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Official Report

PUBLIC PETITIONS COMMITTEE

Tuesday 6 October 2015

Session 4

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PUBLIC PETITIONS COMMITTEE
16th Meeting 2015, Session 4

CONVENER

*Michael McMahon (Uddingston and Bellshill) (Lab)

DEPUTY CONVENER

*David Torrance (Kirkcaldy) (SNP)

COMMITTEE MEMBERS

*Jackson Carlaw (West Scotland) (Con)
*Kenny MacAskill (Edinburgh Eastern) (SNP)
*Angus MacDonald (Falkirk East) (SNP)
Hanzala Malik (Glasgow) (Lab)
*John Wilson (Central Scotland) (Ind)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Dr Catherine Calderwood (Scottish Government)
Neil Findlay (Lothian) (Lab)
Dr Phil Mackie (Scottish Public Health Network)
Shona Robison (Cabinet Secretary for Health, Wellbeing and Sport)
John Scott (Ayr) (Con)
Dr Lesley Wilkie (Independent Review of Transvaginal Mesh Implants)
Dr Rachael Wood (Information Services Division Scotland)

CLERK TO THE COMMITTEE

Catherine Fergusson

LOCATION

The Robert Burns Room (CR1)

Scottish Parliament

Public Petitions Committee

Tuesday 6 October 2015

[The Convener opened the meeting at 09:37]

Decision on Taking Business in Private

The Convener (Michael McMahon): Good morning and welcome to the 16th meeting in 2015 of the Public Petitions Committee. I remind everyone who is present to switch off their mobile phones and BlackBerrys completely, as they affect the sound system. We have received apologies from Hanzala Malik.

Under item 1 on the agenda, I seek the committee's agreement to take agenda items 5 and 6, on a new petition and on witness expenses, in private. Is that agreed?

Members *indicated agreement.*

Continued Petitions

Polypropylene Mesh Medical Devices (PE1517)

09:37

The Convener: Item 2 is consideration of petition PE1517, by Elaine Holmes and Olive McIlroy, on behalf of the Scottish mesh survivors hear our voice campaign, on mesh medical devices. Members have a note from the clerk on the petition. I welcome Neil Findlay MSP and John Scott MSP, both of whom have an interest in the petition. We will take evidence on the petition from two panels. I welcome the first panel: Dr Lesley Wilkie, the chair of the independent review of transvaginal mesh implants; Dr Rachael Wood, from the national health service's Information Services Division; and Dr Phil Mackie, from the Scottish public health network. I invite Dr Wilkie to make a short opening statement, after which we will move to questions.

Dr Lesley Wilkie (Independent Review of Transvaginal Mesh Implants): Good morning. I thank the committee for this opportunity to discuss the interim report of the independent review of transvaginal mesh implants. We have published an interim report at this time because we have carried out an extensive body of work that already lets us make recommendations on actions to improve patient care in the area. We hope that it will be possible, with certain provisos, to begin to take those proposed actions as soon as possible.

The review into the use of transvaginal mesh surgery for stress incontinence and pelvic organ prolapse came about because of growing public concern about the number of women who were experiencing serious and disabling complications. Women felt that their voices were not being heard when they raised concerns about the complications that a number of them had suffered, and lodging a petition with the Parliament was a way of bringing those concerns to a wider arena. As a result of those concerns being raised, the then cabinet secretary, Alex Neil, set up the independent review. He charged the review with taking an objective look at all the routine and published evidence, listening to and valuing the concerns both of those in the Scottish mesh survivors group who have serious and disabling complications and of those women who have found the operation to be an effective solution to troubling and serious problems.

Stress urinary incontinence and pelvic organ prolapse can severely impact on the physical, psychological and social wellbeing of women, and they can have a profound effect on the quality of their lives. The use of mesh procedures to treat

those conditions began in about 2000 or 2001. They were introduced in an effort to improve effectiveness, reduce complications and prevent repeat surgery. We were asked to review the best available research evidence and statistics as well as both patient and expert opinion to find out the nature and scope of the problem that was causing concern and to establish the facts, as far as it was possible, concerning transvaginal mesh procedures. As well as taking an objective view of both the results of the research and the statistical analyses, we have examined what those did not tell us—what was missing, what the patients' stories can tell us and what the experience and knowledge of clinicians in practice can tell us. I will say a bit about each of those strands.

Chapter 3 of the report tries to capture the experiences of women who have undergone such surgery. I know that members will have read the chapter and the quite upsetting stories that it contains. The stories of women who have suffered serious complications describe painful and debilitating experiences that have often been experienced years after their surgery and how, distressingly, at times they have not been believed when they have sought help. We also heard from women about good outcomes when mesh surgery had been successful. Understandably, however, the review heard fewer of those stories, as women have been less likely to come forward after a good outcome because both the condition and the surgery remain personal and private experiences. Chapter 3 confirms that some adverse outcomes that are experienced by women can profoundly affect their everyday lives. When women had experienced a positive outcome, that was reported as strongly as the experiences of those who had suffered a negative outcome. However, in the absence of specific qualitative research, the largest proportion of women who have had mesh surgery have not shared their personal experiences.

Chapter 4 presents an objective epidemiological review of the information from routine health data. That review was led by Dr Wood of the Information Services Division, who is with me today and will be able to answer your questions later. It is a key piece of evidence—we are particularly lucky to have it available to us in Scotland—that analyses health data over a 15-year period and reveals the complex decisions that clinicians are presented with when considering the best treatment options for women.

Chapter 5 presents an objective review of the research literature, for which I am grateful to Dr Mackie of the Scottish public health network. It is a review of research that has been undertaken by the agencies that are responsible for the safety of medical devices on an international and national basis and of the second, peer-reviewed Cochrane systematic reviews and health technology assessments. Phil Mackie is with me today and will be able to answer any questions on that work.

The conclusions of our review confirm that this is a complex area in which decision making is—as it is so often in medical practice—a balance between benefit and risk. The conclusions that are emerging from our wide evidence review also reflect a balance. We have concluded that robust clinical governance should surround the treatment of these conditions and, therefore, that the management of patients should be carried out in the context of multidisciplinary team assessment. Good information is crucial to the process, and another of our recommendations relates to that.

Evidence of clinician involvement in the process, including in audit activity and the reporting of adverse events, should form an important part of the formal appraisal process that already takes place in the NHS. We would like the Scottish Government to review the options that are available for adverse event capture to determine the most effective way of doing that and to improve its take-up. A considerable body of work on informed consent—which is highlighted in the literature as a major concern—has already taken place and we would like that to be reassessed in the light of the review and extended to the other procedures.

The lack of research studies on the long-term outcomes, including outcomes for quality of life and daily living activities, is concerning and we conclude that research on that basis is a priority.

09:45

There is a need for an information system that is universal, robust, clinically sound and focused on good patient outcomes. ISD has already started the essential preparatory work on improved coding of procedures.

In healthcare, good communication is essential to good patient care, and we see an educational need to ensure that there is adequate knowledge of the procedures, their uses and potential complications. Educational programmes should embrace that and should encourage good listening skills.

In our final conclusions, we differentiate between the use of mesh in the treatment of stress urinary incontinence and its use in the repair of pelvic organ prolapse. Although we await the outcome of the PROSPECT—prolapse surgery: pragmatic evaluation and randomised controlled trials—study, which is looking at the use of mesh to treat pelvic organ prolapse, the review group considered that we had sufficient evidence to express concern about the use of transvaginal mesh surgery for pelvic organ prolapse and we

have therefore concluded that it should be considered only in the context of a multidisciplinary team assessment.

The clinical experts on the group have also reviewed the evidence on stress urinary incontinence mesh procedures and their clinical experience of that, and considered the clinical significance of the reported complications. We conclude from that and from the patient evidence that the retropubic approach is preferred when offering routine surgery for women with stress urinary incontinence.

We have recommended that the expert group that has already been set up should oversee the implementation of an improved way of working and of organising services. We are aware that we have still to publish our final report, but we consider that there is sufficient evidence to allow the expert group to start developing services and implementing the recommendations, based on the evidence presented in our report.

As chairman of the review group, I hope that the report goes some way towards ensuring, above all, that patient voices continue to be heard, believed and valued and that women with these conditions can be assured that the treatment that they receive in the NHS is evidence based, audited and likely to produce a good result while keeping to a minimum the possibility of an adverse effect.

The Convener: Thank you very much, Dr Wilkie.

I will begin the discussion by making a couple of comments. I was not the convener of the committee when the petition first came to it, but I know from talking to colleagues on the committee and others who have shown an interest in the issue since it was brought to our attention that it has been if not the most distressing then certainly among the most distressing issues that the committee has heard. I put on record my thanks to Elaine Holmes and Olive McIlroy for bringing such an important matter to the attention of the Scottish Parliament. Their work has been vital. I also thank you, Dr Wilkie, for the work that you have started to undertake. I know that it is not completed, but it has certainly allowed us to keep the foot on the gas in taking forward the issue.

I will allow members to ask questions in a moment but, because I am new to the issue, I want to get a bit of context. You gave us the figure that one in five women who have undergone the procedure have had difficulties of one form or another. How many other procedures that take place in the medical field would adversely affect such a large number of people and would still be allowed to be undertaken as a matter of course?

Dr Wilkie: I find that difficult to answer, because there is such a wide range. I am not sure that I can answer, so I apologise for that. It sounds as if I am putting you off, but the answer depends on what we define as complications and whether we are talking about minor or serious complications. Rachael Wood might want to add something to that.

You might want to direct that question to the chief medical officer when she comes along. I am not aware of anything that would allow me to say what the cut-off point is for such and such a procedure. It depends on the severity of the condition, its impacts, what the procedure is, where it is done and how it is done. I am not sure, and I do not know whether Rachael Wood can help with the answer on that. I apologise.

The Convener: It is fine if you do not have the answer.

Dr Rachael Wood (Information Services Division Scotland): It is a difficult question to answer. As doctors, we definitely recognise that no surgical procedure is without risk. There are always difficult decisions that involve balancing the likely benefits and known risks of any given procedure. We are always on shifting sands, because there is always innovation in medical practice. As new medical devices come in, it is important that we understand the associated balance of risks and benefits.

David Torrance (Kirkcaldy) (SNP): Conclusion 4 in your report identifies gaps in research and in the information that is collected by the NHS. What difficulties, if any, did the review face in reaching its conclusions as a result of those gaps?

Dr Wilkie: As I said, we are lucky in Scotland in that we have good information but, as usual, it is routine data that we rely on. I will let Rachael Wood comment on that. We are lucky in the data sets that we have—the information and the numbers—and the ability to link data and look at that. That gave us quite an advantage in considering the issue.

