OFFICIAL REPORT
AITHISG OIFIGEIL

Health and Sport Committee

Tuesday 7 May 2019

Session 5

The Scottish Parliament
Pàrlamaid na h-Alba

Tuesday 7 May 2019

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HEALTH AND SPORT COMMITTEE

13th Meeting 2019, Session 5

CONVENER

*Lewis Macdonald (North East Scotland) (Lab)

DEPUTY CONVENER

*Emma Harper (South Scotland) (SNP)

COMMITTEE MEMBERS

*George Adam (Paisley) (SNP)
*Miles Briggs (Lothian) (Con)
*Alex Cole-Hamilton (Edinburgh Western) (LD)
*David Stewart (Highlands and Islands) (Lab)
*David Torrance (Kirkcaldy) (SNP)
*Sandra White (Glasgow Kelvin) (SNP)
*Brian Whittle (South Scotland) (Con)

*attended

THE FOLLOWING ALSO ATTENDED:

Jeremy Balfour (Lothian) (Con)
Joe FitzPatrick (Minister for Public Health, Sport and Wellbeing)
Gordon Lindhurst (Lothian) (Con)
Mike Rumbles (North East Scotland) (LD)

CLERK TO THE COMMITTEE

David Cullum

LOCATION

The James Clerk Maxwell Room (CR4)

Scottish Parliament

Health and Sport Committee

Tuesday 7 May 2019

[The Convener opened the meeting at 10:00]

European Union (Withdrawal) Act 2018

Public Health and Tobacco (EU Exit) (Scotland) (Amendment) Regulations 2019 (SSI 2019/142)

The Convener (Lewis Macdonald): Good morning and welcome to the 13th meeting in 2019 of the Health and Sport Committee. I ask everyone in the room to ensure that their mobile phones are off or on silent and not to use mobile devices for photography or recording.

Under agenda items 1 and 2, the committee will consider the Public Health and Tobacco (EU Exit) (Scotland) (Amendment) Regulations 2019, which are related to the European Union (Withdrawal) Act 2018. The purpose of the regulations is to make minor technical changes that are required to correct legislative deficiencies that will arise as a consequence of the United Kingdom leaving the European Union. Under item 1, we will consider the categorisation of the regulations.

Colleagues will be familiar with the protocol that has been agreed between the Scottish Government and the Scottish Parliament for the categorisation of significance of Scottish statutory instruments laid under the European Union (Withdrawal) Act 2018. The protocol sets out an approach for that categorisation and gives the Delegated Powers and Law Reform Committee a role in highlighting to the lead committee whether there is a categorisation issue. In this case, the SSI has been categorised as medium, and the Scottish Government has identified that the negative procedure is appropriate for it.

The DPLR Committee considered the SSI at its meeting on 30 April and agreed that it had been laid under the appropriate procedure and had been given the appropriate categorisation. There were no matters that the DPLR Committee wished to draw to the attention of this committee.

Are members content that the procedure and the categorisation that the Scottish Government has given to the regulations are appropriate?

Members *indicated agreement.*

Subordinate Legislation

Public Health and Tobacco (EU Exit) (Scotland) (Amendment) Regulations 2019 (SSI 2019/142)

10:02

The Convener: Under item 2, the committee will consider the Public Health and Tobacco (EU Exit) (Scotland) (Amendment) Regulations 2019 under the negative procedure. The Delegated Powers and Law Reform Committee determined that it did not need to draw the Parliament's attention to the regulations on any grounds within its remit when it considered them on 30 April. As members have no comments on the regulations, does the committee agree that we should make no recommendations on them?

Members *indicated agreement.*

Human Tissue (Authorisation) (Scotland) Bill: Stage 2

10:02

The Convener: Item 3 is stage 2 consideration of the Human Tissue (Authorisation) (Scotland) Bill. I welcome the Minister for Public Health, Sport and Wellbeing, Joe FitzPatrick.

The Minister for Public Health, Sport and Wellbeing (Joe FitzPatrick): Good morning.

The Convener: Good morning.

The minister is accompanied by Sharon Grant of the Scottish Government bill team; Jackie Pantony and Claire Montgomery from the Scottish Government legal directorate; and Max McGill from the parliamentary counsel office. I understand that members of the team will come and go according to the particular items that we are discussing. I also welcome Jeremy Balfour, who has lodged amendments to the bill. I believe that Gordon Lindhurst will join us later this morning to speak to amendments that he has lodged.

I will briefly explain the procedure, as this is our first consideration of the bill at stage 2.

There will be one debate on each group of amendments. I will call the member who lodged the first amendment in the group to speak to and move that amendment and to speak to all the other amendments in the group. I will then call any other members who have lodged amendments in the group. Other members may, of course, catch my eye and indicate their intention to speak to the group of amendments. If the minister has not already spoken to the group of amendments, I will invite him to contribute to the debate before I ask the member who moved the amendment to wind up. The debate on the group will be concluded by my inviting the member who moved the first amendment in the group to wind up.

Following the debate on each group, I will ask whether the member who moved the first amendment in the group wishes to press it to a vote or to withdraw it. If they wish to press it, I will put the question on the amendment.

If a member wishes to withdraw their amendment after it has been moved, they must seek the agreement of other members to do so. Any member present may object and therefore require a vote on the amendment.

If a member does not move their amendment, any other member may move it. Failing that, I will move on to the next amendment on the marshalled list.

Voting is by members of the committee only, and voting on any division is by a show of hands. If there are divisions, members should indicate their intention clearly and for long enough that their vote can be recorded.

We move directly to consideration of the bill at stage 2. If we are successful in completing stage 2 today, it would clearly be a good thing. If we are not successful in completing stage 2 today, the bill will be reprinted first thing tomorrow morning and further amendments can be lodged. However, let us press on.

Section 1 agreed to.

Section 2—Information and awareness about authorisation of transplantation and about pre-death procedures

The Convener: The first group of amendments to the bill covers information and awareness. Amendment 4, in the name of Jeremy Balfour, is grouped with amendments 56, 57, 7, 8 and 63.

Members should note that amendments 7 and 8 are direct alternatives to each other. That means that both can be decided on and, if both were agreed to, the last one that was agreed to would apply. Clearly, that is a matter for members to consider when they come to it.

Jeremy Balfour (Lothian) (Con): Thank you, convener, and good morning to the committee and the minister. I start by saying that this is a very helpful bill, which I think has all-party support. The amendments that I will put forward this morning seek to strengthen the bill and make it work better.

The key amendment that I am putting forward is amendment 4, which relates to the issue of informed consent. I hope that a positive of the bill will be that it will kick-start a debate in Scotland on organ donation, so that families and individuals will be able to have better conversations, meaning that, when someone is dead, the family is better informed.

The evidence from Wales has been positive. Before the bill that became the Human Transplantation (Wales) Act 2013 was introduced, public awareness in Wales was fairly low. Since then, it has greatly increased, which is very positive. I am aware that the Scottish Government has committed to putting in a lot of resource when this bill becomes an act, so that there will be advertising and suchlike, including on the television. However, the question is how we keep the conversation going over the next five to 10 years. There is a danger that there will be a high take-up initially, when people understand that it is going on, but that it becomes less well known as other issues come on to our agenda and things move on.

If we are to have informed consent, it has to be genuinely informed. People who are 16 or older now will be part of the awareness campaign. However, people who are behind that group in years may not be aware of what is going on. Amendment 4 would simply commit the Scottish Government to ensuring that there is some kind of communication with people in Scotland every two years. I do not suggest that it has to be an individual letter to each person. It could work well if the communication went out with other communication, such as council tax letters or other forms, on a two-yearly basis, so that people would be aware.

