OFFICIAL REPORT
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Public Petitions Committee

Thursday 28 September 2017

Session 5

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PUBLIC PETITIONS COMMITTEE
17th Meeting 2017, Session 5

CONVENER

*Johann Lamont (Glasgow) (Lab)

DEPUTY CONVENER

*Angus MacDonald (Falkirk East) (SNP)

COMMITTEE MEMBERS

*Michelle Ballantyne (South Scotland) (Con)
*Rona Mackay (Strathkelvin and Bearsden) (SNP)
*Brian Whittle (South Scotland) (Con)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Dr Wael Agur
Jackson Carlaw (Eastwood) (Con)
Neil Findlay (Lothian) (Lab)
Elaine Holmes
Olive McIlroy
Alex Neil (Airdrie and Shotts) (SNP)
John Scott (Ayr) (Con)

CLERK TO THE COMMITTEE

Catherine Fergusson

LOCATION

The Robert Burns Room (CR1)

Scottish Parliament

Public Petitions Committee

Thursday 28 September 2017

[The Convener opened the meeting at 09:17]

Continued Petition

Polypropylene Mesh Medical Devices (PE1517)

The Convener (Johann Lamont): Welcome to the 17th meeting in 2017 of the Public Petitions Committee. I remind members and others in the room to switch phones and other devices to silent.

Our only agenda item is consideration of PE1517 on polypropylene mesh medical devices, by Elaine Holmes and Olive McIlroy. The petitioners are in the gallery this morning, and I also welcome to the meeting a number of non-committee MSPs: Neil Findlay, Jackson Carlaw, John Scott and Alex Neil.

We will take evidence from two panels. First, we will hear from Dr Wael Agur, who was a clinician member of the independent review of transvaginal mesh implants before resigning on 1 March. After we hear from Dr Agur, we will take evidence from the petitioners, Elaine Holmes and Olive McIlroy.

Members have a note by the clerk that summarises the evidence that we heard in May from the chair of the independent review, the Cabinet Secretary for Health and Sport and the chief medical officer. The note also contains an overview of the submissions provided by the witnesses in advance of today's meeting. Those submissions are included in our papers, and members have a copy of the timeline of email correspondence referred to in the petitioners' submission.

The committee has also received a number of submissions from mesh survivors describing the impact of mesh on them and their lives, and the submissions that were received before our meeting papers were issued are included with our papers. Submissions received after that date are in the process of being published and will be put on the petition website. We should note for the interest of the committee and others that the scale of the response from across the world has been very significant, indicating that interest in the petition goes way beyond Scotland.

As we have a number of areas to cover this morning, I propose that we move to the first evidence session. I welcome to the meeting Dr Wael Agur, consultant gynaecologist and obstetrician and a former member of the independent review. Thank you for attending this morning, Dr Agur. You have an opportunity to make a brief opening statement, after which we will move to questions.

Dr Wael Agur: Thank you, convener. I am truly grateful for the opportunity to appear before the committee to provide evidence and answer members' questions. I thank the patient campaigners, Elaine Holmes and Olive McIlroy, for bringing this important subject to public awareness by petitioning Parliament to urge the Government to take action on six particular points in order to reduce harm to women considering surgery for stress urinary incontinence and pelvic organ prolapse.

I was invited to participate in the independent review of transvaginal mesh procedures as a clinician member, and I thank all members of the review group for all their efforts and teamwork over the past three years. I signed up to the publication of the interim report on 3 October 2015, but I resigned four weeks prior to the publication of the final report on 27 March 2017.

I believe that the Government's final report could have done more to reduce harm without losing value, to highlight the details of mesh-related risks while maintaining a patient-centred approach and to promote shared decision making between patients and their clinicians while striking a good balance with the trade-offs to be considered. More needs to be done to bring the report up to the standards and principles outlined in the chief medical officer's framework document, "Realistic Medicine".

I request that the committee urge Government officials to open the final report to a public consultation period of, for example, six to eight weeks. As part of what is a well-recognised transparency process, officials can publish the feedback received from various stakeholders and the responses from the review body and amend the report, if necessary. Similar procedures were adopted by the European Union prior to the publication of its final report on mesh procedures and devices, and it is a well-recognised procedure that is undertaken before the publication of clinical guidelines by the clinical guideline development group of the National Institute for Health and Care Excellence in England. I believe that alongside the announced review of the process by Professor Britton, an accompanying review of the outcome or the content—by which I mean the report itself—would restore full credibility and public confidence to the mesh report and, more important, reduce harm to women considering surgery for incontinence and prolapse.

Since the petition was lodged in May 2014, the committee has heard from patient campaigners,

journalists, lawyers, health ministers, medical officers, public health consultants, two chairmen of the review and a representative from the device watchdog, the Medicines and Healthcare products Regulatory Agency. This is the first time that the committee has heard from a surgeon who used these medical devices in surgical procedures and a surgeon who used to be a member of the Government's short-life working group, a member of the expert group and a previous member of the independent review group.

All views expressed in this statement, in my submission and in my answers to your questions are mine and are based on my interpretation of scientific evidence, my values and the standards by which I practise medicine. I hope that my appearance today will be helpful to the committee in taking matters forward, and I am ready to take your questions.

The Convener: Okay. Thank you very much for that. I call Neil Findlay.

Neil Findlay (Lothian) (Lab): With your indulgence, convener, I would like to raise a few issues in relation to Dr Agur's written declaration of interests before we begin the session. I think that it might be helpful.

In the final entry in your declaration, Dr Agur, you point to a piece of work for the University of Aberdeen, which you describe as:

"Ensuring accuracy and integrity of the SIMS pilot (short- and long-term) study".

I want to tease that out a bit. What was the issue with "accuracy and integrity"?

Dr Agur: I collaborated with the single-incision mini-slings study, which was the pilot study that recruited patients in 2010. As such, it was different from the definitive larger SIMS study that finished recruitment last year. I collaborated with the pilot SIMS study, but I did not recruit patients for the definitive SIMS study.

In the 2010 study that I collaborated with, the outcome reported by us—the researchers—had different parameters. In other words, we looked at different parameters to assess the outcome and decide which mesh procedure was the best. I felt that those parameters might have changed during the study, and I wanted to be absolutely sure that what patients had reported to us was what we had reported in the manuscript that was to be published as part of the scientific literature. Given that it was clearly a very high-profile issue, with a lot of interest from several stakeholders, I wanted to be absolutely clear that all the figures and parameters were 100 per cent accurate before we published. I continue to collaborate with the University of Aberdeen to make sure that the two studies—the one on which four papers have been published and the one on which we are about to publish—are 100 per cent accurate before they go into the scientific record.

I am currently waiting for the University of Aberdeen to provide me with a governance report; once that happens, I plan to visit the university to review the data. This issue is so important that, before I will put my name on a publication, I have to be 100 per cent comfortable that it is accurate.

Neil Findlay: Convener, I have more questions about the declaration of interests in relation to the review group. Is it appropriate to raise that issue now or later?

The Convener: Perhaps we should make some progress first, and I will call you back in later to ask that question.

Dr Agur, can you summarise for us the differences between the interim report and the final report and tell us why those differences matter?

Dr Agur: From my point of view, the main differences can be found in chapter 6—the clinician chapter—and the conclusions. The differences between chapter 6 in the interim report and that in the final report are in the way the data were presented. In the interim report, we were very clear on the methodology that was adopted and which I describe in one of the appendices to my submission, entitled "Notes on the deleted Chapter Six".

We approached the issue by summarising, reviewing and meta-analysing the top evidence from international studies on the topic, comparing two different mesh procedures—the two most common mesh procedures performed in Scotland—and identifying the important outcomes for clinicians and for patients. We looked into the details of the trade-offs between the advantages and disadvantages of the two procedures, and we added the accurate figures from the review and put it in a format that the lay person would understand. We highlighted what the authors of the study concluded was the better procedure and what we, after interpreting the evidence—by which I mean, not just going to the authors' conclusions but going deeper into the data—believed was important and believed was the better procedure. We also took into consideration patients' views and the outcomes that were important for them.

The conclusion that we came to at the end of the chapter was, at the time, unusual in expressing concerns about the continence procedure most commonly presented in Scotland. The Scottish independent review group was the first authority in the world to formally express concerns about a procedure that many clinicians and surgeons and other authorities around the world considered to be a gold standard. It was a

big step for us, and it was achieved because we looked at the details of the evidence, not just as clinicians but as patients, regulators and representatives of clinical societies. That is where evidence comes to life. If evidence just sits in the literature and is not interpreted, it does not live; it comes to life when clinicians, patients, regulators and other stakeholders interpret it.

Our approach was a huge success, and other institutions and organisations followed our path. In any case, I am not aware of receiving at that time—in October 2015—any formal feedback that criticised our unique position. The fact that we had expressed concerns about the procedure most commonly performed in Scotland prior to the suspension of procedures was, as I have said, a big step forward.

Unfortunately, that expression of concern was removed from the conclusion of the final report—it is not there any more. When I speak to my clinician and surgeon colleagues about why the concerns were removed, I get different responses. Some say that there used to be concerns, but they are not there any more, which might mean that the procedure is better; or they say that because there are no more concerns, we can go on and perform it. On the other hand, others feel that the complete removal of concerns about the procedure from the conclusions shows that those concerns are being firmed up. In my view—and from speaking to my colleagues—I believe that the recommendation sends an ambiguous message.

09:30

I believe that the concerns were removed with the significant changes that were made to the format and content of chapter 6 between the publication of the interim report and the publication of the final report. All the methodology that we followed prior to the publication of the interim report was completely changed with the deletion of the previous chapter 6 in January. That has now been replaced by a chapter of only four pages that sets out the current opinion of the majority of clinicians and contains no references. Unfortunately, that chapter now very cleverly expresses all the advantages of the mesh procedures for incontinence without mentioning the most common adverse event, which is mesh erosion, or the most debilitating adverse event, which is chronic pain. Those important adverse events should have been mentioned in the current chapter 6. They were mentioned in the chapter 6 that was in the interim report and in the chapter 6 that was deleted in January with the three additional tables. The original chapter 6 gave far more information in a format that patients and clinicians could understand and which would help them reach shared decision-making in considering the mesh procedures.

