Guidelines for the Blood Transfusion Services

21.7: Tracking of tissues

http://www.transfusionguidelines.org/red-book/chapter-21/21-7-tracking-of-tissues

21.7: Tracking of tissues

Each Tissue Establishment shall ensure that it has the ability to locate and identify all tissues/cells during any step from procurement through to distribution to recipient or disposal and vice versa. This traceability shall also apply to all relevant data relating to products and materials coming into contact with these tissues and cells.

Tissue Establishments shall have effective and accurate systems to uniquely identify and label tissues/cells received and distributed.

Tissue Establishments shall keep the data necessary to ensure traceability at all stages. Data required for full traceability shall be kept for a minimum of 30 years after clinical use. Data storage may also be in electronic form. Data that must be kept are shown in Table 21.3.

Table 21.3 Minimum donor/recipient data set to be kept

A. BY TISSUE ESTABLISHMENTS

Donor identification

Donation identification that will include at least:

- Identification of the procurement organisation or Tissue Establishment
- Unique donation identification number
- Date of procurement
- Place of procurement
- Type of donation (e.g. single or multi-tissue; autologous or allogeneic; living or deceased).

Product identification that will include at least:

- Identification of the Tissue Establishment
- Type of tissue and cell/product (basic nomenclature)
- Batch number (if applicable)
- Split number (if applicable)
- Expiry date
- Tissue/cell status (i.e. quarantined, suitable for use etc.)
- Description and origin of the products, processing steps applied, materials and additives coming into contact with tissues and cells and having an effect on their quality and/or safety
- Identification of the facility issuing the final label.

Human application identification that will include at least:

- Date of distribution/disposal
- Identification of the clinician or end user/facility.

B. BY ORGANISATIONS RESPONSIBLE FOR HUMAN APPLICATION

- Identification of the supplier Tissue Establishment
- Identification of the clinician or end user/facility
- Type of tissues and cells
- Product identification
- Identification of the recipient
- Date of application
- Where applicable, date and method of disposal