OFFICIAL REPORT
AITHISG OIFIGEIL

Public Petitions Committee

Thursday 18 May 2017

Session 5

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PUBLIC PETITIONS COMMITTEE
10th Meeting 2017, Session 5

CONVENER

*Johann Lamont (Glasgow) (Lab)

DEPUTY CONVENER

*Angus MacDonald (Falkirk East) (SNP)

COMMITTEE MEMBERS

*Maurice Corry (West Scotland) (Con)
*Rona Mackay (Strathkelvin and Bearsden) (SNP)
*Brian Whittle (South Scotland) (Con)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Catherine Calderwood (Chief Medical Officer for Scotland)
Jackson Carlaw (Eastwood) (Con)
Neil Findlay (Lothian) (Lab)
Tracey Gillies (Independent Review of Transvaginal Mesh Implants)
Alex Neil (Airdrie and Shotts) (SNP)
Shona Robison (Cabinet Secretary for Health and Sport)

CLERK TO THE COMMITTEE

Catherine Fergusson

LOCATION

The Robert Burns Room (CR1)

Scottish Parliament

Public Petitions Committee

Thursday 18 May 2017

[The Convener opened the meeting at 09:31]

Continued Petition

Polypropylene Mesh Medical Devices (PE1517)

The Convener (Johann Lamont): Welcome to the 10th meeting in 2017 of the Public Petitions Committee. I remind members and others in the room to switch their phones and other devices to silent.

The only item on our agenda is consideration of a continued petition. We will take evidence on PE1517, on polypropylene mesh medical devices, which is from Elaine Holmes and Olive McIlroy, both of whom are in the public gallery. I welcome Neil Findlay MSP to the meeting, and I understand that Jackson Carlaw MSP and Alex Neil MSP might attend later.

We will hear evidence from two panels. First, we will hear from Tracey Gillies, chair of the independent review group, and she will be followed by the Cabinet Secretary for Health and Sport and the chief medical officer. Members have a note from the clerk that provides context and background to the session 4 committee's consideration of the petition and addresses the content of the independent review's final report, which members have a copy of. Members also have a copy of the petitioners' most recent submission, which sets out their concerns about the final report. Those concerns include the provision of the shared-decision tables; chapter 6; reporting of mesh-adverse events; recording of mesh procedures; the classification of mesh; and the inclusion of the petitioners' input in the final report.

Given the number of areas that we have to cover, I propose that we move to the first evidence-taking session. I therefore welcome to the meeting Tracey Gillies, chair of the independent review. Thank you for attending. I will give you the opportunity to make a brief opening statement, after which we will move to questions.

Tracey Gillies (Independent Review of Transvaginal Mesh Implants): Thank you and good morning. I am grateful for the opportunity to come here today to discuss the independent review and answer the committee's questions.

As people who are here will know, the review came about because of growing public concern about the use of polypropylene mesh to treat urinary incontinence and pelvic organ prolapse and as a result of the considerable efforts of those who suffered complications after surgery. You will also be aware that Lesley Wilkie, who chaired the review from the beginning through to the publication of the interim report and beyond, resigned towards the end of last year and that, at the end of last year, I was asked to take over the review and see it to its conclusion. Under Lesley's chairmanship, the independent review published an interim report in 2015; she and the other members of the review group put a lot of work into that report, which was well received by clinicians and patients.

Before I talk about the review's findings, it is important to touch on some of the difficulties that the review faced on the way to the publication of its final report and to acknowledge that it is deeply disappointing that one of the clinicians and two patient members felt that they had no alternative but to resign. I really tried very hard to find common ground and compromise so that we could produce a final report that all members were happy with, and I am very sorry that that did not happen. As is often the case with a review or inquiry of this type, members had many experiences and strongly held views and, in such circumstances, it proved to be difficult to reach agreement and, in particular, consensus around the interpretation of the evidence.

The review's final report was published at the end of March, and the view of the remaining review group members was that it actually strengthened the findings of the interim report. The report included eight clear, unambiguous conclusions that I would like to have the opportunity to go through with the committee. [*Interruption*.]

The Convener: I am sorry, but it is really important that we conduct these proceedings as efficiently as possible. I understand the level of emotion and feeling in the room, but we have to take evidence, ask questions and come to a conclusion, and I ask people to restrain themselves, as much as possible, from commenting while we are trying to take evidence.

Tracey Gillies: Broadly speaking, the conclusions cover the very important point that decisions around treatment, particularly with regard to these conditions, must involve patient-centred care, which includes patient choice and shared decision making supported by robust clinical governance. We also concluded that support for shared decision making should take place in the context of a multidisciplinary team and that the recording and reporting of adverse events

should take place in line with General Medical Council guidance. In that respect, we have concluded that the word "mandatory" should be included, and I am sure that you will have some questions about that. Moreover, the patient information in the previous consent leaflet should be reviewed and a similar leaflet should be produced for those who are considering prolapse surgery.

The expert group also wanted to highlight to the research community some of the gaps with regard to the long-term impact of mesh surgery to ensure that further questions in that respect could be addressed. There is a need for work to address the current information gaps and a need to ensure that information that is currently available is used as effectively as possible. Furthermore, we concluded that the expert group should review the training and information available to clinical teams and find ways of ensuring that patient views are incorporated into the recording of multidisciplinary treatment outcomes.

We also concluded that, in considering surgical treatment for stress urinary incontinence, women must have the opportunity to be offered all appropriate treatments, both mesh and non-mesh, as well as the necessary information to allow them to make informed choices. In the case of pelvic organ prolapse, we concluded that mesh procedures must not be offered routinely. I am happy to return to that point, because I think that that is where the final report's conclusions move beyond those in the interim report.

In coming to those conclusions, the independent review members considered the best available evidence. One of the reasons for the gap between the interim and the final report was that new evidence became available that drew on a wide range of sources, including patient surveys as well as stories that women submitted individually to the review or separately to the Scottish Government. Other evidence included the analysis of nationally available hospital record data carried out by the Information Services Division—that is set out in chapter 4—and a number of different scientific studies, which are included in chapter 5.

As I mentioned, it is deeply disappointing that three members of the review felt that they had to resign, but I want to make clear my gratitude to all members for their efforts in bringing the report to the place that it got to. In coming to their conclusions, the remaining members of the review group took care to consider and try to reflect the views of those members who had resigned. That is, in part, why we see the inclusion of the word "mandatory", which we knew was important to the patient members of the group.

I want to conclude by thanking those who took part and the many women who have submitted stories. I hope and firmly believe that, as the conclusions in the report are taken forward, the standard of care that is provided to women will improve. There are many important lessons to learn from the events that preceded the review and from the review itself. I hope that they will improve care in the future.

The Convener: Thank you very much. I will open up the questioning. One of the reasons behind the petition was that women were not being listened to and their experiences were not being treated with respect by clinicians. How do you respond to the views that have been expressed by the petitioners and others that the review was not fully independent and that it lost its transparency and integrity? Can women reasonably be expected to have trust in the conclusions that are reached and the processes that were followed to get there?

I will give you one example, and I am interested to hear your comments on it. Conclusion 6 of the interim report says:

"The Independent Review expressed serious concern that some women who had adverse events found they were not believed".

In the final report, that changes to:

"The IR expressed serious concern that some women who had adverse events felt they were not believed".

In the difference between the two reports, are you not effectively compounding the idea that you do not believe that the women were not being believed?

Tracey Gillies: That was not the intention of the report in any way—[*Interruption*.]

The Convener: I suppose that my question is asking you to reflect on why there is a lack of confidence. Can you explain that change between the reports? What was the purpose of that change? It reports that people "felt" that they were not believed, whereas the interim report clearly accepted that they had not been believed.

Tracey Gillies: I think it is important for me to say that there was no intention or any implication—[*Interruption*.]

There was no intention to imply that people were not believed. I chaired two meetings of the group and went to a lot of effort to try to make sure that we were trying to listen to all views around the table.

The Convener: How do you give people confidence when they say that the review was not fully independent and was not transparent? What is your response to that?

Tracey Gillies: I refute that it was not fully transparent. One of the issues is about the tables of evidence, and it might be useful to explore that

at this stage, because I think that it is what has led people to worry about transparency. The tables of evidence that were included in chapter 6 of the interim report were drawn up by one of the clinicians. They contain extracts from the full critical appraisal.

In discussion with the clinicians, it became clear that certain things might have been highlighted rather than others. Chapter 5 in the report is the critical appraisal of the evidence that was collected through systematic review. I wanted to make sure that there was clear visibility of all parts of those systematic reviews, which is why the tables in chapter 5 can appear to be more difficult to read. They contain every extract from the systematic reviews that have been undertaken. When it seemed difficult for some people that the tables from chapter 6 were being included in chapter 5, we included those cut down tables in front of the full tables and a link to chapter 6 of the interim report at the back.

One of the difficulties that we have when people talk about the assessment of evidence-based medicine and how evidence is assessed is about which parts of the evidence have been looked at. I wanted to make it clear that all the evidence that was taken in those systematic reviews was set out in chapter 5 and that is why it is there.

09:45

The Convener: Do you believe that some women who had adverse effects found that they were not believed? Do you think that that was their direct experience?

Tracey Gillies: I think that women who have had adverse effects have not been believed, and I am very sorry that that is the case, because they should have been believed.

The Convener: The final report does not reflect that view, whereas the interim report does.

Tracey Gillies: I can only apologise for that change in wording. That was not the intention. [*Interruption*.]

The Convener: I remind those in the gallery that we are trying to go through the evidence as effectively as possible.

Angus MacDonald (Falkirk East) (SNP): Good morning, Ms Gillies. Before we move on to the report's conclusions, I would appreciate some clarification in relation to the process for publication of the report and the petitioners' resignations. The petitioners are clearly very angry that their names and input have been included in the report when they requested that they be removed.

For the record, can you clarify when you received requests from the petitioners to remove their input and whether those requests were agreed to? In relation to any requests that were not agreed to, can you explain why that was the case and who took the relevant decisions?

Tracey Gillies: Yes. I have a number of letters that I would be happy to provide to the committee at a later date, if that would be helpful.

Angus MacDonald: We will take as much information as you can provide.

Tracey Gillies: I would be happy to do that.

As I understand it, following a meeting between Mrs Holmes and Mrs McIlroy and the cabinet secretary, there was a request that she then put to me for information to be removed. I wrote to ask for clarification of which pieces of information were to be removed. Following that, there was clarification from the minutes of the meeting of the Scottish mesh survivors women with the cabinet secretary, which stated that it was the minority report that was to be removed. [*Interruption*.] I understand that some might not agree with that, but that is the information that I received.

