

Overview of Reports into Incident of the Transmission of Donor Infection for NHSBT

Donal O'Donoghue and Kevin Gunning

NHS Blood and Transplant, the UK-wide organ donation and transplantation authority, has been asked by the Welsh Health Department to commission an overview report into the events surrounding the deaths of two renal transplant recipients from donor transmitted encephalitis in December 2013 in a Welsh hospital.

The Terms of Reference were agreed by the following organisations and individuals:

- Donor hospital (hospital name redacted to preserve donor anonymity)
- NHS Blood and Transplant (NHSBT)
- Cardiff and Vale University Hospital Board (Transplant centre)
- Public Health England (Donor country)
- Public Health Wales (Transplant country)
- Recipient family A
- Recipient family B
- Welsh Renal Clinical Network on behalf of Welsh Health Specialised Service Committee (Transplant commissioner)
- Welsh Government Department of Health and Social Services

Terms of Reference are as follows:

Scope

The scope of the review is from the point of referral of the potential donor to the point of death of the transplant recipients. Treatment and care of the patient in the donor hospital, before they became a donor is out of scope. Both NHSBT and the transplant hospital have already conducted internal investigations into the events. There is no intention to re-investigate, unless necessary, and existing reports will form the basis of the review wherever possible. Other involved bodies may or may not have investigated formally and written up their findings: the review will seek copies of existing reports from other bodies and will take evidence from them where no investigation reports exist.

Purpose

- *To establish the root causes and key learning from the incident.*
- *To ensure the families involved have the information they need.*
- *To make recommendations to ensure that other organisations and individuals are aware of the risks and lessons identified through this investigation.*

Objectives

- *To establish the facts about what happened throughout the donation and transplant process and subsequently when efforts were made to establish the nature and cause of the infection.*
- *To establish whether failures occurred in care, treatment or transmission of information.*
- *To look for improvements rather than to apportion blame.*
- *To recommend how the risk of recurrence can be minimised.*
- *To provide a report, including specific and general recommendations.*
- *To identify a means of sharing learning from the incident.*

Key questions to be answered:

Donation & transplantation

- *Could more information have been identified to improve donor characterisation within the usual timescales for donation?*
- *Was the donor characterisation accurate and comprehensive given the information available at the time?*
- *Was the donor characterisation information conveyed to the transplant community in line with established standards?*
- *Was appropriate and expert advice sought and implemented to aid decision-making?*
- *Were local and national protocols, guidelines and guidance adhered to?*
- *Review the available evidence for transplantation of organs from donors where the origin of infection is unknown.*
- *Establish whether the consent process prior to transplantation was appropriate.*

Infection

- *Were all relevant and necessary actions taken to identify the infection in the donor and recipients?*

General

- *Any other relevant activity the independent review panel believes is necessary for a full and thorough investigation of the issues.*

Report

As set out in the terms of reference this review is based on the information provided by:

Telephone interviews with members of recipient families A and B.

The following documents:

NHSBT Organ Donation and Transplantation Directorate (ODT) Transmission of Donor Infection – Final Investigation Report and Appendices 1-5 (March 2014).

Cardiff and Vale University Health Board Final Investigation Report (Watson Forsyth & Hollis July 2014).

Report of the PHE Internal Review of the *H. gingivalis* Transplant Incident (Kearney June 2014).

Other documents consulted:

Taking Organ Transplantation to 2020 (NHSBT 2013).
http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_long.pdf

Guidance on the Microbiological Safety of Human Organs Tissues and Cells Used in Transplantation (Advisory Committee on the Safety of Blood, Tissues and Organs SaBTO 2011).
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf

Guidelines for consent for Solid Organ Transplantation in Adults (NHSBT & British Transplant Society July 2013).
http://www.odt.nhs.uk/pdf/guidelines_consent_for_solid_organ_transplantation_adults.pdf

United Kingdom Hospital Policy for Organ and Tissue Donation (UK Transplant 2003).
https://www.organdonation.nhs.uk/about_transplants/donor_care/policy_documents/uk_hospital_policy_for_donation.pdf

National Operating Procedure NOP001 Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation (July 2012).