In the research data, there are two gaps. The main gap that we found is in research that goes into the longer term. I will let Phil Mackie comment further on this. We find research that looks into the effects after one or two years, but some patients report complications after that. The fact that there is no body of research on the longer-term effects caused problems. However, ISD and Rachael Wood were able to provide longer-term information, which helped with that.

The two main issues on research are the need for longer-term follow-up, including routine surveillance, and the need to look at not just clinical outcomes, such as whether the operation worked, but the impact on quality of life. We need

to consider the impact on how people go about their daily lives.

I ask Phil Mackie whether he wants to add anything.

Dr Phil Mackie (Scottish Public Health Network): I will bring up two points that you have not discussed. The first is that many of the studies that are undertaken look very clearly at a precise clinical procedure. A one-year or two-year follow-up for surgical complications is not an unusual practice in many of the randomised controlled trials and in what we call well-constructed trials, which look at the procedure of interest against the alternative current practice. That is a fairly common research approach. A two-year follow-up is common in the material. A five-year follow-up is not impossible but it requires considerable research follow-up time and service follow-up time in the NHS. As a consequence, we make a recommendation on how audit might be a way in which we can do those longer-term follow-ups.

Secondly, many of the ladies who have had adverse experiences discuss them in terms of their everyday life rather than formal indicators of quality of life. There is a tendency in the research literature to look at the formal indicators of quality of life, which are somewhat abstracted from the day-to-day lives that we all lead. We recognised that that is a major gap in understanding people's lived experience. The surgery might well have consequences for the type of day-to-day activities that we accept as straightforward, such as dressing, bathing and being able to get out of the house when you choose rather than when it is arranged for you. The types of indicators that are of interest to people are not necessarily the indicators that we find in the systematic reviews, such as SF-36, which is on whether someone feels happy.

Rachael Wood will probably want to pick up on the availability of longer-term data. Putting that material side by side with what we saw in the systematic reviews provides strong clarity in answering the question.

Dr Wood: I can make some comments on the routine data that are available in NHS Scotland to help to monitor the safety of any type of medical care, including the operations in question.

My analysis was based mainly on routine hospital discharge records. Any operation that a patient receives in hospital is recorded in those national records using an agreed coding system—there is a code rather than a description of what was done.

One issue that we came across was that, in some cases, there can be a considerable lag between an operation becoming available and a specific code that describes it becoming available. In that interim period, the provision of the operations is difficult to identify using the national data. For example, even now there is no code to record the provision of mini-slings, which are a newer type of tape procedure for incontinence. ISD Scotland has specifically asked the Health and Social Care Information Centre in England, which maintains that coding system, to create a code for mini-slings, but we still cannot say how many women have mini-slings.

That is one practical issue that we came across that is about identifying the operations that women are having. There are also issues in capturing adverse outcomes that happen after operations. Sometimes that relates to the availability of specific codes, as well. For example, specific codes are available for the removal of tapes, but no codes are currently available for the removal of prolapse mesh. We have requested that those codes be created.

I want to be clear. The issue is not that those things cannot be recorded; they can be, but currently they have to be recorded using relatively non-specific codes, because there is no absolutely specific code available. That causes issues.

There is another issue when we use routine data to look at problems that women have after operations. We were able to look at only problems that were severe enough for women to be readmitted into hospital and therefore have a hospital discharge record. A lot of other women will possibly have had less serious problems that have been managed in an out-patient setting or by their general practitioner, or perhaps they will never even have brought those problems to the attention of a doctor. We will not have been able to look at them. There is information about care that is provided for out-patients, but it is less detailed than information about in-patient care.

Those are other issues. I hope that that answers the question.

Jackson Carlaw (West Scotland) (Con): I, too, congratulate Elaine Holmes and Olive McIlroy on the work that they have done in bringing the petition to us. I see Marion Scott from the *Sunday Mail* in the public gallery. Obviously, she has been a tower of strength in ensuring that the issues came to us.

I welcome Dr Wilkie. We have heard a lot about you, but this is the first time that the committee has had an opportunity to meet you. I thank you for your report. In fact, I am quite proud that Scotland has produced what seems to me to be the first piece of qualitative research on the subject. It has a lot of robust conclusions, some of which will be for the cabinet secretary to respond to shortly. Unless they are implemented, nothing

will change, so their importance is really in how they are taken forward.

10:00

I picked out a couple of flavour things in reading the report, and I want your reaction to them. First, have we truly overcome the prejudice that seemed to exist among clinicians against the women who reported the issues? The testimonies to which you refer include positive statements on page 19. One says:

"I have been advised by my Gynaecologist that fitting women with tapes to support their bladder has been suspended due to a tiny amount of problems."

That was meant to be one of the positive testimonies and I found it very arresting. It looked as if it had been solicited rather than volunteered—and solicited in rather a prejudicial manner.

The comment left me with the concern that, notwithstanding your report, which has identified concerns that your committee has endorsed, there may still be a broader sense out there that—I am sorry to put it like this—there are some silly hypochondriac women who do not understand that they were very lucky to have had the operation in the first place. Have we overcome that prejudice?

Dr Wilkie: We cannot have overcome it with the report, because it is a report. We felt quite strongly—and personally I feel strongly—that there is an issue with listening to women and valuing what they say. I am a woman and you wonder—actually, I will not go there. There is an issue, although we did not look at that prejudice in particular. As you said, in the patient views it comes across very strongly that patients were not listened to, and I was seized by the fact that there was such a phase.

That is why we put the recommendation about education in the interim report. Education is obviously not just about knowledge of the side effects; it is a balance. People must have the knowledge of how many and what percentage of patients are affected—the majority have not reported poor outcomes, but a significant number have had very poor outcomes—but education is also about empathy and appreciation and the ability to listen actively.

We must involve women. I was not involved in it, but the previous working group and then the expert group did work on consent with members of my group such as Elaine and Olive. We now have a much more detailed idea about informed consent for the procedure in cases of stress urinary incontinence. However, there is still the issue of people complaining about not being listened to.

There is this educational thing out there, and that is something that we do. There is a recommendation on education in the report, but it is quite a wide-ranging issue.

We have not overcome that prejudice yet. However, the clinicians in the group have said that it has been a revelation for them. They are dealing with it day to day, but we are talking about the wider community.

Jackson Carlaw: The cabinet secretary may say that she intends to accept the recommendations. Will a body of clinicians try to set aside the recommendations before the final report is published? The recommendations might go against the experience of some clinicians, who may not agree with them and might try to test them and overturn them.

Dr Wilkie: Based on what the clinicians I have spoken to have said, I would say no. I am no longer a practising doctor—I am retired—but the clinicians I have spoken to are committed to a good outcome. I do not have that cynicism about people; I am trying to think whether that is because of where I am.

I am aware of the problem that you highlighted, but I do not get that impression from the clinicians on the group. We had the Royal College of Obstetricians and Gynaecologists and leading professional organisations for urologists and gynaecologists on the group. That is not to say that they are—

Jackson Carlaw: The fact that some of them thought to challenge the moratorium leaves me wondering.

Dr Wilkie: Indeed. I can understand where you are coming from.

Jackson Carlaw: You have touched on the issues around the research. I am struck by what the interim report says about systematic reviews at chapter 5.5, starting on page 51. It says at various points:

"No long-term adverse outcomes were considered ... No long-term adverse outcomes were considered ... No long-term adverse outcomes were considered ... No trials were included in the systematic review ... No long term adverse outcome data were reported."

One of the key recommendations in the interim report is the advising of adverse incidents. That really has to be put in place not just in the weeks after the operation takes place but for a much longer period if we are truly to continue to monitor the situation beyond the initial report. That is what you would be looking for, is it?

Dr Wilkie: Yes, it is true surveillance, and the idea behind it is to have embedded. The expert group will develop that with an information system so as to consider how adverse events are reported

and recorded. There is a body of work to be done there, separately from the review, on the most effective way to ensure that that happens.

Jackson Carlaw: The single-incision mini-slings trials—or SIMS trials—were exempt from the suspension. That is included in what you identify elsewhere in the report as a "concerning" procedure. What is your view about women in Scotland continuing to be allowed to participate in trials that include a procedure that you regard as "concerning"? Is that really acceptable on the back of the interim report?

Dr Wilkie: I do not think that I have the ability to comment on that on the basis of the report or of my own experience. However, bearing in mind issues around the use of such procedures, we felt that we had done a considerable body of work in the interim review, and we pursued it quickly. We are keen for the expert group to do its work, and we are keen to hear the cabinet secretary's response.

There is numbers evidence, there is information and there is research evidence, which, if you read it, does not give a clear yea or nay. We decided to put on top of that the considerable body of evidence from the women's experience, good and bad, and from the clinicians' expert opinion, asking questions such as, "What does this mean in practice?" Then we came up with the recommendations expressing concern.

The expert group now has to take that work forward and see what the evidence means for practice, which I suppose includes research practice.

Jackson Carlaw: You can understand my concern.

Dr Wilkie: I see what you are saying.

Jackson Carlaw: If there was a loophole whereby participating in a trial allows people to circumvent recommendations that might be accepted within the overall report, that would be unfortunate.

Dr Wilkie: That is something that I have no knowledge of.

Dr Wood: I am not directly involved in the SIMS trial at all but, as I understand it, it considers the relative effectiveness of the newer mini-slings—the single-incision tapes for incontinence and the standard retropubic tapes.

You say that the report indicates some concern about mini-slings—I assume that is what you are referring to. There is indeed a Cochrane review that indicates some concern about that, but almost all the trials in that review relate to the very first type of mini-sling, which has now been withdrawn from the market. We are talking about newer versions of mini-slings. There are theoretical reasons for thinking that they may well be superior to some of the standard tapes, but there is genuine uncertainty, so I would say that it is reasonable to do that trial. No trial would be approved without careful consideration of the ethical issues involved.

Jackson Carlaw: I am not sure that I am entirely convinced—but fair enough.

John Wilson (Central Scotland) (Ind): I welcome the interim report. We have moved a long way from when the petition was first put before the committee—from a situation in which women felt that they were not being listened to, to our having an interim report that actually takes account of many of the experiences that women have faced.

There are still questions that arise regarding the interim report, in relation to some of its conclusions and to some of the issues that it raises. I would like to start by asking about the evidence.

You said that there was very little statistical evidence to highlight the long-term impact that women face. What you have said is that the issues relate to the experiences of women, and we are still talking about a minority of women. At the same time you admit that there is not enough data being collected on those experiences. As Jackson Carlaw indicated, you gave some examples of women feeling that the procedure was a positive experience. In reality, we do not have the whole picture; we do not have the experience of every person who went through the procedure. We were told as a committee previously not only that some of that data was not collected by clinicians but that it did not have to be collected.

