



Cynulliad Cenedlaethol Cymru The National Assembly for Wales

Y Pwyllgor Iechyd a Gofal Cymdeithasol The Health and Social Care Committee

**Dydd Mercher, 30 Ionawr 2013
Wednesday, 30 January 2013**

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Cynnig dan Reol Sefydlog Rhif 17.42(ix) i Benderfynu Gwahardd y Cyhoedd ar gyfer Eitem 1 yn y Cyfarfod yr Wythnos Nesaf (7 Chwefror 2013)

Motion under Standing Order No. 17.42(ix) to Resolve to Exclude the Public from Item 1 of Next Week's Meeting (7 February 2013)

Cofnodir y trafodion yn yr iaith y llefarwyd hwy ynddi yn y pwyllgor. Yn ogystal, cynhwysir trawsgrifiad o'r cyfieithu ar y pryd.

The proceedings are reported in the language in which they were spoken in the committee. In addition, a transcription of the simultaneous interpretation is included.

Aelodau'r pwyllgor yn bresennol **Committee members in attendance**

Mick Antoniw	Llafur Labour
Mark Drakeford	Llafur (Cadeirydd y Pwyllgor) Labour (Committee Chair)
Rebecca Evans	Llafur Labour
Vaughan Gething	Llafur Labour
William Graham	Ceidwadwyr Cymreig Welsh Conservatives
Elin Jones	Plaid Cymru The Party of Wales
Darren Millar	Ceidwadwyr Cymreig Welsh Conservatives
Lynne Neagle	Llafur Labour
Lindsay Whittle	Plaid Cymru The Party of Wales
Kirsty Williams	Democratiaid Rhyddfrydol Cymru Welsh Liberal Democrats

Eraill yn bresennol **Others in attendance**

Dr Alan Clamp	Prif Weithredwr, yr Awdurdod Meinweoedd Dynol Chief Executive, Human Tissue Authority
Yr Athro/Professor Vivienne Harpwood	Cadeirydd Pwyllgor Rhoi Organau Cwm Taf Chair of the Cwm Taf Organ Donation Committee
Dr Tim Lewens	Cyngor Biofoeseg Nuffield Nuffield Council on Bioethics
Victoria Marshment	Yr Awdurdod Meinweoedd Dynol Human Tissue Authority
Dr Peter Matthews	Academi Colegau Meddygol Brenhinol Cymru Academy of Medical Royal Colleges Wales
Yr Athro/ Professor Ceri Phillips	Prifysgol Abertawe Swansea University
Syr/Sir Peter Simpson	Cadeirydd Pwyllgor Moeseg Rhoi Organau y DU Chair of the UK Donation Ethics Committee
Dr Dariusz Tetla	Arweinydd Clinigol, Rhoi Organau, Bwrdd Iechyd Lleol Cwm Taf Clinical Lead for Organ Donation, Cwm Taf Local Health

Board

Yr Athro/Professor Chris Watson Cymdeithas Trawsblannu Prydain
British Transplantation Society

Swyddogion Cynulliad Cenedlaethol Cymru yn bresennol
National Assembly for Wales officials in attendance

Sarah Beasley	Clerc Clerc
Stephen Boyce	Y Gwasanaeth Ymchwil Research Service
Joanest Jackson	Uwch-gynghorydd Cyfreithiol Senior Legal Adviser
Victoria Paris	Y Gwasanaeth Ymchwil Research Service
Sarah Sargent	Dirprwy Glerc Deputy Clerk

Dechreuodd y cyfarfod am 9.01 a.m.

The meeting began at 9.01 a.m.

Cyflwyniad, Ymddiheuriadau a Dirprwyon
Introduction, Apologies and Substitutions

[1] **Mark Drakeford:** Bore da a chroeso i chi i gyd i'r Pwyllgor Iechyd a Gofal Cymdeithasol. Rydym yn mynd i ddechrau ar amser heddiw achos dim ond chwarter awr sydd gennym ar gyfer yr ail eitem ar ein hagenda, ac mae gennym lawer o bethau i geisio eu gwneud yn yr amser hwnnw.

Mark Drakeford: Good morning and welcome to the Health and Social Care Committee. We are going to start on time today because we have only a quarter of an hour for the second item, and we have many things to try to do in that time.

Bil Gwasanaethau Cymdeithasol a Llesiant (Cymru): Y Dull o Graffu
Social Services and Well-being (Wales) Bill: Approach to Scrutiny

[2] **Mark Drakeford:** You will have seen a paper on our approach to scrutiny of Stage 1 of the Social Services and Well-being (Wales) Bill; we need to agree our approach today. I am sorry that we only have a quarter of an hour for this item, but I hope to persuade you that we are not trying this morning to agree on every last paragraph and sentence in the report. However, we need to make a number of general decisions to allow the clerk's team to go ahead and do some of the things that it needs to do in order for us to meet the timetable laid down by the Business Committee for us to conclude Stage 1.

[3] There are a number of decisions to be made, which I am going to put to you. We can return to the detail, if you are content with the general approach. There are draft terms of reference in paragraph 9 in the paper for Stage 1. They broadly reflect the approach that this committee has taken in earlier legislative work in relation to food hygiene, asbestos and organ donation. That is the first question to ask you. Are you generally content with the draft terms of reference as they appear there?

[4] **Mick Antoniw:** To seek a bit of guidance on this, one of the things about the Bill is that it has some very separate and specific items within it, and I do not know whether the children and adoption stuff is sufficiently specifically identified within it.

[5] **Mark Drakeford:** Within the terms of reference? Well, we can certainly look to make sure that it is clear that it is a Bill that covers adults and children all the way through.

[6] **Rebecca Evans:** In previous terms of reference, we have included the aim to ensure that there are no unintended consequences to the legislation. Could we include that here as well?

[7] **Mark Drakeford:** Certainly. Other than that, are the terms of reference sufficient for us to proceed? I see that Members are content.

[8] The approach to Stage 1 scrutiny is in paragraphs 10 to 15 of the paper. The essential bit is the timetable that you see in paragraph 12. We need to get on as quickly as we can with a general call for evidence in order to allow a full six weeks, which is the maximum that we can manage, for people to send in written submissions.

[9] **William Graham:** Do you have a target date for the end of the six weeks?

[10] **Mark Drakeford:** We do. The closing date would be 15 March. Moving on, annex 1 includes a comprehensive, it seems to me, list of potential consultees that we could write to in order to give them the opportunity to provide written evidence. Obviously, it is not exhaustive, because we send out a general call, and anybody who sees it can respond, but these are the organisations whose attention we would draw specifically to the exercise.

[11] **Vaughan Gething:** May I just clarify something, Chair? In the list, there are two lists. There is the list of named and identified organisations, and then there are the respondents to the Welsh Government consultation. Do we automatically write to the people who are respondents to the Government consultation?

[12] **Mark Drakeford:** I think that that is what we do. We make sure that anybody who took part in the Government consultation knows that this committee is now beginning its work, so that they can write to us, if they choose to do so.

[13] **Vaughan Gething:** May I suggest that we add the GMB to the list of trade unions, because it will organise and represent lots of workers in the public, private and voluntary sectors that we are interested in?

[14] **Mark Drakeford:** Okay.

[15] **Vaughan Gething:** I note that all the allied trades and professions, and the Chartered Society of Physiotherapy, responded to the Welsh Government consultation, so I think that they will be covered.

[16] **Mark Drakeford:** Of course. If any Member has other names that they think are missing from the list and need to be added, please let Sarah know so that they can be added to it.

[17] Members will have seen the Bill and will have seen that it is substantial in length. We therefore need to think about how we are going to organise our oral evidence sessions in a way that gives some coherence to the evidence that we take, rather than simply having people in a random sort of way, as their diaries allow. So, in annex 2, you will see that there is a sort of thematic approach suggested, broadly following the main themes of the Bill. I am thinking that we will organise our evidence sessions according to those themes. Are you broadly happy with that way of doing it?

[18] **Kirsty Williams:** What is the difference between the ‘key principles’ and the ‘core principles’ of the Bill?

[19] **Mark Drakeford:** Is there a difference?

[20] **Kirsty Williams:** That is what it says.

[21] **Mark Drakeford:** We appear not to know, really. Maybe it just depends on the keys on the word processor.

[22] **Kirsty Williams:** I would be quite interested to know, because the Minister was not able to answer yesterday, why new legislation is necessary. I asked a very specific question on what they intend to do that they cannot do now, and the Minister did not answer that question. I would therefore be quite interested in being able to tease out what elements of the legislation are necessary to enable the Government to meet its policy objectives. I suspect the answer is, ‘Not many’.

[23] **Vaughan Gething:** I think the Deputy Minister might have been able to answer had she been there.

[24] **Elin Jones:** On the evidence on the work that relates to children, what is the relationship now between our committee and the Children and Young People Committee?

[25] **Mark Drakeford:** I was going to say something about that, because I have now received a letter from the Presiding Officer following the Business Committee’s decision to send the Bill in its entirety to this committee. The Business Committee had a letter from the children committee asking it to remit those parts of the Bill that deal with children to that committee—in other words, to split the Bill. The Business Committee decided not to do that, but the Presiding Officer has written to us, urging us to make sure that the children committee has the maximum opportunity to contribute to the work that we are going to undertake. I will have a discussion with the Chair of the Children and Young People Committee as to the best way of doing that.

[26] Personally, I think that it is important that we do the best that we can to capture the expertise that the children committee has already built up in some key areas covered in the Bill. Its work on adoption was the biggest piece of work that it did last year, and it seems very sensible for us to make the maximum use we can of the work that it has undertaken.

[27] In relation to annex 2—I was thinking of suggesting this to the Chair of the children committee, but I wanted to see whether it was acceptable to Members here first—if we were to reverse the order of three and four on the list of key themes, so that we came to the third item, which is the one that really is just about children—. One of the difficulties of the Bill is that it deliberately puts children and adult services together all the way through. It does not have an adult and a child approach separately in it. At item 3 in the theme paper, those items really are just to do with children. If we took that at our item 4, we could offer the Children and Young People Committee a bit more time to assemble whatever evidence and views it wants to present, in whatever form it chooses, to make sure that they could be communicated to us. Then, when we come to it, we could invite the Chair of the children committee to come to a meeting; she could be a witness to us and present that information to us.

[28] It is then for this committee to decide whether or not we simply want to incorporate in our report the views that the children committee came to, or we might feel that we want to explore some of those issues further ourselves, and there would still be time for us to do that in our own right. In the end, the Stage 1 report that we come to is a report of this committee, not a composite report of two different committees. I thought that that would give the children

committee a decent opportunity to do any work that it wanted to do, and a proper way for it to inform this committee of the work that it has done, while still leaving us with an opportunity, if we wanted, to do some further independent evidence taking of our own around those issues.

[29] I am very happy for people just to e-mail me, or whatever, with other ideas or different ways that we could try to negotiate this. The approach that I would like us to take is to be as open as we can to the children committee helping us in the work that we are going to do, and giving it a proper chance to do that.

[30] **Mick Antoniw:** I agree with your suggestion in terms of giving evidence because that would also enable a number of additional people to sit alongside, and would effectively incorporate them. I think that we need to act proactively, specifically with regard to children.

[31] **Mark Drakeford:** We have a couple of Members on this committee who are also members of the children committee, so we have a bridge between the two committees in that way. My understanding of the Assembly's rules is that another Member can always ask to just sit in on a committee, in any case, if their timetable allows them to do so. If we are happy for them to speak and to contribute, they can do that too. There will be an opportunity for members of the children committee to come and have a dialogue with us.

[32] **William Graham:** I think that I am right in saying that—[*Inaudible.*—]submit a report anyway.

[33] **Mark Drakeford:** They can choose to do it in any case.

[34] **William Graham:** [*Inaudible.*—]negotiation has broken down.

[35] **Mark Drakeford:** Indeed; that is quite right. The formal Stage 1 report will be a report from this committee.

[36] **Darren Millar:** Chair, may I just go back to the list of witnesses? There are no faith groups mentioned on the list, many of which provide services in their own right.

[37] **Mark Drakeford:** Definitely.

[38] **Darren Millar:** The other omission is Age Concern. I know that Age Alliance and Age Cymru are on the list, but Age Concern does not feature on the list.

[39] **Mark Drakeford:** Okay, Darren. If you have any specific ideas on the faith groups—ones that are particularly active and would be relevant—it would be useful to have them.

[40] **Darren Millar:** Yes. I will send a note on that.

[41] **Mark Drakeford:** The last thing on annex 2 is that I wonder what Members think of the idea of our very first session being a less formal evidence-taking session than the ones that we normally have, and a more round-table type of discussion, with a small number of key witnesses, about the basic principles of the Bill. We inevitably end up being drawn into the detail of the Bill—what does it say on safeguarding; how will it operate in this area and that area? I wonder whether it would be useful for us to have at least one session at the beginning that, in some ways, covers a similar point to the one that Kirsty was asking about: what are the really big ideas that lie behind the Bill; what does it have in its mind as to the future of social services in Wales; does it get those principles right; are there things that we ought to be testing as we go through our more specific evidence sessions, to check with witnesses that, if there are core principles and key principles here, those are really reflected in the more detailed mechanisms that the Bill then applies to the various services and proposals that it

contains? It would be slightly more free-flowing, and a slightly less formal way of talking about the Bill than we will end up with when we have witnesses in front of us and questions to get through, and so on.

9.15 a.m.

[42] **Kirsty Williams:** I am happy with that approach. The other thing that concerns me greatly is that you can have those discussions about those principles—whether they are key or core—but the problem that we will have, as always, is that so much of this stuff is left to the regulations. I am concerned about how satisfactory a conversation we will be able to have about impact, because so much of the detail is not on the face of the Bill. I would be grateful if we could try to find out, via the Deputy Minister’s office, in the same way that the Minister for Health and Social Services was able to supply draft regulations, whether there is a way in which some of that could be done. The Bill does not actually tell you who will be eligible for a service.

[43] **Vaughan Gething:** I would not expect it on the face of the Bill, but that is an important point about the practicality of getting through the face of the Bill and all the stuff that sits under it. That is a completely fair point and I would be very interested to hear what they have to say about that.

[44] **Mark Drakeford:** That has reminded me—helpfully, thank you—that, in the draft terms of reference, I think that we have also previously included a question that asks witnesses whether the Bill gets the right balance between those aspects that appear on the face of the Bill and those things that are left to regulations. So, that would allow witnesses who have a view on that to come at us directly on that topic.

[45] **Kirsty Williams:** The financial impact information in the explanatory memorandum is very poor. I am interested in looking at that because the legislation, if it is to be of any worth, has to be deliverable, does it not? It has to work in terms of a legal framework, but it has to be deliverable in other ways that include resourcing. So, one wonders whether we should be asking about the deliverability of the legislation. That is, once you have this legal framework, will you be able to actually deliver it?

[46] **Lindsay Whittle:** Chair, could we perhaps also consider cluster groups of witnesses and meet outside the Tuesday, Wednesday and Thursday slots with, perhaps, groups of Members here? Perhaps we could meet with cluster groups, such as the health boards, trusts, or the safeguarding children’s boards across Wales to talk about the key issues in the Bill. Would that be possible, or is that too onerous?

[47] **Mark Drakeford:** I suggest this to you on that point, Lindsay: we will now, as a result of today’s discussion, be able to work on ideas for oral evidence sessions against the themes that we have agreed, and so on. When we have had a chance to look at that, if we feel that we are simply not able to pour into that time sufficient people to hear from, then I think that we should come back to the idea of whether we can capture the voices of some additional groups in a different way. That is a useful suggestion.

[48] **Lindsay Whittle:** Those groups could meet independently without Assembly Members so that they could at least send representatives here who are hopefully speaking with one voice, so that one or two individuals can represent maybe 30 or 40 groups. There are simply too many to invite them all.