Angus MacDonald (Falkirk East) (SNP): Good morning, Dr Agur. I will follow on from the convener's initial question. You have stated that you have concerns about the use of best available evidence. Can you expand on that and give us some more detail about your concerns?

Dr Agur: Do you mean concerns about the use of best available evidence in the chapter?

Angus MacDonald: In general.

Dr Agur: Several resources are available to the review group. Chapter 5, which was written by our colleagues in the public health department, reviewed several sources of primary and secondary research before summarising the studies. They also looked at reviews by Governments and regulators all over the world.

The evidence can be conflicting, and that conflict needs to be resolved. There are differences in the conclusions of some of the reviews, and differences between international evidence, evidence generated here in Scotland and evidence coming from England. It was our duty to sit together and resolve all that evidence, agree on the most likely outcomes, compare the mesh procedures and bring the patients on board. It was our duty to provide good leadership. I believe that more could have been done, mainly in relation to safety.

With regard to the efficacy of mesh and non-mesh procedures in controlling the condition of stress urinary incontinence, there is no significant difference between the two. The mesh procedures never promised to control stress incontinence better than the non-mesh procedures; all that they promised were recovery-related advantages: shorter theatre time, shorter anaesthetic time, shorter hospital stays and quicker return to normal activities. Those are important outcomes for many, many women, but they may not be as important when the lifetime mesh-related risks are considered. I believe that some evidence could have been scrutinised better and that there has been evidence of some differences in outcomes that we could have brought together to resolve that conflict.

Neil Findlay: You gave a list of advantages. Is it also a cheaper procedure?

Dr Agur: Yes. There is evidence that adopting mesh tape procedures for incontinence saves the NHS a significant amount of money. That is true.

Neil Findlay: Is there a ratio? Is it five times as much? Twice as much?

Dr Agur: The original difference showed it to be—I cannot remember the figure exactly—between £100 and £200 per procedure.

Brian Whittle (South Scotland) (Con): In evidence to the committee, the chair of the review said that they did not consider the evidence presented in the journal *Nature* because it did not meet the Cochrane review criteria. Would you care to comment on that?

Dr Agur: The Cochrane review criteria look only at randomised evidence, on the basis that randomised controlled trials are the best trials that can be conducted and that that is the best evidence. However, the vast majority of randomised controlled trials do not follow the patients long enough and they are not best designed to identify the exact differences in safety or adverse events, particularly if those adverse events happen years later, long after the researchers have stopped following up patients.

The best designed study is to look retrospectively at analysis of large databases. The *Nature* study that you referred to looked into more than 300 studies that describe mesh-related adverse events and is currently the best evidence summary of mesh-related adverse events. The study was commissioned by *Nature*, which is a leading journal, and conducted over at least two or three years. Currently, it summarises the best evidence on mesh-related adverse events. It said that the risk of a negative outcome was 15 per cent—one in seven—which includes the procedure's failure to control incontinence.

I wish that we had had more time to discuss that study in detail. The study was circulated to the group twice—once by the secretary last year and again directly by me—but it was not included in the agenda. If it had been included in the agenda, we would have described the mesh-related adverse events a little better. We would have been more informed.

Brian Whittle: The cabinet secretary has advised the committee that the review to be undertaken by Professor Alison Britton will consider the process of the independent review but will not re-examine the evidence. Again, I would appreciate your comments.

Dr Agur: That is so important. I very much welcome that move, because there were issues with the process. Obviously, the cabinet secretary also felt that a review of the process was necessary. That is really good.

It is important that we have a parallel review of the content or the outcome of the process. If we are concerned about the process, we are concerned about the outcome as well. If the stakes are high and lives are at risk of being ruined, a review of the content is important.

Obviously, we cannot roll it back. I do not think that the review by Professor Britton will change the process that has already happened, but there will be lessons to learn for other independent reviews performed by Government. There will be lessons to learn, to look back on and to reflect on for us as ex-members of the group. The best way in which to look at the outcome of the review would be by opening up the report to a public consultation process. That is a well-recognised process for issuing clinical guidelines and independent reviews.

The Convener: Do you have a view on whether the review was independent? Is that part of the problem with people having confidence in it?

Dr Agur: I heard the criticism that the previous chair was more independent than the current chair. As a clinician member of the group, I do not look much at the independence. I have a task in front of me to find the evidence, discuss it with my colleagues, present it in a way that lay members of the group, particularly the patients, will understand and bring everyone together around the conclusion, even though it is not in line with the views of other organisations. We managed to do that very successfully before the publication of the interim report, but unfortunately that did not happen prior to the final report. I have heard the criticism that an independent review is independent only if the chair is independent. I am a clinician—I am not a politician, really—so I will leave that to politicians to decide.

The Convener: Good luck with that one.

John Scott (Ayr) (Con): Thank you, convener. Good morning, Dr Agur. I thank the committee for making me so welcome.

May I recap? Perhaps I missed it, but could you please tell me—and put it on the record—why you think that chapter 6 was withdrawn and what the implications of that are in medical terms and for patients?

Dr Agur: I do not know why chapter 6 was deleted. To "know" means that I would have asked, "Why was it deleted?" and then I would have received the answer, "It was deleted because of one, two and three". I asked why we were deleting the chapter, but I did not receive a response that was formal or convincing.

I put in one of the appendices a timeline of how the chapter was drafted back in May 2016, in response to the publication of a very important Cochrane review in March 2016. We followed the methodology that we started with in summer 2015 for the interim report. It was important to me that we maintained consistency, even if the conclusions and figures were different from what we believed and challenged our belief.

Prior to drafting the chapter and prior to summarising the review that was published in March 2016, there were no disagreements whatsoever; in fact, the meeting in March 2016 was expected to be the final meeting. The publication of the new review prompted us to go back, look at the figures and address the review in exactly the same way as we had done in 2015. Consistency was important to me, so I drafted the summary of the March 2016 review exactly as I had done the work in summer 2015, and it surprised me, as it challenged my belief. I believed that the vertical, or retropubic, tape was a gold standard and was safer than the non-mesh alternative—colposuspension and autologous sling. The figures challenged what I believed.

I felt as though I was stumbling on the truth and that I could either just stand up, brush it off and carry on as if nothing had happened, in which case there would be no problems at all, or I could sit down, reflect on whether it was really true, present it and ask my colleagues what they thought. I chose the second path: I sat down, reflected, summarised the review exactly and consistently with what I had done in summer 2015, and presented it to my colleagues and the rest of the group. That is exactly what I did.

Rona Mackay (Strathkelvin and Bearsden) (SNP): Good morning, Dr Agur. Your timeline makes a number of references to the calls to delete table 1, which obviously relates to the concerns. Who made those calls? Was it clinicians?

Dr Agur: We sat together, and we looked at the summary of the evidence in exactly the same way as we did with the interim report. There were calls to delete the tables. Several reasons were given, including that the figures were not accurate. We looked at the figures again, and we ensured that they were accurate. The claim that the figures were not accurate was made again, so we went to the original author of the independent review, who is in south-east Asia somewhere, and she responded very quickly—I put an acknowledgement to her work in the deleted chapter, actually. We verified beyond doubt that the figures were accurate. It was the clinician members of the group who decided at the end, by a majority, to remove the tables.

09:45

Rona Mackay: I struggle to understand why they would do that if the figures were accurate.

Dr Agur: The figures were accurate. I do not know why they did that. I asked the question. I am sure that Professor Britton will look into how it came about that the format of chapter 6 changed completely, because I have to tell you that I do not know.

The reason that was given at the time was that the figures were not accurate, but we ensured that the figures were accurate. The reason that was given later was that all the evidence should be in chapter 5, not chapter 6, but my view was that we needed to maintain consistency. If we publish something in the interim report and it has worked well and patients have signed up to it, there is no need to change the format. I put it to the whole group that doing a U-turn on our methodology and risking inconsistency was not healthy for the group.

Rona Mackay: Thank you. Can I just ask one more question? Are you surprised that more than 400 people appear to have been given mesh implants since the moratorium began in 2014?

Dr Agur: Yes and no. There is a Government suspension in place. There was a request to the health boards to suspend all procedures. Some health boards decided to follow the suspension; others decided not to do so. I advised my board to partially suspend; I advised it to suspend the mesh procedures for prolapse, which I had already suspended in my practice. I also advised my board to suspend the mesh procedure for incontinence using the horizontal tape, but I wanted to continue using the vertical tape because, at the time, in 2014, I was convinced that it was the best treatment. However, the managers in my health board decided to follow the Government suspension in full. In retrospect, they were right, and I was wrong, and I told them that.

Rona Mackay: So the health boards had complete autonomy on whether to follow the guidelines or not.

Dr Agur: Absolutely. When the request from the health minister goes to the boards, it goes to the chief executive and the medical director. The medical director will ask the group of clinicians and surgeons who perform the procedures for their views, saying, “A letter has come from Government asking us to consider the suspension. Will we suspend, not suspend or partially suspend?” It is true that there has been variation in practice by the health boards.

Alex Neil (Airdrie and Shotts) (SNP): I will begin by going back to the report. Do you think that the conclusions of the final report are supported by the evidence taken and the research done by the independent review group, or do those conclusions basically ignore some or all of the evidence?

Dr Agur: We could all look at the same thing and see it differently. We could all look at the same figure, but you, sitting on your side, see it as “9” while I, sitting here, see it as “6”. It is important

that we publish that figure as it is and let people decide what it is. That is why I was so keen that we published the tables as they were, consistent with what we did in the interim report. Looking at the conclusions now, I do not feel that I would fulfil my duty as a doctor in reducing harm to patients if I followed those recommendations.

I thought that we could reduce harm without losing value. No member of the independent review group would want to risk patients' lives. No member of the independent review group would want to cause harm, reduce safety or anything like that, but I think that there has been worry about value. From my interpretation of the evidence, I thought that we could still reduce harm significantly without losing that value. I am talking about conclusions 7 and 8 by the way. Conclusions 1 to 6 are about safeguards—information, research, mandatory reporting to the watchdog and so on. I am talking about conclusions 7 and 8, because they relate to the procedure. Conclusion 7 relates to stress incontinence and conclusion 8 relates to pelvic organ prolapse.