In discussion with the review group, there was a very strong feeling among its remaining members that, after individuals have resigned, they should not be able to influence the content of the report as agreed by the review group as it stood at the end of the process. The minority report was part of an appendix and had not formed the basis of discussion within the process as the review was formulated—that is why it was removed.

I received communication that said that my letter had caused distress, for which I am sorry, but, following that, I felt that it was necessary to be clear about what had been removed, so I wrote a further letter, which was sent by post. [*Interruption*.]

Angus MacDonald: Are you continuing or have you finished your answer?

Tracey Gillies: I have finished trying to answer your question. If I have not answered any parts of it, could you tell me which parts I have not answered?

Angus MacDonald: It would certainly be helpful if you could provide the committee with the correspondence that you had. I am not sure, but there might be a suggestion that some of that was not received, so we would be obliged if you could provide that.

Tracey Gillies: Of course.

Neil Findlay (Lothian) (Lab): Could you advise us of what correspondence you received from the cabinet secretary or the chief medical officer in relation to the requests from the patient

representatives to remove the information from the report?

Tracey Gillies: That was in a discussion.

Neil Findlay: Did that discussion go along the lines of, "I have met patient representatives, and they want all their information to be removed from the report"?

Tracey Gillies: Yes, it did.

Neil Findlay: And you did not do that.

Tracey Gillies: As I have outlined, that is what I wrote to Elaine Holmes and Olive McIlroy to ask them about.

Neil Findlay: No—I am sorry. The cabinet secretary made that request to you verbally; you have confirmed that.

Tracey Gillies: Yes.

Neil Findlay: And you did not remove that information.

Tracey Gillies: As I have explained to you, I wrote to ask about that. I took that suggestion back—

Neil Findlay: There was no need to write, because the request had been made by the cabinet secretary, who you are accountable to.

Tracey Gillies: She was passing on what was discussed in their meeting—

Neil Findlay: She agreed at that meeting that—

Tracey Gillies: I am afraid that you would have to take up that issue with the cabinet secretary.

Neil Findlay: Do not worry—we will.

Tracey Gillies: I am trying my best to navigate a difficult process where people have different views. Some of those views are, understandably, incredibly strongly felt. There has been discussion about the integrity of the review, but the review group had agreed the content of the review. I take seriously my responsibility as chair. As such, I needed to go back to the standing members of the group who had not resigned about any significant changes in content. It is right to listen to requests, but that does not mean that I would necessarily accede to those requests. That is the point.

Neil Findlay: On that theme, when the interim report was greatly changed in moving to the final report, did you reciprocate that arrangement and contact others in the group who had resigned or who were members at the time but had rejected that position?

Tracey Gillies: The issue was fully discussed at meetings held at the end of January and on 6 March. The changes to the review were fully discussed as part of those meetings. The agenda sets out that each chapter was discussed, chapter by chapter.

Neil Findlay: Okay. That will do for now. I will come back in later.

The Convener: Were all the remaining members of the review group in attendance at both of those meetings?

Tracey Gillies: All the papers were circulated to them, including those who did not attend in person or by phone.

Let us consider the word "mandatory". That was clearly important to the people who had suffered complications following the use of mesh. Although the group had previously discussed the inclusion of the word "mandatory" and had not felt that that was the way in which to go, at the meeting on 6 March we added into the review the statement about the GMC's expectation that individual practitioners would report complications. The absence of the word "mandatory" was clearly still a source of deeply felt upset to individuals. I agreed to go back to the group and check that they were all right. At the meeting, I said that I would take the chair's prerogative, if you like, and accept that that word could be included, because it seemed to me to be unreasonable to hold out against that.

The Convener: Does the final report reflect the fact that some members of the group had resigned and had asked for some of the evidence that they had given to be withdrawn? There does not seem to be any commentary on that in the final report. I understand your position to have been that whoever remained—whoever was still standing—at the end of the process would comprise the review group and that the report was theirs. Is there any commentary in the report that says that, during the course of the review, you lost two patient members and an expert?

Tracey Gillies: A list at the back of the report gives the dates when people left.

The Convener: The report does not reflect the substance of the dispute that led to their leaving. There is nothing that shows the element that people might have wanted removed but that was not removed. The report does not even reflect that such a request had been made.

Tracey Gillies: When members resigned, I wrote to thank them for their contribution and to express my regret that they had resigned. I would be happy for those letters to be on the website. I am also happy to reflect the comments that you have made to me today and for it to be put on the website next to the review that the report does not make clear the points of dispute over which people resigned and what elements they wanted to have removed.

Part of the difficulty of producing a report that is written by many different people and in which we are trying to build consensus is that, if people choose to leave the process because they are not happy with the conclusions, it is not possible to disaggregate the contributions that they have made in the development of the report.

The Convener: In the extreme circumstance that only two people were left writing the report, would you not take the view that it was unsustainable to produce a report? When the two patient representatives said that they had no confidence in the report and when another member of the group left, rather than plough on with a report in which you could not build a consensus you might have considered pausing the process. Did you consider that option?

Tracey Gillies: Another patient representative and several other individuals remained part of the group. You are right that, if one were left as the chair of a group of two people, one would have to say that any report that it produced would not be credible to the various audiences that one would expect the report to go to. However, a significant number of members of the review group remained, and all of them were in agreement with the content of the review.

Jackson Carlaw (Eastwood) (Con): I presume that, at the point when the interim report was made public, all the members of the review group supported that report, including those who subsequently felt that it was necessary to resign.

I learned something from what you said a moment ago, and I want to clarify it. Until your predecessor resigned, in November, the group supported the conclusions of the interim report. In relation to the tables, you said that you felt that the excerpts did not give the complete picture—you said, "I felt", "I decided" and "I led". Did you instigate the changes to the review group's interim report on the basis of what you felt, having come into the review group? Did you lead that change to the report or did the initiative come from elsewhere within the review group—from people who, by that stage, were concerned that they had managed not to express any concern when the interim review was published?

Tracey Gillies: When I listened to the clinicians discussing how they wanted to frame the conclusions of the clinical part of the report—you must remember that new evidence came forward between the interim report and the final report, which was the reason for the delay—it was clear that there was a lack of consensus around the content of those tables, which were no longer agreed by the clinician members of the group. There was no longer sufficient consensus for people to feel comfortable.

Jackson Carlaw: Did the initiative come from you?

Tracey Gillies: It was a way of considering whether there was a different way in which to express it in order to continue to build consensus.

Jackson Carlaw: The production of tables that contained a blizzard of information and so made nothing clear at all? It was the lowest common denominator, and no one could disagree with anything.

Tracey Gillies: I absolutely refute that. It comes down to who the intended audience is. As I said, I understand that information at that level can be difficult to navigate. However, it sets out each of the outcomes that the systematic review considered rather than a selection of outcomes. For a report to be sufficiently credible to influence clinical practice, it needs to be transparent for clinicians and the broader clinical group need to be able to read through it and see all the different outcomes that might be considered.

That becomes particularly important in the case of surgery for stress incontinence, as there is no single surgical procedure that one would describe as a standard choice. It is important to take a step back and remember that a treatment might be non-surgical. However, each of the surgical options has a range of risks, potential benefits and complications, and each differs in that regard. It is important to make sure that all of that subtlety is set out.

10:00

Rona Mackay (Strathkelvin and Bearsden) (SNP): I am struggling to understand your explanation of the tables and your view of transparency. I find it very hard to understand what you just said. However, let us move on.

The petitioners state that the interim report went into great detail about procedures, whereas the final report covered seven procedures in fewer than four pages. The petitioners argue that the suggestion that the transobturator mesh tape can be removed contradicts what all clinicians agreed on in the updated and approved patient information leaflet. How do you square those two things?

Tracey Gillies: That is not my area of technical expertise. That particular point was expressly discussed by the clinicians, and there was agreement that, in their surgical experience, that was the correct wording.

Rona Mackay: It was agreed on in the interim report but not in the final report. What changed?

Tracey Gillies: No. I think that it—[*Interruption*.] I think that what happened in the time between the

interim report and the final report is that surgical experience moved on, which was why they wanted to alter the statement in the interim report about mesh used via a transobturator route not being fully removable. That was a clinician-led decision about the content of the report.

Rona Mackay: That is not what the patient information leaflet says.

Tracey Gillies: There is a recommendation that the information leaflet be reviewed.

Rona Mackay: Do you mean reviewed as of now?

Tracey Gillies: Yes.

Rona Mackay: Do you think that it is acceptable to put out a leaflet for patients that contains information that is not valid?

Tracey Gillies: It is important that all information is reviewed on a regular basis as practice changes.

Rona Mackay: Okay. Thank you.

Maurice Corry (West Scotland) (Con): Dr Gillies, on the issue of mesh-adverse events, it is to be welcomed that the report recommends that it should be mandatory to report all adverse events. However, I am interested in the process that the review undertook in order to reach that decision. Can you outline the decision-making process on that specific point and include the timeline for the inclusion of that recommendation in the final report?

Tracey Gillies: The word "mandatory" was included when the report was being finalised. As I have previously discussed, that followed a conversation in which the mesh survivors group expressed their view to the cabinet secretary, who then wished to meet me to make sure that I understood the depth of feeling on the matter. At the meeting on 6 March, we had a discussion around the use of the word "mandatory", and the group thought that it could be difficult to implement mandatory reporting. However, at the time, it seemed that, if there was a strongly held view about mandatory reporting of adverse events, it would be appropriate to include the word "mandatory" in the final report. I checked that with the group and it was agreed.

Maurice Corry: Thank you.

Brian Whittle (South Scotland) (Con): Good morning, Dr Gillies. On the evidence of the frequency of adverse events, the petitioners say in their submission that they made repeated requests for what they refer to as "the best study" of mesh-adverse events, which was published in the journal *Nature,* to be included in the report. The study in question shows that one in seven women experiences a serious adverse mesh event, but it is not mentioned in the report. Can you explain what evidence the review group considered and how it decided what information should be included or not included in the report? Was there a particular reason for not including the study to which the petitioners refer?

Tracey Gillies: Yes, I can explain that. [*Interruption*.] Sorry—I am looking at a number of notes here. I understand that the study to which you refer was circulated to the group by one of the clinicians prior to my arrival in the group. There was no discussion at any meeting that I attended of whether people wished to include that study.

