, however.

We are talking about the backlog and the idea of moving towards HPV testing. I gather from our discussion this morning that those topics are interlinked, and until we clear the backlog and stabilise the situation we cannot really move on to HPV testing, which would be a more accurate means of testing. It brings its own challenges, changes and referral pathways, but it is nevertheless a goal we are trying to reach.

In the interests of stabilising the situation, is there a possibility that the cervical screening programme will not be suspended but rather the routine screening will be suspended for a number of months? Those who are in colposcopy would continue to be screened, as per the protocol, and those who are being brought back for smears because of the results of previous smears can continue to have those smears carried out, but those who are on the normal recall system, for every three years or five years, which is the majority of the people coming through the programme at the moment could have their screening suspended for a number of months to allow the backlog to be cleared. That would represent a more rapid solution which could stabilise the situation and allow a movement towards HPV testing, rather than trawling the world for extra laboratory services which do not seem to be available, or developing capacity in the Coombe, which is going to take at least two years because of the need to build a structure and hire staff. By suspending the routine smears for a number of months the situation could be stabilised rapidly and would allow the programme for HPV testing to commence.

Mr. Damien McCallion: We have evaluated that option as part of the option appraisal process on an ongoing basis. We have secured two laboratories which are providing results much more quickly, within three weeks in one instance and seven to eight weeks in the other. We are working with another laboratory in order to reduce its times. It has identified capacity, and we are scheduled to visit it soon, and are hopeful that it will help to address the problem. If we try to change the cycle from three or five years and moving people out it would involve more than a number of months. We would have to move the screening services out for a significant period in order to address the backlog and the throughput, as well as addressing new participants in the programme, who have never been screened before and so are considered high-risk. Some participants would move into the HPV project, because women would then have to be called earlier during the following year, on top of those who would be scheduled for a smear anyway in 2020. I am not dismissing that as an option, but when we evaluated the options our preference was to try to secure capacity. We now have capacity on the table, and our focus now is to see whether we can get it into the system. If we can do that it will help to alleviate the waiting times reasonably quickly. I will not get into the possible timeframes involved today because

we are in the middle of negotiations with a number of the providers around this. It is an option we are considering, and we have set it out and mapped it out in detail, as we have done with all of the other options. As Dr. Doherty said earlier, some programmes did that as a sensible entry into HPV screening in order to give the programme a bit of space so that we could move in in a structured way. Perhaps she could add to that.

Dr. Lorraine Doherty: We will not be taking a decision to stop new entrants to the screening programme. It is important that women who are what I call "screening-naive", who have never been screened before and who are eligible for screening can access a test. We do not know their exact status, but once they are in the programme we have a better idea of how they are doing. As Mr. McCallion said, we need to look at how we are going to address the backlog and capacity issues before we can ever consider taking decisions like those we described.

Chairman: There is no timeline for moving to HPV testing because CervicalCheck cannot do that until it has stabilised the existing system. It could be a number of years, therefore, before we move to HPV testing.

Dr. Lorraine Doherty: What I have described is a programme of work we are undertaking to get us to the point where we could introduce HPV testing, which includes securing a provider for the service. Preferably, we will have addressed the backlog to introduce some stability to the system. As I said, we cannot give the committee a fixed timeline or date for when the HPV primary screening will start, but we anticipate that we would certainly be looking at no longer than early next year to introduce this programme. We must make sure that the steps we take are evidence driven and safe. There is no point in being bounced into rapidly introducing a test without all the other structures that need to be in place around it to ensure the system is safe.

Mr. Damien McCallion: To reassure the Chairman regarding the HPV screening, the critical path is the provision of a provider. At the moment, we are at 9% in the Coombe. This cannot change overnight, as the Chairman described, so we must secure a provider from our tender. That is the critical path. As Dr. Doherty said, our plan is aiming to get that in this year. That would be the target, regardless of whether we can do it this year or early next year. In respect of us trying to set out dates, at the moment given the history of this with dates, we need to be sure of our ground before we publish a date. We can only be in that position when we have gone to the next stage of the tender and are sure we have a provider with which we can work. To illustrate the point, if it is a new provider, there could be quite a lag time for its IT systems to interconnect, so the programme is designed totally around technology. Some providers may be able to connect very quickly while others may have an extensive period to connect. We will not know that until we secure a provider. As I said earlier, securing a provider in this context is quite challenging for a variety of reasons. A very small market of providers provide this type of capacity into Europe.

Chairman: Front-line staff, not only GPs but also staff manning the phone lines, are under extreme pressure regarding the phone calls they receive from women due to complete frustration with not getting their test. The pressure on front-line staff on the phones is almost unbearable. There is a difficulty relating to the stress they are under and maintaining those staff. There is an urgency even with regard to that issue where people are trying to impart factual information to women who are very worried and frustrated, and it is taking a toll on front-line staff.

Mr. Damien McCallion: I met some of the staff last week and I am aware of some of the concerns people have. We are trying to address them in terms of providing more supports from a HR perspective but also trying to get more regular bulletins out to smear takers and GPs

because, ultimately, they are probably best placed to try to give some level of reassurance to women. It is very difficult. If a woman is ringing in, what she wants to know is when her test will come back. While an explanation involving the progress we are making or things we are trying to do is helpful, ultimately, it does not answer the person's question and that is the challenge for the person on the line. We are trying to improve that communication notwithstanding that difficulty, but ultimately we are putting most of our efforts into trying to put this capacity into place so that we can give people a timeline which will give them reassurance.

Regarding the other steps we have taken, which I mentioned at our previous appearance before the committee, because of the risk of expiration of the HPV testing, we undertake those tests now, so that has the added benefit of pulling out those who are HPV-positive and moving them through the system more quickly. There is an element of triage in that. That is something at which we are looking in terms of the entire backlog, that we would try to move that forward using HPV testing first, which would prioritise those who are at greatest risk and move them into the system more quickly. That is part of our overall plan around the backlog.

Chairman: I will bring in Deputy Bríd Smith. We will give five minutes to each of our non-members, so I ask them to be concise in their questions.

Deputy Bríd Smith: I have a good few questions so I will ask them quite quickly and in a row. I thank the witnesses for their submission. I also thank Dr. Gráinne Flannelly for her very informative letter on how the whole system works. It was very well thought-out and delivered. The page where Dr. Flannelly talked about 28 April 2018 is a very important piece concerning her advice to the Department not to proceed with offering a second test. In the letter, she wrote that laboratories would not have sufficient capacity, open access for repeat testing would be difficult to plan and deliver, colposcopy services would not have sufficient capacity and it would fundamentally undermine the screening programme. All of that was very prophetic because that is exactly what has happened where we have a backlog of 80,000 tests with a 33-week waiting period. The task facing the witnesses is enormous.

Was Dr. Flannelly a big loss to CervicalCheck? It seems to me that she must have been a big loss to the service given the struggle to recruit experts in this field. Do the witnesses think that, when this becomes increasingly exposed, there be a loss of confidence in the Department, regardless of whoever is responsible, be it the chief medical officer or the Minister or both, because Dr. Flannelly's advice to the Department was rejected, putting us into the position we are in now?

On CervicalCheck's record in sourcing laboratories to help get through this mess, has it looked to Northern Ireland? It has four laboratories which I believe have capacity. Will the witnesses address the result in Northern Ireland?

The witnesses mentioned challenges with CervicalCheck's other partner, having said that it has made progress with the Coombe and Quest. I assume that is MedLab. I do not want to take up the witnesses' entire day, but could they spell out what those challenges may be and the headline issues around those challenges?

In the section dealing with supports for women and their families, the submission reads that CervicalCheck supports them in the provision of access to their records and ensuring that they can get their slides where they are required for legal review. A total of 118 of 125 slides that have been requested have been dealt with, with an average waiting time of 27.5 days. This is under the headline of supporting families. Seven are still in progress. Are legal proceedings

pending in those seven cases? Is a specific laboratory involved or are multiple laboratories involved?

Under the section on the independent review, the submission reads that in recent weeks the laboratories have commenced the transfer of slides. I am quite passionate about this because we were told last June that the Royal College of Obstetricians and Gynaecologists, RCOG, estimated that it would take six months to conclude. I understood that to mean to conclude its examination on the independent review, but it now looks like the witnesses are being told that it will take time to review the transfer of slides. Has it taken all this time just to get the slides transferred to the RCOG or is the review due to be completed? Did the 221 group of women ask to be removed from that review and dealt with separately? If so, why would they have done so?

With regard to requests I have repeatedly made for information on the laboratories from which the false negatives came, I was told repeatedly in parliamentary questions and at meetings like this by the Minister and his Department that this would be dealt with under the RCOG review and that until that review was conducted, I could not get that information. In a reply to a separate parliamentary question, I was told that an expert was being appointed to look at that and to get me that information. The information is still not forthcoming.

