HEALTH AND SPORT COMMITTEE
HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM LAW SOCIETY OF SCOTLAND

Introduction

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We have a statutory duty to work in the public interest, a duty which we are strongly committed to achieving through our work to promote a strong, varied and effective legal profession working in the interests of the public and protecting and promoting the rule of law. We seek to influence the creation of a fairer and more just society through our active engagement with the Scottish and United Kingdom governments, parliaments, wider stakeholders and our membership.

The Health and Medical Law Sub-committee of the Law Society of Scotland welcomes the opportunity to consider and respond to the Scottish Government Call for Evidence on the Human Tissue (Authorisation) (Scotland) Bill.

We previously engaged with the Scottish Parliament during the parliamentary passage of the Transplantation (authorisation of removal of organs etc.) (Scotland) Bill submitting written evidence\(^1\) and providing oral evidence\(^2\) to the Scottish Parliament’s Health and Sport Committee. In March 2017, we submitted a consultation response to the Scottish Government consultation: Organ and Tissue Donation and Transplantation - increasing numbers of successful donations.\(^3\) Our


response below is consistent with the approach taken in these papers. Finally, we have taken advantage of the fact that there is more data now available concerning the impact that the introduction of similar legislation has had in Wales. We have also made some reference to some recent studies which were not available at the time of our previous response in March 2017.

**General comments**

While we generally support the promotion of good public health and health equality, we are not in position, nor would it be possible for us to comment on, the policy aims of the consultation in its consideration on whether Scotland should move to a soft opt-out system for organ donation. However, if a soft opt-out system was to be implemented by legislation, this would reverse the law which is currently in place. Therefore, two general but recurring themes underpin our responses.

First, proposals should be clear and transparent in their aims and objectives. This would be the case not only for the Scottish public but for those involved in health care practice.

Second, we suggest that there should be advance publicity which is tailored to meet the needs of the diverse groups in our society, be timely and easily accessible. We also believe that targeted information should be available for someone considering organ donation which would promote reflection and discussion with their family and/or their healthcare professional. We will say more on this in our response to question three.

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4 The need for clarity and transparency is a recurring theme in many studies to date. See, for example, Welsh Government, (2013) ‘Soft opt-out system of organ donation: researching the views of Specialist Nurses and Clinical Leads.Research Summary 46/2013; Irving et al, (2014), What factors influence people’s decisions to register for organ donation? The results of a nominal study group. Transplant International 27 617-624
Specific comments and question responses

Question 1. What do you think are the key strengths and weaknesses of the proposals to introduce 'deemed authorisation' for those who have not made their wishes on organ donation known?

Consent/authorisation: In general discussion over different approaches to procuring organs and tissues, the focus tends to be upon two legislative regimes: ‘informed consent’, where an explicit declaration makes the person a potential organ donor (as currently operates in Scotland) and ‘presumed or deemed consent’, which is the model which is now in operation in Wales, in which an explicit declaration is required for not being a potential donor. 5 The English Human Tissue Act 2004 uses the word ‘consent’ but its Scottish counterpart the Human Tissue (Scotland) Act 2006 instead uses the word ‘authorisation’.

Whist the Human Tissue Authority’s Code of Practice on Consent (para 19) regards these as expressions of the same principle, we are not convinced that this is the case. Authorisation is about giving permission - it does not mean the same as presumed, deemed or implied consent. Some commentators reconcile this by saying that, for the purposes of organ donation, authorisation is “used to differentiate the process from what may be understood by ‘usual’ consent”.6 But it has been recognised that the validity of authorisation does not depend on information being given or received.7 We suggest that for consent to be valid, the disclosing and importantly, understanding, of information is required before a decision is made8.

We recognise that the use of the term authorisation is being used in this proposed Bill since it flows from the Human Tissue (Scotland) Act 2006.

In their discussion paper of 2016, the UK Donation Ethics Committee suggested that ‘authorisation’ brought with it an expectation that if someone expressed wishes about

what should happen to their bodies after death, there is “an expectation that these wishes would be respected”.\(^9\) If this interpretation was accepted, such expectation would need to be balanced against any conflicting views of the family or whether proceeding with donation would cause them distress.

