DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE

JOINT COMMITTEE ON HEALTH

Dé Céadaoin, 10 Deireadh Fómhair 2018

Wednesday, 10 October 2018

The Joint Committee met at 9 a.m.

MEMBERS PRESENT:

Deputy Bernard J. Durkan,	Senator Colm Burke,
Deputy Alan Kelly,	Senator John Dolan,
Deputy Margaret Murphy O'Mahony,	Senator Keith Swanick.
Deputy Kate O'Connell,	
Deputy Louise O'Reilly,	

DEPUTY MICHAEL HARTY IN THE CHAIR.

Business of Joint Committee

Deputy Alan Kelly: Given the day that is in it, I propose that we have a minute's silence in acknowledgement of Emma Mhic Mhathúna whose funeral takes place today. Being the Oireachtas Joint Committee on Health it would be appropriate to do so.

Chairman: And also for the other women who died and did not go public.

Senator John Dolan: And for those who are on the way.

Deputy Alan Kelly: It is for the two women, in particular, the second of whom chose not to go public. We should acknowledge them today.

Chairman: We will now have a minute's silence.

Members rose.

Chairman: I thank members for showing due recognition of the women who have been affected by the controversy.

Scoping Inquiry into the CervicalCheck Screening Programme: Discussion

Chairman: This morning we will hear from Dr. Gabriel Scally and Dr. Karin Denton on the report on the scoping inquiry into the CervicalCheck screening programme which was published last month. On behalf of the joint committee, I welcome Dr. Scally and Dr. Denton to give their evidence.

By virtue of section 17(2)(*l*) of the Defamation Act 2009, witnesses are protected by absolute privilege in respect of their evidence to the committee. However, if they are directed by it to cease giving evidence on a particular matter and continue to so do, 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 entity by name or in such a way as to make him, her or it identifiable. I also advise that any opening statement submitted 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 Houses or an official, either by name or in such a way as to make him or her identifiable.

Deputy Stephen S. Donnelly is unable to attend the meeting because he is unwell. He has passed on his apologies.

Perhaps I might open the proceedings by asking Dr. Scally a number of questions. If a screening programme such as CervicalCheck is to have unavoidable false negatives reported, as is the case with all screening programmes, how can it be managed fairly and effectively without recourse to adversarial legal proceedings? Will Dr. Scally address the issue of the failure to openly disclose the audit findings as soon as they became known? Perhaps he might also expand on his statement that a commission of inquiry was not the best way to proceed.

Deputy Bernard J. Durkan: I do not want to disrupt the meeting, but it may be more appropriate for Dr. Scally to make an opening statement.

Chairman: My apologies. Dr. Scally told me that he did not have an opening statement but did want to make some opening remarks. I invite him to do so.

Dr. Gabriel Scally: I add my regrets on the deaths of the two women at the weekend. It was a timely reminder of the seriousness of the problem of cervical cancer and that one of the tasks arising was to try to ensure it would become an increasingly rare event in the next decade or two. We will I hope not see such deaths again in our lifetimes. There is the possibility that cervical cancer will be turned into an extremely rare disease. I am saddened by the deaths of the two women.

It was a great honour to undertake this piece of work and a great privilege to meet many of the women affected and talk to them in person, on the telephone and at meetings, as well as to talk to the relatives of those who had passed on. I took great encouragement from their help and support and what they told me, often in frank terms, about their illness and experiences which I have done my best to fully reflect in the report.

I apologise to the joint committee and the Oireachtas for taking so long to deliver my report. My terms of reference were specific about when it should have been delivered and I failed in that regard. I hope I did not fail in too many respects, but I fully admit that I failed in that regard, for which I apologise. As the committee will understand, the delay was caused by the extremely poor provision of information in response to our queries and requests for information. It took a long time to get the information. Certainly, it was still appearing within a week or ten days of finalisation of the report. However, I am pleased to say we received all of the information we had requested, without redactions. We had interesting discussions about it and are unaware of any document that was withheld that we should have seen. I am satisfied that we had an adequate opportunity to go through the information with which we had been provided. I apologise again for taking so long.

I also apologise for not completing the job. Late in the day, thanks to the efforts of Dr. Denton and others, through our inquiries, we discovered that there were serious issues arising about the laboratories to which the slides of Irish women had been sent. By the end of the inquiry we were unable to complete our inquiries into that and other matters pertaining to the contracts and the process of tendering. We suggested there was further work we could do in the near future and the Minister has so agreed. I hope we will finish work on these important matters satisfactorily within a short time.

The Chairman asked three questions.

Chairman: I am sorry for jumping in ahead of Dr. Scally. The first question was about screening programmes in general which inherently have the reporting of false negatives built into them. How can they be managed fairly and effectively without recourse to an adversarial legal process? Will Dr. Scally address the issue of the failure to openly disclose the audit findings as soon as they became available. He also suggested a commission of inquiry was not the best way forward. He might comment on that suggestion.

Dr. Gabriel Scally: They are important questions which I will deal with in order.

Screening programmes are unusual in the healthcare world because, unlike most healthcare issues, it is not a question of someone who is unwell or feels unwell coming forward to seek

help from the health service. Screening programmes are the health service asking people, on behalf of the State, to come forward. This places increased responsibility on the health service to ensure the programmes are well run and organised. That applies across the screening agenda, whether it be for colonic cancer, breast cancer or cervical cancer. Screening programmes are different in that way. They are also different in that there is a balance to be struck between benefit and disbenefit in screening. Breast screening is a good example because the active screening process exposes and has exposed some women to small levels of radiation which irradiate them. That was certainly the case pre-digital mammography. The benefit is that cancers will be detected early. The benefit outweighs the disbenefit in a well run and well organised screening programme. It it exactly the same with cervical screening. A well run cervical screening programme should prevent up to 75% of cervical cancers or detect them at an early enough stage to allow effective treatment.

Along the way there is the issue of what happens when the screening slides do not reveal the cancer or the pre-cancerous changes. That could occur for three reasons. Even though the woman has an abnormality, no cells may be present in the slide, so the finding will be that the cells are normal and there is no problem. Alternatively, cells may be present but the persons who are reading the slide, which are generally dealt with by more than one cyto-screener, may not spot an abnormality. That may be for one or two reasons. It may not be very distinct or it may be a matter of judgment and their judgment is that there is nothing significant. Alternatively, it could be a very plain error where there are sufficient signs of abnormality but the person misses it.

I think a mechanism should be put in place to compensate a person due to an error which has potentially serious consequences. It should be done in such a way as to avoid adversarial proceedings and there should be a system in place to cover, I would argue, all the screening programmes, and immunisation should be dealt with in that way. In the UK, there is a system in place for immunisation where the Government has dispersed a very sizeable sum of money in compensation to a very small number of people who may be adversely affected by immunisation. That is in recognition of the fact that immunisation happens for the benefit of everyone but some people have, for whatever reason, an extreme reaction where that has resulted in disability to a certain level and there is an expert view that it cannot be ruled out that it was caused by immunisation, and so compensation may be awarded. A similar scheme would be appropriate in the case of screening. We ask people to come to us to have testing done. If they are failed by that through genuine error, there should be a mechanism to deal with that. I hope that Mr. Justice Charles Meenan will consider that but it is outside the remit of our report.

With regard to open disclosure, if one goes back to the review of slides and the way it was conducted, it was initially conceived of as an educational process for the laboratories. When CervicalCheck knew about cases of cervical cancer, remembering that it did not know about all cases, it sent a notification to the laboratories involved and those laboratories generally reviewed the slides. In some cases, particularly those we are interested in, they had an alternative reading of that slide which indicated that there were changes visible that would have indicated a change in treatment. The process was not designed to generate information to go back to CervicalCheck in particular. It was meant for use by the laboratories themselves, for their own educational purposes about the performance of the laboratory and its staff. Although a copy of the report came back, those were not aggregated or passed on to anyone. There was a decision to put those in a structured and ordered fashion and gather that information.

That decision came about at a time when the Health Service Executive implemented its open

disclosure policy. A member of staff heard about it entirely fortuitously because that member of staff had been working in a hospital and still received some emails from that hospital, then received an email with an invitation to a meeting about open disclosure. This person came back to CervicalCheck and said there was a new thing called open disclosure and that it needed to take it into account in what it was doing. That is how open disclosure started to happen within CervicalCheck. We know it was not done at all well. As I made abundantly clear in the report, I find the open disclosure policy and guidelines that were in operation seriously deficient. They were not so much open disclosure guidelines as a policy where clinicians were encouraged to disclose if they wanted to. The guidelines gave them every chance of not disclosing and made it really easy for them not to disclose. It was not really open disclosure at all. That is why my recommendations are very plain and simple about open disclosure, particularly that there should be a statutory requirement for disclosure.

On the commission of inquiry, as the Chair correctly pointed out, it was not one of my recommendations, though it was my view. My view is that we were fortunate enough, partly because of the increased timespan that we had, to be able to deal with a substantial number of the issues in substantial depth. I was very cognisant of the view that had been expressed to me by quite a few of the women and relatives, that a major concern was to make sure that the screening service was fit and safe for their daughters and nieces in the future. Such was the range of deficiencies that I identified that I made recommendations across that wide range to put the system right. I feared that, if there was a move straightaway to a commission of inquiry, it would further delay the implementation of the recommendations and it would distract the system and the HSE in particular from getting on with doing what they should be doing. As I said in my foreword, that was my personal view rather than a recommendation. I would not have made it a recommendation because I would have been usurping the right of the Oireachtas to make that decision for itself and I have no business making a recommendation to the Oireachtas. It is perfectly capable of making that decision for itself.

Chairman: I thank Dr. Scally. I will introduce the members of the committee. Is Deputy O'Reilly ready or does she want to settle for a minute?

Deputy Louise O'Reilly: That is all right, Chair.

Chairman: We will go, for seven minutes, to Deputy Alan Kelly.

Deputy Alan Kelly: The same seven minutes the Chair had. Sorry, that was just a bit of a joke. I welcome the witnesses and thank them for their work. I was embarrassed that they felt they needed to apologise about timelines in the beginning. Their work is excellent. It is one of the best reports we have seen in these Houses in my time, especially one delivered in a short time. I have many questions but will prioritise them. Some of the questions relate to the report and I have discussed that already. I will not go over them because the witnesses have been quite accessible. I have questions about the future and where we need to go.

The most important thing related to the report is that the recommendations are implemented as soon as possible. We should work from that baseline and take that as our priority. Everything else is subsequent to that. It should be all about protecting this generation and future generations. That is what the women who are affected, their families and patient advocates have as a priority too. I have spoken to them numerous times.

I want to drill into the terms of reference the witnesses were given, which are partly our fault as legislators. There is a lot of commentary on this issue. Journalists and politicians need to be

careful sometimes about the language they use because language is very important here. Sometimes there has been a use of language which was not necessarily accurate. Dr. Scally was not asked as part of the terms of reference to go in and investigate what happened in the 221 cases, as regards the laboratories themselves. I believe that is something we probably left out. I am not sure if he would have been able to do that anyway from a timeline point of view, but that did not happen. I am aware there is an ongoing review by the Royal College of Obstetricians and Gynaecologists, RCOG, but let us be clear, the investigation of the laboratories and the 221 cases, or whatever the number is - I think it is slightly more - was not part of remit.

In particular when we outsource such work, and also when we insource, contracts are in place and reviews are built in as part of that. There would be built-in reviews as part of these contracts using organisations such as HIQA. When the HSE became aware of issues, why did it not drill down into what was happening and investigate each of the cases? Why did it not happen? Will it ever happen? Will we ever find out what happened in each individual case? Will we drill into the detail of each individual case as regards the people who were looking at the slides, the fact that they were misread and that the information was not brought to the attention of management? Why did that not happen? According to the contracts which I have looked at, there were meant to be regular inspections but they did not happen. There were five inspections over eight years. Issues did arise in the inspections but they were not followed up. That was a failure. Why did that not happen?

I am sorry for asking all these questions. No inspection has been carried out since 2014. Is that acceptable? On the errors, probably the most important finding was that the laboratories appear to be statistically in line with international norms in their findings, but how do we know that is corroborated in the 221 cases by follow-up investigations in the individual cases? Does Dr. Scally follow what I am saying?

Dr. Gabriel Scally: I do.

Deputy Alan Kelly: Dr. Scally could not get into that detail. We have a view that the laboratories are in line with international standards but we do not have proof of that in the 221 cases. Why do we have a scenario whereby this was not investigated at the time given the consequences of that, which we all know about today? That is my first group of questions. I will list the other questions because the Chair will stop me otherwise. I will not get an opportunity to speak for another hour and a bit. I will quickly ask my second question.

Dr. Gabriel Scally: Was that one question?

Deputy Alan Kelly: Yes, with four components. Dare I say, it is probably-----

Chairman: Deputy Kelly has one minute left.