In the recommendations before us, I note that you have said that you want that data collected and you want better monitoring. How can we be guaranteed that that will take place? How can we ensure that we get data on not just short-term but longer-term impacts? Comments have been made about quality of life and day-to-day experience, but there is also the issue of long-term impact. Some adverse effects may not be noticeable immediately; it may be a few years later—five or 10 years down the road—that there is an adverse effect. How do we ensure that the data on that is collected?

Dr Wilkie: As I said, we have a database in Scotland, and there is longer-term information in that ISD data. Having the long-term data is one of the main recommendations that I would hope for a response on.

Rachael, do you want to say something about the long-term—or otherwise—nature, according to what you have looked at already?

Dr Wood: I find that to be quite a difficult issue, because it is a matter of balance. Any monitoring needs to be proportionate, because otherwise it would cause a really heavy financial strain, if nothing else. Monitoring needs to be sufficient to make it very clear that we can pick up any serious safety concerns but without completely paralysing the system.

It is not true to say that we in Scotland have no information. We do have information. ISD is an important part of the whole NHS in Scotland. We have had, and will continue to get, records from every in-patient admission, every new out-patient attendance and so on. However, because those are high-level national records, they inevitably contain only quite a low level of detail. They do not tell us things such as how the woman feels or the quality of life that she is experiencing.

It is a question of making sure that the routine data that the NHS holds is as robust, relevant and well used as possible and of seeing whether it needs to be supplemented with something else. That something else might be one-off research trials or qualitative work, or it might be some other form of non-routine information gathering.

I think that there is great potential value in some of the professional databases that surgeons are encouraged to participate in. We know that they are not used as well as they could be.

John Wilson: I stop you there, Dr Wood. You said that surgeons "are encouraged" to use. That was part of the problem when the professionals came to us.

Dr Wood: Absolutely.

John Wilson: Surgeons and clinicians were not recording the women's experiences. The women felt that their experiences were being ignored and that therefore the issues were not being addressed. They felt that they were being devalued in some way because the clinicians and the surgeons were not prepared to gather and record that data.

Can we find a way of actually ensuring—not just making suggestions or recommendations—that surgeons and clinicians record when there is a recognised adverse effect relating to the procedures that are being carried out on women?

10:15

Dr Wilkie: That is the basis of some of our recommendations—you might want to raise those questions in the next session, too.

Two of our recommendations relate directly to that issue. They highlight the need for an information resource to enable clinicians to record data in an organised fashion so that comparisons can be made—as Rachael Wood said—at a national and a local level, and the need for clinicians to organise in multidisciplinary teams and groups.

Clinicians are committed, although I agree that that commitment is not universal. We heard about the databases of professional bodies—as Rachael Wood mentioned—that would contain such information. The trouble is that those are stand-alone databases and are not able to provide the necessary richness of information.

We recommend in our report that ISD should work with the professional bodies that have such a database to see whether the information can be obtained. One of our recommendations relates to the need to have the data. There are some very committed clinicians who are collecting data in this area.

You ask about how we can ensure that women's experiences are recorded. That is not within my gift, but there is now a statutory revalidation system for medical staff that is based on enhanced appraisal and focuses on patient outcomes, and evidence must be collected for that.

Our recommendations did not simply come out of the blue. Again, the decision on how far to go is—as Rachael Wood said—not for us to make in the review. It is for the decision makers to look at the situation and at committing resources.

John Wilson: I thank you for that response, but the reality is that it is in your gift, as the chair of the working group, to recommend strongly a way forward for surgeons, clinicians and others in dealing with the reporting mechanisms.

You are quite right that it is then up to the Government to decide how it will take that recommendation forward and fund it. However, it would be useful if you were to place a strong emphasis on collecting such data and on making that mandatory for surgeons and clinicians rather than simply encouraging them to do it, in order that we can be clear about the evidence that has been gathered.

Dr Wilkie: We felt that the requirement for data within the appraisal process is equivalent to making collection of data mandatory for surgeons and clinicians. Nonetheless, I will take on board what you say and keep it in mind for the final report. Thank you for that comment.

John Wilson: I want to go back to the point about review group membership. A number of months ago, the committee heard evidence from representatives of the Medicines and Healthcare Products Regulatory Agency, which unfortunately dismissed women's concerns about the procedures and the impact that the devices were

having on women's lives. Can I take it that all the review group members have signed up to the interim report and to the recommendations that it contains?

Dr Wilkie: Yes. We have no adverse comments. The report was circulated in many drafts. If you are asking whether the MHRA is signed up, the answer is yes: it has not indicated otherwise.

Members of the Scottish mesh survivors group were very clear that they wanted all the criteria to be set down before the commencement of the review, as our report says.

John Wilson: Thank you for that.

Finally, your report's executive summary indicated that you are still waiting for the opinion of the European Commission and that of its Scientific Committee on Emerging and Newly Identified Health Risks. Has the interim report been sent to the European Commission? In my experience, the commissioners are keen to see reports from Parliaments in Europe. Given its significance, the interim report on the devices might help to influence the outcome of any decisions that the EC makes, particularly through its scientific review body.

Dr Wilkie: I should think that they have seen it, but I will check with the secretariat. It will be of interest to you to know that we have had a response from the international professional organisation of urogynaecologists, so there is international interest. I would be surprised if the report has not been sent, but if not, I will ensure that it is.

Neil Findlay (Lothian) (Lab): Some people have congratulated the women that have brought this issue to the fore, but I do not; I sympathise and empathise with them. They should have never had to go through physical and emotional torture to get to this stage. The only reason that they had to go through that was because there was a willingness among the medical profession to believe those people who said that mesh implants were a success and an unwillingness to believe those who said that they were not. That is why we are where we are today.

I want to pick up on a couple of the issues that Dr Wood raised. She mentioned the difficulty of getting a code. That seems incredible. Can you explain why it takes so long to get a code? If Tesco gets a new brand of beans, it will be coded within five minutes and go straight on sale. I know that we are dealing with human beings, not beans, but how on earth does it take such a long time for someone, somewhere, to come up with a code?

Dr Wood: It is a valid question. Codes are not within my gift; I am not the person who decides whether new codes are agreed. The codes for operations are given through the OPCS system, which is now maintained by the Health and Social Care Information Centre in England. The coding system that we use for patient diagnoses is the international classification of diseases, which is maintained by the World Health Organization, which is even more complex because it is a global system. For both those coding systems, there is a process whereby any interested party can submit a request to have a new code generated.

The coding systems are used for international comparisons and there is a value in them being reasonably stable over time, otherwise it is just chaos and you cannot do the kind of analyses that we need to do. It is reasonable to require that the process to agree new codes is controlled. It is quite a lengthy process and I cannot comment on why that is; you would have to ask the Health and Social Care Information Centre about that.

Neil Findlay: I understand that it is not your responsibility.

Two years ago, I asked a parliamentary question about how many adverse incidents had been reported and the answer that I got was six. When we met the previous cabinet secretary, the women round the table said, "That must be us." Since then, through persistent freedom of information requests and various methods of data gathering, we have found out that the figures are at least in the hundreds and maybe the thousands.

How can we provide information to the women who have been affected, if we do not know how many there are and who they are and where they live? How do we alert women to the problem? Surely, if someone has something that has been described as "concerning", we should tell them. If it were me, I would want to know. Given that we know where those people are, why is the recommendation not that everyone who has had a mesh implant be alerted to the potential concern?

Dr Wilkie: How do we alert them? The issue of informed consent is important. The informed consent leaflet that has been developed by the expert group with involvement from patients is probably the most extensive work on informed consent in surgery. When a woman goes through with a stress urinary incontinence or pelvic organ prolapse procedure, being aware of all that is very important. The work that has been done in that group—which is nothing to do with those of us round the table—is leading the way.

There is a lot of information. It is not always just about giving information, but is about people having the time to assimilate that information and to be assisted in doing so, if, for example, they have difficulties assimilating written information.

There is a whole process around giving that informed consent that needs to be put in place.

When we say that we have concerns, we have to be aware that no regulatory body in the world has withdrawn or done anything about the implants. Phil Mackie can comment on that, but looking across all the evidence, we have not found a regulatory body that has done anything. One body has said that there should be reassessment. The written evidence is there.

The regulatory body for Scotland as well as the United Kingdom is the MHRA, so that is the body that would consider the matter. I cannot comment on that. I am just saying that, if we are looking to improve patient care, based on the information that we have and the evidence from the patients and clinicians from the two strands, the two procedures—not mesh itself—are of concern and need to be looked at. That is our specific recommendation because we felt that we had the evidence to say that.

Neil Findlay: I am afraid that although you have said a lot of words there, I do not understand and could not reach a conclusion.

What I am asking is, given what we know, should we not be writing to tell women that there may be a problem? I think that people have a right to be alerted to the fact that they may have something that might be defective in their body. Can I ask you personally—and I would not ask this if you were male—whether, if you had gone through this procedure, you would want to know that there were such concerns?

Dr Wilkie: I think that my gender is irrelevant.

I see where you are coming from, but what I was trying to say is that I do not have the evidence to say that we should do that and nor would it be the business of the review to say that.

John Scott (Ayr) (Con): I also welcome the preliminary report. Taking the combined totals of operations mentioned on pages 23 and 25 of the report, I am not certain how many required mesh implants. Nonetheless, I am concerned about the size of the study, given that the number of operations seems to be approaching 30,000 but the report deals with only a few hundred people. It is a welcome first step, but there is still a huge amount of work to be done to establish the scale of the problem. Hopefully, that will reassure us that very few people have been affected by the issue. It is a major concern that there may be many more women affected than the study suggests.

Perhaps I am getting the wrong end of the stick, and if so, I would be happy to be corrected.

Dr Wood: I hope that I can clarify some of the issues. The study that you refer to is the work that I did in ISD using the national routine hospital discharge data. Unlike a trial, it is not a selected group of women; it is a complete population-based study and we looked at all women in Scotland who had had the procedures. The number of women having tape procedures for incontinence is very high because they have been the dominant procedures for stress incontinence for some years.

10:30

John Scott: Do you have a figure for that—even a ballpark one?

Dr Wood: The tape procedures are the last three procedures that are covered on page 23 of the interim report.

John Scott: Yes. I see that the total is about 13,000.

Dr Wood: You can see that the vast majority of the procedures that have been done in recent years have been tape procedures.

Our study did not quite capture all the operations that go on. We looked at all women, but then we focused on women who were having single procedures and women who had not had an operation in the past. Sometimes, women have multiple operations at the same time, and sometimes women come back for repeat operations. If we had included them, it would have been difficult to see what had caused any adverse outcomes. The study therefore includes not the absolute totality, but a high proportion of the operations.

