POLICY POL246/1

Accreditation of Laboratories under the Organ Quality and Safety Regulations

This Policy replaces *NEW*	**Copy Number**
	Effective **29/01/16**

Summary of Significant Changes

N/A

Policy

Under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 NHS Blood and Transplant (NHSBT) holds a Procurement licence (40056), and are licensed for the activity of 'donor and organ characterisation'. As part of this legislation there is a requirement to ensure that laboratories undertaking screening, as part of donor characterisation, meet certain standards to ensure the quality and safety of organs intended for transplantation, this standard includes having United Kingdom Accreditation Service (UKAS) accreditation to ISO 15189. This policy describes how NHSBT Organ Donation and Transplantation (ODT) Directorate assure themselves that the laboratories they are using for organ and donor characterisation work to ensure patient safety.

Introduction

The EU Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation were transposed into UK legislation through the UK Statutory Instrument (SI) 2012 No 1501. The Human Tissue Authority (HTA) as the Competent Authority will regulate licensed establishments through the Quality and Safety of Organs Intended for Transplantation Regulations 2012 which came into force on 27 August 2012.

As part of this legislation there is a requirement to ensure that laboratories undertaking screening as part of donor characterisation meet certain standards.

The EU Directive 2010/53/EU requires the following:

- *The tests required for organ and donor characterisation shall be carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.*

This has been transposed into UK legislation in SI 2012 No 1501 which states that the Authority (the HTA) shall specify in Directions:

- *The requirements that apply to laboratories carrying out tests for donor and organ characterisation, to ensure that those tests are carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.*

- *The appropriate operating procedures that are to be in place to ensure that the information on organ and donor characterisation reaches the person who will implant the organ in a recipient before the quality and safety of the organ is compromised.*

This requirement has been stipulated as follows by the HTA documentary framework (The Quality and Safety of Organs Intended for Transplantation: a documentary framework) (published 2012 and revised 2014):

'The HTA directs under Regulation 11 that the tests required for donor and organ Characterisation are carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment. The HTA considers that laboratories which hold current Clinical Pathology Accreditation (CPA) will meet this requirement.

Laboratory accreditation status can be checked by visiting www.cpa-uk.co.uk.

The HTA directs under Regulation 11 that for deceased donation, where an individual working under a licence is responsible for ordering the tests for the purpose of carrying out donor or organ characterisation, they should endeavour to use only laboratories accredited by CPA.

In endeavouring to only use laboratories which hold CPA accreditation, the HTA would expect licence holders to establish the accreditation status of laboratories that are frequently used for donor or organ characterisation, and to review and update this information on a regular basis.

Licence holders should not use a laboratory with an unknown or unaccredited status unless justified on the basis of risk to the quality and safety of the organ or to the recipient. This should be documented for reference in event of a serious adverse event or serious adverse reaction'.

2. Operational Implementation

Following dialogue with the HTA about the practical difficulties in complying with this requirement, NHSBT have agreed the following operational implementation of the requirements:

NHSBT ODT facilitate and enable transplantation. NHSBT ODT does not directly commission laboratories and therefore do not have any direct governance over their practices. NHSBT ODT are responsible for requesting the tests, collating the results and passing the information on to the appropriate Transplant Unit for the assessment of risk associated with that donor.

NHSBT ODT use NHS laboratories which undertake the testing of significant numbers of samples for the general population of the hospital concerned. Therefore if there was a significant risk associated with the use of the NHS laboratory this would be managed by the hospital Governance processes and is highly likely to be known by the clinicians caring for the patient. This is of particular relevance for the haematology/blood transfusion, biochemistry and histopathology laboratories.

A Specialist Nurse – Organ Donation (SNOD) working within the Trust/Health Boards on an honorary contract alongside a Clinical Lead Organ Donation (CLOD) would be made aware of any significant laboratory issues which may affect the quality and safety of a potential recipient. The SNOD/CLOD can ensure that this information is shared with their local team and ODT Quality Assurance for advice on how to proceed if an issues exists. On discussions with the Trust/Heath Board involved and a clinical/scientific and regulatory risk review from NHSBT, an alternative laboratory may be used if necessary.

It is envisaged that this would be a very rare occurrence and would be managed on a case by case basis depending on associated risk.