Alex Neil: If I can put the question another way, do recommendations 7 and 8, in your view, maximise patient safety in relation to these procedures, or is there still a big question mark around the patient safety implications of those recommendations?

Dr Agur: I believe that these conclusions could have done more to ensure the safety of women who are considering these procedures.

Alex Neil: So the final report does not maximise patient safety.

Dr Agur: It could have done more.

Alex Neil: Right—I thought that you were not a politician.

That is reasonably clear. Is it your opinion that members of the independent review and other members were nobbled to make the changes?

Dr Agur: Ask me the question again, please.

Alex Neil: Do you think that there were any external influences that had an impact on the difference between the interim report and the final report? In your opinion, were members of the independent review group nobbled to make the changes that happened between the interim report and the final report?

Dr Agur: No, I am not aware of any external influences that have affected the conclusions of the report.

Alex Neil: Was there any additional academic scientific or medical research undertaken or concluded that you are aware of between the interim and final reports that would have impacted on and informed the difference between the interim report and the final report?

Dr Agur: Yes, there have been publications that came into the scientific literature between the publication of the interim report and the final report. We summarised those in the deleted chapter, but they are not in the body of the report now.

Alex Neil: That is the substantial point.

Dr Agur: Yes.

Alex Neil: In other words, the additional evidence that became available after the interim report would have reinforced the interim report rather than led to changes.

Dr Agur: That is correct.

Alex Neil: Can I ask a final question? A key demand of the campaigners, who have done a fantastic job on the issue, is that there should be a ban on the use of mesh implants. Do you support that demand?

Dr Agur: That is a very important question.

Alex Neil: That is why I am asking it.

Dr Agur: Yes. Mesh procedures are not created equal, and this has been a learning process for me and for many of my colleagues. Several months before the suspension of mesh procedures in June 2014, in my practice I had already stopped performing transvaginal mesh for prolapse. A few months before the suspension, I had already stopped performing the transobturator tape procedure. At that time, I did not have any of my patients coming with complications with it. Life is too short to learn only from my own mistakes; I must learn from others as well. After I stopped, I started to see my patients coming back with complications. In retrospect, it was right to stop.

When mesh was suspended in Scotland, I was still convinced that the retropubic tape, which is the original procedure that came out in the late 1990s, was the best procedure, was the gold standard and was much better than the non-mesh procedure. Following a review of the evidence, that belief is not there any more.

Alex Neil: Was that the vertical tape?

Dr Agur: Yes, that is right. That view is not there any more. Do I believe that the use of mesh procedures for prolapse should be banned? Yes, I do. Do I believe that the transobturator tape—the horizontal tape—should be banned? Yes, I do, except in very rare situations. It is like what happens if a young child has a brain tumour and we are thinking of using a laser; we are damned if we do and damned if we don't. This is not the decision of a single surgeon; it has to be a decision made by a group of surgeons nationally.

This is what I suggested to the chair in my comments on the conclusions.

If you asked me whether the vertical tape should be banned, I would say that it should be restricted to situations where the patient had already considered the non-mesh procedure and did not want to have the non-mesh procedure or where at least two or three surgeons had decided that the non-mesh procedure carried significant risk that would outweigh the risk of the mesh procedure.

It is also important to say that it is not only about the incidence of adverse events. As I said, it is not about efficacy; both procedures control incontinence in a similar way. It is all about safety. The trade-off that a patient will need to consider when choosing these procedures is whether she will accept the risk of chronic pain, taking painkillers for the rest of her life and losing the ability for an intimate relationship with her partner for the rest of her life just because she wants to stay in hospital one or two nights fewer or wants to go back to work three or four weeks earlier. That is a very important trade-off. Increasingly, I have found in my practice that, when women are given unbiased, balanced information on mesh and non-mesh procedures, they go for the non-mesh procedures. That could be the influence of the media, though, or maybe I am worried about litigation and, where I used to direct my patients to have the mesh surgery, I now direct them to the non-mesh surgery.

As a result, my unit drafted a shared-decision form, which is in the last appendix in my submission. We started using that form just over a year ago. It completely takes out the influence of the surgeon—the healthcare professional—and asks the patients just to read the leaflets and to document on the shared-decision form what they want. The vast majority of women who had and had not heard about the mesh problems in the media have chosen the non-mesh option. I believe that that is because of the acceptability of the risk. Even if the risk is very small—less than 1 per cent—the stakes are high.

Brian Whittle: Just for my own information, I want to go back to the clinicians' response to the moratorium. Some of my colleagues and I were surprised that health boards had autonomy in accepting or declining a moratorium. Has there been any feedback from health boards to the cabinet secretary on accepting or declining a moratorium? Do you know about that?

Dr Agur: I have not seen that feedback, but my understanding is that there has been correspondence from the cabinet secretary asking individual health boards to suspend the mesh procedures or to consider their suspension. Health boards have considered that—some agreed to suspend; others did not—so I presume that there has been some sort of feedback to the cabinet secretary on the situation on the ground, but I am not sure whether that happened.

Michelle Ballantyne (South Scotland) (Con): In the evidence on 18 May, the committee was told that all the information that was in chapter 6 of the interim report was still available, but concern was expressed about access to that. What is your view around that?

Dr Agur: That is correct. All the evidence has been published, but the important table that made the huge difference in expressing concerns and put Scotland in the lead in restricting the use of the horizontal tape has been moved to an appendix at the end of the main report. The new tables that were generated last summer, which inform the crucial decision on whether a patient should have a mesh procedure or a non-mesh procedure, have been moved into an annex—online, completely outside the report, among the minutes and agendas.

10:00

Michelle Ballantyne: I want to slightly revisit my colleague Rona Mackay's question to you. In your opening statement, you started by saying that there was a very collegiate approach during the development of the interim report; the clinicians discussed it, they came together and the report was pretty much constructed without too much conflict. Then, when you came to do the final report, it seems that that approach suddenly fell apart. In the past five minutes, you have said that the evidence that has come out since the publication of the interim report strengthens some of the arguments in the interim report, yet it was changed. Rona asked specifically where the calls came from to remove chapter 6. I was unclear from your answer: was it the individual clinicians themselves who said that it should be changed or removed, or did the call come from outside the clinician group?

Dr Agur: There are no calls from outside the clinician group.

Michelle Ballantyne: So it was all internal. Can you revisit that and clarify for us what it was that changed in the clinician group that took you from being collegiate and designing that interim report in agreement to suddenly wanting to change it when the new evidence seemed to suggest strengthening it rather than removing it? I am confused about that.

Dr Agur: I have explained—I have also put it in a group email to the group—that, when we are faced with facts supported by top-level evidence that contradict our own belief, it is natural and human that we respond differently. Some will be able to get the belief out, challenge it, examine it,

spring-clean it and put it back in or replace it with something different according to the truth that was in the particular study. It is not just about this study. It is important that, if a study contradicts our views or contradicts other studies, we study them together and resolve any issues. We can then reach a consensus on the content. The content is far more important than the format. The message is so much more important than the package. As long as we agree on the content, we can present it in the form of paragraphs or we can present it in the form of tables.

There was a view that we should move all the evidence into chapter 5. Chapter 5 was written by a public health specialist. It is very meticulous and comprehensive. I admire the way in which it is presented and the amount of effort that went into it. It is probably the most comprehensive review of all the evidence on mesh procedures, but it is difficult for patients to understand. It is difficult even for me to understand some of the things in chapter 5. That was the whole point of presenting chapter 6 in a table format. Some members believe that a table format is not a good idea; other members believe that we should move all the evidence back into chapter 5. I wanted to take the best evidence out of chapter 5 and put it in a table format that is understandable by patients, exactly as we did in the interim report. We had the patients on board with that methodology prior to the interim report.

Michelle Ballantyne: Was there a fear among clinicians that, if it was made terribly accessible for patients and laypeople to read, the work that they had done to date would be very challengeable?

Dr Agur: I am expressing my views here, and my views are probably not shared by the majority. It is so important that the committee hears from a clinician who strongly supports the way the evidence is presented and the way the conclusions are presented. The committee would benefit a lot from the presence of a clinician who did not agree 100 per cent with my views.

Neil Findlay: Reading a number of the submissions from the women affected, I did not know whether to cry or smash the computer up; I was so frustrated. You have said that the issue is not efficacy. If we have two systems of dealing with these problems and efficacy is not the issue, can you talk about the complications of both?

Dr Agur: Talk about the adverse events with both.

Neil Findlay: Yes.

Dr Agur: The mesh procedure—

Neil Findlay: Non-mesh and mesh.

Dr Agur: Okay. There are several non-mesh procedures and several mesh procedures, but we will talk about the standard one for each. The standard mesh procedure is vertical tape, and the standard non-mesh procedure is called "colposuspension", although some patients like to call it "hitch and stitch".

As I mentioned briefly, the advantages of the mesh tape procedure all also relate to recovery. The procedure is minimally invasive; it is easily performed and, therefore, easy to train for—there is a relatively short learning curve; it saves money for the national health service because it requires less theatre time and a shorter hospital stay; and there is a quicker recovery and a quicker return to normal activities.

The disadvantages of the mesh tape procedure are both immediate and delayed. The immediate one is a significantly higher risk of bladder damage during the operation. The vast majority of clinicians believe that damage to the bladder during the operation by the trocar of the mesh tape does not have any long-term consequences. Basically, the needle should come out and go back in in the right place; we do not need to close the bladder, it heals nicely and there are no problems. The reason why there is significantly more bladder damage with mesh tape is because it is a blind procedure. I can see where the needle is going in and where it is coming out, but I cannot see what happens in the 15cm that it is inside the body. It can go into the bladder, which is why the manufacturers suggest that we put a camera in the bladder to make sure that it does not. If it does, we should take it out and place it back in again.

The non-mesh procedure has less risk of bladder damage, because I can see where the needle is going all the time; it is under vision. The non-mesh procedure also respects the patient tissues, so I tailor the procedure to the patient. I know exactly where the needle should go for a particular patient and where it needs to come out. There is usually no need to put cameras in, because everything is under vision. It is a very fine, technical surgical procedure.