Page 25 shows the numbers of women having prolapse operations. If you look at the first two lines, which show the figures for anterior repairs for anterior prolapse, you will see that standard repairs without mesh are much more common than mesh repairs. Mesh repairs have never been used in large numbers in Scotland for that condition, and the same is true for posterior repairs. In the last four lines of the graphic, we get into a slightly more complex area because they show operations for prolapse of the top of the vagina or the uterus.

Incontinence and prolapse are quite different, but the figures that are shown are for the totality of women. Compared with a clinical trial, they are quite high numbers. I accept that, for anterior and posterior mesh repairs, the numbers of women included in our study are 200, 300 or 400, but those numbers are quite high compared with the numbers that would be included in a clinical trial, and they give us a quite robust idea of the proportion of women in normal care in the real world—this is not a trial; the figures show what is happening in the NHS in Scotland—who are coming back up to five years after their operation.

I think that there is a clear signal. Even though quite a small number of women have had mesh anterior or posterior repairs, it is clear that the risk of coming back due to complications in the subsequent five years is considerably higher for those women than it is for women with non-mesh repairs.

John Scott: Is it not possible to go back a great deal further than five years? Recently, I was invited to take part in a trial going back to an accident that I had 18 years ago, in a neurological sense. Is it possible to go back further than the relatively short timescales that you appear to be dealing with?

Dr Wood: The short answer is that it is not possible for this particular condition. Tape procedures were introduced in around 2000, 2001 and 2002, and we have captured all of those. Mesh anterior and posterior repairs really came in only in the mid-2000s, so there is a limit. Over time, we will be able to look at that group of women and say how many came back with complications over a period of 10 to 15 years, but because the procedures were introduced relatively recently, a five-year follow-up is really all that we can do now if we are to get a reasonable number of women in the study.

John Scott: How long are records available for in the NHS?

Dr Wood: Routine hospital discharge records are available for decades. They go back to the 1960s and 1970s. The old ones, up to the early 1980s, are a bit more tricky to analyse, but they are available so it is not a problem for us. However, the operations that we are discussing were not being done at that time.

John Scott: Thank you.

The Convener: We have heard a lot about comparisons between Scotland and elsewhere. It appears that we are further ahead than most other countries in analysing the situation, and that is to be welcomed. It is because we have had the petition and the review was asked to look for the data. However, by your own admission, the data is incomplete. You are looking for information and trying to complete the information that is available.

My recollection is that the Scottish Government's initial response to the petition was that the process should be suspended while the work is undertaken. Subsequently, it appeared that there has not been a suspension. I heard the word "moratorium" being used earlier, but there has not actually been a moratorium. As far as I understand it, the procedures are still being carried out. Is that correct?

Dr Wilkie: My understanding is that the number of procedures has reduced markedly but some procedures have taken place. Again, you might have to direct that question to the cabinet secretary. When we started the review, we were under the impression that the procedures would be suspended but some would take place in the context of clinical trials. I was not directly involved in that, but that was our understanding.

Although there is a suspension, as one member said, the clinicians want to start doing the trials, and women with the condition who have been through the informed consent want them to start. Therefore it is not happening.

The statistics show that some procedures are taking place, although the number is very much less.

I want to return to Mr Findlay's point, because I think that I did not answer it at all.

Neil Findlay: I do not think that you did, either.

Dr Wilkie: That concerns me. You asked me whether we should recall people who have had the procedure.

Neil Findlay: I asked whether we should advise them.

Dr Wilkie: My feeling is that I do not know. The ins and outs of recall are up to the powers that be, as it were. Actually giving GPs good information is important, so that they know.

A woman should be able to have the confidence to say, "I had this procedure, and what I am feeling is true." If you are asking what I would do, I hope that I would do that but not all women can. I would hope that I would go along and say, "I have had this procedure and I am getting these symptoms that I think are to do with the mesh. Here is something that says that, nowadays, the procedure should be recommended only in exceptional circumstances."

I would leave the question about any recall to somebody else. I do not know about that. I do not have enough knowledge to tell you whether that is the best way.

Neil Findlay: That is what you would do as a woman with your mind and your body. However, another woman, who does not have your personality or confidence might sit at home terrified and be completely oblivious to the causes of her problems because she does not give a hoot what the Scottish Parliament or the Public Petitions Committee does and does not read the *Sunday Mail* or listen to politicians. That is the sort of person I am concerned about. How are we going to get the information to them?

While I have the opportunity, I want to ask a final question. Have you seen the minority report that has been produced by some members of the

committee and, if so, will you be commenting on it?

Dr Wilkie: I have not seen the minority report.

Neil Findlay: I will get you a copy.

Dr Wilkie: I would be grateful for a copy, but I am aware of the concerns. That was what I was trying to allude to when you asked the question about the MHRA, which is why I answered in the way that I did. I hoped that we phrased the report in a way that said that all of those things had to be in place.

I understand your concern about the women you mentioned. I see what you are saying. We have to think about how we ensure that they are informed.

Jackson Carlaw: Dr Wood, in response to what John Wilson said when we were talking about contacting all women, you said that a balance needed to be struck or a cost would be involved in all that. I am trying to understand what we would strike a balance with.

With regard to the discussion that you had with Mr Scott, it does not seem that the number of women involved is so large that it would be impossible to have a more proactive strategy of on-going contact with them and associated monitoring. Mr Scott mentioned 30,000 operations overall, of which about half involved mesh. It does not sound to me, sitting here, as if it would be such a huge, impossible or financially onerous responsibility for the health service to contact women proactively and to return to those women later, in light of our concern that someone who has a successful experience initially might have complications later.

Dr Wood: Perhaps I should clarify what I was saying. Working in ISD, I am primarily interested in the routine data that the NHS collects on all patients all the time. That is where I was expressing a desire for proportionality. I do not think that it is sensible to suggest that we massively expand routine hospital discharge records in order to collect extensive information about how women feel, their quality of life and so on. That would not be appropriate. We need a sense of proportionality about the routine data that the NHS should collect all the time on everyone, so that we can do such analyses when the next issue comes up on another aspect of medical care.

The question about what specifically should be done about this type of mesh surgery is separate and different. There are general lessons to learn from this work for the national data, including the fact that it might be a good idea to collect as part of the routine data more precise information about the type of device that is being implanted in a woman. I do not dispute that there might need to be something additional and specific for mesh, but addressing that is possibly not primarily ISD's job. I was simply reflecting my views on the national data that has to be there for all patients all the time.

Jackson Carlaw: So a job of work might need to be done. We might put that to the cabinet secretary, but it does not necessarily fall into your sphere of research.

Dr Wood: There is a balance of what we can learn about the routine data—that concerns what data is collected, how it is analysed and how we direct our energies—and the complementary activities that would be beneficial, specifically with regard to mesh. That might mean a national audit of the professional databases. ISD would be involved in that, but it would not be solely in our gift.

I hope that that gives you an idea of what I was talking about when I referred to balance.

Jackson Carlaw: That was helpful.

Dr Wilkie: There have been national audits of other conditions that go into more extensive detail; indeed, one of my colleagues has just reminded me of the example of hip fractures. The report refers to the British Society of Urogynaecology database, which is the professional database and is more extensive—although, before someone asks, I should point out that it is acknowledged that it does not cover everything. There are also examples where audits, rather than the collection of data that is input in a routine way but not by ISD, have provided more detailed clinical and lifestyle information.

The Convener: I was leading up to a final question a wee while ago before we got into another discussion. However, the discussion was not unhelpful, because it has made the point that I was leading up to, which is about the incompleteness of the data.

The word that Dr Wilkie has used repeatedly and which Dr Wood used at the conclusion of her previous response is "balance". You have referred to the need for balance. Given that the data is so incomplete, given the concerns that we have heard about the implications of the procedures, given that we thought that a suspension was in place when it might not have been, and what with procedures still being undertaken as part of clinical trials, were you asked to consider whether, on balance, we should adopt the precautionary principle of not doing something until we know more about it?

Dr Wilkie: No—not specifically. Our remit was to find and look at the information that was available, not to consider whether the procedure should be suspended. We were certainly not

asked to consider what you suggest for the interim report.

The Convener: That session has helped with what we might need to ask the cabinet secretary. On behalf of the committee, I thank the witnesses for their contributions. We will probably ask you back when your work is more complete.

I suspend the meeting for a few minutes to allow a changeover of witnesses.

10:45

Meeting suspended.

10:50

On resuming—

The Convener: We continue our evidence taking on mesh medical devices with Shona Robison, the Cabinet Secretary for Health, Wellbeing and Sport, who I welcome to the meeting. She is accompanied by Catherine Calderwood, the Scottish Government's chief medical officer.

I invite the cabinet secretary to make a short statement before we go to questions. It is over to you, cabinet secretary.

The Cabinet Secretary for Health, Wellbeing and Sport (Shona Robison): Good morning and thank you, convener. I thank the committee for providing me with an opportunity to respond to the interim report of the independent review of transvaginal mesh implants.

We all appreciate how harrowing this has been for the women concerned and their families. I have met women who have experienced complications and have read numerous letters and emails expressing their pain and distress. It is deeply concerning to hear the extent of their suffering, and they have my full sympathy.

The report came about as a result of the affected women bringing the issue to the forefront. It is clear that this is an emotive subject on which views differ, and the report has provided evidence and informed opinion to help us to understand why there are so many apparently conflicting facts and opinions about transvaginal mesh procedures. Regardless of someone's opinion on the issue, the report will help to improve services to benefit all women who are suffering from such conditions. I will say more later on the legacy of those who brought the issue forward.

As the committee knows, I received the interim report from the independent review only recently, and I thank the review group's members for their hard work in producing it. I understand that the committee has just heard evidence from the review's chair; I will set out the Scottish Government's initial response to the conclusions and recommendations, which, although not yet developed in detail, certainly set out the way forward.

The work supports the call from the women in the Scottish mesh survivors group for improvements in care. The review was asked to determine the safety and relative efficacy of mesh implants for stress urinary incontinence and pelvic organ prolapse. The two conditions are entirely different, and the review has—rightly—considered them separately.

The review has recommended that improvements should be made in the management of individual patients and the Scottish Government agrees. I confirm that the expert group will continue its work with NHS planners on developing pathways of care for stress urinary incontinence and pelvic organ prolapse. That will mean developing pathways of care that, first, are consistent with national guidance and delivered by a multidisciplinary team that includes primary care and other relevant community services and, secondly, ensure that surgery is considered only after conservative measures fail. If surgery is needed, all types of surgery will be considered.

We concur with the view that clinicians should provide evidence of involvement in multidisciplinary team working, including an audit of their activity and a record of their reports of adverse events. The expert group will be asked to develop that protocol with a view to medical directors as responsible officers incorporating that into clinicians' appraisal process.

