OFFICIAL REPORT
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Health and Sport Committee

Tuesday 27 November 2018

Session 5

The Scottish Parliament
Pàrlamaid na h-Alba

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HEALTH AND SPORT COMMITTEE
31st Meeting 2018, Session 5

CONVENER

*Lewis Macdonald (North East Scotland) (Lab)

DEPUTY CONVENER

*Emma Harper (South Scotland) (SNP)

COMMITTEE MEMBERS

*Miles Briggs (Lothian) (Con)
*Keith Brown (Clackmannanshire and Dunblane) (SNP)
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 PARTICIPATED:

Professor Alison Britton (Law Society of Scotland)
Joe FitzPatrick (Minister for Public Health, Sport and Wellbeing)
Dr Calum MacKellar (Scottish Council on Human Bioethics)
Fern Morris (Scottish Government)
Dr Emily Postan (University of Edinburgh)
Claire Tosh (Scottish Government)
Stephanie Virlogeux (Scottish Government)

CLERK TO THE COMMITTEE

David Cullum

LOCATION

The James Clerk Maxwell Room (CR4)

Scottish Parliament

Health and Sport Committee

Tuesday 27 November 2018

[The Convener opened the meeting at 10:00]

Human Tissue (Authorisation) (Scotland) Bill: Stage 1

The Convener (Lewis Macdonald): Good morning, and welcome to the 31st meeting in 2018 of the Health and Sport Committee. We have received apologies from Alex Cole-Hamilton, and Brian Whittle will join us in the course of the meeting. I ask everyone in the room to ensure that their mobile phones are off or on silent. Please do not film or record proceedings, as we do that ourselves.

Agenda item 1 is the final evidence session on the Human Tissue (Authorisation) (Scotland) Bill, which proposes to introduce a system of deemed authorisation. Our first panel will focus on evidence relating to law and medical ethics. We will then take evidence from the Minister for Public Health, Sport and Wellbeing.

I welcome Dr Emily Postan, who is an early career fellow in bioethics and deputy director of the Mason institute for medicine, life sciences and the law at the University of Edinburgh; Professor Alison Britton, who is convener of the health and medical law sub-committee of the Law Society of Scotland; and Dr Calum MacKellar, who is director of research at the Scottish Council on Human Bioethics. Thank you very much for coming to the meeting.

Emma Harper (South Scotland) (SNP): Good morning, panel. I declare an interest as a former liver transplant nurse who worked in Los Angeles. I am still a nurse who is able to practise.

I am interested in issues that relate to the rights of a deceased person. The committee has explored opinions about the role that a family should have in the decision to donate a deceased person's organs. Much of the discussion that we have had has centred on whose wishes—the wishes of the patient or of the family—should have priority. I am interested in your thoughts on whether deceased people have rights and who owns the body of a deceased person.

The Convener: That is a big topic. Who would like to start?

Professor Alison Britton (Law Society of Scotland): From a European and a European convention on human rights point of view, once a person has died, they probably do not have rights, but the question is probably more about respect for what they expressed in life, whether through the parameters of legislation or the opt-in system that we currently have. If a person registered their wishes to have all their organs or none whatever donated, they might not necessarily get that wish. There are reasons why it might not be possible to respect that wish. Their organs might not be compatible with transplant so that, even though they wished for and requested that and had written down and expressed that wish, it cannot be adhered to. There might be other reasons. Emma Harper raised the issue of the weight of the preferences, values and views of the family, for example.

If somebody refuses to give their permission for their organs to be taken, that is almost easier to deal with, because that is clear and fewer questions arise than when somebody has said that they wish to have their organs donated. That is one of many anomalies.

Dr Emily Postan (University of Edinburgh): To complement that answer from an ethical perspective, a deceased person does not have interests, but the person that they were before they died certainly did, and respect for those interests is an essential concern alongside family interests.

Using the language of ownership is commonplace. We all fall into using that language, and it is used appropriately in many contexts but, because ownership implies thinking about property and remuneration, for example, it may be more helpful to think about self-determination. A key interest of the person before they were deceased is an interest in determining what will happen to their body, which need not be construed in ownership terms, but is still a powerful interest.

Dr Calum MacKellar (Scottish Council on Human Bioethics): From a philosophical perspective, a deceased person no longer exists and therefore has no rights. I agree with my colleagues that there is still an element of respect for the memory of the person. That is why sometimes even statues of famous people in Edinburgh are protected to protect their memory.

Nobody owns a body. People have responsibilities to a body, but there is no ownership. In the past in the Soviet Union, before the iron curtain fell, the Government owned the bodies of deceased persons. In places such as Moscow, the bodies of tramps who had died in the street from the cold or whatever were used for transplantation. They were owned by the state, and the state could do whatever it liked with the bodies.

Emma Harper: Realistic medicine and anticipatory care planning are important. If we know the wishes of people ahead of their death, it is easier to make decisions about opting in or out on organs and tissue. When I worked in Los Angeles, I was aware of a case where a family disagreed about the final wishes of a man who was dying of AIDS-related dementia. His partner of 25 years had no say, because he was not the next of kin. The parents overrode the man's decision that he wanted to donate his brain for research.

Are people's wishes protected enough in the bill, if they have an anticipatory plan, or can the family overrule?

Dr Postan: As I understand it, there is no entitlement in the proposed legislation for the family to overrule. The only ground on which the family could challenge anything in an anticipatory care plan or on the register, whether an opt-in or an opt-out, or the deemed authorisation would be if they could bring persuasive evidence that that decision was contrary to the most contemporary competent wishes of the person concerned.

Everything hangs on what counts as the evidence that a reasonable person would be persuaded by and whether the transplant co-ordination professionals have the time to dedicate to understanding and investigating whether there are reasonable grounds. That is the only time that a family's wish could ever alter the course from what the person wished.

Professor Britton: In addition, the realities of the situation have to be looked at. Taking a broad human rights perspective, the law has said in previous cases that the application of legislation on transplants is not theoretical or illusory. It is not about sitting round tables in buildings such as the Parliament writing legislation; it is about being at the coalface.

One of the biggest current anomalies is that although there is nothing in the current provision in Scotland to say that relatives' wishes be taken cognisance of, that happens routinely. That is the reality and the effectiveness of how we behave. We are moving to a situation in which, in theory and perhaps illusorily, we are no longer going to take any cognisance of those wishes.

Even with the provision in the bill, there are some riders. For example, will a more unusual donation, such as of reproductive organs or limbs, be passed without comment? If the family member comes forward with evidence to say that that was not the wish of the deceased, how will that be evaluated? What will be the consistent approach?

The idea in law is that there has to be clarity. It is one thing to say that relatives no longer have any say, but will we apply that all the time? How are we going to apply it? It is not only about having the legislation; it is about the quality of the legislation and how it is interpreted.

Dr MacKellar: On 13 November, Professor Turner told the committee that clinicians will always ask the family, no matter what the law says. If the family refuse to co-operate, organ donation will not go ahead, to ensure medical safety for the organ recipient.

Sometimes, a person who has not registered their wishes on the organ donor register has told their relatives what they want. Normally, relatives respect those wishes. If my relatives wanted to override my wishes, I would be upset. However, about 30 per cent of people never tell anyone what they want and never register their wishes. The Scottish Parliament information centre briefing says that about 65 per cent of those people, who have told no one their last wishes, oppose the removal of their organs for transplantation.

Under the bill, in cases where nobody knows someone's wishes, the nearest relatives of that person would have no legal right to oppose the removal of organs. Not many people have realised that that is a form of hard opt-out system. The bill would legalise a form of hard opt-out when nobody knows the wishes of the person who has died. That creates quite a lot of concern because, so far in the discussion, we have been told that what is proposed is a soft opt-out, yet in some cases a hard opt-out would apply. That should be made clear to the Scottish public, the media and everybody else.

David Stewart (Highlands and Islands) (Lab): I am interested in Professor Britton's submission, which refers to the European convention on human rights and cites the case of Elberte v Latvia in 2015. I am sure that my colleagues are familiar with that case, but a brief summary is that Mrs Elberte's husband died in a car accident, and nothing in his passport indicated that he wanted to donate his organs, but Mrs Elberte found out later that organs and tissue were donated. She brought a successful case under article 8 of the ECHR.

Even if we pass the bill, we will still have to look at the wider issue of the ECHR. At least two recent test cases suggest that, when the deceased has expressed no wishes, some rights of living relatives will still apply. Is the outcome of the Elberte case consistent with the bill?

Professor Britton: One difference is that the legislation in Latvia contained the expectation that relatives or the next of kin would be consulted. As you said, the passport was looked at, and the authorities found no indication that a family member objected, but they took no active steps to check that—there was almost passive acceptance, if that makes sense.

Two years after the gentleman's death, his wife found out that his organs had been taken, because the organisation that did that was being investigated under criminal procedures. She objected because the organisation had not taken positive steps to find out what she wanted.

