OFFICIAL REPORT
AITHISG OIFIGEIL

Health, Social Care and Sport Committee

Tuesday 7 February 2023

Session 6

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HEALTH, SOCIAL CARE AND SPORT COMMITTEE
5th Meeting 2023, Session 6

CONVENER

*Gillian Martin (Aberdeenshire East) (SNP)

DEPUTY CONVENER

*Paul O'Kane (West Scotland) (Lab)

COMMITTEE MEMBERS

*Stephanie Callaghan (Uddingston and Bellshill) (SNP)
*Sandesh Gulhane (Glasgow) (Con)
*Emma Harper (South Scotland) (SNP)
*Gillian Mackay (Central Scotland) (Green)
*Paul Sweeney (Glasgow) (Lab)
*David Torrance (Kirkcaldy) (SNP)
*Evelyn Tweed (Stirling) (SNP)
*Tess White (North East Scotland) (Con)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Rosemary Agnew (Scottish Public Services Ombudsman)
Charlie Bethune (Valproate Scotland)
Alison Cave (Medicines and Healthcare products Regulatory Agency)
Dr Arun Chopra (Mental Welfare Commission for Scotland)
Dr Anna Lamont (NHS National Services Scotland)
Marie Lyon (Association for Children Damaged by Hormone Pregnancy Tests)
Fraser Morton
Irene Oldfather (Health and Social Care Alliance Scotland)
Simon Watson (Healthcare Improvement Scotland)
Bill Wright (Haemophilia Scotland)

CLERK TO THE COMMITTEE

Alex Bruce

LOCATION

The Sir Alexander Fleming Room (CR3)

Scottish Parliament

Health, Social Care and Sport Committee

Tuesday 7 February 2023

[The Convener opened the meeting at 09:01]

Decision on Taking Business in Private

The Convener (Gillian Martin): Good morning and welcome to the fifth meeting in 2023 of the Health, Social Care and Sport Committee. I have not received any apologies. Paul O'Kane will be attending online, but the rest of us are here in person.

The first item is for the committee to decide whether to take items 3 and 4 in private. Do we agree to do that?

Members *indicated agreement.*

Patient Safety Commissioner for Scotland Bill: Stage 1

The Convener: Item 2 is an evidence session on the Patient Safety Commissioner for Scotland Bill. Before we begin, I will provide a brief introduction.

Last week, we heard from Baroness Cumberlege about the independent medicines and medical devices safety review and its key recommendation that a patient safety commissioner be created. A patient safety commissioner has already been established in England and will focus on medicines and medical devices. However, the bill that is before us proposes the creation of a patient safety commissioner for Scotland who will have a broader remit that covers patient safety across all healthcare settings.

The evidence that we hear today will be about issues that were highlighted as part of the Cumberlege review and in relation to wider patient safety issues in Scotland. As such, some of this meeting's content might be sensitive or distressing, and the committee encourages anyone who is affected by any of the issues that we discuss today to seek support. Breathing Space is a free and confidential service for people in Scotland, and it is able to provide a range of support as detailed on its website, which is breathingspace.scot, or you can call 0800 838587.

If anyone who is attending today's meeting needs to take a break during the meeting, please indicate that to me or to my clerks and we will allow you to take that break.

I welcome Charlie Bethune from Valproate Scotland. Sodium valproate has been a treatment for epilepsy since it was licensed in the 1970s, but it is known to carry a risk of birth defects if taken by women of childbearing age.

We also have Marie Lyon from the Association for Children Damaged by Hormone Pregnancy Tests. Primodos was a hormonal pregnancy test drug that was administered to women between the 1950s and late 1970s, and it is associated with miscarriages and some birth defects.

Fraser Morton was among a number of families who called for a public inquiry into infant deaths at Crosshouse hospital maternity unit.

Joining us online is Irene Oldfather from the Health and Social Care Alliance Scotland. She will be speaking from the perspective of her organisation's work with women who have been affected by complications following transvaginal mesh surgery.

Bill Wright from Haemophilia Scotland will be speaking from the perspective of those who were affected by the contaminated blood scandal, when a large number of people, most of whom had haemophilia, were infected by hepatitis C and HIV in the 1970s and 1980s.

I thank you all for coming along. I know that some of you might be sharing personal experiences with the committee, in relation to the bill. That is greatly appreciated by us and will be instrumental in informing our scrutiny, but there is no pressure to, or expectation that you will, share personal experiences.

We will move on to questions. I would like to ask all of you for your views on the proposed establishment of a patient safety commissioner, and whether you think that a patient safety commissioner would or could have made a difference for those whom you represent or for you personally, if you have been affected. I will go to Charlie Bethune first.

Charlie Bethune (Valproate Scotland): Thanks for the opportunity to talk to you all.

The people who have been affected by valproate think that having a patient safety commissioner would be a fantastic improvement. Valproate was first prescribed in the 1970s, and the issues around it were known about within a few years. It has been going on for almost 50 years, and nobody has listened. For years and years, the voices were just being ignored by the medical profession, the regulators—by everyone. Our view is that if there had been a patient safety commissioner at any point during the past 50 years, the time to get this resolved would have sped up.

The problem at the moment is that the issue is not resolved, and we need the patient safety commissioner to finish the work that we as campaigners have been doing for the past however many years. We need the patient safety commissioner to help us because we are still being fobbed off and told that there are delays, and we still do not have the services that are required.

Women are still being prescribed valproate. In England last year, 258 women gave birth to children while they were being prescribed sodium valproate—so that is 110 more affected children, given that 40 per cent of children are significantly impacted and need to be cared for by the health system and the Government for the rest of their lives. We normally assume that the proportion in Scotland is 10 per cent, so a significant number of people are still being affected by the drug. We need to get it stopped.

The Convener: Thank you. I will come to Bill Wright next.

Bill Wright (Haemophilia Scotland): I was infected with hepatitis C in 1986. I now have liver cirrhosis, but I am one of the lucky ones. I appeared in front of the health committee more than 20 years ago. We were still seeking the truth.

Prior to that, in 1999, we lodged a petition—petition PE45—which was one of the first petitions in the Parliament. The petition sought a public inquiry. We were obstructed by the then Government in getting to the truth. It elected instead to have an internal investigation that was led by the deputy chief medical officer. The deputy chief medical officer had a background in haematology and had used, in Yorkhill hospital, the very products that had infected many children who then died.

I have just come back from spending the whole of last week in London, where the closing submissions were made to the United Kingdom infected blood inquiry, led by Sir Brian Langstaff. The closing submissions were harrowing, just like the stories that you will hear from my colleagues here today.

During the four and a half years of that inquiry, which is the biggest ever inquiry in Britain on any subject, a further 104 people in Scotland died—largely, they were infected with hepatitis C, but some were also infected with HIV. Actually, the figure is 105 now. Two weeks ago, I was at yet another funeral for someone who had had a liver transplant then went on to have another tumour.

During the intervening time, the internal investigation that I have mentioned was ordered by the then health minister Susan Deacon. There was a question—this is on record from the infected blood inquiry—from the then First Minister Donald Dewar about the matter. The email said that “an open mind”—in other words, an investigation—might lead to “an open cheque book.” Susan Deacon’s office responded on a handwritten note that it was only “a PR exercise”. That investigation was only a public relations exercise.

Despite the good efforts of your predecessor committee, which conducted its own inquiry, and an inquiry that was led by Lord Ross, it took another seven years before the current First Minister, Nicola Sturgeon, ordered the Penrose inquiry. The problem is that the Penrose inquiry did not look into the workings of Government. However, that is included in the terms of reference of the infected blood inquiry.

If this is all sounding a bit raw, that is because one of the stories that you will hear from witnesses is that we have all waited a very long time to get to a point at which we might get a patient safety commissioner. Such a commissioner might have championed our cause, and many years of fighting could have been avoided. One of the biggest,

most important bits of evidence that has come out during the infected blood inquiry is the compounding of harm. Everyone here and their families have suffered. Obviously, the conditions bring elements of physical harm, but it is because of the obfuscation and our not getting answers to questions or having a champion that we need a patient safety commissioner.

Sorry—I have taken up a lot of your time.

The Convener: Please do not apologise. We have asked you for your story, which you have put very powerfully.

Can I come to you, Marie?

Marie Lyon (Association for Children Damaged by Hormone Pregnancy Tests): You can, indeed. I definitely agree with both the witnesses who have spoken. A patient safety commissioner is there to listen and to champion. Had a commissioner been available when Primodos was around in the 1960s and 1970s, they would have had the authority to remove that drug from the market, ensure that it was safe before it was put back on, if it was to be put back on, and ensure that there was sufficient investigation into the regulator at the time to make sure that they were doing the job that they were paid to do.

Why is a PSC necessary? In addition to what you have heard so far today, there is the issue of surgical mesh, which I know we will be coming on to. In all those cases, there was significant patient harm and there was no one to speak for patients. That resulted in unsafe care, which continued, because there was no one to ask whether, given what had happened with Primodos, we should be looking at the regulator. Today, the regulator is still not fit for purpose, and that is one of the biggest problems.

One thing that really concerns me is that unsafe care is believed to be in the top 10 leading causes of death, resulting in 3 million deaths a year. The direct cost of that is estimated to be around 13 per cent of healthcare costs, which equates to £1.9 billion in Scotland. That is a shocking amount, but it is not even close to the devastating cost to the families who are affected. Compensation payments totalled £60.3 million, but there was an unquantifiable level of distress to many families.

Setting up an office of a PSC would not only improve safety for patients; it makes financial sense. The proposed cost is only £644,000 a year. The PSC is very much needed to ensure that patient harm does not continue. The patient harm to our children could have been avoided if a commissioner had been appointed. Oral hormone pregnancy tests would have been researched. However, the regulator was very close to the manufacturer when all the warnings came in, which they did from 1958, and it was 1978 before they took those tablets off the market. In 1958, they hid the evidence—we found it. They also destroyed evidence—again, we found it. The regulator who was supposed to look after patients actually looked after the drug company. The regulator wrote to the drug company and said, “I have found a 5-2 point of evidence that these abnormalities and deaths are caused by Primodos. However, please don’t worry, because I have destroyed the records, so no one can find out how I came to that conclusion.”

09:15

We started legal action in 1981—my daughter is 52, so I have been fighting for this for 52 years—but eventually we had to withdraw that legal action. The regulator had written to the manufacturer and said, “Because I am a Government employee, I am unable to appear in court. Would you please subpoena me? If you can subpoena me, I can give evidence on your behalf against the patients.”

That is the kind of cover-up that we are looking at. I am sure that it is an issue not just for us but for everybody else. When we found that document, we knew that thousands of babies could have been saved, from 1958. I will send round some pictures that will shock you, because they prove the dreadful damage that occurred.

The other thing is that we had a 97 per cent score on there being no congenital fault; there was no abnormality in the genetic make-up of any of the families. The only common denominator was an oral hormone pregnancy test. As Bill Wright just said, there have been deaths. We have lost seven of our—for me, they are young—40 to 50-year olds from the after-effects of Primodos in the past few months, and we have lost 31 parents. We are all in our 70s now, but parents are still fighting for their children because they are frightened about the care that they will receive. I have a list of the effects, which I will not go through now.

There are 30 Scottish families who are desperate for support, but there is no one for them to talk to and there is no way that they can access the help that they need, because they do not know where to go. The PSC has to listen, but I am sorry to say that the UK one is not listening. She is not meeting with patients; she is meeting with groups. That has to change. She needs to talk to the people who have had the experience and are living with the experience today, as we are.

The Convener: Thank you. I come to Fraser Morton.

Fraser Morton: Good morning. I have been in two minds about whether we need a patient safety commissioner, mainly for the reason that I do not

believe that you can bolt on safety—it has to be woven through healthcare. Then I started thinking about scandals such as the mesh scandal, the infected blood scandal, the surgeon Ian Paterson, Professor Sam Eljamel in Tayside, the Tayside mental health service crisis, the Vale of Leven hospital and the dirty water and infection control issues in Glasgow.

There were also scandals in Gosport, Morecambe Bay and Mid Staffordshire, and although they occurred in England, the Royal College of Physicians of Edinburgh warned that a repeat in Scotland is a possibility. Recently, there have also been maternity deaths in Shrewsbury and Nottingham. If you get the opportunity, you should contrast and compare the Ockenden report with the report that Healthcare Improvement Scotland produced in 2017 on the Ayrshire maternity deaths. There is a distinct difference. You should also read the report on the Morecambe Bay investigation. I was a wee bit surprised at the paucity of that report, especially since the chief medical officer at the time was on the Morecambe Bay panel.

If I think of our ain situation, I am not sure whether a patient safety commissioner would be of any benefit. We need to see how the situation evolves.

The death of my son Lucas was categorised as a category 3 adverse event—that is a near miss. He was designated as being stillborn, which denied the procurator fiscal the opportunity to proceed to a fatal accident inquiry, because Lucas was denied a legal identity. There are serious doubts about whether he was stillborn, which I can get to later. The cause of death on his original death certificate was “Unknown”. We had to go through the process twice, so he had two death certificates.

Lucas’s death was not reported to the Scottish fatalities investigation unit. Not reporting such deaths is widespread. I believe that it is a deliberate attempt to evade external scrutiny and justice. That really bothered me. I sent a freedom of information request to the Crown Office several years ago to ask whether it routinely collates, monitors, audits and reviews the deaths reported to it by each of Scotland’s territorial health boards, to identify any trends or patterns of concern. The answer was no. That flies in the face of the recommendations of the Shipman inquiry, which was a long time ago.