Halicephalobus gingivalis: A Rare Cause of Fatal Meningoencephalomyelitis in Humans Papardi et al Am J Trop Med Hyg. Jun 5, 2013; 88(6): 1062–1064.

Use of Organs from Donors with Higher Risk (NHSBT 2014).
http://www.odt.nhs.uk/pdf/Use_of_Organs_from_High_Risk_Donors.pdf

Responsibilities of Clinicians for the Acceptance of Organs from Deceased Donors (NHSBT & BTS 2012).
http://www.odt.nhs.uk/pdf/nhsbt_responsibilities_acceptance_organ_deceased_donors.pdf

Acknowledgement

A most important part of our review has been the telephone interviews that were conducted with the two recipient families. They have assisted us greatly in drawing up our recommendations and we would like to express our thanks to them for their thoughtful and dignified responses, and for stressing the importance of learning from the incident in order to prevent other patients and families going through the same experience.

We did not interview the clinicians concerned as our remit was to provide an overview of the reports into the incident and the existing reports form the basis of the review wherever possible. The clinicians' views are well documented in the Cardiff and Vale report.

Response to Objectives

Both the NHS Blood and Transplant (NHSBT) and the Cardiff and Vale Report provide clear accounts of what happened and the timeline of the events. Information missing in the Cardiff and Vale Report timeline is the time of investigations and treatment of recipient 2 after they developed symptoms.

The Public Health England Report (PHE) focuses on the events following the onset of symptoms in the recipients and examines critical points in communication, information sharing, the diagnostic process and incident management. It includes a series of recommendations to improve these aspects in the management of any similar incidents in the future.

The Cardiff and Vale Report is very comprehensive and a further detailed report to look at the facts and sequence of events would not add any additional information that would be helpful. However it should be noted that both families are concerned that there are inaccuracies in the reporting of the evidence that they gave. The Cardiff and Vale report also references the relevant National Guidance.

In both cases there is a difference of opinion of what was said to the recipients and their families during the consent process and this is documented in the Cardiff and Vale report. Both the clinicians concerned and the families stated that they have very clear memories of what was said during the consent process and where this took place. The family are clear about what information that they feel should have been given to them at the time of the consent. Unfortunately there are significant differences between the two accounts, which were not resolved by the Cardiff and Vale report. It is unlikely that further investigation or interviews with the families or medical staff will clarify this situation, especially in view of the time that has passed

since the incident. The fact that there is no clear record of what was said is a significant cause for concern.

Response to Key Questions

Donation & transplantation

Characterisation of the Donor

With regard to whether more information was available to improve the characterisation of the donor;

The expected mandatory information required for organ and donor characterisation for the Core Donor Data Form is appropriately documented. The Cardiff and Vale report does not state if any details of the donor's social circumstances were documented in the hospital case records, or whether the ambulance crew who transferred the patient to the hospital had conveyed this information to the hospital staff. Seven centres were offered the liver but turned it down on the past history and four centres were offered the heart but turned it down on the grounds of past history and function. Seven transplant centres had refused the kidneys on the grounds of past history and the cause of death. However it should be noted that in the fast track text message received by the recipient hospital, the reason that the kidneys had been turned down was given as "poor function". This was later found to be incorrect.

Point 3.2.1 of the National Operating Procedure and NHS 2003 policy states that the Specialist Nurse for Organ Donation (SNOD) will:

Undertake a thorough assessment of the potential donor to ensure an accurate medical, behavioural and travel history is available. Sources of information may include:

- *Medical records from the current admission*
- *Medical records from previous admissions where available*
- *Information from the General Practitioner*
- *Information from other specialists e.g. oncologists*
- *Information from the potential donor's family including information regarding medical, behavioural, travel history.*

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) Guidance on the Microbiological Safety of Human Organs Tissues and Cells Used in Transplantation states:

3.6 The donor's family and/or most relevant life partner should be interviewed, and relevant health professionals contacted, such as the donor's GP. Standard questionnaires should be used to seek relevant information and should be kept as part of the donor record in keeping with regulatory requirements. Wherever possible any post mortem findings will need to be available to ensure that an appropriate risk assessment is complete and that all information pertaining to the cause of death is taken

into account.