Finally, a brief comment on the application of such terminology to the family. Whilst their role is addressed in more detail below, the use of consent and authorisation should also be viewed from their perspective. As early as 2003, it was acknowledged that whilst families may be prepared to permit the removal or organs and tissue, “They do not wish to or do not feel able to participate in a process akin to giving fully informed consent to medical treatment in life”\(^10\). What this does highlight is the importance of a potential donor, where possible, taking steps to ensure that their wishes are known.

**The role/wishes of the family**

We find this remains an anomalous situation since, at present, there is no legislative requirement to ascertain the wishes of the family but, through custom and practice, they will normally be consulted and have the potential to veto a decision made by the donor. In other words, there are key differences in what is provided by the legislation and what is done in practice.

An international study was undertaken relating to consent systems for deceased organ donation.\(^11\) The study concluded that where next of kin involvement was sought, their views have a larger and more immediate effect than legislative changes.\(^12\) This was regardless of the type of organ donation model that was adopted and whether the views of the potential donor were expressed or unknown.\(^13\) The study notes that:

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“Nineteen out of the 25 nations [interviewed] with presumed consent provide a method for individuals to express a wish to be a donor. However, health professionals in only 4 of these nations responded that they do not override a deceased’s wish because of a family’s objection.”

Whilst the views expressed by the potential donor are given priority, in the current and possibly future models of organ procurement, family members may be the ultimate arbiters of whether or not donation will proceed. As was acknowledged by Dove et al, “There is... significant space for manoeuvring around the letter of the law”.

Research has shown that health care staff wish explicit guidance to be provided to both families and health professionals on the consequences of a soft opt out scheme. The consultation makes it clear that families will be consulted and have a role, for example, in providing medical history. Having proper communication skills is essential. Awareness of the family’s emotional needs, and being able to skilfully navigate discussions on difficult issues such as brain stem death or bodily integrity may advance a greater understanding from the family of a possible donor of the importance of their decision. Sharing best practice and looking to the experiences of other jurisdictions and international collaboration may contribute towards the further enhancement of communication between the healthcare professional and the family.

It is suggested that further research is required in Scotland to investigate the relationship between family refusal and donation rates.

Whichever system is in operation, it is right that we evaluate the rights and wrongs of countermanning the deceased person’s expressed wishes. Not only can those

16 Dove, E.S. (2015) Elberte v. Latvia:Whose tissue is it anyway-Relational autonomy or the autonomy of relations? Medical Law International 15 2-3 77-96 at p.88
17 The need for clarity and transparency is a recurring theme in many studies to date. See, for example, Welsh Government, (2013) ‘Soft opt-out system of organ donation: researching the views of Specialist Nurses and Clinical Leads. Research Summary 46/2013 at pp3-4.
wishes be overruled by the current system, but also the refusal of transplant denies
another person the possibility of receiving an organ. Thus, we are placing the rights
of the relative far above the integrity of the deceased and the need of a possible
recipient.21 The last autonomous wish of the donor is potentially being thwarted
simply because he or she is in no position to object.22

The Royal College of Physicians Edinburgh has made the point that, in practice,
consent for organ donation is sought from the next of kin and approximately 40% of
families approached refuse consent. They argue that where the deceased was on
the Organ Donation Register (ODR) the next of kin is less likely to refuse consent - in
only 10% of cases, compared to 50% where the deceased was not on the ODR.23 A
recent study24 confirms that a donor’s preference to donate was deemed more
powerful as the donor had taken a positive step to make their preferences known
compared an opt out system where registration is automatic.

An awareness of the discussion and application of what is termed ‘relational’
autonomy25 may also be helpful. Relational autonomy is not a recent concept in
healthcare decision-making and arguably sits alongside the notion of the donor’s
consent. It provides a concept of close relations as shared decision makers.26 The
close relationships and experiences that have been shared by the recently deceased
and now potential donor and family give rise to this special claim27.