The advantage of that would be that it would allow the debate to continue over the next four, five or 10 years. It would also mean that those who are turning 16 would be aware of it. It will be a number of years before those who are eight, 10 or 11 years old at the moment reach that time—will they be informed about the decisions that they are being asked to make?

I would be interested to know the views of the Scottish Government and the committee on the matter. A key part of the bill relates to informed consent, and we need to ensure that there is informed consent not only now but in the future.

As the convener said, amendments 7 and 8 are direct alternatives, which would give either a two-year or a three-year option. The amendments relate to people who come not from the United Kingdom but from Europe or other parts of the world. At the moment, there is a period of one year before a person from a different jurisdiction enters the system. Again, my concern relates to informed consent. If someone pitches up from Australia, will the issue come on to their radar within the first 12 months of their being in Scotland? I am not convinced that it will.

I accept that the Welsh have gone for a 12-month period, and I think that the legislation for England includes the same period, but we do not need to follow suit. We need to be comfortable in ourselves that there is deemed authorisation that comes from individuals giving informed consent. I suggest that a slightly longer period than one year is required for an individual to know what is going on and to be able to have the appropriate conversations with his or her relatives in other parts of the world.

I move amendment 4.

The Convener: I have lodged two amendments in the group, following discussions, particularly with the Law Society of Scotland, on the most appropriate format for addressing the issues, including those that Jeremy Balfour has raised.

Amendment 56 would ensure that the duty to promote information and awareness is continuous and that ministers should promote awareness at least on an annual basis. Amendment 63 would amend the bill to provide for a two-year information and awareness period before the commencement of the provisions in the bill. The amendments are linked, but they need not be agreed to together. They are intended to achieve the same objective: to allow for an adequate level of information and awareness in advance of the bill's implementation.

David Stewart (Highlands and Islands) (Lab): I thank the minister for meeting me to discuss the generalities of the amendments. Like Jeremy Balfour, the Labour Party and I are very supportive of the bill's general principles, but there are opportunities to strengthen the bill through amendments.

Amendment 57 would add to section 3, which concerns the maintenance of the register. At stage 1, it was clear to the committee that the success of the bill in achieving an increase in the number of organ donations would rest on individuals making clear that their wishes were explicit. Therefore, amendment 57 seeks to make the process easier and more commonplace. It would place an obligation on the Scottish ministers and the maintainers of the register to consider and "promote regular opportunities" for individuals to make clear their intentions regarding the donation of their organs or to alter their stated wishes in that regard.

Proposed new section 2E(2) of the Human Tissue (Scotland) Act 2006 would require the Scottish ministers to consider how such opportunities could be made available through the existing interactions that individuals have with the national health service and other health services. Such interactions could include, but would not be exclusive to, the times when an individual registers with a general practitioner or attends clinical appointments. When individuals are asked to confirm their details by the NHS, the information should include confirmation of their wishes regarding organ donation.

Although I am sympathetic to the intention behind amendment 4 and the need to inform the public of changes that the bill will make, I believe the amendment to be too resource intensive. I am also concerned that the link to the electoral register would allow people who are not registered to fall through the gaps. There would be possible practical problems relating to people who do not wish their address to be used for purposes other than voter registration. I consider amendment 56 to be a better alternative, which satisfies the intention behind amendment 4 but which could be delivered more efficiently and does not limit the potential audience who might be reached.

Alex Cole-Hamilton (Edinburgh Western) (LD): I welcome Jeremy Balfour to the committee and thank him for moving amendment 4. Although I support the intent of amendment 4, I agree with David Stewart that it would be resource intensive and would potentially miss out key vulnerable people in our society. Also, I think that it would be counterproductive to attach something as positive as information about organ donation to a council tax demand or similar. The amendment in the convener's name, and annual publicity or media buy-in from the Scottish Government, might lend an air of celebration to what is and should be a very positive development in public policy.

I will not support the amendments in the name of Jeremy Balfour, but I will support the amendments from the convener and David Stewart.

10:15

Emma Harper (South Scotland) (SNP): Good morning, everyone. I thank Jeremy Balfour for lodging his amendments.

As I am a former liver transplant nurse who has also taken part in kidney and pancreas transplants, my input might be different from that of other members. I absolutely support the idea that we need to raise awareness about informed consent, presumed consent and opting in and out, and I am keen to ensure that we raise awareness with schools and encourage conversations to occur within families.

I agree with Alex Cole-Hamilton and David Stewart that it would be resource intensive to implement the process suggested by amendment 4. However, I would be interested to hear from the minister how we would monitor engagement, uptake and whether people were adding their names to the organ donation register. In Spain, they do not even have an organ donation register, because it has become the norm for people to donate their organs and tissue.

I am keen to support the Government's amendments on this issue.

Miles Briggs (Lothian) (Con): Good morning. I welcome my colleague Jeremy Balfour.

I suppose that my question is more for the minister, because it relates to the guidance that will be attached to the bill. Where is the direction of travel for public information on the bill? I completely accept the aim of amendment 4, but a letter may be limiting. What will the public information campaign be, as we move towards far more digitalisation of health information?

Sandra White (Glasgow Kelvin) (SNP): I thank Jeremy Balfour for his amendment, but I agree with David Stewart and Alex Cole-Hamilton about the convener's amendment. Once a year is better than once every two years.

I have some concerns about amendments 7 and 8, in the name of Jeremy Balfour. Changing the period before consent can be given from 12 months to two or three years would be concerning for people involved in organ transplants.

I wonder whether amendment 57, in the name of David Stewart, would cause extra work. I presume that people can say whether they wish their name to be on the register or taken off it, and there might be a bit of duplication there. Perhaps the minister can clarify that point, and Jeremy Balfour can clarify my points on amendments 7 and 8.

Joe FitzPatrick: Agreement to amendment 56 would mean that, as part of their duties in respect of transplantation and donation, the Scottish ministers should have a campaign of awareness raising and information at least once every calendar year.

Amendment 57 would set a duty on the Scottish ministers to promote regular opportunities for persons to make, or to review, their decision to donate or not to donate, and to consider how such opportunities can be provided when a person is receiving healthcare services. Under the Human Tissue (Scotland) Act 2006, Scottish ministers have a duty to promote information and awareness about donation for transplantation. Proposed new section 1(d) of the 2006 act—as set out in section 2 of the bill—will add to that by requiring Scottish ministers to promote information and awareness about how authorisation for transplantation may be given, including deemed authorisation. Awareness raising that is carried out in accordance with the duty will make it clear to people what their choices are, and what the implications of the new system will be.

One of the strengths of the Human Tissue (Scotland) Act 2006 has been the duty on Scottish ministers to promote awareness and information about donation. As a result of the importance that has been placed on that by successive Administrations, and of the evidence-based approach to awareness raising, efforts to fulfil the duty have resulted in high public awareness of donation, which is demonstrated by year-on-year increases in people recording their decisions on the organ donation register.

The duty is fulfilled in a range of ways—from specific initiatives being targeted at various groups of the population, to high-profile media campaigns. Awareness raising is on-going and includes promotion at public sporting or entertainment events, and information being provided in general practitioner surgeries, pharmacies and other public places, which is similar to what David Stewart calls

for in amendment 57. In addition, information is given through various media activities, including on social media, that happen regularly throughout the year. We will build on that as we raise awareness about the opt-out system.

As well as broad awareness raising, it is crucial that we undertake work to reach specific groups. We are committed to working with different groups including disability and faith groups, and to research, develop and test clear and accessible information, which will be available in a range of languages. I know that the committee has made a number of helpful suggestions in that regard.

We are also committed to learning from Wales about its engagement strategy—in particular, regarding reaching minority groups. Officials are also in regular dialogue with English counterparts about developments there. We will continue to work with Kidney Research UK, which will provide updated training for peer educators in order to raise awareness of donation among south Asian communities.