Any interpretation based on the law on the subject needs three things. The whole idea is that there is a public agency, such as the national health service, that could invade an individual's private right, which is captured under article 8. Mrs Elberte also successfully won under article 3, which is on inhumane treatment.

The law requires any invasion of those rights by a public authority to be three things—it must be proportionate, legitimate and in accordance with the law. In the case that you described, the issue was the last element—whether the activity was in accordance with the law. The court said that, although Mrs Elberte had not made an obvious objection, nobody had actively found out what she wanted. That is what she won on. She did not win on the fact that she was the next of kin; she won on the fact that she had not been consulted at that time, as was required within the legal provision. It was a personal right to her.

We have to be careful, because anything in law is always about terminology. If the bill proceeds, the rights of the family and the role of the family need to be very clear, because those are quite different things.

10:15

Dr MacKellar: The Council of Europe, which is a lot bigger than the European Union, has an additional protocol on transplantation. Paragraph 102 of the explanatory report on that protocol states:

> "It is the expressed views of the potential donor which are paramount".

In 2005, I gave evidence on the topic of transplantation to the Health Committee, and I tried to explain that it may be possible to bring a case to the European Court of Human Rights because someone was not asked about what would happen to their organs. The response from one MSP was, "Well, they can't do that, because they're dead and they don't exist." However, we should follow the spirit of the law. Just because someone cannot bring a case to the European Court of Human Rights, that does not mean that what happened is okay. It can still be wrong from an ethical perspective, even though someone would never be able to bring a case to the European Court of Human Rights because they have died. For me, that is stronger—ethics is more important than just having or not having the possibility of bringing things to court.

Keith Brown (Clackmannanshire and Dunblane) (SNP): On Dr MacKellar's point about the Soviet Union having ownership of dead bodies, I think that the Soviet Union also had ownership of children under that law when it first came in.

I am interested in cases in which someone has expressed a definite preference either to opt in or to opt out and that is then overturned. Professor Britton's evidence says:

> "we are placing the rights of the relative far above the integrity of the deceased and the need of a possible recipient. The last autonomous wish of the donor is potentially being thwarted simply because he or she is in no position to object."

If the potential donor, in full possession of their faculties, has taken a conscious decision to opt in or to opt out but that is reduced to a wish that should be respected rather than a right, whose rights then come into consideration? Professor Britton made the point that, if the families are to be the arbiters, surely that should be written into the law. Should the family have that right? At present, it seems that clinicians have the right to say that they feel a bit uncomfortable about the donor's wishes and they will be guided by the discomfort that is felt by the family, even if that changes things. I suppose that I am trying to get an idea of the hierarchy of rights that applies.

Dr MacKellar: In 2007 in Singapore, where there was an opt-out system—I cannot remember whether it was a hard or soft opt-out system, but I think it was a hard one—there was a case in which the body of a young man was being taken away and the family were pleading with the clinicians not to do it because they wanted to be with the person for a few more hours. The mother was on her knees, crying and asking the clinicians not to take the body away. Eventually, nine police officers had to come. That was a scandal in Singapore, and the family were eventually compensated with five years of reduced healthcare costs—there is no national health service in Singapore.

It is a difficult issue. I feel that if the view on opting in or opting out is clear, that view should be respected by the family. It is a bit like a will. Some of us have a will, and that is respected in law. For me, the problem arises when nobody knows what the person's wishes were. I believe that the family should certainly be able to have the last word in cases in which nobody knows the person's wishes.

Professor Britton: The question takes us back to terminology again. We talk a lot about "deemed authorisation" or "presumed consent." Consent, in particular, has a special meaning in law, and increasingly, as the years go on, it implies an understanding of the decision and that there has been an opportunity to weigh up the pros and

cons. In recent case law, post-2000, it has been regarded as very personal to the individual—consent for me might be quite different from what it is for other people.

I do not think that it is possible for families to replicate that, so what we are then looking for from a family is permission, which is very different from consent, because the family might not understand fully the values that led the individual to make the decision that they made. We are not asking families to replicate the views of the individual; we are asking them to decide whether they are willing to give permission if the individual's values, wishes and consent are not known.

Dr Postan: If it is genuinely the case that no one knows the deceased person's wishes, it is misleading to say that the wishes of the family somehow give better access to those wishes and are the preferred option, because the position is in genuine equipoise: whatever the family decides could be contrary to the genuinely unknown wishes of the deceased person. Exactly as Professor Britton said, we then move to a whole different paradigm, which is about looking at the interests of the family and respecting their distress, or their wish to give a gift, by giving permission. We would be moving away entirely from the language of consent.

I add my voice to Professor Britton's, because she made an excellent point. If, despite what is written in the legislation, it is hard for healthcare professionals to move away from a paradigm in which they have acquiesced to the wishes of the family more often than they have respected the wishes of the deceased person, there will be a problem for the success of the law. If it is hard to make that change, the law will say one thing but another thing will be happening, which will serve to undermine precisely the principle that Professor Britton was explaining, which is the importance to consent and authorisation of people having full information and a full understanding of the undertaking to which they are signing up when they opt in or opt out. If the law, as written, cannot function because it is too hard to change the culture, that strikes me as a real problem.

The Convener: There is no formal role for the family in the current legislation, but there was such a role before 2006. If we were to formalise the permission of the family or give the family some other formal legal role, would that reverse the change that was made 12 years ago?

Dr MacKellar: At the moment, the family authorises what happens. The family always has the final say as to whether the organs are used—

The Convener: But not in a formal sense.

Dr MacKellar: In the legal sense, yes, there is authorisation. The family always has the final say. At the moment, even if someone has registered their wish to donate organs and is on the register, family members can veto the donation, because it is the family that gives the authorisation.

It is an authorisation, not consent. We do not use the concept of presumed or deemed consent in medical ethics; we use the system of opting out or opting in. "Deemed consent" is a contradiction in terms in bioethics, because to consent is to make an active decision, as Professor Britton said. The decision is made for oneself; a person cannot consent on behalf of someone else, especially if they do not know what the individual's wishes were.

Professor Britton: Let me qualify that in terms of my understanding of the current position on the role of the family. The anomaly, as I see it, is that there is no legal provision for the role of the family as the law currently stands, but there is a general recognition that specialist nurses will enter into dialogue with the family to gain their views and will not go against the views of the family. The role of the family is custom and practice rather than something that is provided for in statute.

The Convener: Would the provision of a statutory basis for the role of the family revert to the pre-2006 position?

Professor Britton: It would if that were done efficiently. However, I go back to what I said earlier—that the role cannot be arbitrary. If there is an exception on the particular organ that is to be removed and family members have a role, that might lead to the question whether there may be other such circumstances. That may then lead to a presumption that the role is arbitrary.

On the idea of having consistency and clarity in the provisions of the law, I will use the current position as an example, as that will be easier. Hypothetically, if there is no clarity in the law, the courts may often look to custom and practice. That takes us back to the effectiveness of the law and the reality of the situation. What happens is based not on ideology but on practicalities, and, without a doubt, the custom and practice at the moment is that the wishes and values of the families predominate.

Keith Brown: I am concerned about that last point and about the narrower point that somebody has expressed their wishes and been specific about opting in or out. I realise that, for practical reasons, it might not be possible to fulfil that wish and that other considerations apply when no wish has been expressed. I am not making a point about those situations. What is important is the need for clarity in the law about whose rights are being upheld. I feel that the process is, in essence, a charade with regard to the donor. It does not matter whether they consent or say that they want

to opt in or out, because something else can subsequently supersede that wish. I have issues with that, but if that is the case, surely we should be explicit about it—we should say that the donor does not have that right.

I do not get the idea that authorisation does not clash with consent; the two are very much in conflict. Surely, we should be clear about what a donor might have thought, because that is important for the real-life situation of people opting in. They will not give consent if they think that, in any event, it means nothing because it can be overturned by somebody else. It is really important to be clear about whose rights and wishes are being followed—I do not wish to introduce a confusion, as the point is about clarity.

Some people think that the wishes of the family should take precedence, but four countries were identified where that is not the case—where what the donor wants takes precedence—so that is possible. Also, some of the donors' families do not want to be involved in the decision, because they agonise over it. Is it not possible to have a straightforward situation in which the wishes of a donor who has expressed a wish to opt in or out are respected? They have made that decision as an adult in full possession of their faculties, so why should that wish not be followed?

Dr Postan: I understand that that is how the law is drafted at the moment. The concern is that there is a culture in which, or an expectation that, that does not happen in practice because that is not what has been done in the past.

For the bill to work, as it is written, support is needed to change the culture in the healthcare setting and to change social norms and public awareness, with publicity about the significant change that the bill, as drafted, will make. The change is that the wishes of the deceased person cannot be overturned by the wishes of their family; they can be overturned only if the family can bring to bear evidence that the person's wishes had changed. That takes us back to the question of what guidance will be given to the transplant co-ordination team about what counts as good evidence of a changed wish.

