NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1090/2 Bioresorbable stent implantation for treating coronary artery disease**

Your information

Name:	Abdul Mozid
Job title:	Consultant Cardiologist
Organisation:	Leeds Teaching Hospitals NHS Trust
Email address:	abdul.mozid@nhs.net
Professional organisation or society membership/affiliation:	BCIS (number 2986)
Nominated/ratified by (if applicable):	BCIS (Fiona McDonald, general manager)
Registration number (e.g. GMC, NMC, HCPC)	6076210

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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?	I am familiar with Bioresorbable stents, specifically the Absorb scaffold marketed by Abbott. The stent was launched in 2011/12 and was widely available. I have used in the past but as far as I am aware the stent has been withdrawn due to safety concerns. There had been a concern regarding stent thrombosis rates and the Absorb stent is no longer manufactured. So as far as I am aware there is currently no commercially available bioresorbable stent in the UK. There are similar stents being evaluated in other countries including the Magmaris stent from Biotronik.
	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	The procedure to implant bioresorbable stents was predominantly performed by interventional cardiologists but Abbott are now launching a new bioresorbable stent to be used by interventional radiologists for lower limb peripheral vascular disease.

	indicate your experience with it.	
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) I recruited patients to the UK ABSORB registry in 2015/2016
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):	Novel design and technology 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.
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?	No. The data has shown this technology is inferior to current available drug eluting stents so it is no longer commercially available.

Current management

5	Please describe the current standard of care that is used in the NHS.	3rd generation drug eluting stents
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?	No, there is no similar technology available in the NHS

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?	Theoretically, a fully bioresorbable stent would restore the coronary to normal anatomy and function with no permanent implant left and hence reduce risk of implant related event in the long-term.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Young patients required coronary stenting would potentially benefit as lifetime risk of repeat events is naturally higher
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?	No. In fact the data shows wore outcomes with this type of stent
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)	Cost more, due to need for repeat procedures
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)?	Increased resource cost due to repeat revascularisation procedures
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No changes are required, can be carried out in existing cardiac units
13	Is any specific training needed in order to	Yes, implantation technique is different to current drug eluting stents

	use the procedure/technology with respect to efficacy or safety?	

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	The data from multiple registries show increased target lesion failure requiring revascularisation procedures due to restenosis or thrombosis. Three year follow-up of the ABSORB III study showed: The primary composite endpoint of target lesion failure through 3 years occurred in 13.4% of BVS patients and 10.4% of EES patients (p = 0.06), and between 1 and 3 years in 7.0% versus 6.0% of patients, respectively (p = 0.39). TVMI through 3 years was increased with BVS (8.6% vs. 5.9%; p = 0.03), as was device thrombosis (2.3% vs. 0.7%; p = 0.01). In BVS-assigned patients, treatment of very small vessels (those with quantitatively determined reference vessel diameter <2.25 mm) was an independent predictor of 3-year TLF and scaffold thrombosis. There have also been case reports of coronary artery aneurysm formation following the Absorb bioresorbable stent implantation e.g J Am Coll Cardiol Intv. 2016 Jan, 9 (2) e23–e25
15	Please list the key efficacy outcomes for this procedure/technology?	Target lesion failure
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Studies have consistently shown higher target lesion failure with this technology
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes, it is uncertain if device actually fully aborbs and there appears to be increased coronary events
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.- device no longer available

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.	Absorb III randomised trial presented in 2017 provides the most important data of excess risk of this technology J Am Coll Cardiol 2017 Dec 12;70(23):2852-2862. The Absorb stent is no longer available for commercial use. Abbott have restarted evaluating this technology for peripheral vascular disease indication. The Magmaris bioresorbable stent by Biotronik is currently being studies in clinical trials and shows promising results so far in the BIOSOLVE research studies. Catheter Cardiovasc Interv 2021 Jul 1;98(1):E1-E8. But this has not yet been studies in a randomised trial comparing current generation drug eluting stents.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not that I am aware of

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)?	Around 95,000 PCI cases are performed annually and if technology was to work then theoretically most of these patients undergoing PCI would be eligible to receive this stent.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The previous Absorb stent was difficult to deliver to the target area

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?	Absorb stent no longer available
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	A new bioresorbable stent would need to be studies in a large randomised trial prior to approval
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: Angina relief Quality of life, Kansas angina questionnaire Adverse outcome measures: Target lesion failure Early and late stent thrombosis Data should be for 30-day, 1 year, 2 years and 3-years

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.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

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Print name:	**Abdul Mozid**
Dated:	**9th November 2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1090/2 Bioresorbable stent implantation for treating coronary artery disease