I completely agree that informed consent is a fundamental principle that underlies all healthcare and I commend the expert group's earlier work on developing the patient information and consent leaflet for SUI. That valuable work will be developed and the leaflet revised to include additional information, including details of the specific implant that is to be used. That means that if a woman experiences a complication she will have the information that is required to report an adverse event to the Medicines and Healthcare Products Regulatory Agency. The concept of that leaflet will also be extended to POP procedures.

The development of care pathways for the conditions will take account of the time that a patient needs to discuss and reflect on the information that has been provided before making a decision. One of the key areas that the report highlights is the gap in evidence relating to long-term outcome data, and the report has recommended that that be addressed through research. I have therefore asked the expert group to encourage research in that area in discussion

with the chief scientist office and other research funders.

My predecessor, Alex Neil, asked for an independent review because of growing public concern about the number of women who were experiencing complications and about the underreporting of adverse events. The NHS's Information Services Division has undertaken a thorough analysis of existing hospital discharge records that highlights the complex decisions with which clinicians are presented when they treat women who have such conditions, and the report distils that complex information in a way that will help women and clinicians to make informed decisions when they agree a treatment plan.

ISD's work has highlighted areas for improvement, and work on those areas has already commenced. That includes work on a UK basis to ensure that procedures have codes and that those codes are implemented to allow the procedures to be reliably identified in routine data as quickly as possible.

My officials have met ISD to consider how to develop existing information systems, in conjunction with other work on the unique device identifier, to support active monitoring of the procedures. The expert group will lead on that workstream and will liaise with UK-wide bodies to investigate the feasibility of developing and maintaining a registry.

I am happy to endorse the view that the expert group should review the training and information that are available to clinical teams and look at ways of incorporating patient views in multidisciplinary team working. I am pleased to say that a helpline was launched in August, which has been a welcome addition. Officials are continuing to work with those involved, and posters to advertise the helpline are being planned.

I am content to endorse the recommendations on the routine surgical approach when mesh surgery has been agreed, subject to the outcome of the final report. I understand that interpretation of the available evidence and informed opinion support the routine use of the retropubic approach for stress urinary incontinence, with any variation considered as part of the multidisciplinary team assessment. Interpretation of the available evidence for the use of mesh in pelvic organ prolapse repair has also led to the review concluding that the procedure should be available only in exceptional circumstances, with any variation considered as part of the multidisciplinary team assessment.

The independent review awaits the final publication of key research reports before it can publish its final report. Although I am content for the expert group to develop the foundations of the services as outlined in my preceding statement, I have requested that the services not be introduced until I have received the final report and until I am satisfied that the improvements have taken account of all the evidence. We can then work to introduce improved services uniformly across all health boards in Scotland.

I thank Dr Wilkie and the members of the review group for their work. It is clear that both the evidence review carried out by the Scottish public health network and the analysis of health data by the NHS's Information Services Division have been thorough and have brought clarity to what are complex issues.

I understand how incredibly difficult this has been for those who have been involved in the review process. For some, it has highlighted issues that are extremely painful to consider because of their personal experience. I reiterate my gratitude to them and hope that they can see the difference that each of them has made. Because they have been prepared to speak publicly on very sensitive issues and to work through the difficulties that they have encountered, women who need such services in the future will benefit. That improvement in the services for women who experience these distressing conditions is the legacy of those who have been involved.

I understand that the independent review expects to publish its final report early in 2016. Subsequently, the Scottish Government will publish a full response and ensure that the committee is informed of it. Thank you for hearing my initial response to this important work.

The Convener: Thank you, cabinet secretary. I invite David Torrance, the deputy convener, to ask the first questions.

David Torrance: Good morning, cabinet secretary. Alex Neil, the previous Cabinet Secretary for Health and Wellbeing, announced that the use of TV mesh would be suspended in Scotland but some clinicians continued with the practice. Can you tell me why? How will you ensure that the recommendations of the review's report and any future recommendations of the expert group are translated into practice by clinicians?

Shona Robison: The number of such procedures has dropped dramatically, with very few having been carried out since the suspension. I have answered the same question in Parliament on a few occasions. When the woman herself asks for the procedure because of the distress that her condition is causing her, and if the clinician is prepared to continue with the procedure, the procedure can go ahead. However, only a very

small number of procedures have been carried out. I will ask Catherine Calderwood to elaborate on that in a second.

On clinicians' practice, I make it clear that the group's recommendations will be implemented, and they will apply equally to all parts of Scotland. Catherine Calderwood, as the CMO, will ensure through her work and guidance that clinicians adhere to the new ways of working, that each and every one of them takes forward the report's recommendations, and that that will be monitored and appraised.

11:00

Dr Catherine Calderwood (Scottish Government): When the previous CMO wrote to health boards asking them to consider suspending use of the mesh, there were women on the waiting list who were expecting a procedure. I undertook to speak individually to the clinicians, who called in the women from the waiting list to have a conversation with them about the suspension. By that time, we had produced a comprehensive consent form with a lot more detail on it for use in all health boards. The women who subsequently went ahead to have their procedures were fully apprised of the risks. They were made aware of the suspension and the complications that some of the women behind me in the public gallery had brought to light. Therefore, they went into the procedures with a lot more information; they also understood that questions were going to be looked at in the independent review that had been commissioned.

Neil Findlay: How many procedures were carried out?

Dr Calderwood: My understanding is that there have been 76 stress urinary incontinence procedures using mesh. On the prolapse surgery, because of suppression of small numbers, we had to ask individual health boards for the information, but the numbers are so small that we cannot reveal the figure, which makes me think that it was fewer than 10.

The Convener: I was not on the committee at the time, but I was following the issue, as were most MSPs, by speaking to colleagues who were more closely involved in the discussions, and by picking up matters from the media. The then Cabinet Secretary for Health and Wellbeing, Alex Neil, was quite forceful in putting forward a message that the procedure had been suspended. He might have known that the suspension was caveated, in that doctors were being allowed to carry out clinical tests and that some people might be allowed to have the procedure, but do you believe that that message was given?

I distinctly recall the outcry when it was discovered that the procedures were continuing to take place. When the then cabinet secretary said that there would be a suspension, people believed that that meant that there would be no more of the procedures. Was the cabinet secretary clear enough? Do you understand the distress that was caused and that people felt misled or that there had been miscommunication that needed to be addressed when it was later discovered that the procedures were continuing?

Shona Robison: First, we need to remind ourselves that the MHRA has not banned the procedure. It is the regulatory authority that would ban a procedure in the light of evidence that it should not be used. The then cabinet secretary asked boards, in light of the concerns that had been raised, to suspend the procedure while the group was able to do its independent review.

I was not involved in the detail of this at the time, but if we look back at what was said, there was always the chance and the choice for a woman to go ahead with the procedure in the full light of all the information and, as Catherine Calderwood has explained, the far more robust informed consent procedures. Whether the procedure went ahead would have been a clinical decision made in liaison with the patient. There was scope for a procedure to go ahead within that set of arrangements, but with full informed consent and the level of information to which Catherine pointed.

If that was not clear for some people and was not their perception, we accept that there was perhaps a communication issue. However, looking back, I am pretty clear that the procedure was always there as an option for women. Otherwise, we would have been saying to women, "Even though you know all about informed consent and this isn't a banned procedure, we are not going to allow you to have it." Therefore, when I answered questions on the issue in Parliament when I became cabinet secretary, I tried to put across the point that some women might still have chosen to go ahead with the procedure in full knowledge of all the potential risks and with full information about it, and of course with full knowledge of everything that had been in the press regarding what women had brought forward on the issue. If, in light of all that, a woman still wanted to go ahead with the procedure, the clinician would have had that choice.

The Convener: That might be your perception, cabinet secretary, but I certainly do not remember those caveats being added to any Scottish Government press statements, although I could be wrong about that. If you have that information about those press statements, can you send it to the committee? You could not see this, cabinet

secretary, but I could see the people sitting behind you in the public gallery shaking their heads when you said that there was an understanding of the caveats.

Shona Robison: I did not say that; I said that I understood that folk might not have had that perception and that that was a communication issue. Catherine, do you want to say a little bit about this matter?

Dr Calderwood: I think that there was a sentence underneath the cabinet secretary's call for a suspension that talked about a clinical decision in the full light of information where a woman was approaching a clinician because of the severity of her symptoms. There was a phrase that was perhaps not widely reported, but which did allow that clinician-and-woman interaction.

The Convener: Maybe you should have made it clearer at the time, then.

Jackson Carlaw: Yes, it might have said, "Would you like to face a firing squad this morning where some of the soldiers might not have bullets in their guns?"

Dr Calderwood: I do not think that we practise medicine like that.

Jackson Carlaw: Yes.

Cabinet secretary, I am actually very pleased, because I think that what you are saying is that you would like the moratorium to remain in place until you are satisfied that the recommendations of the report, which you accept, have been implemented to a degree that you believe properly reflects their respective importance. I think that that is essentially where we are at in the first instance.

Shona Robison: Yes.

Jackson Carlaw: That leads me to ask three questions. First, I appreciate that this is a subjective comment, but one of the most deeply unimpressive witnesses that this committee heard from was Dr McGuire of the MHRA, who confirmed in his evidence what seemed to us to be an underlying impression of the petitioners—that there was a lack of serious regard for the condition that many of them had found themselves in. In his evidence, as far as the wider research that had been done was concerned, at one stage—rather incredibly to me—it boiled down to three people at some university somewhere with a grant of less than £30,000 who had spoken to a handful of people three years ago. On the back of that, he was asserting to us that, really, all was well.

I note that he was on the review group, so I suppose that this is a question for the Government that goes beyond even the scope of this particular incident. Would you now expect the MHRA to reflect in some way the conclusions of the report, which has validated that there is an underlying concern that the MHRA seemed to be unaware of? As cabinet secretary, are you satisfied in a much broader sense that the MHRA—which pled to us that so great was its workload, with thousands of things that it had to monitor with so few people, that it did not really have the time to do anything more—is a body that is properly able to respond when an incident of the kind that we are discussing occurs?

A great deal of weight is given to what the MHRA says. What was so staggering to me was that we were told that the MHRA says that there is not a problem, but when we asked the MHRA what it had done to find out whether there was a problem, the answer was precious little.

Shona Robison: I would absolutely expect the MHRA to look at all the evidence, including the interim report and the reports that are still awaited. Obviously, there is the English report and there are other reports. I would absolutely expect the MHRA to look at all that evidence and any emerging evidence from anywhere else. That is what it should do.