To pick up what Bill Wright was saying, all those issues and problems that people face when having to fight for years compound their grief and make it last longer. It will never leave ye. The way that we were treated after Lucas died was every bit as bad as losing Lucas. I am not sure that a patient safety commissioner would hold the health board to account on the issues that I just mentioned—and those are just some of the many issues that we have encountered over the past few years.

The Convener: Thank you for telling us that, Fraser.

Irene Oldfather joins us online to talk about mesh survivors.

Irene Oldfather (Health and Social Care Alliance Scotland): Good morning, convener; thank you for inviting us to the committee and giving us the opportunity to speak on behalf of mesh women and our members. We held an engagement event on a patient safety commissioner with our members with long-term health conditions. The comments that I make today will reflect the experiences of both of those groups in relation to the work that we do at the ALLIANCE.

I have some specific comments about parts of the bill, but I will start with some general remarks. As the committee will know, the ALLIANCE undertook work with women injured by mesh implants and we have produced two reports that chart the women’s views and experiences. I will give those two reports to the clerk for the information of members in their deliberations on the work of the proposed commissioner.

If we look at what happened in relation to the experiences of the mesh women, the majority of women experienced complications immediately, and the second-largest group experienced complications in the first two years. If we combine those two groups, they make up almost all women who experienced mesh injuries. The catalogue of experiences focuses around not being listened to. When we analysed what the women told us, we saw that there was a clear impact on their physical and mental health, their relationships with their families and partners and on their finances.

I will quote one woman because it is important that we capture those personal experiences:

> “I have lost and mourn the person I was and absolutely loathe the person I have become. If it wasn’t for my husband, children and grandchildren I would absolutely without a doubt have taken my own life by now.”

That is not an isolated comment by any means. That theme, to different degrees, runs through what we have heard about the frustration of mesh-injured women. To say that they felt that they were not being listened to is an understatement—they were banging their heads against brick walls.

The ALLIANCE thinks that a patient safety commissioner and the role that that office could play in relation to data could offer a safety net for people who experience a patient safety issue, because there would be a way to pick up trends.

Clearly, many women not just across Scotland but across the world were experiencing similar complications, most of which were around pain and urinary problems. However, somehow, we were not picking up that that related to what had just happened to them: mesh implantation.

We are very supportive of having a patient safety commissioner. Safety lies at the heart of delivering our health services. We must be able to instil in our communities and our citizens a confidence and trust in the national health service that they will not go there and end up in the situation that many of those women have found themselves in—that is, facing a life with disabilities and, sometimes, further and more serious health problems.

We hope that a commissioner will allow us to identify trends and to collect data early on. We believe that that will save lives and, as a practical point, that will save compensation problems for the NHS. For us, the issue of saving lives is so important, and we see the opportunity to do that through the commissioner. Our membership supports that role as a way of redressing some of the imbalance that currently sits in the system, in which professionals are often seen as being in charge. We know that, with realistic medicine and everything else, we must start listening to the experience of people themselves.

I have more detailed comments on parts of the bill, convener, but perhaps you would like me to wait before sharing those.

The Convener: We will probably come to that. I just wanted to give everyone the opportunity to put down their general thoughts on a patient safety commissioner and to set out their particular history in that regard.

I will pass on to my colleagues, who have a number of questions.

Emma Harper (South Scotland) (SNP): Good morning, everybody. Thank you for coming. What are your thoughts on whether the patient safety commissioner for Scotland should have a wider remit than that of the commissioner in England, for example? That would go wider than mesh, sodium valproate and Primodos.

The Convener: I am not sure whether you want to direct that to anyone in particular. Obviously, there are some individuals for whom the issue was not medical or related to drugs or devices. Perhaps we could go to Bill Wright, Fraser Morton and Irene Oldfather initially, because any widening of the remit would include their situations, I guess.

Bill Wright: I hope, convener, that you will understand from my initial remarks why, having fought for 25 years on the question of blood and blood products, we feel so strongly about the matter. If I might be so bold, I note that people infected with hepatitis C were mainly infected through blood transfusion rather than through haemophilia. That is a simple blood transfusion that any of you might have experienced. It is important to understand that the issues of blood and infections are close to home.

In some ways, it is a wee bit of an accident that the original proposal from the Cumberlege review was on medicines and medical devices—the inquiry was asked to look at Primodos, valproate and mesh. If, for example, Baroness Cumberlege had not been asked to look at mesh but to look at valproate, Primodos and blood, that would not seem fair to those with mesh issues.

We pressed the Scottish Government to have a wider remit, and we think that that is the correct remit. Something left field might come out from people's experiences—who knows? The whole point is to look ahead at what might happen. If someone gets infected in a hospital not as a result of medicines or medical devices, why should they not have the same services as someone who might have had a pharmaceutical drug that went wrong?

09:30

The Convener: Fraser Morton, do you want to come in?

Fraser Morton: Patient safety campaigners and families in England that I have come to know over the years believe that the restriction on the patient safety commissioner in England is wrong. I tend to agree with them.

I said earlier that I am unsure about having a patient safety commissioner. That relates to what powers the commissioner will have, which are yet to be decided. The current situation is that the media in Scotland are, by default, our healthcare regulator. We do not have a healthcare regulator. The media are also the patient safety commissioner and family advocate rolled into one. I believe that the patient safety commissioner should have a broad scope.

The Convener: Baroness Cumberlege agreed with that position last week.

Charlie Bethune: I can speak from the valproate perspective. Everyone wants their own condition to be addressed. The key thing for my group is that we do not want the same thing to happen to other people in the future. We are not precious about that. We want the patient safety commissioner to look at the issues that are outstanding at the moment and to be able to look at whatever patient safety concerns come up in the future. We do not have a crystal ball to see what is in the future. I do not think that the scope

of the commissioner should be restricted in any way.

Emma Harper: I am also thinking about what you said earlier. In my notes, I have written "listen, advocate, champion". I am thinking about risk assessment and risk management, and about being heard. I do not know if that has been missing in the past. That might have been Fraser Morton's experience.

One of the first things that the website of Healthcare Improvement Scotland says is that

"the affected person receives the same high quality response"

and that

"organisations are open, honest and supportive towards the affected person, apologising for any harm that occurred".

That information was an update about adverse events that had happened previously. I am interested to hear about your experience of interacting with the current systems of scrutiny and clinical governance. Where are the gaps and weaknesses in the current systems? How will the patient safety commissioner help to fill those gaps? Perhaps Fraser Morton would like to come in on that.

Fraser Morton: I appeared at this committee before, in 2018. I do not know if you were on the committee at the time. I came to give evidence on clinical governance. In preparation for today's meeting, I printed off my notes from 2018, because we are nae further forward.

You are asking about the current systems of scrutiny and governance. I have a wee list here. In 2008, the Scottish patient safety programme was launched. One of its core components is the Scottish patient safety learning system. NHS Ayrshire and Arran was one of the four original test sites for the roll-out.

If we fast forward to 2012, a whistleblower claimed that avoidable deaths were being covered up in Ayrshire and Arran. The then health secretary, Nicola Sturgeon, ordered a review. In 2013, a follow-up report by Healthcare Improvement Scotland gave NHS Ayrshire and Arran a clean bill of health. That came from an analysis of evidence that had been provided by the NHS board.

In 2013-14, another survey of the management of adverse event reports from all other NHS boards in Scotland was carried out. There were further progress meetings in 2014 and 2015 and summary reports on progress, in November 2014 and May 2016.

We lost Lucas in 2015, in NHS Ayrshire and Arran. The cause of his death was listed as "unknown" and described as a near miss. It was only following adverse media publicity after a year of frustration when nobody wanted to know us that Shona Robison instructed Healthcare Improvement Scotland to undertake an independent review of the Ayrshire maternity unit.

If we fast forward to Jeane Freeman's tenure in 2019, she wrote to HIS to ask it to take a more consistent approach, stating:

"We have one NHS in Scotland and I expect now to see greater consistency".

In September 2019, the NHS boards published a self-evaluation document. In January 2022, a further report said that the adverse events notification system update reports that significant work is required on a national reporting system for patient safety incidents. We are almost 15 years away from the creation of the self-proclaimed bold and leading Scottish patient safety programme, and I do not think that things have improved.

Irene Oldfather: This law raises two important issues. In relation to the scope of the commissioner's remit, I agree with my colleagues that we are looking for the commissioner to have the widest possible scope so that they can be future proofed against events or situations that we might not know about at this point in time. We do not want replication of the stories that we have heard today on mesh-injured women.

Our organisation has noted in our response to the committee that there is no mention of human rights in the bill. We believe that patient safety is a global health priority and a fundamental component of how we ensure and strengthen trust in healthcare systems. If we are committed to sustainable development goals, as we are in Scotland, central to the delivery of those goals is patient safety, and we must ensure that quality services are delivered. For us, therefore, we would like to see an approach that encompasses equalities and human rights for all citizens in Scotland built into the architecture of the bill. We would welcome explicit reference in the bill to the rights of people who are accessing healthcare services.

Through working for 10 years with people across the spectrum of lifelong health conditions, I feel that there are certainly gaps in the system and that it is a bit siloed. There is something about the patient safety commissioner having a role but not allowing other parts of the system to abdicate responsibility. The package should ensure that, when there is responsibility in other parts of the system, such as the health boards for significant adverse events, the duty of candour and so on, we take a tough approach. Perhaps the patient safety commissioner would have a role in ensuring that we have a much more joined-up system that is

responsive to the individual's needs and respects the human rights of citizens across Scotland.

The Convener: I am going to bring in some colleagues off the back of Emma Harper's questioning. Colleagues, I would like you to direct your questions to individuals, but if a witness wants to come in, they should just let me know and I will bring them in if they have something to add. We have a lot of people who want to ask questions.

Stephanie Callaghan (Uddingston and Bellshill) (SNP): Thank you to everybody for being here today. It is hugely appreciated and very important.

My question is for Irene Oldfather and it is based on what she has just been saying. We have already heard from everyone today about how people are not listened to and need answers to their questions. We need to ensure that investigations are thorough. It is all about saving lives and saving people from experiencing trauma.

The commissioner would largely define their own role. Irene Oldfather talked about that role having as wide a scope as possible and said that it should include equalities and human rights. Some people could look at such a remit and think that it is overwhelming. There is also the idea that it could perhaps pull together everything that is already happening. Do you have any recommendations? Is anything missing from the bill? Do you have any comment on the idea of pulling everything together?

Irene Oldfather: I can see that, in the first year of the commissioner's role, there could be a danger of their becoming overwhelmed. I do not think that the commissioner should look at individual cases, particularly in that first year. Instead, there should be a lot of work on gathering data and trends. The role of the advisory group will be crucial. I might come back to that in a minute.

To be honest, parts of the system have not functioned well to date. For example, women who have been injured by mesh have been really let down. It should not be the commissioner's job to take on responsibility for all parts of the system. Those need to work, and we have to make them accountable.

With David Strang, I was involved in hearing the voices of people with lived experience of mental health services in Tayside. Again, I felt that, in some ways, we let people off the hook too easily. There has to be accountability in the present systems. I feel that that is still lacking a little bit. We need to ensure that there is a whole package. The commissioner will have roles and responsibilities, and it is important that we make those clear and that a communication programme is built around them.

In the evidence session that we held, we spoke to women and others about the role of a patient safety commissioner. Some people felt that the commissioner should deal with individual complaints. I think that, at least in the first year or two, we should look at wider system issues. However, we have to hold to account the people on the boards and in other parts of the system who have the responsibility for responding to people's individual complaints. We have to hold their feet to the fire. I feel strongly about that. The current system is fractured and siloed. It is still not about working together and connecting for the benefit of people. We have to correct the problems in the present system and then add the patient safety commissioner on to that as someone who can look across the piece and join things up a little bit.

I have views on the advisory group, convener. I am not sure whether you or Ms Callaghan would like me to give those at this point or to come back to them later.

The Convener: Yes, just make those views known now. I will come to Paul Sweeney after that.

Irene Oldfather: We are pleased to note that the advisory group should have people with lived experience on it and that there is a proposal on expenses and remuneration. We feel strongly that that should not be just a tick-box exercise. At the end of the day, it should not come down to expenses. We believe that, in order to give the position the gravity and impetus that it needs, people should be paid for the work that they do. Just because they have lived experience should not mean that they get only expenses. We want to emphasise that point.

I will refer to a copy of the bill so that I get the correct wording. Section 16(4)(c) mentions

"persons who appear to the Commissioner to be representative".

We felt that that wording is a little bit woolly and could be strengthened. The approach should be not about appearing to be representative but about demonstrating that—it should be about having people who demonstrate a commitment. We wonder whether the committee might consider making an amendment to the bill in those terms. We would welcome having people with protected characteristics—in particular, women—being represented on the advisory panel. Women have told us that they felt that they were not being listened to in the system, so it is important that sufficient protection is given to ensure that there is a strong voice for them on the advisory group.

My final point is that the bill mentions providing a strategic plan and ensuring that that is consulted on. Again, we suggest going a bit further by co-

producing it with people who have experienced patient safety issues across the piece.

09:45

Paul Sweeney (Glasgow) (Lab): My main question is about the accountability of the commissioner. Mr Wright made a powerful point earlier about the role of the Executive in denying recourse or appropriate investigation. The bill proposes that the commissioner be independent of the Scottish Government—the Executive branch—and of the national health service and instead be accountable to this Parliament, as a democratic body. Do you agree with that proposal and, if so, why? Considering your comments, Mr Wright, I will direct that question to you in the first instance.