Specific work will target young people—I think that that point was made by Jeremy Balfour. We will update the secondary schools education pack; as we did previously, we will work with Education Scotland to do that. We are also looking to identify ways to inform young people of the law shortly before they reach their 16th birthday, and to continue to keep them informed on an on-going basis. The bill's financial memorandum takes that into account.

Our intention, which is backed up by the new duty in section 2, is that regular awareness raising about the opt-out system will be a priority, so opportunities will continue to be taken to promote information and understanding of the opt-out system and the choices under it. That will be supported by monitoring of changes in public attitudes—which was mentioned by Emma Harper—and awareness, as part of the planned evaluation of the opt-out system, which means that we can be responsive, if there is a need to adopt that approach.

I support the principles of amendment 56 to have an awareness and information campaign at least once every calendar year, so I am happy to recommend that it be agreed to. However, given the crossover between the provisions in the bill and the amendment, I think that it would be preferable to refine the text at stage 3. I will be happy to work with Lewis Macdonald before stage 3 in order to achieve that.

I thank David Stewart for lodging amendment 57. I hope that I have been able to provide reassurance about our continuing commitment to use every opportunity to raise awareness—in particular, about the new system. I consider that the duties in the bill and on-going practice already meet the intentions of the amendment, so I ask him not to move amendment 57.

In light of the fact that I hope to have discussions with the convener in relation to amendment 56, I will also be happy to meet David Stewart, to ensure that any refinement of the text takes into account his points and anything that is missed by the committee not passing amendment 57.

Amendment 4 would require Scottish ministers to send information at least once in every two-year period to persons who are registered on the electoral roll. In light of the intended awareness raising and the general approach that I have outlined, although I appreciate the aim of the amendment, I consider it to be too limiting. Even if the law allowed access to the electoral register for that purpose—I understand that it does not—the information would not reach people who had decided not to include their details on the electoral roll, as has been mentioned.

In addition, the proposal in amendment 4 would have a high cost—estimated, at current rates, at about £2.5 million every two years—and would have the effect of reducing the ability of the Scottish ministers to raise awareness in other ways. The awareness-raising work that we undertake is based on evidence of what works best. I do not want inadvertently to limit us by being required to use specific awareness-raising methods that might not be the most effective ones. I reassure Mr Balfour that, as well as the awareness-raising methods that I outlined, there will be a direct mailing to all households within a 12-month period, which will mean that even those who are not on the electoral roll will have access to the information. That is accounted for in the financial memorandum. On that basis, I ask Jeremy Balfour to consider seeking to withdraw amendment 4.

Amendments 7 and 8 are direct alternatives that would increase to two or three years the time that a person need ordinarily be resident in Scotland before deemed authorisation for transplantation would apply. I appreciate that Mr Balfour is concerned that people who are newly resident in Scotland might be subject to deemed authorisation when they are not aware of the system. When developing the bill, a key consideration was the need for the protection of certain groups of people who might not be aware of or understand "deemed authorisation". The "ordinarily resident" requirement is part of those protections, and the required duration of 12 months is in line with the legislation in Wales and England, as Mr Balfour said.

Establishment of what length of time spent living in Scotland is sufficient before deemed

authorisation will apply requires that a balance be struck. Mr Balfour's amendments 7 and 8 seek to lengthen the period to either two or three years. The proposal in the Transplantation (Authorisation of Removal of Organs etc) (Scotland) Bill, which was introduced by Anne McTaggart in the previous parliamentary session, was six months. The Health and Sport Committee at that time considered that to be an insufficient period and recommended that it be increased to 12 months. I appreciate and accept that there are differing views on what is appropriate, but I am not persuaded that the duration should be increased from 12 months. A 12-month residency requirement has been in place in Wales since 2015 and we are not aware that difficulties have arisen from the approach there.

Additionally, the bill contains safeguards that aim to ensure that donation does not proceed when that would be against the potential donor's wishes. The safeguards include awareness-raising duties to ensure that there is public awareness of the implications of the new system, and of the duty to inquire, which applies in all cases and seeks to ensure that the views of the potential donor will establish whether donation is authorised. I hope that the information on awareness raising that I have already outlined provides assurance on that point.

For people who are newly resident, we are looking at what has been undertaken in Wales, which uses various channels for awareness raising, including new GP registrations, universities, estate agents and major employers. Such activity would supplement the broader on-going awareness-raising campaign.

I hope that that provides reassurance that the system will include sufficient safeguards alongside the awareness-raising work and that, therefore, the requirement for residency of a duration of 12 months should be retained. On that basis, I ask Mr Balfour not to move amendments 7 and 8. If they are moved, I urge members to resist them.

Finally, amendment 63 would prevent the opt-out system from being implemented before a two-year awareness-raising period has passed, which would begin from royal assent. We have always been clear that there needs to be a high-profile public information campaign over at least 12 months before commencement of the system, so I was pleased that the committee welcomed that commitment in its stage 1 report. The approach was also proposed in the Scottish Government's consultation, and attracted significant support.

I understand that there is in the Welsh legislation a similar requirement to what is proposed in amendment 63. However, there has been more exposure of the opt-out system since then. There have been many conversations in Scotland over the past few years about the introduction of opt-out, including in this Parliament. Most recently, an awareness-raising campaign, which will run for 12 months, was embarked on in England.

I reassure members that, although we have committed to an awareness-raising campaign of at least 12 months before the introduction of the opt-out, that is not limiting. I am grateful to Lewis Macdonald for taking the time to discuss his amendment 63 with me, and I am happy to give the assurance that, in addition to the 12-month campaign, we intend to provide information about the move to the new system in a variety of ways, which will start as soon as the bill receives royal assent.

As I said, I am pleased that the committee welcomes the Government commitment to having a high-profile awareness-raising campaign. I am satisfied that the awareness-raising duties in the bill, along with the commitments that the Scottish Government has made, including to raise awareness over a period of at least 12 months, support the bill's aims and will ensure that people are aware of the new system and their choices within it.

Although I agree that awareness raising is needed, I hope that members will agree with me that the balance is right, given the additional assurances that I have given today, so I ask Lewis Macdonald not to move amendment 63. If he moves it, I ask that members reject it.

10:30

The Convener: Thank you, minister. I ask Jeremy Balfour to wind up and to press or seek to withdraw his amendment 4.

Jeremy Balfour: I thank members for the helpful debate that we have had. The comments by the minister were particularly helpful. I offer a slight caveat to the minister's view: I am not sure that the public are as aware as he suggested, so that needs work.

Agreement to amendment 65 would achieve more than I sought to do, so I am willing to seek to withdraw amendment 4, and I ask the committee to support amendment 56 and to make the commitment it contains. I will not move either amendment 7 or amendment 8. However, I ask the minister to find out what particular information is given, when they visit a GP, to people who arrive in the country from abroad. Most people will probably register with a GP within a year of arrival, so it would be of some comfort if they could be given an appropriate letter or information when they do.

I also ask the minister to reflect, before we get to stage 3, on whether a letter could go to every 16-year-old, as part of a pack that they get when they leave school. That would not add any extra cost and might start the debate within school, as well as beyond it.

With your permission, convener, I seek to withdraw amendment 4, and will not move amendments 7 and 8.

The Convener: We will come back to amendments 7 and 8 in due course.

Amendment 4, by agreement, withdrawn.

Amendment 56 moved—[Lewis Macdonald]—and agreed to.

Section 2, as amended, agreed to.

Section 3—Establishment and maintenance of register

The Convener: The next group is on excepted body parts. Amendment 5, in the name of Jeremy Balfour, is grouped with amendment 6, amendments 9 to 17 and amendments 19 to 23.