The most troubling delayed adverse event from the mesh tape procedure is chronic pain and pain during intimate relations with a partner. The risks of that are small but, when it happens, it does so significantly and really impacts on quality of life. That is usually due to damage to the muscles or to the nerves, and damage to the nerves also affects mobility. That seems to happen in less than 1 per cent of cases but, when it happens, it is absolutely devastating.

When a patient comes to me and needs to decide between a mesh procedure and a non-mesh procedure, it is not only the percentage that needs to be considered; it is also the severity of the adverse events and their impact on the

patient's quality of life. It is about knowing the best-case, worst-case and most common scenarios. Can I predict the problem? Can I prevent it? If it happens, can I reverse it? If we are talking about nerve pain, the answer is no.

The procedure described by the manufacturer does not respect variation between patients. Let me say that again: the procedure described by the manufacturer does not respect variation between patients. You introduce the needle 2cm below a point and, all of a sudden, it comes out the other end. It is the same procedure, regardless of body weight or anatomy.

Long after I stopped performing some of the procedures, I found publications in the literature from the manufacturers that said, "We've done studies and found out that the mesh is much closer to the nerve than we used to think it was." That really frustrated me, because I would have expected the manufacturer to communicate that to me. That was in a publication from 2011, for example. That is the difference between drug companies and device manufacturers. A headache tablet that works for only four hours and disappears from the body undergoes massively rigorous procedures before it comes on the market and before I can prescribe it; but there are not a lot of rigorous procedures for a medical device and it can come out quickly. That is a system issue, and I alluded to that in one of the appendices about the Swiss cheese model.

Neil Findlay: I would imagine that there is not a huge group of people who can perform the procedures—the number in Scotland must be relatively small—but they seem to be very powerful. You said that you had a conversation with the health board about whether there would be a suspension. I am sure that the health board relies pretty heavily on its local group of surgeons to produce evidence or verification and that, in the review group and in general, the issue of declaration of interests is pretty critical. My understanding is that the review group asked people for one year's declaration of interests in relation to whether they had been involved in trials or anything with some of the companies involved. Some people in the review group produced a much longer list of their involvement, going back several years, but the Government insisted on only one year. Were some of the people involved in the review compromised? Are some of the people who advise health boards—the surgeons—compromised by their connections with some of the companies and organisations that promote these products?

Dr Agur: If there are interests that are not declared, I do not know about that. If you are asking me for my opinion, I do not believe that any member has failed to declare their interests.

Neil Findlay: Because the requirement went back only a year.

Dr Agur: I agree with you, the form could be better; perhaps that is something that Professor Britton could look at. I believe that the review of the process by Professor Britton will look at conflicts of interest and how to ask members of the independent review about conflict—

Neil Findlay: Forgive me, but I am not sure whether it will ask whether if Mr So-and-so or Mrs So-and-so who was on the review group and made their one-year declaration of interest had gone back further, we would have seen whether they had a conflict, or whether the process would have been more transparent. I do not know whether a review of the process will identify whether there were conflicts or whether it will just take a generalist approach that says what should happen in the future. If people had been asked to go back further in making their declarations, would the process have been much more transparent?

Dr Agur: I believe so; the more declared the better. The issue is not only competing interests with manufacturers; there can be other interests—vested interests, if members have invested heavily in a certain position and advised their health boards on a certain position. It is not only about financial—

Neil Findlay: Is it about professional credibility?

Dr Agur: I think so, yes. That is not—

Neil Findlay: You might call it arrogance.

The Convener: Let the witness put it in their own words.

Dr Agur: It is not on the form. I was lucky because my health board suspended everything—against my advice at the time. It was right, and I told it that. That brought me to the independent review on an equal footing. I invested in using the mesh procedures and received funding from mesh manufacturers; and I invested in non-mesh procedures. I came to the independent review with all my competing interests as reconciled as possible, but if my health board had taken a different position, I could perhaps have been a bit more biased. However, the conflict of interests form does not ask for that. I did not declare it and I do not think that those who did not declare it did something wrong.

The Convener: As part of our committee's consideration, we might want to ask the independent review of the review to look at that to give confidence on the independence of the review itself. That might be something that we can pursue.

10:15

Jackson Carlaw (Eastwood) (Con): Good morning, Dr Agur. I will ask two quick questions, because you have given extensive evidence. I also pay tribute to the professional way in which in which you chose to resign from the review group; you have not done anything sensationally.

In relation to conclusions 7 and 8, which have been referred to several times, I have before me the interim report wording, the final report wording and the suggestions that you sent in February 2017, which did not find support and then led to your resignation from the committee. I want to ask again the question that Alex Neil put to you: in the final report, which is the one that is publicly available today and on which people are making decisions, do you think the wording in conclusions 7 and 8 is safe?

Dr Agur: It would be much safer if we took the word "routinely" out of conclusion 8: the full stop should come after "offered" and it should say that prolapse mesh procedures "must not be offered" until there is evidence of the benefits. The conclusion would be safer if we took out the word "routinely"—that was the whole subject of the first page of my submission.

Jackson Carlaw: On conclusion 7, you make quite specific alterations thereto in relation to the balance that, I think, you think is now left in the wording.

Dr Agur: Yes. The concerns expressed in the interim report of 2015 about the horizontal tape, which is the most commonly performed procedure in Scotland, were removed from conclusion 7. I expect those concerns either to remain or to be firmed up, saying that we have now concluded that the transobturator tape—the horizontal tape—has risks that outweigh the benefits and that it should either not be performed at all or should be performed in very highly exceptional circumstances with the agreement of a national team.

Jackson Carlaw: I have a second question in relation to that. You drew a distinction between clinicians and those operating and the manufacturers of the devices. The manufacturers of the devices are regulated by the Medicines and Healthcare products Regulatory Agency, which has a responsibility in this regard. As a consequence of your experience throughout the process, do you feel that the MHRA, in the way that it has performed in relation to mesh devices, has proved itself fit for purpose?

Dr Agur: The MHRA has issued a blanket judgment that the benefits outweigh the risks; I do not agree with that and I believe that a large majority of clinicians believe that with at least one procedure or one device, the risks outweigh the benefits. I would have been happier and far more comfortable if my device watchdog had suspended the procedure or had banned the devices, not the manufacturer, but the initiative has always come from the manufacturer and has been communicated to us as being because it is commercially non-viable.

Jackson Carlaw: Finally, I understand that the MHRA is reserved not devolved. Notwithstanding that, do you believe, as a result of the process that you have seen in relation to mesh, that there is an argument for examining how the MHRA reviews such devices? Has there been sufficient public transparency about the MHRA's regulatory responsibility and how that has been exercised?

Dr Agur: To answer your first question, yes, I believe that the MHRA could have done a lot more. On the point about transparency, the MHRA proposed years ago the publication of a transparent database of reported adverse events for all medical devices. That would bring it into line with Australia. The Therapeutic Goods Administration in Australia—the equivalent of the MHRA down under—appears to have done a lot more work on the publication of adverse events.

As a clinician, when I see patients coming to my clinic with an adverse event from a medical device, I want to find out whether that is down to me, the device, the procedure itself or the surgical package. Did I have a bad day? I want to find out what is going on. I would like to go on the website of the advice watchdog, put the name of the device into the search box and find out what is going on. Did someone in Basingstoke or Surrey have a similar problem? Is it a bad lot? I want to find that out. You can do that in Australia, but you cannot do it in the UK. I think that the MHRA is looking into doing things, but things are not happening as fast as we want them to be.

Jackson Carlaw: So it is not transparent enough, as matters stand.

Dr Agur: It could be a lot more transparent.

The Convener: Michelle Ballantyne has a brief point and then I will take John Scott.

Michelle Ballantyne: I have a final point. We read in a lot of reports about the number of women reporting problems and not being believed and we talk about the chronic pain, but is it your view that there are a lot of women who have had the procedure and have low-level pain who may not be, first, associating it with this and, secondly, reporting it? If they were, would we see larger numbers? Is that what brings you to your conclusion that these devices should be banned?

Dr Agur: What brings me to the conclusion that some devices have risks that outweigh the benefits is a balancing of how the risks outweigh

the benefits, what is published in the literature, the evidence from the retrospective 20-year review in Scotland and my experience, as well as that of my colleagues.

If we are talking about chronic pain, there is some evidence that the average time between having the transvaginal mesh device and the problem developing is about four to five years. We had a peak of performing the procedure in Scotland in about 2010 or maybe 2011, so we have reached the top already. The number of such procedures had significantly dropped, even before the suspension, and the peak for adverse events was reached in 2014-15. I rarely now see patients presenting for the first time with mesh-related adverse events; what I see now in my unit are patients who have been in the system and are coming in for a second review. I would expect that, because we have already hit the top and are on the downwards slope for those procedures and the associated adverse events. There is a four-year gap.

John Scott: I am interested in an analysis of the outcomes. I think that I heard you correctly when you said that it is a 15cm blind procedure: 15cm is 6 inches—half of an old ruler in old money. That blind procedure must be an enormously skilled procedure. Is there an analysis of the health boards in which the problems have been found or is there an analysis of individual hospitals or even individual surgeons? That distance of blind procedure must be subject to very different outcomes, depending on the skills of the surgeon.

Dr Agur: It is a blind procedure. Depending on a person's build, the distance could be 5cm, or it could be 10cm—it could be anything between 5cm and 20cm.

There has been no analysis at health board level to say which boards do the procedure better, and there has been no analysis at surgeon level to say which surgeons are better, but there has been a national analysis to find out whether high-volume surgeons have better or worse outcomes. The result of that analysis was that the vast majority of mesh procedures that have been done in Scotland were by high-volume surgeons.

Surgical skill is important, as is training—the learning curve and maintaining competency by performing a number of procedures every year, if the surgeon wants to carry on doing them. However, the learning curve will reduce only the number of adverse events related to the surgeon—sometimes erosion and sometimes bladder perforation. I do not believe that those have long-term impacts: in other words, if the adverse event is because of the surgeon, the patient is usually treated and moves forward, and we do not get letters from her solicitors.