Bill Wright: You might not be surprised to hear that I strongly agree with that, because any progress that was made in the early years of this Parliament was thanks to the efforts of your predecessors on the health committee. I anticipate that, given that the report from the PSC will come to Parliament, it will probably end up on your doorstep, which would be entirely appropriate. I want to pay tribute to your predecessors. I am sorry that many of the faces here are new to me, because I used to be very familiar with them in the early days when we were pressing on this issue.

It is vital that the role is independent of Government, because the problem in the early days was that the Government had its hands all over this issue. On independence, there is an issue about funding, because the funding came from Government, which potentially limits power. With regard to governance—who you report to is part of your governance—I will return to that question and an issue that is vital. You asked a question about being listened to. Being listened to and governance are not two separate issues, because it comes down to the access to information.

I think that you mentioned a problem with medical records. One of the biggest problems is that patients, even now, struggle to get access to their medical records. In our submission to the infected blood inquiry, we made the point that, in this day and age, you should be able to get your medical records electronically. I can access my bank account on my phone—every transaction—and yet we live in a situation where you have to ask for your medical records. I have a hospital appointment tomorrow. If I say, "Can you send me a letter?", it is debatable whether I will get it. Having access to medical records is a starting point for empowering people and allowing them to bring the issues to those who are governing—that is what really matters.

The Convener: I would like to bring other members in. I am sorry that I need to curtail the questioning a bit. I will bring you back in later, Paul, but Evelyn Tweed has a question on that issue. I remind people of the time—we are halfway through our evidence session and I would like to give most of the speaking time to the witnesses.

Evelyn Tweed (Stirling) (SNP): Fraser Morton, I will follow up on a couple of your comments. Thank you for sharing your family's experience—that was really powerful. I am interested in what you said about the powers that the commissioner would or would not have. If the commissioner had been in place at the time of your case, what would you have been looking for from them? What would have made you feel listened to and supported, and how might the commissioner have taken your case forward to your satisfaction?

Fraser Morton: I will pick up on the point about the commissioner not taking on individual cases. That is the case with Healthcare Improvement Scotland—it does not take up individual cases. I contacted it at the time. I also do not believe that Healthcare Improvement Scotland is a patient safety regulator—it is a quality assurance body. Its whole ethos and approach are based on TQM, or total quality management, and high-volume output—things fae industry. I think that it conflates quality with safety.

Where would we have gone if there was a patient safety commissioner at that time? I would like to think that we could have avoided putting Lucas through a post mortem to finally get his cause of death recorded as perinatal hypoxia at birth. I would like to think that we could have avoided a review that was edited by NHS Ayrshire and Arran's medical director.

One of the many findings of the review was that the review team acknowledged the complexity of managing a system of learning and improvement from adverse events but also expected material progress to have been made since the previous failings were initially identified, in 2012. That was in 2017, and the Scottish patient safety programme began in 2008—there has been no material progress at all.

To be honest, I am really not sure about the proposed powers of the patient safety commissioner. I believe that the former health secretary, Jeane Freeman, is on record as claiming that the Health and Safety Executive is the default regulator for healthcare in Scotland. I ask you to look into the powers of a health and safety inspector under section 20 of the Health and Safety at Work etc Act 1974. You will see that what is being proposed for the commissioner falls far short of that.

In my case, the fiscal wanted to proceed with a fatal accident inquiry, but I wanted to go for a prosecution under health and safety legislation. I believe that preceding what happened to Lucas, NHS Ayrshire and Arran was prosecuted twice on, I believe, ligature points in the mental health unit. The maternity unit was 26 members of staff short, and the board failed to learn the lessons from 2012. A lot of people think that it was just a maternity issue and, because of the narrow scope of the terms of reference, the review focused on maternity, but the adverse event framework for the whole hospital was not applied correctly, and it still puzzles me to this day why there was not a trawl through every department to see whether anyone had slipped through the net.

That is where I would like to go, but I do not believe that that will be in the commissioner's remit. The strange thing is that I pushed the Crown Office for a prosecution under health and safety legislation. Lucas's designation as stillborn removed his legal identity, but you do not need to have a legal identity to get a prosecution under health and safety legislation. However, the Crown told me that, because Lucas's death was due to failings in clinical governance, it was outwith its remit. I have a letter from the chief executive officer and medical director of Ayrshire and Arran at the time, saying that they have "complete faith" in the clinical governance at the maternity unit. Those two diametrically opposed opinions remain unresolved to this day.

The Convener: Thank you. We will move on to questions on monitoring and information gathering, which have been mentioned already briefly.

Paul O'Kane (West Scotland) (Lab): Good morning to the panel, and thank you for your important testimony this morning. I want to expand on how the patient safety commissioner might understand emerging themes and patterns and so might be able to prevent some of the issues that we have discussed. To what extent do the witnesses think that their experiences are rooted in a failure to pick up on early signals of adverse outcomes? We have heard about some of that already, so I suppose that my follow-on is: what confidence do the witnesses have that the patient safety commissioner could improve the capacity to pick up on early signs of adverse outcomes?

I wonder whether Fraser Morton or Marie Lyon wants to comment on that.

Marie Lyon: It is quite difficult to answer that because, with our story being historical, I can look only at what would have happened with us. The pattern would have been identified quickly. If the patient safety commissioner did what she or he will do, I hope, which is to speak to patients—I agree that they cannot solve any issues that arise, but they can monitor and share information—it would have been picked up far earlier.

In relation to the current situations that the other panel members face, once issues are identified, there should be consequences. The big problem has always been that issues have been identified, many people have considered them—as Fraser Morton has just said—and reports have been produced, but then nothing has happened. When someone collates information, looks at all the reports and understands that an issue is not an isolated incident but then nothing is done to solve it, that leaves the door open for further harm in other areas.

The remit of the commissioner should be extended, apart from to the areas of the three campaign groups. I think that those groups were cited originally to enable the patient safety commissioner to show that they could resolve high-profile issues quickly. However, as I have already said, that does not happen with the UK patient safety commissioner, so, unless these conversations continue, my confidence is not particularly high that it will happen.

Charlie Bethune: Over the years, one of our concerns has been that people have been marking their own homework and making available only the information that they want to give to the other side—that has happened a lot in the past. It has been a massive struggle—certainly for valproate, as well as for other areas—to get access to information. Even now, information is not always available, which you would not expect, given that valproate has been in the political sphere for quite a number of years. We still cannot say how many people in Scotland are affected by valproate. It is estimated that there are 2,000. We can say exactly how many people were affected by thalidomide—there are 50 of them in Scotland—but we know only that there are around 2,000 people who are affected by valproate.

There are no statistics on valproate for Scotland or expertise on it here. We had to take our daughter to Manchester to get a diagnosis because there was nobody in Scotland who could provide a proper diagnosis. However, without a diagnosis, you cannot get the proper services, care and support that you need. There are perhaps hundreds of people in Scotland who suffer from valproate who do not even know that at the moment, so they will be receiving the wrong treatment and the wrong support. Some of our members discovered that their children were affected by valproate only when they were in their 20s. I am sure that the doctors must have known, but they did not expose that information and tell them. Parents were fobbed off.

It is essential that the patient safety commissioner is independent so that people do not mark their own homework.

People have been talking about what powers the commissioner should have. I am sitting here today thinking that a really good power to have would be the power to instruct people to collect the right data. We often get told, "Sorry—we don't have that information." How many pregnant women were prescribed valproate in the past few years? That data is being collected now, because we have been pushing for it, but the Scottish health boards were not able to tell us that when we started having discussions with them only a year or so ago.

Fraser Morton: I want to pick up on Charlie Bethune's point about people marking their own homework, which was a finding in 2016 of the Organisation for Economic Co-operation and Development on the current scrutiny situation in Scotland. The OECD recommended that Healthcare Improvement Scotland be split into two separate departments, but there has been no work done on that.

During Covid, I got most of my trend analysis and data news from an app called Travelling Tabby—maybe youse got it from the same source. I was really impressed with it and with what one student can dae with a laptop. I think that it was some time in 2018 that we met Jeane Freeman, and I asked her whether it would be possible to establish a real-time—or as near as possible to it, because there is always a lag—safety dashboard, which would aid active intervention to prevent deaths, instead of having a reactive approach. Jeane replied that we were a long way from that, and we are just as far away from it now as we were in 2018. Having real-time data would point us towards a proactive rather than reactive approach.

10:00

I was watching the health committee online some time in 2017, I believe. I think that it was Donald Cameron who asked the witness from Healthcare Improvement Scotland—it was possibly Robbie Pearson—whether he could provide any examples of the organisation intervening proactively and of its own volition. If it was Robbie, I believe that his response was that Healthcare Improvement Scotland intervened in some hospital but that its intervention was based on the hospital standardised mortality ratio. We are counting bodies before we react—counting deaths to see whether they are above the upper limits.

When it comes to the commissioner and the bill, do not wait for new deaths and for scandals to emerge—learn fae the past or you are doomed to repeat it. I believe that there is a provision in section 2(4) that allows the commissioner to learn from the past—I take the point that initially he or she will not take up individual cases, but that does not mean that he or she cannot learn from them.

The Convener: Thank you. We now move to the commissioner's appointment process. I have three colleagues down for this theme.

David Torrance (Kirkcaldy) (SNP): Good morning. My question is aimed at Bill Wright, considering his answer on the independence of the commissioner. Do you think that the bill in its current form will allow the commissioner to be independent?

Bill Wright: Well, to a certain extent, that really depends on you guys—with the greatest of respect. The commissioner would report to Parliament; one would not expect the matter to take up a great deal of time in the debating chamber—it might be noted at First Minister's questions—nevertheless, I anticipate, hope and pray that time would be devoted to the commissioner's annual report in your business plan for the year. It is vital that there be follow-up on the bill once it has passed; we rely on you and successive health committees to ensure that that happens. I also hope that you invite us back when issues arise, in order for us to say whether we think that the PSC is doing its job properly.

Evelyn Tweed: I know that we are tight for time so I will ask Bill Wright this question, although I am sure that other members will have views on it as well. Do you think that people with lived experience should play a part in the recruitment process for the commissioner?

Bill Wright: Oh, boy!

Evelyn Tweed: I have really got you started now!

Bill Wright: That is a tricky issue. As the chair of a charity for people with haemophilia, I am always wary of using the word "represent"—we seek to support people. Not everyone with haemophilia is a member of Haemophilia Scotland; not everyone who has infected blood is a member of either Haemophilia Scotland or the Scottish Infected Blood Forum. The point that I am making will be familiar to those of you who have had to stand for election. I am not suggesting that everyone would be in such a position. There might have to be some sort of application process—you would need to have an application process for the panel that will then receive the applications from the prospective patient safety commissioner.

It is a very tricky issue, because it also relates to the advisory group that is supporting the patient safety commissioner. The issue that I would find among my community, and Charlie Bethune and

Marie Lyon would find the same, would be that people would ask why it is those people rather than someone else who is on the advisory group.

Marie Lyon: Can I interrupt? We actually did that with the UK Patient Safety Commissioner. We were asked, as a panel of people with lived experience, to do a pre-assessment of the candidates, which we did virtually. We then fed back what we felt about the strengths and weaknesses of each of those candidates and what their position was. All that feedback was sent to the panel with Julia Cumberlege—I do not know who was on the eventual panel—which then made the decision. We were allowed to look at the candidates and give our feedback, but I am not sure how helpful it was. That also gave us a sense of the quality of the candidates who were put forward. We were disappointed, to a man, with the whole panel, but one of those candidates was eventually appointed. Therefore, although we were there, we fed back that view and I would not say that we made much of a difference.

The Convener: I will bring in Irene Oldfather, because she has to leave after this.

Irene Oldfather: I have a few brief points on independence, the future role and how we can future proof that. I do not think that we should underestimate the role of Parliament and this committee. As others have said, the role of Parliament is crucial. I have had many discussions with previous ombudsmen, including the Older People's Commissioner for Wales and various others, and, inevitably, once they have been in the role for a while they see things that they would like to change. The present Scottish Public Services Ombudsman added whistleblowing to her role.

I think that there should be an opportunity, one or two years into the role, for the commissioner to be able to review it and say, “This bit is working really well, but I could do with more scrutiny powers in relation to that bit.” I hope that a very co-operative and constructive relationship could develop with Parliament through annual reports and so on, which could produce an on-going audit, monitor and review. That is really important, because things change and people have different approaches to a role.

I mentioned the advisory group earlier, which is really important. We need to ensure that that is a constant sounding board and can audit, monitor and support the commissioner, working very much in partnership with Parliament. I am a wee bit biased, I suppose, but members of the Scottish Parliament continually hear through their constituency casework about issues that are being raised that need to be given further attention. A very constructive relationship could potentially be built there, but we need to ensure that there is some sort of opportunity for audit, monitor and review within the system.

I am afraid that I have to go now, but it has been interesting listening. Thank you, convener.

The Convener: Thank you, Irene. I appreciate that. Charlie Bethune wants to come in.

Charlie Bethune: Very quickly, I will say that the key thing about the appointment is that the patient groups have to have confidence in the person, both at the appointment stage and afterwards. We need to make sure that there is a mechanism by which, if we lose confidence in the patient safety commissioner, for whatever reason, there is some way in which they can be removed, replaced or whatever. We do not want a situation in which somebody is appointed and they do not do the job, they are biased or are doing all the kind of things that we are trying to fight against and there is no way of sorting that out.