[49] **Mark Drakeford:** Thank you very much; that is very helpful. There is a final annex, annex 3, which is work that can go on on our behalf through the outreach team, and other ways that we can engage people more widely. I will leave that for today and people can read

that. There is plenty of chance for us to come back to that, refine it and add to it, and so on. That is very helpful. Thank you all very much.

[50] **Lindsay Whittle:** I think that there, Chair, you would need to consider the hard-to-reach groups as well. That is essential.

[51] **Mark Drakeford:** I have met the outreach team and that was my message to it. The work that it does that really makes a difference to us is when it can pass to us the views of people who we would not hear from otherwise. We do not need simply a greater amplification of groups that are able to get to us in any case. So, the team will try to do that, particularly by going out to talk to users of services in places that we are inevitably unable to, within our timetable, get to easily. However, thank you very much. It is very helpful to have got through as much of that as we did, because it means that the people who have to write letters and contact people are now able to do that.

9.19 a.m.

Bil Trawsblannu Dynol (Cymru): Cyfnod 1—Sesiwn Dystiolaeth 4 Human Transplantation (Wales) Bill: Stage 1—Evidence Session 4

[52] **Mark Drakeford:** Byddwn yn awr yn clywed tystiolaeth oddi wrth banel o bobl. Bore da a chroeso i chi i gyd. Diolch yn fawr iawn ichi am ddod i'n helpu yn ein gwaith o graffu ar y Bil Trawsblannu Dynol (Cymru) yng Nghyfnod 1. Gofynnaf i'r tystion gyflwyno eu hunain ac, ar ôl hynny, bydd munud i bobl wneud unrhyw sylwadau agoriadol byr. Ar ôl hynny, byddwn yn mynd yn syth at aelodau'r pwyllgor i holi cwestiynau. Dim ond tri chwarter awr sydd gennym ar gyfer y sesiwn hon. Os gallai aelodau'r pwyllgor ddweud os oes ganddynt gwestiwn i unrhyw un o'r bobl sydd ar y panel, byddai hynny'n ddefnyddiol.

Mark Drakeford: We will now hear evidence from a panel of people. Good morning and welcome to you all. Thank you very much for coming to help us with our Stage 1 scrutiny of the Human Transplantation (Wales) Bill. I ask the witnesses to introduce themselves and, after that, you will have a minute to make any brief opening remarks. After that, we will go straight to committee members for questions. We have only three-quarters of an hour for this session. If committee members could indicate whether they have a question for any of the people on the panel, that would be helpful.

[53] Thank you very much indeed for coming to help us this morning. I will ask members of the panel to introduce themselves briefly and to tell us the particular jobs that they do in this field. There will be a minute to make introductory remarks and then we will go straight to questions. Shall we start with Professor Harpwood?

[54] **Professor Harpwood:** I am Vivienne Harpwood and I am professor of law at Cardiff Law School in the university here, where I run a Masters course in medical law, which I established in 1987. So, I have worked with members of the healthcare professions. I am also vice-chair of Cwm Taf Local Health Board and I am its organ donation champion, so I chair its organ donation committee. Briefly, I am in support of this Bill, for a variety of reasons, which will emerge. For that reason alone, I am very concerned about the clarity of the words used and the accessibility of the language.

[55] **Dr Tetla:** My name is Dariusz Tetla. I am a consultant anaesthetist and the clinical lead for organ donation in Cwm Taf Local Health Board. I have been working in organ donation as a clinical lead for more than three years now. My colleagues and I are working to implement 14 recommendations published by the Organ Donation Taskforce. The main goal was to increase the number of donations by 50% in a five-year period. This period of time is coming to an end now and there are three months left to meet this challenge. We have made

quite good progress towards achieving this goal. Our organ donation rate over that period of time has gone up by more than 40%. We now have three months to give it a final push.

[56] **Dr Matthews:** I am Peter Matthews. I am a consultant in intensive care in Swansea. I am here representing the Academy of Medical Royal Colleges in Wales. I am the clinical lead for organ donation in Swansea and I am the immediate past chair of the Welsh Intensive Care Society and the national special advisory group for critical care. I have also been involved with the Faculty of Intensive Care Medicine nationally in drafting its responses to previous submissions. Broadly, we welcome any avenues where we can explore the chances to improve organ donation rates, but we have concerns about the language, as Professor Harpwood does, especially the term 'deemed consent'. We have concerns about critical care capacity and whether that is sufficient to sustain any increase in organ donation. We have concerns about whether the opt-out system might compromise the integrity of critical care specialists when dealing with end-of-life issues and we have concerns about the possible fudging of the legal standpoint where the families have no right of veto over organ donation. The suggestion is that it would not go ahead if there are very strong objections. We do not think that that is clear enough to put the clinicians in a position where there may not be any subsequent sequelae.

[57] **Mark Drakeford:** Thank you all very much; it is very helpful to have those early indications. We will go straight to Members for questions. Mick is first, and then William.

[58] **Mick Antoniw:** I am particularly interested in the points that you raised towards the end about clarity. At the end of the day, in the most difficult of circumstances, someone has to decide whether you can proceed with organ donation. So, there are some very clear legal and ethical issues, but also, there is a potential can of worms in terms of the decision. On the point about clarity, what was being suggested by the Minister to us yesterday was that, in actual fact, if any member of the family objected, that would be sufficient not to proceed. What sort of position would you prefer in terms of that clarity? What needs to be done to ensure that there is clarity in decision making?

[59] **Dr Matthews:** To some extent, the position that is being proposed is no different to the position at the minute. If those people have already opted in, I believe it is correct to say that there is no legal veto for the family currently, but we would never go ahead against family objections. On the point about stating if any member or extended family objected, that would probably lead to a decrease in the organ donation rate because, when we speak to families, very rarely is there complete agreement across an extended family. If there are 20 or 30 people there, somebody is going to object. The proposals do not have a ranking system; we would propose that there is a ranking system, where the husband or wife, followed by the children and so forth, have the right to make the decision.

[60] **Mick Antoniw:** Is it your view, then, that if there is any uncertainty or confusion, it would probably have the exact opposite effect to what we want to achieve, which is to achieve an increase in donation rates?

[61] **Dr Matthews:** Do you specifically mean that introducing an opt-out system might cause confusion?

[62] **Mick Antoniw:** What I mean is that if we are in a situation where there is any level of uncertainty, it would have the capacity—and you mention it in the evidence papers—to undermine the way in which people see the legislation and it could create a reaction and an adverse response, leading probably to people being more sceptical about it and a reduction in donations or more objections.

[63] **Dr Matthews:** I have noted that the surveys suggest that the majority of the public

supports this opt-out system, although I have not seen the details of those surveys. Being fairly cynical potentially, depending on how you ask the question in a survey, you can get any answer that you want. My own experience is that the British psyche has a particular view that what it should do is donate organs as an altruistic gift, and if it is felt that the state is going to take over the organs, then there is the potential that people who may have been willing to become a donor will not do so. We have seen two cases in Morriston where patients who were on the organ donation register, on hearing about this, said to their families that if the state was going to take their organs, they were no longer willing to give them. We lost two donations because of that. So, there is a potential backlash.

[64] **Mick Antoniwi:** I would like to ask a follow-on question to Professor Vivienne Harpwood. In terms of the legal position, there will be concern as to the clarity of who makes the decision. This poses potential risks later not only for the person taking the decision, but the board as well. What is your view on what the legislation seeks to achieve, and what sort of security or guarantees need to be put in, in terms of protecting both sets of interests?

[65] **Professor Harpwood:** In terms of the legislation itself, it would be dangerous, perhaps, to state upfront that if any member of the family disagrees, there is not going to be a donation. That, in itself, would immediately start to ring alarm bells. As far as the wording goes, my concerns relate to the word 'deemed', and I am not the only person here to have concerns about that. However, I do not think that much can be done to improve the particular situation that has just been raised in the Act itself. I think that that is for education, getting families talking and a big publicity campaign, which is planned.

9.30 a.m.

[66] **Mark Drakeford:** Many Members want to come in on this particular issue, and given that it is pretty fundamental, we will allow more questions although it will probably squeeze some other questions. I appeal for brief points.

[67] **Rebecca Evans:** I would like to return to Mick's first question on the role of clinicians. The UK Donation Ethics Committee has raised concerns that there will be an impact on the relationship between professionals and donor families and on the confidence of professionals to explore new and ethically challenging techniques aimed at increasing successful donations. Perhaps you could tell us a bit more about the concerns that you might have in that area. What could be done in the Bill to give professionals more confidence and to take away that grey area?

[68] **Dr Tetla:** Organ donation is one of the most difficult areas of clinical practice and we, as clinicians, would like to stay reassured that we are working in a solid and safe legal framework to avoid causing harm to patients, families and ourselves. It is stressful for families and clinicians to talk about the end of life. Sometimes, we find that some families, when they are in the situation of their loved ones dying, become quite unreasonable with their opinions on organ donation, and we have to respect their wishes, otherwise, if we push too much, we can achieve the opposite effect and it can give us very bad press. That may result in a decreased number of donations in the future.

[69] **Professor Harpwood:** In general terms, whenever a poll is taken of people's trust in various professionals, doctors and nurses are always at the top. A very high percentage of people trust healthcare professionals. I am sorry to say that lawyers are far down the list, and civil servants and politicians are only just above bankers. So, it is a question of trust, and I think that people generally trust people in the NHS, despite the Redfern inquiry into Alder Hey, the Bristol inquiry and all the things that are happening now. There was a Populus poll in 2012 that came up with strong figures to show that people trust doctors and nurses. So, in general terms, that is the case. However, in these very sensitive situations, people are trained

to explain things properly. Since the training has been put in place, it has worked, to a large extent.

[70] **Dr Matthews:** Following on from what my colleagues have said, when we withdraw life support from our patients on intensive care, the decision is made by us, preferably with the support of families, and we make that decision based purely on our objective assessment of whether the patient would survive, even with ongoing care. At the moment, with an opt-in system and an organ donation register, there are two completely separate acts, which are withdrawing a treatment and approaching the family for organ donation. One potential concern with the opt-out system is a compromise of the integrity, or perceived compromise of the integrity, of the decision making of the intensive-care specialist and that the withdrawing of organ support may be perceived as a way of procuring organ donation in the future.

[71] There is also increasing pressure for critical care units to accept patients. We have had patients referred to us purely, potentially, for organ donation, and not for any realistic prospect of surviving intensive care. That is a dangerous precedent. First of all, relatives of patients admitted to intensive care may be under the illusion that patients are being admitted to intensive care for life-saving treatment, whereas, in fact, they are being admitted for organ donation. The faculty of concern is that we do not want intensive care to be seen as an organ-harvesting factory. The other thing is that it can be a slippery slope. Once medical professions start intervening purely for the purpose of organ donation and pushing techniques to preserve organ donation, you are getting to the point where you could get into a legal practice, as happened in Exeter in the 1980s, where they were intervening with ventilation purely for the purpose of organ donation. That was outlawed. I am not saying that that is going to happen but there needs to be some clarification to ensure that ethical and legal standards do not slip to a point where they become unethical and illegal—before you know it, somebody will be held accountable.

[72] **Elin Jones:** I want to go back to the issue around the family and the points that you made in that there is hardly ever unanimity in large, extended groups of relatives. You advocated the ranking of family members according to their ability to say ‘no’ or ‘yes’. The Minister told us last week that even if someone had opted in to a deemed consent system, any family member objecting would be, in practice, a veto on organ donation. She made that view clear to us. Professor Harpwood and Dr Tetla, do you think that a ranking system of family members according to their ability to, in practice, veto organ donation would be a useful addition to our discussion on the Bill?

[73] **Professor Harpwood:** I have thought about this and it is known in other legal contexts, but I do not think that it would help in this situation. Who knows? Some husbands hate their wives or you may have a second cousin who objects—you do not know what the family situation is. It just complicates matters to produce a list. Where someone in the family is very much against it, it is better that it should not go ahead.

[74] **Elin Jones:** Would you advocate shortening the list? The list is quite long.

[75] **Professor Harpwood:** The list is appropriate. It is what you see in other legislation.

[76] **Dr Tetla:** To add to that, we have also situations where patients are on the organ donor register who do not have any family or nominated representatives. If the patient is on the organ donor register and we cannot find the family and they do not have nominated representatives, the current opt-in system allows us, in some situations, to take their organs with some reservations—that the organs will be used in 48 hours and, if they are not used, they will be destroyed after 48 hours. My concern about the new opt-out system is whether deemed consent will be sufficient to carry out such an activity without the family being available with the same kind of patient. If not, the numbers of this type of donor will decrease

in comparison with the numbers under the current system.

[77] **Kirsty Williams:** I would like to go back to the issue of end of life and clinicians making decisions about when to withdraw treatment and whether that would be regarded by families as a way of facilitating transplantation. All of the people who have contacted me about the Bill have mentioned that particular aspect. You say that the way in which the Bill is currently written is not clear on those issues. Is there a way in which you can make some of those issues clear within the legislation? Is there something that we could recommend to the Government that would change the drafting to ease some of your professional concerns about this grey area, while maintaining that professional cover for people like you, which none of us here would want to compromise?

[78] **Dr Matthews:** It is very difficult. In the past, as a critical care specialist, I would have the conversation about withdrawing life support and then I would approach the families later about the possibility of organ donation. With increasing numbers of donation after cardiac death, where withdrawal of care carries with it a far greater significance than somebody who is perhaps brainstem-dead after a trauma, we have gone down a pathway now where the decision to withdraw is done by the doctor, but the approach to the family about organ donation is done by specialist nurses for organ donation to make sure that there is a completely separate discussion with somebody who is not connected. So, I would be withdrawing the life support and the person approaching the family would be completely unrelated to that.

[79] The other issue is that I do not have access to the organ donor register, either, which is important, as a specialist. So, I cannot be accused of having any compromise about knowing their organ donation wishes before withdrawing. So, it might be worth emphasising that; good practice would be that the person who withdraws the treatment has no part in further discussions about organ donation.

[80] **Kirsty Williams:** We have had concerns expressed to us about whether the Bill is clear in how it relates to donation after circulatory or cardiac death. Could we amend this legislation to make those distinctions clearer?

[81] **Dr Matthews:** What are those concerns?

[82] **Kirsty Williams:** We have had concerns from the UK Donation Ethics Committee, which says that, on a practical and legislative level, the Bill needs to be clear on the consent status of potential donors after cardiac death, who might not have opted out. DCD can entail having additional interventions in the last hour of life to make donation possible. Would that be in the best interests of that particular patient? So, coming back to these issues of whether clinicians and families see a compromise in intervention, which might not be in that patient's interests, but the intervention happens because of the potential of donation afterwards. There seems to be some concern that the Bill is not clear.

[83] **Dr Matthews:** I am not sure that it is particularly specific to an opt-out situation, because we are already doing donation after cardiac and circulatory death, with some level of intervention that some clinicians might not feel happy with. However, this has already been cleared from a legal and ethical point of view, to allow current practice to go ahead. So, I do not think that that is particularly relevant in an opt-out system, per se.

[84] **Professor Harpwood:** I would like to come in at this point, because this is something that I picked up on. I think that the Bill is opaque on that, because section 5, for example, which deals with excepted patients, who must be dead to fall within that section, does not actually say that these are brainstem-dead patients. This is a very sensitive subject and it might frighten people and put them off. In section 12, I think that the word 'deceased' could

be removed, and, in relation to children, section 6 says,

[85] ‘a person who is a child or has died a child’.

[86] Those sorts of cases are really referring to donation after brain death as opposed to donation after cardiac death, but nowhere is there a definition or an explanation of what this really means to ordinary people. Ask an ordinary person on the street what they understand by ‘dead’; what is the definition of death? It is a very difficult area and I do not know how it can be approached. It would need to be done very sensitively.

[87] **Mark Drakeford:** Thank you. Darren, do you have a point on this conversation?

[88] **Darren Millar:** It relates to the veto actually, but I have a separate issue that I want to cover later, if that is okay?

[89] **Mark Drakeford:** Okay. Vaughan wants to come in on Professor Harpwood’s last point.

