

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA165; Machine perfusion systems and cold static storage of kidneys from deceased donors

This guidance was issued January 2009.

The review date for this guidance is August 2010. In December 2010 the decision to review TA165 was deferred until the results of the Machine Preservation Trial became available.

Background

At the GE meeting of 19 February 2013 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	The guidance should be transferred to the 'static guidance list'.
Rationale for selecting this proposal	<p>This 3-year data from the machine perfusion trial confirms that the graft survival advantage for machine perfusion seen at 1 year (94% versus 90%, P=0.04) persists at 3 years (91% versus 87%; p=0.04). An economic analysis based on this trial (which was conducted in the Netherlands, Belgium, and the federal state of North Rhine–Westphalia in Germany) found that machine perfusion was associated with more quality-adjusted life-years (QALYs) at lower costs than cold static storage. This new evidence is consistent with that used for the original decision.</p> <p>Although there may be an argument that a stronger recommendation in favour of machine perfusion could now be made (because the evidence is stronger on the basis longer-term data), the current guidance is positive in that it recommends machine perfusion as an option, with other considerations to be taken into account in choosing the form of preservation. The evidence used in the original decision also suggested a graft survival advantage for machine perfusion,</p> <p>Some of the information in section 3.4 of TA165 (describing the regulatory status of Belzer UW storage solution made by Bristol-Meyers-Squibb) is no longer correct and this product does not have regulatory approval in the UK. However, an appropriately CE marked product is available from another manufacturer so the guidance is not affected by this change.</p> <p>Therefore it is proposed that TA165 is moved to the static list.</p>

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	The guidance will be transferred to the static guidance list.
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Respondent	Response to proposal	Details	Comment from Technology Appraisals
British Association of Urological Nurses	No comment	BAUN may not be the best contributors for this but many thanks for forwarding this information to us.	Comment noted
Department of Health	No comment	The Department of Health will not be submitting any comments regarding the above appraisal.	Comment noted
Royal College of Physicians	Agree	The Royal College of Physicians agrees with the proposal that the above Technology Appraisal should be moved to the static list.	Comment noted
Royal College of Nursing	No objection	Nurses caring for people with kidney disease were invited to review the proposal to move the above guidance to the static list. The feedback received suggests that they are not aware of any further evidence to inform this review consultation. There are no objections with the proposal to move this guidance to the static list.	Comment noted

No response received from:

<u>Manufacturers/sponsors</u> <ul style="list-style-type: none"> • Baxter Healthcare (Soltran) • Bristol-Myers Squibb/University of Wisconsin (Viaspan) • Essential Pharmaceuticals (HTK) 	<u>General</u> <ul style="list-style-type: none"> • Allied Health Professionals Federation • Association of British Healthcare Industries • Association of Renal Industries
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- Organ Recovery Systems (LifePort Kidney Transport)
- Sanofi (Celsior)
- Waters Medical Systems (RM3 Renal Control)

Patient/carer groups

- Afiya Trust
- Black Health Agency
- British Kidney Patient Association
- Equalities National Council
- Independent Age
- Kidney Alliance
- Kidney Research UK
- Muslim Council of Britain
- Muslim Health Network
- National Kidney Federation
- Polycystic Kidney Disease Charity
- South Asian Health Foundation
- Specialised Healthcare Alliance
- Transplant Support Network

Professional groups

- Association of Renal Technologists
- Association of Surgeons of Great Britain and Ireland
- British Association for Services to the Elderly
- British Association of Urological Surgeons
- British Geriatrics Society
- British Renal Society
- British Transplantation Society
- Kidney Research UK
- Renal Association

- Board of Community Health Councils in Wales
- British National Formulary
- Care Quality Commission
- Commissioning Support Appraisals Service
- Department of Health, Social Services and Public Safety for Northern Ireland
- EUCOMED
- Healthcare Improvement Scotland
- Medicines and Healthcare Products Regulatory Agency
- National Association of Primary Care
- National Pharmacy Association
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium
- Welsh Kidney Patients Association
- Welsh Urological Society

Comparator manufacturers

- None

Relevant research groups

- Cochrane Renal Group
- MRC Clinical Trials Unit
- National Institute for Health Research
- Research Institute for the Care of Older People

Assessment Group

- Assessment Group tbc

<ul style="list-style-type: none"> • Royal College of Anaesthetists • Royal College of General Practitioners • Royal College of Pathologists • Royal College of Surgeons of England • Royal Society of Medicine • Society for DGH Nephrologists • The Urology Foundation • UK Renal Pharmacy Group • United Kingdom Clinical Pharmacy Association <p><u>Others</u></p> <ul style="list-style-type: none"> • Gloucestershire and Swindon PCT Cluster • Somerset PCT Cluster • Welsh Government 	<ul style="list-style-type: none"> • National Institute for Health Research Health Technology Assessment Programme <p><u>Associated Guideline Groups</u></p> <ul style="list-style-type: none"> • National Clinical Guideline Centre <p><u>Associated Public Health Groups</u></p> <ul style="list-style-type: none"> • None
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GE paper sign-off: Janet Robertson, Associate Director – Technology Appraisals Programme

Contributors to this paper:

Technical Lead: Helen Tucker

Project Manager: Andrew Kenyon

10th April 2013