Paul Sweeney: How can the bill be strengthened in terms of holding bodies accountable in terms of the commissioner’s recommendations? Are there specific measures that you would like to be introduced, such as the ability for the commissioner to levy fines on health boards? Are there any powers that we could implement? What could the Parliament do to hold public bodies to account in addition to backing up the commissioner’s recommendations?

Marie Lyon: There has to be accountability and there have to be consequences. Up to now, as everyone has said, people have tended to get away with it. There has never been accountability and there have never been consequences. There needs to be a mandate for the patient safety commissioner to implement such actions. It is no use saying that we will learn, because the bodies do not learn.

I had the same experience with bodies marking their own homework because the Medicines and Healthcare products Regulatory Agency did the initial inquiry for us into the Committee on Safety of Medicines, which was the initial MHRA. It is like the police investigating their own officers. The patient safety commissioner has to have an independent mandate to say that something has not happened, what the consequence is and what action will be taken, and the person involved should then be named and shamed.

The Convener: Tess White has some questions on more recommendations.

Tess White (North East Scotland) (Con): My question is for Fraser Morton. You have talked us through follow-up towards action. In your submission to the committee, you raise concerns that no person or organisation would be compelled to accept or implement a recommendation. Based

on your experience, how likely is it that a recommendation would not be implemented by a public body? What specific ways would you like the powers of the PSC to be strengthened so that they can enforce the recommendations?

Fraser Morton: We talked about data analysis. Data is useless unless it is transformed into information. The information then becomes useless when it is issued in the form of recommendations. The trouble with recommendations is that they are recommendations.

To pick up on Paul Sweeney's question about what powers the commissioner should have, the statutory powers already exist but they are held by the Health and Safety Executive. It can make enforcement orders, issue fines or take your liberty away in a serious incident.

To go back to our experience, Lucas died in 2015. I have a thick pile of action plans from deaths similar to Lucas's, which public bodies have failed to learn fae.

In Scotland, we have Healthcare Improvement Scotland and the Scottish patient safety programme. People must dae SPSP training. They come out as fellows, have cohorts and put that after their titles. NHS Ayrshire and Arran was awash wi fellows and cohorts fae the Scottish patient safety programme but not one of them—even the ones in the department—picked up that it was operating 26 members of staff short.

On the enforcement of recommendations, I am clear that there have to be statutory powers.

Tess White: Do you mean similar to the Health and Safety Executive?

Fraser Morton: Yes.

Charlie Bethune: I would like to add a brief comment. The Cumberlege review made a set of recommendations and the Scottish Government committed to implementing all of them. We are three years down the track and two have been implemented. One was an apology, which is worth nothing, really. The second one concerned setting up the patient safety commissioner. There is a set of other recommendations that have gone nowhere. It is clear that the commissioner has to have the power to do more than make recommendations. There must be some way in which things can be made to happen.

The Convener: We have talked about individual complaints throughout this evidence session but Gillian Mackay has some additional questions.

10:15

Gillian Mackay (Central Scotland) (Green): Do the witnesses agree with Baroness Cumberlege's view that giving a patient safety commissioner responsibility for handling individual cases would make the commissioner less effective in addressing wider systemic issues of patient safety? If not, why not?

Bill Wright: That is the section of the bill where Ah hae ma doots. If it makes sense to say so, haemophilia is the most common of the rare diseases. Someone with a very rare disease may suffer because of a systemic breakdown. My question is at what point one, two or three individuals become a group of people for whom there is an apparent and systemic problem.

There is another element that is really difficult, which has been alluded to by colleagues. If someone has a problem because their son has been infected, harmed or even killed, where do they go? Do they go to the health board, through its complaints process? That is the initial step. Do they go to that very health board, which will immediately go to its lawyers? It is a culture of defensiveness rather than reflection.

The infected blood inquiry has just heard a series of apologies that we have been waiting 20-odd years for. Those apologies meant something because they said that they were apologising for not doing X, Y and Z over a period of time. They said that they were wrong, that they regret it and that they apologise.

The culture of defensiveness in the health service must change. That is where I have a doubt. If we take social care as an example, someone with a complaint about an elderly person in a care home, or about a care service, can go to the Care Inspectorate and the issue will be fully dealt with, in confidence and completely independently of the social care provider. Then there is Healthcare Improvement Scotland. We heard about HIS earlier, but who on the street in Scotland has ever heard of HIS? That is why the patient safety commissioner must be set up as the first port of call, not the last.

Gillian Mackay: That is really useful; thank you.

Because of the groups that you are associated with, you have all had similar but varied experiences. Some common themes are coming out. I hope that we have enough time for this question, convener, because I would like to hear each person's views. If the patient safety commissioner does not take on individual cases and complaints, how could they effectively listen to and promote the voices of patients, or of wider campaigns such as yours?

Marie Lyon: The commissioner does not need to take on and solve individual cases. I think that there is a misconception. Individual cases should be looked at, reviewed, noted and documented. That information could form a pattern. She will not

have time to solve each case and neither should she. I keep saying "she" because we have a female commissioner in England. It is perfectly right that she should be the first port of call for someone to speak to and that she should listen to what that person says, but solving problems would be difficult. That does not stop the commissioner having a wider net and trawling to find out whether that has happened to someone else and whether it has been documented and followed up.

Following up is important. Things are said and listened to, but does anything happen afterwards? Actions are important to me. It is important that someone does something and lets people know that. Complaints can go into a black hole and people might never know what happens to them. There needs to be accountability. The commissioner should listen, say what they have taken from that, find out if anyone else is in the same position and say what they have done. That is the step that seems to be missing every time. What has someone actually done?

Gillian Mackay: These have obviously been traumatic experiences for you all. What support would you like to see sit alongside a patient safety commissioner to support groups or individuals who raise such cases? As you said, sometimes not hearing back or not getting a resolution to a case can further compound the trauma resulting from a mistake or whatever else has happened that has got that person to the patient safety commissioner. Do any of you have any reflections from your experiences or the campaigns that you are part of?

Charlie Bethune: In our experience, there has been very little support, other than the support that the patients themselves have generated. One of the things that we are looking for, in Valproate Scotland, is implementation of the other Cumberlege recommendations, which are about specialist support and services to resolve that issue.

In Baroness Cumberlege's evidence session last week, there was a bit of conversation about the resources that were required. When we start thinking about how individual cases will have to be dealt with by the commissioner, a whole host of things will spin off from that. We talk about the importance of access to the data and looking at the trends and so on. However, the recommendations and actions that come out of a particular investigation will have a whole host of implications, and we hope that the health boards, trusts and so on will get on board with supporting the patient safety commissioner. We would hope that everybody wants to make patient safety a priority in Scotland and that the commissioner will not be seen as somebody who is going to wield a big stick. This is about improving things for Scotland, and it will have ripples right down to the patients and for everyone in between. If it works and is effective, it should be a massive thing.

Fraser Morton: I have a couple of quick points about the appointment of the patient safety commissioner. Two of the most significant pieces of work on patient safety in the UK are the Francis inquiry and the Shipman inquiry, so I would like to see the patient safety commissioner come from a legal background.

I also believe that it is not a role for an individual. If that individual is from a legal background, they need a team with a specific skill set that is suited to healthcare working with them.

In section 14 of the bill, entitled "Failure to supply required information", there seems to be an escalation whereby

"The Commissioner may report the matter to the Court of Session"

but there is no such escalation process if the commissioner fails to implement the recommendations.

I also see that section 18, entitled "Protection from actions of defamation", says that

"any statement made to the Commissioner has absolute privilege"

and that

"any statement in the Commissioner's report on an investigation has absolute privilege".

However, section 18 also says that

"any other statement made by the Commissioner has qualified privilege."

I do not know why that is watered down—I would like it to say "absolute privilege". I would also like that to be extended to the Scottish Parliament. I want to hear people's opinions without a filter.

Bill Wright: In relation to Gillian Mackay's point about support, during the past four and a half years of the infected blood inquiry, the Red Cross was there every day with qualified people to support individuals who were having to relive very harrowing stories. We have been successful in appointing specialist psychologists to support not only those with haemophilia but those who have experienced infected blood. That has been a welcome move on the part of the Scottish Government, but it took a hell of a long time in both cases to get those psychologists. We have all had different experiences due to the different circumstances, and it needs to be someone who understands the issue, not just a general practitioner referral to a psychologist.

On support, I go back to the patient safety commissioner themselves. With regard to the leadership and clout that will be needed, the

commissioner needs to be someone of such character that they make people feel that "This person—this man or woman—is our friend, and their staff are our friends, against this system that we've constantly had to fight, backed by lawyers."

Marie Lyon: I will give a quick example of one of our Scottish members. She has paid £2,000 for a special bed, because she could not get anyone to step up to provide it. She has had to get a new hob and an accessible smart oven, because she has a wheelchair that needs to fit under it. She has paid for that herself. She has had to have a second amputation—of her leg. She needs a second leg prosthetic, but she has been told that she can have only one. She needs a lightweight electric wheelchair to get upstairs. She has been using a chemical toilet, wipes and hand sanitiser for more than 13 years. Who does she speak to? I do not have a clue.

That is what the support needs to be: it needs to be practical. Someone needs to be able to say, "That is the department that you go to." This girl has done all that herself. She has one arm, a prosthetic leg and various other complications. She carries on with life, but there is no one to help, so I said that I would bring her case forward today.

The Convener: Thank you. Emma Harper has a question and then we will have a final question from Sandesh Gulhane.

Emma Harper: My question might be more relevant for the next panel of witnesses. I am thinking about the system for reporting incidents, which is perceived as punitive by healthcare staff. It is better to deal with near misses than to wait for a significant adverse event. My background is 30 years of operating room nursing. It is highly technical. It is very unsafe—not in the sense of the practice, but there are sometimes so many barriers, and it is a team-driven environment. Errors are not intended, but the Swiss cheese model comes to mind when we talk about patient safety.

I am interested in hearing your thoughts about how we need to encourage the reporting of incidents so that we can put effective measures in place to prevent them and about how that would support a patient safety commissioner's work to look at encouraging reporting so that we can develop safer methods.

Marie Lyon: Reporting needs to be looked at as a benefit. The problem is that reporting seems to be a fault-based event, and it is not. It should be a case of looking at something, seeing that it is not right and seeing that the benefits of reporting it are that it will not happen to somebody else, it will save a lot of distress to a family and it will save a huge amount of money and time. The patient safety commissioner will need to share the fact that it benefits everybody to say when there is a problem rather than trying to hide it.

Bill Wright: I want to pick up on that, because it is fundamental to the whole situation. I would not particularly favour fines, because that extends the culture of defensiveness in health boards and does not encourage learning or reflection. We have talked a lot about this with regard to the infected blood story, particularly recently. There needs to be a situation where patients are not only listened to but are not seen as a threat. We have all been seen as threats because the health boards have thought, "What the hell are we going to do about this? We'd better take legal advice", and we need to move on from that.

It also comes down to the power relationships. Nurses, in particular, should be able to raise issues with the patient safety commissioner; they should be able to go directly to the commissioner. Look at where the power sits in hospitals. It sits with the hospital management, to a certain extent, but then it rests with the medical profession. With regard to our story, in the old days, pre-devolution, the predecessor to the Scottish Executive was simply listening to the chief medical officer who, of course, was listening to the doctors.

We need to get beyond that, which comes back to the point about access to and interpretation of medical records. In addition, if members of the medical profession who are way down the food chain, such as junior doctors, think that something is wrong, they should be able to go to the patient safety commissioner.

10:30

The Convener: Our final question is from Sandesh Gulhane.

Sandesh Gulhane (Glasgow) (Con): Before I ask my question, I will touch on something that Bill Wright said. With regard to the culture of defensiveness, what happened in the past is very different to what goes on now. Doctors certainly do whistleblow, and we have seen that on a number of occasions. As a doctor, when I make a mistake, one of the first things that I do is apologise. We all make mistakes, because that is the reality, so I hope that that comment was about the higher board level rather than about individuals.

NHS Scotland—and the NHS in general—is fantastic, but I am realistic enough to know that improvements can be made. From what I have been hearing, it seems that everyone is keen for the commissioner to take and listen to evidence from individuals, but we need to be clear that, potentially, thousands of people will be writing to or seeing the commissioner. My question is based around the fact that the current budget is for four members of staff plus the commissioner. Do you

want to see a significant increase in the budget and, thus, the number of staff who work for the commissioner? That question goes first to Bill Wright.

Bill Wright: I fully accept what you say about things having moved on with regard to the medical profession. Thank goodness for that because, in the 1970s and 1980s, we were very much victims of paternalistic approaches.

I think that you are right about the budget but, first, we need to get the commissioner and initial staff in place. I go back to my theme about the importance of this committee and the Parliament in all of that. Everyone is accountable to someone so, given that the patient safety commissioner will, we hope, be accountable to Parliament, it is really important that the Parliament devotes time to looking at those issues, and that the PSC is someone of sufficient character and clout to be able to say, "We have had 1,000 people approach us in the past year, and we can deal with only so much, so we need our budget doubled, tripled or quadrupled." I accept the point about the governance. It is hard to see how, even in the initial stages, the commissioner can develop that work with four people, but let us get them in place first, because the other proposal is that the first patient safety commissioner has to develop the principles under which they will work.