Human Rights

This leads us on to a final observation. We note that the Bill makes no reference to
possible rights of individual family members under the European Convention on
Human Rights. Two cases are highly relevant here - Petrova v Latvia in 2014 where
it was argued that a lack of clarity in Latvian law about whether there was an

21 Royal College of Practitioners ‘Organ Donation an Outline for General Practitioners’ Available from :
25 Dove, E.S. (2015) Elberte v. Latvia:Whose tissue is it anyway-Relational autonomy or the autonomy of relations? Medical
Law International 15 2-3 77-96
27 This is explained more fully in Johnston Y (2017) Donation decisions after death: The case for a family veto. Ethics, Medicine
and Public Health 3 486-492 at p.490
obligation to inform or gain consent from close relatives prior to removing tissue or organs was a violation of Article 8 and *Elberte v Latvia* in 2015.

Mrs Elberte’s husband died in a car accident. During forensic medical examination, it was noted that he had no stamp on his passport which would have indicated an objection to use of his tissues and organs. Under a state approved agreement, these were subsequently used by a pharmaceutical company for use in bio implants. Since the tissue had to be used within 24 hours there was only reliance on the passport to ascertain the wishes of the deceased and no attempt was made to contact relatives. Mrs Elberte was only made aware of the circumstances around this donation some two years later following a criminal investigation. The question was whether there was an obligation to inform the deceased's relatives and ascertain their wishes. The court found a violation of Mrs Elbert's right to privacy under Article 8. They also found that she had suffered degrading treatment under Article 3 due to the removal of her husband’s tissues. Given what we noted above about relational autonomy, it was interesting to note that this case was not decided on the basis of family life protections under Article 8 but the focus instead on a private life.

We suggest that the proposed Bill is considered in the light of the outcome of these cases.

**Question 2. What do you think are the key strengths and weaknesses of the plans for authorisation of pre-death procedures?**

**General Comments:**

It is understood that pre-death procedure (PDP) provisions will not be prescribed until deemed authorisation has come in to force, thus the current way of managing pre-death procedures for organ donation would remain the same until that time.

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28 Application no.4605/05 [2014] ECHR 805
29 Application no. 62143/08 [2015] ECHR 1
Although the Bill sets out that deemed authorisation will not come into force in the context of PDP’s until the legislation has passed, it would be worthwhile articulating this in the policy memorandum for coherency.

The Bill defines pre-death procedures (PDP’s) as a medical procedure which is (a) carried out on a person for the purpose of increasing the likelihood of successful transplantation of a part of the person’s body after the person’s death, and (b) which is not for the primary purpose of safeguarding or promoting the physical or mental health of the person.33

Careful consideration must be given to process and ethics otherwise this may be perceived as contradictory to the Hippocratic Oath, where the first consideration is for the health and wellbeing of the patient.34

The Bill distinguishes between two types of PDP’s, type A and type B procedures.35 Type A are described as ‘routine’36 procedures and type B as ‘procedures which could be carried out, including the administration of some forms of medication, but they may not be of a type where people would assume that they are consenting to them by simply authorising donation’.37

Type A procedures will be prescribed by Scottish Ministers in secondary legislation, after consultation, to allow the list to fully reflect current practice. Type B procedures will also be set out in secondary legislation after consultation alongside information on how they may be authorised, and safeguards over and above those which will apply to type A procedures. However, it would be helpful if the official documents gave examples of what draft orders may contain and examples must be clearly communicated to the public as part of the wider education campaign.

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33 Human Tissue (Authorisation) (Scotland) Bill, Chapter 5, s 22 Pre-death procedures relating to transplantation. S. 16 A Meaning of “pre-death procedure”, “Type A procedure” and “Type B procedure”
35 ibid s 125
36 Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32). Policy Memorandum document. Types of procedures, Type A procedures, s 125
37 ibid s 126
Observations on plans for authorisation for PDP’s are limited until the consultation is complete but we acknowledge that authorisation for PDP’s is in line with the general principles of the Bill.38

**Authorisation by relatives:**

As with organ donation generally, as set out above, similar concerns arise regarding relatives authorising PDP’s.

Paragraph 122 of the policy memorandum states:

“The Bill not only provides that authorisation for procedures may be deemed where authorisation for donation for transplantation is deemed, it will also make clear that authorisation for procedures can also be deemed where express authorisation for donation has been given. It will also allow a person to expressly authorise the procedures. A nearest relative or person with PRRs (or other person in a common calamity) who is entitled to authorise donation in respect of a child will also be able to authorise procedures, but only if the person is satisfied that it would not be contrary to the individual’s previous wishes.”

