National Institute for Health and Clinical Excellence

059 – Short-term circulatory support using left ventricular assist devices as a bridge to transplant or recovery

Comments table

IPAC date: 13 April 2006

Consultee name and organisation	Section no.	Comment no.	Comments	Response Please respond to all comments
Patient Advisory Panel, British Heart Foundation	**1**	1	Shouldn't the patients primary carer also be advised of the risks and basic workings of the devise? ie battery failure and how to use hand pump, also the meaning of various error tunes and/or beeps	Information and communication with primary carer should be part of standard patient care. Not customary for NICE interventional procedure guidance to include this level of detail in section 1. No change required.
National Specialist Commissioning Group, Department of Health	**1**	2	This document and the recommendations do not take account of or mention the NHS R&D Health Technology Assessment Programme's Report: ""Evaluation of Ventricular Assist Device Programme in the United Kingdom (EVAD UK)"". This includes UK data on bridge to transplant. Although the bulk of this report is an economic evaluation and thus outside the efficacy and safety remit of IPAC, it does consider additional literature to that covered in the Clegg systematic review as well as UK data.	The following phrase will be added to section 3: The NHS R&D Health Technology Assessment Programme are producing a report on Evaluation of ventricular assist device programme in the United Kingdom (www.hta.ac.uk/project.asp?PjtId=1256) which is due to be published October 2006.

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BUPA	**1**	3	BUPA hasn't been asked about LVADs in this context, but might I suggest that you put "as a bridge to transplantation" in bold or italics to emphasize it, as there are whispers of a UK multicentre study being set up to evaluate LVADs as destination therapy.	It was felt that the title was clear, and section 2.5 states that the guidance does not apply to destination therapy. No change required.
Patient Advisory Panel, British Heart Foundation	**2.1, 2.2**	4	I have seen several LVADS and they seem to vary a lot in size from one you could carry on a waist belt to another that needs a two wheeled trolley. They are also quite noisy and I think the patient should be made aware of this, also the fact that they may need to be accompanied at all times.	Section 2.5.2 states that a variety of devices are available. No change required.
Patient Advisory Panel, British Heart Foundation	**2.3**	5	When quoting facts and figures as above I feel it is always good to see a date, then the reader will have clear knowledge of how old the figures/information is. Remember to you and I they are just figures and numbers, to someone approaching Lvad they are people or lives we are talking about, and soon they could be one of those numbers...	Full details of studies are included in the overview. No change required.
Patient Advisory Panel, British Heart Foundation	**2.4**	6	The above will be quite worry for a patient to read, you have not yet spoken about their chances of survival without an Lvad/transplant, which are probably none. Then the above when taken with the knowledge that without Lvad you would die doesn't seem quite so bad..	Section 2.3.4 includes specialist advisor comments that without treatment the natural progression is often fatal. No change required.

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Patient Advisory Panel, British Heart Foundation	**2.5**	7	With donor organs becoming less and less available, more patients with heart failure will need to be assisted by an Lvad. Which in turn will lead to patients needing to have one for longer and longer periods. Surely while looking at the lvad you also need to look at the organ donor register and encourage more people to sign up, similar to the Drink Drive and No Smoking campaigns?	Not within NICE's IP Programme remit.
National Specialist Commissioning Group, Department of Health	**2.5**	8	This document and the recommendations do not take account of or mention the NHS R&D Health Technology Assessment Programme"s Report: ""Evaluation of Ventricular Assist Device Programme in the United Kingdom (EVAD UK)"". Although the bulk of this report is an economic evaluation and thus outside the efficacy and safety remit of IPAC, it does consider additional literature to that covered in the Clegg systematic review as well as UK data on bridge to transplant.	Will add comment to section 3 – see above.
BUPA	**2.5**	9	Destination therapy is not intended to be "short-term"..... the hope is that it (possibly a sequence of devices rather than one lasting for ages) will sustain the patient until he/she dies of something else, for instance the cancer that means he/she is not eligible for transplantation.	The statement that the procedure is a temporary solution will be added to section 1.2 on consent.