NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP148/2 Extra-corporeal shockwave lithotripsy for calcific tendonitis (teninopathy) of the shoulder**

Your information

Name:	Prof. Patrick Wheeler
Job title:	Consultant, Sport and Exercise Medicine / Honorary Clinical Professor
Organisation:	University Hospitals of Leicester NHS Trust and Loughborough University
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Honorary positions within Faculty of Sport & Exercise Medicine (FSEM), British Association of Sport & Exercise Medicine (BASEM)
Nominated/ratified by (if applicable):	Introduced by Prof. Kevin Harris
Registration number (e.g. GMC, NMC, HCPC)	GMC 4510972

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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:

I give consent for my name, profile to be published on the NICE website. However I do not give consent for my email address (italics above) to be published in any public format.

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?	Very familiar with the technology, although far less experienced with the technology for this tendon location than for other tendons. I am currently the principal investigator for a multi-arm shockwave intervention study which has recruited >430 patients to date across different tendon locations, and performed case series analysis of another 300 patients. Numbers of patients with specific rotator cuff tendinopathy are low compared to other tendon locations.
	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 aware that there is currently very limited availability of this technology within the NHS in this region, although aware that this is available with other clinicians privately in a range of healthcare settings. I do not know the national picture of availability and suspect that this is variable. Does data exist from NHSE/I that can answer this question? This is performed by clinicians in specialities of sport & exercise medicine (SEM), rheumatology, and orthopaedics. Also performed by physiotherapists.

	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. 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):	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?	It may have use as an adjunct, possibly after other treatments including rehabilitation has been tried. It may be best situated at the time corticosteroid injections are considered, &/or before surgical considerations.

Current management

5	Please describe the current standard of care that is used in the NHS.	Patchy and variable. There are a range of different options available for this condition including time, painkillers, different (corticosteroid) injection techniques, and surgery.
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?	(as above) A wide range of different treatments are available, but there are probably considerable variations in clinical pathways between centres.

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?	Reduction in pain / improvement in function. This treatment may be effective in improving symptoms without the need for needle intervention procedures or surgical intervention which may otherwise have been the only treatments that may have been of help.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those not stable enough for surgery due to other medical problems
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?	Potential reduction of surgery numbers, thereby reduction in surgical waiting lists / surgical pressures. Has the potential to therefore improve time to treatment depending on how services are developed / commissioned
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)	Presumed significant reductions in cost to healthcare economy compared to surgical intervention, although health economic analysis may be required to assess this formally.
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)?	There will be capital costs from purchase of relevant machine, training costs, time cost to deliver the treatment and follow-up adequately It may be assumed that as with many things if this is done more often this may be done more effectively – however data would be needed to formally assess this. If this is indeed true, this may be a more suitable procedure for local / regional centres.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Patients will presumably have had/required to have imaging prior to treatment – this is routinely done currently

		Will need appropriate outpatient clinic space in which this can be offered – most routine outpatient rooms should be large enough
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. Training in the use of the specific machine to be used – different machines are set up differently.

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	Low harm – pain, bruising, skin irritation Very low frequency – possible risk of injury to tendon – this *may* be greater risk in focal versus radial shockwave, (but I do not know if this is proven by evidence – seemed to be greater anecdotally?)
15	Please list the key efficacy outcomes for this procedure/technology?	Pain, local function, global well-being, activity / employment return, (see Q25)
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	How well it works. Do any features predict success? What specific features would predict / mitigate risk? How are appropriate patients identified and referred through to an appropriate service at an appropriate time?