[90] **Vaughan Gething:** It is on the issue that Kirsty raised and the way in which you responded, and some of the evidence that we have had about being brain-dead. Section 4 talks about when the person is alive, but I assume that when somebody is brain-dead, you would not say that that person is alive. However, when we are talking about circulatory death, there might be an argument that that person is alive.

9.45 a.m.

[91] It is this whole issue about how you then get consent and the issue of treating someone to preserve their organs. I am not really clear about how that works. Tell me if I am wrong, but if, for example, someone is on the register, having opted in, you could treat them to preserve their organs if we were talking about circulatory death. Would that not work in terms of deemed consent, even if you were able to have a conversation with the family? I do not understand whether, under the terms of the Bill, as written, they are still alive or not, in which case I would understand—looking at the terms of the Bill, as it were—that you could not do that. Or could you read it either way, and is that where you are seeking clarification? I generally do not understand.

[92] **Professor Harpwood:** I agree. I am not clinically trained and I had to go to Dr Tetla earlier this week to clarify this myself. It is a difficult issue. There needs to be much more clarity around it. Certainly, when families are talking about it where there is an education programme taking place, these are precisely the sorts of things that need to be explained.

[93] **Vaughan Gething:** Should that be on the face of the Bill? When you talk about the legislation and making sure that it is clear, there is a point about what is on the face of the Bill and what is in the explanatory memorandum, explaining it in express terms, because lawyers like to say, ‘You might think that it means that, but it does not really mean what you think it does in terms of what looks like ordinary language’. However, many people will interpret ‘being alive’ in completely different ways when we talk about this. Would you want that to be on the face of the Bill to explain what we mean in these particular issues, or would you want to see that come in a different form to try to clarify what practice there should actually be, and what the Bill is actually achieving and setting out?

[94] **Professor Harpwood:** I would like to see the Bill containing something by way of definition. In Wales, we have tabula rasa. We are starting out on a legislative journey—or whatever the word is—of our own. We can do these things. We can be clearer than the Government has been in England for centuries. We should be upfront, clear and make our

legislation accessible. If that involves including a definition of death and something that refers to DBD and DCD, I think that we should go down that route.

[95] **Vaughan Gething:** Okay. That is helpful.

[96] **Mark Drakeford:** Professor Harpwood, we will not be able to prolong this part of the discussion much more this morning, but I wonder whether you will be able, reflecting on the questions that have been raised and some of the points that you have put to us, to provide us with a note setting out some of the views that you have expressed so far and relating them to the specific sections of the Bill in which you started to be able to do earlier.

[97] **Professor Harpwood:** Yes, certainly.

[98] **Mark Drakeford:** That would be really helpful for us. I will be prepared to extend this session, if witnesses are able, for around 10 minutes beyond where we would have finished. However, I will give priority in the next quarter of an hour to people who have not had a chance to ask anything yet. So, I will go to William, Lindsay and Darren for the next three sets of questions. We will then see what is left.

[99] **William Graham:** Dr Matthews, may I ask you specifically to enlarge on the comment that you made about being concerned about the capacity for critical care?

[100] **Dr Matthews:** Currently, Wales has the lowest number of critical care beds per population in Europe. I have the figures here. I think that, on average, there are just over three critical care beds—Abertawe Bro Morgannwg University Local Health Board has 4.8 critical care beds per 100,000 of the population, and Aneurin Bevan Local Health Board has the lowest number at 2.5. In comparison, France has nine, Croatia has 20, and Germany has 25. You can see that the Aneurin Bevan Local Health Board has a tenth of the critical care bed capacity that Germany has.

[101] I know that many of the proposals state that presumed consent has been a major factor in increasing organ donation across Europe, but Wales now has the second highest donation rate across Europe in terms of countries without a presumed consent—or ‘deemed consent’, to be more correct—system in place. However, it appears that all of the other countries have a greater capacity for beds. If you want to look at organ donation rates in a different way, the UK has the highest number of organ donors per critical care bed in the world. So, we are running a very tight system already. We have turned down patients who might potentially have been organ donors, because we do not have the capacity—certainly in Swansea, we are running at about 110% to 120%—and even if we had a marginal increase in numbers it would have a dramatic knock-on effect on the amount of elective surgery that we could get through as well, which is always being cancelled on a weekly basis.

[102] **Dr Tetla:** It will also have an impact on the number of potential donors. It will be a comparable situation to Spain, which is always given as an example, where all potential donors are usually admitted to the intensive care unit, and where treatment will be withdrawn when the patient becomes brainstem-dead. In Britain, however, partially because of limited bed availability, we would withdraw the treatment of a patient slightly earlier, when their death becomes imminent, which means before the patient becomes brainstem-dead. That will also have an impact on the number of organs available, because, for example, the heart can only be removed from a patient who is brainstem-dead. That may also have an impact on the number of potential donors.

[103] **William Graham:** Do you think that the Bill could potentially give rise to more claims for compensation? If so, how could that be avoided?

[104] **Professor Harpwood:** I do not think that that is likely to be the case. There were a lot of claims after the Alder Hey situation, and there was a big settlement to the group litigation, where a lot of money was paid out to about 2,000 families. That was taken care of by the Human Tissue Act 2004, but you can never get away from the fact that some people will want to claim. We are seeing claims increasing all the time, and particularly where there is a lack of clarity in statute, there will be claims around the wording of the statute itself, which is one reason why I want this to be clear. However, I do not think that that is a major concern. After that litigation, there was only one prosecution—no, I do not believe that there were any prosecutions. The Crown Prosecution Service decided not to prosecute anyone, but the General Medical Council took action, which was appropriate. It is right that there should be claims if people do not comply with the law. So, it is not a particular concern. I do not think that we will see a lot more.

[105] **Mark Drakeford:** Dr Matthews, would you be able to supply the figures that you provided orally earlier to the committee?

[106] **Dr Matthews:** That is fine; I can produce a draft at a later stage.

[107] **Lindsay Whittle:** I have carried an organ donor card for decades and, with the greatest of respect, I do not want any weeping, wailing relatives going against my wishes, and I will not be opting out. This is my body when I am alive and when I am dead. I want my organs to be used as the medical profession would see fit. However, I am concerned about the litigation issue, because this country has become far too Americanised in that everyone wants to claim something these days—even by walking down the high street. I am particularly concerned about the protection of the medical professional, whom I normally trust very much. I know that there will be rogues, but, let us be fair, they are very rare. I am old enough to remember the programme *Your Life in Their Hands*. Do you have any opinions on the protection of the medical profession on this issue? I understand what Dr Matthews has told us about the separation of the nurse and the surgeons, so that there is no involvement, but should there be greater protection for the individual medical professionals?

[108] **Professor Harpwood:** Do you mean in the Bill itself?

[109] **Lindsay Whittle:** Yes.

[110] **Professor Harpwood:** I do not think that that is really a concern. The way that it is framed takes care of that, and the very fact that, as the Minister has said, if one family member objects, the donation will not go ahead should reduce the possibility of claims. I am entirely with you; I would not want anyone to go against my wishes, but some family members find, at a very difficult time, that they cannot allow a donation to go ahead. One way of protecting healthcare professionals is precisely what the Minister has proposed.

[111] **Lindsay Whittle:** It is interesting; I generally do not believe that family members should be allowed to object. It is up to the individual who has died. That is just a personal opinion.

[112] **Mark Drakeford:** I understand that, and we will hear something more on that later.

[113] **Dr Matthews:** I have never really felt any concern about legal comeback, even when there have been disagreements with the family. I know that transplant surgeons may be more concerned about that—the people who will actually carry out the surgery. However, the memorandum states that, if the intention of the people involved in the transplant process can be seen to be just, then there is protection for them, even if further information comes to light at a later stage. So, that pretty much covers it.

[114] I am slightly concerned that there seems to be an emphasis that if one family member objects to organ donation, then the process will not go ahead, because that is not the case at the minute. In fact, you are making it a little more stringent. I deliberately do not go into a room full of 20 family members because I know that there will be 20 opinions. As with any family, there will be underlying factors. We will specifically go to the family members who we think are closest to the deceased, and who can give us the most information about the wishes of the deceased—not the views of the family. We will go with that even if there might be some conflict between extended family members. If we went with a complete census of a whole family we would not do any donation at all.

[115] **Mark Drakeford:** Thank you; that is a helpful insight. Darren is next, and then I have lots of other committee members who want to come back in. I am very keen to offer Professor Harpwood a chance to put on the record her concerns about the word ‘deemed’ in the Bill as well.

[116] **Darren Millar:** I had one point of clarification in terms of family vetoes under the current system and how that works, but I think that that has been responded to very well. I want to ask about the new register that will be created as a result of this Bill. It appears to me that we have a situation now where, if we have a separate Welsh register that sits alongside the UK register, you might get individuals who want to remain on the UK register and opt in, but who want to opt out of the Welsh register because they do not want the state to own their organs. Which register will trump which when it comes to a decision as to whether someone has given consent or not?

[117] **Mark Drakeford:** That sounds like a legal question. Professor Harpwood?

[118] **Professor Harpwood:** It had never occurred to me that anyone would do that, but I suppose it is a point.

[119] **Darren Millar:** Do you think that there needs to be some clarity about that?

[120] **Professor Harpwood:** Yes, that needs to be considered. It is not something that had occurred to me, though.

[121] **Darren Millar:** Do you have a view, Dr Matthews?

[122] **Dr Matthews:** It would be more sensible to have a single register run by NHS Blood and Transplant to cover the whole of the UK. That will get around some of the issues as to whether people in Wales who have opted out end up dying in another part of the UK. To run two separate registers is likely to lead to trouble.

[123] **Darren Millar:** Absolutely. In terms of the way that people can nominate a representative to make a decision on their death, a system is proposed whereby that would have to be in writing, witnessed et cetera. Is that appropriate? It seems quite high bar in terms of nominating somebody.

[124] **Professor Harpwood:** I think that it is appropriate because it is in line with the Mental Capacity Act 2005, where there is a similar system. If you want to refuse treatment you have to go through a similar process. That is something else that has occurred to me, because somebody might decide that they want to refuse treatment on an end-of-life pathway, and that might be recorded and placed with their notes, or with somebody who is responsible. That is in line with what is currently happening elsewhere in the UK.

[125] **Darren Millar:** Do you think that we need to raise the bar to get on to the organ donation register? You do not require a witness to opt in to the system, do you? Why should

there be a requirement for a witness et cetera in terms of the nomination that you might make for an appointed person?

10.00 a.m.

[126] **Professor Harpwood:** That is only if you want to nominate somebody to look after your interests. The majority of people will probably not do anything; we are all probably guilty of apathy—an awful lot of people believe in organ donation, but have not bothered to do anything about it. I think that something like 60% of the population—I do not know the exact figure—have not bothered to sign up, even though they believe that it is a good thing. So, I am not aware that it is a problem, really. It is fine as it is.

[127] **Darren Millar:** Is there consensus among you all that there ought to be one register in the United Kingdom that would take into account the views of Welsh residents in terms of our new system in Wales? The suggestion is that a brand-new, single, UK-wide register should be created, but do you think that there should be an opportunity for people to suggest that they would be happy to consent to their organs being taken in England but not in Wales?

[128] **Professor Harpwood:** As I understand it, there will be two clusters: opt-in and opt-out clusters.

[129] **Mark Drakeford:** We explored this with the Minister last week, when you were unable to attend, and she was clear that she is now thinking of a single UK register. There may be an opt-in register and an opt-out register, but they will not be separate for Wales.

[130] **Darren Millar:** I think that the difficulty is that there will be a cohort of people who have expressed to individual Assembly Members, and to some of the clinicians by the sound of it, that they are currently on the register but would want to come off it if this legislation proceeds. There will therefore need to be another category to record people's wishes, depending on where they die. Do you see what I mean? In England, they would be happy to consent, but in Wales, they would not, based on legislation that deems their consent. It is very complicated, I agree, but—

[131] **Mark Drakeford:** Let us see what the witnesses have to say.

[132] **Dr Tetla:** My point is that this system is going to be very complicated and it is going to take a much longer time to find out whether the patient actually consented to organ donation. If we have such a complicated organ register system and we have to spend some time to find out whether someone is or is not resident in Wales, that will require more time to get proper consent, and organ donation is an activity that is quite time restricted.

[133] **Mark Drakeford:** Thank you. That is very helpful. I am going to ask you, Professor Harpwood, to put on the record the concerns that you mentioned at the outset about the word 'deemed' in the legislation. I will then go to Rebecca and, if there is time, to Elin.

[134] **Professor Harpwood:** I have a number of concerns, because deeming clauses have been under sustained criticism for some time by draftspeople and lawyers. I understand how the word 'deemed' got into this Bill, because it is in the Human Tissue Act 2004, so it has a history, as it were. However, its use often leaves important details to be worked out by the reader—I mean, there is not a lot of clarity about what 'deemed' means, and there are many different sorts of 'deeming' in legal terms. So, why not use the word 'presumed'? Everybody understands that. Why not be clear, up front, as to what we really mean, because that is what it is?

[135] I am not a Welsh speaker, so I do not know what the Welsh translation of 'deemed'

is, and we do not want any linguistic disjunction here. We have to be absolutely clear that it will translate properly. We have people, immigrants, living in Wales who will not understand what 'deemed' means—and what we really mean is 'presumed' anyway. That is, a presumption that can be rebutted by reasonable evidence. At the moment, I think that it is a bit of a playground for lawyers, frankly, in that there could be quite a lot of argument over what is really meant by 'deemed'.

[136] **Mark Drakeford:** Thank you very much; it is very helpful for you to have extended your concerns for us in that way.

[137] **Rebecca Evans:** I want to ask you about section 5, which refers to consent for excepted adults. An excepted adult would be somebody who has died and who for a significant period before death lacked the capacity to understand the notion that consent to transplantation activities can be deemed. 'Significant period' means a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed. Do you think that that could put clinicians in a difficult position? Could you be sure, 100% of the time, that the person who has died had no issues of capacity? We know that many people keep their mental health problems to themselves and they often do not tell their closest family or professionals. So, would you have confidence every time that the person who had died did not have capacity considerations?

[138] **Professor Harpwood:** Disputes about capacity are dealt with by the Court of Protection in the case of adults. Quite a substantial body of case law has been built up there now, and it is useful to refer to it. However, at the end of the day, it is the clinicians who have to make those decisions. I assume that any dispute would go to the Court of Protection. I am not sure quite how that would work. I do not know whether there would be problems for clinicians.

[139] **Mark Drakeford:** Would it be a problem to navigate this in practice?

[140] **Dr Matthews:** Certainly, issues of consent or capacity have to be decision-specific. So, just because someone has a mental illness, it does not necessarily mean that they will not have the capacity to understand issues about organ donation and either to opt in or to give their objections. However, the memorandum is a little bit wishy-washy. A 'significant period' of time with a 'reasonable person' does not really say much that you would be able to have as a substantive guideline to suggest what is a 'significant period' or whatever. In practice, though, it is not a major issue, because families are usually fairly well aware of what is going on. If there were doubts about capacity, you would not go ahead in any case. So, I do not think that it is perhaps as big an issue as some people make it out to be. It may be an ethical or a legal concern, but, on a practical basis, it is not such a major issue.

[141] **Mark Drakeford:** Elin, there is time for one more question.

[142] **Elin Jones:** I want to ask you about the fact that all of the publicity and most of the justification for this Bill has been about life-saving organ donation, but this Bill, on the face of it, does not exempt organs that can be used for the purposes of non-life-saving medical work, such as face or limb transplants. Do any of you have a view on whether it would be useful to have, on the face of the Bill, exemptions for the purposes of tissues that relate to the face or to limbs?