3.7 Current microbiological results on the donor should be available from the patient's clinician and must be included in the comprehensive patient assessment process conducted by the Specialist Nurse-OD. In the unusual situation where clinical circumstances dictate the need to consider such an action, the risk arising from the use of materials from potentially infected, or known-to-be-infected donors should be discussed with a consultant microbiologist/virologist. Advice from a specialist centre may be required for defining the balance between risk and benefit. Such discussion is normally between the receiving organ transplant unit and the relevant consultant microbiologist/virologist, in the context of the information gathered by the Specialist Nurse-OD, which must include the relevant microbiological findings. Sections 8 and 9 summarise the recommendations of this guidance for microbiological testing and risk assessment.

10.16 Expert microbiological advice should be sought and any recommendations recorded in the patient's notes.

In this case no information on the patient's social circumstances was available from their General Practitioner or their partner who were unaware of the social conditions in which the donor lived.

The Core Donor Data Form included the microbiology and virology results available at the time of donation. As documented in the Cardiff & Vale report, there is a minor error on the CSF report on the donor form, which states "white count 185, 205 Blymorphs, 80% lymphocytes", instead of 20% polymorphs.

The conversation between the recipient coordinator and the Duty Officer at NHSBT did not include a full discussion of the cause of death (Transcript in Appendix 5 of the NHSBT report).

It is noted that 5 out of 6 kidney centres had turned the kidneys down based on the donor's cause of death. As noted in paragraph 11.2 of the Cardiff and Vale Report, the surgeon Mr B was aware of this and the cause of death. There is no evidence that the surgeon Mr B requested any further information from a colleague on the transplant team, infectious disease specialist or the Specialist Nurse – Organ Donation (SNOD) or recipient coordinator. This is covered in paragraph 11.3 of the Cardiff and Vale report.

Adherence to National Guidance and Protocols

The donor was known to be potentially infected with undiagnosed meningo-encephalitis and there is national guidance from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) in 2011 on the potential transmission of infections from a donor and the use of donor organs in this situation. This is discussed fully in paragraphs 11.6 and 11.7.14 of the Cardiff and Vale report.

The relevant paragraphs from the SaBTO Guidance are:

2.1 However, there have been repeated reports of transmissions of viruses, bacteria, fungi, protozoa and prions following transplantation of organs, tissues and cells. These transmissions can be difficult to manage as the recipients may be immunosuppressed and thus more susceptible to becoming ill from the infection.

3.4 Not all infections present in donors are reasons for donor exclusion, and the balance of risk and benefit may favour the use of donations carrying an infection risk in some situations, whilst in others the same donations would not be considered fit for purpose.

10.2 We accept that there may be clinical need for transplantation of such urgency that it may be appropriate to consider the use of organs and tissues for life-preserving purposes from donors who would not otherwise be considered eligible to donate, due to a known or perceived infection risk.

10.5 In general, derogation of the exclusion of infected donors should only be considered when the donation is truly considered to be life preserving. In this situation the transplant surgeon should, with the informed consent of the potential recipient, balance the risk of infection against the risk of dying whilst waiting for another graft.

10.9 Heart, lung and liver transplants will almost always fit within this definition, generally because the clinical situation of the recipient requiring these organs is likely to be one of incipient death. Other solid organs and some very specialised tissues such as haematological stem cells may also fulfil this definition. Other tissues are unlikely to do so but exceptions may occur.

There are situations where a clinician can deviate from the guidelines as stated in the NHSBT and BTS document Responsibilities of Clinicians for the Acceptance of Organs from Deceased Donors.

The surgeon must act in the best interest of the recipient by balancing the risks and benefits of using that organ with the consequences of declining and so waiting for another, lower risk organ to be offered.