Marie Lyon: Can I add to that as well? There was a suggestion about hybrid working arrangements, which I do not think would work. If the team members discuss the issues by Zoom, and not in a room together like this, that would have a negative effect on the working pattern of the PSC.

The Convener: The last word goes to Fraser Morton.

Fraser Morton: To pick that point back up, Sandesh Gulhane was referring to a no-blame culture, which I believe is derived from the aviation industry. I am not totally convinced about that, because I think that you are comparing apples with oranges. If we go back to real-time data and trend analysis, aircraft have black boxes, which contain flight and voice recorders, and air traffic control has voice recorders, so every input is recorded. That sets that industry apart from healthcare. Although I am paraphrasing, because I cannot remember the exact quote, I think that Bill Kirkup said: "to err is human; to cover up and conceal is unforgivable". That is how we distinguish between the two parties.

The Convener: I thank all four witnesses who were in the room with us, as well as Irene Oldfather, who joined us online, for your time this morning. It has been very important to hear your stories and thoughts on the patient safety commissioner.

10:34

Meeting suspended.

10:43

On resuming—

The Convener: Welcome back. We continue our scrutiny of the Patient Safety Commissioner for Scotland Bill, with witnesses from organisations relating to patient safety. I welcome to the committee Rosemary Agnew, Scottish Public Services Ombudsman; Alison Cave, chief safety officer at the Medicines and Healthcare products Regulatory Agency; Dr Arun Chopra, medical director at the Mental Welfare Commission for Scotland; Dr Anna Lamont, medical director for procurement commissioning and facilities at NHS National Services Scotland; and Simon Watson, medical director at Healthcare Improvement Scotland.

A few of you were in the public gallery when representatives from patients groups were giving their thoughts on the patient safety commissioner. Can you give us your thoughts on the criticisms that they made about the existing systems and structures for patients to have their complaints dealt with and their views heard? There was some upsetting testimony from those representatives about occasions when they felt that they were not listened to and that the systems were not in place to give them support. It seems that they would be relying on a patient safety commissioner to fill that gap.

I would like to hear your reflections on the points that were made about patients not being listened to and the systems not being in place to enable their voices to be heard. I would appreciate hearing views from you all, starting with Rosemary Agnew.

10:45

Rosemary Agnew (Scottish Public Services Ombudsman): Good morning, convener—I knew that you would start with me. Thank you for the opportunity to speak.

I have heard a few times from the patients who spoke in the previous session; I cannot help but be moved by their stories and what they say.

We are, in essence, thinking about a cluttered landscape in which there is a combination of different types of organisation, including oversight bodies, scrutiny bodies, commissions and commissioners. As the SPSO, I am part of that landscape. I think that, individually, we all do well

and understand our remit. I can take personal complaints—that is a third of my remit; I will come back to the other parts in a minute.

We can look at the individual redress side, and there are complaints that lead us to identify systemic issues. I can give you examples of those later. Nevertheless, there is a gap or a lacuna in which the voice of what might almost be the patient equivalent of a whistleblower is not always heard.

Patients end up having to go to one organisation after another. It is not that we, across that landscape, do not want to share issues and talk about these things; it is that we often cannot do so, because the way in which our legislation is set up precludes it. There is absolutely a gap with regard to patients being able simply to tell their story and describe their feelings, their views and, in particular, their experience, and to know—not just hope—that they will be heard.

Yes, there is a gap, and it needs filling, but I do not think that it is because the current systems do not work. It is because we are not always enabled to work together in the way that we would like. A patient safety commissioner will be an essential part of helping organisations across that landscape to work together.

Alison Cave (Medicines and Healthcare products Regulatory Agency): Good morning, everyone. I thank the committee for the opportunity to be here. We heard some powerful testimonies earlier.

I will reflect on the post-Cumberlege environment. My role at the MHRA is a new role, to which I was appointed in July 2021. Part of that role involves bringing together all our thinking on, and responses to, the Cumberlege report, and our activities around both medicines and medical devices, which used to be separate and more siloed.

In thinking about the role of the patient safety commissioner, we have been engaging with the Patient Safety Commissioner for England since she was appointed. We interact regularly, and we are developing how we can best work together synergistically to support her in her role and to ensure that patients feel that they are heard more.

Personally, I answer many questions every week directly from patients. We have, post-Cumberlege, set up a customer service centre, which handles about 50,000 inquiries per year, and we try hard to respond to patients. We have also transformed our organisation, as I have indicated, to try to design in more safety and more patient involvement, and to enable patients to feel that they are more engaged with the regulatory process and that they have more of a voice in the process of drug development and drug authorisation. In particular, we have tried to involve patients more in safety assessment through having more meaningful engagements, listening to them and bringing them into our risk-benefit assessments.

I could talk more about that. I do not know how much time the committee has, but I am very happy to discuss—

The Convener: I am sorry to intervene, but Charlie Bethune talked about valproate in the earlier session. That is a specific example. He flagged up that that is still being prescribed to pregnant women.

Alison Cave: Yes, sodium valproate is a drug that is used to treat not only epilepsy but bipolar syndrome. There are a lot of restrictions associated with it—it is a known teratogenic drug—but there are some individuals who have drug-resistant epilepsy, for whom valproate might be the only effective or tolerated treatment to control their seizures. We try to ensure that the benefits outweigh the risks.

Since 2018, we have had a strong pregnancy prevention plan in place for sodium valproate, which requires that no woman receives sodium valproate unless it is ensured that there is no other effective or tolerated treatment, that they are registered on the pregnancy prevention plan and that they are on effective contraception.

Since 2018, in England, we have put in place an anti-epileptic registry to monitor the prescribing of sodium valproate to women of childbearing age, and we have seen a drop in prescribing. There has not been as big a drop as we would like. At the last count, there remain about three exposed pregnancies per month—

The Convener: If there had been a patient safety commissioner, would that sort of thing have been put in place a lot earlier, which could have prevented some of those cases?

Alison Cave: It is hard for me to look back historically at 2012, 2013 or 2014—

The Convener: But I imagine that what you are talking about was put in place as a result of campaigning.

Alison Cave: Yes. We are also becoming more aware of, and we understand more about, the biological mechanisms and the teratogenic effects of sodium valproate. However, it has been known for decades that it is a teratogenic medicine, so those measures should, potentially, have been put in place earlier to try to reduce that prescribing. It is a difficult situation when doctors tell us that, for some individuals, sodium valproate is the only effective treatment to control seizures. That is the conundrum with the medicine. We are trying to reduce its use to the absolute minimum so that we

are absolutely confident that no one receives valproate when there are other effective or tolerated treatment options, and we are putting new measures in place—

The Convener: I am sorry for going into that specific area, but it is an example of where a patient safety commissioner might have made a difference. I will leave it there.

Dr Arun Chopra (Mental Welfare Commission for Scotland): Good morning, and thanks for the opportunity to speak today.

I was sitting at the back of the meeting room during the first evidence session this morning, and I thought that the testimony was very powerful. It was also very accurate in relation to the lack of focus around investigations and the issues that were raised about governance and the lack of a regulator. The 2018 report from the Health and Sport Committee was mentioned, and I think that the observations in that report hold true today.

The focus on quality assurance and quality improvement as the predominant model was also mentioned, and I agree with the observations on that. The observations about a focus on human rights and equalities were also well made. Those points would be key to the success of a patient safety commissioner.

I know that there was a discussion about other regulators and scrutiny bodies within the landscape. The Mental Welfare Commission for Scotland, of which I am the medical director, is taking a human rights-based approach to the care of patients who use mental health services. One of the ways in which we do that is the forward-facing phone line. Alison Cave spoke about the ability to receive information. Our commission takes 4,000 phone calls a year through its advice line, which enables it to hear what patients, carers and people who use the services, and professionals, are saying. That is crucial. We might come on to resources at some point, but that is a powerful factor.

The commission also undertakes visits, where it gets to hear what people are saying about the places where they are liable to be detained, and it undertakes individual investigations and thematic investigations, which are about combining systemic factors or systems-based issues. We might touch on that when we talk about the role of investigations, but it is crucial to make those points. I thought that the earlier session was powerful.

Some of the points that were made about the role of the commissioner and the wish list relating to their powers started to veer on to the powers of a regulator rather than those of a patient safety commissioner, whose role must be to amplify the patient voice—that is the most powerful thing that the patient safety commissioner needs to do.

Dr Anna Lamont (NHS National Services Scotland): Good morning. I thank the committee for having me. I, too, heard the patients speaking about their concerns and agree that those concerns are accurate.

NHS National Services Scotland very much supports the commissioning of a new patient safety commissioner. It is about supporting that patient voice, with a holistic view.

National Services Scotland is an organisation of multiple parts, including blood transfusion, incident reporting, procurement and specialist services, and all those parts listen to patients, partly through a network of clinicians. A lot of this involves collaboration with UK organisations. We are keen to see a patient safety commissioner collaborate and work with organisations that are already in place. The National Services Scotland incident reporting centre receives patient reports, which are incorporated, particularly in relation to concerns about mesh, for example, about which we produce a six-monthly report for the Scottish Government. Last year, we received 35 reports, most of which were from clinicians, but we receive some from patients, too.

Overall, the role of National Services Scotland is to work with other clinicians and organisations. We are keen that whatever is put in place concerning a commissioner works holistically with existing organisations, including Healthcare Improvement Scotland and the SPSO.

Simon Watson (Healthcare Improvement Scotland): I was not in the room earlier, but parliamentary staff were kind enough to let me watch the earlier session on TV outside. I agree that it was powerful and—rightly—distressing to listen to what was said. I can only imagine what the people who gave their testimony must have gone through and how hard it must have been to talk about that today, so I am very grateful that they did so.

I agree with the ombudsman that all organisations have remits within which they always have to operate. However, we are human beings, too. If people come to us in extremis in difficult situations, we need to have the intelligence to help them to find the help that they need, even if it is not in our power to deal with the issue that they have raised. We also have a moral obligation to provide support so that that can be done as easily as possible.

In Healthcare Improvement Scotland, we have a range of mechanisms for listening to the voices of those with lived experience—patients, relatives and others. That is done most formally through our community engagement directorate, which does

what one would imagine: it ensures that NHS boards in particular have in place the right mechanisms, skills and approaches to hear the voices of patients and people who use their services. The directorate also has a more general supporting function—it is not just external facing—so it helps everybody, including our organisation, to do that.

All of our programmes, whether they relate to medicines, technologies, guidelines, improvement or support and assurance, have mechanisms to connect to the public and patients so that our work is informed. The word "improvement" is in the middle of our organisation's title, and it applies to us, too. I will not say that everything is perfect and that we are all satisfied; we must—and do—try harder.

My final point is, in my view, particularly relevant to the patient safety commissioner. The cases that led to the testimonies that you heard this morning are awful and extremely distressing, but the route by which we can avoid people having to go through such things in the future involves getting right the everyday provision of healthcare all the time. It is not just about the things that go very badly wrong and lead to those appalling and tragic cases; it is about getting right what some might call the small details every time. That is really important, because this is healthcare, and details matter. A big focus of our organisation is how we help healthcare providers to improve, to get things right at every level and to avoid the terrible cases that we have heard about.

It is particularly important that the issues that matter to the public and to patients get the prominence that they deserve and inform what we do. Our organisation definitely sees potential for the patient safety commissioner to help to identify such issues, get them on the table and hold everybody, including ourselves, to account for ensuring that they inform our actions to improve healthcare.

11:00

The Convener: Before I allow my colleagues to come in, I would like to ask you a follow-up question. This morning, we heard people describe a pattern of errors in particular health board areas of which their personal experiences had been one part. They had made the assumption that lessons had not been learned. How would Healthcare Improvement Scotland work in investigating such cases alongside a patient safety review? Would there be partnership working, or would there be an overlap? I would like to understand where you see that work taking place.

Simon Watson: Strictly speaking, our organisation would not normally take on an individual coming to us with one issue of concern. That would be directed to the provider, although we would follow up the matter to ensure that the provider had taken it on.

You are getting to the central issue. We would look for a pattern—or the possibility of one—in what we are seeing, which requires further inquiry. Most of the bespoke inquiries that we have done into systems and services have come about because there is a concern about such a pattern. There is either an acceptance that one exists or a concern that one might exist, so we would look at that.

As for how we would work with the commissioner, I suppose that that would come down to what their role in investigations would be. As the legislation is currently drafted, the role looks quite broad to us. Our organisation believes that it would be helpful to have clarity on the type of investigatory role that the patient safety commissioner would have, so that we could ensure that we were not duplicating what they did but were drawing from their work and vice versa. However, at the moment, the role seems to be drawn quite broadly so it is hard to be specific on how we might work together. Our intention is that, if a patient safety commissioner were to be created, we would work with them in partnership and, in particular, we would seek to hear the issues that they brought from patients and the public to inform our work.

The Convener: Would that include their telling you where they felt that you could step up or do things differently?

Simon Watson: Absolutely.

The Convener: We move to questions from my colleague Tess White.

Tess White: My line of questioning builds on the previous one. It is directed first to Rosemary Agnew and then to Simon Watson. I was particularly interested in your comments about the breadth of the remit of the PSC and the lack of clarity about the role's relationship with the existing clinical guidance landscape. I have two questions. First, how would you envisage your organisation working with the PSC? Secondly, are you concerned about the potential for duplication and overlaps?