The evidence that is included in chapter 5 falls into two broad groups. The safety reviews that were included were published by agencies that are charged with device safety, and Cochrane reviews were the systematic review method that was used to assess effectiveness. The *Nature* review does not follow the guidelines for a Cochrane systematic review report, so it was not considered. If the clinicians on the group felt that the review covered important evidence and thought that there was a gap in the report, there were at least three opportunities when it could have been discussed and included.

Brian Whittle: You are saying that the petitioners asked many times for the review to be included but you did not include it.

Tracey Gillies: Any ask for it to be included was not made when I was the chair.

Brian Whittle: The petitioners are concerned by the information that is contained in chapter 6 of the final report, which they believe

"directs the reader to the conclusion that mesh procedures are better than non-mesh ones."

They are of the view that the chapter describes all the advantages of mesh procedures but avoids mentioning adverse events such as mesh erosion/exposure and chronic pain. It also highlights the disadvantages of non-mesh procedures but none of the advantages. How would you respond to the petitioners on that point? Can you outline the extent to which you consider the final report to address advantages and disadvantages equally?

Tracey Gillies: I disagree with that point. Chapter 6 sets out a synthesis of how the different strands of evidence might be used by a clinician. Importantly, it considers non-surgical treatment options and tries to emphasise that surgery is not the only way for the conditions to be treated. It is really a view from the clinicians on the group. My role as the group's chair is to draw the views together in what has been set up as a multi-author review rather than to pass judgment on the technical views that are contained in the report.

Brian Whittle: The report states:

"This chapter is now used to explore some of the nuances of clinical interpretation of the evidence presented earlier."

What exactly does that mean?

Tracey Gillies: As I tried to say in my opening statement, the review contains different types of evidence. Some of the evidence is quantitative results from research trials that have selected a narrow group of the population and randomised participants between different treatments. Those trials are then put together, like different layers, in a Cochrane review in order to see, by looking at the weight of evidence from those randomised trials with their narrow perspective, whether a particular benefit or risk profile is related to a particular treatment.

There is also the type of evidence that comes from the study that ISD produced, which is routinely collected hospital in-patient day case activity data. That shows the outcomes over a much broader population, so it is a much more pragmatic way in which to look at what the outcomes are.

The review also contains qualitative evidence, which is based on people's experience. [*Interruption*.]

The Convener: I understand the scale of the feeling in the room, but I again remind people in the public gallery that we want to proceed as efficiently as possible.

Neil Findlay: I cannot get my head around the dismissal of the report on the incidence of adverse events that was published in the journal *Nature*. Do you find it strange that such an up-to-date report on the incidence of adverse events was not included in such a review? I find it remarkable.

Tracey Gillies: I have come in at the end of—

Neil Findlay: I know that.

Tracey Gillies: You asked me here to answer questions, and it is important that I am allowed to comment.

Neil Findlay: Of course.

Tracey Gillies: I have come in at the end of a process that was set up in a particular way. If I had started the process, I might not, as the chair, have chosen to approach it in the same way. That is not to imply any criticism of the previous chair; it is simply the case that the review has been running for a considerable length of time.

If matters come forward that do not necessarily fit neatly into one of the chapters that have been set out, I understand why people might think, "Why did the review not consider that?" There have been opportunities for any individual member of the group, and any of the people who are far more steeped in the current evidence in this particular area of practice, to contribute to the process if they feel that it is important for their view to be included.

Neil Findlay: Do you find it remarkable that the matter was not raised?

Tracey Gillies: I do not have a clear view on that. I would not want to comment on the technical validity of the way in which the study was done.

The Convener: Neil Findlay can ask one more brief question, and then we will move on.

Neil Findlay: What about the Food and Drug Administration's alert on mesh counterfeiting in the US? What about the fact that the European Union changed the risk level for mesh from medium to high, despite which the report still concludes that the risk is medium?

I have one final point for Dr Gillies. I have always been reluctant to ask this question of any of the women who are involved in the matter; I would find it much easier to do so if I was a woman. Given what you know about mesh, would you, if you suffered from the same condition as many of the women sitting behind you, choose to have such a procedure?

Tracey Gillies: I am rather unclear about the validity of such a personal question about my own health in this setting—

Neil Findlay: Would you recommend it for someone else?

The Convener: Dr Gillies, you do not have to answer that question if you do not want to. You can answer the first point, and you can choose to answer the second point if you want.

Tracey Gillies: Sorry—in thinking about the second point, I have slightly lost track of the first point. Could you repeat it, please?

Neil Findlay: It was on the FDA's warning on counterfeit mesh and the EU's risk classification.

Tracey Gillies: The Medicines and Healthcare products Regulatory Agency is the regulatory body for devices in the United Kingdom. It was part of the group, and it attended meetings. The specific points that you raise were expressly discussed on 6 March, and that input has gone into the final review. The regulatory body in the UK has been part of the group and has been responsible for the content; that is clearly set out. The FDA is not the regulatory body in the UK.

On the second question, it is important to highlight as a difficulty the fact that we are at the forefront of a necessary and important change in surgical practice, from a more professionally led view of what the right procedure for somebody

might be to a much more participatory and equal relationship between professional and patient. That is a difficult change to navigate, but it is very important that we make it.

The professional's role then becomes not to say what they think should be done for an individual but to find out enough about what is important to that individual and to provide them with information that allows them to navigate the information and come to a shared decision about whether to have a surgical procedure. That type of practice requires many more skills from professionals than we currently provide them with if they are to feel comfortable about asking some of those questions and about not providing the normal professional response.

10:15

In answer to your question, if that was me, I would want to ensure that the professional I was dealing with was able to give me an explanation of the risks and benefits of the different options, and to ensure that they would find out from me the things that would be important to me and come to a joint decision with me. I have considered that question for myself, but I do not think that it is appropriate for me to give you the answer.

We have tried very hard, in conclusions 7 and 8 in particular, to set out that none of the surgical options for stress urinary incontinence is, if you like, a clear option to choose. Each has different risks, benefits and complications, and it is not possible to look at the evidence and say, "Choose this one," or, "Choose that one." That is what makes it complicated to understand.

I realise that this did not go down well when I said it at the beginning, but we think that the thing that the final report has strengthened is around the use of mesh in prolapse. [*Interruption*.] There is now clear evidence of no benefit from the use of mesh in prolapse. That is the thing that has changed between the interim report and the final report. It is based on the evidence that the final report was waiting for. All the available evidence points in the same direction.

I point out an important and subtle difference: "evidence of no benefit" is stronger and clearer than "no evidence of benefit". That is the thing that we have tried to move forward in the final conclusion.

Maurice Corry: Moving from mandatory reporting of mesh adverse events to the non-mandatory recording of mesh procedures, I note that figures say that currently only 27 per cent of surgeons record mesh procedures. Systems are dependent on the input of information and the quality of that information.

I ask you to respond to the questions that have been raised by the petitioners in that regard. How will it be possible to obtain accurate information on adverse event rates if the recording of procedures is not made mandatory? If recording is not made mandatory, will more surgeons use the current recording database?

Tracey Gillies: Those are important questions, but the review's purpose is not to provide an implementation mechanism. We have highlighted that, as it moves to becoming an oversight group, what was the expert group must be clear about how it wishes recording to happen and it must ensure that systems are there to support that.

I completely agree that it is not possible to understand the incidence of adverse events if denominator information is not clear.

Maurice Corry: So, it is important to ensure that incidents are recorded.

Tracey Gillies: Yes.

Rona Mackay: How many members of the review group signed off the final report?

Tracey Gillies: I cannot give you an absolute number. Given the difficulties, we were quite careful to ensure that every member of the review group who remained at the end signed off the report. Each of the members who are listed in the appendix signed off the report.

Rona Mackay: How many people were in the review group?

Tracey Gillies: It was between 12 and 15—a number of that order.

Rona Mackay: Were the members happy to sign off the final report, given all the changes, even if they had been involved in producing the interim report?

Tracey Gillies: Yes.

Rona Mackay: You came to the review group as a new chair, and you must have been aware of the controversy surrounding the procedures. Are you happy that the views of the women who have been affected have been reflected in the final report?

Tracey Gillies: I am aware that some people, particularly those who are in the room now, have strongly held views, which are based on very real experience. There are many other people whose voices are less audible, and the report tries to acknowledge that. I wanted to make sure that the review made it into the light of day because there are many women who are unsure about what they should do and, prior to the review being published, many clinicians were not clear about what was the right thing to do. In terms of the totality of people for whom this is important, it seemed to me that

the right thing to do was try to bring the review to publication.

Rona Mackay: I understand that, but I put it to you that the issue is not the views of the people in the public gallery but their experience. [*Interruption*.]

Tracey Gillies: I am sorry if I phrased that incorrectly, because that is not at all what I meant to imply. I absolutely understand that it is about their experience.

Rona Mackay: You feel that their experience, as severe as it has been, has been reflected well enough in the report. [*Interruption*.]

Tracey Gillies: I am sorry if that is felt not to be the case. I think that that also reflects the group's view in not wanting pieces of the review removed at the final stage because people had resigned. It was almost mission impossible from the beginning. One should always reflect on whether one could have done things differently, but I think that we have produced a report that has tried to look at all the available evidence and assimilate it. The respected clinicians from Scotland and elsewhere who participated and the professional bodies that participated have signed off a report that they feel is balanced and reflects the current state of the evidence. [*Interruption*.]

The Convener: When you say that it was "mission impossible", do you mean that you had a mission impossible coming in at the point that you did or that having the review at all was a mission impossible?

Tracey Gillies: Sorry, that is a personal view. As you said correctly, it was clear that there were different strongly held views at the point that I came in. One could say more fool me for agreeing to chair the review. It was not something that most people would have—"welcomed" would be the wrong word, but it was clearly going to be a difficult task.

Personally, having reflected on it, I feel disappointed that I have not achieved what I set out to do, which was to achieve consensus. I hear the voices from behind me and I feel very sorry—[*Interruption*.] I feel sorry that I have not achieved the bringing together of something that people felt able to stay part of to the end. I am personally sorry that that has not happened. If that is due to any fault of mine, I would want to acknowledge that. However, the reason why I accepted what I might describe as mission impossible—that is my personal view—is that I thought that it was important for the totality of women who might face this problem to try to bring the final report to a conclusion, so that there could be the necessary improvements in information and clinical governance, and discussions around treatment options.

The Convener: Thank you. I welcome Alex Neil MSP to the meeting. I invite Angus MacDonald to ask his question.

Angus MacDonald: Obviously, as Neil Findlay indicated, the issue of the risk classification of mesh that the petitioners have brought up is not being looked at in Scotland alone. Indeed, our predecessor committee in session 4 took the opportunity to raise the issue during a visit to the European Commission in Brussels, which is on the record.