I call Jeremy Balfour to move amendment 5 and speak to all the amendments in the group.

Jeremy Balfour: Amendment 5 would ensure that tissue is not used to create reproductive cells in research. It highlights the fact that while everyone believes that the bill is talking about organ transfers, which we are obviously all very keen to see, there is also the matter of tissue and how it could be used. I am open to the minister's comments on the matter, but my understanding is that currently the bill would allow different body tissue to be taken and used for research into reproductive cells, artificial sperm or eggs, or the creation of human embryos. That goes beyond what most people understand the bill to contain, and there is an ethical difference between working on those types of tissue and a kidney or heart transplant, for example. What is the minister's understanding of the intention of the bill? Do the Government, and this committee, believe that, ethically, that is the direction that we want to move in?

The other amendments in the group all deal with the difference between non-exempt body parts and exempt body parts. My understanding is that such terminology is not found in any of the other acts in Wales or the rest of the world. Again, I hope for a correction of that distinction. There should be no difference between excepted and non-excepted body parts.

As far as I am concerned, we should be encouraging people to use all parts of their body for transplantation. Again, I want to understand where the Government is coming from by drawing up these two different lists. As I understand it, that is not what happens in Wales, and I am interested to know why the Government thinks that it should happen in Scotland.

I move amendment 5.

Emma Harper: I am interested in this, because from discussions that we have had, it seems that the issue is transplantation of not just solid organs but tissue. It is quite common for tissue such as tendons and heart valves to be transplanted, but there are people who can freak out when face transplants and so on are mentioned. That sort of thing does not really happen in this country, but research and development of that kind continue to happen, and I am aware that other types of organ transplants are being trialled such as uterus transplants in Wales. For me, there are issues around pancreas transplants and obtaining islet cells.

We must give people time to engage with and come to an understanding of what is meant by organ and tissue. Most folk understand about common transplants of solid organs such as hearts, lungs, livers and kidneys, but the distinction that is being made here is, I think, warranted to ensure that we do not restrict the transplantation of other tissue and that we do not end up with people not opting in because they are afraid of what meaning of tissue might be applied to them or their families.

The Convener: As no one else wishes to contribute, I invite the minister to respond to this group of amendments.

Joe FitzPatrick: The amendments would remove a protection from the bill. The bill as introduced includes an exemption to ensure that deemed authorisation does not apply to excepted body parts and includes provision for regulations to be made to specify what is included in the excepted body parts category. Those regulations will be subject to affirmative procedure as well as to consultation.

The intention, as outlined in the Scottish Government's consultation, is for deemed authorisation to apply only to those organs and tissues that are commonly transplanted. They are, in other words, the organs and tissues that most people might commonly understand as being able to be donated and include the kidney, heart, lungs and liver. The intention is for body parts aside from those commonly transplanted ones—in other words, the excepted body parts—to be listed in regulations and, as a result, to be exempt from deemed authorisation. That approach has been taken elsewhere; indeed, there are regulations as part of the Welsh legislation that set out that list. As well as that exemption, deemed authorisation will apply only to transplantation, not to research—

again, that comes back to a point that Mr Balfour made—and no body parts can be used for research purposes without explicit authorisation.

Amendments 9 and 10 seek to remove the category of excepted body parts and instead set out protections only for parts of the body that contain "reproductive cells" or which are

"to be used for reproductive purposes".

The effect would be that those parts of the body that it is intended would be excepted could be removed and transplanted under deemed authorisation.

I point out to Mr Balfour that I am very much a supporter of organ donation and, indeed, have opted in to make it clear that I am content for all of my body parts to be used after my death, if I die in such circumstances that they can be used. However, the bill does not assume that that would be covered by deemed authorisation, if the organ in question is not one of those accepted as commonly transplanted. There is a slight difference in that respect, and I think that it highlights how the organ donor register remains important in this legislation.

As I have said, there is a list in Wales, and it includes body parts such as the face and hands. I do not think that it is commonly understood by the public that such parts of the body would be donated and transplanted, and it is appropriate that we provide safeguards to make the limitations of deemed authorisation clear to the public.

I understand Mr Balfour's concerns with regard to reproductive cells and body parts to which deemed authorisation for transplantation does not apply. As I have said, the Government's intention is to ensure that only material that the public commonly understand to be routinely donated should be part of deemed authorisation, and I do not think that the material that the amendments relate to would fall within that. The list in Wales includes the types of material that the amendments relate to, such as the ovaries, uterus, penis and testicles. Subject to consultation and the Parliament's view, it is expected that the list of excepted body parts here will be very similar.

I suggest that the excepted body parts regulations are the vehicle to limit the parameters of what can be donated under deemed authorisation. On that basis, I urge Jeremy Balfour to withdraw amendment 5 and not to move the other amendments in the group.

Mr Balfour asked how reproductive cells will be covered under the bill. The procurement, storage and use of gametes, or reproductive cells, are dealt with under the Human Fertilisation and Embryology Act 1990 and require a Human Fertilisation and Embryology Authority licence. That is completely separate from the 2006 act and the bill.

The Convener: I ask Jeremy Balfour to wind up and say whether he wishes to press or to seek to withdraw amendment 5.

Jeremy Balfour: I have nothing to add, convener. I seek to withdraw amendment 5.

Amendment 5, by agreement, withdrawn.

The Convener: The next group relates to the establishment and maintenance of the register. Amendment 24, in the name of the minister, is grouped with amendments 25 to 33.

Joe FitzPatrick: I have lodged amendments 24 to 33 following further consideration of how the provisions of section 3 on disclosure of information by the register organisation will work in practice. The amendments aim to reflect more accurately whom information needs to be shared with; to clarify that the information that is disclosed must be about a particular potential donor; and to refine the purposes for which information can be shared.

Proposed new section 2C(1)(a) of the 2006 act, as will be inserted by amendment 25, will restrict the powers of the register organisation to disclose information within Scotland to those carrying out functions under part 1 of the 2006 act. New section 2C(1)(b), which is also set out in amendment 25, provides a power for the register organisation to disclose information to persons outwith Scotland who are carrying out functions related to the removal and use of parts of the body for transplantation. The power to disclose information outwith Scotland reflects the collaborative arrangements with which donation and transplantation services operate. New section 2C(1)(a) will allow information to be shared within Scotland by the register organisation with those listed under section 2C(2) for particular purposes but no longer directly with relatives of donors.

In practice, there is a need for the register organisation to disclose information only to specific persons who are engaged in functions related to the removal and use of a part of the body for transplantation. Therefore, amendment 27 reflects that by replacing the existing reference to health boards and so on with a reference to those persons.

Amendment 26 makes it clear that the register organisation's power to disclose information includes the power to disclose that there is no recorded information on the register. Within Scotland, that will support those undertaking the duty to inquire and will, for example, allow specialist nurses to have conversations with the family about the views of the donor.

Amendments 28 and 29 have the effect that those who are listed in section 2C(2) can disclose

information that they receive from the register organisation to another person carrying out transplantation functions under part 1 of the 2006 act as well as to relatives of the donor. In practice, that will, for example, allow a specialist nurse for organ donation to share information with a retrieval surgeon that an authorisation for donation is in place so that, among other things, the retrieval surgeon can be satisfied that the requirements in section 11 of the 2006 act are fulfilled before retrieval takes place.

Amendments 30 to 33 are consequential.

I move amendment 24.

Amendment 24 agreed to.

Amendments 25 to 33 moved—[Joe FitzPatrick]—and agreed to.

Amendment 57 moved—[David Stewart].

The Convener: The question is, that amendment 57 be agreed to. Are we agreed?

Members: No.

The Convener: There will be a division.