The decision ten years ago to outsource the service was a mortal sin because it has led to the deaths of women and the mess we are in with regard to CervicalCheck. This is what I am trying to get somebody to admit. What scares me now is that the only step forward we seem to be making with HPV testing is, again, to outsource it. That there are plans to continue the outsourcing of women's health is very worrying when we know that the decision to outsource testing ten years ago has led to a complete mess. I am delighted to hear that CervicalCheck is reinventing the Coombe as a public clinical service. That is the way to go because, at the time, university courses were shut down because of the decision to outsource and we lost the capacity to do our own screening in terms of clinical experts who can examine these things. I am delighted to hear they will be reinstated. Does Mr. McCallion agree that outsourcing has been a disaster? Is he concerned that we are now being forced to outsource the HPV test?

Mr. Damien McCallion: The RCOG will produce the overall report on the laboratories, not only on the 221 women who were affected initially and their families but also on all of the cervical cases in which women consented, of whom there are over 1,000. On the report to which the Deputy refers, we have completed a report which simply outlines a profile of the laboratories, with an explanation. We got someone from outside the State to do it.

We have always said the first group we will meet to go through the information is the patients. We are due to meet them in the next couple of weeks. Once they are happy with it, we will release the report. That work is done, but, as I said, the patient representatives will be our first port of call.

On the RCOG review and the group of 221, I am not aware of a request that it to be moved. I am not saying it did not come; it may well have, but the RCOG process is independent. Our role is to try and support it. We have a significant team working on the issue because we have had to manage the consent process and the information in a range of areas. The RCOG review is independent and we have a weekly call on it.

I am aware that within the group of 221 women there are a number who have consented. I cannot give the Deputy the exact number, but certainly there are are women who have consented to participate in the review. There are approximately 1,800 women - I do not have the

exact figures - with invasive cervical cancer, of whom over 1,000 have consented to participate in the review. The slides are with or being sent to the RCOG. In total, although I do not have the exact number of women - there are more slides than women - 600 are scheduled to be sent in the next three to four weeks. That will complete the slide transfer.

Deputy Bríd Smith: That is not the completion of the review.

Mr. Damien McCallion: The review process has been started. Once we started to send slides, it started the process of reviewing them. It is also reviewing colposcopy and cancer records. It is a comprehensive review that we are supporting.

Deputy Bríd Smith: Does Mr. McCallion have a date for when he expect the reveiw to be completed?

Mr. Damien McCallion: It is the RCOG that will indicate the date. The indication I have received from it is that it will be completed in a period of approximately six months, but it is for it to confirm the date. We are merely there to support it.

Deputy Bríd Smith: With all due respect to Mr. McCallion and the RCOG, we were told last June that it would be completed in six months.

Mr. Damien McCallion: I can only say the information is from the RCOG. Its expectation is that it will be completed within that sort of period.

On sourcing laboratories, we have identified some capacity. We have been working in the past few weeks to go through all of the capacity, operational and legal elements. As we are at a critical stage, I am being cautious in what I say, but we have identified some capacity that will be of help. As I stated, two of the laboratories have made significant improvements. They have also identified further capacity. As I mentioned to Deputy O'Reilly, we will be making quality assurance visits. There is a new pre-inspection process, to which Dr. Doherty referred, that a laboratory must go through as part of the quality assurance process. There will be on-site visits against an updated quality assurance standard and they are being scheduled rapidly in order to ensure we will get to a point where we can secure the capacity identified. It is a real challenge which I am not underestimating. Globally, finding cytology laboratories, where there is a move to HPV testing, is difficult. That is the other reason we want to move to HPV testing as quickly as possible.

On outsourcing, we have recognised that we need to invest in the public system, as we are doing in the Coombe, but it will take a little time. However, it is not only about construction, although that is an important element. Designs are being pulled together and fast-tracked as best we can and in so doing we have received good support from our own estates people. It is also about ensuring we have the medical manpower, something which can be quite complex. As I said, it is a highly specialised area and there were never many of the people required in the country. We have talked to some of those who were involved in the specialty previously to try to re-engage them. We are trying to grow and develop the consultant workforce, for which we have started to pull together some plans. Recruiting screeners is also challenging. I acknowledge the support the Coombe hospital and its board have given to us throughout this difficult period. We are committed to getting the programme going as quickly as we can. We will still need to have a partner for a significant number of years. Our aim is to get the Coombe hospital up to a figure of 50% within a two-year period, but, as I said, we will need a partner. There is a limited pool of companies that do this work and we must be careful in how we manage our

communications and engagement. The procurement strategy we have picked for HPV testing allows us to engage in dialogue with the market because otherwise there would be a real risk that we would be left without a partner. We must make sure we can secure one. We were involved in pre-market engagement before Christmas which was very successful and in which there was good interest. However, there is only a small number of providers that offer this service and we must try to make sure we will bring someone with us in order to ensure we will move to HPV screening.

Deputy Bríd Smith: Did Mr. McCallion check to see if there were laboratories available in Northern Ireland?

Mr. Damien McCallion: With Dr. Doherty, I met the Public Health Agency in Northern Ireland. Dr. Doherty was in her old role in Northern Ireland and kindly joined us before transitioning. It is in the process of moving from four laboratories to one. The timing is a challenge for it. From that meeting, there is no significant capacity available there to address our requirements. We have also had discussions with agencies in other parts of the United Kingdom, including Scotland.

Chairman: I thank Mr. McCallion.

Deputy Bríd Smith: There are a couple of questions that I want to have answered. I asked Mr. McCallion if Dr. Flannelly was a loss to the HSE. Is it unusual for the Department to reject advice from somebody as expert as her.

Mr. Damien McCallion: In fairness, one must acknowledge that Dr. Gráinne Flannelly has done considerable and phenomenal work in cervical cancer screening during the years. She started the programme. Dr. Peter McKenna kindly stepped in to fill the role of clinical director, even with his other roles, for the intervening period. Dr. Doherty has now moved into the role. Of course, in losing someone in a key clinical role at any point in time there is an impact.

We discussed the other point raised. There is nothing we can add on the history and the timing. We have talked about the context in which the decision was made. Personally, I was not there to judge. I have articulated how we work with the Department and how we give advice. Matters of policy are for the Department. Operational matters are worked through with the HSE.

Deputy Bríd Smith: Is it unusual for the Department to reject advice from somebody as professional as Dr. Flannelly?

Mr. Damien McCallion: We do not know that it did in the sense of how it all operated. We have been through this issue a number of times. We are not in a position where we can add anything. We can explain the context in terms of the difficult circumstances faced at the time by GPs and women. To illustrate them, our cervical helpline would typically have handled a couple of hundred calls in a week. It jumped to thousands at the time, which created its own challenges, as the Deputy may recall, in responding to women. There was also considerable public pressure exerted.

Chairman: I am sorry, but we have been-----

Deputy Bríd Smith: There is one question Mr. McCallion did not answer. That is all.

Chairman: Okay.

Deputy Bríd Smith: On the supports available to women and their families, in his submission Mr. McCallion talks about a figure of 118 out of 125 slides. I asked him about the outstanding seven slides.

Mr. Damien McCallion: There is always a small number where it is a work in progress in the laboratories. They deal directly with a person's solicitor in that regard. I cannot answer the question as to whether there is one case that is active, but I will confirm the position and come back to the Deputy.

Deputy Bríd Smith: My question was if the cases were subject to legal proceedings.

Mr. Damien McCallion: They may be. A woman will typically have asked a solicitor to take on the role of securing her slides for her. It is rare for a woman to come directly. It does happen, but generally she will do so through her solicitor. Whether she then chooses to take legal proceedings is a matter for her. We do not concern ourselves with that issue. We simply try to get the slides to her solicitor as quickly as possible. If the Deputy is asking whether there is a delay in any of the outstanding cases, I am not aware so it, but I am sure the issue would have been highlighted. If it is okay, I will double-check and revert to the Deputy.

Deputy Bríd Smith: I thank Mr. McCallion.

Deputy Lisa Chambers: I thank the delegates for their attendance. I cannot but feel a lack of confidence. When I listen to language such as they "manage our communications" and are engaging in "dialogue with the market" and that there is "pre-market engagement" and that there is no tendering process under way for HPV testing, there is a disconnect between Mr. McCallion's work and the 80,000 women who are affected by the backlog. Mr. McCallion's work to date has not been adequate in dealing with the backlog. It has been completely unsatisfactory. There are women who have now been waiting for up to eight months for a repeat smear test result. They were seeking reassurance which they felt they needed in the context of the entire scandal in which women have lost their lives. There has been a focus on the women involved getting their results back within a reasonable time. Most are not getting them back within a reasonable time.

I can talk to Mr. McCallion about my own case. I am only one of the 80,000 women involved. Last October I presented for a reassurance test. I am still waiting. I have a particular history and I should not be waiting. I got a letter in January inviting me for my routine smear test. Having already been in the system and not having got my results back, the HSE sent me another letter in January telling me to come in for my routine smear. Answer that question. Is the HSE still writing to women in the backlog asking them to come back in because it has not cross-checked these women? That would probably add to the backlog.

