NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1557 Vertebral body tethering for idiopathic scoliosis in children and young people**

Your information

Name:	Ashley Cole
Job title:	Consultant Orthopaedic Spinal Surgeon
Organisation:	Sheffield Children's Hopsital
Email address:	
Professional organisation or society membership/affiliation:	British Scoliosis Society - President
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 3561465

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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	I am familiar with vertebral body tethering having read the literature and followed with interest. I look after patients who have had this surgery performed in Turkey, Germany and US. I was Chair of the NHSE Spinal Services Clinical Reference Group and co-authored the vertebral body tethering policy: https://www.england.nhs.uk/commissioning/publication/vertebral-body-tethering-for-scoliosis-age-8-18-years/ I have never observed or done a VBT although I have seen a recording of the procedure. It is currently being done privately in one NHS Trust and I believe 2 NHS Trusts are doing 'trials' on it on NHS patients. Speed of NHS uptake would be rapid although NHSE would need to change its commissioning policy. No other specialities would do this procedure. No

	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 have done bibliographic research on this procedure. With NHSE – see above I have done research on this procedure in laboratory settings (e.g. device-related research). No I have done clinical research on this procedure involving patients or healthy volunteers. No I have published this research. No I have had no involvement in research on this procedure. Yes 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 concept and design but uses an old approach to the spine (anterior) compared with the more conventional posterior approach Established practice and no longer new. No A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. No Definitely novel and of uncertain safety and efficacy. Yes The first in a new class of procedure. Yes
4	Does this procedure/technology have the potential to replace current standard care or	Additional to current fusion procedure

	would it be used as an addition to existing standard care?	

Current management

5	Please describe the current standard of care that is used in the NHS.	The procedure is aimed at patients with idiopathic scoliosis which is the largest group and current standard of care is a brace for patients with curves 20-40 degrees. There is Class 1 evidence that bracing is effective. For curves greater than 50 degrees, patients are offered an instrumented spinal fusion which partially corrects the curve and prevents worsening. This is usually performed from a posterior approach.
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?	Apifix is another non-fusion technology to correct scoliosis. This implant is inserted posteriorly and works the principle of the patient side bending and extending the rod on the concave side of the curve.

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?	Improved flexibility of the thoracic spine which may reduce the risk of degenerative change in the lumbar spine as the patient gets older.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Adolescent Idiopathic Scoliosis with curves 40-60 degrees who have remaining growth potential
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?	It will change the pathway of care. Whether it will benefit the healthcare system, I am unsure.
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)	Likely to cost more
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)?	Cost more
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Surgeon needs to be very familiar with anterior spinal surgery and how to deal with complications which might arise.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Surgeons must be trained properly to do this. There will be a learning curve.

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	Seems to have a high revision surgery rate
15	Please list the key efficacy outcomes for this procedure/technology?	SAE/AEs Thoracic spine movement Long-term outcome including quality of life
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Possible high revision rate Learning curve for surgeon
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes, this is a controversial area
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK.

		I think it will end up being done in 5-15 hospitals in the UK dependent on final indications. The narrower the indications, the fewer patients who will get it and the fewer number of centres required.

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.	No UK scoliosis conferences recently and this procedure is not being done in large numbers in the UK. We are all watching the FDA trial : https://pubmed.ncbi.nlm.nih.gov/34185722/
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	US FDA trial (see above)

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)?	Previously estimated 80 per year for the NHSE Policy

22	Are there any issues with the usability or practical aspects of the procedure/technology?	No
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?	It has a learning curve and the number of cases are small. It would be better being done in fewer centres
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	I think we need a UK trial with appropriate indications respecting the effectiveness of bracing and with outcomes important to patients
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: Increased thoracic movement – difficult to measure Improved patient quality of life – SRS-22 questionnaire is most accepted Adverse outcome measures: VBT has problems with cord failure and the higher risks associated with anterior surgery

Further comments

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

NICE National Institute for Health and Care Excellence

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
Non-financial professional	Past Chair of NHSE Spinal Services CRG and co-author of previous VBT policy	**2013**	**2019**
Non-financial personal	Shareholder in an Orthopaedic Group. NHS Spinal Surgery performed all non-specialised	**2004**	
Non-financial personal	Shareholder in private Neurological Rehabilitation Company.	**2015**	

☒ 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.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Ashley Cole**
Dated:	**21/10/21**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1557 Vertebral body tethering for idiopathic scoliosis in children and young people**

Your information

Name:	Julian Leong
Job title:	Consultant Spinal Surgeon
Organisation:	Royal National Orthopaedic Hospital
Email address:	
Professional organisation or society membership/affiliation:	General Medical Council
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4743958

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 am running a clinical trial for VBT. I have used it over 15 times. The Trial is ongoing. Not currently available on the NHS Not that I am aware of As above

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):	It is a novel approach, concept and design 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. (although internationally over 500 cases have been performed)** 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?	Yes, potentially replace current standard of care for certain select cases

Current management

5	Please describe the current standard of care that is used in the NHS.	Spinal fusion
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?	Avoiding Fusion. Minimal activity restrictions after operation. Smaller wounds.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Growing children who failed bracing. Very sporty children.
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. Less invasive treatment, potentially improved functional outcome. Potential less future surgery as adult (not proven)
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)	
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)?	
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Specialist centres for scoliosis, and support for thoracoscopic or mini-thoracotomy approach.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training in thoracoscopic or mini-thoracotomy approach. Training for using and indications for using the implants.

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	Revision surgery 10-20% Aorta injury, lung injury, nerve injury. (rare) Chest infection.
15	Please list the key efficacy outcomes for this procedure/technology?	Prevention of progression of scoliosis, correction of curve, avoidance of fusion
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No long-term outcome
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	High revision rate – likely due to poor patient selection.
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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	I currently run a VBT trial

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 100
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Need training for Mini open or MIS approach. Need training for using the implant. Double lumen intubation (for the anaesthetists) to deflate one lung.

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?	Commissioning. Need to define the best patient group to have this operation.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Clinical trial. There are completed international trials.
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: PROMS – SRS 22r, sport activity questionnaire (up to 2 years) Xray measures (up to 2 years) Avoidance of fusion (past skeletal maturity) Adverse outcome measures: Complications Revision surgery Fusion surgery

Further comments

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

NICE National Institute for Health and Care Excellence

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
Non-financial professional	Commercially funded VBT trial	**2020**	**On going**
Non-financial professional	Consultancy for another implant company	**2021**	**On going**
Non-financial professional	**Council member for the British Scoliosis Research Foundation**	**Ongoing**	

☒ 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.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Julian Leong**
Dated:	**21/10/2021**