2.5.3 High-risk organs - Organs from some donors are associated with a greater risk than is generally accepted; where such organs are used, the reasons for their use should be documented and the surgeon should ensure that there is appropriate consent by the recipient.

2.5.4.1 It is recognised that to use organs contrary to current guidance may, in some circumstances, be in the recipient's best interest and so such a course of action does represent good practice.

2.5.4.2 Where a surgeon decides to use organs that are contrary to published

advice, the surgeon must ensure that such an approach has the recipient's consent (see Section 3.6).

2.5.4.3 The reasons for the decision should be recorded in the patient's medical records together with details of any discussions that may have taken place.

For most people with renal failure who are suitable for kidney transplantation the various forms of dialysis can provide an acceptable medium or even long-term bridge to transplantation. In some individuals on the transplant list however, technical difficulties with adequacy of dialysis due, for instance, to failing vascular access or restriction of transplant opportunities caused by prior high sensitisation can increase the clinical urgency. These factors must be taken into account when considering the risks and benefits prior to accepting or declining a particular transplant offer. The patient should also be informed about these factors and why they justify the use of a higher risk donor.

Consent

The Cardiff and Vale Report documents divergent differences of opinion between the clinicians and the families as to what was said and in the case of one of the families where the request for consent took place. (Paragraphs 11.43-52). In the telephone interviews both families stated clearly that they were not given an explanation of the risk of this particular donor and this is obviously of great concern to them. In the case of one of the recipients Mr G (Cardiff and Vale report), the consent process is complicated by the fact that he had been admitted and consented for a transplant two days earlier that did not proceed. The consent form he signed at this time was used when he was readmitted for the transplant. The only alteration to the form was that the word dual was crossed out. The patient and surgeon initialled this change. It is not clear whether there was a full discussion around consent with Mr G on both occasions and that this has led to the difference of views. There is no documentation to confirm that the donor specific risks were explained to either recipient apart from an untimed entry in the notes of recipient Mr F (Cardiff and Vale report). The consent process did not meet the expected standard for obtaining informed consent and follow National Guidance. The SaBTO Guidance states with regard to the use of potentially infected organs:

10.15 The decision to use such organs or tissues ultimately lies with the transplant surgeon and team and must only be taken with the express permission and informed consent of the recipient or, where this is not possible, of the recipient's partner or if not, of the next of kin. These decisions and permissions must be recorded.

The BTS/NHSBT Guidelines on consent also state (page 4):

The recipient is entitled to know:

iv) Whether the donor poses a greater risk of transmission of infection or malignancy.

Consent to transplantation is obtained at the time the patient is accepted for inclusion on the National Transplant List. Consent should also be re-affirmed at least every 12 months where possible and immediately prior to the transplant. The process of obtaining informed consent at the time of a transplant is difficult. It is an emotionally charged situation. For the patient and their family it represents the chance of a life saving operation, which they may have waited a long time for. This is made more difficult by the time pressures that accompany a transplant. It is therefore vitally important that there is the utmost clarity and lack of ambiguity in the process for obtaining informed consent and time needs to be taken to make sure that the patient and their family are aware of any specific risks that are associated with an individual donor. In the telephone interviews the families expressed the view that there is sufficient time to discuss the specific risks attached to the offer of an organ at the time of the transplant. The view of the families was that they must be given the full facts, including the cause of death of the donor and whether any other centres have turned an organ down and if so why. A patient should be given the opportunity to turn down an organ once all relevant information has been presented to them without any pressure being put on them. Both families were very clear that the recipients would not have accepted the organs had they known of the potential risks.

The patient is the only person who can consent or refuse an operation provided they have mental capacity. However it is desirable that the family or nominated next of kin are involved in this discussion.

Infection

Infection in humans with *Halicephalobus gingivalis* is extremely rare. As of 2014 only five cases have been reported in the literature. Neurohelminthoses are rare causes of encephalitis and would not be a usual part of the routine investigation of a meningoencephalitis. *H. gingivalis* is also not likely to be considered even if a helminthic infection was thought to be the cause. There are currently no screening or diagnostic tests for *H. gingivalis* and the diagnosis has only been made following post mortem examination in the reported cases. There are no reports of the use or efficacy of any antihelminthic drugs in these cases. These drugs do not cross the blood brain barrier and are therefore unlikely to be effective.

