NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP972/2 - Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure**

Your information

Name:	Prof Roy S Gardner
Job title:	Consultant Cardiologist
Organisation:	Golden Jubilee National Hospital, Clydebank, Glasgow, G81 4DY
Email address:	Roy.Gardner@Glasgow.ac.uk
Professional organisation or society membership/affiliation:	Chair Elect: British Society for Heart Failure (BSH)
Nominated/ratified by (if applicable):	Email from Bijal Joshi
Registration number (e.g. GMC, NMC, HCPC)	4308881

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	I have implanted 10 CARDIOMEMS devices as part of the UK COAST study and followed them using Merlin ™. These are still the only devices implanted in Scotland. There were several other implanting centres in England as part of this study My understanding is that these devices are not currently implanted under the NHS and have only been implanted as part of research. However, they have a IIb recommendation (“may consider”) in the 2016 ESC Heart failure guidelines (due to be updated in September). Cost is a potential major barrier This technology is only applicable to cardiologists
2	− Please indicate your research experience relating to this procedure	I have done bibliographic research on this procedure. **I have done clinical research on this procedure involving patients.**

	(please choose one or more if relevant):	**I have published this research (named author on an abstract).**
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	This is a very innovative investigational tool, and currently unique in the marketplace. It requires the patient to lie on a special pillow for 18 seconds every day to measure pulmonary artery pressure. These data can allow the health care practitioner to adjust (mainly diuretic) therapy according to results The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Additional to standard care

Current management

5	Please describe the current standard of care that is used in the NHS.	Medical care (Sacubitril valsartan, beta-blocker, MRA, SGLT2 inhibitor), and device therapy (CRT or ICD), with diuretics as appropriate. Advanced strategies for selected patients. Cardiomems can help tailor individual care
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	HeartLogic enabled Boston Scientific devices can also predict cardiac decompensation, although works in a completely different way (and does not require an additional – and very expensive - implant). Wearable technologies may also compete in the marketplace although these are currently still under evaluation

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Reduce hospitalisation in frequent fliers Identify those poorly adherent to (diuretic) therapy
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Frequent fliers – those with multiple and prolonged stays HF with preserved ejection fraction where there are limited other options
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	The CHAMPION study (Abraham WT et al Lancet 2011; 377: 658–66) demonstrated a reduction in hospitalisation in a US cohort. The UK study will hopefully confirm these data
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	More. This device is very expensive (£10-12,000 per device), the device requires a cath lab for insertion (and a degree of skill) and the follow-up is reasonably time consuming
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	I suspect much more (see above)
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	It needs a cath lab, and a technically capable implanter

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes – for implantation

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Any risks related to cardiac and pulmonary artery catheterisation, including PA rupture, and device embolisation, although in the studies (including the UK one) this seemed to be very low. Device reliability also seems good (it doesn't have a battery). There are occasional reports of recalibration being required
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction in hospitalisation. There are no mortality data
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Cost
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Around 10 specialist centres in the UK – at least initially

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent 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.	Heart Failure hospitalisation reduction with remote Pulmonary Artery Pressure monitoring 12 months results of the first 100 United Kingdom patients in the CardioMEMS HF System Outside-US Post-Market Study (COAST) Cowie MR, Flett A, Cowburn P, Foley P, Loke I, Critoph C, Gardner R, Guha K, Betts T, CarrWhite G, Zaidi A, Lim S, Hayward C, Patwala A, Rogers D, Pettit S European Society of Cardiology - Heart Failure Congress 2020 ePoster European Journal of Heart Failure abstract supplement
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	The COAST study (PI: Martin Cowie)

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Potentially thousands, although this would be very resource heavy. As such, if adopted, it should be reserved for use in specialist centres and for patients who experience frequent HF hospitalisation
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Requires skill to implant, and also requires sensible people to look at meaningful data and interpret appropriately
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Cost

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	There are no mortality data
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These 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. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Rate of hospitalisation Adverse outcome measures: Device failure (sensor or pillow) Failure to implant Infection Complication from implant

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

The link to this NICE policy does not work!