Your information

Name:	Dr Gerald Clesham
Job title:	Consultant Cardiologist
Organisation:	Mid and South Essex NHS Trust (Essex Cardiothoracic Centre)
Email address:	Gerald.Clesham@nhs.net
Professional organisation or society membership/affiliation:	British Cardiovascular intervention Society (BCIS)
Nominated/ratified by (if applicable):	British Cardiovascular intervention Society (BCIS)
Registration number (e.g. GMC, NMC, HCPC)	GMC 3262742

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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 a consultant interventional cardiologist at the Essex Cardiothoracic Centre. This is a high volume centre for percutaneous coronary intervention (PCI). We did have a bioabsorbable stent programme at our hospital a few years ago. We evaluated our cases and some of the issues associated with these devices. Like many centres we do not use bioabsorbable stents at this time. I have attended a number of national and international meetings where live cases were shown and the available data on these stents were discussed.
	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	At this time, bioabsorbable stents are generally not used in the UK outside research studies. Only cardiologists implant stents in coronary arteries.

	procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I am an active researcher in the field of interventional cardiology but I have not published on bioabsorbable stents. At our centre we have reviewed this technology at our educational meetings and I am familiar with the literature.
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):	Bioabsorbable stents were used in the UK but Abbott withdrew their bioabsorbable stent from the market in 2017. They are rarely used now. In my view this technology is novel and of uncertain safety and efficiency.
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?	There are theoretical advantages of dealing with coronary artery disease without leaving a metal stent in the artery. The low complication rates and high efficacy of regular drug eluting stent technology means that bioabsorbable stents are likely to be an additional treatment option if clinical studies show them to be safe and effective.

Current management

5	Please describe the current standard of care that is used in the NHS.	Drug eluting stents are the current standard of care when patients undergo PCI.

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?	No

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?	No metal left in coronary arteries after PCI. Less need for long term antiplatelet therapy. Restoration of vessel physiology and geometry. Most important potential benefit is reduced long term clinical events (yet to be demonstrated in a clinical trial)
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Perhaps young patients who may require decades of antiplatelet therapy. Also patients who may require multiple stents.
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?	Very unlikely
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)	Unlikely to affect the care pathway as a whole.
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)?	Bioabsorble stents likely to cost more than regular stents and may require other equipment (eg intravascular imaging catheters)
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	A small amount of training for interventional cardiologists.

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	Bioabsorbable stents are less easy to implant than conventional drug eluting stents. Main hazard with this technology has been early stent thrombosis which has been shown to be more common with bioabsorbable stents. We did see this when they were used in our centre. A toxic effect of the absorbable stent on human arteries cannot be excluded. All PCI procedures carry the risk of cardiac death, myocardial infarction and target vessel revascularisation.
15	Please list the key efficacy outcomes for this procedure/technology?	Early efficacy – procedural success, relief of angina Early safety – cardiac death, myocardial infarction and target vessel revascularisation. Also stent thrombosis Long term (and very long term) clinical events – death , myocardial infarction, repeat revascularisation, ability to reduce antiplatelet therapy.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Early complication rates (particularly stent thrombosis) when used outside clinical trials. Real life experience did not match findings from clinical trials. Effectiveness in dealing with coronary artery disease.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Whether there is any long term measurable benefit of having no metal in the artery after PCI (ie clinical outcomes of absorbable stents vs regular drug eluting stents)

18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	If shown to be safe and effective then bioabsorbable stents could be used in the 95 or so hospitals in the UK where PCI is undertaken.

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.	Biosolve 4 registry, Cath and Cardiovasc intervention 2021 OPTIMIZE study, JACC Int, 2021 DeSolve stent, Nef et al, Cath and Cardiovasc intervention 2018
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Yes

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)?	Perhaps 10% of elective PCI cases

22	Are there any issues with the usability or practical aspects of the procedure/technology?	Previous bioabsorbable stents were more difficult to implant than regular drug eluting stents
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 of bioabsorbable stents
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	The main theoretical advantage of bioabsorbable stents is the lack of metal left in the vessel in the long term (compared with regular drug eluting stents). It would be helpful to have data showing long term clinical benefit (cardiac death, myocardial infarction, further revascularisation, relief of angina and quality of life)
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: Procedural success, freedom from angina, use of anti-anginal medication and quality of life. Ability to reduce antiplatelet therapy Freedom from clinical events (cardiac death, MI, repeat revasc). Periprocedural, 30 days, 1 year and very long term. Adverse outcome measures: Cardiac death, periprocedural and early myocardial infarction, target vessel revascularisation. Stent thrombosis (30 days, 1 year and long term)

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Appropriate and informed patient consent is essential. Probably best that patients are given standardised written information prior to the procedure.

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Print name:	**Dr Gerald Clesham**
Dated:	**4th Nov 2021**