NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

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

This guidance was issued in January 2009
The review date for this guidance is August 2010

Recommendation

- A review of the guidance should be transferred to the 'static guidance list'.
- That we consult on the proposal.

Consideration of options for recommendation:

Options	Comment
A review of the guidance should be planned into the appraisal work programme.	There is currently no new evidence
The decision to review the guidance should be deferred [to a specified date].	There are no ongoing pivotal studies
A review of the guidance should be combined with a review of a related technology and conducted at the scheduled time for the review of the related technology.	There are currently no appraisals of a related technology
A review of the guidance should be combined with a new appraisal that has recently been referred to the Institute.	No related appraisals have recently been referred
A review of the guidance should be incorporated into an on-going clinical guideline.	There are no related on-going clinical guidelines
A review of the guidance should be updated into an on-going clinical guideline.	There are no suitable on-going clinical guidelines
A review of the guidance should be transferred to the 'static guidance list'.	**A review of the guidance should be transferred to the static list as there is no new evidence**

Original remit(s)

To appraise the clinical and cost-effectiveness of cold machine (pulsatile) perfusion systems and cold (static) storage solutions for the preservation of donated kidneys.

Current guidance

1.1 Machine perfusion using the LifePort kidney transporter and cold static storage using Belzer UW storage solution or Marshall's hypertonic citrate solution are recommended as options for the storage of kidneys from deceased donors.

1.2 The choice of storage method should take into account clinical and logistical factors in both the retrieval teams and transplant centres. In situations where different storage methods are considered equally appropriate, then the least costly should be used.

Relevant Institute work

Published

Early identification and management of chronic kidney disease in adults in primary and secondary care. Clinical guideline CG73. Published Sep 2008. Expected review date: TBC

Anaemia management in people with chronic kidney disease (CKD). Clinical guideline CG39. Published Sep 2006. Expected review date: Guidance currently being reviewed (29 Jun 2010).

Renal transplantation - immuno-suppressive regimens (adults). Technology appraisal TA85. Published Sep 2004. Review date: June 2010. Currently under review

Renal transplantation - immunosuppressive regimens for children and adolescents. Technology appraisal TA99 Apr 2006. Reviewed Sep 2009. Review scheduled 'early 2010'.

In progress

Acute kidney injury. Clinical guideline. Publication date: Anticipated publication date Aug 2013.

Organ donation: improving donor identification and consent rates for cadaveric organ donation. Clinical guideline. Publication date: July 2011

Suspended/terminated

None found

In topic selection

None found

Safety information

None found

Changes to the indications of included devices

None found

Details of new products

Drug (manufacturer)	Details
MaPerSol (Preservation solutions Inc [PSI])	Intended for the in-vitro flushing and continuous hypothermic machine perfusion preservation of explanted kidneys. Does not currently hold a UK marketing authorisation.
Celsior (Genzyme)	Originally developed as a preservation solution for lung and heart, but has also been proposed for liver and kidney. Does not currently hold a UK marketing authorisation.

On-going trials Trial name and contact	Details
A multicentre randomised controlled study of cold Pulsatile Perfusion in Asystolic donor Renal Transplantation (PPART study) ISRCTN95022818 Addenbrooke's Hospital (UK)	Ongoing. Anticipated completion date Oct 2013.
A single centre, randomised, controlled study of pre-transplant machine perfusion of heart-beating donor kidneys prior to renal transplantation (Cam Pump study). ISRCTN35082773 Addenbrooke's Hospital (UK)	Ongoing. Anticipated completion date Aug 2010.

Proposal for updating the guidance [to be completed by PM]

If the guidance is to be updated as an appraisal, it would be scheduled into the work programme accordingly.

New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline(R) In-Process and Embase. References from November 2007 onwards were reviewed. The results of the literature search are discussed in the 'Appraisals comment' section below.

Implementation

No submission was received from Implementation.

Equality and diversity issues

No equality or diversity issues were raised during the preparation of the original guidance.

Appraisals comment

The LifePort kidney transporter is CE marked for the continuous hypothermic machine perfusion of kidneys for preservation, transportation and eventual transplantation into a recipient. Marshall's hypertonic citrate solution (Soltran) has a marketing authorisation for use in the preservation of human kidneys before transplantation. These marketing authorisations have not changed since the previous guidance was issued. Belzer UW storage solution is not classified as a device or a medicine and does not require a marketing authorisation or CE mark.

There are two relatively new cold storage and renal preservation for transplantation solutions which do not currently hold a UK marketing authorisation: MaPerSol Organ Preservation Solution and Celsior.

Since the publication of TA165, very little new evidence has been published about machine perfusion using the LifePort kidney transporter and cold static storage using Belzer UW storage solution or Marshall's hypertonic citrate solution for the storage of kidneys from deceased donors. Therefore, no significant new data appear to be available that would indicate the need for a review.

The PPART study compared Belzer UW storage solution with the LifePort kidney transporter, and included only kidneys from non-heart-beating donors. The primary outcome was rate of delayed graft function. The PPART study reported no statistically significant differences between the LifePort kidney transporter and Belzer UW storage solution at 3-month follow-up. The PPART study is ongoing (expected completion date October 2013), but it is not expected that the overall conclusion of the PPART study will change as more data become available. Therefore, it is unlikely that this evidence will change the recommendations in the original guidance.

As no substantial new evidence has become available or is anticipated, no new products have received marketing authorisations or CE markings and no

changes have been made to the existing marketing authorisations or CE markings, it is proposed that the guidance be transferred to the static list.

Key issues

No new evidence has been found that would cause the current recommendations to change. Current information suggests that the evidence base is unlikely to change substantially in the foreseeable future, therefore the technology appraisal guidance can be moved to the static list.

GE paper sign off: Janet Robertson, 02 September 2010

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