The final report anticipates the reclassification of mesh devices as class III, which is the highest-risk category. That is clearly an issue that the petitioners have raised. The date of reclassification as published online was 8 March and the final report was published on 27 March. Was there an opportunity to update the final report?

Tracey Gillies: The final meeting was held on 6 March. In between other agreements on wording, that was not raised and discussed. However, I again point out that we obtained individual sign-off from each constituent member about whether they were happy with the content of the report. It was not raised as something that we could have amended.

Angus MacDonald: Why exactly was it not raised? Do you know?

Tracey Gillies: It is a reason of omission rather than commission. It was not deliberate in any way.

Angus MacDonald: With the convener's indulgence, I will go back to the question that I asked at the start. For the record, as I understand it, the petitioners resigned on 4 March. Will you confirm what was added to the report following the meeting on 6 March? I think that you said that there was some reference to the GMC. Will you clarify that for the record?

Tracey Gillies: I can clarify that. It is the statement that references the obligations on a professional to report adverse events to the necessary regulatory body, which would be the MHRA in this case. If you wait, I will find it. [*Interruption*.] It is in chapter 8. It is on page 91 and is under the heading "Summary". It says:

"The reporting of adverse events is therefore mandatory".

That is the part that was added in later. As we have already discussed several times, that word was added in.

The part that was added after 6 March following the discussion was:

"The reporting of adverse events is therefore mandatory, in line with The General Medical Council's *Good Medical*

Practice which states that, to help keep patients safe, clinicians must:

'report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk.'"

It gives a link to that part in "Good medical practice" and sets out that the MHRA is the organisation that should be informed.

The Convener: A reclassification was reported on 8 March and the final report was published on 27 March. Did no one think that the reclassification merited discussion? Were you not waiting for it? Were you not aware that it was going to happen? I get that something might have happened in the world without anybody noticing, but that was the issue on which the report was focusing. The working group's job was to consider mesh devices. The devices were reclassified and no one thought, "Wait a minute, does this have any impact on the report that we are going to issue on 27 March?"

Tracey Gillies: In terms of how it would change practice, reclassification would not have any other implications for the way in which the mesh is currently used.

The Convener: Sorry—my understanding as a layperson is that the reclassification acknowledges a higher level of risk. The classification is moving from medium to high risk. Is that not significant for a report that is reflecting on the risk that is involved in the procedure?

Tracey Gillies: That point was specifically discussed at previous meetings with the MHRA. I can provide you with an extract of the minutes that outline that discussion.

10:30

The Convener: Do you not think it extraordinary that no one was keeping an eye on the reclassification conclusion? As my colleague Angus MacDonald said, the issue was raised with the European Commission, so it would have been in the minds of people who know a great deal more about it than I do. In the same way as the interim report was waiting for a report to inform its final findings, would the reclassification not have been one of the things to note before signing off the final report?

Tracey Gillies: I understand that point of view. I would be happy to come back to you with a written view on that and I can provide you with the extract of the minutes.

The Convener: You said that it was an omission, but we would be interested to know how on earth it could have been omitted.

Tracey Gillies: That is a fair point.

The Convener: Thank you.

Alex Neil (Airdrie and Shotts) (SNP): Thank you for allowing me to participate in the committee, convener.

I will explore the relationship with the MHRA, which we are told is the regulatory body for devices. A number of issues arise. First, the MHRA has totally failed in its responsibility to people across the UK, not just in Scotland, because of what it has not done. [*Interruption*.] That is not your responsibility or that of the Scottish Government, so we will leave it aside.

As part of the group's work, did you check whether the Scottish Parliament has the ability—particularly under its new powers—to transfer responsibility for regulation in Scotland from the MHRA to the Scottish Government?

Tracey Gillies: No.

Alex Neil: Why not?

Tracey Gillies: When I came in as the chair, the position was that the review was pretty much concluded and we had to move it on. It was not to start unpicking other opportunities to explore—

Alex Neil: The issue is fundamental, given many of the changes that were taking place. I am not a lawyer and I am not saying that the position has changed, but I think that the review group should have checked whether there was any scope for the regulatory function to be transferred from the MHRA to the Scottish Government. You are saying that the group did not look at that issue.

Tracey Gillies: My understanding of what the review was set up to do is that it did not include that question.

Alex Neil: I am sure that, if you had asked the cabinet secretary about extending the review, she would have allowed you to do so.

The MHRA is the regulatory body for devices, but decisions on what can be funded through the national health service in Scotland are controlled by the Scottish Government so, although the MHRA failed in its responsibility to properly regulate the devices, surely the Scottish Government has the power—I exercised such power as the Cabinet Secretary for Health and Wellbeing—not to allow procedures that use devices that may be unsafe and the NHS in Scotland has the power to say that such procedures will not be carried out. Did the group explore that?

Tracey Gillies: I do not think that that is a question for me as chair of the review.

Alex Neil: I have asked whether the review group looked at that issue.

Tracey Gillies: Taking the opportunity to make a recommendation to the Scottish Government about exercising through regulation powers on not undertaking procedures was not my understanding of what the review had been set up to do.

Alex Neil: I set it up and I intended that that would have been covered.

Tracey Gillies: I can only apologise that that message—[*Interruption*.] That was not the brief that I received.

Alex Neil: There was nothing in the terms of reference to prevent the group from asking such basic questions, given the concerns about the devices. Although the regulation of the devices apparently remains the responsibility of the MHRA—that should be checked—if the devices are legal, whether the national health service in Scotland allows them to be used is a separate question that clearly lies within the NHS's responsibility, given that we fund the procedures.

Tracey Gillies: Before you arrived, I spoke about the previous chair, who obviously undertook a lot of hard work and set up the review in a particular way. I do not know her; I have not spoken to her. [*Interruption*.]

The Convener: Will people calm down again, please?

Tracey Gillies: The reasons for the previous chair's resignation are not known to me. I need to respect that situation. I took on the review from the point that it had reached at the end of November 2016. Alex Neil established the review, so he knows what he had in mind, but the questions would probably be more reasonably addressed to the previous chair than they are to me, if he wanted those issues to be explored at the beginning of the review.

Alex Neil: The question is for the whole review group, given that you took over chairmanship of it. Given that, at the same time as it was reviewing the issue, legislation was going through the UK and Scottish Parliaments to transfer substantial additional powers across a wide range of areas, it would have been reasonable, logical and sensible to double-check the scope for taking back regulation of the devices from the MHRA—as I have said, it is not an impressive organisation, to put it mildly—into the Scottish Government's remit.

The Convener: I see that Neil Findlay wants to come in. Please be brief.

Neil Findlay: You had no conversations with the previous chair. Is that correct?

Tracey Gillies: That is correct.

Neil Findlay: A European Union report came out in which the mesh risk moved from medium to high, but your report does not reflect that. Members of the review group—granted, this was before you joined it—went 10 months without meeting. They were excluded from sub-committee meetings and could not access the agenda or minutes of those meetings. Furthermore, it has been suggested that a number of the group's members have conflicts of interest. Many more aspects are at play. Given all that, are you surprised that people see the report as a whitewash?

Tracey Gillies: I can only reiterate what I have said. I have done my best, from the place where I started the work, to include the views as I heard them and to make sure that we considered the evidence, as we had been asked to do, and produced a credible report that set out as much of the evidence as possible.

The Convener: I am conscious of the time—we need to move on. You have said that you found the work to be "mission impossible". There are a number of issues that people are surprised that the group did not investigate. That might have been prior to your time; you had no response to the questions about reclassification. I am surprised that you did not have a conversation with the previous chair, but personal reasons that relate to the other chair might account for that.

Tracey Gillies: That is correct.

The Convener: It would be interesting to know whether there was any attempt to have that conversation or, at least, to have a handover. That does not seem to have happened.

The process that was involved in the independent review work is to be reviewed. Rather than outlining all the issues now, would you be prepared to make an input into that review from the perspective of someone who came into the process late, and particularly on the dilemma of whether a body is broken because so many people have walked away from it?

The group's report tried to bring together the views of clinicians and of those who had experienced the procedures. If those who have had experience walked away, does involving simply clinicians diminish the report?

Tracey Gillies: It is important to remember that another individual who had experience remained in the group.

In answer to your first question, I would very much welcome the opportunity to speak to someone who is reviewing the process of this review, so that future processes are improved.

The Convener: I thank you very much for coming along. If you want to add anything to your evidence—you have highlighted a number of issues—please contact the committee. We would be more than happy to receive what you have

committed to providing and any other further evidence or comment that you want to add. The session has been fairly long and I appreciate that you have been on your own—I know how difficult that can be.

I suspend the meeting to allow a changeover of witnesses.

10:40

Meeting suspended.

10:44

On resuming—

The Convener: I call the meeting back to order. [*Interruption*.] I remind everyone that our time is constrained: we must be finished by 12 o'clock. We have been given permission by Parliament to extend beyond the usual time. I appreciate that we are under pressure; I also appreciate how important the issues are, particularly for the people who are visiting Parliament today. As I said earlier, it is important that we get through the issues as efficiently as possible. I hope to finish questioning by about half past 11, in order for the committee to consider what we have heard, although we can extend slightly beyond that time. I hope that everyone will co-operate with that requirement. I do not want to miss any opportunity to get evidence and I acknowledge the level of interest, but I also recognise the time constraints that are placed on us by issues that are beyond our control.

I welcome Shona Robison, who is the Cabinet Secretary for Health and Sport, and Catherine Calderwood, who is the chief medical officer for Scotland. Thank you both for attending. I invite the cabinet secretary to give a brief opening statement before we move to questions.

The Cabinet Secretary for Health and Sport (Shona Robison): Thank you, convener. I welcome this further opportunity to speak to the committee and members of Parliament on this important topic, following my statement in the chamber at the end of March.

The independent review came about as a result of the efforts of many women who were affected and who strove to make their voices heard. Two of the women—Elaine Holmes and Olive McIlroy—who lodged the petition with the committee, later directly took part in the independent review.

Before I outline the Scottish Government's response to the review's recommendations, I inform the committee—I have written to the convener about this—that I have commissioned Alison Britton, who is a professor of healthcare and medical law, as an independent expert to examine and to report on the process of the independent review. Professor Britton, who works at Glasgow Caledonian University, is a specialist in public healthcare, clinical negligence, mental health law and professional ethics. She will produce a report on how the independent review process was undertaken and, importantly, what lessons can be learned for the future.