Although there was a delay in the admission of Mr G to the ward for more definitive investigations, this was not significant and would not have affected the outcome.

The investigations and treatment of the recipients at the time of presentation of their symptoms was appropriate. It is noted that a protozoal infection was considered and a specimen for amoeba PCR had been sent to the Hospital for Tropical Diseases.

If a post mortem examination on the donor had been performed the diagnosis would have been made more rapidly. The families felt it should be routine practice to perform an autopsy if the cause of death of a donor is unknown. It should be noted however that the decision to hold an autopsy lies with the Coroner/Procurator Fiscal, although the clinicians treating the donor might seek a hospital post-mortem examination with the consent of the donor's family. Unfortunately there is no evidence that this or any other investigations or treatment would have altered the clinical course of the disease.

One of the key questions raised by the families is whether organs from a donor with undiagnosed meningoencephalitis should have been offered to the transplant community.

There is now guidance and data on the use of organs and from higher risk donors on the NHSBT website: (Use of Organs from Donors with Higher Risk 2014). In the context of this incident it is noted that in the period from April 2003 to March 2013 there were 52 donors with meningitis or encephalitis of unknown cause leading to 159 transplants. There were 94 kidney transplants. Apart from the current incident there was no transmission of infectious disease from the donor to the recipients.

Recommendations

We would support and encourage NHSBT to adopt the recommendations made in both the PHE Report and the Cardiff and Vale Report where appropriate, as they are comprehensive and cover the issues raised in the Key Questions.

In addition we would make the following **Recommendations and Learning Points**:

- 1. There needs to be a clear way of documenting adverse social or life style circumstances which could impact on the health of a donor and their suitability to be an organ donor. Where the cause of death is unclear, clinicians in the donor hospital need to consider as wide a range of factors as possible that could be contributory to the patient's illness, especially behavioural and social circumstances if these are not clearly documented. This information should be routinely collected by the SNODs and included in the Core Donor Data Form. We are aware that NHSBT are currently developing the Electronic Offering System (EOS) record so that it can contain information on a donor's lifestyle and other risk factors. We would strongly support this. (Change of practice: NHSBT, SNODs, Donor Hospital Intensive Care Units)**
- 2. The decision to accept organs from a donor where there is a question over the suitability of the organs for that recipient should not be made by one person. There must be discussion with at least one other consultant transplant surgeon and a**

member of the appropriate medical team. This discussion should be documented in the recipient's case records and the recipient must be informed that this discussion has taken place. (Compliance with existing guidance: Transplant Centres)

3. In the case of a potentially infected donor the decision must include discussion with a microbiologist, virologist, or infectious disease specialist. The specialist should be clinically qualified and have an understanding of both the risks of transplantation and or declining organs. (Compliance with existing guidance: Transplant centres)
4. There should to be discussion with the Office of the Chief Coroner about the need to perform an autopsy and the retention of tissue in cases of donation where the cause of death is not fully known. It would be appropriate for NHSBT to lead this discussion. (Change of practice: NHSBT)
5. Whilst recognising that there are often multiple reasons for declining organs, there should be better documentation of the reasons given by a transplant centre. Clinicians should be encouraged to be open and transparent in their reasons for turning down organs and we recommend that NHSBT works with clinicians to see whether the reasons can be defined more precisely. There should also be discussion with patients about what information they need and how to communicate this. (Change of practice: NHSBT, Transplant surgeons, patient representatives)
6. A full discussion of the use of marginal donors and the risks of transplantation needs to take place at the time a potential recipient is placed on a transplant list. This information also needs to be included in the Patient Information booklet. This is currently recommended good practice and should be reinforced by NHSBT so that it is standard practice in all transplant centres. There should also be a checklist or other means of verifying and documenting that the patient has received and read this information. (Reinforcement of existing guidance, new checklist: NHSBT, Transplant centres)
7. All discussion that takes place around the consent at the time of the transplant of a recipient must be clearly documented in the case records. Recipients must be informed of the use of a marginal or high-risk donor. Recipients should be informed why the use of a higher risk donor is justified in their individual circumstances. This discussion must take place before the recipient is taken to the operating theatres. It should be good practice for the recipient's family to be involved in this discussion and to receive the information with the patient's agreement. (Reinforcement of existing guidance: Transplant centres)