Mr. McCallion and his colleagues can probably tell from my tone that there is a huge amount of anger out there. News broke of Ms Laura Brennan passing away and God rest her - I send my sympathies to her family - but every one of those 80,000 women would have felt anxiety and stress listening to the story while still not having results. The witnesses have indicated that two of the three labs have improved their times but which lab has not? I assume it is MedLab, which is dealing with people in rural Ireland. They are the people I represent. The samples from people outside the cities go to that lab and they are looking at an eight-month wait. Nothing has happened to address that.

The suggestion by the Chairman, Dr. Harty, needs to be given serious consideration. Why

on earth would the HSE write to women already in the system to come in for a smear test today knowing it will not have results for them for eight months? Why would it do so? It is utter madness. If the executive delayed sending those letters, it would not block women coming into the system. If somebody comes in for the first time to get their first smear test, they are brought into the system. If a woman is already in the system, there is merit in seriously considering delaying the sending of that letter for three, four or maybe five months in order to deal with the backlog. If a woman comes in today anyway, she will have to wait eight months. If the letter is delayed for three, four or five months and the test is done at that stage, the results will be received around the same time anyway, but at least there would not be extra stress and anxiety. The HSE might get to grips with the utter mess it is currently dealing with.

I listened to Dr. Doherty earlier defending the decision of the Minister for Health, Deputy Harris, to offer that repeat smear test when he knew there were no resources for it. We know he had clinical advice not to do it. He has tried to discredit my questioning and the questioning of others around it. He can say he did not have that advice but we know he did. There is the suggestion that simply because the Minister is under pressure and things are difficult or challenging, it is justification for a bad decision that ultimately harms the health of women and undermines the screening programme, but I utterly disagree with that. It is wrong. When asked about the HPV screening that will be implemented, Dr. Doherty said it would have to be driven by evidence and it must be safe. The Minister's decision was not driven by evidence and it was not safe. Just an hour ago she defended his statement but she has justified the lack of implementation of a new screening programme for that reason. There is a lack of credibility in that.

I ask Mr. McCallion and his team to demonstrate leadership. We have a serious mess and many women are seriously upset, worried and anxious. This is being compounded by the lack of leadership and decisions in dealing with this backlog. I want serious consideration to be given not to stopping the programme but to delaying the numbers coming in at their current rate. At that current rate, we will be five or ten years clearing that backlog and other women will not benefit from the new screening programme that was supposed to be implemented last year, by the way. There is absolutely no confidence that it will be implemented early next year, whatever early next year even means. We need real timelines and a decision from Mr. McCallion and his team. The response of "I was not there when it happened" does not cut the mustard. Mr. McCallion is there now. The decision that was taken was wrong and he must now tell us what he, as the lead, will do to fix this and the backlog. We need a decision. The suggestion from the Chairman, Dr. Harty, is supported by me as somebody in the system. That delay must be given serious consideration as it is the only way to deal with the backlog. As has been said to Deputy Bríd Smith, the capacity is not there and it will not magically appear in the next number of months. I am not at all satisfied with the responses given to the committee this morning. I thank the Chairman for his indulgence.

Mr. Damien McCallion: I apologise for the language on the procurement side. It referred to the HPV process. With respect to the backlog, Quest Diagnostics and Coombe are both now performing, with turnaround times for women's results of three weeks for Coombe and approximately seven to eight weeks for Quest. That is an improvement from where we were many months ago. We have had challenges in sourcing capacity with MedLab, as the Deputy notes, and we now have options on the table that we have been working through over the past number of weeks. If we get them into play they will help shorten MedLab's turnaround times as well. The process has been complex and I can assure the Deputy that we have been trying to find the capacity.

The Deputy made two points around the recall process. One concerned women in the backlog potentially not getting the recall and I will take that away as I cannot answer the Deputy now on that. I will revert to the Deputy directly on that. On the broader point of moving people on three- and five-year recalls out over a period, we will be moving them into 2020 with respect to the HPV process and moving some of the problem that way. We have two of the labs functioning who cover the middle, the north east, the south east and other parts of the country but the Deputy is correct in saying that in other areas, they do not have such turnaround times. We must address that matter.

We now have capacity and we have been working actively over the past couple of weeks with MedLab to try to see how we can get that into the system. We need to ensure this is done with a full quality assurance process, and we are scheduling visits to the laboratories in order to ensure they meet the quality standard outlined by Dr. Doherty earlier today. If that falls into place, it would allow us to ensure we turn things around in a reasonable period. I do not want to go too deeply into that, if members might forgive me for that. We are in the middle of fairly complex negotiations with the lab to try to get that into the system and ensure we can address the issue as quickly as possible. I assure the Deputy it has been our sole focus for the past four or five months since we renewed the contracts with the provider. The first hurdle was to keep the current providers in the programme or it would have crashed. The second problem was trying to get more capacity from those or other providers in order to ensure we could address the backlog. We have considered that and I am happy to revert to the Deputy separately on that if she so wishes.

I will come back to her about her concerns about people in the backlog as I was not aware of it. I will revert to her directly, particularly on her suggestion that people already in the system should not be getting recalled if they have had their smear out of cycle. Dr. Doherty may wish to comment on one or two other points.

Dr. Lorraine Doherty: To clarify, I was asked earlier about the decision about out-of-cycle or free smears. I know this does not cut the mustard with the Deputy but I was not involved in the decision-making process at the time. I was not even working in the programme at the time. On reflection, all I can do is try to understand why one might have taken that decision to offer those smears. There was clearly a crisis relating to confidence in the programme and a heightened anxiety among the population of women eligible for screening as to whether they could have a test or have confidence in the test. I imagine those kinds of factors may have driven decision-making around that time.

Deputy Lisa Chambers: I hear what Dr. Doherty is saying but her professional opinion was sought by the committee. On the one hand she has said decisions must be evidence-driven and safe but on the other she is suggesting that public pressure is sufficient to justify a decision. All I am saying is I disagree on the point. It is the responsibility of being in Cabinet. It is a privilege to serve in Cabinet but a responsibility comes with it. Decisions taken have an impact and consequences. One must always base those decisions on evidence and not populism or public pressure. The right decision must be taken for those who are affected and whom one serves and looks after. In all of the chaos and madness, we must always revert to making the right decisions based on the right reasons. The decision of the Minister at the time was not correct and it was not based on the right reasons. When asked for a professional opinion, the witness would be well within her rights to say that. That is how we learn from such situations.

Mr. McCallion has again spoken about exploring options and working through the process but it is now April 2019. This decision was taken last May and the backlog was becoming evi-

dent in August. We have known about this for quite some time. It is no longer acceptable to say we are working through the process. I do not accept that the witness cannot outline details to the committee as he knew why he had to come before us today. I am asking for definite timelines. When will the backlog be cleared? The HSE should be able to answer that. If the witnesses know the capacity in the two labs where improvements have been made, with one seeing turnaround in four to five weeks and one seeing them in seven to eight weeks, it is not acceptable to not know where MedLab is at this point. Rather than reverting to me personally, I ask that the witnesses revert to the Chairman and that it be circulated to all members. The HSE should tell the public immediately what is happening with those negotiations and when the backlog will be cleared. If the HSE cannot provide that information today, we need a decision from it regarding the out-of-cycle smear tests of women who are already in the system. Is it going to continue to issue letters to come back in after the three-year period is up? Is it going to continue to add to the system without the capacity being in place? That is its decision to make, not mine. For those 80,000 who comprise the backlog and who have had repeat tests and are awaiting results, nobody should be getting the routine letter I received last January. The HSE needs to look at that. If it was not aware of the position, it should have been.

Mr. Damien McCallion: In terms of the backlog, when we have a definitive position, the first people we will write to are those who comprise the backlog. However, until we have a definitive position, we cannot do that. We must ensure we have that and it is not the case that we can just pick a date. We would love to have had this resolved months ago but it is not easy to source capacity in the current market or to attract people to Ireland. I need to reiterate very clearly that it has been hugely challenging to try to identify capacity. If it was there, I assure the committee that we would love to have plugged it in a long time ago. We now have very strong options and we are trying to close those out. Once we do that, we will then revert to the people who are waiting because they are, as the Deputy rightly said, the most important people and they need to understand what is happening.

Chairman: We have been here for three hours so I am obliged to offer our guests a break, if they wish, or perhaps they are fine to continue.

Mr. Damien McCallion: We are fine to continue.

Chairman: I thank Mr. McCallion. That completes the first round of contributors. We will now take a second round. I call Deputy Donnelly.

Deputy Stephen Donnelly: I want to reflect. Mr. McCallion stated earlier, quite nobly, that he took responsibility for a lot of what is happening upon his team and the HSE. I think he is taking responsibility for the wrong thing. Largely, the crisis of confidence was caused by politicians in the Oireachtas. It was partly caused by Members of the Oireachtas outside of Government and by how the Oireachtas reacted given that it conflated clinical outcomes for women with non-disclosure. I am of the view that the Minister largely created the issue. He was warned weeks in advance that the Vicky Phelan case was going to emerge and that it was likely to cause a crisis of confidence. No preparations whatsoever were made and those involved have admitted that. Within 48 hours, the Minister expressed no confidence in the members of the senior management team at CervicalCheck without meeting them. He never met those people and never asked their opinion. That was largely taken as the Government having no confidence in CervicalCheck programme. Having created anxiety and fear, an offer of free tests was made. We now know there was very strong clinical advice not to do that.