On what was said in the evidence session, obviously I cannot say anything other than I get the distinct impression that it was not regarded as a particularly helpful evidence session. I understand some of the issues that are being raised about the attention that the MHRA is able to give to individual products. Given the extent of the concern around the issue, we would expect the MHRA to give particular attention to it.

On what I can do in light of the report, obviously the MHRA is aware of it. In light of what Jackson Carlaw has said and the views of the other members of the committee, if they are the same as his—I assume that they are—I will ensure that the MHRA is made well aware of the committee's views that have been put to me. I would be happy to do that and to express to it the concerns that the committee has expressed.

Jackson Carlaw: I would be grateful for that. The on-going concern is that another episode in a completely unrelated field could arise. Our confidence has been slightly shaken in the underlying research capability of the MHRA, given its willingness to make very emphatic statements on things that the report suggests might not be the case.

My second question relates to the SIMS trials. They were subsequent to the moratorium or suspension and were specifically excluded by the cabinet secretary in order that they could continue. I imagine that they still continue, but they include procedures that the report has identified as being

of concern. Is that approach appropriate in going forward?

Shona Robison: Catherine, do you want to comment on the SIMS trials?

Dr Calderwood: Obviously, we have just received the report, and you are absolutely correct—we need to go back to the research group and we need to look at whether it is feasible to change the protocols of that research or whether a number of women have already been recruited whom we would need to go back to. The other option, of course, is that, if it is not deemed to be appropriate, we do not continue with the research study. There is a very important conversation to have with the researchers.

Jackson Carlaw: Cabinet secretary, I would be grateful if the committee could be advised of what is decided through you and the chief medical officer. I am sure that Parliament would also want to be advised of your consideration, and I hope that that can be done in early course.

Shona Robison: You will appreciate that we have only just received the interim report. Obviously, we came here with our thoughts to date but, as Catherine Calderwood said, we will have to resolve that issue. We will do that as quickly as possible and will ensure that the committee is informed.

Jackson Carlaw: My final question relates to the communication of what we now know to women who have undergone the procedure now that we have a report that has substantiated the fact that there is a concern, and the report's recognition that we do not have long-term data collection to assess whether issues might manifest themselves at a much later point in the process.

You have talked about the posters that advertise the helpline, but from the report, it looks as if we are talking about, to date, somewhere between 15,000 and 33,000 women across Scotland. Should the Government or some official body not be much more proactive in contacting all the women who have had the procedure, identifying that—as I admit—there will not have been an issue for some of them, but making it clear that there are issues for many of them and that we do not know whether such issues might manifest themselves at a later stage, and proactively advertising the helpline in that individual communication? That way, it would not just be a helpline that my mother or my wife might see advertised when they walk into the general practice with a sore throat; it would be the women who have had the operation who would be specifically told about the helpline.

Our concern is that there may be women who are suffering symptoms who still do not realise that they are part of a much wider body of people with those same symptoms or that they relate in some way to the mesh operation that they have had. I suppose that my question is whether, given the number of people involved, we might not have a much more direct, proactive communication strategy, detailing the evidence to them in a helpful way, not in a pejorative way, and making it clear that the helpline exists, rather than leaving it so that the helpline is something that they fall upon by chance.

11:15

Shona Robison: I am happy to consider how we might better communicate with women in that position. We have to be quite careful about what that communication says, as we do not want to cause concern among women. On the other hand, we want to ensure that they have the full information, and the helpline would be a mechanism for them to find out further information. I will certainly consider that, and I will consider what the options might be.

Jackson Carlaw: Okay—thank you.

John Scott: I am concerned about the coding system, which does not appear to work as well as it might. Neil Findlay has already raised the matter. Could the further study include an analysis by code? From what a previous witness said, I appreciate that apparently some of the operations were not allocated a code. Is it possible retrospectively to allocate a code to an operation or procedure, and thereafter to conduct an analysis of those procedures and to ascertain whether one procedure or another perhaps raises more grounds for concern? Do you see what I am trying to say?

Shona Robison: I get what you are saying. ISD has already started to consider the issue, and it will ensure that procedures are coded more consistently in future. However, I am not sure whether that can be done retrospectively. We will have to find out from ISD whether that is possible. If it is, we could consider it, but we would need to know whether it is feasible.

John Scott: It struck me that that might be a way of gathering information retrospectively.

Shona Robison: I understand where you are coming from.

John Scott: It could therefore allow for subsequent analysis.

Shona Robison: If that can be done, it is definitely something that we should look at doing, but I do not know whether it is feasible. We have not had that information back from ISD yet, as it is just getting its teeth into the matter. We will come back to you on that.

John Scott: Thank you.

The Convener: Before we move on, I want to ask about something that has confused me a bit. ISD seems to be saying that it was waiting on the Scottish Government to give it the go-ahead to do that, but you are saying that you have to speak to ISD to see whether you should give it the go-ahead. Somebody needs to make a decision, cabinet secretary.

Shona Robison: My point is that we have no difficulty doing it; the question is whether, technically, it can be done. If ISD can do it, it should get on and do it. What I do not know is whether, technically, it can be done. There is no issue about whether it should be done; if it can be done, it should be done. What I do not know is whether, technically, such a thing can be done retrospectively. It can be done going forward, but I just do not know the answer as to whether it can be done retrospectively, which is what John Scott is asking for. I repeat: if it can be done, it should be done.

Angus MacDonald (Falkirk East) (SNP): I return to the expert group, which you mentioned earlier. How quickly will the expert group meet to discuss the report? Clearly, given that the report came out only on Friday, the group will not have had a chance to discuss it yet. How often will it meet? Will its considerations be made public?

Shona Robison: I do not see why not. I think there should be full openness and transparency around the expert group's work. It has important work to do in taking forward the recommendations. We still have the final report to receive, and work will continue to ensure that we get the final report in the spring of 2016.

The expert group's meeting schedule is down to the group itself—it must decide how often it needs to meet. Its meeting schedule will have to reflect the fact that it has a number of tasks—not just the production of its final report, but the other work that is going ahead.

Dr Calderwood: The expert group has already gathered together, but it has been waiting for the review group's report. Because of the number of recommendations that point to work that needs to be done before the cabinet secretary can be happy and before the final report can be produced, some of the recommendations will be acted on in the meantime. The group is ready and has already done some work, and work can be started on some of the recommendations as soon as the group can meet.

Angus MacDonald: I move on to the composition of the expert group. We heard from the independent review group that it had patient representatives on it, which I think everyone welcomed at the time. Will there be patient representatives on the expert group? Has consideration been given to having such representation in the future?

Shona Robison: I understand that there already is such representation. However, if that needs to be strengthened, we will make sure that that happens. Between the publication of the interim report and the publication of the final report, if the expert group needs to draw on different expertise or needs to have more patient voices on it, there is an opportunity for us to look at that. Perhaps now is the time for us to do that in the light of the independent review group's interim report. It is very important that the expert group has the patients' voice around the table. If the women themselves feel that there needs to be a stronger voice on the expert group, I would not stand in the way of that at all.

Angus MacDonald: That is great. I am sure that that response will be welcomed.

Neil Findlay: When the expert group continues its work, it would be good if there could be a bit more consideration and sensitivity around accessibility—where it meets, when it meets and how often it meets. The patient representatives on the expert group are giving up their own time and receive little support, and it is emotionally exhausting for them. That should be taken into consideration.

Is there anything in the interim report that the Government does not accept?

Shona Robison: You make a good point about accessibility and where and when meetings take place. We will want to look at that. Women from all parts of Scotland may want to engage with the group in some way, and we will need to think about that. I will reflect on what you have said.

Is there anything in the interim report that we do not accept? No. We accept all the recommendations. However, we understand that some of them may take a bit longer than others to implement. In the meantime, it is important that we get on with as much of the work as is possible. As I have said, before there are any changes to the current processes, I want to be reassured, and the chief medical officer will certainly want to be reassured, that safeguards are in place—interim safeguards, if not final safeguards. We also want to be in possession of the full report before any changes are made.

Neil Findlay: Have you read the minority report?

Shona Robison: Yes, I have. I received a letter from Olive McIlroy and Elaine Holmes, which pointed that report out. Officials and I have tried to reassure them that there will be an opportunity to

consider their views before the final report is produced.

I understand that Lesley Wilkie tried in her comments to encapsulate the views and strong opinions of the women. Clearly, however, the final report will give an opportunity for those to be reflected further. I hope that they have had some reassurance on that.

Neil Findlay: It is just that Dr Wilkie said in her evidence that she had not read the minority report. However, you have it, and it might be worth sharing it with her. It would be helpful if, in the not-too-distant future, there was a Government response to that report.

I am encouraged that you are willing to consider contacting people who have been fitted with mesh devices. To echo what Jackson Carlaw said, I think that that is absolutely essential; indeed, it is someone's responsibility to do that—I do not know who, but probably the Government and the NHS. I will not ask you the question that I asked the previous panel; I just assume that, if you or I were fitted with a device about which concerns were raised, we would want to know about it. That is just a simple human instinct that we have to deal with.

On the number of people involved, the situation in the US is alarming, given the potential impact on Scotland's NHS. I have asked several parliamentary questions about the issue but I do not really get an answer; instead, I get a vague answer telling me that the Government understands that people are taking litigation. Has there been an assessment of the potential financial impact on the NHS of hundreds, and potentially hundreds more, cases? In the US, similar cases are being settled for tens of millions of dollars.

Shona Robison: Before I come on to that, I confirm that I certainly will respond to the minority report. I again reassure people that there is the opportunity to feed into the final report.

On potential litigation, there are 360 cases at the moment, but the important thing to bear in mind is that they are on the issue of presumed consent and not about the devices as such, which is a bit different from the American cases. The issue of presumed consent arises from a case that is to do with a completely different issue—it is nothing to do with the mesh issue. That case is an issue for the NHS generally, because it has set a precedent on presumed consent. Therefore, work is being done on the impact of that case on presumed consent across the NHS rather than just on the mesh issue. The issue is presumed consent, rather than the device, if you see what I mean.

There will be without doubt an impact on the NHS from the landmark case on presumed consent. It has of course led to a lot of changed practice around consent generally, and not just in relation to the mesh issue. Catherine Calderwood might want to say a little about that.

Neil Findlay: Before she does so, my question is whether there has been an analysis of the potential financial impact. Has a piece of work been done on that—yes or no?

Shona Robison: No work has been done specifically on mesh, but I have received considerable information about the impact of the presumed consent change. Of course, the 360 cases are around presumed consent rather than mesh itself.

Neil Findlay: I will ask a final question and make a final point. One of the issues throughout has been the real willingness among the medical establishment to believe those who said that it was a fantastic procedure and product, and the real unwillingness to believe those who said that they had problems. That has been my experience from day 1, and not until today have things begun to change.