Rosemary Agnew: On the first question, I echo some of the points that Simon Watson has just made. For me, the approach is about being able to work jointly. The investigatory remit of the PSC is important, but I keep returning to the fundamental objective, which is to ensure that the patient safety voice is heard and amplified. The starting point for the investigatory powers must be to have a sufficiently broad remit so as not to be restricted to

individual issues and to be clear about how they would investigate to test what they have heard.

I suspect that we will come on to data later. Data is only helpful in context, which is not always picked up when we look at data holistically. We should hear the patient's voice and about the experience that led to that data.

In terms of how we work together, I think there are huge opportunities for sharing information and for joint working, if the legislation allows us to.

We also have to be realistic about what each of us can achieve and we must be clear about signposting. Simon Watson referred to a moral duty. We already do a lot of signposting, but I want to be able to signpost with the confidence that I am not just passing somebody on; something should happen as a result of that.

Am I concerned about overlap? I am concerned that there is a risk of overlap. However, we need to be realistic about individual remits and the enabling of working together. The obvious area of overlap would be looking at individual cases and seeking individual redress. I have my doubts that that should be a function of a patient safety commissioner. I can see that there would be opportunities to look at recommendations for collective redress, such as recommending that the Government puts something in place to provide certain services. Individual cases, however, have to remain within the remits that they currently come under.

What would change is the context in which my organisation might look at an individual complaint because we might have better intelligence and data to know that an incident is not necessarily isolated. Equally, we might get only one or two cases about a specific issue, but when we share that information and data—I can see a role for a patient safety commissioner in that—that is when we might see a pattern emerging that is borne out by the lived experience and the voices of patients.

To cut a long story short, I envisage us working jointly. We have to manage the risk of not overlapping. There would be some help in gaining clarity around testing what the patient voice is saying in the context of data. I also really hope that the legislation enables everyone to work together and does not create another silo.

Dr Chopra: I am quite worried about the potential for duplication and that people will have to retell their stories to multiple commissioners. That can be traumatising—Simon Watson mentioned how difficult it must have been for the people whom you heard from earlier to retell their story.

Let us consider someone with a learning disability. We know that they are more likely to have delays in receiving treatment for sepsis. Furthermore, a report from HIS earlier this month showed that people with a learning disability did not have their chronic pain believed. Imagine that they have to tell that story to the Mental Welfare Commission for Scotland and to their health board or partnership, that the matter is escalated to the SPSO, that their details are collected through the community engagement aspect of HIS and that their case also then goes to the patient safety commissioner. That would be a huge risk for people. We therefore need to be absolutely clear about the remit of the patient safety commissioner.

In the remit section of the bill, there is a provision about the patient safety commissioner requiring health boards to work together. It would be helpful for that power to be extended to make sure that existing scrutiny bodies work together. In a previous committee evidence session with Simon Whale and Baroness Cumberlege, reference was made to the PSC being a "golden thread" that pulls those things together.

Sandesh Gulhane: I want to pick up on something that Rosemary Agnew said in her opening statement about patient whistleblowing. I am not talking about the extreme situations that Simon Watson mentioned. Before the pandemic, my experience in hospital was of long waits or of patients who were in wards that were particularly hot in the summer and they were feeling overwhelmed. They would tell me, as their doctor, and they would tell our nursing staff, but they would not put in a complaint because they were too worried about the staff. They saw that they were working as hard as they could and that it was not their fault. I found that, despite our raising those points, it did not make a difference until patients complained. Therefore, we were encouraging patients to complain.

Do you feel that having a patient safety commissioner would be a good way for stories like that to be picked up? We have heard about the golden thread. Alternatively, is the local complaints procedure the best place for such issues to be dealt with?

Rosemary Agnew: I think that the answer is that we need all that. However, the front line is where the voice needs to be heard. If the voice was heard at the front line, we would not need a patient safety commissioner. The question then becomes: how do we capture and listen to that voice, and act on it?

I can understand why people might not want to make a complaint, because it is a challenging thing to do and they might not be feeling in the best of health. In addition, there are occasions on which the issue is about the patient's experience rather than necessarily being about their treatment. There is sometimes a gap when it

comes to people knowing to whom they can say something such as, “I don’t feel unsafe, but I think that the whole patient experience would be improved if the ward was a bit cooler.” I think that the responsibility in that regard should lie with the board. The board should listen to such comments. If a patient safety commissioner also heard that, they could challenge a board and ask, “How are you capturing feedback?” In such situations, it is question of getting feedback.

We can extend that to situations in which someone has seen something that they think is unsafe. For members of staff or people who deliver the service, we now have a completely different whistleblowing regime from the one that we had two years ago. However, a patient might see something that might not affect them directly or that has not caused them to be unsafe but which they might want to report to someone. They might want to be able to say, “I was a bit warm, but I could go and sit by the window. There was a lady in the bed next to me who really looked as though she was going to pass out with the heat. I tried to tell somebody, but there was nobody around because everybody was really busy and I didn’t want to bother people.”

That might sound very minor in the grand scheme of things, but if a few people were to say, “There is an issue about the patient experience. Is this a risk?”, it might get noticed. We talk about data a lot. If people hear something a few times, they might do something, but it is necessary for them to hear the stories. When I say “stories”, I do not mean tales; I mean experiences that a patient safety commissioner could help with.

We are veering towards a view of a commissioner who might be critical or who might say, “Put this right,” but we could turn that the other way round; a commissioner could capture and amplify the voice of people, because it might be support that is needed at the front line, not criticism. It is as much a case of working with organisations to help them to learn and improve.

To come back to your initial question, I think that patients should be able to give feedback at the front line, but as soon as something concerns them because it appears to them to be unsafe or risky, they might not feel safe saying that. Whistleblowers will often come to us first, because they want the reassurance of knowing that they can trust the system. I can see a patient going to a patient safety commissioner in just that way.

The Convener: Simon Watson wants to respond to Tess White’s questions.

Simon Watson: I want to pick up the previous question, which was addressed to Rosemary Agnew and me. Many points have been made but, for me, the critical one is that a patient safety commissioner has the potential to be the voice of the less heard. I think that that was touched on in the discussion with the previous panel. It is absolutely critical that, if people see something that they are concerned about in relation to the safety of care, they speak up and are listened to, whether they are a member of staff, a patient or a relative. I believe that that is happening, and that it is happening much better than it did 20 years ago, but I do not believe that it is happening enough.

We then have the question of how we pick up those individual stories and turn them into a signal that the issue is one that we need to do something about. A patient safety commissioner could really help with that, to help us and other organisations to encourage the process of speaking up and getting these things out in the open. They would also help to bring attention to issues that are new or that have not had as much attention—or, in some cases, those things that we thought were not problems any more but which we hear still are. That is incredibly important intelligence.

11:15

On working together, we do that—I spend a lot of my time working with other national organisations on safety issues. I certainly see our organisation wanting to work with the commissioner, particularly to get that intelligence but also to be challenged on the motivation that we provide to ensure that something happens with it.

I am happy to comment on the duplication issues, but I think that that has probably been addressed, and I do not have much to add.

The Convener: Should patients be able to give feedback anonymously? Is that important?

Simon Watson: That is a really good question. I suppose that it depends on the issue. Ideally, you would have a culture in which people did not feel the need to be anonymous, but if it encourages people to be open and candid, at the end of the day, the most important thing is to find out what the issues are.

Rosemary Agnew: I will pick up on the point about anonymity, if I may. There is a difference between anonymity and confidentiality. Experience of whistleblowing has really brought home that, often, people want to be anonymous because they do not have confidence that what they say will be treated confidentially. One of the challenges, as Simon Watson said, will be to encourage people to speak openly, but that should be in an environment in which they are confident that their name will not appear all over everything and that the issue will be looked at, so it becomes about the issue, not the person.

The Convener: I was asking that question on the basis of comments made by Bill Wright, who was on the previous panel of witnesses. He made the point that people making complaints were almost seen to be the enemy. That point came across very strongly. I am sorry—I have butted in. I will bring in Paul Sweeney.

Paul Sweeney: I thank the witnesses for their comments so far. I will pick up what Dr Chopra and Mr Watson have said about the issues around inclusivity. The commissioner's remit is vast and they will have quite a narrow resource. There is a tendency for the sharpest elbows and well-resourced campaigns to get the attention. How do we ensure that there are protocols and mechanisms in place to ensure that the process remains inclusive? For example, last week, we heard about some medical devices impacting disproportionately on women, who are often ignored and dismissed by the medical profession. How do we ensure that those things are adequately addressed by the commissioner?

Dr Chopra: Your question echoes the conversation that the convener and Rosemary Agnew were just having about anonymity and confidentiality, because how we ensure that we hear the voices of marginalised groups is the nub of that question. We need to ensure that we hear the voices of those groups who have struggled the most to get their points across. In the earlier evidence session, you talked about valproate, which predominantly affected women, and mesh, which again affects women. There was a consistent theme about women not having their voices heard by the profession.

People from other marginalised groups, such as ethnic minorities, are not represented in the data on patient safety, and patient safety events predominantly affect marginalised groups, so it is incredibly important that we collect data about protected characteristics. I was somewhat disappointed when I was seeking to find out what feedback boards receive. When I asked whether feedback that is received at the most basic entry level—at board level—is stratified by protected characteristics, they said, "No, we can't do that. It's just not done." We do not know whose voices we are not hearing.

On how we ensure that we hear and pick up the right signals, we need to collect the board feedback, we need to look at the things that are reported to HIS under adverse events notification systems and we need to collect the data that comes to the Mental Welfare Commission for Scotland daily through phone calls and complaints. All those data sets then need to be brought together in one place. Arguably, that might be part of the strategic plan for the patient safety commissioner on day 1—to bring in those data sets so that they can hear the signals and relay them back to people like us to ask, "What are you doing about them?"

Simon Watson: It is an excellent question. As the committee and Parliament consider the legislation and the resourcing, the quality assurance aspect of the work is one of the important dimensions. The commissioner will need a system to ensure exactly what you said—the quality assurance that we are listening properly, hearing marginalised groups, getting proper samples and so on. That is not my area of expertise, but the expertise lies within our organisation, again predominantly in our community engagement directorate. I speak for our organisation when I say that we would be more than happy to help the commissioner to set that up, provided that it did not compromise their independence. Those standards exist. Part of the resource that the commissioner will need is that quality assurance so that they can assure themselves that, internally, the organisation is getting it right.

The final point is that strengthening that aspect of listening to those who are often unheard in the legislation would help to set the culture and the expectation.

Emma Harper: I will pick up on some of the questions about the patient safety commissioner's remit. Baroness Cumberlege's report wanted the commissioner to look at medicines and medical devices, which is what the commissioner in England is doing, but the remit here seems to be broader. Thinking about all the people who are involved in promoting safe patient care, there is a bit of a crossover that I am worried about. I am interested in how the panel feels about widening the remit to enable the patient safety commissioner to hear from people who have had poor experiences.

Rosemary Agnew: I am happy to go first. There is a difference between remit and scope. The current proposed scope of the patient safety commissioner is very broad. I was taken with something that one of the previous panel members said about the fact that it is all very well to identify things from the past but you do not know what the issues are going to be in the future. What our systems and, we hope, the patient safety commissioner will do is find a way to identify those early warning signals, as I think Simon Watson called them, and flag the issues so that we then look into them. Your remit is the extent to which you are able to do that.

It is right that the remit should cover more than just the two areas of known problems. The remit must be wide enough to enable the commissioner to react to and follow up new issues. The challenge in that regard is the resourcing and

strategic planning. It is about setting clear principles, which is not about a patient safety commissioner setting their own agenda. It is a case of their saying, “These are the principles that I will work to, to ensure that the patient voice is heard, acted on and listened to.”

Yes, it is absolutely appropriate that the commissioner would look at more than just the two areas that the commissioner in England deals with, but the scope or the extent to which those issues can be looked into is the detail of how far those investigatory powers go and how the commissioner works with others. Therefore, we must collectively ensure that the commissioner is able to follow up on those voices as far as they need to; it does not necessarily have to be voices on just those two issues.

Dr Lamont: The patient safety commissioner’s scope is about listening to the patient, taking that holistic view and identifying what we do not already have. If it was purely about identifying what we know with regard to complaints or concerns, we already have those systems in place. We are looking for a body that can take a holistic overview and provide a nurturing and learning culture, to encourage us to look beyond what we already know.

With reference to the previous question, there are barriers to patients presenting a complaint or a problem, and people may not be aware of what is underlying their concerns—they will have observed something or they will be concerned about it. It is important that the patient safety commissioner has the scope to be able to investigate and consider all aspects of patients’ experience.

Experience drawn from the incident reporting and investigation centre, which is part of National Services Scotland, has shown that the identification of even a small number of events—perhaps just one or two—can lead to the sharing, not only in Scotland, but across systems, of issues that present a risk for far more people. We are trying to identify trends before they cause harm. It is important that the patient safety commissioner has the scope to enable even a small number of individual concerns to be raised, so that the underlying issues can be identified and we can understand whether something can be put in place to avoid harm or an adverse experience for other people.

Simon Watson: Emma Harper asked an excellent question. You could argue that both approaches are right. I have been a doctor for 27 years. There is plenty to keep the patient safety commissioner in England occupied with medicines and technologies—they bring an awful lot of good, but the complexity of healthcare is such that they also bring safety issues.