Deputy Alan Kelly: -----the most important question. Is Dr. Scally absolutely certain he has got all of the information?

Dr. Gabriel Scally: Yes.

Deputy Alan Kelly: I mean all of the information. I noted that Dr. Scally said in his introduction that he is unaware of any further documents or information. That does not mean they do not exist.

I helped to provide the colposcopists' minutes to the committee once upon a time and I still

read them. We need to have a process to deal with accountability within the HSE as regards the screening programme and who was in charge. I would like to hear Dr. Scally's comments on that. We need somebody who will be a management person with responsibility for screening, which is a role that does not fully exist at the moment.

For the public, the most amazing revelation was how some clinicians were behaving in terms of how they were communicating the information. In what forum can the matter be pursued in order to lance that boil, because the public need it lanced? It was a watershed moment in Irish healthcare, as regards the clinician-patient relationship. They are my three areas of questions.

Dr. Gabriel Scally: Perhaps Dr. Denton could help me out with the slides. She has been assisting to some extent with putting together the RCOG review. Deputy Kelly's questions are very apposite. He hinted there may be more than the 221 cases that have been identified. I think that is likely. We must go back to the way this review was run. It was entirely unsatisfactory in that they only looked at the cases of cervical cancer that they knew about, so they did not get a full data set, as happens with breast cancer, of all the cervical cancers from the cancer registry, which is the most complete register. They ran an alternative register of their own and the only cases they knew about were the ones they heard about or were notified within the screening service. That is not a good basis for a review, and it does not give one the kind of population data that would allow one to say how many cases of slides being wrongly or differently interpreted post a diagnosis of cervical cancer there were over the entire cervical cancer programmes in the country. There was a really big flaw at the beginning in terms of the design of the review.

In terms of us having the ability to go and look at those slides, first, what-----

Deputy Alan Kelly: There was a misconception about what was happening.

Dr. Gabriel Scally: Even the way in which the reviews that CervicalCheck asked for, which resulted in all the information that has been so contentious, was deficient as well because they left it very much to the laboratories themselves to decide how to review those slides, so we are entirely dependent on how they conducted that. I tried to explain as best I could the problem of review bias. If a very experienced cytologist is presented with a slide to look at from someone they know has got cervical cancer, he or she will spend a lot more time and attention to it and find more things than would be found by a cervical screener looking at the slide within a fixed time span within a whole batch of slides. If one subjects slides to that degree of scrutiny one would almost inevitably end up with more abnormalities detected. I will let Dr. Denton deal with that. It is really difficult then to go back and review what happened under exactly the same circumstances.

The RCOG review is as close as we are going to get to that fully objective analysis of the slides. It may yet take some time and they may not get permission from all of the women to look at their slides.

Deputy Alan Kelly: My question is based on the issue being bigger than the slides. Why was an investigation not done at the time when they knew there were issues? That would happen under any contract in any piece of work.

Dr. Gabriel Scally: Sure. I do not think they were surprised that there were issues and that there were cases where a re-look at slides produced a different interpretation because of the nature of the screening test, given that there are false negatives. They would not have been surprised about that. We must remember that for all that it was badly done, it was an unusual

initiative in the screening world to do that and they must get a modicum of credit for having decided to look back, even if that look-back was done very badly.

Deputy Alan Kelly: I agree with that.

Dr. Gabriel Scally: Deputy Kelly asked about quality assurance, QA. I completely agree. I find the whole approach to QA extraordinarily unsatisfactory. Screening services are absolutely dependent upon a very tight QA process because of the balance between benefit and harm.

Deputy Alan Kelly: Dr. Scally is saying that QA is, frankly, non-existent.

Dr. Gabriel Scally: If we did not have such a process, the Deputy would not be far off the mark. There was no QA visit from 2014, though I do not know if that is worse than having a QA visit and then not following up on its findings. In the context of the internal workings of CervicalCheck, the QA committee met regularly and had an external chair but the committee was almost blindsided by the review, which came to be known as an audit in later days. There were seven iterations of the protocol for conducting the review and none of them was particularly satisfactory. They were never reviewed by the QA committee so not only was there an external deficiency in QA in terms of the laboratory service providers, there was a deficiency in the functioning of QA within CervicalCheck.

There was but one meeting of the medical advisory committee in ten years. No cytopathologist was employed in the programme but cytopathology is the base science for this. There were serious deficiencies in staffing at all levels. Dr. Denton may wish to speak about the 221 women and the look-back issues.

Dr. Karin Denton: The direct answer to the question about the 221 women is that we were not able to look into them in any more detail. We found some documentation about the CervicalCheck executive management team's response to some of the earlier findings of the audit in 2015, when it wrote to one of the laboratory providers with queries about recurring patterns which seemed to have been detected. We covered this in our report but, again, it was not followed through on. They said it would be followed through in the QA visit but that did not happen. There was some attempt to look at some of the 221 women but there was no collation or pulling together of audit results. In this respect there was nothing for us to look at or try to break down.

The review of the Royal College of Obstetricians and Gynaecologists will be helpful, although it may well be that a number of women will not give their consent to participate, thus limiting its findings.

Dr. Gabriel Scally: The minutes of the colposcopists meeting were very helpful. My comment also applies to the medical advisory committee but that was the only meeting of the lead colposcopists in the ten years of the existence of CervicalCheck. There was an annual educational meeting for the colposcopy community but otherwise this was the only one. Colposcopists did not feel part of CervicalCheck, even though CervicalCheck funded them via the hospitals and they often worked in clinics with CervicalCheck branding on them. They were given no role or input into the development of the review or any of its seven iterations and they felt quite alienated from the whole organisation. They did not like the idea that they were expected to talk to women about their results and this did not go well. Some behaviour was terrible and this was front and centre in my report. These attitudes have no place in medicine and it would make any doctor ashamed to hear the comments. On the other hand, some disclosure was done

well. As I said, open disclosure can be done well and this was the case in the Wexford incident, something the external review noted. It was not as if it could not be done well but in a lot of cases it was not.

We can change the culture by working through the colleges, some of which are very interested in making a shift. It is not, however, sufficient. The Medical Council wants to make a shift but I am clear, also, that that is not sufficient. I would look to the Oireachtas for a solution, in particular in the Patient Safety Bill 2018, and to make it clear that open disclosure is not optional. The policy has, so far, made it entirely optional and up to the doctor but it must no longer be optional. I hope there will be a legal requirement on professionals to be honest and truthful to patients.

Deputy Alan Kelly: There was a short question on co-operation and Mr Scally said he was unaware of other documents.

Dr. Gabriel Scally: There are documents we would like to have around the contracting and we would like to see the original tenders.

Deputy Alan Kelly: Does Dr. Scally's team not have them?

Dr. Gabriel Scally: No.

Deputy Alan Kelly: Why not?

Dr. Gabriel Scally: In an unusual exhibition of efficiency, in keeping with policy they were shredded after ten years. The only example of efficiency I came across was in this area of document management. We will, however, hunt the contracts and tenders from the organisations which submitted them. There is more to be done and I am not at all content with the accreditation issues or with the fact that slides were sent to multiple places. I am still after some information because they have not yet been able to provide us with proper information on these matters.

Deputy Louise O'Reilly: Dr. Scally talked about open disclosure and the need for legislative underpinning. I absolutely welcome that. People had the opportunity to vote for that twice in the recent past. They did not do so but the unfortunate events we are discussing will, I hope, put a bit of focus on open disclosure. It is regrettable that it will take legislative underpinning to make it happen but if it does, that is fair enough. There were descriptions of a paternalistic attitude in how the women were spoken to, which takes away from much of the good work done in the health service. I would love to be in a position to say I was wildly shocked by this attitude but, as a woman who uses the health service, I was not shocked. Is Dr. Scally confident that we can address that situation and change it?

I remember that the decision taken to outsource services was purely political and no clinician advised that outsourcing should happen. When the then Minister was questioned about it she said it was good value for money but nobody ever said there was a good, sound, clinical reason for it. It was outsourced and then re-outsourced. Dr. Scally talked about the medical advisory committee not meeting. He expressed surprise at the level of quality assurance and said it was not in line with best international practice. Presumably, according to best international practice the person in charge would have sight or knowledge of the slide and would know where it was. Slides appear to have been sent to one site in the United States and then outsourced to another site. Honolulu is more widely recognised as a holiday destination than a centre of excellence for medicine or laboratories. How can Dr. Scally and members have confidence that everything was in order when the laboratory there does not apply the ISO standard which

I understand to be a benchmark and we do not know how many tests were outsourced to it? Members have asked that question on several occasions. The first time it was put to representatives of the HSE was at a Wednesday meeting of this committee, and the impression was given that we would have the results by the following Friday and that it was simply a case of someone in the HSE pressing a button to give us the breakdown of which labs were doing what. We still do not have that information.

While the average standard in the laboratories may be acceptable, some of the labs could be out of line. We have no way of knowing whether the lab in Honolulu was out of line with what is considered international best practice or international norms. Has Dr. Scally tried to ascertain the figures on what slides went where, who looked at them and whether there were any outliers in that regard? We have asked for that information but, unfortunately, we have not been given it. We want a detailed lab-by-lab breakdown which we can examine. I am not comfortable relying on averages. As a colleague of mine used to say, if a person has one foot in a bucket of boiling water and the other in a bucket of ice, the person's two feet are wrecked but, on average, the temperature is fine. Averages do not tell us anything. We are seeking a detailed breakdown for each lab. Is it possible for Dr. Scally to obtain that?

On contract governance and the shredding of contracts after ten years, I too was quite taken by the efficiency with which that was done. As one quite familiar with the HSE, I can state that it does not have a reputation for being hugely efficient. However, it certainly was efficient in this aspect. Is it possible to get copies of the contracts from the laboratories in the United States? The contracts could be examined in regard to the re-outsourcing. I am concerned that, while there does not appear to have been a very deep and meaningful relationship with the contracted labs in the US, there was no relationship with the labs to which the tests were subsequently outsourced.

Dr. Gabriel Scally: Dr. Denton will answer some of the queries on the laboratories. It is a complex area but we will be pursuing precisely the sort of information the Deputy is seeking.

Deputy Louise O'Reilly: In the absence of that information, is it not somewhat premature to express confidence in the process?

Dr. Gabriel Scally: That provider has not provided screening services for some time. CPL last provided such services in 2013. We have no evidence thus far of similar behaviour by other companies, but we will pursue that. The questions must be answered as far as CPL is concerned.

Deputy Louise O'Reilly: Until 2013, there was no evidence that CPL was outsourcing, but it was. There is a lot we do not know.

Dr. Karin Denton: Up to 2013, no one in Ireland had evidence that CPL was outsourcing. Similarly, a quality assurance visit in 2014 by Irish staff to the premises in Austin did not reveal any such evidence. We do not know if that was because the outsourcing was not disclosed to them or for other reasons. When I went to the laboratory with two of my colleagues, we asked a direct question on the matter and got the partial answer that CPL was unable to give us exact numbers but may have sent some tests to Florida and Honolulu. Subsequently, it turned out that CPL had a record of exactly how many samples were sent to those laboratories, which it later gave to us. Our repeated experience has been that one gets a partial answer to a direct question and that while there are accurate data, they have sometimes been quite difficult to get.

We are going back in a couple of weeks to try to establish what the Deputy is seeking, namely, the exact number of samples that were subcontracted to laboratories and the locations of those laboratories. Many of the labs to which the tests were subcontracted no longer exist and many were very small. We cannot carry out a full review of the level of the services in such locations because the labs are no longer there.

Dr. Gabriel Scally: There is added complexity because in some cases the first screen of a slide was carried out in one laboratory and the second in another.

Dr. Karin Denton: Yes. The definition of "laboratory" is not what one might think. It turns out that screening could be carried out first by a person in a facility which also provided services such as blood tests or histology results and then by a pathologist located elsewhere. We have further inquiries to make regarding the governance and accreditation of all of these services.

Deputy Louise O'Reilly: None of those inquiries was made by the CervicalCheck service or the HSE. There is no documentary evidence that anyone asked a direct question, even if they were only getting a partial answer.

Dr. Gabriel Scally: We are quite convinced of that because when we learned of this, we kept it to ourselves and first discussed it face to face with HSE staff. It was clear from their reaction that this came as a complete shock to them. It is extraordinarily disappointing on several grounds. However, I cannot stress enough that we will pursue the issue with the same rigour as we have displayed in the report and will provide members with as much information as we can obtain. I assure the Deputy of that.

The Deputy stated that she was slightly sorry that legislation for open disclosure will be required. I do not think she should be at all sorry. There is nothing wrong with legislating that patients should be told the truth. It is unfortunate that it has come to this-----

Deputy Louise O'Reilly: I was trying to say that I am sorry that legislation is required to force some clinicians and doctors to comply, which reflects poorly on them. However, if it is necessary, it should be done. I am also sorry that some Deputies voted against such legislation. However, they will probably vote in favour of it the next time it is brought forward, which is to be welcomed.