In our written evidence, we say that the issue will be opaque, to some extent, because the team cannot look into people's souls and tell whether a person is being absolutely straightforward. Perhaps the guidance could contain some indicative forms of evidential support, so that people are not in the dark when trying to work out what counts as someone knowing that their relative's wishes had changed—and showing that—and when someone is trying to fulfil their own wishes by sleight of hand. As drafted, the bill would work as Mr Brown suggests, but there are many instances in which it might not.

10:30

Dr MacKellar: I agree that, from an ethical perspective, it is wrong to go against a person's last wishes. However, as we have heard from Professor Turner, from a practical perspective, the medical team would never go against the wishes of the nearest relatives. I have just checked the Human Tissue (Scotland) Act 2006 and, at the moment, the nearest relatives always have the last word in authorising—or not—what happens to the organs of the deceased. They can authorise their use for transplantation and give legal authorisation for the use of the organs for research, education and other purposes. That can happen even when the person has said nothing—the relatives can still authorise all those things.

I do not know how to get around the issue. If we wrote down in law that the wishes of the deceased should always take priority, in some—very rare—cases that would create incredibly distressing situations. I do not think that medical professionals would be prepared to deal with that problem, and they are the ones who would have to deal with it on the ground.

Professor Britton: As Dr Postan said, the legislation on its own will not be enough; it needs to be accompanied by cultural change and a change in people's attitudes. Several studies have been made of legislation standing alone, and very few jurisdictions agree that that is sufficient. There must be buy-in, understanding and education. The Parliament would be fundamentally changing an active process of opting in to—arguably—a more passive process of opting in by doing nothing, whereby someone would have to actively opt out. Getting support for that would involve getting the support of families, which would be secured through education and people understanding that it would be a fundamental change in culture and approach.

Miles Briggs (Lothian) (Con): I will pursue Professor Britton's point about the rights and role of family members in the legislation. That is an important point, because the current position in law is very different from convention and practice. We know from the most recent data that the wishes of about 10 per cent of potential donors who had recorded their wishes on the organ donor register were overturned by family members. Would it be beneficial for any bill to reflect convention and practice to ensure that those whom we are tasking to work with families to achieve donation feel that they are protected and not exposed to potential legal or regulatory challenges?

Professor Britton: I will focus on the latter part of that question, considering the Elberte case and the idea of rights and roles. Mr Briggs raises the important point that none of this will work unless

there is clear guidance for those who provide information and support for the families at the time. The specialist nurses already do the most challenging of jobs in the most sensitive circumstances—even before the introduction of what is proposed. Under the proposals, they will have to do the same job in the knowledge that there is now a legislative provision to acquiesce to the wishes of the deceased. That brings a greater challenge for them and makes it a more difficult role. Their training and the background and understanding that they bring will need to be much more acute.

Dr MacKellar: I have read the discussions that the committee has had over the previous weeks, and there is always a presumption that people have family members or at least friends of long standing. However, we live in a society in which some people—more and more people, unfortunately—do not even have a friend of long standing. I have a very good friend who is a Church of Scotland minister in north Leith. He sometimes has to ask the congregation if some of them will go to a person's funeral, because otherwise the only people there would be the minister and the undertaker. We must think about cases in which people have no family and no friends of long standing. They may have a few friends who would come to their funeral but who are not really close friends, and nobody would know the deceased's wishes. I do not feel that that has been taken into account in discussions and in some of the legislation.

Miles Briggs: We have met many families who have gone through the process, and they have always highlighted how good the nurses who have dealt with them have been. What is important, though, is that there have often been failures towards the end of the process, when, even though the family has signed up to the relative's wish for their whole body—whatever is needed—to be used for transplantation and donation, the family has decided to veto the donation of the eyes, for example. I wonder whether, as Keith Brown has outlined, we could make the wishes of the individual paramount. Otherwise, families who had supported a family member's wishes may decide that their personal wishes should apply to some aspects of the decision. Many nurses find it difficult to go back to families and ask them whether they will fulfil a family member's wishes.

Professor Britton: That is why it is important to have clarity about exactly what the role of the specialist nurses will be. If there is no clarity from the outset, and if there is no consistent and non-arbitrary approach, the issues that you mention will arise—and, once again, they will become custom and practice. For example, it will become custom and practice to acquiesce in the decision not to remove the eyes, the heart or whatever is considered important at the time. As soon as we start to do that, we are in the realms of medical or ethical judgment and are moving away from the provisions that you have put before us today.

Dr Postan: There is also a risk of tension in how the bill's intentions are drafted in the explanatory notes. For example, it is constantly emphasised that this is a soft opt-out system because of the importance that is given to the views of the family. However, the range of issues on which the family's views will be sought—for example, the medical history of the person and any evidence of differing views—is fairly limited. If that tension between validating the family and limiting their input persists into practice, it could undermine the aims of the legislation and the family's feeling that their views are being valued.

David Stewart: I will continue on the theme of the role of the family in deemed authorisation. Some of my points were covered earlier, at least in part. One point that has been raised is that, whatever the law might say, in practice medical professionals will take into account the wishes of the family. If we accept that that is a given—it is our culture and, in my view, it is a good thing—should that not be reflected in the law?

Dr MacKellar: I believe that it should be reflected in the law. I remember the Health Committee discussing those issues in 2005 and it was made very clear to the MSPs back then that the family will always be consulted because, for patient safety, information is needed about the deceased person. That reassured some MSPs, who, as a result, felt more comfortable about supporting the bill that is now the present legislation.

Professor Britton: It is a small point, but both of my colleagues have talked about the role of the family in providing evidence of underlying medical conditions. That could be problematic. As described by Dr MacKellar, family members may not have such specialist knowledge or may not be alive.

There are also matters of confidentiality to take into account; for example, a potential donor might have underlying conditions that the family have no knowledge of or are not aware of. Therefore, you will place quite a responsibility on them if you ask for information on a person's medical background, because they might not have it. They might simply say, "They had no conditions," when in fact that might not be the case.

David Stewart: Another question has just occurred to me. If surviving family members had power of attorney, would they, under Scots law, have any more clout in decisions that had to be made on possible organ transplantation with regard to their deceased relatives?

Professor Britton: Not really, unless certain issues had been raised about the person's incapacity while they were alive. The rights of the now deceased are not transferable.

David Stewart: As you know, legislation has to be authorised as being compatible with the European convention on human rights but, if I have learned anything in this job, it is that not all lawyers agree with each other. Can the legislation be strengthened to make it more compatible in that respect, particularly in the light of the test case in 2015, which Professor Britton has already given information about?

Professor Britton: If you are trying to strengthen the law, you should bear it in mind that the law is enhanced at the price of the medical and ethical judgments that are highlighted in the examples that were given by one of your colleagues. Would you just go ahead and remove someone's eyes? If the law was absolutely clear and compliant and there was no room for any questions to be raised or for arbitrariness, the eyes would be removed if those were the wishes of the individual. If you were to bring in ethical questions or moral judgment, you might compromise a hard and unequivocal take on the law.

Dr MacKellar: One pillar of medical ethics is informed consent, which is about providing the right information clearly and enabling people to make their own decisions. The more information you provide to the general public on the bill or the present legislation in a way that is clear and which ensures that nearly everyone knows what system is in place and what is involved, the less likely it will be that cases will go to the European Court of Human Rights or against the European convention on human rights. It is really important for that information to be provided because, for those who are still living, the process of consent is continual; it is not just a one-off that people will have forgotten about 30 years later. They have to be reminded again and again about having given it, and they also have to be able to withdraw it. All of that should be explained to the general public in Scotland clearly and continually, not just in a one-off fashion.

Professor Britton: That is a valid point that was experienced and discussed in Wales. One of the initial iterations of the Welsh legislation gave something like a six-month lead-in time for informing the public and providing support but, at the end of the day, that period was changed to two years.

Another important point is that, once that information is given and the education starts to feed through to people, you should not stop. You need to keep going, because the change in culture that means that you do not have to face those difficult legal, ethical and moral decisions will come when people are more familiar with the issues. There is always a knee-jerk reaction to anything new but, if people are educated, they will have a chance to understand the reasons for and benefits of the policy. However, that education has to be on-going.

Dr Postan: I absolutely agree with both witnesses. Education and ensuring that citizens understand what is going to happen are important if deemed authorisation is to have any traction at all with regard to our interest in self-determination over our bodies. If people do not have information about what will happen under deemed authorisation, we cannot even pretend that it has anything to do with respect for interest in self-determination.

Furthermore, there have been bad governance experiences in the United Kingdom—for example, with the care.data programme. Notwithstanding how lawful the use of patient data in research or other areas is, such perfectly lawful initiatives have failed to take off because, as a result of a lack of information, understanding and sympathy for the aims, they have not been given social licence and have not been deeply imbued enough in people's understanding to make that shift in culture.