Thus relatives can authorise PDP’s to take place but it is not clear if they can refuse to authorise. Is this at odds with the Bill’s proposals to disallow family refusal if it was known that the person would have been happy to donate? If families cannot refuse PDP’s from taking place then this should be stated in the official documents.

Scottish ministers are to consult persons they consider appropriate before laying draft regulations on PDP’s before the Scottish Parliament.39 The medical profession’s opinion on PDP’s will be paramount in helping to inform what constitutes lists of type A and B procedures and full engagement with their views is necessary for a thorough consultation. We look forward to ministers prescribing more information on what constitutes type A and type B procedures as currently the only

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38 Namely expressly authorised by the person, authorised by a nearest relative (adult) or person with PRRs (child). It is also authorised where there is in place an express authorisation for donation by an adult or an authorisation by a child aged 12 or over, or in the case of an adult where authorisation for transplantation is deemed (under section 6D). See section 16 of the Bill for more information

39 Under subsection 1 Scottish Ministers duties are prescribed. See also s16 B (3) and 16 C (4)
document providing examples of each is the policy memorandum.\textsuperscript{40} It would have been helpful to include these in the explanatory notes.

It is the duty of ministers to promote PDP’s as part of the awareness campaigns. Much information is available on organ donation and the benefits of this but information on PDP’s has to date been less prominent in the literature. A concerted effort must be made to inform the public about PDP’s, as whilst many are supportive of organ donation itself, there may be a lack of information regarding PDP’s getting through to the general public.

Paragraph 121 of the policy memorandum states that responses to the consultation suggest that many people may be happy to donate their organs without giving an express authorisation, and that they apply the same principle to routine procedures which are necessary to ensure successful transplantation – particularly as without certain tests donation is unlikely to be able to proceed. Section 131 of the policy memorandum states that a significant majority of respondents thought that the common tests (type A) should be able to be carried out on potential donors. A similarly high number of respondents also thought that medication could be given to patients in certain circumstances (type B) to improve the chance of successful donation and transplantation. It is clear that type B procedures do not solely constitute medication being given and it is argued that until ministers produce a list of type B procedures, including but not solely giving medication, it cannot be stated with accuracy that the public support this.

We note that flexibility must be built in to this process to keep pace with medical advancements and provision should be made for this in statute.

There are various procedures already in place to increase the chances of successful organ donation, examples include patient assessments by Specialist Nurse - Organ Donation (SNOD’s).\textsuperscript{41} Seeking feedback on how effectively these current procedures

\textsuperscript{40} Human Tissue (Authorisation) (Scotland) Bill, Policy Memorandum. Chapter 5 – Pre-death procedures relating to transplantation. See s 112-114

are working would be beneficial as part of an overall review of the organ donation process.

**Strengths:**

- We know that timing is crucial if a transplant is to be successful. In the past this has hindered progress because of the bureaucracy of the procedures for consent etc. have held up the process. Teaming PDP’s with deemed authorisation may increase the likelihood of a successful transplant by making the process more efficient.

- PDP’s taking place prior to death gives the person and family time to consider their wishes, which is especially important when working from a position of deemed authorisation. The person can then decide to explicitly consent or refuse. This in turn means medical staff have concrete assertions on how to proceed post death and the likelihood of the person’s wishes being respected are increased.

- Deceased donations come from individuals who have (i) died of circulatory death (DCD), where the heart has stopped beating and the organs must be removed immediately and quickly transported if there is to be a successful transplantation and (ii) donation after death by neurological criteria (DNC) (brain stem death).

- The circumstances in which a person dies from circulatory death means there are significant time constraints and some of the vital tests which are necessary to ensure that the organs are likely to be successfully transplanted, and are a good match for the transplant recipient, need to be carried out shortly before death.

- In the past, most donations proceeded with DNC donors however, there has been a significant increase in donors who have donated following circulatory
death in recent years and if this number is to continue increasing it is vital that PDP’s are carried out prior to death. Therefore, the main strength of PDP’s is that they will give an increased window of time to prepare for donation and start what is a complex process.

Weaknesses:

- In cases of DCD death, family trauma must be considered as the person is still ‘alive’ i.e. breathing and warm to touch. There are specialist nurses trained to help support patients in the intensive care setting but given the current pressures on the NHS, if successful donation levels are to increase, staffing levels and training must be reflected to support this increase.