[143] **Dr Matthews:** There is certainly an acceptance of organ donation with regard to major organs, such as the liver, heart, kidney, pancreas and bowel, even; skin harvest is still unusual but is used in the treatment of burns patients. If we were looking at more experimental treatment, such as limb or facial surgery, I do not think that it could be something that could be assumed to be covered by an opt-out system, because, on the whole,

the surgeons wanting to do this would probably go through an ethics committee within their own health board anyway to go ahead with this level of surgery. So, I do not think that you can make a presumption about that. The other thing is that, if you are going to be doing facial or limb surgery, or whatever, there is an increased chance of identification of where the donor came from, which may have an impact on family satisfaction. So, I do not think that you can include that within an opt-out system.

[144] **Mark Drakeford:** I think that the Minister made it clear to us last week that deemed consent would not extend to the more novel circumstances that Elin has outlined. However, I think that her question was whether that should be on the face of the Bill rather than left to the regulatory framework that the Minister says she will use to make that clear.

[145] **Kirsty Williams:** I can see the difference between hearts and lungs and the experimental stuff around limb and face transplants, but, with regard to issues around eyes, it is not life-saving—it is life transformational, perhaps, but not life-saving. So, where does that lie in this? It is not life-saving but neither is it experimental in the same terms as face transplants. Where does that lie with regard to issues around consent?

[146] **Elin Jones:** On the face of the Bill, none of that is exempted. So, donation of the face and eyes is possible on the face of the Bill. So, what I was asking was whether you would have views that there should be a longer list than section 16 currently has of what is exempted for the purposes of deemed consent legislation.

[147] **Professor Harpwood:** Technology moves on and there will be new forms of transplant that can happen. I think that it would be better to leave that to the legislative framework—the delegated legislation. We have to trust Ministers to be sensible and include things as and when they become possible, and to exclude what might be sensitive or difficult. I do not think that it needs to be on the face of the Bill.

[148] **Vaughan Gething:** It comes back to the point of trusting Ministers to do that. Looking at the way that section 16 is drafted, it excludes only ‘gametes’ and ‘hair and nail from the body of a living person’. Apart from that, nothing is excluded. I would be interested in your view regarding whether, if we were to trust Ministers to do that, or to give them a regulation-making power, that section would need to be amended. Thinking about the other committee that I sometimes sit on, I think that would only be under the affirmative procedure, whereby the Assembly would have to pass those regulations, so that there would be an enhanced scrutiny procedure. Otherwise, a lot of people would be uncomfortable with leaving that amount of delegation to a scheme that we way not otherwise see.

[149] **Professor Harpwood:** Yes, I agree. As I understand it, all of these regulations would be subject to affirmative resolution anyway because of the sensitivity involved. However, families could refuse as well. A family may not like the idea of a face transplant, so that is another a safeguard. However, I agree with you—it should be. Those things that are excluded in section 16 are excluded because they are excluded by the Human Tissue Act 2004.

[150] **Mark Drakeford:** Thank you all very much indeed and thank you for staying on a little bit longer than we had anticipated. It has been very helpful indeed for us to get a practical operational insight into what you have to face when you are dealing with people in the circumstances that we are discussing as part of our work. Thank you for coming. Professor Harpwood, we look forward to receiving anything that you could provide. Dr Matthews, you are going to let us have the comparative figures that you offered us earlier.

[151] Diolch am ein helpu y bore yma. Thank you for helping us this morning.

[152] Rwy'n ymddiheuro i unrhyw aelod I apologise to any committee members who

o'r pwyllgor na chafodd ddigon o gyfle i godi did not have sufficient opportunity to raise
cwestiynau gyda'r panel cyntaf. questions with the first panel.

[153] In the next session, I will try to give priority to people who did not have a set of questions of their own, but we are under the huge pressure of 45-minute slots with all the witnesses that we have this morning.

[154] **Elin Jones:** To be clear, last week, the Minister said that, even if someone has registered their wish to donate their organs in the deemed consent process, even if that positive action has been taken, any member of their family objecting would be enough to prevent it.

[155] **Mark Drakeford:** That is what she said.

[156] **Lynne Neagle:** That contradicts what is in the explanatory memorandum.

[157] **Darren Millar:** That is only in practice, is it not? It is not on the face of the Bill.

[158] **Kirsty Williams:** It is not on the face of the Bill, though, is it?

[159] **Elin Jones:** No, but she did say it. That is what I wanted to be clear about.

[160] **Mark Drakeford:** In practice, that is what she believed will be the case. She was talking about protecting the overall reputation of organ donation against accusations that might catch fire in the press.

[161] **Darren Millar:** From what we have heard this morning, it is much stronger than is currently the case.

[162] **Vaughan Gething:** Is that any member of the family or any member who is in a qualifying relationship, as defined in the Bill? Is it in the list? In some of the discussions this morning, we were talking about a second cousin turning up, but second cousins are not in the list of qualifying relationships.

[163] **Elin Jones:** No, they are not on the list. That was a red herring.

[164] **Vaughan Gething:** It is important to be clear about who is included in that list of relationships.

[165] **Mark Drakeford:** I am going to welcome our next set of witnesses. As you can see, we are still grappling with some of the evidence that we heard in our first session, but we are going to move on.

Bil Trawsblannu Dynol (Cymru): Cyfnod 1—Sesiwn Dystiolaeth 5 **Human Transplantation (Wales) Bill: Stage 1—Evidence Session 5**

[166] **Mark Drakeford:** Mae'r panel ar gyfer yr eitem hon yn cynnwys Dr Alan Clamp a Victoria Marshment o'r Awdurdod Meinweoedd Dynol, a Chris Watson o Gymdeithas Trawsblannu Prydain. Diolch yn fawr i chi i gyd am ddod i'n helpu ni'r bore yma. Yn gyntaf, gwnaf ofyn a oes unrhyw sylwadau agoriadol byr gennych i'n helpu ac

Mark Drakeford: The panel for this item includes Dr Alan Clamp and Victoria Marshment from the Human Tissue Authority, and Chris Watson from the British Transplantation Society. Thank you to you all for coming to help us this morning. First of all, I will ask whether you have any brief opening remarks to help us, before turning to

yna rwy'n mynd i droi'n syth at aelodau'r committee members for questions. We have
 pwyllgor i ofyn cwestiynau. Mae tri chwarter three quarters of an hour for the session. Mr
 awr gyda ni ar gyfer y sesiwn hon. Mr Clamp, would you like to start?
 Clamp, a hoffech chi ddechrau?

10.15 a.m.

[167] Mr Clamp, would you like to begin with any brief opening remarks? I will then ask Mr Watson if he has any remarks that he would like to make. Then, Victoria, if we have missed anything, you can have a go too.

[168] **Dr Clamp:** Good morning. I am Alan Clamp. I am the chief executive of the Human Tissue Authority. The HTA is responsible for ensuring the safe and ethical use of human tissues and organs. We regulate across a number of sectors, but of particular interest to this committee is our work under the Human Tissue Act 2004. We are responsible for the consent provisions within that Act. We need to make sure that all consent is appropriate and valid when we are looking at donation from the living or deceased for the purposes of transplantation. That requires us to have two key duties. One is to superintend the Act, and the other is to issue a code of practice, to give practical, operational guidance to those working in these sectors.

[169] Since the Welsh Government announced its intention to introduce this system of deemed consent, we have been involved, to varying degrees, in providing advice and guidance. Once it becomes law it will be like the Human Tissue Act 2004: we will be responsible for superintending it and for producing a code of practice. As we have outlined in our written evidence, that will present some regulatory challenges for us. I am conscious of your direction to be brief, but I will summarise what those three areas would be. One would be for us, practically, to emphasise the importance of communication for this particular piece of legislation. When we look at consent, we look very carefully to make sure that it is, under the Human Tissue Act 2004, active and informed. In certain cases in Wales, that requirement for it to be active will be taken away, but the 'informed' bit is still vital, and you could even argue that it is even more vital. So, that is why we have made our points in our written evidence about the importance of communication and making sure that everybody is aware of what they need to do to make sure that their wishes are taken account of.

[170] The second point, about which you have heard this morning, is about the register. I understand now that it looks as if the move is towards a single register for the UK. However, that needs clarifying, because we need to provide that clarity for people working in the sector and having two registers, as you have heard, has the potential to create confusion. The third point is another potential area of confusion, which is about those cross-border issues. So, for us, it boils down to clarity. We need clarity in terms of the Bill and in developing working with stakeholders on the code of practice so that we can provide clarity for people working in the system.

[171] **Professor Watson:** My name is Chris Watson, and I am Professor of transplantation in Cambridge, and president of the British Transplantation Society. The BTS represents all of the disciplines involved in transplantation in the UK, from surgeons and physicians to scientists and nursing staff and so on. We very much welcome section 2 of the Bill, where the Welsh Ministers have a mandate to promote transplantation. We think that that is very enlightened of the Bill. It mirrors what is present in the Human Tissue (Scotland) Act 2006, but not in the Human Tissue Act 2004, which applies to the rest of the UK. When the Bill becomes enacted as law, we would be very keen as a society to see a detailed analysis of the costs and benefits come forward so that the other nations in the UK can learn from your pioneering efforts, because it is clearly something that everyone is very interested in looking at.

[172] **Ms Marshment:** I have nothing further to add.

[173] **Mark Drakeford:** I will turn to Members, who have questions. Mick is first.

[174] **Mick Antoniw:** You refer in your paper to concerns that, if we do not get this right, negative coverage could do a lot of damage to the current situation, irrespective of what the legislation says. Some of the evidence that we have had has been around the opt-out system and the role of the family and so on. Do you have any concerns about the clarity of the decision-making process, and particularly about the use of the word 'deemed' as opposed to 'presumed'?

[175] **Dr Clamp:** The point about the family is that there is nothing within the Human Tissue Act 2004 at present that gives the family any sort of right of veto. However, as we know, in practice, families' views are sought. There is a difference in this piece of legislation, as I understand it, around the nature of a hierarchy. The Human Tissue Act 2004 has a hierarchy within it, but this piece of legislation does not. I think that has the potential to create more confusion and more difficulty.

[176] On the phrase 'deemed consent', as far as I am aware, there are no countries or, at least, very few countries, around the world that use that phrase. Those with a similar system will tend to use 'presumed consent' or even 'opt-out'. So, there is a challenge there, not least because 'deemed' or even 'presumed' suggests something that is fairly passive, and consent is an active process. So, I think that that is a difficulty and, as far as I am aware, it is generally called 'presumed consent' in the vast majority of places that have such a system.

[177] **Professor Watson:** If I could add to that, we were privy to the last part of your discussions with the previous panel and there is an issue there that if a member of the family—albeit remote from those who Peter Matthews or his colleagues speak to in order to obtain consent—then objects, you end up with a situation that needs to be clarified in terms of what happens. There is potential to cause significant damage to transplantation.

[178] **Mick Antoniw:** Could you clarify a couple of points? On the current position, what happens with regard to the decision-making process from the medical side? Consultation takes place with the families and so on and someone at a certain stage has to say, 'Yes, we will go ahead.' We had some evidence that, under the current system, there is a designated person. Could you clarify what happens in practice at the moment? How consistent is that and will this legislation require an even greater emphasis on identifying the one person who says, 'Yes, you can go ahead—I am satisfied that all the criteria are met.' Is that necessary or not?

[179] **Professor Watson:** With respect to the current practice, I am a transplant surgeon, so I am deliberately devolved from what goes on in the intensive care unit and I would bow to what you heard from Peter Matthews. I do not know how widespread that practice is, but it sounds similar to the practice locally in East Anglia, for example. I think that it would help to have some sort of hierarchy so that the specialist nurses or the intensive care unit doctors, who talk to the relatives, can identify the person to whom they need to be speaking who carries the opinion of the deceased.

[180] **Dr Clamp:** Similarly, you have evidence from NHS Blood and Transplant, who will be the key practitioners in this area. What would happen is that there is a sort of hierarchy outside the hierarchy, which is the wishes of the individual in life are the first thing that we want to look at, but, if there is an appointed individual, which is relatively rare, but does happen, then they would be the next stage. If that individual cannot be contacted or is not willing to make a decision, then we would look to the hierarchy of people within the qualifying relationship. The practice of how far you would go with that, similar to what Peter

Matthews said, for example, not necessarily consulting every single member of an extended family, is a question for NHSBT and practitioners.

[181] **Mark Drakeford:** William is next, then Rebecca, Elin and Darren.

[182] **William Graham:** Thank you, Chair. Forgive my ignorance, but you state that the Bill will say

[183] ‘lawful (a) to take steps for the purpose of preserving the part for transplantation’.

[184] You go on to raise the point about the coroner. Clearly, it is right that the coroner has precedence after a sudden death, but you say here that the coroner has to give consent to preserve organs. What is the current practice?

[185] **Professor Watson:** Currently in the UK, there is only one active programme where organ donation occurs from the emergency department, for example, when patients who are brought in undergo resuscitation that proves unsuccessful; that is currently being rolled out in Edinburgh. There were programmes in the rest of the UK, but they have stopped. However, that is an area that people are looking at getting into in the future to increase donation possibilities. In that setting, you have someone who has suffered a sudden death and is therefore under the coroner’s jurisdiction. If you wanted to intervene to preserve the organs until such time as we have consent from the relatives you need permission from the coroner to proceed, because it is up to him as to whether this sudden death means that there has to be an inquest and he wants the body to be untouched. There is potentially a significant wait involved, depending on where he is—it could be minutes or an hour, I do not know. There are certain things that we could do to preserve organs—simple things to preserve the kidneys and more complex things to preserve the liver or the pancreas, and perhaps even the lungs. So, there is a tier of things that we could do. The Human Tissue Act 2004 talks about minimal steps but does not define them clearly, but there are minimal steps to be taken, depending on the different organs. It extends as far as practices in Madrid where the donor, upon verification of death by the clinicians in the emergency department, could be put on a modified form of a heart and lung bypass machine to restore circulation to the abdominal organs, pending consent from the family, or consent from the coroner in this situation.

[186] **William Graham:** To follow that through, you are completely dependent on the coroner’s wishes at that point, are you?

[187] **Professor Watson:** You cannot retrieve the organs if the coroner has not given an opinion.

[188] **William Graham:** In practice, has that had an effect on the number of organs available for transplant?

[189] **Professor Watson:** At the moment, no, but this uncontrolled donation is a developing area, where potential donors are brought into the emergency department requiring resuscitation.

[190] **William Graham:** So, in your opinion, how could the Bill be improved to increase the number of donors?

[191] **Professor Watson:** It would be helpful if ‘minimal steps’ was better clarified as to what that could involve. There is a phrase about the coroner in the Bill—section 13(3), which says that the consent of the coroner is required before the person may act on authority for the preservation of organs for transplantation. If we have to wait for the coroner to do that, there will be a delay. If the Bill allowed us to take minimal steps up until getting the coroner’s

permission to remove the organ, that would be helpful.

[192] **Mark Drakeford:** Your point is that, at the moment, the legislation appears to be self-contradictory in that, on the one hand, it allows steps to be taken to preserve organs after circulatory death, but then introduces a hurdle that you would have to overcome that would mean that those steps would not be possible.

[193] **Professor Watson:** That is right. It has not considered the more novel areas that will come into practice soon—understandably.

[194] **Mark Drakeford:** Thank you; it is very useful to have that made clear.

[195] **Rebecca Evans:** The Human Tissue Authority's written evidence tells us that the operational process, as laid out in the explanatory memorandum, does not differ significantly from that which operates at present, in the sense that the register will be consulted and a conversation will then be had with the family. A previous witness this morning also told us that the Bill will not make much difference to current practice. Do you think that the Bill can achieve its aim of increasing the number of organs available for transplant, given that you think that it will not make much difference to current practice?

[196] **Dr Clamp:** The difference that the Bill will make will be to introduce a new register. That is one thing that will be different. The other thing is that relatives will be approached if someone has not made a decision in life, with the assumption that they would be willing to donate. There may be something around that interaction with specialist nurses, for example, at that point where they are consulted. I think that there has been some research into who takes consent and how they do it, which seems to influence the number of organs that are donated. So, potentially, it could do, but, fundamentally you are quite right in that it is not much different from the way the system operates at present, especially given the Minister's comments last week about consulting the family.

