

Proposal to remove the requirement for face-to-face interviews for living donors

Guidelines for the Blood Transfusion Services in the UK 7th Edition 2005, Addendum 2007 states for Living Donors:

- 22.2 Consent must be obtained and documented by appropriately trained professionals competent in the issues and processes of tissue donation.
- 22.3 Medical and behavioural history must be sought by appropriately trained professionals and in compliance with the following guidance:
 - Information must be obtained by face-to-face interview with the donor. This must allow for the exclusion of lifestyle infectious risks. During interviews, a mechanism should be in place to ensure that donor confidentiality is maximised.
 - If the medical interview is not done at the time of admission for surgery, a system must be in place to capture any relevant medical and behavioural history changes that may occur in the interval between interview and donation.
 - The medical records, if available, must be consulted to review the medical and behavioural history and the medical examination.

The HTA Code of Practice – Consent (July 2006) states:

- 90 The guidance in the code is based on these key principles:
 - Consent need not always be given in writing to be appropriate and informed
- 99 Written consent is good practice for significant procedures such as post mortem or organ donation. If verbal consent is obtained, this should be clearly noted in the patient's records.

Proposal:

Due to the changing strategies at Trusts, it is not always possible for pre-assessment staff to be able to obtain the consent from potential tissue donors, as the pre-op assessment can be performed at out patient clinics or GP surgeries. Nor is it deemed appropriate at some Trusts for Theatre staff to obtain consent on our behalf.

In light of this, NHTSB Tissue Services propose a request to change the Guidelines to allow the living donation consent process to be performed without the requirement for a face-to-face interview.

The standards detailed in the current Guidelines and HTA Codes of practice can be met by using the NHTSB deceased tissue donor model which has been assessed / inspected by the Human Tissue Authority and considered to be exemplary

Excerpt from NHTSB Tissue Services HTA Inspection Draft Report, 5th June 2008

"Consent processes were observed to be of an exemplary standard at both the hub and satellite sites visited. NHTSB Tissue Services has a person commitment with suitably

trained staff that give consideration to the needs of both living donors and the relatives of deceased donors.”

Operational aspects of the proposal:

- Leaflets detailing main exclusion criteria are currently sent to all potential donors therefore enabling them to “self-exclude” as per the current process
- Full details of how to participate in the donation scheme will be given in the leaflet, either a reply card or dedicated number to call where a Tissue Donation Nurse Practitioner will respond at a convenient / appropriate time for the donor
- The consent and medical / lifestyle questionnaires will be performed by telephone at a convenient time to the donor (the same process as the deceased tissue donation family interview) and will be digitally recorded. The Nurse Practitioner will also complete paperwork alongside the interview conversation.
- A donation authorisation form will be sent to the Trust informing them of the consent
- A questionnaire will be sent to the GP to gain / confirm any detail from the medical notes that the donor has given
- As with the current process, Theatre staff confirm consent remains prior to the donation with every donor

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