CervicalCheck failed in not closing the audit loop, although it is worth noting that it failed to

complete a loop that no other programme on earth even tried to perform. It failed at the end of an audit process in trying to be the best programme in the world in terms of audit and feedback to the women involved. To suggest that this failure would lead to a crisis of clinical confidence among women is, I believe, not true. The mishandling of this matter by the Minister caused the crisis of confidence which, as we now know, gave rise to this huge backlog, to there being no date for the HPV test to be introduced and to 79,500 women waiting for their results.

What the HSE needs to accept responsibility for, and it may well do, is the response to that. I do not think Mr. McCallion's team created this mess at all and it was largely created by the Minister and the Government, aided and abetted by the Oireachtas. There was certainly loose language within the Oireachtas which was very unhelpful as well. However, it is the HSE's mess to clear up. I was deeply disappointed when I received a reply in the past few days stating that the number had risen. On the previous occasion on which we met, the number was 78,000. It was the expectation of all here that when we met again, that number would have fallen, particularly as many of these women are experiencing acute anxiety. In fact, the number has risen. That is extraordinary, particularly when one considers the free tests which caused all of this were stopped months ago. I was expecting Mr. McCallion to state that it had been 78,000, it had fallen to 55,000 and it will be cleared by whatever date. Unfortunately, his team does have to accept responsibility for some of that, notwithstanding the very difficult international context, which is what I want to come to next.

Mr. McCallion stated, "Our market engagement has identified significant challenges and concerns in the provider community". What is the problem? Is it that there is just not the cytology capacity anywhere? Is it a fact that there is capacity but that international providers are scared of the political, reputational or litigious contexts relating to Ireland? While this is not the HSE's fault, it is galling that women, in a phenomenal public screening programme - one of the most successful public screening programmes of its kind anywhere in the world - are waiting eight months for results. What they hear is that it is not possible to access cytology capacity but that if they want to pay €100, they can get their results in two weeks. Clearly, cytology capacity does exist because women who can afford to do so are just paying for their results. One of the wonderful things about the screening programme is that it did not fall foul of our awful two-tier healthcare system. If it is the case that the HSE simply cannot source the capacity because the capacity is not out there, how is that women can bypass that and obtain results by paying? If there is cytology capacity out there and if those who have it are refusing to provide it to the HSE, why is that the case?

Mr. Damien McCallion: In terms of the scale of the capacity, we need to address the backlog. To put it in context, the private capacity that is there is minuscule in the context of challenges for the public screening programme in this jurisdiction and other jurisdictions. The NHS has a huge backlog, as has been reported widely in recent weeks, due to its own challenges, which are different to the challenges we face. That is not a significant factor in the scale of those challenges, although I am not saying it is not a wider issue. As the Deputy rightly stated, our challenge is to get the capacity in place in order to get the turnaround times back for women. We made some inroads with two of the laboratories where the turnaround times are down to more reasonable levels, and one is back to pre-crisis levels. We are working with MedLab on solutions for that and we have identified capacity with it. Some of that is taking the opportunity whereby, for example, if a site moves with HPV primary screening, that releases cytology capacity and we try to step in quickly to avail of that to ensure we can use it to help us address our backlog and get the programme back on an even keel where the capacity equals the demand.

Deputy Stephen Donnelly: Mr. McCallion does not think it is an issue with Ireland. It is not that there is capacity out there and the international market is cautious of engaging with the HSE.

Mr. Damien McCallion: I concur with the Deputy's assessment on the wider issue. In terms of the backlog, we are trying to identify capacity with the current providers we have. The reason for that is the lead time to connect a new laboratory is significant and that would add further delays. We have identified potential capacity in other jurisdictions that we may be able to avail of or may be able to encourage to compete for our HPV project.

The Deputy's assessment in terms of the risk within Ireland, or the perception of our market in Ireland, is fair. There is a lot of concern in the wider community in that regard, which is one of the challenges I mentioned in terms of the market engagement process. To simplify, as we all know, in a normal tender, one puts out a specification, people bid, the process is closed, everyone sees what comes out at the far end and that is assessed against various measures. If we did that, the risk, given the factors the Deputy has outlined, is that we would not understand what the market is feeling and we would not be able to reflect it in our tender. The option we have taken allows us to have a dialogue which allows us to make sure that when we put in a specification, we have a good chance of getting providers to bid for that. That is trying to address the issues-----

Deputy Stephen Donnelly: I understand that, on an ongoing basis, there is a public procurement process which is very detailed and which has to be dealt with in a very clever way. However, we are dealing with a backlog of 80,000 tests. In the context of finding temporary additional capacity to ensure that the women involved get their results on time, what is the problem? Are international providers nervous about dealing with Ireland? Are they asking for prices the State is not willing to pay or for indemnity against risk it is not willing to provide? It appears that a person willing to pay privately can get access almost immediately.

Mr. Damien McCallion: The private access reported is misleading in the context of the backlog. It is so small in this context that it is not a factor. The main factors are the other two points mentioned by the Deputy. One is environmental and the other is cytology availability. We have source capacity with two of the laboratories. They have introduced capacity to help get the backlog down and we are now working to finalise a plan with the third laboratory to try to get that capacity as well. We will write to the people anxiously waiting for the results from the programme once we do that. It will be in line with what Deputy Lisa Chambers articulated earlier.

Deputy Stephen Donnelly: Does the HSE now have an expected date for the availability of the HPV test? It did not have one the last time it was before the committee. What is the HSE's view on temporarily suspending tests to clear the backlog? As Deputy Lisa Chambers stated, the media has reported that one of the labs has proposed that as well. What is the HSE's view? My final question concerns the women recalled because their test date had expired. Have all of those women now been retested and have they received their results?

Chairman: I ask that answers to those questions be as brief as possible.

Mr. Damien McCallion: I will take the final question first. Some 800 of the 2,500 women subject to the expiration of the HPV test now have their test results. I cannot distinguish between those gone out and those going out. The target is to complete the balance within two weeks. Approximately 2,500 women requested a test and others may choose to do so in the

coming weeks. There was, however, an initial surge and I anticipate the additional numbers will be low.

Deputy Stephen Donnelly: If I understand Mr. McCallion, all 2,500 women will have their results within two weeks. Is that correct?

Mr. Damien McCallion: Yes, that is correct. Quest Diagnostics fulfilled its aim of returning 800 results. The target is to complete the balance within two weeks from next week. Regarding the point made by the Chairman earlier, we have examined that possibility and kept all options on the table. At the moment, however, we believe we have capacity identified and a plan we can secure. We will try to nail that down over the coming week or two, including quality assurance visits. The reason we cannot be as specific as we would like to be is because we need to schedule those quality assurance visits and then tie down some of the contractual details.

Once that is in place, as I stated earlier, we will write to those people in the backlog to give them the timeframe. That is the priority now. We have on several occasions examined how we could logistically manage moving people on normal three and five-year recall periods out. That, however, also creates a problem straightaway in 2020. We would be just shuffling everything and not changing anything. Dr. Doherty earlier gave an example from the Netherlands where the programme was paused. They had the advantage of being able to oversee a larger number of people. Instead of missing people, the final six months of people who were due to be tested before the suspension were seen during the previous the six months. There was then a pause to let HPV come in. It was a slightly different model than the scenario we face.

Deputy Stephen Donnelly: If I understand Mr. McCallion, there is no projected target date for the introduction of the test. Is that correct?

Mr. Damien McCallion: The key date will be determined by the tender. That is the main factor. If we can get a provider through the tender process that can interact with us quickly, then we believe we can achieve this in a much shorter timeframe, perhaps by the end of this year or early next year. That is our key priority. The contract advertisement is going out now. I assure the committee that the procurement process is running. We will mitigate the risk concerning the environmental factors mentioned earlier by allowing a dialogue with the market. That is possible through a certain procurement process. The contract notice for HPV will be going out in the next couple of weeks and then we will be able to see if we can get a vendor to work with us on that.

Deputy Stephen Donnelly: Regarding the HSE's view on the temporary suspension of the programme-----

Chairman: I am sorry, we have to move on.

Mr. Damien McCallion: I was just reflecting on that. There is language here, but what we are effectively talking about is moving people on three and a five-year recalls out. We would always still want to see new women because they are high risk, as well as people from colposcopy and short-term recalls. There are categories of women that have to be seen and for whom the programme could not be suspended. We would then simply move some of the standard recalls out further in time. We have examined that option but if we can secure this capacity, that is clearly the preference. We are focused on that.

