

**National Institute for Health and Care Excellence**  
**IP1746 Permanent His-bundle pacemaker implantation for heart failure**

IPAC date: 11/02/2021

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
				Please respond to all comments
1	Consultee 1 Abbott Medical UK (company)	<b>General</b>	This draft guidance specifically refers to His Pacing, but there is a trend towards Bundle Branch Pacing. Whilst this is in the region of the His, it isn't the same location and stimulates a slightly different aspect of conduction.	Thank you for your comments. Bundle branch pacing will be dealt as a separate topic when the procedure is notified to NICE. Interventional Procedures Advisory Committee (IPAC) considered your comment and added a committee comment in section 3.7 of the guidance.
2	Consultee 1 Abbott Medical UK (company)	<b>1.1</b>	We would disagree with a research only recommendation and suggest that this should be changed to special arrangements on the grounds that there are already publications on His Pacing and research continues. For example, the His Pro registry is currently enrolling.	Thank you for your comments. IPAC considered your comment but decided not to change the recommendation.  The committee noted the existence of His Pro registry and agreed that it does not meet NICE requirements of independent clinical supervision. The details of this registry have been added to the list of ongoing studies in the overview. When this data is published, NICE will consider reviewing the guidance.
3	Consultee 1 Abbott Medical UK (company)	<b>2.5</b>	Abbott's solution involves a standard pacing lead, not a dedicated His bundle lead.	Thank you for your comments. IPAC considered your comments and amended 2.5.
4	Consultee 1 Abbott Medical UK (company)	<b>3.6</b>	It would be sensible not to say that the pacemaker lead does not usually need to be passed through the tricuspid valve. In most cases the tricuspid valve does need to be passed, particularly for bundle branch pacing.	Thank you for your comments. IPAC agreed and removed 3.6 from the draft guidance.

5	Consultee 1 Abbott Medical UK (company)	<b>2.4 to 2.5</b>	It may be useful to note that recently, HBP has been proposed as an alternative to CRT to treat the specific subgroup of heart failure patients who suffer from LV dysfunction (EF<35%) and LBBB. This proposal is still under debate because it is not known in how many patients pacing the His bundle you can solve left bundle branch block simply because the His bundle is over the left bundle branch and therefore pacing from there may not solve a block which is more distal.	Thank you for your comments. IPAC considered your comments and amended 3.5.
6	Consultee 2 Medtronic (company)	<b>3</b>	<p>"Thank you for the review of the clinical evidence for Permanent His-Bundle Pacemaker implantation for treating heart failure.</p> <p>The documented rapid review of the published literature has sufficiently captured the key body of clinical evidence and associated treatment benefits and outcomes.</p> <p>As recognized in the published literature and highlighted by the committee members and the clinical expert during the primary meeting, the therapy does provide an alternative treatment option for patients in preventing pacemaker-induced cardiomyopathy and for patients where conventional cardiac resynchronisation therapy (CRT) is clinically contraindicated. It could be helpful to highlight this subgroup in any public facing document to avoid confusion."</p>	Thank you for your comments. IPAC considered your comments and amended 3.5.

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*