For

Briggs, Miles (Lothian) (Con)
Cole-Hamilton, Alex (Edinburgh Western) (LD)
Macdonald, Lewis (North East Scotland) (Lab)
Stewart, David (Highlands and Islands) (Lab)
Whittle, Brian (South Scotland) (Con)

Against

Adam, George (Paisley) (SNP)
Harper, Emma (South Scotland) (SNP)
Torrance, David (Kirkcaldy) (SNP)
White, Sandra (Glasgow Kelvin) (SNP)

The Convener: The result of the division is: For 5, Against 4, Abstentions 0.

Amendment 57 agreed to.

Section 3, as amended, agreed to.

Section 4 agreed to.

Section 5—Express authorisation by adult

10:45

The Convener: The next group is on how authorisation, declaration or withdrawal is to be made. Amendment 34, in the name of the minister, is grouped with amendments 36, 40 and 42.

Joe FitzPatrick: I will speak to all the amendments in the group. They seek to enable a person to verbally withdraw a decision that they have given to the register organisation. At present, in Scotland, a person can withdraw their donation decision only in writing. When contacting the organ donor register helpline to withdraw a donation decision, individuals in Scotland are advised that it can be done only in writing, either by changing their decision online on the organ donor register, or by writing to the organ donor register requesting the change.

Amendments 34, 36, 40 and 42 will provide flexibility as to how a person can withdraw a previously recorded decision from the register and bring Scotland into line with practice in the rest of the United Kingdom. NHS Blood and Transplant has welcomed the fact that the amendments will mean that callers from Scotland to the organ donor register helpline will not require to be directed away from the call centre to withdraw decisions online or separately in writing. As a matter of good practice, any withdrawal of a recorded decision is followed up by the organ donor register in writing, as confirmation.

I move amendment 34.

The Convener: Thank you. I invite other members to comment.

Miles Briggs: I seek clarity about how a verbal withdrawal will be logged or recorded. Can the minister provide more information on the procedure for someone to verbally withdraw consent?

The Convener: The minister may respond now, or once we have heard from other members, if any of them wish to comment.

Sandra White: I have a small comment on an issue that I raised during the debate on amendment 57, which I thought duplicated this. It is important that people have the opportunity to say whether they wish to continue and amendment 34 fills that gap, so I support it.

The Convener: I concur that it will be a useful improvement to the bill. I am interested to hear the minister's comments as he winds up.

Joe FitzPatrick: To respond to Mr Briggs's point, the change will bring us in line with practice in the rest of the UK. I understand that the procedure there is for a person to telephone the ODR, which then verifies their ID and follows up the call in writing. The ODR holds the register for the whole of the UK, but currently it has the two different systems—one for the rest of the UK and one for people from Scotland, who are diverted away to do things differently. The amendments will mean that there will be one system for the whole of the UK.

The Convener: Have there been issues with the different methods in use under the current legislation, or is the change a precaution against a possible issue arising in the future?

Joe FitzPatrick: I am told that NHS Blood and Transplant will be very pleased if the amendment is agreed to. Currently, if someone from Scotland telephones to say that they have decided to

change their registered view to opt in or out, they are turned away, and members of the public are often not happy when they are told that they cannot do what everybody else can.

Amendment 34 agreed to.

The Convener: The next group is on the standard of evidence. Amendment 35, in the name of the minister, is grouped with amendments 37, 58, 59, 38, 60, 61, 39, 41 and 43.

Joe FitzPatrick: I note Mr Rumbles's interest in the standard of evidence. When we met to discuss the amendments that he intended to lodge on that point, we found that we shared the aim of ensuring that authorisation for transplantation is not deemed when it would be against the potential donor's wishes. Safeguards that are included in the bill aim to achieve that.

The Government agreed to look further at whether we could amend the test that is in the bill, in order to address Mr Rumbles's concerns. Amendment 38 will amend the test; I am pleased that we have reached agreement and I am grateful that, on that basis, Mr Rumbles will not lodge amendments.

Amendment 38 relates to the test to displace deemed authorisation for transplantation. The amendment will ensure that a person must provide evidence to a health worker that would

"lead a reasonable person to conclude"

that the potential donor would have been unwilling to donate. That evidence will be about the potential donor's most recent view. The revised test will also apply in establishing whether a potential donor would have been unwilling to donate in the circumstances—perhaps because, in the particular circumstances of death, donation would be incompatible with their faith.

The formulation that evidence would

"lead a reasonable person to conclude"

will apply instead of the existing threshold in the bill, which requires evidence that

"would convince a reasonable person".

When we met, Mr Rumbles expressed concern about the word "convince", and I am glad to address his concern. The change to the word "conclude" rather than "convince" is also in line with the wording in legislation in England and Wales.

As a consequence of amendment 38, amendments 35, 41, 37 and 43 will replicate the test that evidence would

"lead a reasonable person to conclude"

when an adult or a child who is aged 12 or over has expressed authority for or opted out of donation. That will change the test for the evidence that is required to show that a potential donor had changed their previous decision or to show that, in the circumstances, they would have changed their mind if they were capable of doing so. The test will be replicated in those contexts to reflect the intention that deemed authorisation should have equal status with other decisions and to avoid operational confusion from the application of different tests in different scenarios.

I reassure the committee that, as with the previous test, the new test is designed to enable in all circumstances evidence about a potential donor's views to be provided and to enable their views to determine whether donation is authorised. The test is robust enough to ensure that donation will proceed only when it would not have been against a potential donor's wishes, and the test has been designed with the kind of decisions that take place with families by the bedside in mind.

Operationally, evidence will most frequently come from a family telling a specialist nurse for organ donation or tissue donor co-ordinator about conversations that they had had about donation and the views that their loved one had expressed. However, the test is flexible enough to enable any evidence to be provided.

In addition to the test to establish views on donation, a revised test will apply to establishing incapacity. Amendment 39 will amend the

"example of when an adult is to be considered 'incapable of understanding the nature and consequences of deemed authorisation'"

in proposed new section 6D(4) of the 2006 act. Under new section 6D(2)(b), deemed authorisation will not apply when someone is considered to be so incapable. In practice, a specialist nurse or tissue donor co-ordinator will seek to establish whether a potential donor had the capacity to understand deemed authorisation. Staff who have been caring for a patient are likely to be aware of whether they lacked capacity, but a potential donor's family member could also provide evidence of incapacity.

Although evidence is not required to establish incapacity, the example in the bill will make it clear that, when evidence is presented, it should

"lead a reasonable person to conclude"

that the potential donor was incapable of understanding the nature and consequences of authorisation.

A great deal of consideration has been given to the tests that are set out in the bill to ensure both that information can be submitted to respect a potential donor's wishes and that there are sufficient safeguards for those who are incapable

of understanding the nature and consequences of deemed authorisation. I confirm that NHSBT and the Scottish National Blood Transfusion Service were consulted and are content with the bill's approach to those issues and with the associated amendments. I accordingly ask members to support them.

I turn to amendments 58 to 61, which I am unable to support because they undermine the very principle of an opt-out system. Authorisation for donation for transplantation is able to be deemed in the context of the Scottish ministers' duties to raise awareness about the new system. If an adult is made aware of how the system operates, and such operation is by means of deemed authorisation, we consider it reasonable to assume that they are willing to donate unless they opt out. We recognise that that assumption may be displaced in ways other than by opt-out declaration. If a person's most recent view is that they are unwilling to donate, that should also be given effect. That is the reason for the safeguards in the bill, which ensure that evidence about an adult's latest views can be submitted.