17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	There are two types of shockwave therapy, radial and focal (although some machines generate both at the same time). There are some differences between these energy wave-forms. There may be differences between outcomes from these two overlapping treatments, which may need to be considered in this guidance. The guidance needs to be clear if this is purely focussed on the calcific form of rotator cuff tendinopathy, or of this should be broadened to include non-calcific tendinopathy, partial tears, and other rotator cuff tendinopathy.
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.	Recent work includes: Mai Ahmed Abo Al-Khair, Radwa Mostafa El Khouly, Sameh Ahmed Khodair, Mervat Abd Al Sattar Elsergany, Mervat Ismail Hussein & Mohamed Ezz Eldin Mowafy (2021) Focused, radial and combined shock wave therapy in treatment of calcific shoulder tendinopathy, The Physician and Sportsmedicine, 49:4, 480-487, DOI: 10.1080/00913847.2020.1856633

20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	I am peripherally aware of the “ASSERT” database although I am sure whether this is running currently

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)?	Do not know
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Availability, service planning, commissioning, Issues with follow-up consideration, particularly if longer-term follow-up is needed
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?	Capital cost for machine & any servicing and replacement costs. Knowledge / expertise. Belief / certainty of its efficacy in this patient group
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Predictors of outcome Comparisons between different machines / techniques – for example, is one machine superior to another, or are all machines the same. There is at least one (relatively small) study that suggests a combination of radial and focal shockwave may be better than either one on its own (Abo Al-Khair, 2021) Further comparisons against other treatment options Specific treatment regimes – numbers of treatment sessions / treatment protocol
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe:	Beneficial outcome measures:

	− 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:	Typically outcome measures have included measurements of pain, although this has not always been done with validated measures. Suggest validated patient reported measures (PROMS) of some/all of the following: Shoulder pain / function – various questionnaires exist, a relatively easy one is the DASH questionnaire, but alternatives exist Global function – various questionnaires exist eg. EQ-5D-5L or SF-36 Musculoskeletal function – MSK-HQ Mood state – PHQ-9 / GAD-7 or HADS Return to work, return to activity rates Longer-term follow-up is always encouraged, but practically is very difficult to achieve without resourcing this, as there are costs / inconvenience to both patients and healthcare services in routine longer-term follow-up of patients who are doing well. Adverse outcome measures: Pain Tendon injury Rates of further intervention –what further treatments are required, and did they work?

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	As highlighted above, I am involved in ongoing NHS intervention research using ESWT current for a range of different tendon conditions (current recruited >420 patients to DB-RCTs for ESWT in chronic tendinopathy), although my experience / expertise with this treatment modality if much more for other tendon conditions than rotator cuff.

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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.	I have no specific conflicts of interest to declare		
Choose an item.			
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.

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

Print name:	**Patrick Wheeler**
Dated:	**4th Feb 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP148/2 Extra-corporeal shockwave lithotripsy for calcific tendonitis (teninopathy) of the shoulder**

Your information

Name:	Stephen Gwilym
Job title:	Consultant shoulder surgeon and associate professor in Orthopaedics
Organisation:	Univeristy of Oxford
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC, British Elbow and Shoulder Society, British Orthopaedic Association
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4724821

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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 have undergone training in the procedure and performed a handful of cases on calcific tendonitis myself, and referred to others to perform.
	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	Yes – used in the past Less common in NHS than private practice due to relatively labour intensive delivery method. Orthopaedic surgeons Sports physicians Physiotherapists

	procedure/technology, please indicate your experience with it.	Patient selection and referral; Variable results which may reflect heterogeneity in patient disease
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	. 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):	Established practice and no longer new.
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?	If effective, it may replace current standard of care procedures (barbotage, steroids, surgical debridement)

Current management

5	Please describe the current standard of care that is used in the NHS.	Ultrasound guided barbotage, steroids or surgical debridement

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?	Pain relief without invasive procedure
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Needle-phobic patients
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?	Potentially less invasive treatment
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?	Machine and probe (roughly size of a microwave in total) Consultation room / treatment area

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes – there are training requirements as the location and 'dose' of the interventions are left to clinical discretion.

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	Painful to administer
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction in pain Improved function Reduction in calcium deposit size on xray
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	There is a wide range of treatment variables (dose, duration, frequency, location)
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	There is a wide range of treatment variables (dose, duration, frequency, location)
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.