Deputy Louise O'Reilly: Mr. McCallion stated the HSE examined the option of temporar-

ily suspending the programme for women who are not symptomatic. I refer to those women who get their letter to go for a routine smear test in the normal course of the programme. The HSE, however, is not going to suspend the programme because it believes it is going to source capacity from these additional laboratories once quality assurance and everything else is completed. I do not mean to be disrespectful to anyone in the room but the HSE has not exactly covered itself in glory in sourcing capacity. I understand the Minister was also not helpful. In the event that capacity cannot be sourced, will temporary suspension be back on the table?

Women in a high-risk category or new women who may be at high risk would not be included in the suspension. It would just be for ordinary run-of-the-mill routine tests. Will temporary suspension be back on the table if the additional capacity cannot be sourced? Is there a timeline or deadline for when that decision will be made? Women are waiting while all of this is going on and they are, of course, anxious. Confidence in the programme has been undermined. I take every opportunity to tell people screening saves lives and they should always go to get tested. Mr. McCallion alluded to that earlier as well. Having said that, however, he will understand women are nervous.

Mr. Damien McCallion: It is not so much a suspension. The programme still functions. As the Chairman stated earlier, it is about moving people on three and five-year recalls out.

Deputy Louise O'Reilly: I was referring to a suspension for that group.

Mr. Damien McCallion: That is fine. We hope to have close out the timeframes over the next month. There are a number of elements. We have identified the capacity and we are working through the contractual element now. We are also working on the pre-inspection aspect. We are trying to gather information to ensure the laboratories meet the quality standards. As Dr. Doherty stated earlier, quality assurance visits will follow. That is the sort of timescale we are looking at. We have worked up all the options and we have been constantly looking at them.

There is, however, a downside to temporary suspension because we would simply be moving the problem. We would alleviate something now but we would also create another problem that we may or may not have capacity for to solve later. We have looked at variations regarding time periods but our focus in the next month will be to try to nail down the capacity we have identified and get it into place. That will, hopefully, help to alleviate the backlog. Two of the laboratories have managed to do that. We now need to do it for the third. It is working closely with us to identify capacity.

Deputy Louise O'Reilly: There was reference earlier to how this decision was taken and what exactly was offered to women. I took the liberty of checking on Twitter. The Minister tweeted:

> Have heard from many women today who have had smear tests & would like a repeat test to reassure them. Am arranging for this facility to be available & the State will meet the cost of the repeat test. Arrangements on how this will operate will be outlined next week.

The public announcement from the Minister was that anyone who wanted a test would get one. It was nothing to do with bedside decisions, a doctor or anything like that. He offered a free test to any woman who wanted one.

It is now clear he had not done any homework and, indeed, was going against the only available clinical advice. He either got that advice and ignored it or he did not get it. It is con-

cerning, whichever it might be. Dr. Doherty is now the head of the programme. I am sure it is concerning for her that her predecessor gave advice and it was ignored. Will she comment on that? She is going to be the lead in this area. If she raises an issue of concern with the Minister, or senior officials in the Department, does she expect she will be taken seriously or does she expect her advice to be ignored in the same way?

Dr. Lorraine Doherty: I expect departmental colleagues to listen, take my advice on board and then decide how they will brief the Minister. I cannot comment on what happened before, what advice was given and how it was communicated.

Deputy Louise O'Reilly: The same personnel are still involved. Is Dr. Doherty concerned that advice she might give will be ignored? That appears to be what happened with her predecessor.

Dr. Lorraine Doherty: My own working relationship with the Department is very good. I have direct communication with officials in the Department, with medical colleagues and with senior civil servants. Those relationships are working well and we have regular meetings and briefing sessions. I have not had any experience to date of any advice I might have given being ignored.

Deputy Louise O'Reilly: I am asking a different question. Is Dr. Doherty concerned that the advice of her predecessor was ignored? Does that give her cause for concern in her current position? I have to say that if I was in Dr. Doherty's position, it would give me cause for concern. Her predecessor was a qualified person and was definitely capable of giving that advice. In her current role, given what happened, is Dr. Doherty concerned that her predecessor's advice was ignored?

Dr. Lorraine Doherty: As I said, I cannot comment on how her advice was given, received or acted on. That is not within my remit. I can say that what I see around me now is a process of meaningful engagement with the Department on all issues concerning CervicalCheck. I would expect any advice I give to be considered and advice given to the Minister to be based on my clinical advice. I do not have concerns at this point that my advice will be ignored. As I said, I am quite confident in the relationships I have right now. Who knows what will happen in the future?

Deputy Louise O'Reilly: I dearly wish I shared Dr. Doherty's confidence.

I have some very brief questions. I checked on social media for the tweet that was referred to. I saw a tweet from Mr. Stephen Teap reminding us that we should focus not only on the past but on the future. In that regard, what is the status of the steering committee? I know some of its members are concerned that efforts are being made to somehow sideline or disband it. The witnesses might comment on that.

I would like the witnesses to walk through this process with me. If a woman has received a negative result smear test in the past six months but is symptomatic today and goes back to her doctor, can she expect her test to be fast-tracked? Second, how soon can she expect a result? Let us say this woman is not going to pay for it but is in the public system. How soon will she get her test back? Does it make a difference if a woman is symptomatic? Can she expect her result more quickly? Can the witnesses give us a timeframe? Can she get a result more quickly if she pays for it?

Dr. Colm Henry: I will make a start on that question. To reiterate the point for anybody

listening or watching, it is really important to emphasise the difference between people who are symptomatic and people in the screening programme. To be blunt about it, if someone shows symptoms corresponding to any of the three screening programmes, such as bowel symptoms, a breast lump or vaginal bleeding in the case of cervical cancer, the screening programme has no relevance to him or her. Such people must go straight to their GP. We have urgent access pathways for these patients, which we measure and report on monthly. Those patients bypass screening. They should go straight to their general practitioner. As the Chairman knows, the general practitioner will refer that patient straight to urgent cancer referral clinics.

Deputy Louise O'Reilly: How quickly will that happen?

Dr. Colm Henry: As for endoscopy, bowel screening and breast clinics, we have eight cancer centres, as members know. We offer endoscopy in a large number of centres. We measure performance for urgent referrals for each of those centres. We interrogate our hospital groups and hospitals on those performances monthly. The results are published on the HSE website.

Deputy Louise O'Reilly: The fact that a woman has had a clear smear test result in the last six months will not impact on that. Is that correct? If she is symptomatic she will be fast-tracked straight away.

Dr. Colm Henry: Absolutely. That is a really important question to ask. If she is symptomatic, the easiest thing is to bypass the screening programme, go straight to her doctor and get an urgent referral. That is the important message.

Deputy Louise O'Reilly: The previous result will have no bearing on that.

Dr. Colm Henry: Absolutely not.

Deputy Louise O'Reilly: Can Mr. McCallion comment on the steering committee?

Mr. Damien McCallion: The steering group continues to meet. We had a meeting last week or the previous week. It is not a committee as such. It is convened by the Department and the HSE participates, as do the patients and others. We have certainly met in the last couple of weeks and will continue to do so. Another meeting has been scheduled.

Deputy Louise O'Reilly: There are no plans to disband or sideline the committee, then? Is Mr. McCallion happy that it is working well?

Mr. Damien McCallion: It is functioning, yes. As Deputy O'Reilly has said, the patients provide a unique input. I mentioned it earlier myself. The perspective and the challenge that they bring is good and healthy.

Deputy Louise O'Reilly: It is the patients who are concerned.

Mr. Damien McCallion: I am aware of the wider concerns. The HSE is a participant in it. All I can say is that the committee is continuing to meet and the HSE is continuing to participate. We are continuing to meet with the patients to discuss all the work that is ongoing.

Deputy Louise O'Reilly: Is Mr. McCallion happy that the committee is performing its purpose, that it is useful and that it is advisable to keep it going?

Mr. Damien McCallion: Absolutely. The committee is functioning and the work is continuing. We are continuing to implement Dr. Scally's report, which is one of the committee's

primary objectives.

Dr. Colm Henry: I would like to reply to Deputy O'Reilly on that issue. She raises a very important point about screening. A negative screening result does not mean that somebody does not have cancer. That is a really important public message for all of us to convey.

Deputy Louise O'Reilly: That is precisely why I asked the question. I am conscious that we are not clinicians, with the exceptions of the witnesses and the Chairman, Deputy Harty. Sometimes we have a function of putting information into the public domain, which is what I was seeking to do.

Dr. Colm Henry: I would like to use this forum to say that. The same applies to bowel screening and breast screening. If somebody gets a negative result in population health screening, that does not mean his or her symptoms are not due to cancer. They could be.

Chairman: The point Dr. Henry is making is that screening is for people who have no symptoms whatsoever.

Dr. Colm Henry: Correct.

Chairman: Once someone has symptoms, screening is not the appropriate service to attend.

Dr. Colm Henry: Correct. Nor do the previous tests have application in that case.

