National Institute for Health and Clinical Excellence

715 – Corneal endothelial transplantation

Consultation Comments table

IPAC date: Thursday 16th April 2009

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1, Specialist Adviser	**1**	These recommendations are appropriate.	Thank you for your comment.
2	Consultee 2, Notifier and Specialist Adviser	**1**	• NICE to provide specific recommendation regarding the necessary requirements on how to learn this new technique (e.g., skills transfer courses, slide scripts, videotapes and self- assessment material, assistance of a skilled mentor, etc).	Thank you for your comment. The guidance will be changed to include a recommendation on training in section 1.3.
3	Consultee 2, Notifier and Specialist Adviser	**1**	• NICE to support a proposal that the return of ocular tissue transplantation follow-up forms to UK transplant (NHS BT) is part of the surgeons' clinical duty as stipulated by the Royal College of Ophthalmologists in London. As this will provide more complete surgical outcome data for future analyses carried out by UK Transplant. In addition, the follow-up forms will help to identify unreported adverse reactions.	Thank you for your comment. Section 1.2 of the guidance supports submission to the NHS Blood and Transplant (formally UK Transplant) register.
4	Consultee 2, Notifier and Specialist Adviser	**1**	• NICE support to disseminate the need for all surgeons in the UK to report all severe adverse reaction after ocular tissue transplantation as established by the Human Tissue (Quality and Safety for Human Application) Regulations 2007.	Thank you for your comment. We would expect clinicians to adhere to these regulations. NICE assumes that clinicians carrying out the procedure and their trusts are aware of the regulations surrounding use of individual procedures, and do not routinely include these in Interventional Procedures guidance.

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5	Consultee 2, Notifier and Specialist Adviser	**1**	So, it is important to stress to all corneal surgeons in the UK that a) the reporting of serious adverse reaction is now a statutory obligation as established by the Human Tissue Authority (HTA) and b) that the mechanism for reporting it is via the NHSBT website.	Please see response to comment no. 4.
6	Consultee 3, NHS Professional	**1**	Adequate training is required by those undertaking the technique.	Thank you for your comment. The guidance will be changed to include a recommendation for training in section 1.3.
7	Consultee 1, Specialist Adviser	**2.1**	Ok.	Thank you for your comment.
8	Consultee 3, NHS Professional	**2.1**	Acceptable.	Thank you for your comment.
9	Consultee 1, Specialist Adviser	**2.2.1**	2.2.1 line 2 should read is replaced with a cadaveric...	Thank you for your comment. Section 2.2.1 of the guidance will be changed.
10	Consultee 1, Specialist Adviser	**2.2.1**	line 4: should read an 8-9mm diameter central portion of the diseased corneal endothelium is outlined and removed by manual peeling through a self sealing peripheral corneal incision. A thin donor sheet of posterior corneal tissue including a healthy endothelial layer is then inserted and compressed against the posterior aspect of the host cornea by filling the anterior chamber with air, and adheres without sutures. Air fluid exchange completes the procedure.	Thank you for your comment. This section of the guidance is intended to be a summary of the procedure.
11	Consultee 3, NHS Professional	**2.2**	Clarification: It is the DONOR that can be prepared mechanically (manually or automated mechanical) or by laser. The RECIPIENT (patient) is prepared by mechanical removal/dissection of the endothelial layer.	Thank you for your comment. Section 2.2.1 of the guidance will be changed; however, this section of the guidance is intended to be a summary of the procedure.

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12	Consultee 2, Notifier and Specialist Adviser	**2.2**	The diseased endothelium is separated from the cornea: it can be either dissected amnually or with the aid of an automated keratome (NOT LASER). Systemic antibiotic and immunosupressants are not normally necessary after this operation. Â Only topical antibiotics and steroids.	Thank you for your comment. Section 2.2.1 of the guidance will be updated; however, this section of the guidance is intended to be a summary of the procedure. The Committee considered the consultee's second comment, but decided not to change section 2.2.2 of the guidance.
13	Consultee 1, Specialist Adviser	**2.2.2**	2.22 delete short period - topical steroids are normally continued for at a low dose for at least 2 years	Thank you for your comment. Section 2.2.2 of the guidance will be changed.
14	Consultee 1, Specialist Adviser	**2.3**	ok	Thank you for your comment.

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15	Consultee 4, Human Tissue Authority	**2.4**	The NICE guidance document should reference the Human Tissue Authority (HTA) as the body which regulates the removal, storage, use and disposal of human tissue for a scheduled purpose. Additionally, the HTA is the competent authority under the European Union Tissue and Cells Directive 2004/23/EC and associated Directives which were transposed into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations. Under these Regulations, storage of cadaveric tissue for corneal enthothelial transplantation must take place in licensed premises and the activities of Â procurement, testing, processing, import/export and distribution of the cadaveric tissue, must be carried out by HTA licensed establishments or by establishments which provide services under a third party agreement to an HTA licensed establishment. Â The clinician (end user) must report any serious adverse events or adverse reactions to the tissue establishment which distributed the cadaveric tissue and participate in any investigation into these events. It is a statutory duty for tissue establishments to notify the HTA of any serious adverse events and reactions.	Please see response to comment no. 4.
16	Consultee 3, NHS Professional	**2.4**	no comment	Thank you for your comment.
17	Consultee 1, Specialist Adviser	**2.4.2**	2.4.2 line 3 should read ...often because of graft failure rather than graft rejection.	Thank you for your comment. Section 2.4.2 of the guidance has been changed. The overview provides more details about individual studies and reasons for repeat procedures.
18	Consultee 1, Specialist Adviser	**2.5**	Ok.	Thank you for your comment.

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19	Consultee 2, Notifier and specialist adviser	**2.5**	• NICE to provide specific recommendation regarding the necessary requirements on how to learn this new technique (e.g., skills transfer courses, slide scripts, videotapes and self- assessment material, assistance of a skilled mentor, etc) and continued update as part of ones CPD regarding frequent new developments relevant to this technique.	Thank you for your comment. The guidance will be changed to include a recommendation on training in section 1.3.
20	Consultee 3, NHS Professional	**2.5**	Agree and more recent techniques have improved outcomes further.	Thank you for your comment.

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21	Consultee 5, Clinician	**General**	By co-incidence I have received a flurry of emails about hand decontamination of an instrument used to prepare endothelial grafts. The concern is that cornea is regarded as a medium risk tissue for CJD (bit like blood transfusion – should be a low risk tissue - but the volume involved in blood and the duration of contact involved with cornea have both been responsible for documented transmission of CJD). This kit is used to prepare endothelial grafts at the point of implantation by trimming the whole grafts provided by eye banks. Our eye bank advisor mentioned central preparation of endothelial grafts as a way of reducing wastage and improving graft quality. I wonder if we should consider graft preparation and reduction of risk of CJD (not necessarily for the guidance but to help the advisory committee on dangerous pathogens resolve this issue). I have in any case suggested that ACDP consider contacting the eye banks to see if they can work something out between them.	Thank you for your comment. A comment on CJD transmission will be added to the guidance at section 2.5.3. Section 3.1 of the guidance will be changed to refer to related NICE guidance on vCJD. In this guidance, posterior eye procedures that involve the retina or optic nerve were classed as 'High risk procedures'. Procedures on the anterior eye were classed as 'Medium risk procedures'.