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.	Nil
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	As listed on clinicaltrials.gov

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)?	I am unable to estimate this
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Requires frequent administration ie: every week for 4 or 5 weeks, probably 30 mins appointment.
23	Are you aware of any issues which would prevent (or have prevented) this	nil

	procedure/technology being adopted in your organisation or across the wider NHS?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Research to address the uncertainties highlighted above (dose, frequency, location) and whether this can be administered by any trained technician with good efficacy
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 – Pain and function Xray measurements Adverse outcome measures: Pain

Further comments

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

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Declarations of interests

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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:	**Click here to enter text. Stephen Gwilym**
Dated:	**31.1.22**

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Professional Expert Questionnaire

Technology/Procedure name & indication: **Extra Corporeal Shockwave Therapy of Calcific Tendinitis**

Your information

Name:	Mr David Kevin Jones
Job title:	Specialist Shockwave Practitioner & Researcher
Organisation:	Impact Medical Ltd & University of Chester
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Society Of Radiographers (SOR)
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	RA32320

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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?	I was responsible for introducing ESWT into the UK back in 1996. I have Storz SLX, Storz Minilith SL1, Piezowave 100, Piezowave 300, Piezolith 3000, Raver radial device, Piezowave, Piezowave 2 over a 25 year period devoted purely to shockwave devices and their use. I have developed treatment protocols, I am a Richard Wolf approved engineer. I teach with BAUS and have delivered lectures in Russia, Austria, Germany and UK. I have worked with UK Olympic team, Celtic FC, Warrington Wolves, English National Ballet and Godolphin stables, to name a few. I am a BAUS (British Association of Urological Surgeons) trainer on North West stone Course and finishing my first year as a part time PhD student investigating effect of shockwave frequency and voltage ramping on novel biomarkers and clinical outcomes during Lithotripsy . I have taught Physiotherapists, Osteopaths, Chiropracters and orthopaedic surgeons on clinical and theoretical ESWT.
	– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	As evidence becomes more available with increased studies, there appears to be greater understanding of the role of ESWT in the NHS. There has been a lack of true understanding of the modes of mechanism and varying technology. It is now become far better accepted.
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	Tends to be within a specialists own field. I am lucky to have been a dedicated practitioner in all fields of Urology, Orthopaedics, Sports medicine, Vascular wound healing, Andrology etc.
	– If your specialty is involved in patient selection or referral to another specialty for this	Orthopaedic cases may be referred to Rheumatologists and vice versa. Orthopods may refer to physios and the same revers pathway.

	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. YES I have done research on this procedure in laboratory settings (e.g. device-related research). YES I have done clinical research on this procedure involving patients or healthy volunteers. YES I have published this research. YES Other (please comment) I have performed >22,000 patient cases since 1996 and been technical advisor for various peer reviewed publications.
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):	Orthopaedics has become mainstream by now but there is still little understanding of the pros and cons of focussed versus radial technology. The novel aspect is the design of Linear technology used by the Piezowave 2. This is pretty novel in adopting 5 energy zones combined into one giving an F2 area of 46mm X 18mm x 4mm versus other conical transducers such as the F10G4 manufactured by Richard Wolf. Wound Healing, CPPS, EDSWT indications for Erectile Dysfunction are still relatively new but I have been doing this work for about 12 years. 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	I would consider this treatment to be an addition to standard care but believe it's use should be 1st line versus it's use for purely recalcitrant presentations.

	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.	Physical therapy and steroid seems to be mainstream, but clinicians are seeing the strength in the medium to long term benefits to shockwave versus steroid with lesser side effects.
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?	Compression therapy. Laser Radial technology but it is limited. Again, cost of treating patients is key with good efficacy. The devices and methods described amy be cheaper but there is a trade off against efficacy. Accuracy of focussed ESWT is key advantage.