Deputy Bernard J. Durkan: I listened as carefully as I could to the various points. We need to think about the situation a few months ago, when the issue first became public. If I was the Minister, I would want to know what went wrong. The Minister quite correctly did everything possible to ensure that all the available buttons were pushed to begin a new era with a new confidence into the system. As the Chair knows I have been a critic of the structure of the HSE, though not its personnel. I do not and will never agree with the structures because to my mind they are not workable. I asked a question at this meeting; who is the boss, the Minister, or the HSE? I have to raise that question again. The Minister quite correctly made the decision to reassure those women who might have been under the illusion that they either were or were not cancer-free, in order to address their anxiety.

I fully accept Dr. Doherty's response on responding and dealing with a situation as it arises, but however this situation was dealt with was not adequate. It did not work correctly. If it did, there would not have been a problem in the first place. Somebody said that a clinical decision was made. A clinical decision was not made; a management decision was made by a clinician on the basis of experience suggesting things might happen in a certain way. The critical issue at that stage was the need to reassure the public that the system in place was adequate and those who had gone through screening, whether they got a negative or positive result, would receive another test. The issue then was to separate the two and create a second line. The solution could not add to a waiting list or to the problem that was already there. A second channel was needed to deal with that review for women who might or might not have a concern or might or might not have a condition. That was where the problem arose. That is what needed to be done at that particular stage. That is a management problem too. It concerns how to manage a situation.

I am not being critical at all. We have a lot of experts. Somebody mentioned that we are not clinicians. That is right. However, we have a duty to raise the issues and to ask whether the system is fit for purpose and does the job. That is also essential if we are to be fair to the clini-

cians. If we do not have a system that is adequate to the caseload, the clinicians' job will become impossible. No matter what they do, a problem will come down the tracks at some time in the very near future. It is very easy to pick out a scapegoat and say that he or she is responsible for this, be it a clinician, a Minister or somebody else. The fact is that the situation arose that was totally unacceptable. That is a fact. That is not a theory. It was there, plain as a pikestaff, in front of everybody. The system had not worked. There was confusion over whether it was a diagnostic system, a smear system or simply a check system, and we knew what that meant with 80% accuracy and so on. Some people acted on the basis that it was 100% accurate. Of course it was not. We came to the conclusion early on that it was the wrong system and that we need a more accurate system. We cannot put our political or medical reputation on the line unless we have a reasonable degree of reliance on whatever we are dealing with.

It goes back to capacity - this has come up again and again. Sadly, the necessary capacity was not in place to do the job as it should have been done. There are various reasons for that, whether it was a lack of money or personnel or a failure to attract clinicians from abroad and so on. Whatever it was, it was there then and it is still there.

We should be fair to all concerned. I can play politics with this as much as anyone else. I am sure the Minister could do so if he were here as well. Playing politics does not address the issues or concerns of the women. It is easy to do that with sound bites left, right and centre. We can accommodate that and I can accommodate that too.

I am keen to emphasise one point now as I did at the beginning. I believe we now need a clear indication that we are attacking the problem at both ends. We need to contain the existing problem and make inroads insofar as waiting lists are concerned.

I received a reply to a parliamentary question last week in another context. I nearly had a seizure when I read it. It related to a condition that was progressive and serious. Whoever dictated the reply decided that the question was submitted by a stupid ridiculous politician who would not know the difference. We do know the difference. We know cynicism when it is incorporated in a reply. We know the mind-your-own-business mindset when it is incorporated in a reply. This is our business. This is what we are here for. When we ask a question it would not necessarily be a good idea to come to the conclusion that the stupid idiot who raised the question in the first place does not know what he or she is talking about. We have to be alert, on-the-ball and able to do the job. That is why I have said many times in the past that when the health boards were in existence what happened in a crisis situation was that there would be a meeting on the same evening or same day – not a week afterwards or anything else. By the following morning we all knew what was happening.

Chairman: Sorry, Deputy, is there a specific question?

Deputy Bernard J. Durkan: I have measured the time for all the other speakers to prove my point. You can measure my time as well, Chairman. I insist on taking adequate time to deal with the subject. I am trying to do that. With the exception of this morning I have been here every morning at the start of the meeting and I have stayed right through to the end, which is more than can be said for many people. I do not simply make a sound bite and then walk out.

Deputy Bríd Smith: Are you deliberately delaying us?

Deputy Bernard J. Durkan: If the Deputy waits, she will find out.

The point that I wanted to make is that we need to know now – we need an honest opinion

– whether we can be assured that we will find in two or four weeks time an improvement in the situation sufficient to allow us to say that we are moving in the right direction. Alternatively, we could find in two or three weeks that we have another problem that we did not see beforehand. In that case we would be in a worse situation. Worse still, public confidence in the system will have diminished in the intervening period and that must be dealt with. It is now a crucial and critical issue.

Excuse me for coughing, Chairman. I also have a cold. You might be able to administer something before the meeting is over.

Chairman: Will we put that question to our witnesses. When could we realistically see an improvement in the backlog?

Mr. Damien McCallion: I will address the point on the backlog. I outlined earlier in response to previous questions that we have seen improvement in two of the laboratories. We are working with the third laboratory. We have identified the capacity and we are working to close that out over the coming weeks. That is the point at which we would communicate with people who are in the backlog first in terms of the suggested timeframe. The idea is to give people some level of assurance, if possible, around the delays.

Deputy Bernard J. Durkan: We shall wait and see.

I should have said to my colleague that I am a member of the committee and I am entitled to raise questions as often as I like. When I go into other committees I do not delay and I do not delay on this committee either.

Deputy Kate O'Connell: At the risk of being accused of catching whatever Deputy Durkan has, I will try to keep it as brief as possible. We have the benefit of hindsight. We have heard many history lessons and assumptions this morning.

I am keen to make it clear because I have been straight on this since the start, when the offer of an additional smear was given. Mr. McCallion will correct me if I am wrong because I imagine he will know the answer. I do not follow Twitter in the sense that it is not where I get my official press releases. Anyway, the chief medical officer made a press statement stating any woman who had had a cervical smear test should have a further test as part of a reassurance measure provided the GP took the view that she required it. Moreover, the Minister asked CervicalCheck to make arrangements, including payment provision.

The first point in respect of the correspondence we got last night is that I want to make it clear that GPs got paid for this. Second, there were two strands to the payment. There was a consultation payment and a further payment if the procedure took place. Previous commentary referred to a free token for a smear but the Minister was offering a free smear.

The Minister is not a medic but he acts on medical advice. I speak as someone who has worked as a clinical pharmacist and who has worked in community pharmacy for 15 years. We have two well-qualified doctors before us today. If it was as simple as making clinical decisions based on data, we would not need any doctors or pharmacists. We could simply throw data into a computer and allow it to throw data out the other end. Doctors need the autonomy to make decisions that they need to make with regard to men and women in the comfort of their practice and in the context of their relationship with their patients. The very fact that the payment was divided into two strands, consultation plus procedure, points out that the power was in the hands of the GPs.

The next point is based on anecdotal evidence and not some major study. I live and work in Dublin. I have busy city centre pharmacies. People were presenting terrified. Let us look back at the history. I hope I do not attribute the wrong questions to the Chairman, but I remember questions were raised about custody and even the question of who owned the smears. We did not know that in the early years. When Professor Flannelly went on "Morning Ireland", she could not tell how many women were affected. I am not taking from her role and I know she did extraordinary work and started off all of this, but she did not know how many women were affected. There is a letter from July 2016 in which Professor Flannelly specifically pointed to non-disclosure to the families of deceased people. On the one hand we have a document released overnight and some people are taking it as gospel, while on the other hand we have historical references to a person whose contribution on "Morning Ireland" contributed considerably to the stress around this.

Chairman: Sorry Deputy O'Connell, Professor Flannelly is not here to defend herself. Keep that in mind.

Deputy Kate O'Connell: I will keep it as tidy as possible. Reference was made to scaremongering. The normal response from most women was one of terror that no one had read the smear, although it had been tested three years or two and a half years before. There was almost a perception that it was on a shelf somewhere and no one had looked at it. It is fine looking back at these things. Let us take ourselves back to where we were at this committee and at the Committee of Public Accounts. Many of those present were treated in an aggressive way. It was adversarial but that stemmed from our concerns about the system. We know the system has improved the lives of 65,000 people since it started. On the question of capacity, a comment was made that the Minister was not helpful in sourcing capacity. What is the evidence for that comment or can it be retracted?

Mr. Damien McCallion: I do not believe that we made that comment, in fairness.

Deputy Kate O'Connell: No, a member did. I am wondering where the evidence was for that comment was?

Deputy Kate O'Connell: The Minister is not here to defend himself either.

Mr. Damien McCallion: I did not pick up that comment from anyone.

Deputy Kate O'Connell: We can get it back on the audio and have it retracted next week.

Dr. Doherty referred to the HPV "reflex". Was that the word she used?

Dr. Lorraine Doherty: Yes.

Deputy Kate O'Connell: Can she elaborate on that? We are in cervical screening and are transitioning to HPV. If there is HPV reflex going on, would it be fair to say that we are in a transition period? I thought it was a move from "A" to "B" but it is really a transition.