- The term ‘pre-death procedures’ may not be the most appropriate, as prior assessment arises in the context of living donors too. Presumably living donors will continue to be regulated by the provisions of the 2006 Act, but this too should be made clearer.

- Discussion focuses around cardiac and brain stem death. It does not consider those people who are actively dying, for example of terminal cancer, and take the decision to refuse food and fluid with the intention to bring about their death – would they be approached regarding PDP’s to expressly consent to or defer until death the procedures under deemed authorisation? It is not clear given that the first priority of the medical staff is always to save life, as prescribed in the Bill, even if that is not the wishes of the patient.

- Timing of authorisation – the wording of the 2006 Act has been replaced with ‘at the relevant time’ instead of ‘immediately before death’ but it is not clear what constitutes the ‘relevant time’. The Bill also now refers to the patient’s death being ‘imminent’. Section 128 also states PDP’s will be discussed when the

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42 In 2017/18 there were 41 such donors from a total of 102 deceased donors overall
44 Human Tissue Authorisation Bill PART 3: Authorisation of removal and use of part of body of deceased person, chapter 1, timing of authorisation
45 See for example section 16E ‘Carrying out of Type A and Type B procedures’, subsection 2 and others
person is likely to die ‘imminently’. Uniform phraseology must be adopted for consistency and ease of understanding.

- Doctor/Patient relationship: PDP conversations are likely to arise when the person is facing severe illness or pending death\textsuperscript{46} and having to consider what will be done with one’s body parts may be difficult to comprehend. Often patients and families are encouraged to ‘stay positive’ and are hopeful that they will continue to live. Could PDP tests and conversations have a negative emotional/psychological impact on the patient and family and hinder the doctor-patient relationship if not approached very sensitively? Could organ donation discussions and PDP paperwork be seen as the doctor ‘giving up’ on the patient? Might the PDP discussions trigger persons to think that they must be dying, when in fact the health care provider may be premature with the discussions? At which point PDP’s are discussed must be considered thoroughly but perhaps the best alternative is to leave it up to health care provider to use their clinical judgement to decide when is appropriate to have this discussion, as part of the ongoing care of the patient.

- The policy memorandum references the ‘end of life pathway’\textsuperscript{47} and how certain things would continue to be dealt with under this. However, following the removal of the Liverpool Care Pathway in 2013 there are questions as to whether there is a regulated end of life pathway to follow. If so, this should be named explicitly.

- PDP conversations and procedures will be taking place during very emotional and trying times for the person. The circumstances surrounding reversal of PDP’s should be considered. If the patient decides at the last minute that they do not wish to donate, what is in place to circumvent procedures already in place to collect organs? Has an individual waiting for an organ transplant been told they may receive one as they have a ‘match’ who is actively dying? What if the chain

\textsuperscript{46} S.16E (2) The requirements mentioned in subsection (1)(a) are met if— (a) in the view of the health worker primarily responsible for the person’s medical treatment, the person is likely to die imminently (including as a result of the withdrawal of life-sustaining treatment)

\textsuperscript{47} Section 128. In all cases where pre-death procedures may be undertaken, a decision will have been taken that the person is likely to die imminently and that, if the person is receiving life sustaining treatment, this will be withdrawn. This is a familiar part of the end of life pathway, and it is only after this point that discussions about donation are carried out.
is then broken if the person decides they do not want to donate? The fact that the person can change their mind at any time and is not bound by their prior consent should be made clear.

Question 3 Do you have any other comments to make on the Bill?

_The short title of the Bill_

We feel that the title of the Bill does not clearly reflect its purpose, which is to effect a radical change to the legal basis on which organs can be used for transplantation. Such a change has the potential to affect the whole population and so it is particularly important to be as transparent as possible to draw the public's attention to the proposed changes.

We recognise that the Bill is designed to make amendments to the Human Tissue (Scotland) Act 2006 and the words “Human Tissue” are bound to appear in the title to make the link with that Act, but we think that it is unhelpful not to include a reference to transplantation in the short title. We note that the long title refers to transplantation, but do not feel that this is a sufficient signal to the general public of the real nature of the provisions.