Do you think that someone—I am not necessarily saying that it should be you—should apologise to these women? They were not believed, and there are probably many in the medical establishment who still do not believe them. Do you think that someone needs to apologise?

11:30

Shona Robison: I am very happy to apologise to the women for the fact that they have had to run a campaign to bring the issue to everybody's attention. They should never have had to campaign in that way in order to shine a light on the issue.

As I said in my opening remarks, I thank all the women for what they have done. They have created a legacy for other women so that things will be better in future, although that is probably cold comfort for the ladies who are sitting behind me in the public gallery.

We need to learn the lessons. We have moved on a long way from the paternalistic medical model of doctor knows best, but there is still a long way to go. There is a need for informed consent so that people know what is happening. All procedures carry a risk, and it is very important that patients, whoever they are and whatever the procedure or the medication, know about all the risks.

We need to get better at the feedback loop with regard to patients who receive new medicines or procedures. There are always ground-breaking

developments in medicine, and new procedures and new ways of treating patients. We need to get better at getting feedback and ensuring that research into the experiences of those patients feeds back as part of the evidence gathering.

Neil Findlay: I thank you for that apology, cabinet secretary, and for putting it on record. I was not necessarily pushing you to apologise, but, now that you have done, will you join me in asking the others whom we have come across in this long and very painful process to step up to the plate and make an apology? They may be from the medical profession or from the manufacturers, or from elsewhere, but they must now show that they accept that many of the concerns that the women have raised are genuine and that they were wrong to dismiss them and try to shove them to one side.

Shona Robison: I can say only what I have said regarding my view, which is that women should not have had to campaign in that way to have their voices heard. Government, along with anybody else out there, needs to be better able to pick up on issues at an earlier stage when concerns are raised. This campaign has shone a spotlight on the need to ensure that, when concerns are raised, there are ways for us to pick up on and respond to them.

As I said, women should not have had to do what they have done in order to have their voices heard.

Dr Calderwood: The campaign has highlighted a real issue, which is that women with genuine long-lasting problems came for help and did not receive the help from the medical profession that they should have had.

We are moving in the direction of having more openness and transparency, and I hope that the interim report and the subsequent final report will allow us in Scotland to move much further forward on the issue of truly informed consent.

We have already come some way, because we now listen to women as patients more than perhaps we did in the past. These women have been injured by something that the medical profession did, perhaps with the best intentions but not with the best information.

I reiterate the apology that the cabinet secretary has given to the women sitting behind me, whom I have met and got to know over a period of time, and to the other women who are not here but who have been part of the campaign.

The Convener: I thank you very much, cabinet secretary; I also thank Catherine Calderwood for her evidence.

As I said at the beginning of the meeting, I have been made aware of how distressing an issue this is for those who have been involved. Having sat here through almost two hours of evidence this morning, I can tell just how distressing it is from the faces of those who are sitting in the public gallery.

We have not completed our work on the issue, just as the expert working group has not completed its work. We should take the time to consider what we have heard this morning. I suggest that, at a future meeting, we review the evidence that we have heard and decide how the committee should proceed. If Neil Findlay and John Scott would like to contribute to the on-going discussion, I would welcome input from them as that would be most helpful to us.

We will take on board everything that we have heard and contact those whom we need to speak to. I thank the cabinet secretary and all the witnesses who have come along this morning to discuss the interim report with us.

I also thank everyone who has joined us in the public gallery this morning. I know that today's session has been difficult for you all, and on behalf of the committee I thank you very much for all that you have done to highlight the issues. I am sure that you will continue to do so.

To add to Jackson Carlaw's earlier message to Marion Scott, who is in the gallery, I note that her work is an example of the way in which the media can be positive and beneficial for those who need their voices to be heard, and I congratulate her on championing the cause on behalf of those who have been affected.

I suspend the meeting briefly before we move on.

11:36

Meeting suspended.

11:42

On resuming—

Alzheimer's and Dementia Awareness (PE1480)

The Convener: Agenda item 3 is consideration of PE1480 by Amanda Kopel on behalf of the Frank Kopel Alzheimer's awareness campaign, on Alzheimer's and dementia awareness. Members have a note from the clerk and submissions on the petition.

I thank Shona Robison, the Cabinet Secretary for Health, Wellbeing and Sport, for staying with us; indeed, I appreciate her taking so much time out this morning to help us look at the petitions before us. For this item, she is accompanied by David Fotheringham and Mike Liddle from the

integration and reshaping care division of the Scottish Government.

I invite the cabinet secretary to make some opening comments, after which we will go to questions.

Shona Robison: Thank you, convener. I welcome this opportunity to come back to the committee and speak about social care, in particular Amanda Kopel's petition on charging and dementia awareness. I have met Amanda to discuss her campaign on a number of occasions, most recently on 25 September, and I pay tribute to her tenacity in pursuing this issue in memory of her late husband Frank.

At that meeting on 25 September, I explained some of the work that we as a Government have been doing to improve the fairness of and consistency in social care charges. Over the year, my officials have been working with Professor David Bell from the University of Stirling on a full assessment of the costs involved in a number of different scenarios related to social care charging. We have completed that work and are now using its findings to look at the budgets for the spending review period and to work out, in partnership with local government, precisely what the best options are to make the system of charging for social care fairer. That aim will be at the heart of any changes that we make, because the system has to be fair to everyone with a long-term condition who requires social care.

Amanda Kopel has widened her petition from its original focus on those with Alzheimer's or dementia to include those with other degenerative diseases such as motor neurone disease. We must ensure that any charging system is for people born with a range of conditions, not just those that I have mentioned, and that any changes that we make to the charging system are fair to all service users. That is the focus of our attention. Moreover, any change must also be sustainable. After all, we cannot make changes to the system without ensuring that they will be affordable further down the line.

11:45

In addition to the work that I have mentioned, we have over the past year worked with our partners in local government on some changes such as ensuring that those who are assessed by their doctor or consultant as being in the last six months of a terminal illness are not charged for the care that they receive at home. That has been an important step forward in improving the fairness of the charging system, as it ensures that those with only a short time left are able to spend time with their loved ones without worrying about paying social care bills.

Nevertheless, there is more to do. The Government is treating the issue as a priority, and we will be looking at the best ways of improving the fairness of the charging system for all service users.

The Convener: Thank you, cabinet secretary. I will kick off our questions. Do you in principle support the petition's aims?

Shona Robison: In principle, the petition calls for something that I agree with—a fairer charging system—but we cannot have such a system for only specific conditions. You will understand that, if we were to say, "We're going to have a fairer charging system for this list of conditions", people would say, "Wait a minute—that's not fair" and highlight another list of conditions. What we have had to do, and what we are doing, is to look at how we can make the system fairer for everyone.

The bones of the petition relate to having a fairer charging system, and Amanda Kopel will get agreement from me on that. We are working on what such a system should look like; as you will appreciate, there are various models and various things that we could do. What we need to do is to come up with the fairest, best and most sustainable model, and of course we have to get agreement from local government on taking that forward.

The Convener: I understand that, but that is a consideration that we always have to make. If everything was a priority, nothing would be. The fact is that we do have priorities. There are lots of areas in the health service and social services where support is given to one group in our community but not to others. Those are choices that we have to make. They are difficult ones, but they are made regularly. Could we not accept that the example that has been brought before us is one of those areas that require to be a priority? Arguments might well be made for other areas, and we can hear them, but if we accept the principle in relation to Alzheimer's, we can deal with that problem and move things forward.

Shona Robison: I am worried that if we were to say that, for example, we were going to have a fairer charging system but it would apply only to people with Alzheimer's, such a move could be legally challenged by someone with another condition who would say, "Why have you selected only people with Alzheimer's or dementia?"

To be fair to Amanda Kopel, I think that she has recognised that, which is why, when I met her recently, she talked about people with life-limiting conditions. She recognises that the focus has to be broader than just people with Alzheimer's or dementia, and that is why we are focusing on how we reform the system and make it fairer to all service users who currently have to pay charges.

The Convener: As I have said, we accept that such considerations have to be made. How long do you think it will take to finalise your deliberations?

Shona Robison: We are in the midst of the spending review period and as yet we have not heard what our budgets will look like in the light of UK Government decisions. Indeed, we will not hear about that until November.

In advance of that, however, a lot of detailed work is going on around the priorities for social care, and that is forming the basis of our discussions with local government. There are three elements to that work: fairer charging; progress on the living wage; and social care capacity. As you will appreciate, those are all social care issues, and we want to make sure that we can move forward on all of them. We need to get agreement with local government on that and, as far as the spending review is concerned, we need to make sure that we can afford whatever we do not just for one year but for the entire spending review period.

The Convener: I accept that such decisions are very difficult. However, the fact is that in a whole host of areas we already differentiate not just between certain conditions and others but, within those conditions, between people of a certain age and others. As you will also understand, it could be argued that differentiating in that way within illnesses and conditions could also be open to challenge; for example, people over a certain age can benefit from financial support, while those who are below that age cannot. That, too, might be seen as discriminatory. Therefore, allowing someone with a particular condition but not someone else with a different condition to receive support requires a judgment to be made at some point.

Shona Robison: I think that it would be very difficult to take that approach. You would no doubt get people sitting before you, saying, "Hang on a minute. You made personal care free for those with Alzheimer's and dementia, but what about multiple sclerosis, motor neurone disease and cystic fibrosis?" Before long, the committee would get a petition that focuses on one of those conditions and says that the system is not fair.

Instead of waiting for that to happen, I have taken the approach that any changes to charging must be based on the principle of fairness and applied to everyone who is entitled to receive care. If we do not do that, we will get into a very difficult position. To be fair to her, Amanda Kopel has, as I have made clear, recognised that you have to look at other life-limiting degenerative conditions, not just at one.

Jackson Carlaw: I think that the case that you have outlined is reasonable, cabinet secretary. I understand what you are saying.

However, just to be clear, am I right in thinking that, in the work that you have done, you have isolated a series of conditions to which you think the new charging regime should apply to in order for it to be fair and that you are now waiting on budgetary confirmation in order to go forward, or are you saying that the budgetary confirmation will determine the list or the inclusivity of the basket of conditions—if I can refer to them that way—to which the new regime would apply? Are you saying that the regime would just have to be universal and that, irrespective of the condition, it would have to be available for absolutely everything? I am not quite clear what you are trying to narrow down.

Shona Robison: We are absolutely trying to avoid lists of conditions, because we will always miss one, and that will be the condition that will form the basis of the next petition to this committee and to me, saying that the system is not fair. We are trying to avoid that scenario.