Dr. Lorraine Doherty: What I mean by reflex testing is that under our current system of cervical screening, a woman has a smear taken upon which the first test is cytology. If there is any indication of any abnormality on her smear, she has a reflex HPV test. This test is to identify oncogenic types of HPV, particularly type 16 and 18, which are responsible for 70% of all cervical cancers. If a woman has change on her smear plus a positive reflex test, that highlights the fact that she needs to be prioritised for management and referral. That is what we mean by

reflex testing. It is a secondary test; it is not the primary screening test.

Deputy Kate O'Connell: It is on the same slide or product-----

Dr. Lorraine Doherty: Yes, but it is not the primary screening method. Cytology remains the primary screening method.

Deputy Kate O'Connell: When did the reflex test start? Has it always been in place?

Mr. Damien McCallion: No, it started in 2015. It has been a gradual transition, in the sense that we had pure cytology. Some jurisdictions did not introduce the reflex test but we have done that. As Dr. Doherty has said, the plan is to transition, where HPV becomes the primary screen and cytology becomes almost like a diagnostic on the HPV test.

Deputy Kate O'Connell: I get that Professor Flannelly is not here, but the Minister is also not here.

Another comment made earlier was that the clinical advice was not taken by the Minister and that this would harm women's health and undermine the screening programme. That is a fair charge coming out of this committee this morning because the sole focus here is getting this sorted for the future. We must move forward from where we are, where many of us are concerned about whether the entire system will collapse. The backlog issue is not great. As I pointed out in my initial contribution, we do not seem to be getting traction on the capacity issue. I am aware that other members have asked about this and I acknowledge that it is difficult to get timelines as to when we can eat into that backlog.

That is a major concern for us because, again, there have been a couple of comments that it could take ten years or so to get through this. If the progression of cervical cancer is three, six, and nine years that is then sending a message out of this committee that is incorrect, which will feed the scaremongering and the anxiety related to this issue.

Other contributions have been made about the Oireachtas having contributed to this issue. I believe the vast majority of Members were trying to get answers to try and improve the system.

As we move forward from today, the day of political point-scoring, and the historical look back at who did what and when, could leave us forever looking into this but to what end? At the end of the day, the point of this is to save lives, to ensure better outcomes for women and families, and to examine at the exposure of the open disclosure issue, which many obstetricians and gynaecologists here have dealt with in the past.

How do we eat into this backlog and hammer home the message that screening saves lives, improves outcomes in respect of fertility and improves people's life experiences; the healthy population is screened; women with symptoms move to a different phase and those at a higher risk move to a different area.? I do not want the message going out from this committee that there are 80,000 people who are likely to have cervical cancer sitting in a room. I understand, with reference to Dr. Henry, that this is not the truth. We do not want additional erosion of our screening and our engagement.

Mr. Damien McCallion: I want to reinforce the important point that while we all accept that it is not a good position to have women waiting on the results, the clinical risk is very, very low in this context. Equally, we are focused on trying to resolve the backlog so that people who are waiting - we have made some inroads but not enough - are addressed through the capacity

provision, and we will continue to look at all options as we get through this over the next while.

Chairman: One of the benefits of the screening programme was that a woman got a result within four or five weeks-----

Mr. Damien McCallion: Originally.

Chairman: -----and that has broken down now. The risk is low but the reassurance is missing.

Mr. Damien McCallion: I want to be very clear that we fully recognise that and having talked to are own staff last week who man the information lines - the Chairman described it well himself earlier - women are anxious and worried. We are trying to address that as quickly as we can. We also have to ensure that we do that factually and can deliver on what we go back to them with and not give them false assurance.

Deputy Kate O'Connell: Regarding information for women, the CervicalCheck leaflet was presented to the committee a year ago. Has any work been done on that? In the aftermath of this, many GPs did not understand or know the limitations of the test at 70% or 80%. There was the concern that they did not relay that to their patients in the correct way. I was not aware of the limitations. The leaflet presented to us was very wordy, and no one is going to engage with it. It was essentially not fit for purpose. If it was, there would not have been as much false or ambiguous information out there. What work has been done on that information going to a woman who is in the system perhaps a girl in her leaving certificate year, who has been through the HPV vaccination programme, and moving into the contraceptive period of life? How are we communicating in a better fashion compared to what was done prior to this crisis?

Ms Michele Tait: I thank the Deputy for a question. I agree and referred to this point earlier. As part of the scoping inquiry, Dr. Scally made a number of recommendations on the information we give to women and service users of the programme. One of the outputs from the work that he did was that we undertook a complete overhaul of all the information we provide to women and to other service users. I have the old leaflet and letter that we provided previously to patients with information about the screening programme. We now have a suite of information that patients get, depending on where that patient is, or if they are a healthcare provider and so on. All of that was done in consultation with patients who were affected directly by the issues that arose in 2018, and a wider pool of patients with whom we work closely on all of this.

The range of materials that we have produced are incredibly clear and unambiguous and they provide information to women in a way that identifies the limitations of screening. Nobody fully understood that. Looking at the "before" and "after" products, there is no comparison between the information sources. Online resources have been vastly improved. I mentioned earlier that since we put the new information online in September-October of last year, there has been 165,000 or more visits to that website. Feedback from patients we have received has been positive. This is something that we keep under review. This is not something that we have just done as a once-off exercise.

In the context of all the recommendations made by Dr. Scally in his report, this is significant work that is taking place, alongside everything else that we are trying to manage and all the challenges that my colleagues have described. We have to start looking to the future with all of this. A great volume of work has been done by us on the information leaflets to address the deficits that were in the type and volume of information we were giving to people, and much

other work is under way as well. All of this information is readily available on our website. Women will get information when they are called for screening. They will be given different information when they attend for their screening test. It is really good information. Part of the work we have done in recent months has been to engage significantly with Dr. Scally and his team in reviewing all of the information. He has given us some good feedback as to how we can make improvements. This is something we keep under review. We have already vastly improved the information we provide to women.

Deputy Bríd Smith: There is one question I omitted to ask. The section of the report dealing with the progress report on interval cancer audits indicates that the expert group is looking at processes that should work in the future. Is it not the case that, after the Vicky Phelan case last April, the internal audit was shut down and that, since then, between 250 and 300 women who were excluded from the group of 221 women who were affected initially - the 221 group - have been diagnosed with cervical cancer? In other words, these women's cases have not been audited and the women have not been given access to the care package which members of the 221 group received, yet it is likely that they have a smear history because the smear test programme was in operation for 11 years. Was the audit shut down to keep the figure at 221 and stop it growing? Is the HSE not deliberately denying women access to the full healthcare package and to an audit, which would allow them to look at their history in the context of what happened to others? Given the law of averages, there could be 50 to 60 women out there who are dying of, or at the very least suffering from, cervical cancer who may have fallen into the 221 category were they not shut out because the HSE closed the audit and did not replace it. Nobody ever said there was a problem with the audit. The way in which the audit was carried out seemed perfectly fine. The problem was that patients were not told about the results. The HSE shut down the audit and is looking at a new type of audit but in the meantime a whole cohort is being excluded. Do the witnesses acknowledge that is the case?

Mr. Damien McCallion: I will respond to the first question and will then ask Dr. Henry to speak. The issue of women who had cancer who were outside the original audit is being addressed through the review being carried out by the Royal College of Obstetricians and Gynaecologists. The outcome of that review will determine what needs to be put in place for those people.

Deputy Bríd Smith: That review has been delayed repeatedly.

Mr. Damien McCallion: I appreciate that; I am just identifying the position regarding that group. I will ask Dr. Henry to talk about the interval cancer audit group and why it is needed. Dr. Scally made the point that there were issues with the audit. I will ask Dr. Henry to expand on that.

Dr. Colm Henry: I cannot remember Dr. Scally's exact words but he characterised this audit as flawed in terms of its design and implementation. It is easy to forget that there was not only a failure to disclose information, which the Deputy pointed out, but that the design and implementation of the audit were also found to be faulty. It was also incomplete in that it did not include patients who were characterised as having cancer on the National Cancer Registry Ireland, NCRI. There has been much discussion about quality assurance this morning and in other fora. Auditing interval cancers is but one component of quality assurance. Quality assurance in any programme looks at its whole scope, range and pathway of care, from the credentials of the laboratories to smear-taking to communication with women. It looks at the whole range. One other component involves looking at interval cancers in order to learn from what is found. With regard to this programme and other screening programmes, there is very little

information internationally as to how open disclosure of interval cancers should be dealt with. After the Scally report came out, we undertook to examine all three cancer programmes and design a way to look at interval cancers in those screening programmes, bearing in mind that we all want screening to flourish and thrive and for women to have confidence and partake in the programmes. We sought the best international advice and the best expert advice available here in Ireland as to how we should deal with interval cancers, whether in respect of breast, bowel or cervical cancer. That working is ongoing. It is led by Professor Susan O'Reilly who previously headed the national cancer control programme, NCCP. We hope to see the outcome of that work in the summer.