10:45

David Stewart: I have a final question. Are there any obvious gaps in the proposed legislation that we are discussing? If we were starting from scratch, is there anything that you would change so that the legislation could be better? We all want the same thing—increased donation rates—but is there something in the bill that is getting in the way of that? Are we missing anything obvious that the committee could change in order to make the bill better?

The Convener: Feel free to think about that and come back to it, if you want.

Professor Britton: The only observation that I would make is that the legislation should be tied into the smaller detail of education, lead-in, change in culture and opportunities for all members of our society from all backgrounds, faiths and cultures. There might be slightly different perspectives in people's cultures, so it is about taking cognisance that one size does not fit all and ensuring that there is a tie-in to the bill so that it reaches the widest possible audience.

Dr Postan: In our evidence, the Mason institute suggested the possibility—I do not believe that it is a current provision—of a statutory requirement for reporting to ministers on any research and monitoring on the uptake, effectiveness and impacts of the legislation. That would ensure that such reporting happens on a timetable that is rigid

and frequent and that certain standards are met. Collecting and reporting on the evidence of effectiveness, and remaining alert to whether further nuancing and changes are needed, will be essential because, as we can see from the international evidence, it is not clear how authorisation systems work.

David Stewart: So it is about the assessment of the effectiveness of the legislation.

Dr Postan: Yes, but in qualitative as well as quantitative terms. It is about not just numbers of donors and donations but the nature of the discussions that are happening in healthcare settings.

David Stewart: That is a good point.

Dr MacKellar: You also have to ensure that your legislation is scandal-proof. At the moment, there is a lot of trust in the system, but you need only one scandal for all the trust to be undermined and for people to stop donating their organs. As I used to do as a member of a research ethics committee for the NHS, we must always consider whether there is a situation in which a scandal could take place and how we ensure that it does not so that trust in the system is not undermined. If there is one scandal, it is too late.

Brian Whittle (South Scotland) (Con): Good morning, panel. I have a quick supplementary question. Professor Britton has discussed the need for continual education. We know that roughly 40 per cent of the population would give consent but have not yet done so. I was one of them until last week, but I did not find it that easy to find a way to sign up. With regard to a continuing education programme, would it not be simpler to ensure that it was easier for people to make a decision one way or the other? We would not need deemed consent if that was the case, because we would have an expressed wish. Would that not make the bill much clearer and make the nurses' role easier?

Professor Britton: I am sorry, but I am not clear about that. What would you be expecting the individual to do in those circumstances?

Brian Whittle: I would expect them to make a decision. We could give everybody a much clearer opportunity to make a decision to opt in or out, which would negate the need for deemed consent.

Dr Postan: That would be a mandated-choice model.

Dr MacKellar: There was a proposal for that two years ago when Mrs McTaggart introduced a bill in the Scottish Parliament. There was an MSP—I cannot remember what party she was in or her name—who said in her speech in the hemicycle that we should bring in a mandated system where everybody has to make a decision. That would make things a lot easier. There would probably be more organs available and there would be a lot fewer ethical challenges and problems, because everyone would know what the position is.

There are places—Belgium, one canton in Switzerland and some states in Australia—where people are obliged to vote in elections. Would it be possible to have a mandated system in which everyone has to make a decision? Personally, I would not be opposed to that.

Dr Postan: These arguments have perhaps been rehearsed in front of the committee previously, but one of the problems is enforcing that mandated choice and another concerns the fact that all the problems that we have been discussing today around people changing their views or families believing—genuinely or otherwise—that they have contrary evidence about the person's view persist in a system in which there is a mandated choice. With that system, you add an onerous layer of enforcement and penalty, but the dilemmas are still there.

Brian Whittle: To be clear, I was not suggesting that we force people to make a choice; I am suggesting that the opportunity to make a choice should be more readily available.

Sandra White (Glasgow Kelvin) (SNP): On that point, we have been told that people are happy to see donation as a gift. A mandated choice might affect that.

I am interested in the ethics and the law behind the pre-death procedures. I am not an expert in that area and I was surprised by some of the evidence that we heard. People were suspicious that doctors would accelerate death in order to get someone's organs, perhaps for experiments. People—even people who were in favour of donation—were suspicious when the issue became one of deemed consent.

I am interested not only in those issues but in how deemed consent affects the Hippocratic oath, and how that sits with the current medical law. Would it be seen as a conflict of interest in that regard? I know that we have an expert panel here today, so I am keen to hear your views.

Dr Postan: I will start on the issue of ethics, which might lead to the issue of law.

On whether deemed consent is contrary to the Hippocratic oath, it would not be—it certainly would not be if it were not contrary to the person's best interests. It might not promote their best interests, but as long as it was not contrary to their best interests, it would not necessarily raise ethical concerns.

What I would say, with more force than that, is that the issue of what is in someone's best

interests is not solely determined in terms of medical treatment or even physiological interests; someone's best interests also concern whether their wishes have been fulfilled and they can fulfil the life plans, projects and commitments that they value. If those involve donating their organs, an intervention that is non-painful and minimally inconveniencing—or however it is described in the policy memorandum—is by no means necessarily contrary to the best interests of the individual.

Sandra White: You are talking about a procedure that is done by someone's consent and is not painful. However, what if the procedure under deemed consent was not to the patient's benefit and was intrusive and potentially painful? That is the opposite of what you are saying, but that is what patients—

The Convener: Perhaps they are separate issues. I guess that the key question in relation to our current consideration is that, if we have deemed consent rather than explicit consent, does that affect the argument that you are making?

Dr Postan: If we understand deemed consent or deemed authorisation to be operating in a context in which people are informed, which means that it is in line with people's wishes, a minimally invasive, non-painful procedure could be understood as being in their interests.

Professor Britton: Another ethical—and perhaps cultural—consideration, particularly for family and next of kin, is about whether, if there has been an expression of the intention to donate organs, those caring for a person might not go the extra mile to try to preserve life. That may be what Sandra White was alluding to in talking about the Hippocratic oath, but there would be no reason to believe that that would be the case, because the current position is that there is usually some time—although not always a great deal of time—to recognise a situation of potential donation, and at that point specialist nurses will start to have communication with those who are with the person who is the potential donor.

Those conversations already take place, but it highlights the need for greater clarification, because people are frightened. There are different definitions of death; there are ethical definitions and legal definitions, and the ones that the current proposals tend to focus on are very much focused on brain stem death, but what is not covered is the situation of somebody who may have a longer death—somebody who is terminally ill and may die in a longer time—so perhaps those definitions could be broadened out. Once again, it comes down to the skill of those who have that communication and to the cultural understanding that, at the end of the day, the person is going to die and the specialist nurses are trying to maximise the opportunity to donate those organs to someone else.

Dr MacKellar: As I said, the really important thing in medical ethics is informing people. If they are informed and know what is going to happen to them after they have died, that is acceptable. Problems arise when things happen to people and their families were unaware that that was going to happen to their bodies. That is why it is really important to support the provision of information. Of course, there is a lot of skill among specialist nurses, but they can do only so much. If people are not informed at all and it all comes as a surprise, the nearest relatives will be very upset, no matter what the specialist nurses say, so it is extremely important to inform people about what is going to happen.

There is a lot more work to be done in our society in the area of transplantation. Even in the SPICe briefing, we see how confused everybody is. On page 34, we read that there is a lot of confusion in the area, which causes me a lot of concern as an ethicist.

Sandra White: I take on board exactly what you are saying and I recognise that an awareness campaign must be carried out so that people understand. However, you mentioned that, if people have not filled in a donor card, the family have to be asked, and they can overrule their loved one's wishes, whatever they may be. They would have to be asked about keeping the organs alive and the pre-death procedures. Even if there is deemed consent, you still have to ask the family. We are trying to pinpoint whether that goes against the Hippocratic oath or against the law or the ethics of doctors. Are you saying that, whether or not there is deemed consent, those procedures would not go against the law?

Professor Britton: What would normally happen at the moment in clinical practice is that there would be two medical teams—a medical team caring for that individual on the basis of whatever ill-health or condition they have, and a specialist transplant team. Those teams do not interact—they are separate. One is totally focused on the health and wellbeing of the individual patient, in so far as that can be achieved, and the other team deals with transplants.

Dr MacKellar: In medicine, there is always a bit of a balance to be struck. If the interventions are not very serious, such as taking blood samples or doing something that involves no pain, that would normally be acceptable. If the interventions actually reduce the life of the patient, that would certainly not be acceptable in any way. It is a bit of a grey area.

David Torrance (Kirkcaldy) (SNP): Good morning, panel. Previous witnesses have raised

concerns about the bill in relation to adults with incapacity. Is the bill clear enough about the level of capacity that will be sufficient for deemed authorisation to go ahead? Should the bill be clearer about the length of time that incapacity has existed?