Importantly, the bill provides that evidence of an adult's unwillingness to donate can be submitted by a wide range of people, to ensure that relevant information is not excluded from consideration. However, amendment 59 restricts the provision of evidence to the adult's nearest relative, which reduces the likelihood that relevant information will be produced. Taken together, the amendments would mean that deemed authorisation would apply only if a person's nearest relative provides evidence that that person is willing to donate. It destroys the basis on which deemed authorisation operates, because there is no assumption of willingness; instead, willingness must be demonstrated by the nearest relative.

Crucially, amendments 58 to 61 could risk the progress that we have seen happen under the 2006 act. Currently, under section 7 of the 2006 act, which would be repealed by the bill, if an adult has not authorised donation, their nearest relative may authorise it upon their death, unless that relative has actual knowledge that the adult was unwilling to donate, which is the opposite test to what the amendments propose. Part of the reason for introducing an opt-out system is that we know that many more people support donation than register their willingness to donate. That is why we want to move to a system of deemed authorisation, which makes donation the default position.

The Scottish Government hopes that the provisions relating to deemed authorisation, together with raising awareness of the new system, will contribute towards the on-going improvements that we have seen in donation rates. However, amendments 58 to 61 would damage that progress and undermine the efforts of those who are working in the system to increase donation. I therefore urge members to resist them.

I move amendment 35.

The Convener: I welcome Gordon Lindhurst to the meeting and invite him to speak to amendment 58 and other amendments in the group.

Gordon Lindhurst (Lothian) (Con): I have heard what the minister has had to say on amendments 58 to 61. Nevertheless, I would like to set out the reasoning behind them.

Amendments 58 to 61 relate to the formulation of the consent principle. Rather than that principle being expressed in a negative way—or, indeed, as a double negative, as it is set out in the bill—the amendments seek to express it in a positive way. That is in keeping with modern best practice, as is set out in the European convention on human rights and biomedicine, which is numbered 164 in the European treaty series; and its additional protocol concerning transplantation of organs and tissues of human origin, which is numbered 186. The simplest way to illustrate the point is to consider one of the most up-to-date European regulations: the general data protection regulation, which requires conscious affirmative consent to be given in relation to personal data, rather than the previously allowed passive consent.

As amendment 58 is a probing amendment, it has been drafted in relation to only one section. If it were to be agreed to, further amendments would be lodged at stage 3 in relation to the wording that is intended to be amended where appropriate in the rest of the bill.

Mike Rumbles (North East Scotland) (LD): This set of amendments from the minister is all about the potential donor's wishes and the safeguards that are in the bill to ensure that they are carried out.

I was pleased to withdraw on Friday the amendments that I had lodged, because we reached agreement with the minister on this point. We both want to do the right thing.

My background is that I have been on the organ donor register for the past 20 years. A campaign on the issue was the first that I was involved in after being elected to the Scottish Parliament. I was on a previous Health Committee that spent many months taking the Human Tissue (Scotland) Act 2006 through—the convener was the minister at the time.

11:00

I support this bill, except for the phrase

"convince a reasonable person",

which is a particular standard of law that is used in many bills. I think that the legal team may have put the phrase in the bill. Amendment 38 is key, with the minister's other amendments setting the rest of the bill as a result of amendment 38.

I voted against the bill at stage 1 because I was worried that the word "convince" was unintentionally putting in a barrier to the success of the bill—when I met the minister, it was clear that it was unintentional—and that there might be a problem further down the line.

The minister's amendment uses the phrase,

"lead a reasonable person to conclude",

and I am pleased that the minister listened to and accepted the arguments. We all want to achieve the right thing with the bill. I hope that the committee will unanimously support the minister's amendments in the group.

The Convener: A reasonable person would conclude that Mr Rumbles supports the amendments. [*Laughter*.] As no other members wish to comment on the amendments in this group, I ask the minister to wind up.

Joe FitzPatrick: The principle behind the bill is to respect the primacy of the views of the potential donor. Safeguards are in the bill to ensure that it is the donor's view that establishes whether donation is authorised.

Against the backdrop of the move to a soft opt-out system and the awareness raising that will take place, it is entirely appropriate to set the default in favour of donation when an adult has not opted out. The safeguards in place are a check to make sure that donation would not go ahead against the donor's wishes. That is the appropriate balance, and the Government's amendments have sought to address concerns about that. I urge members to support amendments 35, 37 to 39, 41 and 43 and to resist amendments 58 to 61.

Amendment 35 agreed to.

Section 5, as amended, agreed to.

Section 6—Opt-out declaration by adult

Amendments 36 and 37 moved—[Joe FitzPatrick]—and agreed to.

Amendment 6 not moved.

Section 6, as amended, agreed to.

Section 7—Deemed authorisation for transplantation as respects adult

Amendments 7 to 11 not moved.

The Convener: I call Gordon Lindhurst's amendment 58, which has already been debated with amendment 35. Do you wish to move your amendments?

Gordon Lindhurst: I am not sure that the minister has responded to my point, but I will not move the amendments.

Amendments 58 and 59 not moved.

Amendment 38 moved—[Joe FitzPatrick]—and agreed to.

Amendments 60 and 61 not moved.

Amendment 39 moved—[Joe FitzPatrick]—and agreed to.

Amendment 12 not moved.

Section 7, as amended, agreed to.

Sections 8 and 9 agreed to.

Section 10—Excepted body parts: authorisation for transplantation by nearest relative

Amendment 13 not moved.

Section 10 agreed to.

Section 11 agreed to.

Section 12—Authorisation by child 12 years of age or over

Amendments 40 and 41 moved—[Joe FitzPatrick]—and agreed to.

Section 12, as amended, agreed to.

Section 13—Opt-out declaration by child 12 years of age or over

Amendments 42 and 43 moved—[Joe FitzPatrick]—and agreed to.

Section 13, as amended, agreed to.

Sections 14 to 20 agreed to.

Section 21—Removal of part of body of deceased person: further requirements

The Convener: We move to the next group. Amendment 44, in the name of the minister, is grouped with amendments 45 to 49.

Joe FitzPatrick: I lodged amendments 44 to 49 following an approach from the Scottish National Blood Transfusion Service, which is responsible for tissue retrieval. SNBTS is seeking the opportunity to amend section 21, which amends section 11 of the Human Tissue (Scotland) Act 2006 and concerns the requirements that must be satisfied before retrieval takes place.

The amendments in the group are intended to amend sections 11(1) to 11(4) of the 2006 act, to clarify the role of the registered medical

practitioner in cases in which another person has been authorised to retrieve tissue. The amendments will allow SNBTS to operate more effectively and to be responsive to practice development.

Section 11(1) of the 2006 act provides that removal of a body part for transplantation must be undertaken by a "registered medical practitioner" or someone who is

"authorised to do so in accordance with regulations".

Regulations can provide that a registered medical practitioner may authorise removal by a non-practitioner; current regulations provide that a registered medical practitioner may authorise any person, provided that they are satisfied that the person who will undertake retrieval is sufficiently qualified and trained to perform the operation competently.

Amendments 44 and 45 and 47 to 49 will amend section 11 to make it clear that the body parts of a deceased person may be removed by a person who is authorised to do so under a general authorisation made in accordance with regulations, and to enable the regulations to make provision for general authorisations for a "description of person".

Amendment 44 will also remove section 11(3)(b) from the 2006 act, which implies that authorisation must be given in individual cases, to ensure that only the person who proposes to remove the body parts is required to be satisfied that the requirements of section 11(4) are met.

Amendment 46 will amend section 11(4)(a) of the 2006 act so that where the person who proposes to remove a body part from a donor is a registered medical practitioner, that person may examine the donor's body to confirm that the donor is deceased or satisfy themselves that another registered medical practitioner has examined the donor's body to confirm that the donor is deceased.

