

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert questionnaire

Before completing this questionnaire, please read [Conflicts of Interest for Specialist Advisers](#).

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: Permanent His-Bundle pacemaker implantation for heart failure

Name of Professional Expert: Mark A Tanner

Job title: Consultant Cardiologist,
Honorary Clinical Senior Lecturer

Professional Regulatory Body: GMC
Other (specify)

Registration number: 4441823

Specialist Society: Member of British Heart Rhythm Society and
European Heart Rhythm Society.
Fellow, European Society Cardiology.

Nominated by (if applicable): NA

1 About you and your speciality’s involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

- Yes.
- No – please answer no more questions and return the form

Comments:

I am a consultant cardiologist with a specialist interest in cardiac device therapy. I have been implanting His-Bundle pacing devices since 2017; predominantly in heart

failure patients as part of a clinical trial (HOPE-HF- see below). Beyond patient selection and implantation I am also responsible for ongoing management and trouble-shooting of these devices. I am well-versed in the literature of His pacing and was a faculty member of the 1st UK His-Pacing Symposium (2017) and have presented in this field at Heart Rhythm Congress UK (2019). I am currently a member of the Data Monitoring Committee for a BHF funded His pacing study (Cardiac resynchronisation by His pacing: patient selection by high-precision invasive and non- invasive phenotyping).

1.2 Is this procedure relevant to your specialty?

Yes

No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

Procedure would appear to be performed exclusively by cardiologists (in the UK)

1.3 Is this procedure performed by clinicians in specialities other than your own?

Yes – please comment

No

Comments:

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

I have never done this procedure.

I have done this procedure at least once.

I do this procedure regularly.

Comments:

I initially trained in this procedure as part of my involvement in the HOPE-HF study; receiving animal lab training in Utrecht and performing implants at the Hammersmith Hospital. I have subsequently introduced a service at my base hospital (DGH) where I have performed 13 cases (11 research, 2 clinical).

1.5 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

1.6 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

I am Principal Investigator at Western Sussex Hospitals for a UK multi-centre His-Bundle pacing study (HOPE-HF study). Excluding the hub centre our institution has recruited more than any other centre in the UK (27 sites). I am currently a member of the data monitoring committee for a study comparing His-bundle pacing with Cardiac Resynchronisation Therapy in heart failure patients with broad QRS.

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

- Yes
- No - If no, please suggest alternative titles.

Comments:

Although the scope could be extended to the role of His-Bundle Pacing in other areas Eg. In the treatment of AV block where long-term ventricular pacing could be provided without inducing ventricular dyssynchrony (seen in conventional RV pacing) and thereby potentially avoiding pacing induced cardiomyopathy and heart failure

2.2 Which of the following best describes the procedure (choose one):

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

This is to an extent a refinement of existing pacing techniques/cardiac resynchronisation therapy although confirmatory evidence of longer term safety/efficacy is required

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

Cardiac Resynchronisation Therapy through bi-ventricular pacing

2.4 Are there any major trials or registries of this procedure currently in progress? If so, please list.

HOPE-HF study (recruitment closed; due to report findings 2020). Reference: Rationale and design of the randomized multicentre His Optimized Pacing Evaluated for Heart Failure (HOPE-HF) trial. Keene D, Arnold A, Shun-Shin MJ, Howard JP, Sohaib SA, Moore P, Tanner M, Quereshi N, Muthumala A, Chandresekeran B, Foley P, Leyva F, Adhya S, Falaschetti E, Tsang H, Vijayaraman P, Cleland JGF, Stegemann B, Francis DP, Whinnett ZI. ESC Heart Fail. 2018 Oct;5(5):965-976.

Direct HIS-pacing as an Alternative to BiV-pacing in Symptomatic HFrEF Patients With True LBBB (HISAlternative). ClinicalTrials.gov Identifier: NCT03614169

- 2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.**

Abstracts at Heart Rythm UK October 2019:

ECGI derived left ventricular activation patterns predict correction of LBBB by His Bundle Pacing. European Journal of Arrhythmia & Electrophysiology. 2019; 5(suppl. 1): abstr 32. AD Arnold et al.

Safety and Feasibility of His Bundle pacing at a tertiary cardiac centre. European Journal of Arrhythmia & Electrophysiology. 2019; 5(suppl. 1): abstr 116.

Key publications

Zanon F et al. Permanent His-bundle pacing: a systematic literature review and meta-analysis. Europace (2018) 0, 1–8

Sharma PS et al. Permanent His Bundle Pacing as an Alternative to Biventricular Pacing for Cardiac Resynchronization Therapy: A Multi-Center Experience, Heart Rhythm (2017), doi: 10.1016/j.hrthm.2017.10.014.

