

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL 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 with a review date of August 2010

**Background**

At the GE meeting on 28 September 2010 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.

<b>Proposal put to consultees:</b>	The guidance should be transferred to the 'static guidance list'.
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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.

<b>Recommendation post consultation:</b>	The decision to review the guidance should be deferred until the results of the Machine Preservation Trial are published.
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Respondent	Response to proposal	Details	Comment from Technology Appraisal
Bristol Myers Squibb	Agree		
Department of Health	No comment		
NHS Quality Improvement Scotland	No comment		
Organ Recovery systems	Disagree	<p>We do not agree with the statements in the Guidance Executive Proposal (Appendix B to your letter) that there is currently no new evidence or ongoing pivotal studies. In our previous letter of 6<sup>th</sup> August 2010 while we commented that an immediate review is not required we did recommend that the Institute re-consider the situation within the next 12 months in line with the availability of new data we are therefore disappointed in the proposal for TA 165 to be moved to the static list and ask the Institute to reconsider their proposal and defer the decision on if and how to update the published guidance for 12 months.</p> <p>Within the next 6-12 months the full results of the Machine Preservation Trial will be published In addition there are two further activities derived from the Machine Preservation Trial, which will provide the largest and most comprehensive database of transplanted kidneys. Along with data</p>	<p>Comment noted. We have updated the recommendation to read “The decision to review the guidance should be deferred until the results of the Machine Preservation Trial are published.”</p>

		published since the completion of TA165 these activities have the potential to impact on the current recommendations	
Royal College of Physicians	Agree		
Royal College of Nursing	No Comment		
Welsh Assembly Government	No comment		

**No response received from:**

<p><u>Manufacturers/sponsors</u></p> <ul style="list-style-type: none"> <li>• Baxter Healthcare (Marshall's Solution)</li> <li>• Waters Medical Systems (RM3 Renal Preservation)</li> </ul> <p><u>Patient/carer groups</u></p> <ul style="list-style-type: none"> <li>• Afiya Trust</li> <li>• Black Health Agency</li> <li>• British Kidney Patient Association</li> <li>• British Organ Donor Society (BODY)</li> <li>• Chinese National Healthy Living Centre</li> <li>• Counsel and Care</li> <li>• Equalities National Council</li> <li>• Kidney Alliance</li> <li>• Kidney Research UK</li> <li>• Muslim Council of Britain</li> <li>• Muslim Health Network</li> <li>• National Kidney Federation</li> <li>• Polycystic Kidney Disease</li> </ul>	<p><u>General</u></p> <ul style="list-style-type: none"> <li>• Association of British Healthcare Industries</li> <li>• Board of Community Health Councils in Wales</li> <li>• British National Formulary</li> <li>• Care Quality Commission</li> <li>• Commissioning Support Appraisals Service</li> <li>• Department of Health, Social Services and Public Safety for Northern Ireland</li> <li>• EUCOMED</li> <li>• Medicines and Healthcare products Regulatory Agency</li> <li>• National Association of Primary Care</li> <li>• NHS Alliance</li> <li>• NHS Blood and Transplant</li> <li>• NHS Commercial Medicines Unit</li> <li>• NHS Confederation</li> <li>• Public Health Wales NHS Trust</li> <li>• Scottish Medicines Consortium</li> </ul>
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- South Asian Health Foundation
- Specialised Healthcare Alliance
- Transplant Support Network
- Transplant Trust

Professional groups

- Association of Renal Industries
- 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
- British Urological Foundation
- Kidney Research UK
- Renal Association
- Renal Pharmacists Group
- Royal College of Anaesthetists
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal College of Surgeons
- Royal Pharmaceutical Society
- Royal Society of Medicine
- Society for DGH Nephrologists
- United Kingdom Clinical Pharmacy Association

Others

- Cwm Taf Health Board
- NHS Hillingdon

- Welsh Kidney Patients Association

Comparator manufacturers

- AQIX (RS-1)

Relevant research groups

- MRC Clinical Trials Unit
- National Institute for Health Research
- Policy Research Institute on Ageing and Ethnicity
- Research Institute for the Care of Older People

Assessment Group

- National Institute for Health Research Health Technology Assessment Programme
- tbc

Associated Guideline Groups

- National Clinical Guideline Centre

Public Health Groups

- None

**GE paper sign-off:** Janet Robertson 01 December 2010

**Contributors to this paper:**

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