Amendment 46 will also add new paragraph (ab) to section 11(4) of the 2006 act so that where the person who proposes to remove a body part from a donor is not a registered medical practitioner, that person must satisfy themselves that a registered medical practitioner has examined the donor's body to confirm that the donor is deceased.

I ask the committee to agree to amendments 44 to 49, which will allow the SNBTS to continue to respond effectively to increases in tissue retrieval.

I move amendment 44.

Sandra White: I fully support the minister, but I would like clarification on amendment 46. It says:

"if the person is not a registered medical practitioner, that a registered medical practitioner, by personal examination of the body, is satisfied that life is extinct".

The person in question does not have to be a registered medical practitioner. I presume that the body would be examined first, and there would be paper authorisation from a registered medical practitioner. I would like a wee bit of clarification on amendment 46.

Joe FitzPatrick: The point that I made was that the person who is removing the organ needs to be satisfied that a registered medical practitioner has examined the donor's body to confirm that the donor is deceased. That could happen in the hospital, for example. It is about confirming that that will be done and ensuring that the bill works in practice.

Sandra White: That satisfies me. Thank you for the clarification.

Amendment 44 agreed to.

Amendments 45 and 46 moved—[Joe FitzPatrick]—and agreed to.

Amendment 14 not moved.

Amendments 47 and 48 moved—[Joe FitzPatrick]—and agreed to.

Amendment 15 not moved.

Amendment 49 moved—[Joe FitzPatrick]—and agreed to.

Amendment 16 not moved.

Section 21, as amended, agreed to.

Section 22—Pre-death procedures relating to transplantation

The Convener: The next group of amendments is on pre-death procedures relating to transplantation. Amendment 50, in the name of the minister, is grouped with amendments 51 and 18.

Joe FitzPatrick: Amendments 50 and 51 will make minor amendments to the provisions in the bill relating to pre-death procedures. They are aimed at ensuring that the provisions will work effectively when they are applied in practice.

The provisions in the bill that support the carrying out of pre-death procedures are robust and provide a clear legal framework by specifying the circumstances in which they may be carried out and in which they may be authorised. Transparency is important to that, and amendment 50 will enable the procedures that may be specified as "Type A" to be described more accurately by making it clear that they may also be described by reference to how they are carried out. The ability to specify the procedures in regulations will also ensure that the statutory

framework is responsive to changes in practice and particularly to developments in medical practice and care. The minor change that amendment 50 will introduce to the enabling power will further enhance that.

11:15

Amendment 51 also seeks to make it clearer how the system is intended to work in practice. As the committee is aware, pre-death procedures are not new; those that are currently carried out include taking blood and X-rays, and it is not intended that, for example, a radiographer who is asked to take an X-ray will have to be involved in the authorisation process or to carry out the duty to inquire. Amendment 51 makes that clear, while also retaining the important safeguards in the bill, including that the procedures cannot be carried out if it is known that the person is unwilling for that to happen. I hope that members share my aim to ensure that the bill works in practice, and I invite them to support the amendments.

On amendment 18, I understand Mr Balfour's concerns about pre-death procedures not bringing about the premature death of a potential donor. As I have said, the provisions in the bill that support the carrying out of pre-death procedures are robust and include significant safeguards with regard to how and when they can be carried out. Importantly, they should not be carried out if they are

"likely to cause more than minimal discomfort"

or harm

"to the person",

and I believe that not shortening someone's life expectancy would be captured in that requirement not to harm people.

Equally important is that the bill also explicitly provides that procedures can be carried out only if, in the view of those responsible for the patient's care, "the person" in question

"is likely to die imminently"

and, where "life-sustaining treatment" is being administered, a decision has been taken to withdraw that treatment. That provision takes account of the very specific context in which such procedures are carried out; they happen in a very narrow window at the end of a patient's life, when they are being cared for by medical professionals with family involvement in discussions about care and end-of-life procedures.

As I am satisfied that the bill includes significant safeguards, I am not persuaded of the need for amendment 18. I hope that I have provided sufficient reassurance and therefore invite Jeremy Balfour not to move amendment 18.

I move amendment 50.

Jeremy Balfour: First, I want to say that I support amendments 50 and 51 in the name of the minister.

Amendment 18 will put down in law what we all hope should happen, but it will also give individuals who decide to opt in an absolute guarantee that they will be treated no differently from those who have not opted in. That will happen anyway, but the amendment sets it out as a legal requirement. I do not think that it will take anything away from what the minister has proposed in amendments 50 and 51 or, I hope, make any difference in practice to what medical teams do. In the past, a concern was expressed about people being treated slightly differently according to whether or not they were on the donor list, and amendment 18 will simply clarify that that will not be the case. It is a safeguard that will assure people about putting themselves on to the list, which is, after all, what we want them to do.

Emma Harper: Having worked on both the donation and recipient sides of transplantation, I can say that the situation in question is really difficult. In my professional working life, I have never seen anyone wish to hurry someone's death so that we could get them to an organ donation site or operating theatre. I therefore think that, given current healthcare practice across Scotland, amendment 18, though well intended, is not required.

Sandra White: I thank the minister for lodging his amendments, given that I have been raising this particular matter from the beginning of our scrutiny. As a layperson, I did not know a lot about pre-death procedures. After meeting people whose loved ones had passed away and hearing about what happened and the information that they received, I was comforted, but I still wanted to raise the issue. I therefore thank the minister for the proposal with regard to type A procedures and for ensuring that there will be transparency for the families involved. My concern was always about people not knowing a lot about what was happening.

I understand why Jeremy Balfour has lodged amendment 18. It is probably just a probing amendment that might well not be moved—although I cannot speak for Jeremy in that respect—but I have to say that I am very pleased with amendments 50 and 51.

Joe FitzPatrick: As I said earlier, the bill sets out provisions for pre-death procedures that are robust, transparent and responsive to change, with the important aim that they work in practice. Amendments 50 and 51 are minor changes that

add more to that. I invite the committee to support them.

Safeguards are important, and the provisions in the bill for pre-death procedures have been carefully developed to ensure that they recognise the particular circumstances in which they are carried out. People will be under the care of health professionals who work within an ethical framework and for whom patient care is a priority.

The bill provides that procedures may be carried out only if necessary and only if they are not likely to cause any harm. I am satisfied that that addresses Jeremy Balfour's concerns; I therefore urge the committee to reject amendment 18.

Amendment 50 agreed to.

Amendment 51 moved—[Joe FitzPatrick]—and agreed to.

Amendment 17 not moved.

Amendment 18 moved—[Jeremy Balfour].

The Convener: The question is, that amendment 18 be agreed to. Are we agreed?

Members: No.

The Convener: It seems clear that there are no votes in favour of amendment 18. However, to be absolutely clear, we had better have a vote. There will be a division.

Against

Adam, George (Paisley) (SNP)
Briggs, Miles (Lothian) (Con)
Cole-Hamilton, Alex (Edinburgh Western) (LD)
Harper, Emma (South Scotland) (SNP)
Macdonald, Lewis (North East Scotland) (Lab)
Stewart, David (Highlands and Islands) (Lab)
Torrance, David (Kirkcaldy) (SNP)
White, Sandra (Glasgow Kelvin) (SNP)
Whittle, Brian (South Scotland) (Con)

The Convener: The result of the division is: For 0, Against 9, Abstentions 0.

Amendment 18 disagreed to.

Section 22, as amended, agreed to.

Section 23—Duty to inquire

The Convener: The next group relates to the meaning of the term "health worker". Amendment 52, in the name of Joe FitzPatrick, is grouped with amendments 53 and 54.

Joe FitzPatrick: Amendments 52 to 54 seek to change the definition of "health worker" in the bill. Following the bill's introduction, and after speaking to key people who deliver donation and transplantation services, we have reviewed how the current definition of "health worker" in the bill will work in practice and are of the view that these amendments are necessary.