However, regardless of the surgeon's skill and whatever we do, there will be patients who sustain injury. The risk is low—it is less than 1 per cent—but injury could be close to a nerve and cause nerve damage, which can have serious consequences. No one can tell you the figures on that because no studies have looked into the impact on quality of life of nerve damage following the procedure.

Training surgeons is important. It will reduce the risk, but the risks that we are reducing are the ones that do not have long-term impacts. To eliminate the risk of nerve damage and long-term impacts, the procedures would have to be stopped completely. There will be women who may require the procedures in the future with the agreement of surgeons. Such people must consider very carefully whether the problem is severe enough. Is the risk too high? Can it be reversed? That conversation must be had using the full detail. All the information that is required for that conversation was present in the deleted chapter 6.

The Convener: We will take a final question from Angus MacDonald, then we will finish.

Angus MacDonald: Thank you, convener. I am conscious of the time.

I will move on to the shared-decision tool, which you have included in the appendices to your submission. It has been helpful to have sight of it. What do you see as being the benefits of the shared-decision tool, and how much time might you expect to spend discussing and talking through the form with a patient?

Dr Agur: The shared-decision tool has been an eye-opener on a lot of things. It was not my idea, I have to say; it was an idea that was expressed within the expert group by the chairman last year, when discussing the concept of the request for treatment perhaps being offered alongside consent. Instead of me going to the patient and saying to her, "I have these two procedures, and I believe that this one is better than the other" and getting her consent, the patient reads all the information, then comes to me and requests a treatment. The shared-decision form has been crucial in teaching me about what patients understand from the leaflet. Some patients will read the leaflet and not understand anything at all—they believe that they understand, but they do not. Health literacy could be a lot better.

I have gained a lot of insight into individual patient's values and what is important to them simply by reading what they write on the form. I encourage them to tick the boxes and to tell us what is important to them. Then they choose which procedure they want, and they write down why, and why they do not want the other three procedures.

It is not only me who interprets the form: I take the forms to our monthly team meeting with the physiotherapist, who has already seen the patient to supervise the pelvic-floor exercises, and the incontinence nurse, who has already seen the patient to do the bladder test before the procedure. We also have a clinical librarian to find for us the answers to important research questions about individual patients' cases.

The form has been absolutely brilliant. We have been using it since September 2016, and we have been relying on it to a significant extent. In a recent team meeting there was an incomplete form from a patient, so the team decided not to discuss her because we did not know what she wanted. That is absolutely brilliant: it really is patient choice, which is very much in line with the chief medical officer's document, "Realistic Medicine".

Angus MacDonald: That is a prime example of good practice coming out of all this. I have a final question.

In your submission, you request that the final report be the subject of a public consultation process and suggest that that could be included in Professor Britton's review of the process. Can you expand on that?

Dr Agur: The main reason why I am here today is to open the report to a public consultation process. Stakeholders will register their interest in giving feedback on the report and they will put their views on it. Government officials will then publish the feedback and responses on the decision why we are or are not changing the conclusions, in a very transparent process—exactly as was done for the European Commission mesh report.

That is not part of Professor Britton's remit: Professor Britton's remit is the process. My request is regarding the content or the outcome of the process. If we suspect that something is not quite right with the process, there may be something not quite right with the outcome.

The Convener: Thank you. That is obviously a matter for the committee to reflect on further. I will take a very brief question from Neil Findlay.

Neil Findlay: Of those who have completed your form, how many have chosen to use mesh?

Dr Agur: Twenty-two patients have completed the form in the past year, and only one chose mesh. The team realised that she had not read the leaflet well.

The Convener: Thank you very much, Dr Agur, for your time and the thoughtful way in which you have responded to questions. We got a great deal from that and we appreciate your tackling this serious issue in such a measured way. I know that there are people in the gallery for whom it matters a great deal. We have found your evidence to be very thought-provoking indeed. I thank you again.

I suspend the meeting briefly before we take the next panel of witnesses.

10:30

Meeting suspended.

10:36

On resuming—

The Convener: We need to finish by 20 to 12 at the very latest, because of parliamentary procedures. I intend to stop by half past 11, which allows a little flexibility.

If the witnesses do not get to say everything that they want to say, please contact the committee through the clerks, and they will make sure that any further points that you want to make are provided to us. We may come back to you with more questions. However, we have just short of an hour, so we should be able to pursue the questions as intended.

I welcome petitioners Elaine Holmes and Olive McIlroy, who were patient representatives on the independent review before they resigned on 4 March. I thank you very much for attending and invite you to make a brief opening statement before we move to questions.

Elaine Holmes: Good morning, convener and committee. Thank you for inviting us to speak today. We thank our Scottish mesh survivors, and our families and friends who are sitting behind us in the gallery, as we spare a thought for the mesh-injured women who are too ill to be here. We appreciate all the submissions that have been received in support of our petition from Scotland, England, Northern Ireland, Wales, Australia and New Zealand. As you can now see, mesh truly is a growing global scandal.

Sincere thanks go to Dr Wael Agur for giving comprehensive and compelling evidence regarding the whitewash final report. Unfortunately, Dr Agur's experiences mirror our own in several respects. The adversity and pressure that we endured for almost three years as patient representatives in the review group came flooding back as we heard his words. We agree with almost everything Dr Agur has said. His is an accurate account of how he—and we—were marginalised, and of how vital evidence was ignored, deleted or hidden. After the independent chair resigned—much to our regret—the review group lost its focus and transparency. In fact, it completely lost its way.

When former health secretary Alex Neil asked us to participate in the mesh review, we did so despite our health issues. We did so because we firmly believed that we had a role to play in ensuring that changes were brought in such that, in the future, hundreds of women would be protected and saved from life-changing injuries such as hundreds of thousands of women around the world have needlessly suffered. We knew that nothing that we did would change the course of our own lives or those of the women who had already been injured by the devices, but we felt that we could not stand by and do nothing.

Mr Neil took one look at us in our wheelchairs, struggling to stand without walking aids. He listened and decided that we were all the evidence that was necessary: he recognised that something was terribly wrong with mesh. We believed him and trusted in him when he promised that patients would be at the very heart of the review and that we would be listened to, but through no fault of Alex Neil, those promises were not fulfilled. Our voices were not heard; in fact, once he was no longer health secretary, things changed dramatically.

We are here today to state clearly that justice was not done. Our voices were drowned out and stifled by the pro-mesh lobby, which did its best to silence and marginalise Olive McIlroy and me. Despite that, we carried on, determined as we were to bring change to ensure that women were giving fully informed consent. That is something that few of us were given—which the chief medical officer has already admitted to the committee.

When the original chair resigned from the review, things took an even more pernicious turn. Apart from the review not including us in meetings for 10 months, the proposed final report exposed women to unnecessary risks. It bore no resemblance to the interim report, which had achieved group consensus.

We went to the Cabinet Secretary for Health and Sport for help and asked that she delay publication of the report at least until our concerns had been investigated. It was to no avail. She accepted the final report and its conclusions, ignored our concerns and published the final report just 11 days after our meeting. Any hope that we had for change was completely dashed.

The final report is certainly not in our name: it is nothing more than a whitewash. We repeatedly asked that all our evidence be removed, because we did not want to be associated with the report. Our requests were ignored and denied. It is apparent to us that there was never any intention of removing our input. We were cynically used to make the report appear less biased to the public and to those of you here today. We were duped; we were used.

We are not politicians, doctors or statisticians. We are ordinary women—but we are horrified by the failure rates of an operation and by the severity of injuries that can be life-changing and life-threatening. The benefits of mesh simply cannot outweigh the risks.

Mr Neil and the MSPs who have all voiced their concerns over the issue are correct: we are all the evidence that you need to know that surgeons cannot continue to put mesh devices into women when safer alternatives are available. We fully back Mr Neil's call for an international summit to uncover the truth about plastic polypropylene mesh, and we hope that Scotland continues to lead the way and takes a central role in this.

We ask you today to use the power that you have to ensure that the suspension of mesh remains firmly in place. You have the power to make the changes that are needed to protect patients once and for all, and to change the system so that nothing like this ever happens to other patients.

We can see that medical watchdogs across the world have been useless, toothless and far too close to the manufacturers who make billions from the medicines and medical devices that they are supposed to police. We need new health watchdogs that will insist on proof that devices and medicines are safe as well as effective. You have the power to ensure that we have proper registers and mandatory recording of data, as well as mandatory reporting of adverse incidents so that patients are not put at risk.

Please do not let what happened to all of us happen to others. Please do the right thing. Thank you for hearing our voice.

The Convener: Do you want to add anything at this point, Olive?

Olive McIlroy: Ditto to everything. That was a joint statement from both of us. I thank Dr Agur for his integrity and honesty. The evidence that he has given is basically that mesh is off the menu and that mesh should be stopped right now.

The Convener: Thank you very much. We move to questions.

Brian Whittle: Good morning, and thank you very much for coming to give evidence.

Your written submission states that you consider that the final report downplays the significance of the reclassification of surgical mesh to the highest risk category, which is class III. I think that you are referring to the information that is set out on page 12 of the final report. Will you clarify your main concern to the committee?

10:45

Olive McIlroy: That was just a discrepancy about when the EU regulations came into force. There was a miscommunication. The health minister and the CMO seemed to think that it was 5 April 2017, but a fact sheet from the EU about the reclassification to class III said that all ministers in the EU had been notified in October 2015 and had agreed to the content of the new package of device regulations and the upgrade to class III. The package was adopted by the EU on 7 March. I think that 5 April 2017 was just a legislative date. It was more than anticipated that the reclassification was going ahead: it had been passed. The final report should not have said that that was anticipated; it should have said that it was going to happen. It was happening, not anticipated.

Elaine Holmes: Just to add to that, the report stated:

"From a European perspective the current position is that reclassifying these medical devices would not confer any material difference".

That is just nonsense. Why would the EU consider putting the devices into the highest risk category if there was no material difference?

Michelle Ballantyne: In your submission, you refer to the fact that over 400 women have received mesh implants since the moratorium was announced by Alex Neil, in comparison with fewer than 100 women having received treatments using non-mesh alternatives. To clarify, am I correct in understanding that those numbers include only the women who have received surgical interventions and will be much lower than the total number of women who have sought assistance due to SUI or POP?

