Consideration for Change to Red Book Regarding Testing of Neonatal Deceased Tissue Donors from SACT

Introduction

There has been an ongoing debate for some time, both within UKBTS Tissue Services and between SACT and SACTTI, regarding the testing requirements for deceased neonates who are suitable tissue donors in particular, for heart valves. The discussion started as a result of the legislative position in the EUTCD permitting the testing of the mother only in neonate situations. The current requirement of UKBTS is to test the mother and the neonate where the neonate is deceased. This paper intends to propose a potential solution following the debate that has taken place.

Rationale for change

NHSBT Tissue Services are currently one of only a couple of BTS tissue banks in the UK to procure and the only one to process and provide very small heart valves. Hearts for valves can be taken from the deceased from 32 weeks gestation. The problem arises due to the difficulty in obtaining a sufficient blood sample from such a small donor in turn compounded by the difficulties in testing a post mortem derived sample.

Normal blood sampling methods from deceased donors involve subclavian or femoral vessel stabs as, in adults, these vessels are large and therefore easily accessible and enable drawing a sufficient volume from a donor with circulatory arrest. However, in neonates these vessels are tiny and contain insufficient static volumes. A final blood sample option is a heart stab (to draw blood from the ventricle) but this is not an option for valve donation as the needle may damage the valves, and the static volume is small in these individuals. In these circumstances even 2 or 3mls of whole blood is extremely difficult to obtain.

SACT debated whether the sample could be obtained directly from the aorta during the donation process. The main difficultly here is damage to the vessel (cardiac surgeons prefer an intact vessel as long as possible) and after the vessel is cut, any blood runs into the cardiac chamber where it mixes with pericardial fluid, hence there could be local dilution and possible effects on the validity of the test results. In fact occasional practice to take blood samples from cavities post tissue donation was stopped some years ago in NBS by Testing. Finally it is still questionable in these neonates whether, with circulatory arrest, sufficient sample would be obtained given the size of the heart and circulatory cessation.

Further discussions were had regarding whether a cord blood sample could be taken. Where the donor dies during child birth, there will be no consent to take a sample (it has already been confirmed with the Human Tissue Authority that to take a blood sample without consent would be illegal, even where the intent is to protect the option of donation). A donor dying shortly after birth may have a sufficient cord blood archive, but clearly the situation would be too late to take a suitable alternative sample from the placenta if this is not the case.

Admittedly the number of donations this situation relates to is small. Therefore it could be argued that clinical concession routes could be applied in these cases. This is in fact current practice, whereby 2 of the last 3 neonate donations since Sept 06 (data supplied Dr Chandrasekar, NHSBT) have had to be cleared on medical concession as there was an

insufficient blood sample. These grafts are unique and life saving. Clinical concession does bring with it risks e.g. manual labeling or technology safety overrides, and requires discussion with the user regarding the risks and their acceptance of those risks. However, most cardiac surgeons (or indeed most tissue users) cannot comprehend the relevance of deviations in donor screening, and rely for UKBTS to advice as the experts.

The current concession process is based on the following points.

- Babies born dead can only have acquired infection from the mother. Given an immature immune system, any positive serology from the neonate is likely to be from the mother anyway and would be picked up from the mother's tests.
- Post natal neonate deaths can be assessed for potential infection risk from intervention in the SCBU and there are circumstances where there is no perceived risk (i.e. has had no intervention at all or no with risk intervention e.g. blood transfusion) which can be assessed as part of the routine medical history risk assessment.

Discussion

The Red Book already allows for only testing the mother for amnion donation and not the baby. Hence it is already accepted that testing of the newborn is not required. Therefore presumably death in utero or during birth (with no infection or intervention risks) can be considered on the same no risk basis.

In the case of neonatal donors (dictionary definition as up to 28 days from birth)the EUTCD allows for samples from the neonate to be exempt from testing with only the maternal sample being tested, despite there being potential transmission risks in SCBU units. Therefore a rationale for not testing the neonate would be within the law (although the logic of a 28 day cut off is disputed).

If, as found, in over 50% of neonate cases, a neonatal sample cannot be obtained it has become routine practice to release on a maternal sample and an evidence/risk based concession, then the standard should be reconsidered. The concessionary process could actually increase patient riskand in reality the concessionary process is used for the majority of cases.

Serology on a neonate with an immature immune system is not representative of infectious risk that is not derived from the mother (who is tested anyway). This may warrant NAT only screening as a compromise/preference, or full screening as a preferred safety measure, but not an essential requirement.

Even were the neonate to be infected by one of the mandatory markers of infection at, or shortly after birth, all microbiologial screening assays would test as negative for a number of days following infection.

Proposal

SACT request consideration from SACTTI to update the standard as follows:

- All still births or deaths up to 48 hours after birth only require the full microbiology screen on the mother.
- Deaths from 48 hours up to 28 days after birth (to comply with the EUTCD) where there has been no identifiable transmission or intervention risk, only require the mother to be tested.

- Deaths from 48 hours up to 28 days after birth where there are identifiable risks of transmission require the neonatal sample to be tested by NAT only in addition to full maternal screening.

- No change to the post 28 day rules (regarding breastfeeding etc.) with full screening required for both the infant and maternal samples.

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These proposals were endorsed by the JPAC Standing Advisory Committee on Transfusion Transmitted Infections on 2 June 2008.