However, a broader remit for a patient safety commissioner in Scotland would create the opportunity for there to be a good chance of understanding some of the more profound issues that might manifest with safety concerns in particular areas. A patient safety commissioner might spot patterns of safety issues with medicines or clinical practice that are all linked by common issues of—hypothetically—leadership, resourcing, changes in the way that staff are used or any number of things in a particular organisation. Logically, the broader the commissioner’s radar is set up, the greater the opportunity to spot the issues that would provide a more profound knowledge of safety concerns, which would then give us the opportunity to address them and solve a number of problems at once.

Those are the opportunities that a broader remit could create. It would require a lot of resource and support, but it is an important aspect of the commissioner’s potential that it would be good to keep sight of.

Dr Chopra: The Mental Welfare Commission supported the broader scope as outlined in the Scottish bill in comparison with the English legislation. It is important not only to focus on medicines and medical devices but to look across healthcare, because most patients and members of the public do not differentiate between their medicines and the systems through which those are derived. That is why we were supportive of the scope being broadened.

In some ways, the scope might be too narrow. Currently, delayed discharge from hospitals is the issue that is of the most concern to many of the people who phone us; we pick up on that on our visits, too. Delayed discharge causes harm. I wonder whether the remit to focus purely on healthcare goes against the grain of where we are trying to go with integration. It might be important to think about health and social care. How that would fit across the integration agenda needs to be thought about, which suggests that we might need to broaden the remit.

We would then face a question about what we would give up, because the resourcing is quite small. I have already said that the primary function must be to amplify the patient voice, rather than to start doing things around systemic improvement, which probably fits more with HIS.

I am also worried about investigations, because in the bill as it is currently drafted, it is not clear whether the reference is to individual investigations or thematic ones. We have experience of doing both types of investigation and they are resource intensive. If the commissioner and four members of staff were to start doing investigations, I do not think that they

would have the scope to do some of the work, such as bringing the data together, investigating it or being able to relay information. Those members of staff would have to be solely focused on investigations. A forward plan could be to start small and to look across the remit of health and social care, but focus on only certain aspects of it. It would be for the patient safety commissioner to determine the priorities, but I think that that might be the way forward over the next few years.

Emma Harper: Dr Lamont, I want to pick up on what you said about amplifying the patient's voice and about avoiding harm in the first place and addressing concerns. I will use an example that I used last week. People in the south-west of Scotland get radiotherapy in Edinburgh, which means that on their way they pass within 4 miles of the Beatson cancer care centre. I think that it is a 240-mile round trip. People's voices in the south-west of Scotland are not being heard when it comes to cancer pathways, for instance. Harm has not necessarily occurred, but the simple fact of being those miles away from their family, Monday to Friday, might lead someone to drop out of radiotherapy. They might say, "I'm fed up. I'm no doing it any more." Is that something that the patient safety commissioner could consider? They could go to NHS National Services Scotland or Healthcare Improvement Scotland—whichever pathway it is—to help to sort it out.

11:30

Dr Lamont: We have to recognise that some of this is about resource limitation. Providing resources and services from multiple sites is always desirable. At the moment, we are considering expansion of some specialist services to multiple sites for exactly those sorts of reasons.

There is always a challenge because, in a very resource-constrained situation, if you move resources to use at one site, you take them away from another. There is a role here for a holistic view of where resources can best be used to provide the best services for patients. There will be a lot of issues for a patient safety commissioner to consider, and there will be a lot of demand when it comes to things that they might want to consider, so how things are prioritised will be an important part of how the approach is constructed.

In the first instance, that might involve responding to small numbers of adverse incidents and events, and concerns that are raised, and trying to identify trends. Baroness Cumberlege's report was primarily about identifying trends and about listening to a small number of voices, amplifying them and understanding whether other people shared those concerns. The organisations in NHS National Services Scotland listen to reports from professionals; we do not receive many reports from patients, which is where I think the gap will be.

Paul Sweeney: Those were really important points about anticipating problems. Service design is done in the context of resource constraints. There is a finite resource that cannot neatly match increasing demand. Inevitably, decisions that are made will have safety implications. A recent example is that the Glasgow health and social care partnership has advised that, under the current settlement for local government, it will not be able to meet its statutory requirement for service delivery in Glasgow. There is clearly a patient safety consideration there.

Is there scope for the commissioner to have a role in assessing decisions within different public bodies about the potential impact on patient safety, and perhaps making a recommendation to Parliament on what the commissioner thinks is the optimum balance or solution in that context? It is not necessarily a patient referring an issue that they are reacting to; rather, it is anticipating the allocation of constrained resources in a difficult environment, such as the one that we are looking at now, in the budgets, and considering the impact of such decisions. The impact, for example, on discharges from mental health estates into more appropriate settings, is that patients might have to stay in hospital as opposed to being discharged.

Rosemary Agnew: Let me make a reflection on the discussion that we are having. The patient safety commissioner will not be there to put the NHS right in every single way. In thinking about this, because I have been involved in consultation, I bring myself back constantly to the amplification of the voice. It would be quite helpful if it were more clearly articulated in the bill that the patient safety commissioner is not simply an organisation with an interest and remit in patient safety but will have a clear and important focus on making sure that the patient voice is heard.

I have been trying to think of examples from my experience of looking at really upsetting and tragic complaints about audiology services in a board. On that matter, one of the recommendations that I made was not, "Go and do this, this and this," but that the outcomes that were needed for all patients who receive that service should be defined. I recommended an independent audit from specialists, and it was that independent audit that was able to identify the detailed clinical issues.

We have to be careful to include in the remit of the patient safety commissioner the power to be able to recommend that others take action, so that the PSC does not necessarily feel that they have do everything themselves. Speaking from my experience, I have a whole host of expert advisers on whom I can call for complaint handling. We run the risk of expecting so much from the patient

safety commissioner that they will not be able to achieve it all—they will get blinded in the headlamps.

Alison Cave: This is a really valuable conversation, and I am reflecting on all the comments that have been made. The scope is so broad that it might be impossible to achieve, so we really need to think about how the patient safety commissioner would amplify patient voices, which is absolutely key. I refer back to the question about sodium valproate that was asked right at the beginning: amplifying the patient voice earlier might have led to earlier action.

It will be really important that the commissioner can identify gaps where systemic change could make a difference. If we reflect on the Cumberlege report, we can see that a small team was able to identify systemic problems where change could make a difference. Even for the MHRA, the team identified what the system did not know, and that we needed a new, comprehensive system to ensure that we were capturing signals and were able to understand where the harm was.

It is important to reflect on the scope. Like Rosemary Agnew, I have people who do extensive benefit-risk reviews; it would be impossible for four individuals to be able to achieve that. Obviously, it is a case of charging other organisations within the health ecosystem to take up the challenges or address the gaps that they find.

The Convener: I will bring in Simon Watson then move to questions from Gillian Mackay. We will look at the medicines and medical devices aspect before we go back to data and information gathering.

Simon Watson: I will try to be brief. The last two committee members' points were very interesting and I just reflect that there is a duty, across all the boards in the NHS, to consult on major service change and that our organisation supports the processes to do that well. Of course, part of doing that well is about recognising that every solution will inevitably carry risks that need to be monitored. All our organisations have duties around properly hearing the voice of patients when those risks relate to patient safety. Again, I can see how the commissioner could add to that, by spotting and amplifying issues.

Gillian Mackay: I think that my questions will probably mostly be to Alison Cave. How can the new patient safety commissioner add value to the existing monitoring systems around medicines and medical devices?

Alison Cave: As I indicated, we have something called the yellow card system, and we recently invested significantly to upgrade and improve it. It collects spontaneous reports—as we call them—or suspected adverse events from the whole of the UK. Before I came to the meeting, I was reflecting on how a patient safety commissioner adds value. It is, again, about amplifying the voice of the patient. We get reports, but we do not hear directly from the patient when it comes to all those reports, so that is a very valuable point.

It might be valuable for the commissioner to reflect on what might be more of a local issue that could lead to a safety concern or issue. That might be about how healthcare is delivered locally, or human factors in a local area that might be harder for a UK-wide organisation to understand. The commissioner would also be valuable in helping us to communicate safety messages, to ensure that they are heard appropriately and acted on, and in helping us to understand whether such messages have the intended impact. That could also involve highlighting whether there are unintended consequences of our actions of which we should be aware, or whether further actions are needed because current actions are not having the intended effect.

That work could be extremely valuable in a number of areas. When the individual is appointed, we would look to work with them to understand how we can best work synergistically rather than duplicating effort.

Gillian Mackay: We discussed the duplication of effort across the UK with the Patient Safety Commissioner for England. What working arrangements will need to be put in place to ensure that there is no such duplication and that individual issues in different jurisdictions can be tackled, while enabling information to be shared where there might be a UK-wide issue?

Alison Cave: It will be important for us to understand how we would share data and information. We already have quite a complex ecosystem to help us. For example, we have the Yellow Card Centre Scotland in Edinburgh, along with an incident reporting and investigation centre and a network of safety officers who help to identify and spot trends. All the colleagues who are sitting at this table would be involved, too.

It would be important, in reflecting on the conversation, to say, "Where are the gaps? Where are we missing things? Where are things falling through the cracks?" and work together to put in place a plan. That will ensure that the role of patient safety commissioner has the greatest chance of making a real, meaningful impact for patients, so that they feel that it makes a difference to their lives and ultimately improves patient safety. However, careful reflection will be required to ensure that we are not duplicating effort.

The Convener: We go back to talking about data and information gathering, with questions led by Evelyn Tweed.

Evelyn Tweed: Good morning, panel. Gillian Mackay asked a really good question, because it segues nicely into my question.

We have been speaking a lot about data and trends—we hear in evidence, no matter which committee meeting it is, that we need to be on top of that. That area is obviously key for the patient safety commissioner.

On Alison Cave's last point about a plan for working strategically with the new patient safety commissioner, that will be key to making sure that the role works in practice and that we move forward. How are your organisations going to do that strategically? Do you see any barriers there?

Alison Cave: I can start. The current Patient Safety Commissioner for England is relatively new in her role; her report on her first 100 days in post has just been released. I am having regular meetings with her and we are setting up a framework under which we can work together, because it is key that she retains her independence within any process. I would look to have the same framework with the patient safety commissioner in Scotland, whereby we have regular meetings and interactions and together develop a framework that the commissioner thinks can best support their work and their strategic plan.

It would be good to feed back on where we see that better data gathering or processes could improve patient safety. Thinking back to the valproate issue, a key aspect has been to understand the impact of risk minimisation measures that were put in place in 2018 and whether they have had the required impact. Those sorts of processes, including data-gathering and monitoring exercises, will be key to working with the patient safety commissioner to understand how we can best support each other.

11:45

Dr Lamont: There is an opportunity here for the patient safety commissioner to improve that data gathering in order to make it consistent. At the moment, local authorities, health boards and patients have multiple ways of recording data—in fact, if incidents take place in boards, there are different systems to report them locally and nationally, which do not talk to each other or collaborate. There is an opportunity here to prioritise that collaboration and bring that data together. It is about working with existing safety organisations. At the moment, for example, under the yellow card system, data is reported in England and then back into Scotland, so it is about making those processes work better for us.

We have talked about the duplication of roles, but there is also duplication of reporting. It is sometimes quite difficult to understand the true numbers of incident reports. Some areas report more diligently than others, which is sometimes to do with the amount of time and resource that can be put into that process.

The heart of the matter is the identification of trends. Sometimes, those trends are very small signals—we are quite a small country, so it is important that we have a four-nations approach to understand where they can be brought together. The MHRA is an organisation that spans the countries and is a great example of how such signals can be amplified.

At the moment, many of the systems focus on reporting from professionals. There is an opportunity here for parallel mechanisms that amplify the patient voice. Where there are small signals within individual nations, they can be brought together to recognise the concern.

That is applicable in Scotland. Many of the examples that I have from the NHS National Services Scotland incident reporting centre are very small—two, three, four or five events that have happened across the UK, which lead to investigations about concerns, then to collaborations with manufacturers, then to checking and changing the process, and then to future patient safety. With the patient safety commissioner we have the opportunity to mirror that system for patient voices.

The Convener: Can I move to questions from your colleagues, Evelyn?

Sorry—Dr Chopra wants to come in.

Dr Chopra: It is an excellent question about how we use those data sets. Some of it is about improving the existing data sets. When the patient safety commissioner comes into role, one of the first things that they will grapple with is the question of what the signals are. If we look at the HIS adverse events notification system, which lists the top five areas, we see that the top area for the most adverse events is mental health—it dwarfs the other four put together. Some of that is to do with the standardisation of what gets reported and ensuring that we are not comparing apples and oranges. It is about ensuring, too, that the existing upstream data sets are improved to a quality that makes them meaningful for the patient safety commissioner to use.

The second point is around merging the existing data sets. We have already mentioned a few. Care Opinion, which we use, would need to be brought in, and would be part of getting those data sets

together. An equalities focus would be needed so that we do not leave anyone behind.

Those things are already in use, and that is where the patient safety commissioner role could add value. Last week, I was speaking to the Patient Safety Commissioner for England, Henrietta Hughes, and I asked her what were the top things that she was hearing in the area of mental health, in which I work. She was immediately able to give me a response about the suicidality that is related to people using particular medicines for skin conditions, post-serotonergic difficulties—which people get when they have been on an antidepressant for too long—and electroconvulsive therapy or ECT. Those are the signals that her team and she are picking up from emails and phone call conversations. That work adds value to the existing mechanisms that we have.