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?	Minimally invasive procedure allowing patients to carry on working. Lees invasive than other treatments. Linear technology has benefits with larger structures such as Achilles Tendinosis. No GA. No Local anaesthetic. There is also a misunderstanding within clinicians that focussed shockwave is for deep tissue only compared to radial pressure which is superficial. The fact is that focussed technology can have depth adjustment from superficial to deep and a whole range of energy output. I have read guidelines and literature who just don't understand the technology well enough.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	All adult patients in orthopaedics. Diabetic patients for wound healing. CPPS for prostate pain is difficult to treat. Patients who are not suitable for surgery and not able to take PDE5 inhibitors such as Viagra in Erectile dysfunction. Also shockwaves are used for spastic conditions of muscles for release.
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, in Hypertrophic non or delayed union, the patients would have 1 treatment session against GA, Graft and months of recovery. Tendinopathies means that patients would be discharged quicker and reduce waiting times versus other management such as steroid or release procedures. ESWT should reduce the follow up process, be more efficacious than steroid and be easily accessible at GP level and outpatient clinics.
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)	Some hospitals would rent or hire a mobile unit to attend. This saves capital outlay, servicing, training, sickness etc. In the long term a hospital purchasing it's own ESWT unit would be operated by Physiotherapists. Initial costs would be more, but higher efficacy would mean that more patients would be treated per year and managed safer than surgery or repeated steroid injections, which are limited.
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)?	The cost of repeated procedures, waiting times, eventual Surgical intervention means that ESWT is ideal for treating nearly all resistant tendinopathy patients. Some patients are seen for years before discharge whereas ESWT would limit this to 3-6 months.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Non. Clinic rooms with stretcher/trolley is all that are needed. They are mobile on wheels therefore can be transportable.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, Usually a clinician / practitioner would spend 2 /3 sessions with me until they are happy to proceed. Good online support and teaching aids help develop competency.

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	Petechiae. Rupture. Haematoma. Again, petechae in focussed is extremely rare whereas radial is a common finding on patients. Haematoma is rare but possible. Patient self-medication home therapies can have an effect. Rupture always possible with tendons under stress, such as Achilles. One cannot exclude natural degenerative pathological ruptures or history of steroid injections prior to ESWT
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction of pain, improved movement, less myofascial referred trigger point pain, resolved calcification due to dissolution, improved blood flow and angiogenesis for new tendon growth.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Use of correct treatment protocol in terms of dose. Accuracy of localisation and patient positioning, lack of practitioner experience, proper check of contraindications. Patient compliance post ESWT regarding activity.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Often, Focssed technology is deemed as for deep tissue therapy and radial for superficial. Focussed technology can do both and is more accurate. Repetition rate up to 20 shocks per second is a concern due to lack of evidence on efficacy of treatment at this high rate, especially if shockwaves not accurately localised first. Radial is not a true shockwave 33m/s as it does not

		travel past mach1. True shockwave devices do transmit energy greater than 331 m/s or 768mph at sea level at 20oC.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Very safe in the right hands. 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.	Due to COVID over past 15 months there has been little in terms of conferences as they have been cancelled. I am member of the ISMST and know that this year's conference is not until November, unless it's cancelled again. I have personally given talks for hospital consultants and registrars at journal club meetings but nothing official on the conference tour as yet since about 2 years.
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)?	I practice personally at 3 hospitals with a total of 40 per month.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Training takes approx. one day with follow up training to check competency. Understanding the indications and contraindications, post ESWT physical therapy and advice in event of post ESWT complications or regular side effects such as an acute inflammatory flare up.
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?	Steroid injections still seems to be used and very much consultant led. Lack of understanding means that ESWT is not adopted as much as it should. Instead of being used for recalcitrant cases following failed steroid or physiotherapy, ESWT should be 1st line of treatment due to low complication risk.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Compare radial versus focussed technology. More studies comparing ESWT to steroid in short, mid and long term. I trained physios at Robert Jones & Agnes Hunt in trial comparing both ESWT and steroid in Trochanteric pain syndrome. ESWT outcomes were far superior in long term especially.
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	Beneficial outcome measures: All tendinopathies should not be assessed until 12 weeks after 1st ESWT session. 3 sessions given. Shoulder should be assessed for range of movement, pain, function and strength plus radiographic evidence to test dissolution for tendinosis calcarean patients. Adverse outcome measures: Check for no pain improvement, ruptures, reduced range of movement & referred pain.