Keene D, Arnold A, Shun-Shin MJ, Howard JP, Afzal Sohaib SM, Moore P, Tanner M et al. Rationale and design of the randomized multicentre His Optimized Pacing Evaluated for Heart Failure(HOPE-HF) trial. ESC Heart Failure (2018) DOI: 10.1002/ehf2.12315

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

Please list any adverse events and major risks (even if uncommon) and, if possible, estimate their incidence:

Adverse events reported in the literature (if possible please cite literature)

Complications are those of any cardiac pacing procedure ie pneumothorax, lead displacement, infection etc. A recent long term performance and safety in His Bundle Pacing has been reported by Zanon F et al, J Cardiovasc Electrophysiol. 2019; 30:1594-1601. His pacing lead thresholds are on average slightly increased (compared with conventional RV pacing) and successful His bundle pacing is not always achievable (78-91% in a recent study [1]). However this is a relatively new technique with a demonstrable learning curve [1] *His Bundle pacing, learning curve, procedure characteristics, safety, and feasibility: Insights from a large international observational study. Keene et al. J Cardiovasc Electrophysiol. 2019; 30:1984-1993.*

Anecdotal adverse events (known from experience)

Acute injury to the His bundle resulting in AV block (usually transient) or persistent RBBB

Theoretical adverse events

Longer screening times might result in clinically significant radiation exposure; higher pacing thresholds may result in premature battery longevity. Extraction of His Bundle leads is not established and may provide additional challenges

3.2 Please list the key efficacy outcomes for this procedure?

[In heart failure indication] Objective parameters such as LV ejection fraction, LV volumes, Exercise Capacity (mVO₂), Qualitative measures such as NYHA functional class, QoL indicators

3.3 Please list any uncertainties or concerns about the efficacy of this procedure?

Despite compelling observational data there remains no randomised controlled data currently published re efficacy

3.4 What clinician training is required to do this procedure safely?

Cardiologists already trained in complex pacemakers should be able to transition with relatively little additional training especially those with experience in electrophysiology. Additional training would involve appraisal of theoretical knowledge and ideally a period of observation/proctoring. Keene et al [1] suggests experienced implanters of devices will need to perform approximately 40 cases before plateauing of key performance markers

3.5 What clinical facilities are needed to do this procedure safely?

Can be performed safely in any cardiac catheter lab equipped for permanent pacing

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

No major concerns however there is a lot enthusiasm for this technique in the pacing community in the UK, but little consensus regarding its current role with high variability of practice in the UK.

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes.

Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:

Improvements in heart failure remodelling parameters eg LV ejection fraction, LV dimensions at 6-12 month

Improvements in heart failure symptoms (NYHA class) and QoL measures at 6-12 months

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

Failure of placement of His bundle pacing lead (at index procedure)

Subsequent failure of His Bundle pacing (at 6 weeks and 1 year)

Re-intervention rates (at 6 weeks and 1 year)

Infection rates at 1 year

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

- Rapidly (within a year or two).
- Slowly (over decades)
- I do not think the NHS will adopt this procedure

Comments:

The infrastructure for this procedure is already available (ie in existing pacemaker implanting centres. The hardware is commercially available, and there remains a clinical need for improved heart failure treatments so I think adoption will be relatively quick

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Comments:

There are a number of tertiary and DGH centres in the UK performing this procedure

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

- Major.
- Moderate.
- Minor.

Comments:

The demand on resources will be offset to an extent by the fact that eligible patients may have otherwise undergone a conventional pacing procedure (ie brady pacemaker or cardiac resynchronisation) and if efficacious there will be cost savings from the reduction in heart failure burden

6 Other information

6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

Whilst there is a lot enthusiasm for this technique in the pacing and heart failure communities in the UK, there is a high variability of practice and the number of implants between centres differs widely. There is therefore a great need for a systematic review of the evidence and development of national guidelines.

7 Data protection and conflicts of interest

7.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The professional expert questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our [privacy notice](#)

7.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the “Conflicts of Interest for Specialist Advisers” policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures. [Conflicts of Interest for Specialist Advisers](#)

Declarations of interest form			
Type of interest	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-specific/non personal	5,000£ Departmental Educational grant from Medtronic (who manufacture His pacing devices)	4/2019	4/2020

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	<p>Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest.</p> <p>Types of interest:</p> <p>Direct interests</p> <p>Financial interests - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. <i>For examples of financial interests please refer to the policy on declaring and managing interests.</i></p> <p>Non-financial professional and personal interests - Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. <i>For examples of non-financial interests please refer to the policy on declaring and managing interests.</i></p> <p>Indirect interests - Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit.</p> <p>A benefit may arise from both a gain or avoidance of a loss.</p>
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair **Mirella Marlow Programme Director**