I turn to the report. On its publication, the chief medical officer wrote to the chief executives and medical directors of all health boards about the review's conclusions. In particular, she highlighted the conclusions on the circumstances in which mesh procedures should and should not be offered in cases of pelvic organ prolapse and in cases of stress urinary incontinence. She also made clear the importance of health boards ensuring that detailed and patient-friendly information is available to all women. That information must be provided so that women can make careful and fully informed decisions on the best treatment in their case. In addition, the CMO has instructed all health boards to limit the number of surgeons who carry out mesh procedures and to ensure the mandatory reporting of adverse events.

The Scottish Government will establish an oversight group, which will be expected to work with health boards in progressing the review's conclusions. That will include working on guidance for nationally agreed pathways, publishing patient-centred versions of sections of the independent review's report, and producing leaflets on pelvic organ prolapse and post-operative information. I expect patients to be involved in the oversight group's work. I also confirm that Scottish Government officials continue to work with colleagues across the UK to explore a mesh registry pilot. The development of e-learning packages is also being considered for use in general practice.

I want it to be absolutely clear that the key safeguards that are to be put in place as a result of the review must be implemented before any procedures using mesh are reintroduced routinely to healthcare services in Scotland. The chief medical officer has met the medical directors of the health boards to gain assurance that those measures will be in place.

As the people who are here today know, during the independent review's concluding stages, three members felt that they had no choice but to resign from it. That was, of course, deeply disappointing, and it caused me a great deal of concern. I met Olive McIlroy and Elaine Holmes after their resignation because I was very keen to hear directly about their concerns, which I put to the chair of the independent review when I met her.

I turn to the petition that was presented to the committee in 2014. It is worth briefly considering the demands that are contained in it and the progress that has been made towards meeting those demands. First of all, the petition called for the suspension of the use of polypropylene transvaginal mesh procedures. The Scottish Government requested that health boards suspend use of mesh until the independent review published its final report. As I have said, routine service provision will recommence only once the medical directors and chief executives are assured that the recommendations have been implemented.

Secondly, the petition called for a public inquiry and/or comprehensive independent research to be initiated to evaluate the safety of mesh devices using all the evidence available, including evidence from around the world. The independent review was initiated to fulfil that request and has published its final report.

Thirdly, a call was made for the introduction of mandatory reporting of all adverse incidents by health professionals. The final report makes it clear that that is mandatory.

Fourthly, the petition requested that a Scottish transvaginal mesh implant register be set up, with a view to linking it with national and international registers. Scottish Government officials are exploring that with colleagues in NHS England.

Fifthly, it was requested that fully informed consent be introduced, with uniformity throughout Scotland's health boards. Health boards will be required to make every woman fully aware of all the options that are available in her individual case.

Sixthly, the petition asked that the MHRA be written to, to ask it to reclassify mesh devices. The reclassification of surgical mesh has been under consideration by the European Commission and was adopted by the European Parliament on 5 April this year.

Despite the concerns that have been raised, which I fully understand, I believe that progress has been made on the issues that were raised in the original petition. I am happy to take questions.

The Convener: Thank you very much.

Last night, we received information from you about the review of the review. Does not the fact that a review of the review is to be carried out suggest that there is a lack of confidence in the final report? In those circumstances, is it possible that you will revisit the independent review of mesh implants?

Shona Robison: I know how the women who came to see me feel about the final report, because they expressed their feelings about it to me very directly: they feel very strongly indeed about it. I wanted to get an external expert to look at the independent review process because of those concerns and because members of the review group, including a clinician, had resigned. That is not how we want independent reviews to be conducted.

We must look in detail at the reasons for that. If we were not to do so, it would be a missed opportunity to examine the concerns that have been raised about the process, to consider what lessons can be learned about independent reviews in general, to understand the roles and responsibilities of those who take part in independent reviews, and to look at the way in which the evidence was presented and the decision making and governance around that. I think that Professor Britton will be the right person to do that. I hope that she will make recommendations that will help us to ensure that lessons are learned for independent reviews in the future—I am sure that there will be more such reviews—and that we can avoid some of the issues that arose in the independent review of mesh implants.

The Convener: If Professor Britton establishes that the process and the balance of evidence between the professionals and those who suffered as a consequence of the procedures in question were wrong, what will that say about the final report?

Shona Robison: We need to see what Professor Britton says about the independent review process; we will have to wait for her to undertake that work. She will meet everybody who took part in the process. It has undoubtedly been an extremely complex and difficult process; everyone involved has had to deal with a lot of complex clinical information. I have asked Professor Britton to focus on whether there are things that could have been done better and to make recommendations on how to proceed in the future so that, if possible, we avoid difficulties that the independent review of mesh implants faced.

The Convener: I do not want to labour the point, but if the professor, in looking at the review, establishes that the process had an effect on the final conclusions and on the ability to achieve consensus and agreement around them, surely that would take you to the point at which you would have to revisit the review to look again at the conclusions and how they would inform practice in Scotland.

Shona Robison: I am not going to prejudge what Professor Britton comes up with—we need to wait for her to do the work—but obviously I would not have asked her to do the work on the independent review if I did not have concerns

about it and where we ended up with it. It is clear that there are well-established concerns.

We need to wait to see what Professor Britton says. She will speak to everybody who was involved in the independent review and she will make recommendations. I am not going to ignore those recommendations; let us see what recommendations she brings forward and what her analysis is of the process.

The Convener: Can you confirm that the moratorium will remain in place until after the conclusion of Professor Britton's work and your response to it?

Shona Robison: It is very important that the recommendations from the final report are implemented, not least because, for example, the recommendation on the use of mesh for prolapse says that that procedure should not be routinely offered to women. That is an important recommendation. If we were not to implement it, that would not be—

The Convener: With respect, cabinet secretary, that is not what I asked you. I asked you whether the moratorium will remain in place until Professor Britton has concluded. That is a pretty substantial point. Will that moratorium, which I think matters a lot to people, remain in place until such time as you have received and responded to her report?

Shona Robison: As the chief medical officer has made clear, the suspension will not be lifted until the recommendations of the report are implemented. The recommendations are important. Not the least of them is, as I have said, as stated in the final report, that mesh for prolapse should not be routinely offered.

We have to accept that, even during the suspension, when we called for health boards not to go ahead with the procedures, many procedures still went ahead, because it is not a banned procedure. That they did was down to the choice of women, who had full knowledge and who, after discussion with their clinicians in the light of concerns that had been raised, still wanted to go ahead with the procedure. Only the MHRA can ban the procedure and it has not done so. Therefore, it is important—[*Interruption*.]

The Convener: I remind people in the gallery again to be quiet

Shona Robison: It is important that the recommendations that tighten up the use of these procedures—not least the mandatory reporting—are put in place. That is something that the women have called for. This report calls for mandatory reporting. If we were to do nothing and not implement the report, the mandatory reporting would not be implemented. So there are elements of this report, in the recommendations, that are very important and need to be—

The Convener: But the moratorium will remain in place.

Shona Robison: The suspension will not be lifted until the medical directors can assure the CMO that the recommendations, such as the mandatory reporting, are in place. The CMO has been very clear with medical directors that all that has to be in place before these procedures are offered on a routine basis. That is very important.

Angus MacDonald: I think that we will come back to mandatory reporting before the close of this meeting. The petitioner's submission to the committee dated 8 May states:

"Following the resignation of the ex-Chair Dr Lesley Wilkie in November 2016 and the appointment of Dr Tracey Gillies, a serving medical director, this became a government review rather than an independent inquiry. The review has simply lost its independence. The Current Final Report is clearly a whitewash and the recommendations expose women to unnecessary harm."

What reassurances can you offer to the committee, the Parliament and, most important, the petitioners that this report is the conclusion of a wholly independent process, that women can be assured that their experiences have been listened to and that they can have trust in the conclusions of the report and in the processes that led to those conclusions and recommendations?

11:00

Shona Robison: First, Lesley Wilkie's resignation was unfortunate. It was for personal reasons, as she has confirmed to me in writing. It was very difficult for Tracey Gillies to take over that position. This is a very complex issue on which there have been strong differing views, not least within the clinical group in the independent review. It is not unusual for clinicians to disagree, and they did so in the independent review process. That issue has been discussed on a number of occasions.

I will let the CMO say a bit more about the position of Tracey Gillies. It is important to note that she took over as medical director in NHS Lothian after she was appointed as chair of the review group. Catherine Calderwood can say a little about the timeframe.

Catherine Calderwood (Chief Medical Officer for Scotland): Tracey Gillies was previously medical director in NHS Forth Valley, which has not done any procedures using mesh since June 2014. On 1 February, she took up a new position as medical director in NHS Lothian. She was therefore in a health board that was not performing mesh procedures at the time she was appointed as chair of the review group.

Angus MacDonald: That still does not assure us, or the petitioners, that we or they have been listened to.

Concerns were raised at a previous evidence session that Tracey Gillies had made no attempt to contact the previous chair of the group. There may have been personal reasons for that. However, would you not have expected that she would at least have attempted to contact the previous chair?

Shona Robison: Whether or not to contact the previous chair would have been a judgment for Tracey Gillies to make. The previous chair resigned for personal reasons; it is not for me to go into those reasons, but it was clear that she could not commit her time to the review process. On whether there should have been a handover, the new chair would have made a judgment on whether it was necessary to make contact with the previous chair. For continuity, there might have been some advantage in doing so.

On your question about whether the women feel that the independent review process has been positive or has come to the conclusions that they would have liked it to reach, that is clearly not the case. The review has not come to the conclusions that the women wanted—in fact, from most of the correspondence that I have received from women who have been adversely affected by mesh, it is clear that the conclusion that they wanted from the independent review was a ban on mesh. Unfortunately, that could never have been the case, because only the MHRA can ban mesh, and the procedure is approved for use in the UK.

I know that there has been some criticism of the MHRA's evidence to the committee. I have written to Jeremy Hunt to ask him for his view on the way in which the MHRA goes about its business and on whether there are any lessons to be learned on how it can improve its communication and the way it takes evidence.

I am not in charge of the MHRA—that responsibility lies elsewhere—but it is a key organisation in the process, and it is the only organisation that can ban the procedure. I cannot ban the procedure, which is why, during the suspension, women were still able to have the procedure if they consented to it and were fully informed about the risks. We know that that happened during the suspension.

Jackson Carlaw: I want to come in on that specific point. I was a member of the predecessor Public Petitions Committee when we heard evidence from the MHRA in 2015. It was some of the most deeply unimpressive evidence that I have heard in my lifetime, to be frank, never mind in my political career. It was patronising and arrogant, and—much more fundamentally—it was crassly superficial.