11:00

Dr MacKellar: I was talking to a psychiatrist who said that capacity is the holy grail and that everybody is different. It is very difficult to legislate in the area, because every case is different. Personally, I believe—as does the Scottish Council on Human Bioethics—that for adults with incapacity who cannot make decisions, it is appropriate for the persons in charge to make the decisions for them, although the adults with incapacity should be involved as much as they can be. It is a bit like the situation of children between the ages of 12 and 16, who should be involved as much as they can be in decisions about them. However, I think that the present legislation and the proposals in the bill are quite good in relation to how to address those situations for adults with incapacity.

Dr Postan: I have a question about whether the way in which capacity is spoken about is too "all or nothing". There is a lot of emphasis on the persons having capacity for sufficient time during which deemed authorisation has been the law. I assumed that that was so that they appreciated that it was the context within which they functioned and that they would have had the opportunity, if they wished, to opt out. However, the understanding in both law and ethics is that capacity is context specific and question specific. It does not strike me that that comes through sufficiently in the bill or that there is the potential for people with fluctuating capacity to have help and support to work out whether they can make decisions about whether to opt in or opt out, or to change their mind about previous decisions. There should be nuancing of the fact that things can be more context specific and fluctuate more.

Professor Britton: I completely agree with that point. The current mental health legislation in relation to incapacity is very good because it takes cognisance of the person's beliefs and values and of what they can contribute to the discussion of what they understand at the time. As Dr Postan said, the bill's proposals should contextualise that a bit more.

David Torrance: Do the bill's provisions fit with the Adults with Incapacity (Scotland) Act 2000 and would there be any benefit in linking them with the 2000 act in some way?

Professor Britton: It is probably not necessary to link them. I have at least tried to answer that already in saying that the 2000 act's provisions give the opportunity for context for decision making. The act provides that the individual is encouraged to make a decision to the best of their ability and capacity at the time. There are therefore already good provisions that capture what we hope to be able to do in terms of respect for the individual and their contribution. For me, it is not about linking the bill to the 2000 act, but we should refer to the fact that the tests are there and ensure that the proposals that are before us take cognisance of those.

The Convener: I thank all our witnesses for their helpful evidence on a range of questions this morning.

I suspend the meeting briefly to allow a change of panels.

11:03

Meeting suspended.

11:07

On resuming—

The Convener: I welcome the Minister for Public Health, Sport and Wellbeing, Joe FitzPatrick.

The Minister for Public Health, Sport and Wellbeing (Joe FitzPatrick): Thank you, convener, and good morning.

The Convener: Good morning, minister. Mr FitzPatrick is accompanied by Scottish Government officials Claire Tosh and Fern Morris, from the bill team, and Stephanie Virlogeux, from the legal directorate. I welcome you all. I believe that the minister will give us a short opening statement before we proceed with questions.

Joe FitzPatrick: Thank you, convener. I am grateful for the opportunity to speak to the committee about the Human Tissue (Authorisation) (Scotland) Bill. The primary aim of the bill is to introduce a soft opt-out system of organ and tissue donation from deceased donors. The bill will amend the existing Scottish legislation that supports donation—the Human Tissue (Scotland) Act 2006—by introducing a new, additional form of authorisation called deemed authorisation.

Deemed authorisation will apply to most adults from the age of 16 who have not otherwise explicitly opted in or opted out of donation. In practice, that will mean that where a person is not known to have any objection to donation, the assumption will be that the donation can proceed. The bill contains safeguards to ensure that donation will not proceed if that is not what the person would have wanted.

The bill is necessary in order to build further on the improvements that we have seen in this area. Despite the real benefits of transplantation and the advances that have been made over recent years, there are still over 500 people in Scotland on the transplant waiting list at any one time. There is an absolute limit on the number of people who could ever become donors—only around 1 per cent of people will die in circumstances in which organ donation is possible—but if there are steps that we can take to allow more of that 1 per cent to donate, I am keen that we do that.

Evidence suggests that there is not one answer to increasing organ and tissue donation, and that opt-out systems work better as part of a package of measures. A lot of work has been done over the past 10 years in Scotland to improve our infrastructure and systems, learning from countries such as Spain and responding to major reviews such as that of the organ donation task force. We have seen associated increases in donation and transplant numbers, but as support for and awareness of organ donation have grown in recent years, so has interest in a move to opt-out.

The member's bill that was introduced in the previous session by Anne McTaggart began the conversation and, although the bill was not supported, both Parliament and the Government recognised that there was an appetite to move towards a different form of authorisation.

The bill is the product of a great deal of work over the past few years, following the previous committee discussions. We have worked with a lot of people including the NHS, professionals and people affected by donation and transplantation, to consider how best to introduce a system of opt-out in a way that contains appropriate safeguards and which will not compromise the already complex and lengthy donation pathway. I know that the committee has been interested in how long donation can take, and we are concerned not to lengthen that process.

We place particular importance on making the changes in a way that is transparent and open to the public. Organ donation enjoys and depends on a high degree of public support and we do not want to do anything to put that at risk. The bill therefore builds on the requirement in the 2006 act for Scottish ministers to support and raise awareness of donation by introducing a further requirement to raise awareness around the changes that the bill will introduce.

I know that the committee has had some discussion about the provisions relating to pre-death procedures—or ante-mortem interventions, as they are known to those who work in donation and transplantation. The area is complex, but I want to reassure the committee that those procedures are not new and are already an important part of the donation and transplantation pathway. The procedures help to ensure that donated organs are more likely to be transplanted successfully and that a donor's wishes can be fulfilled. However, we recognise that clinical procedures have changed, and will continue to change, and we want to ensure that there is a clear framework in place that sets out how and when pre-death procedures can be used and what safeguards must be in place.

It is important that potential future donors understand that those procedures can form part of the donation process. The bill does that by ensuring that we are open about what is involved and by putting in place certain requirements around communication and awareness raising. As with provisions around opt-out, our approach is to be transparent and to maintain a high degree of trust in donation.

I am grateful for the expertise, dedication and experience of the NHS clinicians and professional organisations who have helped to shape the bill. In particular, I acknowledge the work of the Scottish donation and transplant group, which advises the Government on such matters. I pay tribute to every person who has donated in the past and to every family that has supported donation. It is through such selfless acts that lives are saved and improved. I hope that the bill will lead to further increases in donation and to further lives saved. I would offer any such progress as a tribute to all those who have donated in the past.

I am keen to hear from the committee and I know that we will have an on-going conversation as the bill progresses. I will give careful consideration to any proposals by the committee that will strengthen and improve the bill.

I am happy to take questions. I hope that my colleagues and I will be able to provide further clarity in what has been a very thorough stage 1 process.

The Convener: Thank you, minister. I welcome that commitment to pay attention to any proposals that are made as a result of the committee's consideration of the issue.

This morning, we heard evidence that has reminded us of the debate around the 2006 act and you have just said that the purpose of the bill is to increase the level of donations. The Scottish Government's review of evidence found that there is only weak evidence that simply changing from one authorisation system to another will make a difference to donation levels and that any change would need to be put in a wider context.

Can you give the committee confidence that the bill, in and of itself, will result in an increase in donations and transplantations?

Joe FitzPatrick: We are aware of the view that opt-out on its own would not result in a significant increase in donations. However, opt-out is part of a package of measures that we have been developing over several years. There is international evidence that opt-out, added to the other measures that we are taking, is what will make the difference.

The Convener: Given that those other measures have been in effect since 2006 and are on-going, what does the bill's introduction of an opt-out system bring to the party? In other words, if awareness raising and engagement are proving effective under the current law, what additional benefit will the change to the law bring?

Joe FitzPatrick: There is no question but that the changes that we have made have made a difference. I will quickly go through some of the numbers. In the past 10 years or so, there has been an 89 per cent increase in donor numbers, which is a lot, and a 22 per cent decrease in the number of people who are on waiting lists. In 2008, the waiting list was 689 and, in 2017-18, the figure had gone down to 534. However, that still represents a lot of people who are waiting for a donation. The international evidence is that, if we do this correctly as part of a package of measures, it will lead to an increase in donations.

11:15

The Convener: Some might argue that the numbers show that progress is being made and therefore the efforts should be dedicated to further progress along the same lines, such as by making it easier for people to express a wish or more likely that they will do so, and that that would make the difference.

Joe FitzPatrick: Those things are not contradictory—we can and should do both. The process of the bill going through Parliament and, assuming that it is passed, its enactment will increase awareness of donations in general and, I hope, the number of people who are on the register. The two things go hand in hand—there is no conflict.

Keith Brown: I thank the Minister for Public Health, Sport and Wellbeing for his evidence and congratulate him on doing the daily mile at Murrayfield on Saturday, which I have to say was more interesting than the match.