Elaine Holmes: We do not know how many other women have received help. Those are just the official figures for surgical procedures. We were given the mesh data, which was just over 400 women, and there were 100 non-mesh procedures. Many more women may have sought help, but we do not have those figures.

Michelle Ballantyne: That is really the point, is it not? They are not absolute.

Elaine Holmes: Yes, they are not absolutely—

Olive McIlroy: They are not accurate.

Rona Mackay: Good morning. Before I ask my main question, I want to go back to something that Elaine Holmes said in her opening statement. Who are the "pro-mesh lobby" in your opinion?

Elaine Holmes: If you had sat round the table with us at the review group meetings, you would know who the pro-mesh lobby are. Let us say that Olive McIlroy, Dr Agur and I are not it.

Rona Mackay: Would you say that it was clinicians, manufacturers and the whole medical establishment?

Elaine Holmes: Yes. We were marginalised.

Rona Mackay: Okay. That is interesting.

Olive McIlroy: If you read the minutes, you will find that the group was "not unanimous" in some decisions or discussions. The phrase "not unanimous" usually meant that Elaine and I objected. We had to fight at every meeting. We had to fight even to get the words "safety" and "mesh" put in. We had to fight to get the word "mesh" put in front of the word "tapes", because they kept saying that tapes were not mesh.

Elaine Holmes: We had to fight to get the word "safety" put in the heading of the review. At the start, we were told that safety was not the remit.

Rona Mackay: That is pretty shocking to hear.

I will move on to informed consent. You will have heard the previous evidence about the fact that there is a lot of outdated information lying about in doctors' surgeries and that the information for women is not available or out of date. Your submission suggests that there is still outdated information on a number of Government and NHS websites. You refer to the leaflet that was developed by the Scottish Government expert group being adopted and published in the rest of the UK but not Scotland. Will you explain a bit more about that?

Elaine Holmes: It is just not on the Scottish Government website. Until yesterday, the leaflet that was still displayed on the Scottish Government website was the initial leaflet that was developed in 2014 on mesh tapes for stress urinary incontinence.

Olive McIlroy: I checked this morning, and it was still there.

Rona Mackay: So nothing has happened since our previous meeting when the issue was discussed.

Elaine Holmes: If women are looking for up-to-date information, they can go to the website of the British Society of Urogynaecology or the English NHS and they will find the leaflet that was actually developed in Scotland by the Scottish Government's expert group. Anyone consenting to mesh tape procedures can go there for up-to-date information, but they will not receive it in Scotland. Maybe it is available in an appendix or something. I do not know, but we cannot find it.

Olive McIlroy: It is nigh on impossible to find it. I asked one of the girls who contacted us to go to the NHS inform website to see whether she could find the leaflet. She was back on the phone to me saying, "Jeezo, how am I supposed to find this?" I

explained to her how, eventually, after going round the houses, we had found it on the NHS England website. If you go directly to the NHS England website, you will find it with two clicks. On NHS inform, it is not even with the transvaginal mesh information; you have to go through information on prolapse and you come to an NHS choices logo and you have to click on that. You have to go round the houses before you find it.

Rona Mackay: That sounds like something that could easily be put right but has not been.

Elaine Holmes: Absolutely.

Olive McIlroy: Yes. The Government has been notified on several occasions that it has that older version on its website, but it still has not changed it.

Rona Mackay: Thank you.

The Convener: That was quite an issue at the previous evidence session, when the chief medical officer made a rather throwaway remark about out-of-date magazines. It is a concern that the information still has not been updated.

Alex Neil: Just on that point, I am not a member of the committee, and this is up to the committee, but I think that the committee should email the health secretary today to point that out to her. It is very important that that is easily accessible. Patient safety is supposed to be and is the number 1 priority for the national health service in Scotland. At the very least, the website should properly reflect that, and we should demand that that be sorted this week and not any later.

I have two or three questions to probe issues to do with the review. First, have you had an opportunity to meet the professor who is reviewing the process, or has a date been fixed for that? Has she been in touch?

Elaine Holmes: No.

Alex Neil: She has not been in touch.

Olive McIlroy: No.

Alex Neil: Right. Secondly, during the 10 months when you said that you had been kept in the dark, were the rest of the review group members meeting, and were you not invited to those meetings?

Elaine Holmes: There were certainly sub-group meetings. Even if there were sub-group meetings that perhaps were not pertinent to us, there were never any minutes published or updates on what had happened. We were involved in a sub-group meeting several years ago, and afterwards the minutes were published and shared with the wider patient group. We had no updates for 10 months.

Alex Neil: That is a major area for investigation, and I hope that the professor will look in detail at it, because that seems absurd to me. Looking back, it seems to me that one of the lessons for the future is that the percentage of people in a review group representing patients has to be substantially higher so that the so-called experts do not have an inbuilt majority, as it were, and more genuinely independent people—

The Convener: Or that there are not means by which they are excluded from the process.

Alex Neil: Exactly. We could spend all day on those issues. It seems to me that the group has not been administered genuinely as an independent review group, which was the intention.

Thirdly, it has become clear this week that, allegedly, the MHRA has been involved in a cover-up about pregnant women not being told about their unborn babies potentially developing epilepsy because of a particular medication that was presented to them. That is the third major scandal in the past two or three years that I can think of, including the one we are considering today, in which the MHRA's role has been less than professional or helpful.

One of my concerns is that part of its funding comes from device manufacturers. I do not see how it can be an independent regulator if it is even partially funded by the people who are being regulated. I presume that you share my concerns about the MHRA. I know that it has already given evidence to the committee, but I think that that is a major problem in the system. Issues to do with the independence of the MHRA have been part of the problem.

When I was health secretary, in my dealings with the MHRA on this issue, I was, to say the least, less than satisfied. I do not think that it is a very professional organisation or a very caring one. I do not think that it cares at all about Scotland or that it has patient care as its number 1 priority. That is my impression, although it might be unfair. How have you found the MHRA in your communication and contact with it?

Elaine Holmes: I found the MHRA totally frustrating, as well as being a waste of space. I do not know what purpose it serves apart from saying that the benefits outweigh the risks. When regulators around the world have issued safety alerts and advice, the MHRA just continues to say that the benefits outweigh the risks. The girls have made posters on which the MHRA is portrayed as burying its head in the sand, and nothing could be closer to the truth. We do not even rate the MHRA.

Olive McIlroy: I do not know how it can talk about that benefit to risk ratio when it has already acknowledged the severity of the adverse

incidents that go unreported. It does not have the information to make that analysis and that statement. Dr Agur kindly backed that up in his earlier evidence.

Alex Neil: The convener of the Health and Sport Committee is sitting next to me. This is an issue in its own right to be flagged up to the Government. The failings of the MHRA are potentially endangering lives, not just on this issue but on a range of other things. We need to address that sooner rather than later.

Jackson Carlaw: I should say that, in tribute to the work that Elaine Holmes has done, she was my local hero at the opening of Parliament. She can maybe answer my first question, although it might be better to ask Alex Neil, but I cannot ask him a question. Were you surprised that the MHRA was on the review group in the first place?

Elaine Holmes: Yes.

Olive McIlroy: Yes.

Jackson Carlaw: Given that it was the regulator of the device into which the review group was undertaking an investigation, was there not in your mind a sense that whatever it said would be compromised by the position that it had already taken? Was it, in your experience, one of the principal cheerleaders for the mesh lobby, as you describe it?

Elaine Holmes: I do not know whether it was the principal cheerleader. We tried hard to bring more balance to the group by requesting that surgeons who were not pro mesh be invited to participate. The MHRA found a problem with every surgeon whom we suggested—it could not contact them or they did not respond to emails. It was just ridiculous. All the surgeons participating in the group were pro mesh. You heard Dr Agur say that he was partially for some devices when he joined the group, although his opinion later changed. The others never changed their opinion. You know from reading the report who participated in the group, and we know which hospitals they work in and which hospitals have flouted the mesh suspension.

The Convener: It would be interesting and intriguing to ask about that, given the way in which you describe the balance of the group. We have not had the opportunity to speak to other members of the group, so they have not had an opportunity to respond to that comment. Unanimity was achieved on the interim report and yet the final report was a disappointment. It looks as if, with the interim report, people were at least willing to come together and be a bit more open in their thinking.

Elaine Holmes: Absolutely. We did not agree with the interim report 100 per cent and we published our thoughts and concerns in a minority opinion. However, there was consensus, and we really believed that we were heading in the right direction.

We were waiting for studies to publish, such as PROSPECT—prolapse surgery: pragmatic evaluation and randomised controlled trials—which was the largest study of prolapse mesh in the world. It was a Scottish-led study, and, in fact, it worked in our favour, because it backed up everything that we said: that there is no benefit to polypropylene mesh in prolapse. If anything, the studies that we were waiting for should have strengthened the conclusions and the recommendations in the final report. When we saw the draft final report, we could not believe what we were reading. It told of the benefits of mesh but not the risks, and it mentioned the risks of the non-mesh alternative but not the benefits. It was directing patients towards mesh.

11:00

Jackson Carlaw: You used the word “duped”; you felt that, in a sense, both of you ended up being window dressing in the review group so that it could say, “Here are a couple of sufferers as evidence.” When did your frustration grow about the credibility and weight that were being given to your contribution, evidence and views on the review group? Was it with the dropping of what was in the interim report, or was there a growing perception on your part?

Olive McIlroy: When we got the draft final report in an email, we were shocked. I think that Elaine Holmes commented that she was nearly physically sick at what we saw. We realised then what was going on. We asked—I do not know how many times—for all our input to be removed from the report because it was not in our name, yet the group went ahead.

Jackson Carlaw: You continued to trust the process until you finally got that report.

Olive McIlroy: Yes—until we saw the draft report. It was like day and night; the approach had been totally changed. The most important thing in the interim report was that transobturator mesh tapes were giving cause for concern. That was totally brushed under the carpet in the final report. Removing that put more patients at unnecessary risk.