Dr. Gabriel Scally: Such legislation is to be welcomed not only because it will compel people to disclose, but also because it provides a protection for those who are aware of something that is going wrong to be able to tell their colleagues or bosses that they are legally required to disclose even if told not to do so. Such protection should not be underestimated.

The Deputy is quite right that changing the culture will be difficult. Many women who have been patients of or worked in the health service have stated that the observations of the women and relatives affected by this issue regarding the deeply unsatisfactory nature of some comments by doctors are not atypical of their personal experiences. Even women doctors working in obstetrics and gynaecology have stated that they have been the subject of paternalistic and unhelpful comments during their career. Robert Francis wrote in the report of the Mid Staffordshire inquiry that, "for all the fine words printed and spoken about candour, and willingness to remedy wrongs, there lurks within the system an institutional instinct which, under pressure, will prefer concealment, formulaic responses and avoidance of public criticism". That strikes me as being almost perfect.

Deputy Louise O'Reilly: It is quite succinct.

Dr. Gabriel Scally: I think the culture will change. I hope the change in the gender balance in medicine, which is coming through in force, will help to change that as women occupy more and more senior positions over the coming years. I think there is a job for the colleges and the Medical Council to do. I will be very pleased if the Oireachtas does its bit this time around.

Deputy Louise O'Reilly: I thank Dr. Scally.

Chairman: The Deputy also asked about the data coming from each laboratory. Was there a difference between one laboratory and another?

Dr. Gabriel Scally: Yes. In the appendix to the report, we have provided whatever details we can regarding the data from the laboratories. Deputy O'Reilly is quite right when she says that an average is only an average. Some 50% of laboratories will be above average and some 50% of them will be below average. It is a question of ascertaining the position in respect of the slides. One of the good things about contracting is that some of the quality standards that are demanded in Irish contracts are higher than the US standards. For example, there is a limit on the number of slides that screeners can look at. During her visits, Dr. Denton has been looking at the screener records to ensure they are accurate. We are very reliant on the information we are able to attain. As Dr. Denton has said, a couple of laboratories are gone.

Chairman: Was it an issue that some slides from colposcopy clinics were mixed with slides-----

Dr. Gabriel Scally: Yes, it was very unsatisfactory.

Dr. Karin Denton: I agree that there are problems with looking at averages, which is what the programme has tended to do. It appears superficially that there are differences in the rates of certain categorisations from the various laboratories. The problem is that these differences are very difficult to interpret. There could be perfectly legitimate reasons for them. One of the things that makes it particularly difficult to interpret the data that CervicalCheck has collected, and is still collecting, is that it includes samples taken from colposcopies, which tend to be taken from women who are already known to have abnormal smears. This increases the rate of abnormality significantly, which means that the proportion of the slides which come from colposcopy determines the abnormal rate for that laboratory. Obviously, this is not satisfactory. That is why it has been recommended that the data specification should be altered to exclude such samples. A number of recommendations were made about improving the quality and robustness of data to allow for links with other factors which we know to have an influence on the rate of abnormality. If all of those recommendations are implemented, they will give a CervicalCheck a toolbox for making meaningful comparisons between the laboratories. I feel that should be a priority. It might transpire that there are differences which require further investigation, and such investigation might or might not indicate that there is a problem. CervicalCheck cannot start to discuss or consider that until it has robust data to work from in the first place.

Chairman: I thank Dr. Denton.

Senator Colm Burke: I thank Dr. Scally and his team for a comprehensive report which deals very well with all of the issues. In fairness, a great deal of work was done in a very short period of time. I think everyone appreciates the work that has been done and the report that has been presented.

Dr. Gabriel Scally: I thank the Senator.

Senator Colm Burke: I would like to ask about cases in which clinicians who were dealing with people who had been identified as having cancer were aware that those people had received smear test results at an earlier stage. Did it occur to front-line staff that they should go back and look at the smears that had previously been taken? Did front-line staff raise concerns to the central management system of CervicalCheck at any stage? Dr. Scally said earlier that there seemed to be a disconnect between front-line people and central management. Did he conduct an examination to ascertain whether people who were involved in CervicalCheck on a front-line basis might have dropped out at an earlier stage because of their concerns about central management? Does any documentation indicate that concerns were raised at a far earlier stage, perhaps before the audit was done?

The second question I would like to ask relates to the number of cases covered by the audit. It was decided to do an audit. As I understand it, the front-line staff were not aware that the audit was being done. Why was that information kept from the people who were dealing with the patients? It was only at a later stage that they became aware of the audit and the results of the audit.

I would also like to ask about the period of time that elapsed between smears being done and people being identified with cancer. Were there some cases in which the all-clear was given six or 12 months earlier? We have heard about cases in which mistakes were made in the reading of smears not once but twice. Serious questions are raised when a patient's smear is misinterpreted on two occasions.

I would also like to raise with Dr. Scally the number of people we have in the country and the number of front-line clinicians here. I understand there are approximately 135 consultants in obstetrics and gynaecology in this country, even though all the reports indicate that we should have 180. Do we have a sufficient number of people working on the front line at the moment? If not, what would be a sufficient number, based on a comparison between the ratio in this country and the ratio in other countries? Should we have many more people with the requisite expertise dealing with this area? What do we need to do to get more people into this area? I am raising this aspect of the matter in the context of the need to provide a far more comprehensive service and ensure the same errors are not made again.

The final matter I would like to raise is the educational process. This will not give an exact result every time. Regardless of the system that is introduced, there will be a failure in it. I understand that cervical cancer does not identify womb cancer. A clinician told me recently that there has been a huge increase in womb cancer in this country. It seems that there is some connection with the increase in obesity. I am not clear what the connection is. There is a higher incidence of womb cancer where there is obesity. The level of education regarding this issue has not been as comprehensive as we would need it to be. I wonder what Dr. Scally would do to get information out there. We need to make sure information is made available at an earlier stage to those who have a higher ratio of risk.

I will recap some of the issues I have raised. I referred to a ratio. I asked about the time gap between being given the all-clear and the cancer being identified. Has any information been identified in that regard yet?

Dr. Gabriel Scally: I thank Senator Burke for a varied group of questions. Dr. Denton and I will try to provide some answers between us. The Senator asked whether the colposcopists were aware. I believe they had some awareness that a review was going on. The laboratories received notifications, particularly when it began to become more structured. There is a clear

breakdown in the report of what happened when the cases were being re-examined. Although the bulk of the cases where a review was needed concerned cytopathology, there were also cases where there were possible failings in colposcopy or in the administrative system. Therefore the colposcopists would have known something was going on in that regard.

The major problem was that their connection and engagement with CervicalCheck was very poor. I logically expected that there would have been routine meetings. These were very important people in the whole process of cervical screening and looking after women whose smears were abnormal. I would have expected that there would have been regular meetings. After all, the health service was funding those clinicians to work for CervicalCheck as part of the screening programme. There was not that engagement with them and they certainly were not involved in the construction of the review and the audit process. Perhaps more tellingly, we did not see any clear evidence of cytopathologists involved in this and yet cytology was at the heart of what they were trying to review.

Does Dr. Denton wish to say anything about the colposcopists?

Dr. Karin Denton: One comment would be that colposcopy is a subspecialty of obstetrics and gynaecology. We have not looked specifically at the numbers, but the number of accredited colposcopists is very much smaller than the total number of consultants in obstetrics and gynaecology. I understand there are pressures on the workforce in terms of seeing all the women in a timely fashion. That was not specifically part of our remit. I agree with Dr. Scally that the most important thing is that they were not engaged with the programme. They were signed up to management meetings and they were not involved in drafting policy. Fundamentally, that is why they were disengaged. The number of individuals is quite small. It is considerably less than the number the Senator is quoting.

Senator Colm Burke: Should that issue now be looked at? If we do not have the required number of people with the expertise at the front line, we need to focus on that area. I also asked if Dr. Scally was aware of people who had been in the service and had left the service because they were unhappy.

Dr. Gabriel Scally: I am not aware of colposcopists who left because they were unhappy. It may well have happened. Certainly at the time of the outsourcing of the laboratory work, there was clear evidence of cytopathologists being extremely unhappy about that.

On the issue of the overall numbers, workforce planning was not part of our remit. However, we made it clear in the report that there needed to be a workforce review of the cervical screening programme to ensure it was properly staffed and had proper access to the expertise it needed. One of the most important recommendations is that there should be a national screening committee because the means of making policy decisions on the screening programmes, including issues relating to staffing, is quite unclear. There needs to be a national screening committee with expertise and independence which can advise about the programmes, about new programmes and about any changes or modifications needed to existing programmes. That does not exist, which is why it is one of our key recommendations.

Education is extremely important. I take that two ways. I draw the committee's attention to one thing I did not address in the report and perhaps should have done. There is no requirement for training in taking samples or indeed working with women to have a successful cervical screening experience, in other words, getting a good sample and getting the consent of the woman. Some very good training is carried out, but it is entirely voluntary. I wonder whether

that should be compulsory and that a modicum of training should be provided for all the clinicians involved in taking the samples and dealing with the women, if only to ensure they can explain properly to the woman what is happening and also in the context of the whole programme shifting quite significantly next year to the HPV testing as a primary test, which will be much more accurate.

Senator Colm Burke: I seek clarification. Is Dr. Scally saying no training was provided?

Dr. Gabriel Scally: No. Training is provided but it is entirely voluntary. There is no requirement for people to be properly trained.

Senator Colm Burke: Therefore someone could be providing the service without-----

Dr. Gabriel Scally: Yes.

Senator Colm Burke: Would that be unusual?

Dr. Gabriel Scally: It would be far from ideal, let me put it that way. I will give a classic example that I came across several times. Some women had a normal smear result and then relatively shortly after developed symptoms that would otherwise have been regarded as really quite serious symptoms and indicative that something serious might be going on. When they came forward with those symptoms they were told they had just had a normal smear, they had no need to worry, and that they should go away and come back if it did not stop. There seems to be a failure of education there in that the staff did not understand that the test might not pick up everything and that serious symptoms should be dealt with on a serious basis irrespective of when they occur. There was some evidence of delays in the treatment of women because of them having had a normal smear and it was regarded that it could not possibly be a serious cervical cancer issue.

Education of staff is extremely important. Education of patients on cancer in general about early recognition of symptoms is also important. We need to give patients the knowledge to recognise their symptoms, encouraging them to come forward and be able to engage in discussion with doctors and others about how these symptoms need to be investigated. Public education is important as well as professional education.

Senator Colm Burke: The results of more than 200 smear tests were found to be false. At the time the audit was carried out, were all of those patients receiving cancer treatment?

Dr. Gabriel Scally: Some of them may have finished their cancer treatment because it might have been at an early stage, but they had all been diagnosed.

Senator Colm Burke: Was that prior to the audit?

Dr. Gabriel Scally: Yes, prior to the audit. A diagnosis of cancer was the starting point of the review.

Senator Colm Burke: Therefore they had all been diagnosed prior to the audit being carried out.

Dr. Gabriel Scally: Yes. That was one of the misunderstandings which has been quite common in the press in the past six months. Some people mistakenly thought that a diagnosis of cancer was being kept from some of these women, but that was never true. The review of the slides only took place in cases where there was already a diagnosis of cancer.

Senator Colm Burke: When the audit was carried out, were any additional people identified as having cancer who had not been previously identified?

Dr. Gabriel Scally: No. As I said, it was only carried out on women who had been diagnosed with cancer. As I pointed out in answer to one of the other questions, CervicalCheck only knew about the women who had been diagnosed with cancer because it had no arrangement for exchange of information with the National Cancer Registry of Ireland to get the full notification of all the women.

Deputy Alan Kelly: I seek a quick clarification on that. As we sit here on 10 November-----

Dr. Gabriel Scally: October.

Deputy Alan Kelly: Sorry, October. This election stuff is going through my head.

Senator Colm Burke: Is the Deputy calling it?

Deputy Alan Kelly: Has the HSE given permission to the National Cancer Registry of Ireland to transfer all that information?

Dr. Gabriel Scally: Yes. The Minister has.

Deputy Alan Kelly: Is Dr. Scally certain it has happened?

Dr. Gabriel Scally: I am, yes. The Minister was requested, I think by the HSE, to give permission and the he did. I understand that there was a data transfer. I am not sure whether ministerial permission was actually required; I could not see the obstacle.

Deputy Alan Kelly: I asked this question months ago. I never thought it was required but they hid behind it - the fact that they believed it was required.

Dr. Gabriel Scally: I find that unsatisfactory. They managed it with regard to breast cancer. If they thought there was a problem, all they had to do was ask for a transfer to take place. As the committee has seen from the report, I was very concerned that, apart from a one-year contract document that we are not even sure was signed by both sides, there were no agreements between the HSE, CervicalCheck and the National Cancer Registry. There were no written agreements in place to cover this transfer of information, which was really unsatisfactory and bad practice.