I do not think that the MHRA should have been part of the review committee, but that is neither here nor there. Here comes the point. I have asked you, and the First Minister in the chamber, questions about the MHRA. The responses that have been received remind me of a programme that was on when I was a boy called "Hogan's Heroes", which had a character called Sergeant Schultz whose response to everything was, "I see nothing." That has been the MHRA's response.

I am concerned that this is a skirt that you are hiding behind, cabinet secretary, so let me ask you a question. You say that the MHRA is the only body with the power to ban this and that it is a UK-reserved body. I understand that, but if you had the power, would you ban the procedure?

Shona Robison: If the MHRA were a devolved organisation that reported to me and it said that this medical device should not be used, I would, of course, accept that evidence. However, I am not a clinician; I cannot decide what medical devices or procedures should be banned—

Jackson Carlaw: I understand that—

Shona Robison: That is a matter for the experts.

Jackson Carlaw: So the fact that this body—which I believe has fundamentally failed in its analysis and its contribution—is reserved is irrelevant. What you are saying is that, even if it reported to you, you still would not be implementing a ban.

Shona Robison: If a body that is designed to say whether a medical device or procedure should be banned told me that this device should not be banned and I as a politician were then to say, "Well, I'm going to ignore that and ban it anyway," that would be irresponsible of me. I am not a clinician; I rely on those organisations and bodies for advice on whether a procedure should be banned, and this body has said that it should not be.

I agree with you about the way in which the MHRA has gone about its communication in the previous evidence session on this matter. I understand that point—I saw the evidence, too. There is absolutely a need for the MHRA to look into all of that, and I have written to Jeremy Hunt, asking for his view. Obviously, a report on mesh will come to NHS England in the summer and what it says will be of further importance to it. However, with regard to the MHRA's position on all of this, the fact is that, no matter whether that body was devolved or reserved, I would have to follow any recommendation that it made to me as

cabinet secretary on whether to ban a medical device. On what basis would I not?

Jackson Carlaw: I understand that, but I come back to your evidence that no ban is possible because the MHRA is a reserved body. That is actually a convenience, because the fact that it is reserved is irrelevant. Unless the MHRA made such a recommendation to you, you would not implement a ban. That is the point that I am getting to. Given the dissatisfaction that has been expressed about the MHRA's conduct and given the reservations that I think you have expressed, what steps have you taken to have these matters devolved to the Scottish Parliament?

Shona Robison: We want all matters devolved to the Scottish Parliament. I would be very happy for the MHRA's powers to be devolved, and we will continue to make those arguments about that and many other matters.

Jackson Carlaw: Have you made them, though?

Shona Robison: We have to separate out the MHRA's conduct and its recommendations. Whether we think its conduct is right or wrong, its recommendation determines whether a medical procedure can go ahead. No matter whether that is devolved or reserved, on what basis would I as a politician reject that recommendation? We would be getting into very serious territory if I were to decide what procedures should or should not go ahead and what medicines should or should not be used in the NHS. We rely on clinical expertise to determine such matters, and I hope that you would accept that limitation on my powers.

Jackson Carlaw: I accept it to that extent, but surely if we as politicians feel that a body is not acting appropriately and believe that its conduct in an investigation was not comprehensive in a way that inspires confidence, we should intervene—and we have not in this case.

Shona Robison: Every time concerns have been raised about the MHRA—for example, the concerns that were raised about the evidence session and the concerns that you yourself raised in Parliament—I have communicated them to and raised them with the body directly.

The Convener: Is the logic of your position, then, that had you been health secretary when this issue emerged, you would not have called for an independent review, because you could not second-guess the work of the regulatory body?

Shona Robison: The independent review was to look at a number of issues relating to mesh, including the guidance for health boards and what clinicians are asked to do in following the best evidence and guidance. The independent review could not have banned a procedure that is not a banned procedure in the UK.

The Convener: With respect, it could have said that public money should not be spent on it.

Shona Robison: The clinical evidence that has been gathered as part of the independent review process is the clinical evidence. It was probably never going to meet the understandable expectations of many of the women who have written to me saying that they want a ban. That expectation was probably never going to be met through the independent review process, because the process was going to look at when mesh should and should not be used in the NHS in Scotland.

Rona Mackay: Good morning, cabinet secretary. At topical question time on 7 March, you said:

> "at the end of all this"
>
> we must
>
> "make sure that whatever guidance is given to the NHS and clinicians is based on the most robust evidence."—[*Official Report*, 7 March 2017; c 10.]

What constitutes the most robust evidence and how will that evidence base be reviewed to ensure that it reflects the most up-to-date information?

Shona Robison: Catherine Calderwood will come in with some details about the evidence. Whether it is in the interim or final report, a lot of evidence has been looked at through the independent review process. Some of that evidence was from external reports that came into the public domain between the interim and final reports, but all the evidence has been looked at by the independent review process.

It is fair to say that there were clinical disagreements about it, and the fact that the view of one clinician was different from those of the others has been well aired. As I have previously said, that is not necessarily unusual but it has taken on additional significance given the controversy and strong feeling on the issue. Perhaps Catherine Calderwood will say a little bit about the evidence, how that has been handled by the independent review and, importantly, what happens with it in terms of the guidance to boards.

Catherine Calderwood: One of the reasons for the delay between the interim review and the final publication was that we were waiting for several very large pieces of evidence, including a European study that was looking at the safety of the use of mesh, and the prolapse surgery: pragmatic evaluation and randomised controlled trials—PROSPECT trials—which are a long-term follow-up on the use of mesh in prolapse.

It was the evidence from the PROSPECT trials that has led to the conclusion about the use of mesh in vaginal prolapse. The full text in the chapter says that it

"must not be offered routinely"

and that it may be used only in complex situations and then only with the agreement of the full multidisciplinary team. That evidence, which was well worth waiting for, has led the clinical community to completely change the way in which we talk to women about using mesh for vaginal prolapse. We will not discuss the use of mesh, except in very complicated examples of prolapse, and we will use only native tissue to repair prolapse when women come forward with symptoms.

As for stress urinary incontinence, we have waited to collate as much evidence as possible. We knew that trials were going to be published—we had publication dates—and it was well worth waiting for them because we now have a much broader body of evidence and complication rates can be discussed with women based on the most up-to-date evidence.

I have asked that our current information for patients is completely reviewed. We have a standard leaflet for stress urinary incontinence, but it now needs to be updated. There is an instruction to medical directors that mesh is not to be used for vaginal prolapse. We expect the oversight group to keep reviewing the evidence that comes forward and to review the data that ISD is collecting for us. We have new codes because, after the women brought the petition forward, we made changes as we realised that our coding for the procedures was not adequate. It did not reflect the complications and—as the women will affirm—it did not talk properly about removal or the number of procedures that women were having. Those codes have now been revised and will be used in ISD to collect all our data going forward. I expect the oversight group to look at the data for the use of mesh and procedures that do not use mesh across Scotland.

11:15

Rona Mackay: Does that mean that you agree with the petitioners that the final report, which you say will be progressively updated, does not strike the right balance and does not reflect their experience of the procedure as much as it should?

Catherine Calderwood: Absolutely not. I have been meeting women since this process started and I have listened to their stories. You can hear those stories from the women themselves, but they are clearly documented. We know that there are women who have had mesh inserted into them who should not have had it because they were not properly consented. They did not have a full description of what might happen to them in the worst-case scenario. For that, I have already apologised. No clinician intends to harm patients or to harm women.

We have moved from that situation to needing to find out more about exactly what this mesh was doing to women. When some women had the procedure, the full evidence was not available. The clinicians were working on the evidence that they had, but some of it was very short term. Mesh has been used only for around 10 to 15 years. The evidence that we now have has come partly from the brave efforts of women in flagging it up. There is a need for more research and for long-term complications to be followed up.

We have changed the way in which we talk to women who come forward with it. We must remember that around 50 per cent of women will have incontinence at some stage in their lives, so this is an extremely common condition. In some cases, it is very life limiting. It restricts people so they come—[*Interruption*.]

Rona Mackay: I am sorry; I understand that, but the point that I am trying to get at it is this: given the level of risk involved—it is now a category III—would it not be safer to say, "Let's not do this"?

Catherine Calderwood: As I say, the condition is common, so a lot of women come forward. Those who have particularly severe symptoms will be referred up to hospital to a gynaecologist or a urologist to discuss their symptoms. In some cases, the woman will have such severe symptoms that they want to have something done. What we read in the review is that all options must be offered.

Some women will have no treatment at all, and that will be their decision or a shared decision between them and their clinician. However, we want the other women to have all the options laid out with all the complications and risks and the things that these women were not fully aware of because, at the time, they did not have what we now see as fully informed consent.

Maurice Corry: With regard to the shared-decision tables, are you content that all the relevant information is clear, reliable and easily accessible for all those who need to use it in considering treatment options? Does it sufficiently support informed decision making on the part of the person who is seeking treatment?

Shona Robison: I understand that a lot of the discussion in the previous evidence session was about how the information is presented in the review report and the changes that were made between the interim report and the final report. All the information is there in some form, but it is in a different form from how it was presented in the

interim report. The chair has explained the rationale behind that.

I understand the complexity of the issue. The report is not particularly easy to read, which is why there is a commitment to producing a version of it that will be easier to understand. That is the right thing to do, and Professor Britton will look at how complex information—some of it is very clinically complex—is translated into a public-facing report.

Does Catherine Calderwood want to say a bit about that?

Catherine Calderwood: I think that the way in which the review—

The Convener: In the interests of time, I would prefer you to write to us if you have a view on the issue, but I think that the cabinet secretary's points have probably covered it.

Maurice Corry: I clarify for the cabinet secretary and Dr Calderwood that I asked the question because it has been reported that surgeons are reporting only 27 per cent of mesh procedures. Given that low rate, I am concerned about the reliability of the information on which you are basing some of your decisions.

Shona Robison: I ask Catherine Calderwood to respond.

Catherine Calderwood: I, too, am concerned about the issue that Mr Corry raises. Immediately after the review's publication, I wrote to the medical directors. I have my letter here and I have provided a copy of it to the committee to look at afterwards. I said in my letter:

"The Report provides clear guidance on the use of mesh for the two clinical indications. At all times information must be shared with patients and mandatory reporting ... of procedures to a recognised database. In accordance with the General Medical Council guidance, adverse events involving mesh as a medical device must be reported".

I have spoken personally to all medical directors. They received my letter and have welcomed it. They have since been asked to confirm with me their arrangements for starting to audit all the procedures on a recognised database so that a surgeon will not be able to do the procedures unless they are recording their outcomes, including complications, on a recognised database. All the medical directors have said that they will support that.