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	Investigator for the COAST study		
Indirect	Abbott fund a clinical fellow in our department	**2011**	**ongoing**
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

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Print name:	**Prof Roy S Gardner**
Dated:	**17th March 2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP972/2 - Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure**

Your information

Name:	Professor Martin R Cowie
Job title:	Professor of Cardiology,
Organisation:	Imperial College London (Royal Brompton Hospital)
Email address:	m.cowie@imperial.ac.uk
Professional organisation or society membership/affiliation:	N/A
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 3323676

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Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am very familiar with the technology. I chaired the UK study of CardioMEMS as part of a global study (COAST), where 15 Uk hospitals implanted the technology and used it to monitor and adjust medical treatment for the patients' heart failure. My own centre was the first in the UK to implant CardioMEMS, and we have gained hard won experience of all aspects of patient selection and decision making, implant procedure and after care, remote monitoring, staff support and education required, and the impact on reducing re-hospitalisation risk from heart failure decompensation. I also sit on the data safety and monitoring committee of a randomised trial of this technology in Germany (PASSPORT-HF).
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	I was involved in health economic modelling some years ago – from the UK NHS perspective – but that model requires updating with the much larger evidence base now available internationally, and also now in UK NHS practice. As part of COAST 15 UK centres implanted CardioMEMS, but this has stopped during the pandemic and reduction in capacity. With exit from the healthcare emergency the programme will likely restart, but an update to NICE advice on this technology is essential to support appropriate utilisation in the NHS.

	procedure/technology, please indicate your experience with it.	Procedure is confined to use by cardiologists – partic those with an interest in heart failure, and/or remote monitoring My speciality identifies and manages patients with this technology.
2	– 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 published this research. I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	This is a novel approach – and one of the few remote monitoring technologies for heart failure tha has a large evidence base including randomised and real world data – and experience in real life in the UK. The medical interventional briefing from > 5 years ago desperately needs updating or progressing to a formal tech assessment to give guidance to the NHS on this technology that could be applied to thousands of high-risk patients living with severe chronic heart failure with impact of stabilising the syndrome and keeping them out of hospital. 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. (but now with hugely more data than when MIB performed > 5 years ago – when NICE asked for more real world data to be collected in the NHS -this has now been done and requires NICE to synthesise the evidence and issue definitive guidance.

		The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	As an addition to standard of care for severe heart failure .