[197] **Rebecca Evans:** What proportion of the £8 million that has been set aside for the delivery of the Bill over the next 10 years do you think should be invested in training people to have those difficult conversations with families?

[198] **Dr Clamp:** I do not think that that is a question for me to answer, although, quite clearly, that training is fundamental to a successful system, and by 'successful' I mean a system that works well and respects people's wishes. However, in terms of putting a figure on that, that is not something that I would be willing to do.

10.30 a.m.

[199] **Rebecca Evans:** You have expressed some concerns, however, about the funding set aside for the communication element of the delivery of the Bill. Perhaps you could expand on that.

[200] **Dr Clamp:** It comes back to one of my first points, which is that it is critical that people understand this process, their decision making and how things will work. That is a challenge. You have heard again this morning about people whose first language is not English or Welsh, complexities around what is meant by 'deemed', and so on. The communication will have to be comprehensive and it will have to be sustained, as you will have a lot of people turning 18 every year and new people moving into the country. Looking at the figure, which, I think, is a total of £2.9 million over 10 years, and thinking about comparators, as far as I recall, the Department of Health's Change4Life programme had a marketing budget of £14 million for just one year, 2011-12. Of course that covers England, which has about 10 times the population of Wales, but that is still just in one year. So, that

figure of £2.9 million seemed, to us, to be very much on the low side, given the criticality of the communication.

[201] **Mark Drakeford:** Rwyf yn mynd at Elin nesaf, ac wedyn Darren. **Mark Drakeford:** I am going to Elin next, and then Darren.

[202] **Elin Jones:** I want to take you to paragraphs 27 and 28 of the Human Tissue Authority's evidence, where you discuss the issue that the Bill refers to 'relevant material', but that your understanding is that the Welsh Government's plans in regard to deemed consent only address solid organs at this time. Do you have a view on whether it should be more explicit on the face of the Bill that that is the case, that deemed consent is for solid organs only, or do you consider that the code of practice would cover this? I think that the Minister referred to that in her evidence last week. I also want to understand the code of practice a bit better. Currently, do you operate a common code of practice for England and Wales? Do you therefore foresee that the code of practice would need to change and there would need to be a different code of practice for these issues around novel transplantations, especially for Wales, as a result of this? Are you already working on draft versions of that?

[203] **Dr Clamp:** I will start at the end and work backwards. Yes, there would need to be a new code of practice for Wales. We have been formally invited by the Welsh Government—I think that we had the letter in October last year—to start working on that code of practice and a joint working group to start that development had its first meeting this month, I believe. Developing a code of practice is critical to the success of a process such as this and it is very important that there is wide stakeholder engagement in this to make sure that it will work, because this is practical guidance. It is not a quick process. It also has to involve a public consultation and it would have to be laid in Parliament for 40 days, I think. So, from the start of the process to the publication of a final code of practice might typically take somewhere between 15 and 18 months. In order to have a draft to consult upon, the very rough timeline that we are looking at at the moment is probably to have that draft towards the end of this calendar year. So, that is something that we need to focus our attentions on. One of the things that the code of practice attempts to do is to try to marry up the differences between what is explicit in the Bill and practice, to the extent to which that can be done. So, going back to the starting point on paragraph 28 in the evidence, which is about the Bill being quite enabling in terms of what could be removed and used, you can see the arguments for that, because it futureproofs it and it brings into account such things as novel transplantation. Our view is that things that are novel should have express consent, rather than deemed consent, because people will not necessarily have thought of them, especially because we do not know what 'novel' will mean as we go in to the future. So, it is enabling, but there is a difference between what the Bill says and what people say will happen in practice. The code of practice needs to try to marry those two up and our position would be to try to do that.

[204] **Elin Jones:** I think that you have said there that, for the purposes of this Bill on deemed consent, it should be on the face of the Bill that 'relevant material' should only be solid organs for the purposes of deemed consent—because this Bill is about deemed consent.

[205] **Dr Clamp:** In terms of what would be routine transplantation work at present, I think that that would be useful clarification—I come back to the point that, for us, it is all about clarity as to what deemed consent would include. There is also an issue for the register there as to what is on there. However, for things that are new or novel, or beyond these solid organs, yes, our preference would be for those to be expressed for the reasons that I have outlined.

[206] **Elin Jones:** I want to raise one issue about the timetable of your work on the code of practice, because that relates quite closely to the legislation and some of the issues that we are exploring here. The legislation and the code of practice are interlinked in terms of how I

might end up viewing some of the issues in the legislation. So, the timetable does not seem to be running concurrently in terms of providing us, as legislators, with some idea of where the code of practice will take us. There is almost a need for us to take a leap of faith in our scrutiny of this legislation on what the code of practice might well end up saying on issues that relate to transplantations of face or limb, so I wanted your view on that.

[207] **Dr Clamp:** There is potentially a chicken-and-egg situation here, which is that in order to start developing a code of practice, we need sufficient detail in a virtually finalised Bill from which to start working, and then we need to engage with people who are going to be doing that operation or the delivery of it. So, it will always work that way, but the sooner we have that detail and clarity about what is in and what is not in, and therefore what the code needs to do, the more helpful that would be. On your point about a leap of faith, I suppose that we can point out the Human Tissue Act 2004 and the code of practice that we have on consent now, which will at least give us a framework for people's understanding of what the code does and how it is applied.

[208] **Mark Drakeford:** Thank you. Darren is next and then Kirsty.

[209] **Darren Millar:** Thank you. In paragraph 48 of the Human Tissue Authority evidence, you say,

[210] 'A further condition is that consent should be informed. It appears to us that for deemed consent to have legitimacy; people affected by it must clearly understand the circumstances under which their consent will be deemed.'

[211] You talk about the need for widespread understanding across Wales. You made reference to the differential that you have seen in costs in terms of the Department of Health campaign and the allocation here. How would you measure whether that threshold for widespread understanding has been met? Do you think that it would be wise for us to put something in place that measured whether people were fully aware and whether there was widespread understanding?

[212] **Dr Clamp:** With any form of communication programme, it is very sensible not just to send the messages out, but to ensure that they have been heard and understood, particularly by the harder to reach, the more vulnerable groups, people who have recently moved into Wales, and those who are turning 18, for example. There is an education element there and it is something that Scotland has reintroduced to its national curriculum recently. So, yes, I think that it would be very wise to measure whether those messages are being heard and really understood, in order to ensure that the population and the people who are affected by this Bill really do have an understanding of what they need to do to make sure that their wishes are complied with.

[213] **Darren Millar:** What is your definition of widespread understanding—understanding by 40%, 30%, or 60% of the population?

[214] **Dr Clamp:** I would not want to put a figure on it as I sit here. Those figures seem pretty low to me, instinctively, in terms of what you would expect, because this has the potential to affect everybody who is covered by the Bill. So, I think that it comes back to the point that, we must really try to do a thorough job in the first place, follow that up with some sort of review as to how effective it has been, and see if there are any pinch-points where the messages are not getting through, whether that is in terms of age, locality or language. That really has to be a very comprehensive and continuous campaign. The only answer that I can give to that would be for it to be as high as it possibly can be and not to stint on that. Given that, if we are looking for consent to be active and informed, and if, in certain cases, it is not active, then being informed becomes even more important.

[215] **Darren Millar:** The financial memorandum that came with the Bill makes it clear that this cash is only for a limited period; it does not say anything about ongoing investment in raising awareness thereafter. So, you would suggest that there needs to be that ongoing dialogue in terms of information.

[216] **Dr Clamp:** Yes.

[217] **Darren Millar:** I wish to ask you one further question on this issue of widespread understanding. What is the situation in other countries where there is a presumed consent system operating? Presumably, they have awareness-raising programmes. What is the prevalence of knowledge of the system in those countries? Does the Human Tissue Authority have any evidence on that?

[218] **Dr Clamp:** I cannot provide any evidence on that. One of the critical things here, of course, is that it is a change—although, it would be an interesting question to ask whether people really understand how the current system works. In terms of international comparators, I do not have any information. Do you?

[219] **Ms Marshment:** No. I think that there is a slight difference with Wales because, obviously, you will have part of the country, if you are taking the UK as a whole, and cross-border issues in a way that you do not have, perhaps, in other countries. From the top of my head, I do not have any specific examples. Spain is obviously the country that is looked towards quite a lot in terms of running examples. Spain has had this embedded for 30 years or so; therefore, this is clearly embedded within the culture. I know that that is something that the explanatory memorandum is very keen to stress. This is not just about a short-term rise in the number of organs, but it is about a change in culture. So, you have the matter of communication being continuous, but it is also a matter of it becoming embedded in culture. So, there are different aspects to it.

[220] **Darren Millar:** I would also like to check on the cross-border issues. I am glad that you mentioned those, because one of the things that has been flagged up with us, as a committee, in the previous evidence session, and to individual Members, is that there are currently people who are opting into the existing UK-wide register who have indicated that they would want to opt out under any new Welsh arrangements, but could still potentially want to opt in in other parts of the United Kingdom. Do you think that the new organ donation register, which is much wider, needs to be able to incorporate the distinctive view that someone might make in terms of whether they are expressing consent in Wales, as compared to other parts of the UK?

[221] **Dr Clamp:** It is easy for me to say that, whatever it is, it has to be clear in order that people who are consulting the register know what they should be doing. Knowledge of current practice means that if there is any confusion at all, it is highly likely that the donation will not go ahead. With that as a general principle, there needs to be as much clarity as possible. Coming back, perhaps, to the point about the code of practice, that is one of the reasons why we need to be able to explain to people how the register works and what the implications are, and we need more clarity about the register before we can do that.

[222] **Darren Millar:** Okay. So, just to confirm, you are suggesting that anyone who opts into the UK-wide register that will be used ought to be able to determine whether their organs can be taken in other parts of the UK, but not in Wales, given that their consent has been deemed, perhaps?

[223] **Elin Jones:** Only if they were to die there.

[224] **Darren Millar:** It is an issue. People have said to us that they will come off the list if their consent is being deemed under the new regulations.

[225] **Dr Clamp:** I think that the person filling in the register needs to make the decision on what is presented to them in the register, and whether they have a fundamental objection that outweighs their willingness to donate elsewhere in the UK. However, it needs to be something much simpler than what you described in order to avoid that confusion.

[226] **Mick Antoniwi:** Are there any training implications and costs with this? I do not know what happens at the moment, but we are changing the nature of the advice and the handling of this quite substantially. Is there an issue in that respect?

[227] **Dr Clamp:** There is definitely a training issue. People are dealing with a new register. There would have to be national training in terms of what is in there and how to interpret it. That would be vital. It is part of that communication, I suppose, and about people who are practitioners in the area also understanding it, not just the people who are signing up to a register.

[228] **Mark Drakeford:** I now call on Kirsty. This may be the last question.

[229] **Kirsty Williams:** All of us want to achieve more organs for transplantation, I guess, but it is just a question of how best that is achieved. This, in some cases, looks like a high-risk way of potentially achieving it with lots of reputational risk for clinicians and for the system as a whole. Perhaps that would be worth it if we knew that it would actually increase the number of organs that were available.

10.45 a.m.

[230] We heard this morning from Dr Matthews that a shortage of intensive care beds and other facilities and practical stuff might mean that we could go through all this, but not end up with more donations anyway. Mr Watson, on behalf of the organisation that you represent of clinicians working in the field, do you have a view about whether Wales has sufficient capacity to handle any increase in potential donors that may arise out of this system?

[231] **Professor Watson:** There are two aspects to that: the first is who will retrieve the organs and the second is whether there is capacity to put the organs into the recipients. The retrieval is organised UK-wide, and Cardiff and Birmingham have a joint retrieval service as part of the national organ retrieval service. There is capacity there to rise to an increase, and they would like to rise to an increase. As far as implantation is concerned, the organs are shared throughout the UK in a UK-wide sharing scheme, which ensures better matching for the recipients. So, the increase in capacity in the Cardiff transplant centre will not be enormous. I envisage that it has ample capacity to do more; it will just take its focus from dialysing patients to transplanting patients.

[232] **Kirsty Williams:** We heard this morning that we have a relatively low level of ITU beds, compared with continental European countries, which potentially causes a problem in these areas. Is that your experience or is it just that Dr Matthews has a particularly difficult unit to work in?

[233] **Professor Watson:** No, it is a UK-wide problem. We have a low provision of intensive care unit beds. That is one of the reasons why looking at Spain and thinking that you can adopt Spanish practice in the UK is not straightforward, because it has a huge ITU capacity and we do not. We triage patients much more before they get to an intensive care unit bed, because we have to. Nevertheless, 60% of donors' families consent to donation, while 40% do not. So, there is a 40% gap that this Bill may satisfy.

[234] **Kirsty Williams:** Finally, some concern has been expressed in the evidence that we have received from ethical-based organisations about the clarity in the Bill about circulatory death and brain death. Do you have a view about whether the Bill is sufficiently clear in that regard?

[235] **Professor Watson:** The way to diagnose circulatory death and the way to diagnose brain death have been outlined clearly in a document by Sir Peter Simpson's group in the Academy of Royal Medical Colleges. That is very clear. With the UK Donation Ethics Committee, it has produced guidance for retrievals and for donation after circulatory death. So, that is clear outside the Bill, without being within the Bill.

[236] **Mark Drakeford:** Mr Graham wants to come back on a point.

[237] **William Graham:** Would you indulge me for a moment? It concerns what you were talking about regarding the coroner. In practical terms, at present, there is no significant impediment in terms of a coroner's consent for the preservation of organs.

[238] **Professor Watson:** Taking away the casualty deaths that I mentioned, there is still a small proportion of donations that do not proceed because the coroner is not happy to let them proceed, but coroners are consulted about sudden deaths in which they may be interested, so there are separate reasons for the coroners vetoing it.

[239] **William Graham:** My question is: is there any significant problem in obtaining that consent?

[240] **Professor Watson:** No.

[241] **Mark Drakeford:** There is one last, brief question from me, which is probably for you, Dr Clamp. It is about the issue of appointed representatives, which we rehearsed with the Minister last week. When an appointed representative is nominated when someone's name goes on the register, that will be clear-cut, but when someone names a representative outside that system, either orally or in writing, I do not think that it was quite as clear to us as to how that nominated representative would be known to the system and how that would operate. Within the existing 2004 Act, how is that negotiated? Are there any lessons that we can learn from it and is there anything that we should be thinking of in relation to this Bill that we could recommend to improve that position?

[242] **Dr Clamp:** I will ask Vicky to answer that.

[243] **Ms Marshment:** In the 2004 Act, we have nominated representatives, which are similar, in terms of the wording, to the appointed representatives in the legislation that is currently before you. The slight difference is that, at the moment, it is very explicit on the face of the Human Tissue Act 2004 that if that person cannot be found in the time that you need to seek consent, or if that person is unwilling to act in that capacity, then you move on to the family, so you have gone from the person's consent to the nominated representative, to the family. That is the flow-through as things stand. In the draft legislation, there is no clarity as to what happens if that person cannot be found or that person is unwilling to act, and I know that NHS Blood and Transplant finds that particularly useful in the training of its specialist nurses to give them the confidence that as long as they have asked the question about a nominated representative, and if they cannot find them or they are unwilling to act, they can then move to speaking to the families. There is confidence that they are complying with the legislation.

[244] At the moment, there is that slight difference that if you are moving through there is

no presumption that donation is going to go ahead. So, as you move through that list, there is no presumption. The difference under the system of deemed consent, I should imagine, would be that if a thorough examination is not done to find that person or to find out whether that person exists, and consent is then deemed, there is greater reputational risk to the system, if somebody comes forward and says 'I was the appointed representative; why wasn't x, y and z checked?'