For it to work properly in practice, there needs to be more flexibility in the definition of "health worker" in the bill. The definition should apply consistently to those who might be involved in the authorisation process and those who might carry out inquiries into the wishes of potential donors, which is likely to be the same person. The definition is also relevant to pre-death procedures, as other people who work in healthcare—who are not registered medical practitioners or registered nurses—might be involved. For example, radiographers who carry out X-rays would not be covered by the current definition.

Our view is that the amendment achieves the appropriate level of flexibility by enabling "health workers" to include not only clinicians or nurses, but others who are suitably qualified. We also think that it is precise enough to maintain appropriate restrictions as to who can fulfil the health worker role in the different contexts in which it applies. The additional power for ministers to issue directions means that it also includes adequate safeguards to maintain the integrity of the process.

As we all know, practice and procedures develop all the time. We are mindful that the system has to work in practice, and our view is that the amendments are responsive enough to allow for further developments in procedures and practice. I therefore ask members to support amendments 52 to 54.

I move amendment 52.

Amendment 52 agreed to.

Section 23, as amended, agreed to.

Sections 24 and 25 agreed to.

Section 26—Interpretation

Amendment 53 moved—[Joe FitzPatrick]—and agreed to.

The Convener: Before we proceed, I suspend the meeting to give Jeremy Balfour a moment to return. I understand that he will be back with us any second.

11:25

Meeting suspended.

11:26

On resuming—

Amendment 19 not moved.

Amendment 54 moved—[Joe FitzPatrick]—and agreed to.

Section 26, as amended, agreed to.

Section 27—Minor and consequential modifications

Amendments 20 to 23 not moved.

Section 27 agreed to.

After section 27

The Convener: Amendment 62, in my name, is in a group on its own.

Again, the amendment follows discussions and reflects the experience elsewhere. It would insert a new section—headed "Review and report on operation of Act"—which would place an obligation on ministers to research and report on the impact of the provisions in order to determine the efficacy of the legislation. It imposes a duty to undertake a review and report back to Parliament.

A similar exercise was carried out in Wales, where the evaluation was published in December 2017. However, that was done so close to the legislation in Wales coming into effect that the evidence of the benefits did not appear in the evaluation. Committee members will recall that we heard that in the 12 months following the publication of that evaluation, evidence began to come through of an increase in donations. Amendment 62 is designed to ensure that there is an adequate period before a review takes place and calls for that to happen five years from when the bill is given royal assent.

I move amendment 62.

Alex Cole-Hamilton: I seek clarification, convener. Although I am generally in favour of reviewing the impact of legislation, I am concerned that doing so might open the door for the bill, if enacted, to be repealed or its provisions overturned. The bill is much needed, and I want to check the motivations behind your amendment and ask for assurances that you do not imagine that that would happen.

The Convener: I am happy to do that, and will have the opportunity to do so in a moment.

Emma Harper: I agree that, if we want to increase the number of people who donate, we should be able to review whether the legislation is working, including in relation to how many people opt out.

Joe FitzPatrick: I support amendment 62. I am content that it is not a so-called sunset clause and, on that basis, I am happy to recommend that it be accepted. However, I think that it would be preferable for the start of the period to begin not on the date of royal assent but on the date of the opt-out system's introduction. I suggest that change on the basis of the experience of the Welsh Government's evaluation, which concluded that two years of data were not enough to give an indication of the early impact of system. Five years after the system's introduction feels like the right length of time. I would be happy to work with the convener before stage 3 to achieve that.

11:30

The Convener: I thank the minister for that suggestion, which is much appreciated. I am likewise happy to work with him, as we will in relation to amendment 56, which we discussed earlier. I hope that Alex Cole-Hamilton will agree with the minister that there is no intention—or route—for amendment 62 to become a sunset clause. The intention is simply to ensure that there is a review.

Alex Cole-Hamilton: With that clarification, I am happy to support the amendment.

Amendment 62 agreed to.

Section 28—Commencement

The Convener: Amendment 55, in the name of the minister, is in a group on its own.

Joe FitzPatrick: Amendment 55 seeks to remove references to certain sections of the bill from section 28, so that those sections are not commenced on the day after royal assent.

Following the bill's introduction and our engagement with stakeholders, including NHSBT and SNBTS, we have reviewed the approach in the bill. We consider that amendment 55 is necessary to ensure that there is sufficient time for guidance to be produced and training to be provided, so that the pre-death procedures and timing of authorisation provisions can be implemented successfully, and those working in the system are able to adhere to the new legislative framework. Further, following the introduction of the bill, sequencing issues were also identified that make amendment 55 necessary.

Before the pre-death procedures regime can be fully implemented, the regulations specifying the procedures need to be in place. Commencing the provisions for the regime before that process is complete would be unworkable. If we did that, the regime would be in place but the procedures would not be specified and so could not be carried out. In addition, the duty to raise awareness of pre-death procedures cannot be met if the procedures are not yet specified.

It is the Scottish Government's intention instead to commence those provisions and the remaining provisions in the bill by commencement regulations. As set out in the public consultation and the bill's accompanying documents, the intention is to carry out awareness raising over a period of at least 12 months following the

introduction of the opt-out system. As I have said, a period of at least 12 months for awareness raising is appropriate, given the increased debate about opt-out, and people's exposure to the issue, across the UK since such a regime was introduced in Wales in 2015. More recently, the start of the 12-month awareness-raising period in England will inevitably have some reach in Scotland.

I move amendment 55.

Amendment 55 agreed to.

Amendment 63 not moved.

Section 28, as amended, agreed to.

Section 29—Short title

The Convener: Amendment 64, in my name, is in a group on its own.

The amendment reflects discussion with the Law Society on the short title. Clearly, the bill amends the Human Tissue (Scotland) Act 2006 and therefore the short title should start with "Human Tissue", as it does. There is currently no reference in the short title to transplantation. Given that, in newspaper and other public comment, it is the short title that is referred to, I suggest that amendment 64 would improve clarity and allow the use of the bill's title itself as a means of raising awareness of its content.

I move amendment 64.

Joe FitzPatrick: I am grateful to the convener for his attention to the detail of the bill, but I will resist amendment 64, which seeks to amend the short title.

We take care in selecting bill titles to ensure that they meet the Presiding Officer's recommendation that they should accurately and neutrally reflect what the bill does. We considered adding a reference to transplantation to the short title during the development of the legislation. However, such a reference was not added because it was felt that it would potentially mislead readers, who might then think that the bill was about transplantation only. The short title reflects the fact that the bill is also about authorisation of donation for other purposes, not only transplantation. That is further reflected in the long title, which sets out that the bill is about authorisation

"for transplantation and other purposes".

It seems to me that transplantation is given sufficient prominence in the long title.

The bill makes significant changes to authorisation for transplantation by introducing deemed authorisation for that purpose, but it also ensures that authorisation for other important uses—such as research, education, training, audit and quality assurance—will require express authorisation from a potential donor or by their nearest relative. The current short title acknowledges that point.

Therefore, although I understand why Mr Macdonald has raised the issue, I ask him to consider not pressing amendment 64.

The Convener: In the light of the minister's comments, I am minded not to press amendment 64. Of course, members will be able to revisit the issue at stage 3.

Amendment 64, by agreement, withdrawn.

Section 29 agreed to.

Long title agreed to.

The Convener: That completes stage 2 consideration of the bill. I thank the minister and his team, as well as members and non-members of the committee, for their attendance. The bill will now be reprinted, as amended at stage 2. Members will be informed when a date has been selected by which amendments can be lodged for stage 3.

11:36

Meeting continued in private until 11:53.

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