Deputy Alan Kelly: The Chairman might just check that. I would encourage a check because I am not sure it was transferred.

Deputy Margaret Murphy O'Mahony: I welcome Dr. Scally, Dr. Denton and Ms McEntee. I thank the witnesses for coming in to the committee and I thank them for a very good report. Well done to them all.

Many of my specific questions have been asked. I am quite concerned that confidence in the system has been lost. Besides the implementation of the recommendations, what else do the witnesses believe can be done? I would hate if women were to ask why bother getting tested. Going forward, what else can be done besides the implementation of the report's recommendations? Do the witnesses still maintain that there should not be a commission of inquiry? If they were to go back, would they change, add or take away any recommendations?

Dr. Gabriel Scally: I thank the Deputy. I will deal with those questions, taking the final

question about the commission of inquiry first. It was not me maintaining it. It was my view, as expressed in the foreword, that I did not think it was necessary. I still do not believe it is necessary. There will be another opportunity for me to reflect on that when we finish the next piece of work, and how satisfactorily we finish that.

The Deputy asked if there were recommendations I would have included, and I have mentioned one. I probably should have said something about the issue of training. It is particularly crucial because of the shift to the primary HPV screening, it is hoped within the next 12 months. That is a big shift and is a whole new set of learning about the system for all the people who are involved in women having the test, and also the health professionals with whom they interact in doing the test. If I had a 51st recommendation-----

Deputy Margaret Murphy O'Mahony: That would be interesting.

Dr. Gabriel Scally: If the committee would allow me to have a 51st recommendation, it would be compulsory training for everyone involved. Will the Deputy remind me of her other question?

Deputy Margaret Murphy O'Mahony: The lack of confidence in the screening process.

Dr. Gabriel Scally: Improving confidence in the process is extremely important. One of the most distressing aspects was the degree to which many of the women with whom I interacted had lost confidence in their treating clinicians. I was really disturbed by that. It was brought home to me in the first of the meetings I had with the women in Dublin early in the process. Two young women came to that meeting and sat down beside each other, purely by accident, and found that they knew each other, were from the same place and had been at school together. They were both in the same boat with having cancer. Both of them believed that they had not been told or disclosed to properly when they should have been. They had both lost confidence in their clinicians who had been looking after them. As they were discussing this, they discovered that they had both decided to shift to the other's clinician. They thought this was very funny. It was the only light-hearted moment in the meeting. It brought home to me how difficult this is for many women, and we are still not through that at all.

At the outset I said, and I hold it even more strongly to be true, that when things go wrong, there are three things patients want to happen. First, they want to be told what went wrong and why. Second, they want someone to say sorry for something having gone wrong, and they want it to be someone who means it. Getting a letter from the chief executive, or the same letter being sent to all those affected, really does not cut it in this regard. Things went wrong, people were not disclosed to and those who did not do the disclosing, the people who probably should have done the disclosing, should be the ones saying sorry-----

Deputy Margaret Murphy O'Mahony: Yes, and that they made the mistake.

Dr. Gabriel Scally: -----and sitting across the table from these women. Third, patients want to be sure that it will not happen to anyone else. Those are the three things patients want.

We have gone a long way to find out what went wrong in the system and why. I believe we have not got to the stage. It was in the media so members will be aware that I had a very long meeting last night with the women, and it is very clear that they are still very angry about the way they were treated. That will not go away without some active intervention, if it ever will. I really hope it will.

Deputy Margaret Murphy O'Mahony: I hope so.

Dr. Gabriel Scally: Then there is the more general issue of loss of confidence in the screening programme. Happily, screening numbers have not dropped off, but it is still only at around 80%. We should not be satisfied with 80%, because 20% of women are at risk. The system needs to get better at convincing women that this is a good service, that they should come to it and that they would be welcomed to it and looked after properly. There is a new opportunity now with the new, much more accurate test coming in. There will be a large amount of work on that and on the HPV vaccination. Those two things together are the way forward, but it will not happen without people putting the effort into regaining the sort of confidence the Deputy has spoken of; the public confidence and the confidence of the women who have been affected.

Deputy Margaret Murphy O'Mahony: I thank Dr. Scally.

Chairman: In other screening programmes elsewhere, is the uptake better than 80%?

Dr. Karin Denton: The answer to that is mostly not. Many countries are struggling with a fall in uptake, for reasons that are not fully understood. I would add that although the numbers of women having samples are very high at the moment, many of those are women who are taking up the offer of additional tests. We do not necessarily know that they are the ones whose tests were actually due. This programme in particular should be focusing on raising the level of uptake because it is still quite young. If one compares it with the English screening programme, for example, that programme has been running for very much longer and has a whole different calculation around uptake. In a programme that has only been running for ten years, achieving the high uptake is especially important.

Deputy Kate O'Connell: I thank the witnesses for attending the committee and for the work they did on this report. Over the summer I was conscious that people were saying it was a very good report. It is a very well-written report. Any of us who were involved in the discussions at the Committee on Health and the Committee of Public Accounts wonder how the witnesses got so much information out of them when we here failed to extract the information. The report, however, is very damning reading. While it is well put together, the content is not good.

The first part of the report focuses on the move from the current screening to the HPV screening and the benefits of HPV screening. That is great and we are all for that. I want to focus, however, on the problems I have come across. Upon reading the report I am concerned about some issues and perhaps the witnesses could shine some light on these and on the matters that have come up today.

With regard to quality assurance, QA, am I correct in saying that the members of the quality team in the HSE were not the people who went over to audit the labs and did not know that another secret team was going over? Am I correct that there was a meeting when that team returned from the United States of America where everyone said they did a great job and then they moved on? Is that what happened or did I misinterpret the report? This is referred to on page 30 of the report.

Dr. Gabriel Scally: Yes. I think I understand what the Deputy means.

Deputy Kate O'Connell: Am I right in saying that the people who were the actual QA team were not the people who went over?

Dr. Gabriel Scally: No, it was a QA team but it was not the QA committee.

Deputy Kate O'Connell: It was a team within.

Dr. Gabriel Scally: As I said earlier, the quality assurance committee had an external chairman and met regularly for the duration. The quality assurance visits were carried out by a mixture of CervicalCheck staff, with an external cytopathologist on those visits. They came back and there was a discussion noted in the minutes of the quality assurance committee. What is really missing is a process for following up on quality assurance assessment visits and following through on recommendations.

Deputy Kate O'Connell: The quality assurance committee went to the laboratories in the States. When it came home, was it blissfully unaware that the laboratories it had just audited were sending slides to other laboratories?

Dr. Karin Denton: Yes, in one case.

Dr. Gabriel Scally: Yes, in one case so far, of which we know.

Deputy Kate O'Connell: It was stated in the contracts that the laboratories had to be International Organisation for Standardisation, ISO, accredited. There is a table on page 60 of the report which shows the difference in ISO and College of American Pathologists, CAP, accreditation standards. To me, there is a distinct difference between the two. Our contract asked for ISO accredited laboratories, but what we got were CAP accredited laboratories. It is claimed that they are of a equivalent standard, but the CAP accreditation standard might be what we term the yellow pack version. I think it would be Safeway in the United Kingdom. I have a background in science and it sounds like it is a distinctly lesser standard of accreditation. Am I correct that CAP and ISO accreditation standards are not the same?

Dr. Gabriel Scally: The Deputy is absolutely right. She read the intention of the table very well, namely, that there are significant differences between the two. That is one of the issues we will be examining in the areas of contracting and tendering. Although we have been told by the laboratories that, at some point, it was recognised by CervicalCheck that CAP accreditation was accepted, we have not seen any documentary evidence of this. We are still hunting for it.

The table on page 60 referred to by the Deputy lays out some of the differences. We hope to carry out a much more detailed analysis of the two systems to find out what the differences are. One interesting point is that the CAP's training arm also covers the area of ISO accreditation. Some of the laboratories are seeking ISO accreditation.

Deputy Kate O'Connell: The simple fact of the matter is that what was sought in the contract was not the standard on the other side.

Dr. Gabriel Scally: That is right.

Deputy Kate O'Connell: Not only that, nobody told us. Nobody wrote an email stating CervicalCheck wanted ISO accreditation but that the laboratory was CAP accredited and whether that would do.

Dr. Gabriel Scally: We do know that, despite their not having ISO accreditation, they were given the contracts, even though it was stated plainly in the call for tenders that ISO accreditation was a requirement. There is disputation about the degree to which CervicalCheck agreed that it was equivalent. That is one of the issues we are digging into to get an answer. As well as that, we are going to look at how equivalent are the two accreditations. We will make a much

more detailed comparison of the two. Dr. Denton and other colleagues visited all of the current providers, as well the College of American Pathologists, to conduct their own detailed look at the quality of the services offered. It was on that basis that we were able to say we could not see any reason the current contracts could not be rolled forward, not on the basis of the accreditation standard, although they met all of the standards required in the United states.

Deputy Kate O'Connell: We are not in the United States.

Dr. Gabriel Scally: Indeed, we are not.

Deputy Kate O'Connell: I asked before about the baseline from which we were operating. Today it was mentioned that colposcopy samples were blended in with regular smears. To me, that results in baseline distortion and one is just going to get bad data. This morning there is a big light shining on that distortion. I asked the question before of the HSE, when we were trying to get to where Dr. Scally got in his investigation, but it was pretty much dismissed. There is a concern that the baseline is distorted and that the limitation on one's testing is a 30% failure rate. The audit process has been stopped. Let us take as an example a person who has had two false negatives such as the tragic case of the lady who is being buried today. I do not believe we can have confidence in the 30% rate if the figures have been distorted by colposcopy slides. Am I correct? If a cohort of 100 definitely have cancer, that will mess up the figures.

Dr. Karin Denton: There are two separate issues involved. The figures at which we can look are not telling us about the women with cancer who are being missed. They are telling us about the proportion of women who have abnormalities detected. The majority will not have cancer, but there will be changes which, if left untreated, might at some point over many years develop into cancer. It is not an absolute measure of a laboratory's ability to prevent cancer from developing, but it is a reasonable surrogate because they are data that are relatively easy to get and are current.

Much of the problem is that when there is a look-back, many of the samples in respect of which the diagnoses were altered may have been taken many years before. Although it tells us something useful, it does not necessarily tell us how a laboratory is functioning today. It is important to keep the two matters separate. There is no measure of how likely it is a laboratory will miss a diagnosis that will lead to cancer in a sample reported today. We simply cannot measure it. As a surrogate, we look at how good they are in detecting precursor abnormalities today, which we can do.

On real-time monitoring, that is the best we can do. The audit tells us something different, which is what it should be doing from the point of view of improving laboratory practice, namely, identifying samples where a diagnosis was missed. It could have been difficult, as Dr. Gabriel Scally said, but could then be used to feed into training and supervision. I would think it would be unusual for a poorly performing individual member of staff to be detected through the audit because it would be too late. They already have been reporting for five years at that point. Accordingly, many of the quality assurance measures at which we look are process measures such as how does one check up on members of staff, monitor their performance and detect problems in real time. That is what one needs to do to improve the service.

Deputy Kate O'Connell: One of the major concerns is the audit of the two-to-one cases; the language used included misreading and obvious cancer cells on the slides. This process has been ogoing ten years and there is a 25% to 30% limitation rate. Has it not improved over ten years? Has anything been done to reduce it to 19% or 20%? It seems strange that anything

with a limitation rate has not improved over the years? Is it the case that nothing has changed? When the screening programme was being designed, were there slides with obvious cancer cells that were used as examples? There is a major concern that the slides which have been reviewed - I have not seen them and I would not be qualified to examine them - were riddled with very obvious cancer cells. Perhaps that is just media reporting. When CervicalCheck was in its genesis, was it normal that within the 30% there were people like those with whom we are dealing now?

Dr. Karin Denton: We have not seen any published outcome of the pilot that was done over a number of years prior to implementation of the CervicalCheck programme. I do not believe it included any look back of women who developed cervical cancer but there is some comparative information from England, where a similar audit has been carried out. We included the outcomes from that, which have been published, in the report. That shows a degree of lack of concurrence which, superficially at any rate, looks broadly in line with what has been reported or what we think the CervicalCheck audit shows, although we do not have an equivalent report with which we can compare it.

In terms of whether things have changed, I am sure that they have and we did see evidence to that effect. If one looks at the reporting rates for abnormalities over the years, one can see step changes which must indicate that there was some change in policy which occurred over a short period, for example, with inadequate reporting. There is evidence of constant intervention, evolution and improvement, as one would expect but we do not have specific information about look-back findings in individual women's samples. The Royal College of Obstetricians and Gynaecologists review may be helpful in that respect

Chairman: The next contributor is Deputy Durkan.

Deputy Bernard J. Durkan: I thank Dr. Scally and his team, including Dr. Denton, for the work they have done in such a short period. There was no need for them to apologise for any perceived delays at all because it was far better for them to do the job thoroughly, given its importance. They are to be complimented on the way they set about doing their work. One could involve oneself in a long tirade about the who, why, where, what and when and still end where one started.