[245] There is also the potential legal aspect. We know in the legislation, like in the Human Tissue Act 2004, that a clinician will not commit an offence if they believe that they were acting with consent. So, that is there and that is very helpful. However, there is that slight difference; they are quite cursory checks at the moment, but the question is asked. From our reading and understanding, and from listening to NHSBT's evidence, there is more concern about what lengths should be gone to, and also if that is something that people may choose as an option, namely that they do not want to go on the register, but they would like to nominate somebody to make that decision for them. So, it would be explained to them the kind of areas that would be checked, so that they would be clear in life that that process would be followed through. Does that help?

[246] **Mark Drakeford:** Yes. Thank you all.

[247] Diolch yn fawr iawn i chi i gyd am ddod i'n helpu ni y bore yma. Thank you very much to all of you for coming to help us this morning.

[248] That is the end of this particular session.

[249] Cymerwn egwyl fer nawr, ond down yn ôl ar yr awr, am 11 a.m.. We will take a short break now, but we will return on the hour at 11 a.m..

*Gohiriwyd y cyfarfod rhwng 10.52 a.m. a 11.05 a.m.
The meeting adjourned between 10.52 a.m. and 11.05 a.m.*

Bil Trawsblannu Dynol (Cymru): Cyfnod 1—Sesiwn Dystiolaeth 6 Human Transplantation (Wales) Bill: Stage 1—Evidence session 6

[250] **Mark Drakeford:** Croeso yn ôl, bawb, i eitem 5 ar ein hagenda. Rydym yn bwrw ymlaen â'r chweched sesiwn dystiolaeth ar Fil Trawsblannu Dynol (Cymru). **Mark Drakeford:** Welcome back, everyone, to item 5 on our agenda. We will go straight on to our sixth evidence session on the Human Transplantation (Wales) Bill.

[251] Hoffwn groesawu'r panel o dystion, sy'n cynnwys Syr Peter Simpson, cadeirydd Pwyllgor Moeseg Rhoi Organau'r DU, a Dr Tim Lewens o Gyngor Biofoeseg Nuffield. Diolch i chi'ch dau am ddod i'n helpu'r bore yma. Fel arfer, rydym yn gofyn i'n tystion a oes ganddynt sylwadau agoriadol byr, ac wedi hynny, rydym yn troi'n syth at aelodau'r pwyllgor er mwyn iddynt ofyn eu cwestiynau. Tri chwarter awr yn unig sydd gennym ar gyfer y sesiwn hon, felly apelïaf at bawb, fel arfer, i geisio cadw'r cwestiynau a'r atebion yn fyr. I would like to welcome the panel of witnesses, which comprises Sir Peter Simpson, chair of the UK Donation Ethics Committee, and Dr Tim Lewens of the Nuffield Council on Bioethics. Thank you both for coming to help us this morning. As usual, we ask our witnesses whether they have any short opening remarks to make, after which we turn directly to the members of the committee for them to ask their questions. We have only three quarters of an hour for this session, so I appeal to everyone, as usual, to try to keep questions and answers brief.

[252] So, let us open things up straight away. Sir Peter Simpson, do you want to begin with a few opening remarks? We will ask Dr Lewens to do the same, and then go straight into questions.

[253] **Sir Peter Simpson:** Thank you very much indeed for inviting me to come to talk to you all. We are very pleased to be able to try to help in whatever way we can.

[254] I represent, as you said, the UK Donation Ethics Committee, which is UK-wide, and therefore we have as much remit for Wales as we do for the rest of the United Kingdom. It is worth outlining that the UK Donation Ethics Committee contains a wide variety of people. It does not just contain ethicists; it contains a lot of people who are involved in clinical practice. Therefore, the breadth of our comment reflects the fact that we have intensivists, we have surgeons, we have ethicists, and we have laypeople. We therefore hope that it will provide a broad view of what you want.

[255] In outline, we do not see a fundamental ethical objection to deemed consent. We cannot actually pick on something and say, 'I'm sorry, but ethically, it is not acceptable'. However, we have concerns about the practicalities of it and, indeed, sometimes from an ethical point of view, the effect that it may have on other people, albeit unintended. For example, if, by doing this, the confidence in the whole process of organ donation diminishes elsewhere, then of course the actual adverse effect is greater than the benefit, because we will have a sort of *Panorama*-style effect elsewhere. Now, that is an extreme view, but nevertheless, it is one that is worth mentioning.

[256] Another thing, which I think is linked to that, is the overall question of unintended consequences, which we can talk about if you want.

[257] The third thing that I would mention briefly is that the Bill largely looks at what most people look at, which is donation after brainstem death—that is relatively easy to manage. However, donation after cardiac death, or circulatory death, is much more difficult to manage from an ethical point of view when you link to deemed consent, and I can enlarge on that point if you want.

[258] **Dr Lewens:** My name is Tim Lewens and I should explain that I am not a medical doctor. My primary job is as a philosopher of science in the University of Cambridge, but I am also a council member of the Nuffield Council on Bioethics, and it is in that capacity that I am here today. We wrote a report in October 2011 looking at a very broad range of issues associated with ethics and organ donation—opt-in and opt-out systems were just one small part of that report. We considered the ethical issues associated with the systems, though. Cutting to the chase, the conclusion that we came to is that we would be opposed to hard opt-out systems, but a soft opt-out system of the sort envisioned here is one that we did not think posed any fundamental ethical problems. However, as we have heard several times today already, we did have some concerns around the practicalities of implementation, and some ambiguities regarding the likely efficacy of the system, as well as some potentially adverse consequences, depending on precisely how it is implemented with regard to overall trust and so forth.

[259] **Mark Drakeford:** We will now go to questions. Kirsty is first, then Lindsay, and then we will take the long list of other Members after that.

[260] **Kirsty Williams:** On the issue of DCD, donation after cardiac death, and whether that can be more easily accommodated within this Bill, given that it potentially already supplies quite a lot of organs, and there may be the potential for more, is there some way in which we could address your concerns and try to stop the unintended consequences that you

outline in your paper? Is there something that we could recommend to the Government on the drafting of the legislation that could ease those concerns, or is it impossible to do?

[261] **Sir Peter Simpson:** It is not easy. Forty per cent is the rate of DCDs at the moment, and that is a large number. It is increasing, because donations after brain death are diminishing, or have plateaued, as I am sure you have heard from other people. The problem with DCD is that decisions are made while the individual is alive, and the whole principle behind it is that somebody says, 'I want to be a donor, and I therefore want my end-of-life care to include being a donor'. If they say that, that is fine. If, on the other hand, somebody has never said that, and they are dying, but we do not know what their express wish is, to deem that they have agreed to that when, actually, they just have not expressed an opt out, is a stage that we think is quite a long way down the track. I do not have a magic answer for it. It may need a group to look very carefully at it. We have not done that yet, because we have not been asked to, but it is a complicated area.

[262] **Kirsty Williams:** You mentioned unintended consequences and the potential controversy around such legislation, which could result in fewer donations being made. I have certainly had constituents telling me that they will take their name off the register because of this change. In balancing it up—the risks and the opportunities that this legislation gives us—as someone who has obviously spent a lot of time looking at this, is this a risk worth taking, given that, ultimately, it will lead to greater levels of donation because it will come to be seen as the norm; or is it not a risk worth taking? Are there more optimum ways in which we could raise the number of donations?

[263] **Sir Peter Simpson:** I used to be an intensive care consultant, so I have dealt with organ donors since 1970. I have had a lot of experience in a positive way about people wanting to be donors, but that is because they want to be, and they express a wish or express the wish to their relatives to do so. Deep down, a large number of people are supportive of organ donation. Whether persuading those who are not—or indeed deeming those who are not, by saying, 'If they haven't said they're not, then they are'—is quite a big step forward for people. A lot of people have very private issues as to why they do not want to contemplate it. A number of them are related to the process, and others are personal factors. Perhaps they have not been strong enough to express that in a negative way. The problem is more the families and the relatives if you use a soft system than it is with an individual person. The individual person is dying or has died. Leave aside donations after cardiac death; I am just talking about donation in general. The person who is dying or has died is not the one who is confronted by the problem. The people who are confronted by the problem are the relatives, and they are ones who, if they are confronted with things that are too difficult, will be affected in terms of their attitude to donation when it comes to them, or others. That is one of the unintended spin-offs that we would look at.

11.15 a.m.

[264] **Dr Lewens:** This is a risk, but the question of how significant it is depends a lot on how the communication issues are managed. So, you have heard—and the Nuffield Council on Bioethics also heard this in the consultation that it did—that, for many people, the move to an opt-out system is equivalent to the state gaining ownership of their organs. Whether or not that is the widespread perception depends a lot on precisely how the communications are managed. There is a sense in which what is really going on, when one moves to a deemed consent system, is that one is simply setting up a new convention for the way in which consent is to be indicated. It is rather like saying in a meeting, 'Unless anyone has any objections, I will proceed with this', and then one explicitly takes silence for agreement. This is what is happening here. It is taking silence for agreement. So, one expresses one's consent via keeping quiet.

[265] That does not mean that there is no room for consent. It does not mean that one does not have to take an active decision in terms of what one understands by ‘organ donation’, nor does it mean that one is removed from the decision, but it still means that it is important for people to understand these issues. In a way, it makes people even more responsible for making sure that they take control of those decisions via opting out, if they wish to do so. So, there are potentially ways of managing the way in which this measure is put in place that might dampen down those potentially adverse consequences.

[266] **Lindsay Whittle:** Thank you for coming to meet us today. It is the ethical issues that I am concerned about. I have already said in this committee to previous witnesses that I know what I want to be done with my organs. I am quite happy for them to be donated and I do not want my relatives to object. I decide what happens to my body when I am alive, and I hope that I will do so after my death as well. I do not approve of relatives objecting. However, the issue is very different for children. Do you have any thoughts on that? You have two parents and, potentially, four grandparents who might all have different views. What is your view on that?

[267] **Dr Lewens:** If I may quickly say something on the issue of the family’s involvement, even under the current practice, families do not strictly have a right of veto but, nonetheless, their views will be taken into account. As I understand it, that will continue to be the case under the proposed system. There are two good reasons for taking family wishes into account. First, family members may be well placed to know of recent events that inform the team about the wishes of the individual. So, there, the involvement of the family need not override your own views, but it rather helps the team to understand what your views are. That will still be the case—and I think it is an important part of the case—under the revised proposals.

[268] It is also just a fact that transplant teams are understandably very unwilling to cause family members undue distress at what is already a very difficult time for them by going against their wishes. That is one reasonable consideration to be borne in mind here. That said, one thing that I worry about—and, once again, this came up earlier this morning—is that it is one thing to say that the family should have an input into explaining what the donor’s wishes may have been, but it is another thing to say that it is important not to bring about undue distress to family members; to translate that into a claim that any family member has a right of veto, with a long list, may well involve adverse consequences and counter-productive consequences in terms of the overall ability of the proposed legislation to increase rates.

[269] **Sir Peter Simpson:** With regard to children, at the moment, the ethics committee is producing some guidance on decision making in the case of children and children giving consent. I do not want to pre-empt that, but I can tell you that it is under way. That work is in the final stages, so it will not be long before that is published.

[270] The issue really is that, with children, by and large, we consider it at the moment as donation being a positive act. Usually, it occurs because the parents want it to happen. In other words, you get a child involved in a tragedy, such as a car accident, and the parents say that they want their child to be a donor—in other words, the decision is almost taken by them, rather than by the child. We are getting a number of cases, which are always publicised, where children say that they want to be a donor. If they want to be a donor and if—as we would hope and, I am sure, that you would hope—that positive decision is taken because they discuss it with their family, so that everybody knows where they are coming before it happens, we need to support that. The issue is what happens if a child, a teenager or somebody underage dies and has not opted-out and will that allow this to happen. I have a personal view which is that that would be a stage too far at the present time. I know that you are only considering this for people over the age of 18 anyway, but I think that you are going to have to set the children’s issues to one side in the way that I described earlier.

[271] **Dr Lewens:** It also returns to the general principle of what is going on under deemed consent, where, effectively, the way in which you indicate the willingness to give organs is through not doing anything. That relies on a good understanding of the nature of the new convention for signalling consent that is to be introduced under the proposed legislation. It is therefore reasonable to impose a slightly higher bar for comprehension with regard to children and to exclude them from the normal operation of deemed consent.

[272] **Mark Drakeford:** Every single Member of the committee has indicated that they want to ask a question and several Members want to come in on the last question too, so somebody is going to be disappointed. I am going to go ahead with the list of questions that I have and Members will have to decide whether they want to use their turn to follow up stuff they have already heard or to follow a new line of questioning.

[273] **Lynne Neagle:** I want to ask about communication. Dr Lewens, you have emphasised how important that is, yet we heard evidence in the previous session that the £2.9 million that has been set aside for this may not be adequate. Would you like to comment further on that?

[274] **Dr Lewens:** I am not a health economist. I would not want to comment on the particular nature of the budget. I would say that one has to consider the content of the communication and its recipients. First of all, as you all know, it is going to be important that the communication is phrased not only in English and Welsh; it will also have to be phrased in other languages. It is going to have to be accessible to people who are deaf and people who are blind. It is also important to think about the content of the communication because a lot of stress has been placed on allowing people to understand the nature of the new system. It is also important to remember that consent needs to be informed, which in this context means that all people do not necessarily have to prove that they have understood what is involved, but, nonetheless, everybody—even people who are passively, so to speak, remaining on the register—will need to have access to information regarding what is involved in organ donation. It is important that there is a place where they can seek that information easily if they want it. That is an extra aspect.

[275] **Darren Millar:** I want to explore the issue of understanding, because it is important that people are aware of the system if there is going to be an ethical argument to allow them to participate in it. Do you have a view as to how the level of understanding can be assessed? Is there a threshold that ought to be met prior to the implementation of the system et cetera as regards awareness in Wales of the deemed consent system that is going to arise as a result of the Bill?

[276] **Dr Lewens:** As regards how it is assessed, you are not going to be assessing the understanding of every person in the country. It will be important to design selective research projects that will give you a picture of how well different strata of society—for example, people who do not have access to the internet—have been able to pick up on the new proposals. The Nuffield Council on Bioethics took a view that the level of information and understanding required is potentially lower in the context of something that happens after your death, as opposed to, say, the standard level of informed consent that you would insist on if you were undergoing an operation, for example, where an invasive procedure would go on during your lifetime with potential knock-on effects for your own health. In that case, it is reasonable to insist on higher levels of understanding than in this context. However, it will be important at some stage to assess how well people seem to have understood the matter.

[277] **Darren Millar:** Do you not think that there should be a minimum level of understanding prior to the procedure?

[278] **Dr Lewens:** I find it hard to see how one would specify that. It is very hard to

quantify understanding.

[279] **Darren Millar:** Do you have a view?

[280] **Sir Peter Simpson:** I have. The view that we have is that, at the moment, we require people to put their name on the register and, if they are not on the register, we would hope that our discussions with the patient, but more often with the relatives, would yield a donor. However, both of those things are fundamentally dependent on their level of understanding—they would not do it if they did not understand what they were doing, or, at least, you would hope so. I am somewhat dubious, as is the committee as a whole, about the quality of the consent that is achieved. Do people actually think about it when they put a tick in the driving licence box? The key response to that is, if they put their name there, they should discuss it with their family, which then makes them think about it. I am not convinced that what you are proposing as deemed consent is any less or greater, in terms of knowledge, than somebody ticking a box on a driving licence. I still think that the whole issue of organ donation is misunderstood by a lot of people and is poorly understood by others. I do not think that you should necessarily go against what you are trying to do on the basis that you cannot assess it. I think that it is pretty equal across the country.

[281] **Darren Millar:** One thing that neither of you pick up in your evidence—and I wonder whether it is something that you might want to consider—is the potential for recipients of donations to be uncomfortable about receiving a donation, potentially from someone who has had their consent deemed, rather than expressed. Is that an issue that we ought to consider as a committee? If so, what are your views on it?

[282] **Sir Peter Simpson:** That is an interesting angle, but we have not discussed it. It is not in our submission. If you are asking for a view on that, I think that people who are recipients are always incredibly grateful to somebody who has donated an organ, by whatever route. I would be surprised if they felt terribly guilty about that, as long as there is a system in place that governs how that organ has arrived. They might think differently if it was being paid for or if someone else had suffered as a result.