We heard earlier about public support and the need for the public to buy into the measures. Under the system that is proposed in the bill, if somebody decides to opt in or opt out, is it possible to say that their decision will be respected? There may be practical reasons why donation cannot happen because the organs might not be suitable, or evidence might be brought forward to show that the person had changed their mind. Notwithstanding that, and given that we are trying to get public support, will the express wishes of the individual be followed through?

Joe FitzPatrick: The bill is clear on that, and it follows on from the principle that was in the 2006 act that the right to authorisation is the donor's right. The law on that is not changing. Clearly, there are discussions that have to happen with families, which might determine whether donation proceeds, but there is no family veto as such in most cases. That is consistent with the law as it stands in the 2006 act. That is not changing—it is a continuation of the law.

Keith Brown: That is my concern. As you rightly say, that is the current situation. A family override is not written into the current legislation, but I think that you are saying that there is a family override. My point is that, if there is a family override, when people are being subject to the education that we intend that they should have about their rights under the new legislation and when they are deciding what to do, they could easily say to themselves that there is no point, because their family—there is an interesting issue about what happens when there is no family—will be the ones who decide, along with the medical professionals. People might think that their decision is not relevant because it will be taken as an expressed wish rather than a right, and that might limit take-up or people's involvement in the process.

Joe FitzPatrick: The current legislation and the proposed legislation are clear that the right to authorisation rests with the potential donor. Clearly, the decision to proceed with a donation is a clinical one, and that is a different aspect. The bill will add to the current provisions a duty to inquire and to try to find out what the last wishes of the donor were. When the family are asked, they will not be asked for their views; they will be asked about what they believe were the views of their deceased relative who is the potential donor. That is the family's role in authorisation.

There is obviously a different role in the process relating to donation. There has to be a clinical decision to proceed with donation and it would be difficult for clinicians to make a decision to proceed with the donation if they had not managed to go through all the safety questions. They have to make that choice so, in practice, I do not think that there is anything that we could put in law that would change a family member's ability to say, "I'm not going to co-operate." That would put the clinicians in a very difficult position, because they have to make a choice about safety.

There are two big things that a clinician has to respect. One is the right of the donor, in terms of

their donation wishes, but the safety of any recipient must also be considered. However, on the right to authorisation, the legislation as it stands in the 2006 act and as it would stand in the bill makes it very clear that that is a right of the person who would be donating.

Keith Brown: My very clear impression from previous evidence that we have heard is that that would still leave substantial doubt in the mind of somebody who is considering whether to opt in or opt out.

Leaving that aside, you made a point about the information that is required from the family being necessary in a decision to donate or for a transplantation to take place. A witness gave us an example earlier in today's meeting of a person who has no family and nobody else to consult, and perhaps you or your officials can give us some information about what would happen in that circumstance. Is it possible that the tests that can be done would be sufficient to allow donation to take place, if you are unable to ask the dozens and dozens of questions that you would normally ask of the family or somebody else who is close to the potential donor? Could transplantation still take place?

Joe FitzPatrick: I will ask Claire Tosh to answer that. I heard what was said earlier and, to answer your other question, I think that the point that you were trying to make emphasises the need for us to have a strong publicity campaign to encourage people not just to get on the donor register but to ensure that they have that conversation with their family beforehand. It will make conversations with clinicians much easier if the family conversation has taken place before any unexpected circumstances arise.

Claire Tosh (Scottish Government): In the bill as introduced, there is a duty to inquire, and it would be quite difficult to fulfil that duty to inquire if there was nobody to seek those inquiries from. The bill puts a duty on clinicians to find out what a person's wishes were, and if somebody did not have a family or anyone else clinicians would not be able to find out that information. As mentioned earlier, there is also a question about a person's medical history, which would need to be gone into, and it is unlikely that that could happen.

In developing the bill, we spoke to people about some of those issues, not just around big publicity campaigns but also how to reach different groups. We have spoken to some faith groups about how to reach people, and that will be part of implementation as well. We are trying to ensure that the publicity is as widespread as possible, so that it could be assumed that, where a person has not registered a decision to opt in or opt out, their families should be aware that there may be deemed consent. There is also the additional duty to inquire, which would be difficult to fulfil if somebody did not have any family.

Keith Brown: I am pursuing a narrow point that is not about consent. If a person has nobody that clinicians can speak to about their medical history, is it possible, based on the tests that can be done, for transplantation still to happen?

Joe FitzPatrick: It would be for the clinician to decide whether they were comfortable with that.

Claire Tosh: It would be a matter for the clinicians and for NHS Blood and Transplant. However, our broad understanding is that it would be quite difficult for them to proceed in those circumstances.

The Convener: The point that Keith Brown explored about authorisation came up in the earlier evidence this morning, as you probably heard. The suggestion was made that, ultimately, under the 2006 act, despite the sense that it puts the donor at the centre, final authorisation may in fact still lie with the family. The NHS Blood and Transplant leaflet that is currently in circulation states:

> "When a person dies, and organ donation is a possibility, we rely on their family to agree to donation going ahead."

Rather than giving a detailed answer now, I wonder whether your officials could reduce to a flow chart—or some similar form—an indication of how the wishes of family members are taken into account under the 2006 act and how, if at all, that would change under the bill.

Joe FitzPatrick: I have asked for that flow chart.

The Convener: Excellent—I am glad that we think in the same way on those matters. That is very helpful.

Miles Briggs: I want to ask about the Welsh system. Last week, the committee heard evidence from officials from Wales. What did you learn from the Human Transplantation (Wales) Act 2013 and the progress that the Welsh have made in some areas? Is there anything that we in Scotland could learn from them? Specifically, although it is not contained in the bill, concerns have been raised about the infrastructure in Scotland and the potential to do something about that. Do you have any comments on that?

Joe FitzPatrick: In drafting our bill, we spent a lot of time learning lessons from how the Welsh act has been implemented in practice and the impacts that it has had. Positive figures are coming out of Wales, particularly when it comes to increasing rates of consents, as they call them in Wales—in Scotland, we call them authorisations. Wales now has the highest level of consents in the

United Kingdom. We have certainly looked at the experience in Wales.

The financial memorandum covers a number of areas where there will be significant investment in donation pathways. Does anybody else want to add anything?

Fern Morris (Scottish Government): The Welsh undertook an evaluation, and we looked at some matters that came out of that—for example, clarity about the role of the family. To begin with, there was uncertainty about the family's role. Therefore, as the minister set out, the expectation in the bill is clear—it is the individual who decides whether authorisation or consent is in place. The family's role is to give evidence on that. Another matter that came out of the evaluation was the need for on-going awareness raising, so that awareness is maintained over time.

Miles Briggs: I have been taken with the cultural change that we will need and how we can achieve that on a positive note. Sometimes, Government advertising does not achieve the outcomes that we hope it will and the money that we spend on public information does not necessarily drive the change that we want to see. What work have you done on future publicity if the Parliament passes the bill, so that we can generate a national conversation and ensure that, outside of the bubble, people understand the issue and want to engage with it?

Joe FitzPatrick: The Government would not necessarily be the main organisation fronting the education—it is more likely that NHSBT and the Scottish National Blood Transfusion Service would do that. We need to work with all our partners to make sure that the messages reach the widest possible range of people. We have agreed to work with religious groups to make sure that, where there are particular issues, people understand what the legislation means.

Claire Tosh: There is the duty on ministers regarding information and awareness; that is led by the Scottish Government and it follows the general marketing principles. The minister said that there will be work under way to develop the right messages about what the changes are and on how to reach different groups of people. We can learn from Wales about that, but we should also take into account the marketing work that the Scottish Government has already undertaken. There has already been consideration on how to take that work forward. The prospective costs of the work have been included in the financial memorandum. The schools pack has been developed and it could be further developed in the future.

Miles Briggs: We have discussed the age difference and the fact that 16 and 17-year-olds in Scotland will be included. You mentioned discussion about the schools pack. To ensure that the information is age specific, that is welcome, but what work have you done on the potential for the parents of 16 and 17-year-olds living at home to be part of that discussion?

11:30

Joe FitzPatrick: As I said earlier, it is always best if such decisions are made after discussion with families. That is good practice and something that we should be encouraging. In Scotland, the age of legal capacity is 16, and that is the age at which the 2006 act says that a young adult is able to make the decision. We are not making a change to that; we are keeping the age at 16, as it is just now. That is appropriate. We want to ensure that young people understand the legislation before their 16th birthday. That is why we will be sending packs to schools. There is also a proposal for a direct mailing to all young people as they approach their 16th birthday so that they can make a decision.

Once someone has made their decision, we would still encourage them to register on the organ donor register and to let their family know what their decision is. That would make it a lot easier for families if they ever found themselves in those unfortunate circumstances.