I have a number of questions relating to open disclosure. Do the witnesses think that there was a resistance to full and open disclosure and a culture of resistance to same which may have had a bearing on the degree to which the various professionals responded to their patients? There must be confidence in any system for it to operate properly. I fully appreciate that confidence in the system has been dented and understand why this is so. Regarding the two ladies referred to by Dr. Scally who switched consultants, what was their experience afterwards? Did they have a similar experience or a different one, having changed consultant?

My next question concerns the accuracy of the tests and the screening programme. Do the witnesses think that 80% or 85% accuracy had a bearing on the seriousness with which those examining the slides treated the task? Did the expectation of only 85% accuracy mean that they felt that they did not have to be entirely accurate and could move on? In terms of how the slides are examined, is it better to have two different people examining a slide at different intervals or at the same time, rather than having the same person review his or her own slide? Which is better? I would have thought that examination by a different person would be better, provided that he or she had no prior information on the earlier reading of the slide. In that way, he or she would go about it in an unbiased manner.

How many other countries or jurisdictions have screening programmes similar to the one that operates here and how do those programmes compare? Do they work better than ours? Are they more accurate? What are the comparative statistics in that regard?

Reference was made to inoculation programmes in various countries and the fact that there can be reactions in some cases. Is it possible to identify patients, with any degree of accuracy, who may react to a particular inoculation programme? It would be hugely beneficial to all practitioners if that were possible. Finally, are the witnesses satisfied that the recommendations in the report will be implemented unconditionally? There is no sense in the witnesses having gone to all the trouble to which they went in order to examine the issues if their recommendations are not taken into account and put into operation immediately.

Dr. Gabriel Scally: Deputy Durkan has asked an interesting set of questions. On open disclosure and how it operates, the acid test is how it operates in hard cases. These were hard cases and it operated badly. I would like to be able to say that there is really good experience elsewhere but I cannot do so. The hyponatraemia inquiry in Northern Ireland, for example, with which I had some involvement, actually uncovered a much worse situation of cover up, lies and dishonesty among clinicians. I am deeply disappointed that medical colleagues would behave in that sort of way. When it comes to hard cases, there is an element of collegiality in the medical profession that is sometimes good but at other times, unhelpful. It can be really unhelpful when it comes to telling patients and authorities the truth when things are going wrong. I am very hopeful that this can and will be changed.

On the issue of switching clinicians, I do not know if the women went ahead with doing that. I was hoping to ask them that last night but as they did not come along, I could not do so. Like Deputy Durkan, I would like to know more. I do not know if they have done so but I suspect that they may have gone ahead and switched clinicians. Sometimes it is easier to start afresh with a different clinician and to build a new relationship, especially if there is any resistance to going back, sitting down and speaking the truth to each other. That is difficult. I look forward to hearing about that. I worry about the fact that women continue to tell me that they are worried about their relationships with their clinicians because of all of this. They would love resolution to it and I would hope that they find it. I would certainly encourage any attempts that might be made in that regard. I know that some of the women would like to sit down with their clinicians and discuss what happened in the light of my report and of everything that has happened. They would very much like to say how they feel about what happened and would like their clinicians to tell them honestly about what went on. I know that some women would like that.

Deputy Durkan's question about the inaccuracy of the test being used as an excuse for complacency is interesting. I will think on that further but certainly some of the clinicians in their dealings with women dismissed things that went wrong on the basis that everyone knows that the test is not completely accurate. I agree with the sentiment that lies behind the Deputy's question that it is not right or helpful. It is our duty to make the tests as accurate as we possibly can. I am hopeful that the shift next year to the HPV vaccine, which is a much more accurate test, will reduce that problem.

On the question about inoculation, we are not really here to discuss immunisation but part of the issue with it is that there are people who should not be immunised because of the likelihood of them reacting to a vaccine. They are then entirely dependent on the rest of the population who can have the vaccine having the vaccine. I wish there was a way to identify everyone who reacts but, sadly, that is not possible. It comes back to what I was saying at the beginning about

a compensation scheme that runs in the UK for immunisation. It is a limited amount of money and there is a high level of disability involved in the judgments about that. It is an important thing to look at nonetheless. I invite Dr. Denton to continue.

Dr. Karin Denton: There are a couple of other questions the Deputy asked that were laboratory specific. On whether the perceived accuracy of the test had an impact on those doing the audit, I heard two aspects of that: the clinicians and the laboratories. Having spoken to people in all the laboratories, I found they were all committed and keen to look again at the slides and learn what they could from them. It interacts with the question of bias, however, because they knew these women had all developed cervical cancer. Different individuals had different approaches to how much they tried to compensate for that bias, but it was not their fault because no one told them what to do. There was no protocol that said one either must or must not compensate for this review bias. The clinicians were all keen to learn what they could from reviewing these slides.

The protocol, such as it was, listed cases that had to go for an external review, and this can be found on pages 86 and 87 of the report. Slides that were identified on internal review as having a significant difference were sent for an external review, which addresses the question the Deputy asked of whether there was another pair of eyes on them. The difference between those internal reviews and the subsequent external reviews is what precipitated CervicalCheck to wonder if there might be an issue with the internal reviews.

I was also asked about how many other countries do an audit like this, and the answer is not many. It is quite unusual. The one we are most familiar is that which runs in England and Wales. It should be recognised that trying to do the audit is a laudable thing, but not every country does it, and most countries have not had this experience. There is not much comparison, therefore, to go on.

Deputy Bernard J. Durkan: Is the audit beneficial in general to the quality of the service?

Dr. Karin Denton: My view is that it is beneficial. We should also note that it is the whole patient pathway, from sample taking, cytology and colposcopy to management afterwards, as well as histology and anything else that happens to the patient during the pathway. Most of the cases that have been identified as problems have at least some cytology component, but there are issues that have been picked up in other parts of the pathway also.

The audit is producing good outcomes that should give grounds to implement changes. What we would like to see is a better process for identifying them in order that a national screening committee could examine the audit's findings and ask what could be done about them before implementing evidence-based changes.

Dr. Gabriel Scally: There was one further question about implementation, which is a subject on which I am keen. I have seen too many reports with lists of recommendations that are still gathering dust. I was part of the Madden commission which looked at issues of clinical governance some time ago. Plenty of those good recommendations are still awaiting attention.

I was cognisant of trying to keep my recommendations to a reasonable number, and I did my best to do so. I am also keen on the implementation, which needs external scrutiny, as I stated in the foreword of my report. The Minister has asked me to carry out that scrutiny after three months to see how the construction of the implementation plans is going.

I made a promise to the women and their relatives that I will not disappear on this. I take

these issues extraordinarily seriously, which is why I have spent the past four or five months working extraordinarily hard with my team to deliver this report. My team and I very much appreciate the members' complimentary remarks. We have not worked this hard just to walk away and let the report sit there. We will be as engaged in the process as we can be within the limits of what I am asked to do by the Minister to ensure implementation takes place, and the committee can be assured of that.

Chairman: I thank Dr. Scally. Have all the cases of patients who went through cervical screening and were identified as having cancer been re-examined?

Dr. Gabriel Scally: Only the cases that CervicalCheck knew about. The National Cancer Registry knew of a wider range of cases.

Chairman: Are the 221 cases in the group which CervicalCheck knew of cases where there was a misreading of the smear on their previous smear or two? CervicalCheck knew about many cases which had a clear previous smear, that is, a clear false negative.

Deputy Alan Kelly: It is an important question.

Dr. Gabriel Scally: It is an important question, and between the two of us we will try to give a precise answer. First, there is a set of criteria used to look at all the cases CervicalCheck knew about. We have slight doubts about at least one of the criteria it used, which is that there is an 18 month cut-off point, which Dr. Denton will address and explain exactly what our problem with it is. CervicalCheck made a decision as to where the areas of the screening process that needed to be looked at lay, whether in colposcopy, management, the recall system or cytology. It decided to look at that broad sweep of areas.

The 221 cases are situations where notification was sent to the laboratory that this was a case where it should do a review. A notification came back from that laboratory with the result of that review, which was then judged within CervicalCheck and the cases for disclosure were identified on the basis of there having been an alternative reading of the slide which, had it been the original reading, would have resulted in a changed pattern of management.

Deputy Alan Kelly: Will Dr. Scally elaborate on the pattern of management?

Dr. Gabriel Scally: There would have been a different intervention at an earlier stage.

Deputy Alan Kelly: That is clearer for the public.

Dr. Gabriel Scally: It could be either one of those two, but there would have been a different intervention. Perhaps an intervention did take place.

Deputy Alan Kelly: I understand.

Dr. Gabriel Scally: It should have been a different intervention or there should have been an intervention at an earlier stage.

Deputy Alan Kelly: That is the critical point.

Dr. Gabriel Scally: Yes, it is.

Chairman: The intervention might have been an earlier recall as opposed to-----

Dr. Gabriel Scally: It could have been any one of a range of interventions.

We need to deal with the other issue of the 18 months, about which we expressed our concerns in the report. It is worth explaining. Dr. Denton will continue.

Dr. Karin Denton: CervicalCheck appeared to have made a decision in trying to identify the management of which women would have been different if the cytology report had been different that it would have a cut-off at 18 months prior to the diagnosis of cancer. It was basically stating that if the missing of the abnormality occurred 12 months before she was diagnosed with cancer, it would not have made any difference to the final outcome, whereas if it had occurred 20 months before it, it would have. We feel disquiet about this because cancer can progress quite a lot over a period of 18 months. In our view, that might make a significant difference to the outcome. There was certainly one point when this was discussed in a meeting and agreed to as a criterion. What I am still not clear on - we received some more information from HSE on Monday of this week - is how it relates to the group of 221 women. I have not yet been assured on the exact criteria used in identifying them. They were certainly women who had had a diagnosis altered on review. I cannot at this time tell the committee whether there are more who had a diagnosis altered on review and it was held that it would not have made any clinical difference.

Chairman: To clarify, if there was a review of the reading of the slide and it was done within 12 months of the diagnosis of cancer, the case did not become part of the group of 221 women?

Dr. Karin Denton: I do not have the answer to that question. I am concerned that it might not have, but as yet I do not have the answer to it.

Chairman: If it had been done more than 18 months previously, it would have been included in the group of 221 women?

Dr. Karin Denton: Yes.

Deputy Alan Kelly: That is extraordinary.

Dr. Gabriel Scally: It is in the report.

Deputy Alan Kelly: I am aware of that, but it is extraordinary the way it is now being outlined here.

Dr. Gabriel Scally: We are outlining it because we want to draw attention to our concern about it.

Deputy Alan Kelly: It is the tidying up of it that is what is extraordinary about it.

Deputy Kate O'Connell: The assumption of a difference between 12 and 18 months was decided on by CervicalCheck at that meeting. Was the decision based on international data, that is, for having a 12 to 18 months cut-off time?

Dr. Gabriel Scally: We are not aware of any basis for it, which is why we drew attention to it.

Deputy Kate O'Connell: I do not know of international data-----

Deputy Alan Kelly: Have the delegates asked the question as to who, why and how they came up with this assumption?

Dr. Gabriel Scally: Yes.

Deputy Alan Kelly: I do not remember these questions being raised in the report.

Dr. Gabriel Scally: As Dr. Denton was saying, we are still seeking explanations for it. When one looks at the protocols for the review, they are scanty in the extreme.

Dr. Karin Denton: I will refer to the key part which is mentioned on page 90. The reason it may come across that I am being somewhat indecisive is we do not have exact definitions of which patient groups were involved. If one looks at the first few paragraphs of section 8.4, one will see we found a partial presentation of the audit in 2015. It talks about review outcomes in 190 cases that were then known. It runs through the number of women involved and how it was decided whether it had impacted on their management. What we do not know is how a proportion of those 190 women relate to the group of 221 women. This is a matter about which I have been very concerned, which is why I have been trying to get more information this week, but it is still incomplete. I have not been assured, but it may be that there was no delay factored in in the group of 221 women, but it may also be that there was. We have to be aware of this. There may, in fact, be other women whose samples were altered on review who have not been included in the group of 221 women, plus the cases that were included in the cancer registry group who we know have not been included.

Deputy Alan Kelly: To clarify because this is slightly complex., essentially we know about the group of 221 women. We also know that there are others from the cancer registry group. Dr. Denton is going to clarify the point about which I asked about the passing over of information, on which we still do not have 100% certainty, but the delegates think it is the case. Owing to the parameters that we now know were set - the full reasoning behind which is not known to us to date - with the timeline of 12 to 18 months, there could have been other women where alterations were made who were not included. Is that what we are seeing?

Dr. Gabriel Scally: That sums up our concern. As we said, the decision to view 18 months as being the cut-off point for clinical impact was undoubtedly flawed and it is hard to see the logic for it. That is what we said in the report.