[283] **Dr Lewens:** That is a potential hazard of the term ‘deemed consent’. It is important to remember that if everything proceeds as it is envisaged, then deemed consent is not a sort of a poor man’s consent—one has genuinely consented. One has reasonable evidence of consent if this all works out, precisely because the communication plan will be so thoroughly undertaken that it will be reasonable to assume that if someone has not opted out, they are thoroughly behind that procedure. That is the idea behind deemed consent. So, it should not be the case, if everything works properly, that if you receive an organ from somebody who has not opted out, that you should be worried that they did not really care about this. Again, that is all contingent on the communication plan working properly.

[284] **Sir Peter Simpson:** We did discuss—and I know that it has been discussed elsewhere—this question of being sure if there is still the opportunity for somebody to express a positive wish to be a donor. It would be a terrible shame if that was lost.

[285] **Vaughan Gething:** I will ask one follow-up question on that, and then I will go back to the issue of family. On this point about the current system, where people can still be organ donors even if they have not opted in, and a discussion is held with family members, who say that they think that that person would have wanted to do that, how ethically different is that from the proposals for deemed consent within the Bill, in terms of the decision made and if there is such a discussion with those people?

11.30 a.m.

[286] My second question relates to the point about family and its influence on the practical reality of organ donation. We have heard a lot of evidence on this. Do you have a view on whether there should be a ranking system of people in a qualifying relationship or do you support the view that the Minister has outlined that anyone in a qualifying relationship can object and, in practice, that objection would be enough to prevent donation from taking place, regardless of where they are on the list?

[287] **Sir Peter Simpson:** On your first question, at the moment, as you say, if someone does not carry a card and the relatives are asked about consent, the question that they are asked effectively is, ‘Do you think that they would have wished to be a donor and would you support that?’ It is not, ‘We know that they do not want to be a donor, but do you want them to be a donor?’ So, effectively, they are halfway down the track already because they will not encourage relatives to give consent if they think that the person themselves would not have done so. It is a presumption that the person would have done so, but that they just did not carry a card. Put like that, it is not that different from what you propose, provided that you have a soft opt-out on both, which is effectively what we are talking about. The opt-out is soft in both situations, but is applied slightly differently. Shall we deal with that question first and then come back to the other?

[288] **Vaughan Gething:** Yes, that is very helpful.

[289] **Dr Lewens:** I would say the same. However, it depends on precisely how the communications occur at the moment at which the question is put to the family. If the question put to the family is, ‘This person has not opted out, but I wonder if you have any further information about what their likely wishes are’, and if that information is then taken into account, which is compatible with how the system is envisaged, then it would not be all that different. If, instead, the communication is phrased as, ‘Our intention is to go ahead with this unless you can provide us with very good reasons why we should not’, then the presumptions are rather different. However, that depends on precisely how the training would occur. It seems to me that the first, gentle way of approaching it would be much better in terms of overall confidence, trust and sensitivity.

[290] On your second question, I am not sure what to say about ranking. As I said, if the reason for approaching family members is, on the one hand, because family members may have evidence regarding the likely wishes of the potential donor and, on the other, because some family members may be extraordinarily distressed and the team wishes to avoid that, then it is hard to predict which members of the family will fall into those positions. It might be a spouse, but it might be a cousin. Potentially, all kinds of different people could have that kind of valuable information regarding the wishes of the person. That would tell against a ranking system.

[291] **Sir Peter Simpson:** My belief about the ranking systems of qualifying relationships is that it was put in place to allow for the fact that whoever the closest relative was could ultimately say, ‘Yes’ or ‘No’. The idea was that there was a ranking so that you could get the person who was highest up the ranking. As I understand it, if anyone on the list can say, ‘No’, so that even if the top three say, ‘Yes’, if someone at the bottom says, ‘No’, they are effectively a person on the list and their response is therefore sufficient. Is that what you are asking because from a clinical point of view, that is a logistical nightmare? Time is of the essence in these situations and if someone who is in a qualifying relationship happens to be on holiday in Australia, you can forget it. You cannot have a situation where subsequently the person returns and says, ‘Well I am in a qualifying relationship and I would never have allowed that to happen, but I just was not contacted.’ I do not believe that that is why the qualifying relationship ranking was originally put in place—I think that it was put in place for very sound reasons, but adapting it would mean that a lot of opportunities would be turned down.

[292] It is important to realise that we all assume that a donation can proceed in a very calm and measured way, but what realistically happens is that it is a Sunday night, it is a tiny hospital that does only two organ transplants a year, the surgeon who knows anything about it is on holiday and they have two patients who need to get into the intensive therapy unit bed. Any excuse that makes it difficult, so that people say, 'I'm really sorry, we just do not have the time to do this; ethically, we must take care of these other patients who need the bed' will mean that the potential donation is turned down. The difficulty is trying to put in too many obstacles that are unanswerable within the time frame, so the donation is ultimately not pursued. I hope that it will be, but it will not be pursued as vigorously as it might have been. That is what happens. If you look at NHS Blood and Transplant's donor audit, these are types of things that come out of that. Anything that rocks the boat is difficult.

[293] **Elin Jones:** The Bill as it is currently drafted deems consent for relevant material, which includes solid organs and tissues that could be used for novel forms of transplantation, such as face and limb transplantation. The list of exemptions in section 16 of the Bill is quite short. Do you have any views on whether that list should be lengthened on the face of the Bill so that consent is only deemed for live-saving solid organs?

[294] You have said quite a bit about communication. The communication that I have seen to date on the Bill as presented by Government has been mainly on the discussion of deeming consent for life-saving purposes, although this legislation is much wider in its scope. We have been told by the Human Tissue Authority and the Minister that these issues will be covered in the code of practice currently being developed alongside the Bill, although we may end up voting on the legislation before that code of practice is even made public in draft form. Do you believe that communication on deemed consent for the purposes of a vast array of potential transplantation is sufficient, or should there be something on the face of the Bill that specifies that this is deeming consent for live-saving purposes and organs that relate to that?

[295] **Dr Lewens:** I am not sure that I have a clear answer to that. If you restrict the Bill to life-saving organs, people can survive under dialysis for a reasonably long amount of time, so you do not want inadvertently to exclude kidney transplantation on the grounds that, on some understanding, you might not necessarily think that it is life-saving. At the same time, it is important that, as you try to introduce what is effectively a new convention for how consent will be indicated, you have to rely on the tacit understanding that people have of what counts as organ donation. Asking for very novel forms of transplantation to be contained within the Bill might be rather risky in terms of stretching the credibility of the notion of deemed consent.

[296] **Sir Peter Simpson:** I think that it is very risky. If you look at people who express a wish to donate only certain organs, you find that the ones that they do not wish to donate are corneas and hearts, because for some reason they have a personal feeling about those. They will certainly have a personal feeling about a face or a hand. Faces and hands are still being researched, and I would like to say something about research in a minute. The danger is that if you try to make the Bill all-encompassing, you will lose the main thrust of it in order to try to include the fringe things. I am adamant that you should just concentrate on solid organs that are effectively life-saving, because that is their expectation; in other words, they are what most people would regard as being organs for donation, namely kidneys and gradually other organs. When you talk about transplantation, the majority of people out there think about kidneys. To introduce lots of other organs will muddy the waters.

[297] **Elin Jones:** Do you think that it should be explicit in the legislation that consent is deemed only for solid organs and not for other purposes?

[298] **Sir Peter Simpson:** Personally, I would do that. I think that you are much more

likely to get an understanding, which is the crucial thing. It is not about acceptance, it is whether people understand. They can contemplate solid organs. There is going to be the opportunity to say, 'I don't want that', but that will be the same as opting out. They will opt out of certain things, presumably. I presume that there is an opportunity to opt out of some, but not others.

[299] **Mark Drakeford:** Yes, there would be, but it is not on the face of the Bill. I think that is the point that Elin is making. The Minister explained to us last week that it would be done outside the Bill. I think that you are saying that, for deemed consent purposes—

[300] **Sir Peter Simpson:** I would approach things gently. There is nothing to stop people revising it in five years' time when the donation of hands is more common, or whatever; there is nothing to stop that.

[301] **Mark Drakeford:** Rebecca, William and Mick have questions, so we will all have to be brief.

[302] **Rebecca Evans:** You have both stated that you do not have any ethical objections to the system being proposed. However, in response to our consultation, a number of stakeholders, including the Catholic bishops of Wales and the Archbishop of Wales, have stated that deemed consent cannot be classed as consent as it is no longer a voluntary donation, but an act of taking that contradicts the rationale and the ethos of donation. What is your response to that?

[303] **Sir Peter Simpson:** We would say that people still have to have the opportunity to make a choice, as Tim was saying. It is a matter of educating them to make a different choice. It is not saying that deemed consent means that you have no choice in it at all. You certainly do; it means that you have to make an active choice. So, our view is still the same. We have ethical differences of opinion with the Catholic Bishops' Conference of England and Wales over certain issues. They have a view on things and are perfectly entitled to that. Ethically, I do not think that we and the Nuffield council differ, do we?

[304] **Dr Lewens:** No. What is going on here is that one is saying to the population, 'Henceforth, we will take it that you have consented, unless you register an objection'. So, one is not taking against people's will; one is simply imposing a different convention for how they indicate what their will is. So, I would not agree with the interpretation of the Catholic church there.

[305] **Rebecca Evans:** On a different issue, you have both expressed some concerns about the possible negative effects this might have on clinicians. You say that it might have an effect on the confidence of professionals. Could you expand on those concerns and, perhaps, suggest how the Bill might address those concerns?

[306] **Sir Peter Simpson:** Organ donation is a very difficult thing for clinicians to manage. It is not easy, it is very emotional and whoever you are and however detached you try to remain from it, you get wrapped up in it, because you have looked after the relatives and the donor, and so on. The issue that we are really concerned about is the extra things that can happen. Clinicians are always trying to achieve the best result. Ethically, your responsibility as a clinician is to the donor, while they are alive, but then, at this funny time, your responsibility transfers to the recipient, to make sure that the organ is in the best possible condition. There is quite a lot of work being done at the moment on how you can—by using physical, organisational and pharmacological methods—make sure that the organ quality is top notch. You do that in the knowledge that the person wants to be a donor. The person says, 'I don't only want to be a donor, I want to give top-notch organs, thank you very much'. That is quite difficult if consent is simply deemed. Our concern is that, if that happens, people may

not have the confidence to implement initiatives to improve organ quality simply on the basis of a deemed consent.

[307] **Dr Lewens:** Our concerns were primarily to do with issues about precisely how families would be approached and making sure that they would not be approached in too much of a heavy-handed manner; in other words, using the fact that opt-out had not occurred in an overly heavy-handed way with regard to consulting with the family. We also had potential worries about perceived loss of trust in the system as a whole, if people seeking the wishes of the family were subject to significant targets, for example, regarding how many organs that they were supposed to procure.

11.45 a.m.

[308] **Mark Drakeford:** I have wondered, once or twice, during your evidence this morning, whether what you are really saying to us is that DCD ought not to be included within the Bill, whether it is simply not suitable to deem consent.

[309] **Sir Peter Simpson:** What I am saying is that I think that we need to do quite a lot more work around DCD. Like many of these issues, you start off with a very straightforward idea based on DBD and it looks as though it is workable. The danger is that if we try to be all-encompassing and talk about rather unique tissue transplants, we run the risk of making it too complicated. The difficulty that you have is that DCD donations are going up and DBD donations are not. Whether people would say that it was sufficient to have deemed consent for DBD only, that is a matter that you will all have to decide.

[310] **Mark Drakeford:** Thank you. I have broken my own rule by intervening, so I will let Kirsty speak next, as this started with her question.

[311] **Kirsty Williams:** You say that there potentially needs to be a lot more work around this area. Whose job is it to do that work? What are the timescales? My colleagues and I will have to make a decision to vote on this shortly in the absence, I suspect, of the 'lot more work' to which you referred. Whose job is it to do the 'lot more work'?

[312] **Sir Peter Simpson:** The UK Donation Ethics Committee has produced a whole guidance document on all the ethical considerations around donation after cardiovascular death. I am sure that you have looked at it, but I suspect that you need to look at that in relation to what is being proposed. In other words, the guidance is there as to what DCD involves and what the ethical issues are around that. To reiterate, the problem is that it is fundamentally something on which people decide prior to death. To a certain extent, it overlaps with the issues around people who lack competence as well: lacking competence and DCD are not unconnected in some ways. So, when I say that I think it needs more work, I think that there is a decision to be made. You need to look at that document and decide whether it is satisfactory and answers your questions. We could take away a question that asks whether deemed consent is ethically compatible with DCD. Fundamentally, we believe that it is, but it is the logistical issues behind that that are difficult. I am sorry, I cannot give you a magic answer—

[313] **Mark Drakeford:** No, we are not expecting you to, and we see your point exactly about where the logistical issues impinge very heavily on that ethical dilemma.

[314] **William Graham:** Returning to the desirability of research, is it ethically desirable for organs to be used in research? I notice that there is a marked difficulty in obtaining diseased and aged skeletons, for example. That is a fairly minor issue in terms of personal views, but should we not include research in the Bill?

[315] **Sir Peter Simpson:** We must consider the normal processes that go on. Research can mean a whole range of things. In other words, research will be done on perfusing donated lungs in order to improve their function, and then a recipient will be told that the lung has had that treatment and asked if they are happy to receive it. In other words, research is going on with donated organs at the present time. Research also takes place in organs that are deemed unsuitable for transplantation. Research is necessary, particularly, as I have highlighted, in the areas of trying to improve organ function by chemical means or whatever. So, if we are not going to have the opportunity in a patient who is deemed to have consented for their organs to be used for research or included in a research project, if not suitable for immediate transplantation, it adds another dimension to the problem. It means that there is only a fairly unique area in which the organs can be used. Therefore, I think that the Bill ought to take account of research. The difficulty, I suppose, is whether you have research in an active way or, in other words, that you are deemed to consent to not only transplantation but research, or whether research is a part of the donation process, which I think is an easier thing for people to understand, because they realise that new treatments are always being evolved that are linked to the transplantation process.

[316] **Dr Lewens:** We are not talking particularly about research in the sense of novel forms of transplant. Rather, we are talking about the use of various kinds of materials for various sorts of biomedical research purposes. It is important to remember that that is one way in which people can contribute towards the health of future generations—it is via the impact that this might make on research. The Nuffield Council did not take a particularly strong view on the issue about whether or not the opt-out scheme should apply to research, but nonetheless, I think, some awareness of the importance of research is useful here, even if it is simply to ensure that, at the moment, for example, families are approached. Issues about consent to research are regularly raised.

[317] **Mark Drakeford:** The last question is from Mick.

[318] **Mick Antoniw:** In the light of all these problems, complications and questions over ethics and so on, who should be taking the decision to actually proceed?

[319] **Dr Lewens:** To proceed with the legislation, or to proceed—

[320] **Mick Antoniw:** To proceed with the decision. Who in the hospital? You have the issue of organ transplantation that has arisen, and all sorts of issues that you raise. You say that communication is of the essence in this whole process. Also, there is the question of legality, and so on. How should a decision be taken? Is it just left open for it to be decided among the staff, or should there be a designated person, a specifically trained person or a person who is designated with the authority to proceed? What are your views on the ethics of that?

[321] **Dr Lewens:** I will defer to Sir Peter on that, who knows more about the coalface issues in that respect.

[322] **Sir Peter Simpson:** Essentially, with the current system we have specialist nurses for organ donation; we have an organ donation register; we have a large number of guidance documents, which they all follow very accurately; we have guidance on diagnosing death; and we have guidance on how to proceed with organ donation and so on. People use the guidance. There are very clear designated divisions between responsibility for a patient who is in an intensive care unit and dying, and who finally dies, and those who are then responsible for liaising with the organ retrieval teams and so on. I think that that is clearly set out. At the moment, if someone is on the organ donation register and the discussions are held with the relatives, and with specialist nurses who are specifically trained to communicate in that area, we would regard that as satisfactory. If you are asking, ‘What are we now going to get into if

we get into legal challenges because someone is only deemed to have consented and we are not sure whether all the people in the qualifying relationship have been consulted?', which is possibly where you are, then I would say that a legal challenge is possible.