**Ethical Issues:** The current system is based upon an altruistic approach and research\(^{48}\) shows that the problem is often not a lack of willingness to donate but rather, a lack of incentive. In other words, it is human nature to procrastinate which may mean for some, passively accepting a default position that involves less effort. However, consideration should also be given to other influencing factors, for example, dignity, fear of clinical neglect, family attitudes, religious belief and grief may also influence an individual’s decision as to whether or not they will donate\(^{49}\).


\(^{49}\) Irving M. J et al. (2014) What factors influence people’s decisions to register for organ donation? The results of a nominal group study. *Transplant International* 27 at p 617
The introduction of an opt-out system also raises a wide number of ethical issues including the importance of each individual being able to make an autonomous decision in relation to organ donation.\textsuperscript{50}

We agree that being made aware of cultural sensitivity to issues such as apprehensiveness to discuss death among certain groups or individuals and the importance to many of death rituals may improve dialogue regarding organ donation.

More generally, it may also help families understand how their loved one has made their decision. Additionally, having some knowledge of what was important to them in shaping their decision may perhaps remove some of the burden of decision-making from their family.

Finally, gaining a greater understanding about why individuals take the decision that they do in relation to organ donation will aid in the development of strategies to enhance organ donation.

\textbf{Existing consent}

We also note that the Bill is not clear on what happens in relation to those individuals where there is existing and express consent, for example where a person has actively registered with the NHS Organ Donor Register.

\textbf{Evaluating the impact of the opt out approach in Wales:}

We noted in some of our previous submissions\textsuperscript{51} that it was too early to make any observations on the impact of introducing opt out legislation in Wales. Data is now becoming steadily available and with it, some insightful commentary. The terminology used in Human Transplantation (Wales) Act 2013, is ‘deemed consent’ which applies to adults over the age of 18 who have been resident in Wales for a


period of 12 months and who have not registered any opinion regarding organ donation.\textsuperscript{52}

Following the introduction of the legislation, the number of organ donors rose higher per million population (38.08\%) than it did in the UK as a whole (33.93\%).\textsuperscript{53}

However, that does not provide a complete picture as there are also national and regional variation rates in donation to consider\textsuperscript{54}. Further study and monitoring of jurisdictions that have adopted ‘soft’ opt out legislation is required to develop further understanding.

A number of education initiatives and awareness raising campaigns accompanied the introduction of the Welsh legislation. These appear to have been effective, but it has been suggested that there they should be subject to a continuous approach\textsuperscript{55}. We have noted previously that when legislation has been introduced, it seems to be more effective if accompanied by prominent education and public awareness campaigns. The debate in how the data should be evaluated since the passing of the Welsh legislation continues\textsuperscript{56} but it is reassuring to see that such studies are being rigorously undertaken.

\textbf{Brexit and organ donation}

Within the European Union, health policy tends to fall within four themes:

1. Mobility - including healthcare professionals and EU citizens cross border access to healthcare;

2. Free trade - for example authorisation and regulation of medicines;

\textsuperscript{52} The Human Transplantation (Wales) Act 2013. This would apply to a person who would have been regarded as having the capacity to make such a decision. However if the person had appointed someone to make a decision on their behalf credible evidence if presented which evidences wishes of the person that they did not wish to donate. see Albertsen, A (2018) Deemed consent: assessing the new opt-out approach to organ procurement in Wales. J Med Ethics;44:314–318 at p. 314 Available from https://jme.bmj.com/content/medethics/44/5/314.full.pdf [Accessed Aug 26 2018]


3. Research and new technology;


The emphasis here can lean towards policy rather than politics\textsuperscript{57} but it is yet unclear what impact leaving the European Union will have on healthcare policy in general and the picture is no more clear in relation to organ donation and transplantation. Concerns that have been raised include lengthy passport and immigration bureaucracy and the need to strive towards bilateral compliance\textsuperscript{58}. Maintaining collaborative and sharing practices in relation to organ donation and procurement should remain a priority\textsuperscript{59}.

\textsuperscript{57} For a discussion on these themes, see Chapter 3 of Laurie G.T, Harmon S, H E, Porter G. (2016) Mason and McCall Smith's \textit{Law and Medical Ethics} 10\textsuperscript{th} edition. Oxford: Oxford University Press.
