In this edition of Cautionary Tales, we have deviated from our usual practice of using recent incidents to illustrate governance issues. Instead, we have included three longer pieces to share some of the advice we have received on the legal aspects of organ donation and transplantation.

The items cover a view on obtaining consent in light of the Supreme Court ruling in Montgomery vs Lanarkshire Health Board, on working with Coroners and Procurators Fiscals, and implementation of the Human Transplantation (Wales) Act 2013. We would emphasise that this is guidance and further advice should always be sought from your employer’s legal team in case of uncertainty.

Finally, do please remember to report any incidents that require reporting under the terms of your HTA licence. Also where things have not gone well or could have gone better, and any other issue that needs investigation or where the service we give can be improved. Please use the form at:

https://www.organdonation.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx

Consent - Montgomery and beyond

Before the decision in Montgomery, the courts deferred to medical opinion as to the information to be provided to patients to obtain informed consent. The law on risk moved on with Chester [2004] under which failure to inform of risks constituted negligence even if it made no difference to the outcome.

Montgomery – v – Lanarkshire Health Board [2015] UKSC 11

The facts:

- Mrs M was of small stature and Type 1 diabetic.
- Diabetic woman are likely to have bigger than normal babies and Mrs M. argued that she should have been advised of the 9-10% risk in such cases of shoulder dystocia.
- Mrs M expressed concerns during her pregnancy as to her ability to deliver the baby safely. The risks of shoulder dystocia were not discussed and nor was the option of a caesarean section.
- If she had been advised of the risk she would have opted for a caesarean section.

On appeal, the Supreme Court set out the duty of care for medical professionals in obtaining informed consent as being:

‘to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatment’.

The test of whether a risk is material is whether:
‘in the circumstances of a particular case, a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is/should reasonably be aware that patient would be likely to attach significance to it.’

Material risk cannot be dealt with just by percentages and is based on factors such as: the nature of the risk; the effect on the life of the patient; the importance to the patient of the benefits of the treatment; any possible alternatives; the risks of those alternatives.

The assessment includes the characteristics of the patient. The information must be ‘comprehensible’ and the patient must not be bombarded with technical information. Information as to a risk can be withheld though if the doctor “reasonably considers that...disclosure would be seriously detrimental to the patient’s health”. The doctor is also excused in circumstances of necessity ‘if the patient requires treatment urgently but is unconscious or otherwise unable to make the decision’.

In practice - In the case of Spencer decided after Montgomery, damages were claimed on the basis that before discharge Mr S should have been provided with verbal and written information as to: signs and symptoms of DVT/PE; and the importance of seeking medical help and who to contact if DVT/PE/any adverse event was suspected. The judge applied the test of:

‘would the ordinary sensible patient be justifiably aggrieved not to have been given the information …..when fully appraised of the significance of it’.

He concluded that the hospital was not required to warn of the risk of DVT/PE pre-operatively but that following Montgomery, there had been a duty to inform Mr S on discharge of the signs and symptoms despite the risk not being material. The information should be given to all patients except those where no risk could possibly arise. This principle was taken as now likely to apply to all aspects of advice given to patients by medical and nursing staff, not just consent.

Learning point

- Consent remains a crucial aspect of the medical professional/patient relationship but the emphasis is now firmly on the patient and not on what the doctor thinks is best.
- The courts will consider cases based on an objective assessment of what risks a reasonable patient would have regarded as material, as opposed to prevailing medical practice.
- Consent procedures should be reviewed to ensure all material risks are discussed.
- A risk may be tiny in percentage terms, but still be material.

NHSBT and the British Transplantation Society have published updated guidance on obtaining consent for transplantation and is available at [www.odt.nhs.uk](http://www.odt.nhs.uk)

Neonatal Retrievals and Consent

Informed consent/authorisation is fundamental to the donation and transplantation pathway. For organ and/or tissue donation from deceased donors, there is not only a legal requirement that appropriate consent/authorisation is obtained, there is also a moral and ethical duty to ensure that families are informed.

Whilst the process of consent/authorisation is much the same, irrelevant of the situation, there are specific situations where additional information or conversations may be required. This is often the case in areas that are new or emerging, such as donation in neonates (babies less than 28 days old) and young infants (less than
12 months). Since the 1st September 2010, there have been just 17 donors under the age of 12 months, with 27 transplants from these donations.

In a recent case, the family of a young infant consented to organ donation. Because of the infant’s age, kidneys were the only organs to be suitable for donation: consequently, consent was sought and given only for the kidneys, and both were accepted and retrieved for transplantation. During the retrieval procedure, it was noted that there were two haematomas present near the kidneys; to ensure that they were safely retrieved, a decision was made to retrieve the pancreas and liver en bloc with the kidneys to enable them to be prepared for implantation on the back-table at the recipient centre. The liver and pancreas were retrieved to facilitate the kidney transplant and not for transplantation. The following morning, whilst arranging disposal of the liver and pancreas, the recipient coordinators reviewed the consent form, and realised that there was no consent documented for removal of the pancreas or liver.

The family were contacted later that day and informed of what had happened. They were happy that the donation had proceeded and the dual transplant had gone well, and understood the reasons why the decision was made. The option of returning the liver and pancreas to the infant was offered, however they were subsequently disposed of following agreement with the family.

Clinicians should be aware that it is acceptable to remove additional organs to facilitate transplantation provided consent/authorisation has been given.