Elaine Holmes: Prior to receiving the draft final report, we had not been invited to participate in meetings for 10 months. We then received an email to tell us that there was no new evidence and that we would receive a draft of the final report soon. We thought, “No new evidence?” We sent a list of the new studies and said, “You know, this is important new evidence.” We got an email back that said, “Oh, yes—I knew about that.” We said,

"Why wasn't it shared with the group? We haven't received any communication." We asked what had happened to the tables and were told, "We're doing it this way now." That was totally confusing for patients. There was no dialogue. I do not know what meetings or discussions went on in the 10 months, but we were not party to them. It seems that the group almost had the report ready to go, and I think that it was hoping that we would just quietly put our names to it.

Jackson Carlaw: Were the emails that you received from the new chair?

Elaine Holmes: No—they were from the Scottish Government. They were from—am I allowed to say names?

Neil Findlay: Yes.

Elaine Holmes: They were from Dr Sara Davies.

Jackson Carlaw: I have two quick questions. You have subsequently given evidence to the investigation that is taking place under the auspices of the Parliament in Australia. Have you formed an impression that Scotland, which was very much at the forefront in the eyes of the international community, has been compromised by the process and that other countries are now taking a more direct and dramatic interest in these matters? How do we remedy that?

The other quick question comes back to an issue that was previously raised. It was me who asked Dr Calderwood the question in response to which she, unfortunately, drew an equivalence between out-of-date copies of *OK!* magazine and information leaflets. Do you have a network of supporters in your group who keep you informed about the availability of literature in general practitioner surgeries?

When the committee previously took evidence, it received an assurance that there would be a further clear-out and updating to ensure that nothing other than current information was available in GP surgeries. To your knowledge from your group, has that taken place?

Elaine Holmes: Australia is forging ahead and is more organised. I would say that the changes happened after we lost Alex Neil as health minister, and, after we lost the independent chair of the review group, things started to go haywire. I am sorry—what was the next part of your question?

Jackson Carlaw: It was about information in GP surgeries.

Elaine Holmes: My understanding is that there is no out-of-date information in GP surgeries that I am aware of. There is no mesh information in any hospitals; I am told that it is printed on a need-to-print basis. If someone requests mesh, the leaflet will be printed—I think that it is about 20 pages long. There is no information on display; it will just be printed if and when necessary. That is positive, but the negative is that the out-of-date information is still on the websites.

The Convener: We will take Michelle Ballantyne briefly and then Neil Findlay.

Michelle Ballantyne: Convener, my question has been answered. Jackson Carlaw asked it.

Neil Findlay: You said that your views had been ignored, evidence was skewed, you were excluded from meetings for 10 months, there were no minutes from the sub-group, there was a complete change between the interim report and the final report, and chapters were removed. If that is not a whitewash, I do not know what is.

Ninety-seven members of this Parliament signed a statement saying, "No whitewash." This is the clearest evidence that there is an oil tanker full of whitewash in the report. I do not know what the committee will decide, but we have to do something. This is completely unacceptable. The world was watching Scotland, and we have flunked it big style. The situation has become absolutely embarrassing. I do not know what the committee's decisions will be, but we could suggest a number of things.

I will ask about your experience of the people who were sitting around the table and your knowledge of the conflicts of interest that might have been there. Do you know about that or do other people need to look into that?

Elaine Holmes: I think that we would get ourselves into a whole lot of bother if we said anything. You will see that conflicts have been declared. Does it concern us that there were witnesses for the central legal office—the NHS lawyers—in the independent group? It does, but that is all in their declaration of interests; at least they declared that. I am not going to say anything else.

Olive McIlroy: There is even the fact that the new chair was an acting employee of the NHS.

Neil Findlay: Did the tone and practice on the review group change when the chair changed?

Olive McIlroy: Yes.

Elaine Holmes: Yes—the group would not listen at all. We had a teleconference call because, latterly, we gave up physically attending meetings. The pressure on us was enormous; sometimes, we left in tears. To be honest, we could not hack the stress. One meeting lasted five hours; it was actually two meetings rolled into one. At one meeting, I had had enough—I embarrassed myself and had to leave.

Olive McIlroy: There was an independent—I hate saying that word—review group meeting on 23 January this year, when we laid out again all our concerns about the final report in its present form, as it was not in our name. We asked for our concern to be documented in the minutes of that meeting, but it never was. We were just pooh-poohed.

Elaine Holmes: It was as if we had never been at some meetings.

Olive McIlroy: That is how bad it got. I printed a list of how many were on the review group, and I think that the number came to 26. It was two against 24.

Elaine Holmes: The other members of the group would all be sitting at one end of the table, while Olive McIlroy and I would be at the other end.

Olive McIlroy: They always sat as far away from us as possible for some reason—I do not know why.

Elaine Holmes: Incontinence is not catching.

Neil Findlay: I have been to a few meetings like that, too.

The Convener: I am saying nothing. I do not want to get myself into bother.

Angus MacDonald: Before I ask my question, I must concur with the comments that were made about the MHRA. It is fair to say that, when representatives of the MHRA gave evidence to the committee on 24 February 2015, their performance was poor, to say the least. I am sure that I speak for the whole committee at that time when I say that we were all left extremely frustrated by those witnesses' stance and the evidence that they gave.

Elaine Holmes and Olive McIlroy have covered the dropping of salient points from the report. Dr Agur mentioned his frustration about the dropping of what was in chapter 6. Do you have anything to add specifically about chapter 6?

Olive McIlroy: The only thing that I would say is that, when it started, the review represented patients with a good outcome and patients, like us, with a not-so-good outcome, and the approach should have been the same for clinicians. There were four clinicians on the review group, but one was basically bullied into resigning, as far as I can see. Even if the others did not agree with his opinions, those opinions should have been in the report so that people could make up their own minds.

Elaine Holmes: Even if the views were there as a minority opinion.

Olive McIlroy: The group dismissed those opinions out of hand and completely changed the report. Transobturator mesh tape is what is most used in Scotland, and that tape cannot be removed in its entirety, which is another issue. At one meeting, one of the clinicians eventually admitted—after going round the houses again—that that tape could not be removed in its entirety. That was in the interim report as giving cause for concern. However, you will read in the final report that any surgeon can remove any mesh at any time if they have the experience. That is a big change—from "giving cause for concern" to, "Och, we can remove it any time—don't worry about it." Those are the extremes.

Elaine Holmes: The final report said that surgeons may be able to remove that tape at any time, which is not true. They could remove it, but then again so could my local butcher. Safety is the issue.

Olive McIlroy: What are the consequences?

Angus MacDonald: I will move on to the review of the review. You said that you had not heard from Professor Britton, and I presume that you hope to contribute to that review. Are there aspects of the process that you would like to be considered?

Olive McIlroy: The review of the review is a waste of money and time. Maybe the health minister should have considered contacting every patient in Scotland who has had one of the mesh procedures to find out what their health status is and going from there, rather than having a review of a review, which will have no effect on the outcome of the final report.

Angus MacDonald: I presume that you agree that the review can make sure that this does not happen again.

Olive McIlroy: That is true.

Elaine Holmes: Unless the review considers the content of the report, it will not help us.

Olive McIlroy: It will not help us at all.

Elaine Holmes: We understand that it will help future patients, but it will not help us.

Angus MacDonald: Have you had any indication that Professor Britton will contact you?

Elaine Holmes: No, but only a couple of months have passed. We have quite a few to go yet.

The Convener: Can I ask about the inclusion of your input in the final report? I understand how contentious that must be for you. You provide a timeline in your submission, which has been published. The committee also had sight of the email exchanges, which were not, I think, with the

cabinet secretary but with the new chair. Was there a point along that timeline when you felt assured that your input would not be included? Were your concerns about your input being in the report taken seriously at any point?

11:15

Elaine Holmes: When we met the cabinet secretary, she was noting it down. We said, "Now, we want everything removed, all our input." She said, "You've already said that. I've got a note of this. I'll pass it on in the meeting with Dr Gillies." We felt quite assured that Dr Gillies would listen to the cabinet secretary about our concerns. We had already put the concerns to her, and we were quite shocked by all the excuses and the blame. You have the timeline.

The Convener: Dr Gillies said that she could take the requests but would not necessarily have to accede to them. Who do you think finally took the decision that your input would remain in the report?

Olive McIlroy: I am not sure, because that was getting thrown about the houses as well. The chair said either that she had gone back to the review group, or that it was the health minister, not her.

Elaine Holmes: And then we were too late to get it—

Olive McIlroy: The evidence from the last meeting was absolutely shocking. I was astonished at the evidence at the last Public Petitions Committee meeting, when the chief—

The Convener: A general issue that, we hope, Professor Britton will look at is the role of patient representatives and your responsibility to your broader group. It must also be quite a pressure on you that you are not somehow brought into a group to give—I think the word was used earlier—cover. There must be some kind of procedure.

You talked about a 10-month period when you were not involved at all. You are not really sure whether people were attending meetings or whether there were sub-groups. Then, at the end of the process, you were brought back in to look at the final report. How many meetings would you have attended or been involved in at that point?

Olive McIlroy: It was just that one in January, I think.

Elaine Holmes: There were three years of meetings. I do not recall or have in front of me how many meetings it was.

The Convener: I just want to get a sense of where the gap came. Did the gap come when the new chair came in, or was it before that? Was there then an attempt at least to bring you into the very final conclusions?

Elaine Holmes: There was a gap because it was the summer recess. Then the new chair resigned, and we got told that, since the interim report, there had not really been any new evidence. That was when we begged to differ, and it was then admitted that there was evidence. We took it on from there.

How did things change? It definitely changed when the new chair came in. We tried to have discussion with her to put across our points of view, but they were not taken on board. When we met the cabinet secretary and the chief medical officer, we felt that our views would be conveyed to Dr Gillies. You asked who had the final say regarding our input remaining. I do not know. Was it Dr Gillies? Was it the cabinet secretary? Was it the CMO? We do not know. All we know is that they went against our express wish.

The Convener: I am tempted to ask a former cabinet secretary whether he would have an expectation that he would be able to direct a group in that way.