Deputy Kate O'Connell: On page 90, on the sixth line from the bottom, if I am reading it correctly, it is mentioned that the audit in the United Kingdom extended to a period of two years, or am I comparing apples and oranges?

Dr. Karin Denton: No, the audit in the United Kingdom assumed that samples taken within six months of the diagnosis of cancer were diagnostic. Obviously, one does not want to include in a review the sample that actually precipitated the diagnosis because that is the one that worked. One has to have a cut-off point. In the United Kingdom it is six months. A period of 18 months is very long.

Deputy Kate O'Connell: To support the six months period in the United Kingdom, what evidence was used?

Dr. Karin Denton: We knew that samples taken within six months were usually the ones that had actually led to the diagnosis of cancer. I stress that we know that in 2015 it set what we consider to be a non-evidence based time limit. What we do not know is whether it was reversed. We also do not know to whom exactly they wrote in the group of 221 women. I believe that is a fair summary of the position.

Deputy Alan Kelly: Has HSE been asked these questions?

Dr. Karin Denton: I have started to ask them because until very recently I did not realise it was a problem. I have received a response through the Royal College of Obstetricians and Gynaecologists, RCOG, that states the diagnoses of the women in the group of 221 were altered on review. It does not state anything about timescales. Therefore, I need to pursue that issue further.

Deputy Kate O'Connell: At this committee and the Committee of Public Accounts we have heard continually that the trigger for the audit was having cancer. At no point in our discussions did anyone ever mention a 12 to 18 months cut-off period. It was never mentioned.

Dr. Karin Denton: Having cancer is still the trigger for the audit.

Deputy Kate O'Connell: I know that.

Dr. Karin Denton: Women who had had smear tests in a period greater or less than 18 months were all reviewed. What we are uncertain about is which of these reviews generated a letter.

Dr. Gabriel Scally: They will all be included in the RCOG review. It will encompass all of them, as well as the cases identified by the cancer registry group.

Deputy Alan Kelly: However, that does not answer the question of what happened here.

Dr. Gabriel Scally: No, it does not.

Chairman: Is it the case that there could be more than 221 women who have been affected?

Dr. Gabriel Scally: That is undoubtedly the case and will be the outcome of the RCOG review.

Chairman: I apologise to Senator John Dolan for interrupting his entry.

Senator John Dolan: I have been elevated to the Lower House. The Chairman's full apology for repeatedly and mistakenly referring to me as Deputy Dolan is very appropriate, as it is an apology from a doctor and an example of full disclosure.

Dr. Scally puts his finger on the problem. When it comes to the hard cases, it sticks in our craw to come out and say it. I thank the Chairman for his introduction, which gets me going. I also thank Dr. Scally and his colleagues for the work they are doing.

My remarks and questions relate to the position, comfort and status of girls and women in Ireland. There is something going on here that goes beyond what is in the eye of this storm. It goes to the heart of how comfortable, included and well-treated women and young girls are in this country. Dr. Scally spoke of ensuring this would become an increasingly rare event and said he was honoured to meet and talk to many of the women concerned and took great encouragement from their help and support. Those remarks need to be underlined and repeated.

Does Dr. Scally have a view on whether there may be governance and organisational issues that stretch from the Oireachtas? This committee deals with health and has a relationship with the Department of Health and Health Service Executive. While it is easy for us to talk about what happened elsewhere, everything that happens elsewhere is subject to oversight and responsibility.

No one would regard CervicalCheck screening or other health screening programmes as anything other than very positive developments. As time goes on, I expect there will be more of these proactive interventions to try to catch nasty conditions before they come our way. I am intrigued that despite our good motives, we have had unnecessary deaths and cases of near death, which have caused major anxiety? I would appreciate any observations on that.

Speaking about the issue of open disclosure, Dr. Scally stated that many of the attitudes displayed by clinicians have no place in medicine. He then spoke about attitude and culture and indicated he was hopeful that the culture would change. He said that open disclosure had to be the rule rather than part of a menu. What else will be necessary to encourage this change of culture? Dr. Scally spoke about collegiality being both a good and bad thing. This is evident in other areas of public service, including policing.

Dr. Scally spoke strongly on compensation being a core element, if I understood him properly. Should a compensation fund become part of the cost of providing a service? One will always hope that one does not fully expend it but it strikes me that if there is to be open disclosure and honesty, we must all be honest with people. This means saying that sometimes, even with the best will, honest mistakes will be made. We must have an upfront system that tries to remediate that.

Dr. Scally refers to the range of deficiencies he found. He made 50 recommendations and may have made a 51st recommendation this morning. We have had 25 or more years of tribunals, inquiries and scandals. It strikes me that this could, sadly, become another inquiry with a big report, which lays out all the issues. If Dr. Scally met someone at a bus stop or in a waiting room and the person realised who he was and asked him what are the three, four or five things that need to happen to turn this around, what would he say?

We have had a love affair with finding people and entities to blame and responsibility must be borne. However, when something like this happens we need to immediately start to right the ship in whatever way we can and get a better system in place.

Senator Colm Burke took the Chair.

Dr. Gabriel Scally: I thank the Senator for a fine set of questions. He asked about the Oireachtas and its potential role in this matter. I will link that with his final comment on finding people to blame. It is undoubtedly true that there is an appetite to find people to blame. In this situation, I do not know where one stops. Senator Dolan invited me to speak about the role of the Oireachtas and politicians in all of this. A reason we have this problem, as Dr. Denton has indicated, is that cervical screening is relatively recent in this country, having been in place for only the past ten years. It has been in place in the UK for 20 years and in a number of other European countries for much younger. I find it difficult to understand why it took an eight-year pilot before the programme was introduced. An eight-year pilot for a programme that has been well tried and tested elsewhere does not make sense to me. I have no idea why that occurred.

As the Senator will have gathered from the report, I am critical about the removal of the external governance of the HSE and that situation going on for so long. I am very pleased that it has been restored and with the appointment of the chair. A fine chairman has been chosen and I have confidence in that person. It is very unfortunate that certain things happened, for example, the decision to postpone the implementation of the HPV vaccination. I am very pleased that is in place now and that vaccination are on the way up. There was a decision to postpone its implementation.

As I have expressed already, I am a strong advocate - I hope there is no longer any argument about it - for the necessity of a statutory duty of candour being placed on individuals. The Oireachtas had the opportunity to do that and chose not to, for whatever reason. One can look at the entire system, from legislators all the way down to people on the ground, and find things that did not go well. I said I am hopeful that the culture will change. By nature, I am an optimist, but I come from Belfast where there is a saying that an optimist is someone who has not heard the bad news yet. I hope there will not be bad news about these 50 recommendations. I hope they will be implemented and that the country will get the cervical screening service it deserves. I will certainly be doing what I can and what I am asked to do to help in that respect.

Regarding changing the culture, I have indicated in the report that certain provisions need to be put in place, including a national screening committee centre. On the Deputy's question on the future of other programmes, particularly in this modern age of genetics, I am quite confident other screening programmes will come forward. Ireland does not yet have a proper mechanism for looking at screening in a highly professional and consistent way, which is why I have recommended that a national screening committee be put in place. That would serve the country well in the future and would enable a rational approach to screening and oversight.

It will not have escaped the Deputy's attention that among my recommendations I made two regarding matters I have mentioned. I recommended there should be patient advocates on the board of the HSE. I also recommended that there should be patient advocates on the national screening committee, and I have made other similar recommendations in the report. I have been deeply impressed by the advocacy shown by some of the people affected, notably Vicky Phelan, who exposed much of it. I was also deeply impressed by some of the patient advocates involved in the Madden committee some time ago. I would encourage that approach to involving patient advocates at the highest level but with one caveat. I recall one day chairing a committee, on which we had included patient advocates, and as I looked around those attending it occurred to me that the only people who were not being paid to be there were the patient advocates. I am conscious that is unfair and exploitative.

Deputy Alan Kelly: It must be dealt with.

Dr. Gabriel Scally: There are people with respect to this issue who are making enormous sacrifices to try to aid and move it forward.

Deputy Alan Kelly: Hear, hear.

Dr. Gabriel Scally: We should not in any sense be seen to be exploiting patient advocates. We need to find a way of helping them to actively participate. There are good reasons for that. We want a mix of people from different backgrounds and at different stages of life involved, not only those who have retired and have the time to do these things.

Deputy Alan Kelly: I could not agree more.

Dr. Gabriel Scally: We need to sort that out, and that is part of changing the culture. I firmly believe that.

Another element is to ensure there is a better understanding of citizenry among the citizens of the Republic of Ireland. I am still not convinced that the people do not have too deferential an idea of doctors. They need to be more robust in dealing with the medical profession and to have higher expectations of doctors. The public should not hold them in awe any longer. Those days have long gone. I hope this report and the exposure of some of the ridiculous attitudes

that they hold will encourage the public to be intolerant. Because I come from Belfast I am an advocate of intolerance at times. Being intolerant of doctors who are patronising and sexist is a good thing to be. I would encourage people to address that.

In terms of compensation, the Deputy's point was very well made. Part of the cost-benefit analysis of a screening programme should include issues of compensation for those who are actively damaged by the screening programme just as it needs to take into account the physical damage that can sometimes be caused by over-investigation as a result of a screening test, or the anxiety that results from having a screening test and then having to wait a very long time for the results. That is a stress on people that should be avoided if at all possible.

I firmly believe that patients turn to lawyers and litigation as a last resort in the absence of any other way of getting their issues dealt with. The best way of stopping the lawyers getting involved and the costs associated with that is to return to the points elements I mentioned, namely, telling patients what has gone wrong and why, getting someone who is responsible to say "sorry" and mean it, and assuring them that everything will be done to try to ensure it is not repeated. All the evidence from across the world shows that if that is done properly the public is much less likely to go to court to seek satisfaction. I have seen it happen many times where people go to court, sue and the only way the courts have of responding to that is in terms of a financial settlement. Such a settlement may be fine in one sense, but it does not bring resolution for many people. I look forward to Mr. Justice Meehan's proposals and to reading what he has to suggest in regard to that.

Regarding three, four or five key points, one is open disclosure; the second is a national screening committee; the third is that screening services need to be brought out of the cold, given a higher profile within the HSE and better management; and the fourth, which is a negative rather than a positive point, we should not indulge in the blame game anymore that we have to.

Acting Chairman (Senator Colm Burke): Deputies Kelly and O'Connell want to raise two brief issues and then I will bring in Senator Swanick.

Deputy Alan Kelly: In fairness, Senator Swanick should speak before us.

Senator Keith Swanick: I had to step out to deal with a Commencement Matter in the Seanad. I welcome Dr. Scally and his colleagues. I welcome the call for the establishment of a national screening committee. That is an excellent call in terms of the introduction of new programmes and the modifying of existing ones. Does Dr. Scally consider it is acceptable that there is still no manager within the HSE in charge of the cervical screening programme? Is he satisfied with the timelines for the introduction of the HPV testing? Does he believe that Mr. John Connaghan will hold relevant HSE managers accountable for their lack of performance as a consequence of this report? Who will be held to account for the contract mismanagement, the lack of quality assurance, the non-disclosure and the utter lack of communication? Also, why were the laboratories not fully investigated when the HSE knew that there were issues? This may still not have happened even though the laboratories have admitted liability and many of them have settled in court. Dr. Scally may already have touched on some of those issues.

Dr. Gabriel Scally: We touched on those issues quite extensively already. Some of those points are subject to the recommendations in the report. The Minister has asked me to review progress and I will be doing that at the three-month point. I will be able to give the Senator my view on those when I have seen the implementation plans that I believe are being prepared by the organisation. If he will forgive me, I will leave answering that point for a period of time.

The Senator's points were well made, they are in line with the recommendations and I expect to see them implemented.

On the Senator's question on whether I believe the HSE will do what it promised, which is to conduct its own internal investigation into the performance within the organisation, that is an assurance that was given by the acting director, John Connaghan, at an Oireachtas committee. I cannot recall if it was at a meeting of the health committee or the Committee of Public Accounts but he clearly said that would happen. I expect the HSE will do that and I certainly hope it does.

Senator Keith Swanick: I agree with Dr. Scally that we do not want to get into the blame game but we need accountability for the 221 ladies who have been affected.

Dr. Gabriel Scally: I quite agree that we do. I found it quite difficult to understand the level of poor management that went on. I met some excellent cervical screening staff in Limerick. There were two things about it. First, I was horrified to hear the way in which they had been subject to death threats and that one person had been spat on in public and so on. Some of those staff members are excellent and dedicated people who deserve a great deal of gratitude for their efforts over the year. They may not have been well led, but many of them are very good. The second thing was that I knew there was a problem with people not having proper job roles and job descriptions. At the meeting, I asked if those among the staff attending who had a job description would raise their hands. One person raised a hand in that room which was full of people and everyone laughed. I asked why they were laughing and they pointed out that the person had only just joined the organisation which was why there was a job description. None of the others had one. It is very difficult to blame people for failing to a carry out a job when there is no job description. It is very difficult.