**Learning point**

- All those involved in this case did what they did to ensure that the kidneys were successfully transplanted, and the actions taken after were timely and appropriate.
- This case highlighted that the processes around small infant retrieval requires review to ensure that all those involved are fully aware of the surgical processes required.
- A full Root Cause Analysis has been completed and actions are being implemented. This has highlighted that it is advisable for SNODs and clinicians at transplanting centres to discuss and agree not only which organs will be accepted for transplant, but also which organs may require to be retrieved to facilitate the transplant to enable informed discussions with the family.

**Human Transplantation (Wales) Act 2013 and its implications for clinical practice**

From December 1st 2015 there will be three legislative frameworks in operation to ascertain consent/authorisation for organ and tissue donation in the UK.

All three acts, The Human Transplant Act 2004 (HTA), Human Tissue (Scotland) Act 2006 and the Human Transplantation (Wales) Act (HT(W)A) are consistent in ensuring that consent/authorisation is the fundamental principle for the lawful removal, storage and use of organs and tissue. In addition the HT(W)A has introduced a soft opt out system for deceased organ and tissue in Wales.

Under all three legislative frameworks individuals are able to say ‘yes, I want to donate all or some of my organs’ or ‘no, I don’t want to donate’. In England, Northern Ireland and Wales, individuals are able to nominate/appoint a representative to make the decision on their behalf. In Wales only, if an individual chooses not to either record a decision on the ODR or tell family or friends their decision if certain criteria apply their consent to organ/tissue donation will be deemed to have been given.
The sequence of ascertaining consent in Wales remains very similar to that currently undertaken within the HTA 2004.

- First, the ODR should be checked for a registration and the family informed of the registration status. If the patient has a registered decision then that is the information that is acted upon.
- If there is no registered decision on the ODR then it needs to be established with family and friends whether the patient had made a decision in regards to organ donation.
- If the patient had not, then the family and friends need to be asked if the patient had appointed a representative to make the decision on their behalf.
- If they had not then it needs to be established if the patient fulfils the criteria to be able to apply deemed consent, if it is not possible to apply deemed consent then consent from the qualifying relationship will be required.

Establish with family/friends whether first person consent exists i.e. had the patient made a decision regarding organ donation?

If not

Establish with family whether the patient nominated/appointed a representative to make a decision about donation on their behalf.

If not

In Wales - establish if patient fulfils criteria to apply deemed consent.

If not applicable

Family consent/authorisation from person in highest qualifying relationship.

The introduction of the deemed aspect of consent in Wales does not make organ donation automatic nor compulsory. The family will continue to be involved in discussions in particular to help confirm residency. The family will also be able to object to donation proceeding if they are able to demonstrate that the deceased did not want to be a donor.

It is important to note that where an individual dies, is the legislative framework under which consent/authorisation is ascertained. A Welsh resident dying in England cannot have their consent deemed as the HTA 2004 requires express consent, neither can someone from England visiting Wales as they fail the criteria to apply deemed consent.

The legislative change in Wales is expected to be a lever for a cultural shift in behaviour and attitudes towards increasing consent rates by 25-30%, clarifying people’s organ donation decision and sharing that decision with those closest to them.

**Working with the Coroner**

In the last edition of Cautionary Tales we highlighted a recent case where an organ donor was not referred to the Coroner. Following donation the Coroner became aware and stated that as the cause of death was hypoxic brain injury secondary to hanging, the case fell within the Coroner’s jurisdiction. The SNOD had discussed the case with the medical team who did not feel that the patient required referral, and the SNOD did not question this further.
Following this case we have sought legal guidance as to the requirements of referral to the Coroner.

**In brief** - legal responsibility to report a death to the coroner rests with the Registrar of Births and Deaths: regulation 41(1) of the *Registration of Births Deaths Regulations* 1987, but practice dictates doctors should inform the coroner directly. Most coronial jurisdictions have their own set of local reporting guidelines for doctors.

**Additional detail** - There is now provision for the Lord Chancellor by regulations to require registered medical practitioners in prescribed circumstances to notify Coroners of the deaths of which the practitioners are aware. Before making such regulations, the Lord Chancellor must consult the Secretary of State for Health and the Chief Coroner. **HOWEVER, so far no regulations have been made and the Coroners and Justice Act 2009 s18 is not yet in force.** On this basis the only statutory obligation upon the doctor is to follow section 22 of the *Birth Deaths and Registration Act 1953* which requires;

> A registered medical practitioner attending a person in his last illness to sign and transmit to the Registrar a certificate in the proper form stating, to the best of his knowledge and belief, the cause of death.

Technically speaking, a doctor could fulfil this obligation by issuing a Medical Certificate as to cause of Death (MCCD) and sending it (usually via the relatives) to the Registrar of Births and Deaths, even if it was known (and made plain on the certificate) that the death was unnatural and required referral to the coroner. However, it is the proper and universally accepted practice that the coroner is informed directly, where appropriate.

**Common law duty upon all citizens** – It has been argued for many years there has been a common law duty upon all citizens to give information which may lead to the Coroner holding an inquest. The ancient origins of this duty have led to the duty being questioned. In the text book *Coroners’ Courts - A Guide to Law and Practice* (3rd Edition), Christopher Dorries OBE (HM Senior Coroner South Yorkshire) submits that the common law duty must still exist and that to hold otherwise might be to render valueless the whole ‘fail safe system’ of scrutinising deaths.

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**Learning point**

- Whilst practice is normally that the doctor makes the notification that does not entirely relieve others of the obligation.

- SNODs should seek confirmation from the medical team regarding coroner/PF referral when donation is an option and may request the medical team to refer if it is felt the death falls into coroner/PF jurisdiction

If you have any comment, feedback or suggestion regarding the Cautionary Tales, please contact [clinicalgovernance.odt@nhsbt.nhs.uk](mailto:clinicalgovernance.odt@nhsbt.nhs.uk)