Current management

5	Please describe the current standard of care that is used in the NHS.	Guideline-based introduction and titration of medical therapy (drugs) such as diuretics, ACE inhibitors, beta-blockers, aldosterone antagonists, SGLT2 inhibitors. CardioMEMS allows a more personalised and physiological adjustment of such therapies to stabilise the syndrome, and has been shown in RCT and RWE to reduce the risk of emergency hospitalisation quite dramatically. But requires expert selection of patients, an implant, and then a heart failure service able to remotely monitor the data and make adjustments to medical therapy on a week by week basis.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Attempts have been made to use data from other implants (such as CRT or ICD devices) but as yet this has not proven to add value over and above SOC. Other manufacturers are attempting to develop similar implantable pulmonary artery pressure monitors but none have yet to reach market and are 10 years behind CardioMEMS in terms of RCT and RWE data.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Substantial reduction in risk of decompensation of chronic heart failure, with a 30-70% decrease in risk of emergency re-hospitalisation in RCT/RWE studies in many countries, including the UK.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Chronic heart failure (HFrEF and HFpEF subtypes) with moderately severe symptoms despite "standard of care" – technically NYHA III class.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes – reduced hospitalisation risk and stabilised disease progression. Also strong signal of mortality benefit. Also less urgent clinic visits.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	A little more than the SOC but giving additional benefit. But assessment of cost effectiveness is essential to give advice to the NHS. Minimal increased staff costs – cost of implant and procedure is the main cost.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Same staff will be able to give greater benefit for their patients (reduced hospitalisation and urgent visit costs) – but does require the implant.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Minimal changes – cath labs already available for the implant to be done, and most HF units already remotely monitor some patients.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Some training in interpreting the PA pressure readings – but after that the process of monitoring and adjustment of treatment is straightforward and well within the competence of UK heart failure services.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Implant complications (bleeding) – but UK real world data now suggest this is very low risk. Failure of sensor after some months occurs in <1% of implants Patient fatigue with remote monitoring daily is surprisingly low, as they are sick and feel much more stable on personalised therapy: estimates suggest >95% of patients comply with monitoring in Uk setting.
15	Please list the key efficacy outcomes for this procedure/technology?	Mortality; hospitalisation rate; QOL
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	NICE asked for more RWE when it issued its MIB > 5 years ago – this has now been done in the UK at 15 centres, and is also supplemented by data from many other countries, including Germany and USA.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Uncertainty about cost-effectiveness. Clinical effectiveness is now much more secure than when NICE issued its MIB >5 years ago.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please 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.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent 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.	Abstract at Heart Failure Association of the European Society of Cardiology Annual Meeting, June 2020 (based on prelim UK data from 10 centres) (can be supplied if you cannot access) Design paper of the UK-driven COAST study: Cowie MR, de Groote P, McKenzie S, Brett ME, Adamson PB; CardioMEMS Post-Market Study Investigators. Rationale and design of the CardioMEMS Post-Market Multinational Clinical Study: COAST. ESC Heart Fail. 2020 Jun;7(3):865-872. doi: 10.1002/ehf2.12646. Epub 2020 Feb 7. PMID: 32031758; PMCID: PMC7261560. Multiple other publications including a RCT (CHAMPION); and RWE studies from USA; Recent results paper from the Germany-based MEMS-HF study: Angermann CE, Assmus B, Anker SD, Asselbergs FW, Brachmann J, Brett ME, Brugts JJ, Ertl G, Ginn G, Hilker L, Koehler F, Rosenkranz S, Zhou Q, Adamson PB, Böhm M; MEMS-HF Investigators. Pulmonary artery pressure-guided therapy in ambulatory patients with symptomatic heart failure: the CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF). Eur J Heart Fail. 2020 Oct;22(10):1891-1901. doi: 10.1002/ejhf.1943. Epub 2020 Aug 9. PMID: 32592227.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	PASSPORT-HF; MONITOR-HF; COAST-HF

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an	At most DGHs with a HF service there will be 25+ patients per year likely eligible – so perhaps 2000-3000 patients per annum.

	estimated number, or a proportion of the target population)?	
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Does require a right heart catheterisation to implant (day case or overnight stay in a cardiology unit) but very few problems for patients or heart failure services in long-term monitoring using data from the device thereafter.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No NICE tech assessment has meant no mandate or advice on when and where to use this technology. Very variable use across the country because of this.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Research has been done in UK and elsewhere -what we need now is a formal appraisal and a recommendation to the NHS.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These 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. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Hospitalisation HRQOL Mortality Adverse outcome measures: Implant complications (on day and first 4 weeks after implant) Sensor failures (over time)

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	NICE MIB called for more data to be collected in RWE in UK - these data have now been collected and add to the considerably enlarged global experience. As an exemplar of a digitally enabled technology for remote monitoring of an expensive serious chronic condition (heart failure) this should be a technology that is assessed, with view to firm recommendations to the NHS to guide patients and clinicians in when and where to use it for patient benefit.

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	I provide a small amount (a few hours per year) consultancy advice to Abbott - the manufacturer of CardioMEMS – for their clinical trial and real world evidence programmes.	**2001 onwards**	
Non-financial professional	As a clinical academic I have been involved in trials of a range of remote monitoring technologies for heart failure – and (of course) share the findings with the clinical community by presenting at conferences and publishing the results in peer-reviewed journals.	**2001 onwards**	
Choose an item.			

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Dated:	**17 March 2021**