Neil Findlay: I have no doubt that suffering from incontinence or prolapse is a completely miserable experience, but it does not lead to the loss of someone's job, home, career, marriage or ability to walk or enjoy a life. The report simply does not cut it. I find it remarkable that, for whatever reason, the chairs—the people who headed the inquiry—did not meet each other. Some members of the review group did not attend meetings for 10 months and were never included in the distribution of agendas or minutes, which they asked for but did not receive. The study on adverse incidents that was published in *Nature* was omitted from the report, as were the EU reclassification and the FDA advice note. The original report was completely changed for the publication of the final report. I made freedom of information requests to the cabinet secretary's department for information to tell us what has been going on, but that has still not been released.

The litigation on the issue will be the biggest litigation against the NHS in Scotland's history, and the review simply does not cut it, cabinet secretary. You need to act now to do something about that. All the information about EU reclassification and the new information that came forward after the review and before the report was published was omitted from the report. That is not good enough. [*Interruption*.]

Shona Robison: Since the report was published, there has been the reclassification on 5 April, which was in the offing and was anticipated. However, it actually happened on 5 April. [*Interruption*.] No, it was on 5 April that the European Parliament reclassified mesh. [*Interruption*.]

The Convener: Can the people in the public gallery quieten down?

Cabinet secretary, the date that the committee was given was 8 March, and Tracey Gillies confirmed that it was 8 March.

Catherine Calderwood: I have seen the paper from the European Parliament, which has the date 5 April.

The Convener: Were you surprised that the independent review did not reflect that movement at all?

Shona Robison: As I understand it, the independent review talked about the anticipation of that reclassification, but it had not been confirmed.

The Convener: Would there have been any issue if the group had come to you and said that it wanted to delay publication until post whatever the date was that the reclassification was to be announced by the European Commission? Could it have said to you, "You know what—this is coming up and it might affect what we want to say in our report"? This is quite a significant issue, which you reflected on. The final report was delayed until the PROSPECT report was concluded, so such a request would have been reasonable. If the group had asked, would you have acceded to that request?

Shona Robison: If the chair had asked for more time in the light of that or any other report

that was forthcoming, of course I would have agreed.

The Convener: Would it have been reasonable for you, having been informed by the chief medical officer and given that the announcement about reclassification came out after the report was issued, to ask the group to reconvene for one meeting to reflect on that, consider its significance and add it to the recommendations?

Shona Robison: I understand that the report refers to what the group anticipated would be the change in classification.

Catherine Calderwood: The expectation was that such devices would be reclassified as class III and the report reflects the fact that that was in draft consideration with the European Parliament. We did not have the European Parliament decision at that date, but we can provide it to the committee.

The Convener: I do not want to hog the discussion, but is the European Parliament's decision material to the question?

Shona Robison: As Catherine Calderwood said, the independent review anticipated that the devices would be reclassified, but that had not yet happened, so the report was written with the view that that was likely to happen.

Catherine Calderwood: It is also important to realise that all surgical meshes were reclassified, and not just vaginal mesh.

Shona Robison: We will send the committee the information about the European Parliament.

On the FOI requests, members will understand that there were a great number of FOI requests that involved a lot of information. I reassure Mr Findlay that we will respond to his FOI request as quickly as possible. His office has requested a great deal of information, which it will take time to gather. However, the response will be issued as quickly as possible.

Brian Whittle: Conclusion 8 in the report says that in cases of pelvic organ prolapse,

"mesh procedures must not be offered routinely."

During your statement to the Parliament, you referred to those recommendations as

"clear, unambiguous and incredibly important."—[*Official Report*, 30 March 2017; c 59.]

Will you make clear exactly what is meant by the phrase

"must not be offered routinely",

given that it is open to interpretation?

Shona Robison: The full wording is:

"The use of polypropylene mesh or biological graft should not be offered routinely but may be considered in complex conditions—only after discussion at an appropriately constituted MDT."

As Catherine Calderwood suggested, there may be exceptional cases in which absolutely no other treatment is available to the woman, who decides to go ahead in the full knowledge of the risks, having had them explained to her. Such circumstances would be exceptional. The MDT would be really important in such a case, because the view would not be just that of the clinician but would be discussed by the multidisciplinary team.

Catherine Calderwood: We would anticipate that approach in a very few cases in Scotland. It would usually arise in a case of procidentia, which is when the whole womb is outside the woman's body and there is no other way of keeping that tissue from being outside the body. We can do a hysterectomy, where we remove the womb, but then sometimes the vaginal vault prolapses. That is extremely uncomfortable and causes terrible urinary problems. The only treatment that would suspend the tissue inside the woman's body, in exceptional circumstances, would be mesh. Those are the circumstances in which I would expect it to be used. As we read in the full chapter, for other forms of prolapse, only native tissue must be used and not mesh.

Brian Whittle: My point is that the phrase is open to interpretation—it is not absolutely clear.

Shona Robison: That is why the work that Catherine Calderwood is doing with medical directors makes very clear the exceptional cases in which mesh would be used and the reduction in the number of surgeons who will carry out such procedures. All that tightening up will ensure that the procedures are used only after all the other options have been considered, and with the woman's full consent and understanding of the risks.

As Catherine Calderwood said, we are talking about specific circumstances in which no other treatment is available and, in such a case, the woman must fully understand the risks. It is important to tighten up all of that. Catherine Calderwood is taking that work forward with the medical directors.

11:30

Angus MacDonald: I will go back to mandatory reporting. Dr Calderwood, you mentioned your letter of 27 March to the medical directors of health boards, which we have a copy of—we got it during the meeting. I believe that an instruction was given to cascade that to general practices, too. It sets out your expectations of clinicians and says that

"At all times information must be shared with patients"

and that there must be

"mandatory reporting ... of procedures to a recognised database."

When do you expect the incident reporting and investigation centre procedure for mandatory reporting to be in place? Will there be consistency in the level of information that is recorded?

Catherine Calderwood: The IRIC procedure is in place—it is used for reporting any kind of adverse incident in Scotland, and not only an adverse incident that involves mesh. We have evidence—because the women drew it to our attention—that a great many women had had a number of complications. When we looked at the IRIC data, we saw that tiny numbers were being reported through that system.

We know that clinicians do not report when they should and that there is not a full understanding of the types of complications that they should report. I am taking that forward with the medical directors. Many fewer surgeons will be performing the procedures in question, because I have said that each surgeon who performs them must perform a minimum of 20 a year. Each medical director will know the names of the surgeons who perform those procedures. We will have the data on the database that I described, so we will know the number of procedures involved; the complications will also be recorded. In addition, the clinicians will need to report the complications to IRIC as part of the external adverse review process. We will use those data in the oversight group as we monitor what happens and what complications arise in Scotland in the future.

Angus MacDonald: What is the timeline? Is the IRIC procedure in place now?

Catherine Calderwood: It is already in place. I have met all the medical directors, who have cascaded the instructions to their health board staff who are involved in performing the procedures—not only those that involve mesh, but the other ones—so that they have heightened awareness of the need to report any complications to IRIC.

Angus MacDonald: Is there any sanction if staff do not report complications?

Catherine Calderwood: We have GMC revalidation, which is based on yearly appraisals. I have also discussed with the medical directors the need to discuss the data for the surgical procedures in question. Each surgeon must be asked how many procedures they have performed, what the complications were and whether they reported those complications as per the IRIC criteria for the reporting of adverse incidents. On the basis of the yearly appraisals, revalidation of a doctor is necessary every five years, so that they have a licence to practise.

Alex Neil: At the heart of the concerns about the final report are the perception that it might not have been independent and the issue of the ban. Those are the two core concerns that people have.

On the first issue, I go back to Angus MacDonald's original question, because I think that Professor Britton needs to look at that. I say with all due respect to Catherine Calderwood that I do not think that it really matters whether, when Lesley Wilkie resigned and was replaced by Tracey Gillies, the board of which she was medical director did or did not do mesh procedures; the point is that, at the time, she was an employee of the national health service. Therefore, the perception is that the process was an inside job rather than an independent review. One of the lessons for the future is about how we define what an independent review is and who independent members are. Looking back, maybe the MHRA should not have been on the review group for the same reason, but that is my fault. There is an issue there.

That leads me to my question. Who actually sat down at their computer and drafted the report?

Shona Robison: I will take the first point. I agree that perception can sometimes be everything. Once a perception is out there, it is difficult to change it in any way. I could sit here all day, but the perception will still be the perception.

As you point out, we absolutely have to learn lessons about who sat on the review, who was invited to take part in it, what their expectations were, what the remit of the review was, and what the roles and responsibilities of each and every one in that independent review were. Professor Britton should look at all that to see whether lessons are to be learned. People might still disagree with the conclusions of a future independent review on a different subject, and we might end up in the same place because of that. If people feel that the process has been conducted in the right way, that will be helpful in countering perceptions and the allegations that have been made about this review. Professor Britton absolutely needs to do that; that will be very important going forward.

I understand that the chair drafted the report.

Catherine Calderwood: Yes. I understand that the review group wrote some sections, although, obviously, I was not there.

Shona Robison: The clinicians wrote the clinical section and then—

Alex Neil: The draft was not written by a civil servant or somebody like that. It was written by the members of the working group—is that right?

Catherine Calderwood: That is my understanding.

Shona Robison: That is also my understanding. I understand that the chair wrote the overview, because there was obviously the matter of the lead-in and recognising some of the difficulties. The overview is therefore very much her reflection. The clinicians wrote the clinical bit. Different people drafted different parts of the report.

Alex Neil: It would be useful to see a breakdown of who the authors of the various parts of the report were. That might—or might not—answer questions about the reliability of the report in people's minds.

As well as Olive McIlroy and Elaine Holmes resigning from the working group, a consultant resigned. I do not think that he has spoken publicly yet, so what were his stated reasons for that? Why did he resign from the working group?

Shona Robison: That person has not been named in the public domain, so I will talk only about the clinician. As I understand it, the main reason for his resignation was a disagreement with the other clinicians about the evidence. His preference was for a procedure called colposuspension; he felt that that should be the main procedure offered to women. The other clinicians disagreed and said that it should be one of the options, but other options should be offered. If we boil it all down, there were probably other issues, but I understand that that was the main problem. There was a fundamental disagreement on that point, which led to the clinician's resignation.

Alex Neil: That leads me on to the ban. Catherine Calderwood can correct me if I am wrong, but I understand that a ban has been imposed in some jurisdictions, specifically Australia and parts of North America. Is that right?

