National Institute for Health and Clinical Excellence

844/1 – Hand Allotransplantation

Consultation Comments table

IPAC date: Thursday 9 December 2010

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultation 1 Professor hand surgery Univ Leeds	**1**	I agree with these requirements. Ideally only one centre in the UK should undertake this work in collaboration with al interested parties from around the UK. Â That centre should make its data openly available within the constraints of confidentiality to all interested parties and should welcome independent scrutiny under the auspices of a bona fide professional body or society such as transplant UK.	Thank you for your comment. NICE IP guidance does not make recommendations on the location of services. Consultee agrees with guidance.
2	Consultation 2 Associate Medical Director, NHS Blood and Transplant	**1**	NHSBT has worked very effectively with clinicians to enable face transplantation. there are major considerations of this is to be done properly without significantly adversely affecting organ donation as well as protecting the rights and privacy of the donor and the family. We would strongly urge that, before such a procedure is contemplated, clinicians need to discuss with NHSBT obtaining consent for donation and work with donor coordinators and intensivists, retrieval surgeons and others to ensure that the identification of suitable donors, retrieval, surgery and follow-up is done in accordance with governance and the legal framwwork	Thank you for your comment. Section 1.3 of the guidance will be changed.

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3	Consultation 1 Professor hand surgery Univ Leeds	**2.1**	Indications should NOT include amputation for malignancy because of the serious risk of provoking recurrence. Consideration should b given to reducing the interval between amputation and transplantation because of the pernicious effect of delay on nerve regeneration. Â Children who form a common source of amputations (through meningococcal disease) and can be expected to benefit greatly in functional terms should only be accepted if they are bilateral amputees and after extremely cautious consent and ethical processes. Blind amputees (commonly sequel of military blast injury) and existing organ recipients are strong candidates. Â Contraindications also include chronic infections with virus or fungi or mycobacteria.	Thank you for your comment. Section 2.1.1 of the guidance will be changed. There is insufficient evidence to determine the best timing of transplantation.
4	Consultation 2 Associate Medical Director, NHS Blood and Transplant	**2.1**	no comments	Thank you for your comment.
5	Consultation 1 Professor hand surgery Univ Leeds	**2.2**	Psychological assessment should be followed by psychological support throughout the post operative course. Long term compliance with monitoring, and antirejection medication is essential and patients who are unable (by virtue of circumstances') or unwilling to comply should be excluded Matching is an important part of the acute process and suitable consent should be in place for matching not just by antigens but also by age, gender, racial characteristics and size. Â This should form part of the evolved consent process The key to procedural success will be the coordination of two teams: those harvesting the donor limb and those preparing the recipient limb. Standard replantation protocols should be followed and for this reason the surgical teams should combine great experience in this area as well as in organ transplantation	Thank you for your comment. This section of the guidance is intended to be a summary of the procedure. Section 1.2 of the guidance refers to the consent process and the need for immunosuppression compliance.

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6	Consultation 2 Associate Medical Director, NHS Blood and Transplant	**2.2**	no comments	Thank you for your comment.
7	Consultation 1 Professor hand surgery Univ Leeds	**2.3**	I agree. Â Poor outcomes have been associated with non compliance which has some times been culturally or environmentally determined, or with poor patient selection. Where these factors have been controlled the outcomes have been very good or excellent and in those cases function has depended on surgical actors and selection factors. Â Younger patients with discrete zones of injury and high motivation have benefited most. Â Assessment of outcome should include measures of participation as well as simple function and ability (using the WHO model of disability)	Thank you for your comment. Consultee agrees with guidance.
8	Consultation 2 Associate Medical Director, NHS Blood and Transplant	**2.3**	no comments	Thank you for your comment.
9	Consultation 1 Professor hand surgery Univ Leeds	**2.4**	Safety is paramount although the risk profile of immunosppression means that each patient must be capable of understanding and making a risk-benefit assessment based on accurate presentation of existing and up to date data. The procedure cannot be risk free and careful consideration should also be given to how far function would be downgraded if re-amputation were required. Â The impact of this can be managed by standard reconstructive planning. Â All patients must commit to comply with careful and long term monitoring for infection, premalignancy and rejection.	Thank you for your comment. Section 1.3 of the guidance refers to the assessment of patients for their suitability, and the consent process is covered in section 1.2.
10	Consultation 2 Associate Medical Director, NHS Blood and Transplant	**2.4**	Experience with solid organ transplantation suggests that in the longer term, transplant recipients are at 2-3 fold increased risk of cardiovascular disease and some malignancies	Thank you for your comment. The safety outcomes reported are those which are described in the available evidence for hand allotransplantation.

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11	Consultation 1 Professor hand surgery Univ Leeds	**general**	I am directing an initiative to develop hand allotransplantation in leeds in collaboration with the department of Plastic surgery and the department of Transplantation	Thank you for your comment. More data on outcomes following this procedure would be welcomed. Section 1.5 of the guidance states that NICE may review this procedure on publication of further evidence.
12	Consultation 2 Associate Medical Director, NHS Blood and Transplant	**general**	As AMD in NHSBT, I would be closely involved in the delivery and monitoring of such a service (although not for commissioning). There are major issues with respect to retrieval and monitoring so NHSBT needs to be prepared if this were to be recommended	Thank you for your comment. NICE is grateful for the comments received from NHS Blood and Transplant in developing this guidance.