Brian Whittle: Good morning and welcome, minister. I will start with a straightforward question. I have heard from the specialist nurses that their conversation is made easier and the number of family overrides is reduced if people have already given consent and opted into the programme. The bill proposes three different options: opt-in, opt-out and deemed consent. Would it not be better to maximise the number of opt-ins and remove the ambiguity of deemed consent?

Joe FitzPatrick: Having deemed consent will make conversations easier, because the starting point of those conversations is about what the family thinks the person thinks about donation, so rather than thinking about their own views on donation, the family is thinking about the person they have just lost or are expecting to lose.

I am clear that there is a two-track approach. We will have the new system, but we will continue to try to encourage people to register and, most importantly, have those conversations with their families. It is more important that someone who is registered has that conversation with their family than it is that they are registered—having the conversation is the most important thing for everyone. The bill does not prevent us from encouraging people to sign up to the organ donor register and tick the box.

Brian Whittle: The part that I am struggling with is that, for deemed consent to be effective, we must ensure that everyone has an easy opportunity to opt out. That is the only way in which deemed consent can be effective. We know that 40 per cent of people who have not opted in would opt in. As I have said many times during the discussion on the bill, I was one of the 40 per cent. I managed to opt in last week, but that was only because I changed address and wrote away to change my driving licence—that is one of the ways in which people register.

If we agree that, to strengthen deemed consent and make it work well, we have to ensure that people have really good and on-going opportunities to opt out, can we not agree that by using education and publicity we can increase people's opportunity to opt in, which is a much stronger statement than deemed consent?

Joe FitzPatrick: You are evidence that the passage of the bill has encouraged people to start thinking about such things and to make decisions on them, which is good. Welcome to the organ donor register club.

As part of the process, we want to make it easier for people to record their preference and their decision on organ donation and that goes either way—-they might want to express whether, should they find themselves in circumstances in which their organs could be used for donation, they want their organs to be used or not to be used. We want to encourage people to make that decision and record it on the register, but it is equally important for people to ensure that their families are aware of their decision, either way.

David Stewart: Good morning, minister. I welcome you and your officials.

What assessment have you made of the Spanish system of organ donation?

Joe FitzPatrick: Spain has very high levels of donation. In drafting the bill, the Government has looked at all countries that have an opt-out system. It looks as though the opt-out system in Spain is part of the reason why there is such a high level of donation, but there have been other cultural changes that explain why the level is so high there. We have looked at all the international examples.

David Stewart: Thank you, minister. The officials should feel free to contribute as well.

You will know that we have had considerable evidence on the bill, including an article that appeared in *The BMJ* in 2010 that argued that the evidence suggests that the consent system in Spain is not the real factor in the increase in donation rates there. It argued that the really effective thing has been to have transplant co-ordinators, donor detection programmes and the greater provision of intensive care beds. Just for completeness, to compare Spain with the UK—obviously, we operate within the UK system—even if we reduced family refusal rates here from 40 per cent to 15 per cent, the donation rate would still be only half that in Spain. Clearly, the best practice is in Spain. Of course, other evidence has said that we cannot compare apples and oranges. I appreciate that there is also the cultural issue and in particular the role of the Catholic church, which has supported the measures, which is obviously welcome.

If we place the consent system to one side, there is an argument about the opportunity cost. Instead of looking primarily at consent, you could invest the money that is set out in the financial memorandum in increasing the number of intensive care beds, which are important in the Spanish example.

Joe FitzPatrick: Clearly, we need to look at other examples. The financial memorandum makes significant provision for extra resources for staff for registration, training and development and recruitment. A large amount of extra resource is set out in the financial memorandum. Even if we increased donation to the levels that we hope for, it is unlikely that that would lead to the number of transplant units exceeding the forecast in the current strategy—"Commissioning Transplantation to 2020"—which runs until 2020. There is no expectation that the levels would go above that in that short period. There will still be capacity in the system.

David Stewart: I was struck by your opening comment that you are willing to listen and to consider amendments to the bill. I think that I speak for my colleagues when I say that this is not a partisan issue—all members want more organ donation, and we want to do it right. As someone said, what is right is what works. Although I accept that there might be some different cultural issues in Spain, it is top of the league among the European examples. Will you have a look at the issue of intensive care beds? I realise that the situation cannot be turned round overnight, but that seems to be a much more relevant factor than the consent issues.

Joe FitzPatrick: Obviously, we need to look at all the circumstances around donation. However, I do not think that that direction of travel would be dealt with in the bill, because it is not relevant to the bill—it is more of an organisational factor. However, I hear your points and we will feed those in and consider your suggestion.

David Stewart: To ask my question another way, have you looked at cost alternatives to the financial memorandum? In other words, have you

considered whether you could do something better with the funding that you have allocated to the bill?

Joe FitzPatrick: The financial memorandum is about how we fund what we are trying to do with the bill. I do not know whether Claire Tosh wants to add anything.

Claire Tosh: The financial memorandum and the business regulatory impact assessment were prepared with input from NHSBT, the SNBTS and other partners. The financial memorandum takes account of the on-going work on the package of measures that is currently in place, including the high-profile awareness raising. However, as we go forward with the bill, the intention is to work with those partners to see what measures could be put in place, if necessary, to further support the implementation. As the minister said, with regard to the work with the National Services Division on the taking organ transplantation to 2020 strategy, there will be a further commissioning strategy as a result of the work on transplantation costs that is under way. There are therefore opportunities beyond the bill.

David Stewart: I am sorry if I am stressing this point too much. I believe that the consent system has a place; all that I am saying is that it appears from the Spanish example that we might be missing a trick by not looking at their best practice, given that their donation rate is double ours. Even adjusting for cultural differences, the Spanish example shows the importance of having intensive care beds, transplant co-ordinators and donor detection programmes. I ask you to have another look at the Spanish example. Provisions for such good practice might not appear in the bill, but I believe that learning from the Spanish example would make a big difference.

Joe FitzPatrick: We are introducing the bill because we want to increase the number of donors and transplantations to help the 500 people who are waiting for a transplant at any one time—that is our ultimate aim. We have never said that the bill on its own will get us to where we want to be, so I am happy to look again at the specifics to which Mr Stewart referred.

Fern Morris: I think that it was Lesley Logan of NHSBT who highlighted some of the differences in Spain, such as higher discard rates and organs being retrieved without recipients being identified, which is very different from the system that we have in the UK.

The Convener: If the objective is to increase the number of transplants, which is clearly a shared objective, we heard from Dr Robertson of the British Medical Association, who described transplant surgeons as

"a bunch of very tired people ... working very hard".—[*Official Report, Health and Sport Committee*, 13 November 2018; c 23.]

How confident is the Government that the transplant infrastructure that we have can cope if the Government is successful in significantly increasing the number of donations?

Joe FitzPatrick: As I said, we would not expect the bill in the short term to lead to a number of transplants that is above the 2020 target, which is what the current infrastructure supports. If it looks as if the bill is going to be more successful than expected, we will have to look at the future strategy beyond 2020.

The Convener: Thank you. Can you say a little about opting in? We understand from the bill and its accompanying documents that that remains a focus of Government effort. How significant is that as part of the overall picture that you have painted this morning?

Joe FitzPatrick: People recording their views on opting in or opting out is very important. If we can encourage people to do that, it will make the conversations with families easier. It is important that they record their decision and then have that conversation, because the conversation is so important.

The Convener: So when you are increasing awareness of the bill, that will include awareness of opting in—the existing register—as well as that of how to opt out.

Joe FitzPatrick: We will obviously engage with stakeholders to ensure that our messaging works and that people understand what the bill does and what their options are.

David Torrance: Why do options for registering opting out not match those that are available for registering opting in, such as when applying for a driving licence or a passport?

Claire Tosh: Perhaps I can take that one. On opting out, the organ donor register is operated by NHSBT on a UK-wide basis and there is also the organ donation Scotland website. I think that the specific opt-out box was placed on that website after the introduction of the Welsh legislation. Publicity could also direct people there for the opportunity to opt out.

Joe FitzPatrick: So it is already there on the register. Brian Whittle may be able to tell us about that, because he registered just last week.

11:45

Brian Whittle: It is very easy to do.

Fern Morris: I think that the specific issue that you are alluding to is with the Driver and Vehicle Licensing Agency. At the moment, you can only

opt in via the DVLA and those other routes, and there is a delay in those registrations being processed in the central NHSBT ODR so that is why there is no option to opt out through those routes.

David Torrance: You touched earlier on working with religious groups. Can you expand on how you will communicate with minority groups and hard-to-reach groups, including people who do not speak English and adults who have difficulty reading and writing?

Joe FitzPatrick: That is a very important question. We want to ensure the widest possible understanding, so there has already been engagement with religious groups and other stakeholder groups. A lot of work has been done so that we understand what we need to do.

Claire Tosh: More work will be undertaken to understand what is needed. The plan is to have public information to target different groups. There is also updated training for peer educators, who are currently important in on-going work that is being done under the Scottish donation transplant group on raising awareness about organ donation among south Asian communities.