	these should be measured: 3,6,12 months	

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Having been a Storz and Richard Wolf approved engineer plus guest lecturer for under and post graduate students, then I have an insight into technology and physics of shockwaves. I believe that I was one, if not the first dedicated practitioner of ESWT in the UK back in 1997 having trained all grades of staff in NHS and private. Currently I have treated 22,000 patients in past 25 years. Being a PhD student also makes me appreciate literature and the quality of data produced. I often use PRISMA tool to check for biases. My own area of specialism in my PhD is in novel biomarkers and their evaluation when altering shockwave repetition rates and also inducing the priming phenomena. A comparison with standard practice will be made. I am also a qualified HE/FE lecturer and also a qualified electronics engineer and ultrasonographer /shockwave specialist radiographer. I'm a qualified medical technology regulator approved by BSI. Practically, I manage patients who require ESWL & ESWT across the UK and understand the various methods in managing patients and their conditions. I often get involved with pathway development within departments and advice when requested. Having such broad experience of working across the UK, Sweden, Germany and Israel has helped broaden my own knowledge in shockwave applications and technology. I am involved within very specialised fields of diabetic wound care, Elite sports, Urology, Orthopaedics, ENT and Andrology.

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
Direct - financial	Shareholder of Impact Medical Ltd & distributor of Richard Wolf lithotripters	**2001**	**-**
Choose an item.			
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.

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

Print name:	**David Kevin Jones**
Dated:	**13/7/21**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP148/2 Extra-corporeal shockwave lithotripsy for calcific tendonitis (teninopathy) of the shoulder**

Your information

Name:	Nick Aresti
Job title:	Consultant Orthopaedic Surgeon and Vice Chair of BOA Orthopaedic Committee
Organisation:	Barts Health / BOA
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Click here to enter text.
Nominated/ratified by (if applicable):	British Orthopaedic Association
Registration number (e.g. GMC, NMC, HCPC)	7021132

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 an Orthopaedic surgeon who specialises in disorders of the upper extremity. Calcific tendonitis of the shoulder is a relatively common complaint I deal with and I do so both operatively and using non operative treatment modalities. ECSWT is a modality of treatment I do not personally use in my practice but I have referred people for it in the past, particularly when an SpR. It is a known treatment option although it is not particularly commonly used. Shock wave therapy is used in other specialities, for example in urology. As the vice chair of the BOA Orthopaedic committee, I would offer support on behalf of the BOA and its members.

	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. 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 non invasive modality and so if found to be beneficial would offer advantage over operative means. 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	I think if it were to do so, it would have already happened. This may offer a non invasive alternative in my mind, but is unlikely to show benefit over surgery in the severe cases.

	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.	Non operative treatment with analgesia and physiotherapy and in cases which fail this, arthroscopic surgery.
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?	None

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?	The greatest benefit is the fact that it is non invasive and therefore does not offer a risk
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those who are in considerable pain who either do not want surgery or can not have it
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 would potentially offer less invasive treatment for some patients who later have surgery
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)	It is likely to cost less than surgery but further evaluation needs to be given to the number of people who do avoid surgery and the number of patients who do have it but still need surgery later. It may be that if the latter number is high, it proves to not be cost effective.
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)?	Less than surgery, more than analgesia.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	A machine needs to be purchased and a nurse / technicians employed to use it. The admin staff would also need to be provided.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	I would have thought it would not be particularly onerous.

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	Side effects from ESWT are limited to mild bruising, swelling, pain, numbness or tingling in the treated area, and the recovery is minimal compared with that of surgical intervention.
15	Please list the key efficacy outcomes for this procedure/technology?	Improved pain and function
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	It's efficacy and cost effectiveness compared to surgery
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not particularly
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.	No recent literature
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	No

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)?	In my practice, approximately 10 – 15 people per year. It is worth noting that the machine can be used for other UL problems such as tennis elbow.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	None that I am aware of

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 effectiveness
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	None that are not already outlines
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: Shoulder function scores, such as the Oxford shoulder score, the Constant score. The Versus Arthritis MSK score, VAS pain score Adverse outcome measures: None that I can think of

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	None

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Choose an item.			
Choose an item.			

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

Print name:	**Click here to enter text.Nick A. Aresti**
Dated:	**Click here to enter text.11/2/22**