[323] **Mick Antoniwi:** It seems to me that the situation is much more complex now because there are more people to consult. There may be a list of people to consult and there may be all sorts of issues as to when, where and how you actually take the decision to proceed. That is putting an onus. At the moment, what seems to be suggested is, 'Well, there is quite a number of people on the list and any one of them can do it'. Is the existing system satisfactory for this type of legislation, or is it necessary—particularly as you say that the problem with deemed consent arises out of silence—that you take specific steps to say that, in terms of all those requirements, there is someone who has been specifically trained, perhaps, or has a specific responsibility, to whom everyone else will defer?

[324] **Sir Peter Simpson:** Right. Obviously, this is yet to be worked through. However, our belief would be that we have a perfectly well-trained person as a specialist nurse for organ donation. Her brief would change. She would now have to fulfil all these extra things that are required with deemed consent. She is used to handling qualifying relationships, because she does that now. There might be different ones, there might be more or the process might be slightly different. I think that you have the mechanics in place to do it. I do not think that you will suddenly have to have more people involved, but the brief will be different. The problem that I have, as I said earlier, is the time that it will take to do it as balanced against the time that is available to make it happen.

[325] **Mark Drakeford:** We hope to adjust our schedule over the next couple of weeks to take evidence directly from someone who is a practising nurse in this field, and we will be able to explore some of these matters further with them. Thank you both very much for helping us with this. I have a feeling that Members will want to read the record of this session pretty carefully, and there may well be issues arising out of that that we will want to contact you about, to see whether there is anything further that we can explore with you. In that sense, this has been a particularly useful session for us.

[326] **Diolch yn fawr i chi'ch dau am ddod i'n helpu ni y bore yma.** Thank you both very much for coming to help us this morning.

[327] My apologies to Members who did not manage to get back in on all the things that they would have liked to have pursued, but we are already significantly over time.

11.56 a.m.

Bil Trawsblannu Dynol (Cymru): Cyfnod 1—Sesiwn Dystiolaeth 7 Human Transplantation (Wales) Bill: Stage 1—Evidence Session 7

[328] **Mark Drakeford:** Trown yn syth at ein sesiwn olaf y bore yma. Diolch yn fawr i'r Athro Ceri Phillips am ddod yn ôl atom ar ôl cyfarfod wythnos diwethaf. Rydym yn symud i bwnc hollol wahanol i'r hyn rydym wedi ei drafod yn ystod y bore achos byddwn yn siarad am faterion ariannol yn ystod y sesiwn hon.

Mark Drakeford: We will turn immediately to our final session for this morning. I thank Professor Ceri Phillips for returning to us after last week's meeting. We are moving to a completely different topic to the one that we have been discussing this morning, because we will be talking about financial issues during this session.

[329] Thank you very much, Professor Phillips, for your evidence, primarily in relation to the costing issues and their service implications from the Bill. Do you want to offer us any brief opening remarks before we turn to questions from Members?

[330] **Professor Phillips:** Yes, I should apologise, because when I initially read the report, I thought that the department for health had not used current prices, but on re-reading it, I realise that it has, so my statement may be misleading. The estimates of costs are based on current prices.

[331] **Mark Drakeford:** Thank you; that is useful to know. We will go straight to questions, first from Vaughan and then Rebecca.

[332] **Vaughan Gething:** I want to start by looking at paragraph 5 of your paper, where you refer to,

[333] ‘The situation whereby the level of supply of organs exceeds levels of demand in Wales need to be factored into the cost-benefit analysis’.

[334] Can you set out exactly how you think that that should be factored in and how you think that it is missing at present? In addition, you talk about,

[335] ‘the system of charging other systems for transport’.

[336] We know that, even at present, the organs of donors within Wales are not necessarily guaranteed to go to somebody in Wales. There is a clinical list, and it is about need, which may mean that donors in England donate organs to people in Wales and vice versa, and an increase in donors would just see that continue. So, I am interested in whether you are talking about that in terms of charging other systems for the transport of organs but, as I said, I am also interested in how you think that the cost-benefit analysis would need to be changed in the way that you have set out, because I honestly do not quite understand what you are saying.

[337] **Professor Phillips:** I agree that it can be confusing. When you undertake a cost-benefit analysis, you undertake it from the perspective of a system, a country, the NHS or whatever. In a sense, the costs of implementing the system and then the subsequent costs of providing ongoing treatments will be managed by the respective health board in Wales or primary care trust in England. However, the relationship between Wales and NHS Blood and Transplant will perhaps be affected by this policy coming in. I did not see that that was necessarily reflected; there was a statement in the impact assessment, but it was not necessarily considered in terms of the sensitivity analysis with regard to ‘What if there are going to be differences in terms of costs because there will be potentially more organs being transplanted? What are the current arrangements?’. Without doing that sort of investigation, I was not clear whether there might be some knock-on costs that were not included in the cost-benefit analysis.

[338] **Mark Drakeford:** I call on Rebecca, William and then Kirsty.

12.00 p.m.

[339] **Rebecca Evans:** Given the increase in donor numbers that we are already seeing in Wales, do you have a view on whether the system proposed offers best value for money, or whether an intensive communications exercise, using the £8 million over 10 years put aside for this, would achieve the same or more?

[340] **Professor Phillips:** It is an interesting question; I do not have a direct yes/no answer. There are elements of the appraisal that are based on assumptions—the £8 million fixed cost for Welsh Government, inflated to £10 million, depending on the IT implications—and then, when you look at the way in which the benefit stream has come through in the appraisal, a lot of the emphasis is on what they call the gains in quality adjusted life years, which the

economists in Welsh Government have derived from Department of Health estimates. They have used a base figure value of £60,000 per QALY. I have slight concerns about that, because the National Institute for Health and Clinical Excellence, when it does appraisals of new therapies, usually approves therapies that come in at £20,000 per quality adjusted life year—£60,000 seems high. Even when you consider that, when we are talking about end-of-life therapies, NICE may allow for a slightly higher value QALY, it is not usually at the £60,000 estimate.

[341] The number of organs that will materialise from additional donors is also based on assumptions. If you look closely at that, the ongoing treatment costs from the transplant will be greater than any treatment savings in the case of liver transplants, heart transplants, and lung transplants. It is only in kidney transplants, where the cost of dialysis is saved, that the costs are reduced by the offsetting of benefits. The analysis is based to a large extent on the value put on those health gains.

[342] That said, I would argue, in terms of the 15 donors who are expected to materialise, that that does produce a cost benefit. I did some number-crunching myself, and I suspect that, if you get six to eight donors and look at the worst-case scenario in terms of cost benefits, then that would also represent value for money. So, I think that there is value for money in the policy, comparing it with the current arrangements, but what we do not have information on is the relative value for money compared with increasing communication and getting more people aware of the benefits of opting in, as opposed to opting out.

[343] **Rebecca Evans:** The Government is proposing £50,000 per annum to communicate with people who are turning 18 and people moving into the country in order to keep the level of understanding and awareness going. Do you think that that is a sufficient amount of money for such a big project?

[344] **Professor Phillips:** Fifty thousand pounds does not necessarily buy you a lot. One could spend probably spend 10 times that amount and not necessarily get the message across. However, if it is targeted and people are aware, and they are likely to be aware—the media is already picking this topic up and people are aware of what is going on—then I agree; it is an ongoing message that people need in order to be kept abreast of what is happening. However, it is possibly an underestimate and, in fairness to the impact assessment, it acknowledges that the £8 million fixed cost, which includes communication, may well be an underestimate, and so it has been adjusted it upwards by 25%.

[345] **Mark Drakeford:** William is next, then Kirsty.

[346] **William Graham:** Your comments on added pressure and capacity issues were borne out by evidence this morning from a practitioner. Do you think that the explanatory memorandum is realistic? The Minister suggests that this will be managed within current NHS resources, but we know that, if there are increased numbers, the capacity is not there.

[347] **Professor Phillips:** It does need to be recognised that 15 a year does not seem like an awful lot of additional procedures or of people coming in requiring procedures. However, looking at ITU services across Wales, we know that they are under severe pressure. We know, for example, from some work that we did in Swansea that, even though the advice from the royal colleges is that they should be operating at 80% capacity and no more, most of the ITU services in Wales are probably approaching greater than 100% capacity. So, it is something that does perhaps need to be taken into consideration. I heard a snippet of the previous session, in which the gentleman was saying that the policy can be full of good intentions, but, in translating that to the harvesting of organs, there may be so many obstacles that it might not materialise. That, perhaps, needs to be borne out in some of the sensitivity analysis around the number of organs that will materialise per donor.

[348] **William Graham:** Thank you for that. I seem to remember from evidence to a previous health committee that the Spanish experience was that it invested very heavily in that capacity and in its urban ambulance service. Do you think that the local health boards' resources are sufficient at the moment? The Minister seemed to suggest that there would be savings that they would be able to use.

[349] **Professor Phillips:** Accepting that the estimates are from the Department of Health in England for most of the costs associated with the transplant and then the treatment costs that would be offset, I am not too sure whether those cost estimates are realistic. They simply sourced Department of Health statistics, so one was not able to explore those in detail. There is probably some more work to be done to look at the costs of transplant subsequent to the transplant happening and what services are required. The research base for kidneys is pretty conclusive: dialysis is expensive, therefore that is, in a sense, a no-brainer. However, for some of the other areas of transplantation, there is less evidence and therefore the assumptions need to be challenged, perhaps.

[350] **Kirsty Williams:** I would like to come back to the issue of the QALY and the points that you were trying to raise in point 8 of your paper. Would you elaborate on your concerns regarding the QALY and why you think we should be concerned about that?

[351] **Professor Phillips:** The QALY is a currency that has been used by agencies—not just in the UK—to value healthcare interventions, so that one is comparing using a common currency, instead of saying such and such a number of hips or hearts. It is obviously contentious as it is based on quality and quantity of life, and how do you assess quality of life and what do you use to do that? So, it is more of an art than a science.

[352] A number of years ago, NICE set up a sort of citizens' jury that looked at the value that society would be prepared to pay for one year of perfect health, which, in essence, is a QALY. It came up with a value of around £20,000. That has been challenged recently and some people now think that it is probably nearer to £18,000. Some people feel that, given that we are talking about health, we should value it more highly and therefore £30,000 has also been used as some sort of threshold.

[353] NICE was challenged a few years ago when Herceptin hit the headlines and, because of the impact of Herceptin and other drugs in providing additional life for people who had two years' life expectancy, it agreed to weight the QALY slightly higher. No-one has given a specific figure, but it would appear that it is between £40,000 and £50,000 per QALY. This appraisal has been, in a sense, predicated on a QALY of £60,000, and that is what I have concerns about. It does say that, even if the value that you put on a QALY is £45,000, then this would still break even if we got one additional kidney donor, one additional heart donor, et cetera, per year. I am suspicious of that and from my, again, rough calculations, I think that we are talking about needing six to eight donors to break even. Anything around eight to nine would represent value for money.

[354] **Mark Drakeford:** I think I am clear on it now. If you set a QALY at £60,000, the effect in a cost-benefit sense is to exaggerate the benefits. Depending on the figure you take, you get a different result in a cost-benefit analysis.

[355] **Professor Phillips:** Exactly. NICE would not monetarise the QALY, it would simply identify the number of QALYs and, therefore, there would be a zero benefit in terms of money from the QALY, and, when you do that, as I say, it comes out as six donors representing a break-even point, and probably eight donors would give you value for money.

[356] **Mark Drakeford:** In her evidence to us last week the Minister said more than once, I

think, that one donor would be enough to break even.

[357] **Professor Phillips:** I would challenge that. In the way in which the calculations have been done, the emphasis has been on monetarising the QALY to get that one additional donor.

[358] **Mark Drakeford:** You say six to eight, but the intention of the policy would be to get 15.

[359] **Professor Phillips:** Yes, so it is well within that. It is not as if you need 20 additional donors. However, I think that one additional donor would not necessarily be as efficient as perhaps the estimates within the assessment suggest.

[360] **Mark Drakeford:** I want to follow up one question that you were asked earlier and then I will see whether there are any further questions from around the table. On the issue of balancing the cost of transplantation against the offsetting costs, particularly in relation to kidney transplantation and dialysis foregone, in your evidence, are you saying to us that the Government's cost-benefit analysis does not fully take into account the very realistic possibility that the costs of harvesting a kidney would fall on the Welsh NHS, but, if that kidney is used outside Wales, as it may very well be, the compensating savings in terms of dialysis would not be savings that the Welsh NHS would have at its disposal?

[361] **Professor Phillips:** That is very realistic, yes. The NHS in Wales would be incurring the cost of harvesting and the benefits would be to non-Welsh patients outside Wales. I am not saying that we should deny English people organs or anything like that, but it is perhaps something that the cost-benefit analysis should reflect.

[362] **Mark Drakeford:** I do not think that we want to enter into an ethical debate about that, because I do not think that we would have one, but, in terms of the costs as the Government has reflected them to us, that is an issue that ought to be further pursued, is it?

[363] **Professor Phillips:** Indeed.

[364] **Mark Drakeford:** Thank you very much. Are there any further questions from any Member on this part of the evidence? I see that there are none.

[365] Diolch yn fawr iawn i chi i gyd am Thank you all very much for coming in today
ddod i mewn heddiw unwaith eto i'n helpu once again to help us in our work.
yn ein gwaith.

[366] That is the end of the substantive agenda for today.

12.13 p.m.

Papurau i'w Nodi Papers to Note

[367] **Mark Drakeford:** Mae gennym **Mark Drakeford:** We have the minutes of
gofnodion ein cyfarfod diwethaf i'w nodi. last week's meeting to note.

12.13 p.m.

**Cynnig dan Reol Sefydlog Rhif 17.42(ix) i Benderfynu Gwahardd y Cyhoedd
ar gyfer Eitem 1 yn y Cyfarfod yr Wythnos Nesaf (7 Chwefror 2013)
Motion under Standing Order No. 17.42(ix) to Resolve to Exclude the Public
from Item 1 of Next Week's Meeting (7 February 2013)**

[368] **Mark Drakeford:** We will begin next week's session in private, because we are looking at the issues arising from Stage 1 consideration of the asbestos Bill. I think it is easier for members of the public if we resolve today to meet in private at the beginning of that session, so that they do not have to come in, then go out, and so on.

[369] Cynigiaf fod I move that

*y pwyllgor yn penderfynu gwahardd y the committee resolves to exclude the public
cyhoedd ar gyfer eitem 1 yng nghyfarfod 7 from item 1 of the meeting on 7 February
Chwefror 2013, yn unol â Rheol Sefydlog 2013, in accordance with Standing Order No.
Rhif 17.42(ix). 17.42(ix).*

[370] **Mick Antoniw:** Just one thing on that, Chair: because of the position of Vaughan and myself on that, perhaps it could be done in such a way that, rather than looking for substitutes and so on, it was dealt with at the beginning, and then we could come in immediately afterwards and remain there, if that is satisfactory to the committee.

[371] **Mark Drakeford:** So you would not be here for that item.

[372] **Mick Antoniw:** No.

[373] **Mark Drakeford:** That is absolutely fine. We will do that item before you arrive.

[374] Gwelaf fod Aelodau'n fodlon â'r I see that Members are content with the
cynnig. motion.

*Derbyniwyd y cynnig.
Motion agreed.*

[375] **Mark Drakeford:** Thank you all for bearing with me this morning when it was not possible to get back to everyone who had questions that they wanted to pursue.

*Daeth y cyfarfod i ben am 12.14 p.m.
The meeting ended at 12.14 p.m.*