Alex Neil: In such situations, I would have expected the CMO and the chair to take guidance from the cabinet secretary, obviously, but, unfortunately, as we heard with the suspension, in the health service it does not always happen that way. When I issued the suspension, I made it absolutely clear to every chief executive and chair that I expected the wishes to be carried out by every health board, not just some of them. You can issue a formal directive, but nine times out of 10 that is not necessary. Clearly, there were forces at work here, as became apparent later, that allowed some health boards effectively to ignore the suspension.

The Convener: I suppose that the challenge for a cabinet secretary who creates an independent body is that he or she cannot be seen to direct it as well. The independent review could perhaps wrestle with that.

Alex Neil: There is also an issue of delivery. One thing that I think is needed in government is a central delivery unit to make sure that the instructions of ministers are carried out, particularly in the health portfolio. The Public Audit and Post-legislative Scrutiny Committee, of which I am a member, recently heard evidence on various things that has made it very clear that, under successive health secretaries and successive Governments, some of the instructions, going away back to the time of the Lib-Lab pact here—

The Convener: Happier days.

Alex Neil: Those instructions just were not carried out. That is a general issue that needs to be addressed.

Brian Whittle: First, I reiterate what Alex Neil has said: when a directive or a moratorium is sent out from the health minister, I find it surprising that there is no feedback to say whether a health board has upheld that directive. That is probably something that we should look at.

Given your consistent desire to have your evidence removed from the final report, and given that there was a 10-month period in which you were not involved in any input to a report, does that make the final report void in your opinion?

Elaine Holmes: Yes.

Olive McIlroy: Definitely.

Elaine Holmes: We do not agree with a large part of the content. That is why we went to the cabinet secretary for help, but she did not listen. Eleven days later, she published the report. We asked her to wait and at least to investigate our concerns. What harm would it have done to suspend publication for a month or two to investigate the concerns that we and Dr Agur had and to speak to the previous chair, who had resigned for personal reasons or whatever reasons? I feel that it was rushed, and we would like to know why it was rushed. What was the hurry?

Brian Whittle: That is a consideration for us.

The Convener: We will hear briefly from Michelle Ballantyne and Neil Findlay, then we will need to come to a conclusion.

Michelle Ballantyne: I want to ask you about the tone. You have talked a bit about things changing and then being excluded. From reading the papers, it looks as though, when you started out on this journey of the independent inquiry, you were very much looking at what we needed to do going forward. The interim report talks about the need to change processes and to look at the benefits and detriments of mesh and so on. Was that conversation ever about looking backwards? In the past couple of minutes, you have asked, "How will it help us?", by which you mean those of you who have already had the procedure. At what point, if at all, up until the interim report did that conversation take place in the review group?

Elaine Holmes: Yes; we spoke about that. We asked about retrospective studies and about every health board doing a study to find out how many patients had suffered. A lot of patients do not even know what device they have inside them. We have women in our group who have three medical devices inside them, yet that is not in their medical records. Records have been lost, so we asked for a comprehensive study. We were told that it would take far too long and cost too much money.

Neil Findlay may be able to correct me, because he asked the parliamentary question, but I think that the cost of the entire review was £4,000 and something. Perhaps if more money had been spent and there had been a retrospective study of all the women who had been harmed, those who had not yet come forward and those who had been told that they had sciatica or some other obscure disease, we might have been looking at a very different scenario. At the start, we were told that safety was not in the remit of the review, and we had to ask quite strongly to get it put into the title. That said it all for us.

Michelle Ballantyne: I will ask this bluntly. Looking forward, in terms of the review body being blunt and saying, "Okay, there is a problem with this, and we should not do it any more", did you discuss whether it should have known that and whether there was any liability?

Elaine Holmes: It is more about what was known then as opposed to what is known now. We have come a long way. You heard Dr Agur say that he had used all mesh at one time, then reduced it to one procedure and is now not for it. It is about what is known now. I do not think there should be—gosh, I do not want to get myself into bother or put my foot in my mouth.

Michelle Ballantyne: I am asking whether there was any discussion in the review group.

Elaine Holmes: No.

Michelle Ballantyne: Was there none at all?

Elaine Holmes: No.

Michelle Ballantyne: Thank you.

Neil Findlay: Briefly, I want to confirm that Jackson Carlaw and I were in the room when the request was made to Shona Robison not to include Elaine's and Olive's evidence. As far as I was concerned, at that meeting the inference was that a guarantee was being given, but that did not materialise.

Olive McIlroy: I think that that happened twice. The cabinet secretary told me that I had already said that, and I said that I was just making sure that she understood what we wanted.

The Convener: Okay. I think that we have come to a conclusion about the questions that we want to ask.

Thank you very much for responding so honestly and thoroughly. I realise and appreciate that this is a very personal matter for you and the people behind you, and that it takes a great deal more energy to deal with this than would something that had not had such a direct and massive impact on your lives.

The committee now has to think about how we will take this forward. A letter to the cabinet secretary around accessing the relevant

information on the website can easily be done. If the committee is agreed, that can be done today, because that is a concern.

There are broader issues around how the health service treats people. One thing that struck me was that, between the interim report and the final report, wording changed from

"the women were not believed"

to the women

"felt they were not believed".

It could seem like semantics, but that is actually a pretty substantial point.

Broader issues have come out about how an independent review should be conducted, including the role of patients and the balance of medical interests. That is also something that the committee will want to consider. There are process issues that we obviously want to explore with the cabinet secretary: what she expected of the group, what its limits were and so on. Those are all issues, but the really substantial issue is what actually happened in the process and whether women are now any safer for the review having taken place. That is a massive question.

We have been taken aback by the response from literally across the world. It rather spooked me when I read that somebody in New Zealand was carefully watching our proceedings. This is a matter that goes beyond Scotland, so the committee is keen to take further action. We have secured a debate on the subject in the chamber, which will allow Parliament more broadly, and the people who watch, to understand some of the very complex issues and some of the, to be frank, quite straightforward issues. The cabinet secretary will have to respond to that.

As we think through what we want to do next, it would be useful to get a note from the clerk that brings together all the strands, including oversight by the MHRA. That will allow us to come back in a public meeting to report on what we think we need to do next. All of us are very alive to the strong interest in and concern about issues that the witnesses and their campaigning group have been so effective in highlighting.

Does anyone else have suggestions for what we might want to be included in the clerk's note to members on taking action forward?

Alex Neil: Can I just mention two things, convener? I am not a member of the committee, so this is just a personal opinion, but Dr Agur's suggestion about putting the final report out to formal public consultation even today is definitely worth considering. That seems to be quite a sensible suggestion and is perhaps one way of eventually getting its content changed.

Secondly, as you know I have suggested a global conference; I know that there is support for the idea from the campaigners and others around the table. It might be a good idea for the committee to consider hosting that global conference, because it has the advantage of being cross-party and representing Parliament rather than a party or group. It may be that it would be a first for the Parliament. We host conferences as a Parliament: we are hosting the business in the Parliament conference today. The committee would obviously need appropriate support and authorisation from the parliamentary authorities, but such a conference would give the matter a dimension that it deserves.

Michelle Ballantyne: Could we write to the chair of the review group and ask for sight of minutes from all the meetings? That would be worth our while. All its meetings should have been minuted.

The Convener: I assume that that would be part of the remit of the review. Some of this is about technical questions about whom we can speak to. You are right to raise the issue of minutes and records of meetings: let us think about whom we should then have that conversation with.

11:30

Michelle Ballantyne: I am concerned that the review group is not planning to report until the middle of next year. I hope that we will move a little bit quicker.

Brian Whittle: I am struck that there is, perhaps, a cultural issue. I do not know whether it is specifically the case for this petition, but across a number of other petitions and evidence on the matter, most of which I have heard from constituents, there is, to be frank, a culture of protectionism in certain sectors of the NHS. I wonder whether that should be considered by the committee in relation to this issue, or be looked at more broadly.

The Convener: If we are producing a report and having a debate, those are all legitimate issues to raise in them. It is clearly an issue that is specific to women, so is there an issue about women's health and the way in which people respond to that? Points have been made about the impact of a ministerial directive. Naively, I had assumed that if it said that something should not happen it would not happen: that there would be no such procedures while there was an investigation. It would be worth our while to look at that. The point about the retrospective study is also important. It is about properly understanding the impact and exploring that further.

Neil Findlay: I would like to pick up on something that you said about the matter affecting women. It now affects men too—we are getting men coming through who have had hernia mesh implants. The situation has also affected the partners and husbands of the women. We should just be a wee bit careful about that.

The Convener: I appreciate that: the point is well made. We know that, even from my distance from it, it is clearly having an impact on families that goes beyond the individual patients.

Olive McIlroy: I do not know what power the Public Petitions Committee has, but from today it is very clear that mesh procedures should stop until we have all the answers, because we do not have them. The procedures should stop right now and not put any more patients at risk.

The Convener: As part of our deliberations, we will obviously want to have a conversation with the cabinet secretary. Of course, when the debate comes to Parliament, committee members will bring their experience of the Public Petitions Committee. Members right across the—

Olive McIlroy: Will there be a vote at the end of that chamber debate?

The Convener: There would normally not be a vote. The Public Petitions Committee would probably produce a report that would be noted, and all the issues could be explored. That is not to stop these matters being—

Alex Neil: The Government has to respond to a committee report within eight weeks: it is absolutely compulsory that it come forward with its response to the committee's recommendations.

Neil Findlay: I do not want to attempt to direct the committee—God forbid—but, if the committee were to recommend that there should, given the evidence that it has heard, be a suspension and that that suspension should continue, that would be very powerful.

The Convener: Without misrepresenting the power of the review group and its capacity to make those decisions, we can reflect those views in our report and ask the Scottish Government to reflect on them. It is certainly not for the committee to make clinical judgments, but we have afforded the opportunity for the arguments to be presented in public, which has been useful.

There is clearly a great deal more to be done. I thank our visitor MSPs for being here, and I thank our witnesses and the people in the gallery for their attendance. I reiterate that we recognise that a number of issues are of great importance. One assurance that I can give you from the committee is that we take seriously our responsibilities in this regard. We will reflect on the evidence and come back in a public meeting to report on what further action we want to take.

Meeting closed at 11:34.

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