Of course, people will always have to meet eligibility criteria for care, which means that this will always be about people who require care rather than about people having a condition and wanting care. Those eligibility criteria and requirements for care will always be there. However, we are trying to get to a position where the system is fairer to everybody who at the moment has to pay charges, which in some cases can be considerable. Indeed, for those under 65 years old, it can be quite challenging.

That said, there are various models for and ways of making charging fairer. For example, we can look at free personal and nursing care for the under-65s, and we can also look at the threshold at which people start to pay charges. What I am saying is that we have not reached our final conclusions on what is the best option, what we can get local government to agree to deliver and what is sustainable and affordable. At the moment, we are considering those options and discussing them further.

Jackson Carlaw: If I understand you correctly, you are talking about a universal provision, subject to eligibility criteria, that would not be specifically condition related, because you want to avoid that scenario. The matter of the threshold is the subject of another petition that we are pursuing and which has been with local government for quite some time, but that is not an issue for today.

I return to the convener's question about when you expect progress to be made. You have identified budgetary constraints that will become clear this year. Is that or is that not the point at

which you will know what you are going to be able to do and at which you will be able to make a decision on about how things will progress?

Shona Robison: What we decide to do and what spending decisions we make will be part of the spending review. Those announcements will be made in due course.

The problem at the moment is that we can anticipate what the landscape will be and make decisions based on that, but we will not be entirely sure about what the landscape will look like until decisions are made elsewhere and we know what the budgets are like. Despite that, we will be reaching positions about where we would like to get to and what our priorities are in the spending review. Obviously, the spending review process is quite detailed and involves not only my directorate but a dialogue with other directorates and local government.

We have done a considerable amount of work, which forms the basis of how we make those decisions, but within that there are choices to be made about what options we choose. Although all of them have merit, some might have more merit than others. We need to come to final conclusions on that.

Jackson Carlaw: From what you are saying, is it reasonable to expect that, before the dissolution of Parliament next March, we will have an understanding of what the Government feels that it will be able to do?

Shona Robison: Absolutely.

The Convener: That has been helpful, cabinet secretary.

As members have no further questions, does the committee agree to wait until a future meeting so that we can collate information and then come to a decision about how we should take forward the petition?

Members *indicated agreement.*

The Convener: I thank the cabinet secretary and her officials for joining us, and I suspend the meeting for a few minutes to allow them to leave.

11:58

Meeting suspended.

11:59

On resuming—

Social Care (Charges) (PE1533)

The Convener: Agenda item 4 is consideration of seven continued petitions. The first is PE1533, by Jeff Adamson on behalf of Scotland against the care tax, on abolition of non-residential social care charges for older and disabled people. Members have a note from the clerk and other submissions for their perusal.

Do members have any suggestions on how to take this forward?

Jackson Carlaw: The cabinet secretary referred indirectly to the matter in the evidence that she has just given. It seems to me that the issue is part and parcel of the broader review that she suggested was under way, in respect of which she talked about thresholds and other such issues. It would certainly be sensible to remind the cabinet secretary that we want to ensure that the issue is incorporated in anything that comes out of the work that is being done.

12:00

Kenny MacAskill (Edinburgh Eastern) (SNP): I agree with Jackson Carlaw. Now that we are coming into the election period, it might be useful to get an indication of where things are at with regard to the round-table discussion and, indeed, what the ballpark figure is, given that at some stage people are going to have to take a decision on the matter. As you have said, convener, politics is about choices. We need clarity on the matter. I appreciate that the numbers have to be crunched, but it would be useful if, at some stage, the numbers that were crunched were available to all so that people could see what could result from what might be in the manifesto from the Government party or indeed in alternative manifestos.

The Convener: Shall we write to the cabinet secretary in those terms?

Members *indicated agreement.*

John Wilson: I also suggest that we join this petition with PE1480 for future consideration. After all, as Mr Carlaw has outlined, the petitions have very similar objectives. Given that we are going to get a report from the cabinet secretary at some point, it would be useful to consider the two petitions at the same time.

The Convener: Is everyone happy with that?

Members *indicated agreement.*

Concessionary Travel (War Veterans) (PE1549)

The Convener: The next continued petition is PE1549, by Alan Clark Young, on concessionary travel passes for war veterans. Again, members have received documentation on the petition.

Do members have any comments to make? It is interesting that a similar project is running in

London through the Oyster card. That seems to address the issues that are raised in the petition, and it might inform our decision on how we take the petition forward if we were to get information about the costs of the project and other considerations that had to be taken into account before it was introduced. Is that okay with members?

Members *indicated agreement.*

Disabled-friendly Housing (PE1554)

The Convener: The next continued petition is PE1554, by Jacq Kelly on behalf of Leonard Cheshire Disability, on improving the provision of disabled-friendly housing.

Kenny MacAskill: It would be worth asking for the Government's position on the new information that we have received. There might be cost implications that make the proposal unaffordable or other technical matters to consider, and I think that, out of courtesy as well as the desire to get all the appropriate information, we should ask for clarification.

John Wilson: My suggestion is similar to that made by Kenny MacAskill. We should ask the Government about the implications of putting into Scottish building regulations two new lifetime homes standards on incorporating disability facilities into new homes. There has been a growth in the number of social rented houses that are being built, and it would be useful to know whether the Government is working with local authorities and other social housing providers to ensure that they are making adequate provision with regard to incorporating disabled access and other adaptations into the design of new-build stock instead of having to retrofit housing stock, particularly the new houses that are being built.

The Convener: Does the committee agree with that?

Members *indicated agreement.*

Sewage Sludge (PE1563)

The Convener: The next petition is PE1563, by Doreen Goldie on behalf of Avonbridge and Standburn community council, on sewage sludge spreading.

Angus MacDonald: In response to the Scottish Environment Protection Agency's response, the petitioners have raised a few more questions and salient points that I think the committee should follow up with SEPA for clarification. I suggest that, if it is within the committee's remit, we get back to SEPA for clarification on those points.

The Convener: So you want to go specifically to SEPA.

Angus MacDonald: We should also write to the Scottish Government, because we need some detail as to when the findings of the sludge review and the Scottish Government's response will be made public. We should write to both the Scottish Government and SEPA.

The Convener: Does the committee agree?

Members *indicated agreement.*

Violent Reoffenders (Sentencing) (PE1565)

The Convener: Are there any comments on the next petition, which is PE1565, by James Dougall, on whole of life sentences for violent reoffenders?

Kenny MacAskill: We could send it to the Scottish sentencing council. It is in the process of being established, but it will soon be up and running and I know that we have sent it other matters for consideration. It seems to me that the issue is something that should be part of its workload.

The Convener: Is that agreed?

Members *indicated agreement.*

National Service Delivery Model (Warfarin Patients) (PE1566)

The Convener: Petition PE1566, by Mary Hemphill and Ian Reid, is on a national service delivery model for warfarin patients. People who know better than I do have suggested that the University of Birmingham primary care department is involved and that it might be useful to contact it to get more information to inform our consideration of the petition. Are members happy with that recommendation?

Members *indicated agreement.*

NHS Centre for Integrative Care (PE1568)

The Convener: The final continued petition is PE1568, by Catherine Hughes, on funding, access and promotion of the NHS centre for integrative care.

Other members have had a chance to look at the paperwork and will be more familiar with the discussions on the petition than I have been until now. I welcome your recommendations on how to deal with it. Is it worth going back to the Government to explore some of the areas that have been raised?

John Wilson: I am keen to go back to the Government to explore some of the issues that the petitioner has raised.

If the committee will indulge me, it might also be useful to bring in a couple of health boards so that we can ask questions about the decisions that

were made to withdraw the funding for the integrative care provision. The difficulty is that the service can continue only if the individual health boards contribute to it and, as we know from the petitioner and others, a number of health boards have decided to withdraw funding and not make any new referrals, although on-going referrals will continue as long as they are required.

Lanarkshire NHS Board is one health board that has withdrawn funding. I would be interested to hear its views on the process that it undertook to make such a decision and what alternatives it is putting in place for patients for whom such a treatment path has been identified. The petitioner has indicated that Lanarkshire NHS Board, as well as deciding not to continue to make new referrals, has decided to close two of the clinics that were provided in its area.

As I said, it might be useful to question the health boards on those issues, so that we have a better idea of the issues when we come to question the Scottish Government about how it envisages the national centre continuing to deliver services for the whole of Scotland.

Jackson Carlaw: I have a slight concern, which is that we are bordering on entering into a much larger inquiry on the merits of homoeopathic care. If that was our intention, we would have to understand that that is what we were doing. The Government does not have a policy on homoeopathic care—there is no national guidance to health boards. I am uncertain whether that is a matter for the Public Petitions Committee or whether, if we felt it appropriate that such a review take place, it should be remitted to the Health and Sport Committee to undertake, if it agreed that that was appropriate.

The Convener: Do you think that we are at that point now?

Jackson Carlaw: I understand where John Wilson is coming from, but I am slightly nervous that, once we start bringing in health boards we will be asking them why they are doing it and inevitably we will get into a discussion as to whether they believe in homoeopathic care. I presume that they do not if they are not funding it. Then we get into the unevenness of the way in which homoeopathic medicine is treated across Scotland, which is quite a big job of work.

I do not know whether the Health and Sport Committee has discussed the issue in recent times but, if such a review were to take place, it would be more appropriately led by that committee, rather than this one.

The Convener: I take on board that point. Equally, the issue seems to be about funding and access, rather than whether there should or should not be homoeopathy—although I understand what Jackson Carlaw says about the danger of straying into that territory if we start to analyse the health boards' attitude towards homoeopathy. It might be useful to get the views of Highland NHS Board and Lanarkshire NHS Board as to what drove their decisions—if we have not yet obtained that information—and see where we go.

I suggest that we continue the petition and try to get more information about the types of funding decisions that had to be made. Do you think that that would prevent us from going too far?

Jackson Carlaw: I will leave that to your discretion, convener. I am not being prescriptive, but I am not inclined to see the committee immerse itself to that end, which goes slightly beyond the terms of the petition.

The Convener: The petition is about funding and access so, if we ask the health boards to explain purely the funding decision, we would stay within the boundaries of the petition. We will not ask whether the boards support homoeopathy. Health boards might support many procedures that they cannot afford. If we stick to the considerations on funding, we will not be asking them to debate the merits of homoeopathy or otherwise.

Jackson Carlaw: Okay.

Angus MacDonald: There are three NHS boards in question. As well as NHS Highland and NHS Lanarkshire, there is NHS Lothian.

The Convener: Okay, we could ask NHS Lothian, too. Do members agree to write to the Scottish Government and to the health boards in those terms?

Members *indicated agreement.*

The Convener: That concludes the public part of the meeting. We will continue in private to discuss agenda items 5 and 6.

12:12

Meeting continued in private until 12:37.

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