- 8. The use of an organ specific consent form for transplantation should be routine. Consideration should be given as to whether the record or transcript of any discussion should be signed by both a consultant surgeon and the patient or their responsible next of kin. (Reinforcement of existing guidance: Transplant centres)**
- 9. Work that is currently being undertaken by NHSBT into improving patient understanding of the risks associated with transplantation should continue. This is important work and we would support the production of a standard booklet on risk that is available on the NHSBT website. (New information: NHSBT, Transplant clinicians, patient representatives)**
- 10. The Transplantation Society and NHSBT should recirculate the SaBTO Guidance on the transmission of infection to the transplant community including doctors in training, SNODs and Clinical Leads for Organ Donation (CLODs) stressing the importance of adhering to the guidance. (Reinforcement of existing guidance: NHSBT, SNODS, Transplant centres)**
- 11. This report, the NHSBT report and recommendations should be circulated to the British Transplantation Society, the Intensive Care Society and the Faculty of Intensive Care Medicine for circulation to their members. (NHSBT, transplant community, ICS, FICM)**
- 12. NHSBT should ensure that all SNODs, regional and hospital CLODs circulate the reports to their local hospitals. We do not think there should be any change to the policy where all potential donors are referred to the SNODs. (Reinforcement of existing guidance: NHSBT)**
- 13. The Case Report should be presented at national transplant and critical care meetings and we are pleased to note that this has already been done.**
- 14. The incident should be written up in the peer-reviewed literature. (Article: Recipient hospital)**
- 15. An article on the importance of the consent process should be published in a transplant patient magazine such as Kidney Life. (Article: BTS and NHSBT)**
- 16. The recommendations should become standard practice throughout England, Wales, Scotland and N Ireland. NHSBT should establish a working group to look at how the recommendations in all the reports (NHSBT, Cardiff & Vale, PHE and O'Donoghue & Gunning) can be put into practice and**

disseminated to the transplant teams in England and Wales. The group should have met and established a time line for implementation of the changes within three months of the publication of this report. A major focus should be on the communication and documentation of donor risk and the consent process. (Change in practice: NHSBT, BTS, patient representatives)

17. An audit should be performed one year after the recommendations have been put in place to ensure that they are embedded in current clinical practice. (Audit: NHSBT)

The SaBTO Guidance states “the risk of infection during the whole process of transplantation can never be completely removed”. There are however clearly documented precautions that will keep the risk as low as is reasonably possible whilst at the same time facilitating the maximum clinical benefit from transplantation. These points are documented in paragraphs 10.2, 10.5 and 10.15 of the SaBTO guidance. They caution that the use of donors with an infection risk should be limited to recipients in a life-preserving situation and with discussion of the risk benefit balance and the consent of the recipient. It is not clear that these precautions were followed in this case. The balance of risk and benefit in transplantation is coming under pressure. Although it is encouraging to note there has been a fall in the number of patients on the kidney transplant waiting list, there may be an increase in the complexity of the cases, necessitating the use of marginal organs. It is inevitable that situations will occur in which some element of risk is justifiable. In this instance those risks need to be clearly documented and understood by both the health professionals caring for the recipient, the patient and ideally their family. Every effort needs to be made to ensure that all those involved in transplantation are aware of the current guidance. As stated in Taking Organ Transplantation to 2020, more evidence based risk assessment guidance is also needed to support clinicians to assess the risk benefit of using an organ. This should also form part of a wider discussion on the need to increase organ donation numbers.

Kevin Gunning/Donal O’Donoghue: 14.11.14

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Declaration of Interests

None declared by either author