Deputy Kate O'Connell: The point is that if there is no description, one cannot be held accountable because no one knows what one's job is.

Deputy Alan Kelly: I have found today's session very useful. I have gone through the report in great detail but I found particularly useful the information on the 18-month and 12-month cut-off being dialled up. In the last week, it has become an issue of higher importance for the inquiry team and today it becomes an issue of huge importance for us. The comment on patient advocates is spot-on. Demographically, it is impossible to get the appropriate people to sit on all of these groups unless there is going to be some form of recompense for their time off work. One will not get people of my age or younger to join a group because of the cost of child care and so on. That must be dealt with and as a committee we should advocate a payment.

We will not get to it now, but the RCOG review will not deal with the question I have asked about why the laboratories were not investigated under their contracts when issues were found. That needs to be dealt with somewhere. In fairness to Dr. Scally, he has said that quality control was, in effect, a joke and was not in place after 2014. We do not even know what was going on or who was accountable. All of that must be encapsulated somewhere. It is a big chunk that was missing. It is no one's fault, but it is missing.

I have a question on the inquiry team's follow-up work on the laboratories and outsourcing. I have read the commentary on this in the report in detail. Is the team confident that there are not other locations and laboratories to which some of these laboratories may have outsourced on top of what we know now? In other words, is this limited to just those laboratories?

As regards accountability, I have no confidence in the HSE investigating itself. Given the

day that is in it, there will have to be some second-phase forum involving Dr. Scally on accountability for what we have just discussed, namely quality assurance and contract management. I am with Dr. Scally on the people working in CervicalCheck in Limerick. They are not the issue here. It is higher up the food chain.

It has often been missed that the audit has stopped. What are the consequences of that? Are we going to have a delayed problem here? If everything has stayed the same, including the parameters, are we going to have additional issues with women potentially not having information? Given that the audit has stopped, there will be no disclosure. How is that going to be dealt with? This is a live issue today.

My final question relates to another live issue. To be fair to the Minister, he has probably admitted, albeit it may have been a mistake, the fact that slides are going out of date and that women are having to wait long periods for their smears. How are we going to deal with that fact given the commitment the Minister has made?

Dr. Gabriel Scally: I am not in a position to provide the Deputy with reassurance regarding other laboratories. It is an issue of concern to me and we will pursue it with rigour. By the time we come back with a report, I hope I will be able to reassure the Deputy. I would not rule it out at this stage.

Deputy Alan Kelly: Mexico has been spoken of.

Dr. Gabriel Scally: Mention of Mexico is an important part of this whole story because a rumour was circulating about Mexico for some time among the cytopathology community. We do not believe laboratories in Mexico were used.

Deputy Alan Kelly: Nor do I. It is just that I heard the same rumours.

Dr. Gabriel Scally: We understand now how the rumours started. It was because of the laboratory in San Antonio, which is very close to the Mexican border, and the staff heading it, who were of Mexican-American origin. As such, we can well understand how that rumour started.

Deputy Alan Kelly: As such, we just do not know. We will find out in future where-----

Dr. Gabriel Scally: About the laboratories, yes. On carrying out an investigation, I share the Deputy's sentiments about the HSE. However, I am optimistic about the appointment of the new chair of the board. I hope board members are appointed soon. I would look to that board to ensure a proper investigation is carried out. That is the correct place to start. The board should have the independence and control to ensure it happens. If I was interacting with that organisation in my context, it would be part of my discussion with the Minister and the board members that I would want that to happen.

Audit has indeed stopped. I am not sure what the way forward is. We have this time period now preceding the implementation of the new system and a system of audit will have to be designed for that. We will have to deal with this issue. Clearly, it is not part of my report, but the Deputy is quite right to point-----

Deputy Alan Kelly: This could cause additional problems.

Dr. Gabriel Scally: -----to it as an issue.

Deputy Alan Kelly: On the law of averages, it will.

Acting Chairman (Senator Colm Burke): Can we let Dr. Scally answer?

Deputy Alan Kelly: I know.

Dr. Gabriel Scally: Dr. Denton will discuss the issue of slides going out of date.

Dr. Karin Denton: The existing providers are unable to cope with the volume which is resulting from the additional uptake of samples. As it is in excess of what they are contracted to do, it is not really surprising that they cannot cope with the volume. That is resulting in long backlogs building up. Those backlogs will continue to increase as long as the number of samples carries on at current levels. There is very little they can do to mitigate that because, as they have learned from all of this, it is not a good idea to send the samples out elsewhere. It is a real problem.

The cervical cytology slides themselves do not really have a life-span problem. They will last more than long enough to allow them to be properly reported. The problem comes with the HPV testing which is currently undertaken as a reflex for certain grades of abnormality because that has a lifespan limit. We are probably getting quite close to the point at which some women may not be able to have the reflex HPV test because it is out of date. As such, while it is beginning to reach a critical point in terms of laboratory process, in terms of the individual woman's experience, it is already critical because a lot of people are very anxious, understandably, and have already waited a long time for their reports. It is a genuine problem which, unfortunately, will worsen if no action is taken.

Deputy Alan Kelly: What type of action should be taken?

Dr. Karin Denton: One of my other concerns is that, unfortunately, women who are due to have a sample taken and are at greater risk than those who have been tested, possibly quite recently, are also getting stuck in the backlog. It is, therefore, disproportionately disadvantaging those who are due to have a test. That includes the women we really want to engage in the screening programme, those other than "the worried well". It is not for us to say what action should be taken. All I can do is point out that the current volume is unsustainable.

Deputy Alan Kelly: It is very worrying.

Dr. Karin Denton: Implementing HPV primary screening would solve the problem very rapidly. This issue is very urgent. I do not know what the current timescales are but it is a case of the sooner, the better.

Deputy Alan Kelly: I thank Dr. Denton. That was very helpful.

Deputy Kate O'Connell: We earlier spoke about the counselling or information given to people when they went for a smear and the idea that when one's smear returned a clear result, everything was fine. According to the report, CervicalCheck organised the training of those responsible for imparting that information, so it is, surely, at fault for the poor training in that regard.

My main concern is that before any of this started I assumed that CervicalCheck checked the slides. I assumed there was a lab somewhere with people checking slides. We now know that doctors or nurses take smears in the community and labs abroad test some of the samples. Page 26 of the report details the organisational structure of CervicalCheck. If outside services were responsible for the testing and screening, the people whose roles are detailed on page 26

seem to have only been administering a service. As they only had one meeting in ten years and nobody was joined up, they do not seem to have had any proper role. The early part of the report twice refers to nobody being in charge. A concern of mine is that in January 2014 the NSS moved into the directorate of health and well-being. I cannot see any logical reason for that and such is not detailed in the report. Is there any reason for that move?

On the job description, although it is a funny anecdote it is very serious because even in the smallest business one is required to have a job description. It is very easy to ensure it is in place. I worked in the NHS. It is very easy to make sweeping statements that the NHS or the HSE is dysfunctional but this is a prime example of an arm of the organisation that is as bad as we could imagine.

On page 29 there is a reference to the recession. Is that the only excuse for incompetence that was offered to Dr. Scally? It seems like a fairly weak excuse.

On page 30 it states: "The QA Committee had a number of subgroups that concentrated on the development of standards for key functions in the screening process, such as cytopathology, primary care, histopathology, colposcopy and administration." Is there a reason screening standards were not included in that or am I missing something?

The report states on page 32 that all was not well in the screening process. On what evidence is that comment based? Do we know anything about why CPL stopped screening in 2013? Is there any reason for that other than financial concerns?

The National Screening Service risk register report for October 2017 is quoted on page 35 as stating, "*Clinical Audit process established and embedded in CervicalCheck by December 2017*." The report then states: "This is also difficult to understand, as the audit process commenced many years previously." Discussion of the audit process began in 2009. It seems the relevant CervicalCheck staff were just making forms, creating standard operating procedures, having meetings and basically doing nothing.

Although he may not have wanted an answer to the question, Dr. Scally asked why there was an eight-year pilot and why it took so long to roll out the HPV vaccine. We were coming from a very primitive background in this country in terms of women's health. If one looks at the media coverage of the roll-out of screening and the HPV vaccine, one will note comments by some religious organisations that one would not need a HPV vaccine if one led a pure and chaste life. That is the reason for the delay. There was huge pushback when the Minister for Health at the time, Ms Mary Harney, brought in cervical screening. Connections were made between a person's lifestyle and positive screening results. There was also significant pushback against HPV testing from what could be called interest groups or destructive people, which contributed to the low vaccination rate. The primitive attitude to women's health held by some in Ireland is probably the answer to the question to which Dr. Scally may not have wanted an answer. We are now beginning to catch up in that regard, albeit far later than would be ideal.

I am very concerned that this arm of the HSE which employed all these people who were getting paid big money, judging by the wage bill, some of whom were eminently qualified rather than people who came in off the street, seems like such a basket case of an organisation that it could not even manage its data right.

Dr. Gabriel Scally: I am having difficulty disentangling the questions from the observations.

Deputy Kate O'Connell: I ask Dr. Scally to do his best.

Deputy Alan Kelly: That is normal for Deputy O'Connell.

Deputy Kate O'Connell: It is normal enough.

Dr. Gabriel Scally: I am happy to respond to some of the questions in detail in writing. Considering the budgetary profile of CervicalCheck over the years, there is no doubt that its financial management was not satisfactory. Money was removed from CervicalCheck and moved elsewhere and it is very difficult to see why.

The absence of someone being in charge of CervicalCheck and a champion for it is of note in the overall matter, as Deputy O'Connell correctly pointed out. I have previously commented on that.

On the quality assurance, QA, subgroups, the reference on page 30 is to the QA committee of CervicalCheck, which had subgroups looking at these issues. My point was that one would expect that it would have had some engagement with the development of the review, the audit and its seven iterations, but it did not. I engaged with members of that committee who were very surprised that all this had been going on elsewhere-----

Deputy Kate O'Connell: In parallel.

Dr. Gabriel Scally: ----and they had not been involved in it.

I thought my report was fairly clear about things when I said that there was appreciation at the top of the HSE that all was not well, mainly because they engaged an external consultancy company to do a report on it. When one looks at the findings of that report, the one I quote in particular is as follows:

> *there continues to be a somewhat negative relationship and clear disconnect described by the programs between themselves and the HSE chain of command. Issues of isolation, suspicion, lack of trust or support and poor or non-existent communication were cited.*

That shows there was clearly some understanding that things were not going well at that point.

Deputy Kate O'Connell: Did Dr. Scally mean the organisation?

Dr. Gabriel Scally: Yes.

Deputy Kate O'Connell: Right.

Dr. Gabriel Scally: CPL stopped in 2013. We are looking at all of the contracting and procurement issues as part of this, I hope, final bit of our work. I will be able to give the committee better answers on that when we have done that, if I may.

I ask Dr. Denton to explain some of the background to the changes in the laboratory.

Dr. Karin Denton: CPL is part of the Sonic Group and it was actually a planned transition to using a MedLab facility, which was a newly established subsidiary, also of Sonic, established in Dublin. From Sonic's point of view the move from CPL to MedLab was planned, and that was part of a long-term strategy to repatriate the work that they did for the Irish programme.

Deputy Kate O'Connell: I thank Dr. Denton.

Deputy Louise O'Reilly: On page 59 of the report there was a reference to accreditation. As someone who uses the service, I find it outrageous that we are only asking these questions now. I understand that Dr. Denton will compare CAP accreditation with ISO accreditation. Did I hear Dr. Scally correctly?

Dr. Gabriel Scally: Yes.

Deputy Louise O'Reilly: I do not mean to be disrespectful to the witnesses when I say that this is shutting the stable door after the horse has bolted.

Dr. Gabriel Scally: Unfortunately, I had no control over the stable door until now.

Deputy Louise O'Reilly: I fully respect that.

The report states: "Both laboratories do have CAP (College of American Pathologists) accreditation which they view as being equivalent." Is it written down anywhere that people in the HSE viewed it as equivalent? Did anyone in the HSE or the CervicalCheck service bother to run a slide rule over it to see if the accreditation was the same, equivalent, different or even substandard? Without a time machine there is a very little that we can do if the accreditation turns out to be substandard. It is very disturbing that people in very senior roles within the HSE and the screening programme appear to have been not bothered in the slightest about the accreditation. Did Dr. Scally find any evidence-----

Dr. Gabriel Scally: No.

Deputy Louise O'Reilly: -----even when they visited that they did not ask to see the accreditation? I worked for a company years ago and the firm secured an ISO 9000 accreditation. I recall the huge amount of books, manuals and protocols that staff had to adhere to in order to get the accreditation. Did Dr. Scally find evidence that accreditation was sought or that questions were asked about it? Did people just sign the cheque at the end of the year?