We are also considering presenting information in different ways. We understand that there is a need for that from focus groups of people with learning difficulties about providing information and enabling people to make choices.

There will be consideration of how best to communicate, and there is, obviously, the bill's duty on ministers to raise awareness and to promote information about donation.

Emma Harper: I am interested in aspects of the medical questionnaire. We have heard evidence about the questionnaire and learned that up to 350 questions could be asked of a family or the next of kin in order to obtain a medical history to enable clinicians to make informed decisions about whether organs or tissue can be donated and transplanted.

I am sure that you are aware of yesterday's news about Pauline Hunt, who is 49, from Kilmarnock in my South Scotland region. She received a donated kidney and has now developed cancer. This might be an opportunity to talk about the process of assessment of donors and of organs and tissues for transplant, to assure people that the current process is robust and safe and that it supports optimal practice. What review is intended, or is taking place, following yesterday's news? Is there room for a review of the current process or of the medical questionnaire?

Joe FitzPatrick: First of all, let us separate those two questions. The case that you mentioned is absolutely tragic, and my sympathy goes out to Pauline Hunt and her family. I cannot imagine what she is going through. It is clearly important that, if there are lessons to be learned from that case, they are learned and are understood across the whole donation and transplantation system. That has to happen, and the Cabinet Secretary for Health and Sport has said that she wants to ensure that lessons are learned. As I said, it is a tragic case and I genuinely sympathise with Pauline Hunt and her family.

I know that the committee's concern is that there seem to be an awful lot of medical and social history questions. In some cases, there are a lot of questions, but the process is about safety, so that is the amount of questions that clinicians say they need to ask. There are about 40 questions that have other questions underneath them, so if you add them all together you get a much bigger number. We have shared with the committee information on how questioning is done elsewhere: similar numbers of questions are asked in other places. Our specialist nurses ask the questions in a very sensitive way—they are trained to do that. We need to take the lead from clinicians to ensure that we get the balance right in assessing safety in the donation process.

Emma Harper: The questionnaire is not the only approach to determine whether organs or tissues—we keep talking about solid organs, but it can be tissues, too—can be donated. We can use case notes, we can connect with general practitioners and we can use other information to ensure that organs are used optimally.

Joe FitzPatrick: Yes. All that information comes together so that we do what we can in the relatively short time that is available in which to determine whether a donation can proceed, in order to make the process as safe and sensitive as possible.

Sandra White: I will continue on the theme of pre-death procedures, which I raised in the previous evidence session. I thank the minister for his opening remarks—especially his points about this being a very sensitive area and about more information being given to people.

You will be aware of the concerns that folk have raised about the procedure, including concerns from people who are very supportive of organ donation. I, and others, lack knowledge about what happens, so I welcome your comments about an awareness campaign.

I have two specific questions. Could PDPs be carried out under deemed authorisation before any conversation about donation has taken place with the family? My second question relates to the opposite position. What are your thoughts on

requiring expressed consent for PDPs from the patient or the family?

Joe FitzPatrick: The answer to the first question is no: there is a duty to inquire in the bill. Whether the procedures are type A or type B, that duty will exist.

Could you repeat your second question?

Sandra White: The second question relates to the opposite of deemed consent. What are your thoughts on requiring expressed consent for PDPs from the patient or the family? Would that be the best way forward?

Joe FitzPatrick: For some of the procedures—

Sandra White: The family or the patient would be spoken to.

Joe FitzPatrick: Yes. There is a range of procedures. Procedures might involve a urine test or a test of a blood sample, for example. Through the bill, we are trying to bring transparency to a process that has been being carried out throughout the UK since before the 2000s. It is important that we have a framework that can adapt to changes. That is why it is appropriate to have the two lists that will come to Parliament in regulations. It is important that people understand the processes.

Sandra White: That was the point that I wanted to make. Again, I thank you for your opening remarks about an awareness campaign. At previous meetings I have asked why people are not aware of the tests. The answer that I received was that, if such tests are to be done, the family will be spoken to: the family is informed, but the people who are donating an organ will not necessarily be informed. In the awareness campaign, will you let people know that, when they opt in and donate their organs, they might be subjected to certain procedures—or whatever language is used? Is that the type of awareness that you are talking about?

Joe FitzPatrick: That will be a new duty on ministers. The existing legislation places a duty on ministers to inform people about the organ donation register; the bill creates a duty to ensure that we raise awareness about the opt-out system and pre-death procedures. More transparency is good, because we can build trust in the system if more people understand it.

Sandra White: There will be no secrecy. That is great.

The Convener: We discussed earlier the circumstances in which there are no family members to whom questions could be put. It seems from what was discussed that that could, in terms of organ donation, be a show-stopper, in the sense that people would be unable to access vital medical and social information.

Emma Harper was right to draw our attention to the fact that the bill covers tissue as well as organs. When there is no family to consult and no access to medical and social records, is there still the possibility that tissue could be used for research or other purposes, when that question would need to be addressed before the donor had died?

Joe FitzPatrick: Deemed authorisation refers to the main categories of donation. One of the officials will talk about the specifics.

Fern Morris: There is a higher threshold for tissue donation because in most cases it is life enhancing rather than live saving, so a lower level of risk than for an organ would be accepted. The medical team would seek assurances and more information about the safety of the tissue before a transplant could take place.

The Convener: You are saying that they would require more information, so it would be more difficult when there were no immediate family members who were able to answer any questions.

Fern Morris: Yes.

The Convener: That is very helpful.

Joe FitzPatrick: The other point about the main categories of donation is that deemed authorisation would not apply to unusual categories of transplantation, such as face transplantation.

The Convener: Would deemed authorisation not apply because there is a greater level of risk?

Joe FitzPatrick: No—it would not apply because such procedures are not what people generally understand by “donation”.

Claire Tosh: Similar to the Welsh model, there will be excepted categories that will be set out clearly in regulations for Parliament to consider, after consultation about organs or tissue that might not be expected to be the subject of deemed authorisation. That is a slightly different question about what deemed authorisation would or would not apply to. That is what is understood by “excepted categories”.

The Convener: So, that is acknowledged in the bill, but would be set out in regulations to be laid before Parliament.

Claire Tosh: Yes.

Emma Harper: Is there an argument for calling pre-death procedures, “pre-donation procedures”? We are talking about cardiac or neurological death, but there are now issues around anticipatory care planning, when the person knows

that they are going to die, and might choose to donate a kidney or even both kidneys. It might be better to use the term “pre-donation procedures” instead of including the word “death”, with all its finality.

Joe FitzPatrick: It is difficult. If we are to be transparent, we should stick to the most accurate language. The medical term “ante-mortem interventions” might be preferred, but I am not sure whether that will be understood. If we want to ensure trust in the system, we need to be careful not to use language that is unclear.

The Convener: I suspect that we may come back to that subject. David Torrance will ask the final question.

David Torrance: Does the minister agree that the provisions on incapacity need to be strengthened in the bill, and that it would be better if the bill were linked to the Adults with Incapacity (Scotland) Act 2000?

Joe FitzPatrick: We need to understand people’s ability to understand the legislation. People need to be able to understand “deemed authorisation” for a period: we specifically make the point that there needs to be a period of time to allow people to make a judgment. That is clear in the bill.

Stephanie Virlogeux (Scottish Government): The definition of an adult who, over a period of time, has been incapable of understanding “deemed authorisation”, has intentionally been left flexible. That is to take account of the different circumstances of individual potential donors before their death. A more rigid definition could lead to unintended consequences and difficulties in fulfilling the wishes of people who want to become donors.

The Convener: I thank the minister and his officials for attending the committee, and I look forward to our further engagement on the bill as it progresses.

Joe FitzPatrick: Thank you, convener.

Petition

Gender-neutral Human Papillomavirus Vaccination (PE1477)

12:00

The Convener: We move swiftly on to agenda item 2, which we will consider in public before moving into private session.

PE1477 calls on the Scottish Parliament to urge the Scottish Government to extend the current HPV immunisation programme in Scotland to include boys. The committee is invited to consider our next steps in relation to the petition. Committee members will be aware that the Government has acted to change the law as has been suggested. Are members content to close the petition?

David Stewart: I congratulate the petitioners. David Torrance and I were both members of the Public Petitions Committee when the petition was lodged—it was so many years ago that I have forgotten when. The key point is that it is important to have a gender-neutral vaccination. The UK-wide authorisation is a very positive move. The development has been evidence led, but it also shows the strength of the Scottish Parliament’s Public Petitions Committee. I am delighted that we can see the end in sight.

Keith Brown: I agree. I record that I might know the petitioner: I know someone called Jamie Rae, although I do not know whether it is the same person.

The Convener: Okay. Do members agree to close the petition?

Members *indicated agreement.*

The Convener: Thank you.

12:01

Meeting continued in private until 12:25.

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