Rosemary Agnew: We cannot ignore that there needs to be a culture of valuing data and what it is telling us. I fully support everything that everybody has said, but ultimately the richest data is probably within boards themselves. We need to be able to use that data easily, so we would need consistency between boards on not just what they collect but how they collect it.

It is important that that is linked into an expectation of what happens with governance. Using, reviewing and ensuring the accuracy of your organisation's data should be an integral part of a governance system.

The Convener: Colleagues, I am going to move us on. We have got only 20 minutes left and we still have two substantive themes to discuss: independence from the Scottish Government and the NHS, and resourcing. If we have time at the end, we can come back to any outstanding questions that members have, but it is important that we give those two themes a good airing.

Our questions on independence from the Scottish Government and the NHS will be led by David Torrance.

David Torrance: Good morning, everybody. Do you think that the patient safety commissioner should be independent of the Scottish Government and the NHS, and, if so, do the provisions in the bill ensure that independence? I will go to Rosemary Agnew first.

Rosemary Agnew: I thought that you might. When I was preparing for this, in my head I was using phrases such as "the benefits of independence" and "I value independence", but I have decided that I treasure the independence that I have, because being completely independent of the Government and the NHS ensures not only that I can be objective but that I can be seen to be objective. It means that I can be objective in any decisions that I make on complaints or complaints standards, in what I investigate, in the scope of my investigations and in how I go about them, supported by the powers that I have to obtain information. That is completely and utterly critical to the role. Three words that I consistently heard from the previous panel were "confidence", "trust" and "truth". If you do not have somebody who is not just independent but demonstrably independent, it will be hard to establish that confidence and trust.

I would raise only one question. The focus has been on the commissioner being a parliamentary body. I know that there is lots of debate about whether there are too many parliamentary bodies and what have you, but if you focus on the independence, and on the appropriate model to deliver that, that will probably lead you to the answer that is appropriate.

David Torrance: How can the patient safety commissioner embed themselves in the current system and still stay truly independent?

Dr Chopra: The Mental Welfare Commission is independent of the Scottish Government and the NHS. I, too, treasure that. It is vital to be demonstrably independent from both those organisations. It matters to people. People notice biases or perceived biases, so that independence is crucial.

David Torrance's second question, about how the commissioner remains embedded in the system while retaining their independence, is an issue of resources. It is about how the commissioner discharges their function, how they do their outreach, how they do their broadcast, how they hear from people, and how they visit and see hospitals or communities. We need to move the focus into communities and social care. That will be the important bit. How will the commissioner receive intelligence? That will allow them to be embedded in the system and yet maintain their independence.

Simon Watson: Those are excellent questions. We in Healthcare Improvement Scotland believe that the patient safety commissioner should be independent, as David Torrance has described. The reasons for that are focused on adding value. HIS is part of the NHS. We are there as a national organisation to drive improvement, and much of our focus, as has already been alluded to, is on getting it right first time out there in the system, and on how we help others. That is a very specific role.

We have a role in independent healthcare as well, but the NHS is where most of our work is focused. There are advantages to being embedded in the NHS. When we do our inspection work, we do it with a high degree of

independence. We have a framework that describes how we should do that, and it is in nobody's interest, including ours, not to follow that. I think that we can demonstrate that we do.

However, this is about a new role. I think that the committee has talked about duplication. If I can put the focus on adding value, as I think some of my colleagues have said, the public would see the commissioner as their person, who is there to listen to their views, hear their stories and raise issues that either they are seeing or their stories help to describe. If the commissioner is to be their person, the purest way to do that is to give them such independence.

David Torrance's question was about how we do that. That is complicated, but my suggestion is that, as a broad principle, the commissioner should focus on adding value and guiding those of us in public bodies and others to new areas—in other words, the commissioner should not necessarily focus on what we are already doing, unless they think that we are doing it badly, in which case they should call it out. They should be able to say, "You are all focused over here, but I've been speaking to the public and I think there's something over there that you need to look at." By definition, if we are not there doing something about it, we are not embedded.

I realise that that is a bit of a conceptual answer, but I hope that that is helpful.

Dr Lamont: I have a brief point to add, if I may. One of the benefits of independence is that the remit does not have to be just in healthcare, although "just" is probably an understatement. The commissioner also needs to cover the private sector, the third sector and organisations that would not necessarily be covered if they were associated with a health board or health services, or even local authorities. We need to recognise that care has a broader definition than simply applying to health and social care. It includes the element of harm that could happen because of lack of access to services, which might not be being provided. There might not be an organisation that is accountable at that stage.

The Convener: Paul O'Kane has a question on the same theme.

Paul O'Kane: What has been said about the commissioner's independence is helpful. I want to pick up on what Dr Lamont said.

Do you see the patient safety commissioner having a wider role in social care? Given the debates that we are having in Parliament around a national care service and the potential for the provision of care to change, do you think that the commissioner might be able to go beyond their present scope? How would we hold the commissioner and ministers accountable in that space?

Dr Lamont: We have already said that it is important that the commissioner has a remit that would be broader than healthcare alone. Primarily, that is because we have been speaking about amplifying the patient voice. The patient, or the person, does not necessarily differentiate between care that is provided by a health organisation, care that is provided by a local authority and care that is provided by a private sector or third sector organisation. The commissioner has to have independence, so that they can provide the necessary oversight.

Mention has been made of the need to be able to take a holistic view and of the golden thread that weaves services together. We have identified that there is a gap there. Therefore, independence is required to be able to cover all those services and to look at a person's journey between all services and how their voice is heard.

As far as accountability is concerned, that is outside my remit. It will be for the Government to understand what the commissioner's accountability will be. We can look at examples of other organisations that are here today, whereby they remain accountable but are also independent.

The Convener: Does anyone else want to come in?

Alison Cave: Transparency will be key in ensuring that independence and in ensuring the trust of the patients who come to the patient commissioner. There needs to be transparency on actions, the governance framework and communications.

Rosemary Agnew: We hear a lot about processes, systems and legislation, but if we reflect back on the voices that we heard earlier this morning, we realise that we are very much talking about people and human beings. Whoever the patient safety commissioner is is important, so recruitment is important. The values and principles that they put in place for their organisation are important, too. Independence is what led me to that, because it is one of my organisation's values. It is not one that I have imposed; it is a value that we, as an organisation, hold dear. We strive to maintain that independence.

Therefore, it is really important who becomes the patient safety commissioner, because you cannot amplify a voice if people do not talk to you.

The Convener: As Paul has no more questions, we move to our final theme, which is resources and resourcing. The questions will be led by Sandesh Gulhane.

12:00

Sandesh Gulhane: I asked this question of the patient witness panel, and I am keen to ask you the same and also to bring in the threads of what has been said already. Dr Lamont talked about the fact that the commissioner will need to hear from individual patients. Simon Watson spoke about capturing patterns and about how, ideally, individuals will speak to the commissioner. The policy memorandum estimates that the commissioner will have four staff. Clearly, a lot more individuals will come forward, and, if patients are going to go directly to the commissioner, the numbers could be in the thousands. Do we need to significantly increase the number of staff and, if so, do we need to significantly increase the budget?

Alison Cave: I give the example of the incident reporting centre that we have in Scotland, which has four staff. It receives all the incident reports relating to estates, facilities and medical devices across Scotland. That works because there is a network of safety officers across all local authorities and health boards—that is a requirement on all the health boards—and they work together. It would be necessary for a commissioner to work with existing networks.

It is not for me to state whether the proposal for four staff would be effective to do that. It is important that we do not try to remake existing networks and that we link in with services such as the MHRA and Healthcare Improvement Scotland and utilise what is already there. If it can be made to work, we must try to work with existing services, because, as I said earlier, we work in a very resource-constrained service across health and social care, so we have a responsibility to work with existing services and budgets wherever possible.

Simon Watson: That is a critical question. I refer to the sections in the bill on investigation and the investigatory aspects of the role of the commissioner. We operate close to that space in that we do reviews and inspection work, and we know how important it is—for obvious reasons—to get that right, in a timely way. If we have learned anything about patient safety issues over the past few decades, it is that what might seem straightforward on the surface is usually very tangled and complex underneath, and teasing it apart requires clear methods, skilled people who do stressful jobs and require quite a lot of support from managers and, as I alluded to in the previous conversation, quality assurance to get it right. As you start to describe that, you suddenly see the expanding array of resource that is needed to do all that.

Therefore, if independence is going to be a key feature of the role, a central question for the role of the commissioner is whether they need independence from all the investigatory machinery or can work in partnership with others and use the knowledge that others already have. That is quite a tricky question to answer, because it could be perceived that, if the commissioner was using other people's investigatory work, they were dependent and not independent.

I see the question about the investigatory remit and its breadth as possibly one of the more significant factors in how big the resource needs to be. If the committee wishes to see further information on what we do in that regard, we are happy to provide it. You might want to look at what other organisations, such as the Healthcare Safety Investigation Branch in England, do, too.

Rosemary Agnew: I will share my experience of taking on new functions. When I took on the Independent National Whistleblowing Officer function, there was very little data about the number of whistleblowing cases in health boards, and I experienced the fact that, when you first set up such an organisation, you actually do not really know what you will need. The very first bit of funding comes from Government. It directly gave us the funding to do a bit of research and some setting up, but, because we are a parliamentary body, the annual budget then became part of the Parliament's budget.

The issue is that you do not know at the start what you will need two years down the line. How such bodies are set up in the first place and, in particular, how the financial planning for them is done is important. If it is decided that a significant increase in resourcing is needed, how does that reflect what, in effect, was a Government policy? Those bodies become part of the parliamentary budget-making system.

You could argue that what has been allocated for the commissioner is or is not the right amount of resource, but it will probably come down to the officeholder being realistic about what they can achieve with the level of resource that they are given. As an officeholder, I consider that question every day. It is not just about how the organisation is funded and set up; it is about the planning for review and how the organisation can adapt once the officeholder has a better understanding of how the role has evolved. If you listen to all the discussions that we have been having, you can see that the organisation could be set up in many ways, but you do not really know until you start. It might be a case of starting small with a framework to get bigger and a clear plan of how that is likely to happen if it is needed.

Dr Chopra: Briefly, duplication must be avoided. From my perspective, Simon Watson's point about investigations is crucial. We have been making some comparisons with the role of the

patient safety commissioner down south. Baroness Cumberlege said clearly to the committee that the commissioner in England does not do investigations, and Henrietta Hughes said the same thing to me. That leaves a gap as to who will do the individual investigations in our landscape. In England, the Healthcare Safety Investigation Branch will become a statutory body, and it undertakes that role as well as training on investigations. That is the kind of gap that might remain in Scotland. The committee's deliberations on whether the investigation function needs to remain within the scope of the commissioner is crucial to the question whether the resource is adequate or requires to be expanded in order to replicate the landscape in other parts of the UK.

Sandesh Gulhane: Thank you for your answers. We would love to see that information, Simon.

I return to what Rosemary Agnew said. I know that I am veering outside of the resource theme, but this is important. If we set up an organisation that had the scope to expand, what would our measure of success be that would indicate that it needed to expand?

Rosemary Agnew: You could argue that the measure of success would be that it did not need to expand. I will reflect on the period when Henrietta Hughes took up the national guardian role. In the first couple of years, not many cases were taken to that body, but it grew exponentially. The measure of success would probably be something basic such as volume, because the exponential rise in the cases that she received and heard represented a growth in confidence. Another measure—I do not know precisely how this would be done—would be impact: if the patients' voice was amplified, what happened as a result and what was the impact? Is there another way of demonstrating that patient safety has improved?

That is where I think that it will be important to combine data and to have an overview of it. Some of the indicators of success will not be within the patient safety commissioner's remit. The indicators that demonstrate that something has changed might come from the data that the officeholder receives, but it might be from the mental welfare commissioner's data. On straightforward things, measuring success will be a matter of the officeholder doing what they are able to do. If the budget does not extend to investigations because they are resource intensive, the patient safety commissioner might have to take a strategic decision and say, "Strategically, I am listening to my advisory board, identifying the issues and getting them looked at somewhere else," which is important. The measure of success would then be whether patients were listened to and taken seriously and whether something happened as a result.

The Convener: I apologise to members who want to ask more questions, as we have run out of time. We go to Tess White for a final question.

Tess White: I have a quick question for Rosemary Agnew. The Finance and Public Administration Committee recently highlighted concerns regarding the financial impact of having yet another commissioner. This builds on what Dr Gulhane has said. What resourcing is necessary for the officeholder to be effective?

Rosemary Agnew: That is a hard question, because the resourcing that is necessary is what is enough. I am not being flippant when I say that. It comes back to the points that have been made about remit. If there is a serious requirement for the commissioner to have an investigatory capacity, the body will need more staff than it has currently been allocated. If the remit includes amplifying the patients' voice, focusing on awareness raising and passing on issues to other organisations, the commissioner's resource might be enough. However, I return to my earlier point, which is that you do not really know until you start. The resource is very small. In my organisation, it is not just about the team that answers the phone, gives advice and signposts information; it is also about the communications team—we struggle to have the level of stakeholder engagement that I would like us to have. There will always be a balance between what is available and what you can do with it. Instinctively, I think that the allocated resource for the commissioner feels a bit light, if I am honest.

The Convener: We have run out of time, sadly. I thank all our witnesses for what they have told us and the opinions that they have given on the Patient Safety Commissioner for Scotland Bill. We will continue our scrutiny of it in our next meeting. That concludes the public part of our meeting.

12:12

Meeting continued in private until 12:41.

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