Dr. Karin Denton: One of the things about the quality assurance visits is that they did not have a protocol and did not have sight of the procurement specification. They were looking at a series of things that they thought needed looking at. I do not think that they were even aware of the accreditation requirements. That is why one of the recommendations is to ensure that there is a clear protocol for quality assurance, which reflects and references what the contract specification is. I just wanted to comment on the quality assurance and its impact.

Dr. Gabriel Scally: The Deputy's observations might well be proven to be spot on. We will be reporting on that very issue. I have seen no evidence to date that would satisfy me that the questions that should have been asked were asked.

Deputy Louise O'Reilly: What about slides that might go today? Has anybody looked in the intervening time? That is important to know as everyone in the media is focusing their attention on this matter, there has been an outcry and what is happening today will also put a focus on this matter. Is Dr. Denton saying that nobody in the HSE or the screening programme has begun the process of even considering what CAP accreditation means and how it might translate to ISO?

Dr. Karin Denton: I cannot answer whether they have started looking at a comparison but they have certainly started looking at trying to ensure that ISO accreditation is gained by these laboratories. One of the challenges about that, as the Deputy has pointed out, securing accredi-

tation is a very hefty documentation process. Also, the pace of accreditation is controlled by the ISO. The measure is not a quick fix and will take some time. Even if they put their application in today it will still take several months before accreditation is granted. There is some action.

Deputy Louise O'Reilly: There is no scope for us to recoup any of the money that was given because the contract was signed on the basis that the laboratory would be ISO 15189 accredited. Do the witnesses understand my concern?

Dr. Gabriel Scally: I understand the Deputy's concern.

Deputy Louise O'Reilly: People come to my office and ask me whether I have faith in the programme. I respond by telling them that I am 100% sure that screening saves lives, that I have seen it with my own eyes and know that it save lives. Given that we are here discussing this matter and there has been an awful lot of attention on the screening programme the HSE is only now moving to acquire accreditation. The HSE has no control over the laboratories in the US and cannot compel them to comply with standards. The mechanism that one would use to compel someone to apply a certain standard is to say, "Well, I will withhold a contract until you demonstrate compliance." Clearly, the HSE has not bothered to do that so that has not happened. The laboratories are still getting money for providing the service but nobody quite knows. The witnesses might be right that the CAP accreditation is the same as the ISO accreditation but that is not what is written in the contract.

Dr. Gabriel Scally: Correct.

Deputy Louise O'Reilly: Plus nobody thought to follow this up.

Dr. Gabriel Scally: We will be exploring that. We will also be exploring almost the identical issue in that the contract, for example, with CPL was for Austin, Texas, and not for San Antonio, Honolulu or Florida. The contract specifies Austin. We are having some discussions about what the terms of that contract actually mean. We will, I suspect, have to take legal advice on the contracts and if there are legal implications in terms of both of those areas.

Deputy Louise O'Reilly: It is an awful pity that nobody looked at that at the time.

Dr. Gabriel Scally: Yes.

Deputy Louise O'Reilly: Securing accreditation takes ages.

Dr. Gabriel Scally: I find it astounding that there is no trail of documentation around both of those issues. If the HSE was going to accept CAP as an equivalent then there should have been a document trail.

Deputy Louise O'Reilly: The HSE should have determined that CAP was equivalent but it has not.

Dr. Gabriel Scally: We have yet to find anything.

Deputy Louise O'Reilly: Dr. Scally has talked to a lot of people. I understand that there was issues with getting documentation from the HSE. Believe me, as someone who has dealt with the HSE, I was that soldier. One could sing it if one had an air to it. I know sometimes that it can be difficult to get information from the HSE. In the course of Dr. Scally's discourse with the HSE, did he get the impression, and I know they did not have job descriptions, that a hero took it on to look at or monitor the contracts in any way, shape or form? Did anyone monitor

compliance? The HSE fell at the first hurdle because the contract stipulates ISO accreditation.

Dr. Gabriel Scally: I have concerns about that whole area, which is why I have said I do not want to comment.

Chairman: Sure.

Dr. Gabriel Scally: If Deputy O'Reilly will excuse me at the moment.

Deputy Louise O'Reilly: Fair enough.

Dr. Gabriel Scally: I share Deputy O'Reilly's concerns.

Deputy Kate O'Connell: Is there evidence that ten years ago, before this started, ISO accredited laboratories tendered for the work? Do we have any idea of the basket of tenders that came in for the job? Did Dr. Scally find anything? Did he find anything that showed that this decision to go with the potentially less-----

Dr. Gabriel Scally: Yes.

Deputy Kate O'Connell: -----effective-----

Deputy Alan Kelly: Does Dr. Scally have access to the original tender?

Deputy Kate O'Connell: Is there any evidence to show that a decision was made to go with the certified analytics professional, CAP, model rather than the International Organization for Standardization, ISO, model? Did someone not actually read them? Does Dr. Scally have any evidence?

Dr. Gabriel Scally: I am concerned about that original tender process both in terms of the way in which it was conducted and the way pre-tender discussions were had with laboratories which might have wished to take part in the tendering process but which did not.

Deputy Kate O'Connell: These laboratories were ISO accredited.

Dr. Gabriel Scally: They were potentially or very nearly ISO accredited.

Deputy Alan Kelly: Does Dr. Scally remember-----

Dr. Gabriel Scally: I will be exploring that issue. I will touch again on-----

Deputy Kate O'Connell: I am sorry, I have a final question. The first thing in this contract, which I spoke about when Deputy O'Reilly was out and about and which she followed up on, was ISO accreditation. However, also within the contract - it may have been at clause 39, I cannot remember off the top of my head - was that this facility for subcontracting out and giving away slides was included in case one's plant went on fire. That is my reading of it. I have looked into it and my reading of it was that the clause - I think it was clause 39 - was there so that if 1,000 slides were coming from Ireland and the laboratory burned down or another disaster happened they could be sent elsewhere. It is under that line that the laboratory was saying they could be sent to Honolulu or wherever they were sent. To my mind that is breach of contract. Obviously there is also this ISO element, so there are two very critical points in the contracts which, to my mind, are very serious.

Dr. Gabriel Scally: Any rational human being would think exactly along those lines. I

thought exactly along those lines. There is, however, something else in the contract which indicates that the headings on those subsections are not to be taken as part of the contract. This is something we will be exploring.

Deputy Alan Kelly: I would like one clarification. Earlier on we spoke and Dr. Scally said that the actual contracts had been shredded.

Dr. Gabriel Scally: Yes, the tenders were.

Deputy Alan Kelly: All the tendering documentation has been shredded.

Dr. Gabriel Scally: Yes.

Deputy Alan Kelly: Obviously Dr. Scally has all the contracts.

Dr. Gabriel Scally: Yes, I have the ones that are in place. That is correct.

Deputy Alan Kelly: Just to clarify, does Dr. Scally have all the contracts that have ever been signed?

Dr. Gabriel Scally: I believe so.

Deputy Alan Kelly: Dr. Scally believes so.

Dr. Gabriel Scally: I will confirm that for the Deputy.

Deputy Alan Kelly: For the committee's purposes, can we find out whether Dr. Scally has access to everything? I understood that he had but I am now concerned. I asked at the beginning whether he had been given access to everything. Does he have a copy of every single contract and subcontract ever made with any laboratory?

Dr. Gabriel Scally: I believe so.

Deputy Alan Kelly: That does not-----

Dr. Gabriel Scally: The reason we are carrying on with this work is because we are not yet finished. We are reconstructing a trail which we hope will enable us to reconstruct the whole tendering and contracting process, including the call for tenders and the tenders that were submitted. We will also be exploring those who did not tender but who might have, if the Deputy understands me.

Deputy Alan Kelly: Yes. That is all good.

Dr. Gabriel Scally: As far as I am aware, we have been given access to all of the contracts. We had some discussions about it in respect of some of these matters possibly being commercially sensitive or confidential. We resolved all of those satisfactorily.

Deputy Alan Kelly: Surely the HSE would have access and would be able to tell Dr. Scally that all the contracts and everything had been handed over.

Dr. Gabriel Scally: Yes. I will tell the Deputy.

Deputy Alan Kelly: Dr. Scally does not know yet, however.

Dr. Gabriel Scally: No. I believe we have. When Deputy Kelly asks questions he asks

them with a purpose, which makes me uncertain of my certainty.

Senator John Dolan: Deputy Kelly is a lovely fellow.

Acting Chairman (Senator Colm Burke): On the National Cancer Registry, has all relevant information been exchanged and given over in respect of CervicalCheck? Has that issue been resolved?

Dr. Gabriel Scally: Yes, I believe so.

Acting Chairman (Senator Colm Burke): All of the documentation that-----

Dr. Gabriel Scally: About the cases? Yes.

Acting Chairman (Senator Colm Burke): All the documentation that was relevant has been given over in order to have one platform on which all the information is stored.

Dr. Gabriel Scally: Yes.

Acting Chairman (Senator Colm Burke): The second issue I wanted to check with Dr. Scally is about the issue of engaging with laboratories into the future. Obviously in any contract negotiations laboratories are now going to look for new terms and conditions, in particular in respect of dealing with the issue of litigation. From what he has learned from his work over the last four or five months, does Dr. Scally think that will pose a problem in the future?

Dr. Gabriel Scally: Again, it is not entirely part of the scoping inquiry's work, but it is pretty obvious from what we know about the discussions that have been going on that this issue is a central element in contracting. I very much hope it will be resolved because we absolutely need to continue the programme, at least for the next 12 months or until the HPV testing comes in. I am not privy to those discussions about liability, but I do hope they are resolved.

Acting Chairman (Senator Colm Burke): Does Dr. Scally believe it is going to be a problem?

Dr. Gabriel Scally: From the reports that have appeared about those discussions, it does appear so. However, I am no better or worse informed on that than many around this table.

Acting Chairman (Senator Colm Burke): I call Deputy Durkan.

Deputy Bernard J. Durkan: I had my hand up a long time ago.

Acting Chairman (Senator Colm Burke): I am sorry. I apologise to the Deputy.

Deputy Bernard J. Durkan: I will not suggest anything. I know that sometimes the right hand side of the room is a bit difficult to see. An improvement in the Acting Chairman's peripheral vision is needed. Two questions come to mind. First, Dr. Scally made an interesting reference a few minutes ago in respect of the chain of command. This is something we have raised at these meetings on many occasions. Is there a chain of command? To what extent does it work? It used to be a product of the old health boards. In the health boards there was a programme manager who was responsible for a series of issues and protocols. He or she was regularly held responsible for those. I believe that has disappeared and does not exist any more.

The other question that comes to mind, to which reference has already been made, relates to tendering. I used to be a kind of half-expert on tendering once upon a time and in a differ-

ent capacity. To what extent did visits take place to the laboratories that were likely to tender? Were all laboratories visited? Were the terms set out in the tender documents such as to ensure that all possibilities were catered for in the future, including the issues about ISO standards and so on? Whenever I see reference to tendering I get uneasy. It is a feeling which has affected me on many occasions in the past. I wonder about that. Are there grounds for optimism in respect of the tendering process? How was it gone about? Who actually promoted it? Who was in charge of it? How were the tenders opened? Were they opened in public? Perhaps Dr. Scally would like to comment on those issues.

Dr. Gabriel Scally: I do not have answers on those points, as Deputy Durkan will understand, but they are valuable and we will include them in the work we are doing. It is important that the points are answered.

Deputy Kate O'Connell: If I may contribute briefly, Australia has HPV testing. It has been rolled out very successfully and it is in line to eradicate cervical cancer within the next ten years. How quickly was this testing rolled out? In an international context, what is the quickest the change from screening to HPV testing ever been done? How fast can we do it, if we do not let the laboratory that did it before do it?

Dr. Karin Denton: Australia went from a decision to implement to implementation in about 12 months. I would have to check the exact duration but it was of that order. The UK, or England at any rate, will probably take approximately 18 months. Scotland and Wales will be somewhat quicker. Obviously, we are not starting at the point of making a decision. A decision has already been made and I think that implementation within 12 months is achievable.

Acting Chairman (Senator Colm Burke): We will finish on that. I thank Dr. Scally, Dr. Denton and Ms McEntee for their contributions this morning. I also thank them for the very comprehensive report that they delivered, which sets a very high standard for future reports, no matter the subject. They have shown how a report should be done and how an investigation should be carried out. The Scally report provides a clear template for future investigations, regardless of the area, and for disseminating information to the general public. I thank our witnesses for their valuable contributions and giving so much of their time to the committee. They have been here since 9 a.m. and we very much appreciate the information they have imparted and the honest way in which they have answered our questions.

I ask members to remain in the room after the witnesses have left as there are one or two issues that must be discussed.

The joint committee went into private session at 12.12 p.m. and adjourned at 12.18 p.m. until 9 a.m. on Wednesday, 17 October 2018.