Catherine Calderwood: I think that there is a restriction on use, which is much the same as what we recommend.

Alex Neil: So are you saying that there is a total ban nowhere?

Catherine Calderwood: Yes. That is my understanding.

Alex Neil: Are you sure about that?

Catherine Calderwood: I can certainly clarify that for you.

Alex Neil: I have been told that there is a total ban in parts of Australia. That information would be quite useful.

Shona Robison: We can look into that. Places will have their own regulatory regimes—their equivalents of the MHRA—but we would expect all of them to draw on similar evidence bases for the recommendations that they make.

Alex Neil: That was my point. If they have introduced a ban, why did they do that whereas we did not, and what lessons can we learn from them?

Catherine Calderwood: We can write to you about that.

Alex Neil: I think that the whole committee—

Shona Robison: We will write to the convener.

The Convener: Okay. Thank you very much. Are there any final, brief questions from the committee?

Brian Whittle: The way in which evidence is gathered is crucial in any review. Concerns have been raised today about consistency among NHS boards of the reporting of adverse events and the consistency in the guidelines on what constitutes an adverse event. Could those things be better addressed?

Shona Robison: We have been working with NHS boards on reporting of adverse events in something that is completely unrelated to mesh—namely, maternity services. The issue emerged in NHS Ayrshire and Arran, and it brought to my attention that the guidance needed to be implemented, although the guidance to boards on adverse events is clear. Work is going on with boards to ensure that they classify and report adverse events in the same way. That will be strengthened by the duty of candour provisions that will come in next year. There will be a requirement in the law around the information that is put into the public domain on adverse event reporting.

Catherine, do you want to add anything on that?

Catherine Calderwood: We know that the guidance has not been adequate and has not been standardised. On this particular topic, the oversight group will produce standardised guidance and scrutinise adverse event reports. On adverse event reporting more widely, Healthcare Improvement Scotland has done a lot of work recently to try to improve levels of reporting, standardise it and, more important, look at adverse events and learn lessons so that we can improve the services.

Jackson Carlaw: At the meeting that Elaine Holmes and Olive McIlroy had with the cabinet secretary following their resignations, they drew to

her attention that out-of-date information was still residing in a number of NHS facilities and general practitioner surgeries. I think that the cabinet secretary gave an assurance that she would take steps to have that information removed and updated. Can you give an assurance that that has happened and that no out-of-date literature is still being circulated?

Catherine Calderwood: I can certainly assure you that, as Angus MacDonald pointed out, my letter was cascaded right through the system, including to general practices. Everybody should have received that letter so, when there are discussions, people should be talking to women using the up-to-date information from the review.

I cannot say that there will not be an out-of-date leaflet sitting in a GP surgery. There are out-of-date *OK!* magazines and all sorts sitting—[*Interruption*.] I am sorry—I did not mean that to sound as it has been interpreted.

The Convener: Can people just calm back down?

Catherine Calderwood: I would not want to assure the committee that you would not find an out-of-date information leaflet in a GP surgery or a hospital, but I know that we have made sure that the information is available to those who will discuss the women's problems with them.

Shona Robison: We are striving to make sure that that is not the case. I think that you will appreciate that it would be difficult for me to give an assurance that there are not out-of-date leaflets in surgeries anywhere. We are working hard with health boards to disseminate information to GP practices to avoid that where at all possible, but that is work in progress. I am happy to keep you updated about that.

The Convener: Thank you. I have two very brief final questions. We do not have time for you to respond in full. Are you concerned that although there was full sign-up to the interim review, the final report was not able to attract full sign-up?

Secondly, there was discussion during our earlier evidence from the review chair about your reporting a request that information that the women had provided be removed from the report. My understanding is that you asked for that to be done, but it was not done. You might want to reflect on what Tracey Gillies said to us, but it would be good if you could come back to us on that. We are concerned that a request was made to you that what the women had contributed to the report be removed, which you then pursued with the review chair, but the request was not seen as significant. I do not want to put words in their mouths, but the sense is that their having participated was almost being used as a means to have the women take part in a process that they did not agree with.

11:45

Shona Robison: I understand that. We talked at length about that when I met the women on 16 March, when we talked in detail about a number of issues. They also mentioned their support for the interim report, as opposed to the final one. I understand that position, but it is still important to recognise that there are important recommendations in the final report—not least, the one on mesh for prolapse, which we have talked about. Mandatory reporting was also not recommended in the interim report, but was in the final report.

On the information, when I met the chair on 22 March, I relayed to her all the concerns that the women had expressed. She then contacted them to ask about a number of pieces of information and to seek clarification of what should be removed. The women responded on, I think, 23 March with a list of information that they wanted to be removed. It was, ultimately, the chair's decision on whether to accede to that request. She clearly agreed with some of it: she agreed to remove, for example, the minority report and gave her reasons earlier about why she did not remove the other material.

It is not my report. It is an independent report and it was for the chair to make that decision—[*Interruption*.]

The Convener: Shh!

Shona Robison: —but I relayed to the chair the concerns that the women had raised.

The Convener: We might have to write to you about that, because there is a feeling that people thought that you would at least indicate your support for removal of the material. It would be useful for you to look at the exchange in the committee and we can pursue the matter further. I am genuinely concerned about time and I appreciate that the issue is so significant for so many people that we do not want to lose the opportunity to get it absolutely right.

Shona Robison: I will do that, convener.

The Convener: We are nearly 10 minutes away from having to stop altogether, so I thank you, cabinet secretary, and the chief medical officer for your evidence. The committee will now consider how the matter should be taken forward. If there are further things that you want to feed into the committee's consideration in the coming period, that would be helpful.

My sense is that the difference between the interim report and the final report that was agreed

is so significant that we should ask the petitioners to come back and give oral evidence. It would be worth our while to ask everyone who was on the review group, whether or not they resigned, to give evidence about their feelings about how the conclusions were reached. The extent to which they want to do that will be a matter for them, but it would be useful.

Do members have other suggestions?

Angus MacDonald: First, we should reflect on the evidence that we have heard today. We have received a great deal of additional information and the petitioners' views should be sought. In the meantime, I am keen to instruct our committee clerks to seek time for a debate on this serious issue in the chamber to allow other members of Parliament to raise the concerns that they no doubt have. We had a ministerial statement on 30 March, but a parliamentary debate would be justified. I am not sure whether it could be put in the diary for before the summer recess, but a full debate in the chamber is long overdue and should be explored further.

The Convener: We could certainly explore that with the Conveners Group, but there are limited slots for committee debates. However, I am sure that the Scottish Government is also aware that it would be important to have a debate, so perhaps it can be flagged up to the Minister for Parliamentary Business through the cabinet secretary.

I think that we are agreed that this is certainly not a petition that we want to close. There is further information that we need and further concerns that have to be addressed, some of which I have already suggested. Does anyone have any other comments?

Rona Mackay: I fully support having a chamber debate. As for getting more evidence, I would be keen to hear from the members of the group.

Maurice Corry: And the MHRA.

The Convener: I think that we have already heard from it.

On Alex Neil's comment, we should ask the clerks to find out whether the regulatory powers are coming to the Scottish Parliament. If so, that might be something that we could ask the Scottish Government about. The question for me on many of the issues is where the authority of the clinician stops. It is very difficult: with clinical decisions, we just have to say, "Fair enough" but, as Alex Neil mentioned, if there is a regulatory system, does the national health service have to sanction the decision? It would be useful to understand how that works.

Alex Neil: The other issue that might be clarified is whether there are any waiver powers. A parallel example—when I say "parallel", I must point out that I do not know the up-to-date regulatory position, given the new powers—can be found in housing, where we did not have the power to licence the private rented sector. I understand that we now have that power, if we want to use it, but none of us would have known that from the way in which the legislation was presented at Westminster. It would therefore be useful to get an advisory update on the scope, if any, for repatriating MHRA powers under the new legislation.

Brian Whittle: For me, there are now more questions than answers. Listening to the testimonies, particularly in the first evidence session, I found so many blank spots that I need time to reflect on everything that we have heard today. Without doubt, we need to hear from the petitioners again and get their views on the review and what happened between the interim report and the final report. I also support Angus MacDonald's call for a debate in the chamber, because somehow or other, we have to bring the matter to a conclusion.

The Convener: We want to take more evidence from the petitioners and other stakeholders whom we have identified, including the people who were on the review. I know that the chair of the review changed, but a group of people remained; we need to hear their views of how things changed and the views of those who resigned. We will respect the privacy of those who do not want to say anything either in public or to the committee, but it would be worth our while to seek that information from them.

Alex Neil: This might be more for Professor Britton, but perhaps we should get an understanding of the process. If members of the review group were drafting sections of the report rather than one person pulling together the draft on the basis of the group's discussions, that would, I think, be a recipe for a lot of things happening—for example, the entire group endorsing something without necessarily realising what had been written up. Such a process is highly unusual for an independent review.

The Convener: I can give you an example that was highlighted before you came in, Mr Neil. The interim report says:

"The Independent Review expressed serious concern that some women who had adverse events found they were not believed",

whereas the final report says that

"women who had adverse events felt they were not believed".

It is clearly the same report, but in different versions. It is not as if the final version is a new report or the review had started again. The group

worked on the interim report and, in my view, softened it up.

Alex Neil: Having more than one author draft a report leaves it wide open to things becoming problematic. I have never heard of a process in which members of a group draft different sections of a report; there is usually a secretariat. I am pretty sure that we had agreed that an independent secretariat would do that work. [*Interruption*.] Is that what happened?

The Convener: I am sorry, but we are not going to have a dialogue. [*Interruption*.] It is okay. Everyone has been extremely well behaved, but I know that we all start to get jumpy five minutes before the bell.

It would be useful to find that out, but Professor Britton will probably look at that issue, too, given the reference in the cabinet secretary's submission to

"management and presentation of evidence".

We can pursue the matter, but we should recognise that the independent expert might also look at it.

There are substantial issues for us to pursue. There is also work for the clerks to do, and there will be, I think, an opportunity for people who have an interest in the matter whose voices have not yet been heard. Obviously we will keep people informed of progress, especially the petitioners, who might wish to give us more information in response to what has been said at this meeting—although we will be calling for evidence from them, too.

I am sorry for keeping the cabinet secretary here. I thank everyone for their attendance. I recognise the scale of the interest among the people in the gallery, and I thank them for abiding by the general constraints of the committee meeting. It was very much appreciated by me and, I am sure, by the other committee members. I also thank non-committee member MSPs who attended the meeting.

Meeting closed at 11:56.

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