Deputy Bríd Smith: We are still talking about a cohort of women who were excluded from an audit and who are likely to have a screening history that should be examined. What is the answer to them? They are being excluded from a group that has access to a certain healthcare package which, in the case of Vicky Phelan in particular, is proving to be excellent. It is disgraceful that these women are being excluded from that group. If they have been diagnosed but have not had their case audited, they should be included in the group.

I want to take up Dr. Henry's point about it being difficult to know how to inform patients of results. I am told that there is a step-by-step guide available on the NHS website. I have not looked at it, but I believe it is very good and substantial. What is the problem other than the fact that the audit was shut down to exclude other women and stop the number growing from 221 to 421 or 491? If that is the truth, as increasingly appears to be the case, it is disgraceful, particularly when the HSE reports that it is sitting down with committees and groups to determine the best type of audit. There has been no proper audit of these women's screening history.

Dr. Colm Henry: My understanding is that the package provided to the 221 group was given in recognition of the fact that there had been a failure of open disclosure of the audit to those women. To return to my point, the audit was not paused to deny anybody else access to those supports but because there were faults in its design and implementation and it was incomplete. That is why it was paused. The Deputy references-----

Deputy Bríd Smith: It has been paused for a whole year.

Dr. Colm Henry: May I finish the point? With regard to England and Wales, the Deputy is absolutely correct that Public Health England has had guidance in place with regard to the communication of interval cancers since 2016. Cancer programmes in other healthcare systems, including those of Germany, France and Australia, have no active policy on open disclosure in respect of interval cancers because they are population screening programmes. There is a variation of opinion on this issue internationally. We want to design something which will enjoy public confidence and also allow the screening programmes to thrive.

Deputy Bríd Smith: I contend that, in not having an audit in place that will sufficiently address their concerns about their screening history, the HSE is doing a big disservice to a cohort of women who are suffering. The only conclusion I can make from the failure to have such an audit in place is that the HSE does not want that figure to grow. If that is the case, it is another example of a lack of open disclosure.

Dr. Colm Henry: We have actively included patient representation in the group looking at interval cancers which I have described. Those patients are contributing to that work and they understand, as do we and the Deputy, the importance of public confidence in the screening programmes. That involves public participation and quality assurance across the whole range

of screening activity.

Deputy Bríd Smith: I understand that but, in its report, the HSE states it has established an independently chaired group made up of clinicians, patient representatives, public health professionals and representatives of medical bodies which has met four times to date. This was a whole year ago. Between 250 and 300 women have been diagnosed with cervical cancer since then. If I was one of them, I would feel let down by the State, the system, the HSE and everybody concerned on the basis that no audit of my screening history is available to me. There have been four meetings over a year to decide with what that audit system is to be replaced. It is not acceptable.

Mr. Damien McCallion: Those groups were only created on the back of Dr. Scally's report, so they have only been in place for a matter of months. They were deliberately set up-----

Deputy Bríd Smith: It is still not acceptable.

Mr. Damien McCallion: We must make sure we get it right.

Deputy Bríd Smith: The HSE cannot reinvent the wheel. The representatives keep making reference to other systems and other countries such as Australia. It should look at their models and adopt one of them.

Mr. Damien McCallion: That is what we are doing.

Deputy Bríd Smith: It should at least reopen the audit it had because it served some purpose.

Mr. Damien McCallion: It was flawed, however. Dr. Scally was very clear about that.

Deputy Bríd Smith: The lack of open disclosure was the flaw, not the audit itself.

Mr. Damien McCallion: Dr. Scally said the audit was flawed.

Chairman: Audit is obviously carried out for quality assurance purposes. It is done to see if the system is working. Is there a place for anonymised audit as opposed to a named audit in which people are identified? Would the former be easier to manage? Would it provide the same information in respect of quality?

Dr. Colm Henry: Other healthcare systems make use of anonymised audits. While it is very difficult for us to look at this through the prism of our experience over the past year, other healthcare systems which did not have that experience consider screening to be outside the expectations of a diagnostic pathway. Audits of interval cancers are carried out in some systems, but they are anonymised because the primary purpose of the audit is to inform the quality of the programme.

Chairman: Is that system better or worse? It was the failure of the named audit here which led to the controversy. The purpose of audit is to inform quality. No screening service is 100% accurate. Unfortunately, a number of people will always be missed. Obviously the system is working if one compares the 65,000 people who have benefited with the 221 who had their smear upgraded on the audit - or 1,800 as the case may be. The audit is to learn from that rather than being an adversarial system.

Dr. Colm Henry: That is correct. We heard today, as well as from other useful discussions

in other fora, about expectations concerning screening programmes. They are not set up or designed to diagnose all cancers. Part of the relative risks and benefits of a screening programme is that one is persuading healthy people to undergo a test to identify something before a serious intervention is required or a life-threatening illness develops. In doing so, the test cannot be overly sensitive in that it will then subject many people to unnecessary tests, investigations and possibly adverse events.

Our group will be comparing other systems and examining the relative need to allow a screening programme to thrive and flourish with the expectations people have regarding cancer audits as part of the quality assurance programme and what they need to be told. It is not an easy question. Other healthcare systems are facing the same question and are looking at great interest at the problems we are facing. There is no easy answer to this.

Deputy Kate O'Connell: My understanding is that the trigger for audit was having cancer. Then we were missing a chunk of people on the national cancer registry but we are sorting that out. On the one hand, we have people talking about populism and scaremongering and then contributing to it. I feel strongly about dealing with this situation in order that, ultimately, lives are saved and outcomes are better for women and their families.

The audit was flawed in its essence in that, from my recollection from the committee, nobody ever considered what to do with the audit results. The audit process identified the 221 women who then received a package based on non-open disclosure. However, falling within the acceptable parameters of testing the 70% to 80%, have we no evidence to date that any lab was underperforming?

Mr. Damien McCallion: On the laboratory aspect, Dr. Scally's report stipulated and he was clear that there was no reason we would not renew the contracts to ensure continuity of the programme. At the end of last October, if we could not renew the contracts, we would not have had a programme. He made his decision independently of that and then we moved forward. Obviously, we still face some challenges.

Deputy Bríd Smith: I want to correct the record. Dr. Scally said to me that we had no other choice but to renew the contracts. He still had many doubts about the quality of the performance of the labs.

Mr. Damien McCallion: All I can say from my discussions with him is there were areas where he identified clear scope for improvement both within the programme and laboratories. What he said was that, in terms of parameters for performance within the laboratories – we had this direct conversation and it is in his report specifically - there was no reason not to do that. That does not mean there are not things we need to tackle like there are with any provider both on our side in terms of CervicalCheck and also within the laboratories themselves.

Deputy Kate O'Connell: With ISO accreditation and the American labs, are there internal audit processes and quality assurance procedures to ensure they fall within the correct parameters?

Mr. Damien McCallion: Yes. All laboratories have an accreditation standard and their own quality assurance. We have a level of quality assurance which is fairly standard. As Dr. Lorraine Doherty identified earlier, our new pathology lead is updating that standard to strengthen it.

Dr. Scally is doing a follow-up report on laboratories. It does not mean that there are not is-

sues that we need to tackle, as there would be with all laboratories on an ongoing basis. We will continue to do that and work closely with Dr. Scally and his team on it. We met them last week.

Deputy Kate O'Connell: Regarding the halting or pausing of the audit process, is it correct that it is not true to say that people have been left out or there has been a shutdown? We do not want the message going out that, for some reason, there are people not getting treatment because of the audit process status.

Deputy Bríd Smith: It is because of the lack of audit, not because of it.

Mr. Damien McCallion: There is no impact on people's care. I accept Deputy Bríd Smith's point that we need to get to a point where we have a defined audit process. The Deputy described a range of options in different jurisdictions. The point of an expert group with patients, professionals and providers involved at the heart of it is to ensure we come up with a model for all that will work for the cancer screening programme but also for the persons themselves. We need to do that expeditiously. That was put in place in December following Dr. Scally's review. It has met on several occasions already.

Chairman: Is it correct that a significant number of the 221 cases have had their cancer successfully treated and are not in a situation where their cancer is untreatable?

Dr. Colm Henry: In collaboration with the 221 group, an audit was carried out. I cannot recall the exact figure but I believe 179 are considered disease-free. I will send the committee further information.

Mr. Damien McCallion: The report was circulated to the committee. We did an update on the condition for the 221 group which we provided to it and then circulated it to others. I have met with many of the group. That is not to say that many people do not face emotional, psychological and other impacts from their cancer. If one puts 221 women and their families into a room – remembering some of them are deceased – the impact of cervical cancer is stark, irrespective of anything to do with audits and the impacts on people. We recognise that. The report set out the clinical condition for people. That was published in conjunction with the 221 group.

Chairman: I thank the witnesses. We have been here four hours and it is time to conclude. I thank the witnesses for providing the committee with an update on the backlog which will hopefully be cleared in the not-too-distant future.

The joint committee adjourned at 1.07 p.m. until 9.30 a.m. on Wednesday, 8 May 2019.