National Institute for Health and Care Excellence

[IP1521] – [Artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure]

IPAC date: Friday 13 October 2017

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	British Society for Heart Failure (BSH)	**1 and General**	Thank you for inviting the BSH to respond to the consultation on the Total Artificial Heart (TAH). Whilst we welcome technology that might improve the outcome and symptom burden of patients with heart failure, the national experience of TAH is very limited ([redacted] states only 3 cardiothoracic surgeons [1% of the total] have implanted this device in the UK, and "this procedure has only been done approximately 10 times in the whole of the UK over the last 10 years"). Sadly, the data available are from registries, non-randomised studies, and case reports from highly selected (and often conflicted) sources. Historical controls (therefore introducing selection bias), or older generation (pulsatile) BiVADs have been used as comparators. According to the INTERMACS registry, only 13.6% of those with a TAH are alive at one year without transplantation. Despite a bridge to transplant indication, currently only around a sixth of LT-VAD patients in the UK go on to have a heart transplant. What proportion of the UK's limited TAH experience underwent a successful heart transplant? Of other significant concern is the complication rate associated with TAHs, including bleeding, infection, stroke, and device failure, which largely	Thank you for your comments. In the current guidance, section 1.3 states that 'clinicians should enter details about all patients having total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure onto an appropriate registry and review local clinical outcomes'. 1.4 recommends careful patient selection by a multidisciplinary team. 1.5 recommends that "this technically challenging procedure should only be done in centres specialising in heart transplantation. Only cardiothoracic surgeons with specific expertise and training in inserting the device should carry it out". 1.6 recommends further research.

			account for poor long term outcomes. However, we are excited to see ongoing (although, again non-randomised) studies of competing devices. In summary, from a UK perspective, TAH is a niche device with limited applicability until better long-term outcomes can be documented. Until then, implantation should be limited to the (larger) transplant centres as part of a recognised research programme/registry.	