

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

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Professional organisation or society membership/affiliation:	<input type="text" value="British Society of Interventional Radiology (BSIR)"/>
Nominated/ratified by (if applicable):	<input type="text" value="Click here to enter text."/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="GMC: 7037062"/>

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X 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:



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.

<p>1</p>	<p>Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"> - 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? 	<p>I have extensive experience of performing genicular artery embolization (GAE). I am PI for the Geniculate artEry embolisatioN in patiEnts with oSteoarthrItis of the knee (GENESIS) study, the first European prospective study investigating the role of genicular artery embolization (GAE) in the treatment of patients with knee osteoarthritis (OA) (https://doi.org/10.1186/ISRCTN18266598). The study has closed for recruitment, and the interim analysis has been published (1).</p> <p>GAE is not a new procedure. It has been performed for many years to treat patients with haemarthrosis of the knee joint. Many interventional radiologists throughout the country will have experience of GAE for this indication. There are many causes of haemarthrosis, but the two most commonly encountered are following knee replacement surgery, or in patients with haemophillia. In fact GAE is included in the UK Guidelines for the management of joint bleeds in patients with haemophillia(2).</p> <p>The first peer-reviewed publication on GAE for patients with knee OA was published in 2015(3). The procedure is performed by an interventional radiologist, and is the same technical procedure as that already used for patients with haemarthrosis of the knee. However, instead of embolising the hypervascular synovium that is causing bleeding, GAE for OA targets the hypervascular synovial process that has been shown to contribute to structural damage and pain in OA(4).</p> <p>Unfortunately, patients with mild to moderate knee OA resistant to conservative treatments (e.g. analgesia, physiotherapy, intra-articular steroid injections, education programs, weight-loss, and</p>
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	<ul style="list-style-type: none"> - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. 	<p>anti-inflammatory preparations) who are not candidates for knee replacement surgery pose a significant management challenge. Given the large number of patients with mild to moderate knee OA, GAE has the potential to offer hope to a patient population that have limited options.</p>
2	<ul style="list-style-type: none"> - Please indicate your research experience relating to this procedure (please choose one or more if relevant): 	<p>I am PI for the GENESIS study, and first and corresponding author for the interim analysis of this project (1).</p>
3	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>GAE for knee OA is a new indication for an established technique.</p>
4	<p>Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?</p>	<p>GAE has the potential to offer a new treatment to patients with mild to moderate knee OA who have failed conservative treatments (e.g. analgesia, physiotherapy, intra-articular steroid injections, education programs, weight-loss, and anti-inflammatory preparations) but who are not yet suitable for joint replacement surgery.</p>

Current management

<p>5 Please describe the current standard of care that is used in the NHS.</p>	<p>The number of patients with knee OA is vast. Many will self-medicate with analgesia, or over the counter medications at home. With persistent symptoms of pain, reduction in function and decreasing quality of life, patients will then present to their general practitioner (GP). GPs may advise alternative analgesia, physiotherapy, intra-articular steroid injections, education programs, weight-loss, or anti-inflammatory preparations. If symptoms persist, or radiological features on x-ray deteriorate, patients will be referred to an orthopaedic surgeon for further management. The orthopaedic surgeon may arrange specialist imaging in the form of an MRI scan to further evaluate the OA disease. Based on patient's presentation, symptoms, and imaging, a management plan will be devised. This may involve further conservative treatments, and the addition of injections such as steroids or platelet-rich plasma (PRP). Patients may even undergo arthroscopy to gain symptomatic relief. Joint replacement surgery is generally reserved for patients with severe joint disease, pain and functional limitation(5). Many patients with mild to moderate knee OA will have persistent symptoms despite the treatments described. It is these patients that may benefit from GAE.</p>
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<p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p>	<p>No, GAE fits into a unique treatment space. It is offered to patients with mild to moderate knee OA that have failed conservative therapies, but do not warrant joint replacement surgery.</p>
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Potential patient benefits and impact on the health system

7	<p>What do you consider to be the potential benefits to patients from using this procedure/technology?</p>	<p>GAE for knee OA is performed as a day case procedure. Under x-ray guidance, tiny wires and catheters are navigated into the small genicular arteries from the artery in the groin. The entire procedure takes approximately 40minutes. Patients are awake throughout, and go home a few hours afterward the procedure. From patient engagement analysis we have performed, patients were in favour of GAE as a procedure for their OA(1). The potential benefits are a reduction in pain, improvement in function and quality of life. This in turn has the potential to reduce reliance on analgesia, particularly opiate medications, which has been highlighted as having a number of detrimental impacts in patients with chronic pain. Furthermore, the specific patient group that GAE targets are challenging to treat, often utilising repeat NHS clinic appointments, and NHS services in pursuit of a therapy to improve their pain; GAE therefore has the potential to improve patients' psychological health and wellbeing as they exit a cycle of chronic pain.</p>
8	<p>Are there any groups of patients who would particularly benefit from using this procedure/technology?</p>	<p>Patients with mild to moderate knee OA that have failed conservative therapies, but do not warrant joint replacement surgery.</p>
9	<p>Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?</p> <p>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?</p>	<p>GAE has the potential to change the current management pathway for patients with mild to moderate knee OA. Currently, patients who fail conservative treatments, but do not have severe enough disease to warrant joint replacement surgery, have no established treatment options. As a result, they may frequently attend orthopaedic clinics or GPs. This places additional strain on the healthcare system as their treatment need cannot be met with the currently available therapies. If GAE were to be offered to these patients, it has the potential to dramatically reduce the number of GP/outpatient appointments attended, reduce reliance on analgesia, and facilitate a return to activities of daily living. Aside from the direct health economic benefits to the NHS, improving this patient groups symptoms may also enable a return to employment, benefiting the economy, the individual, and society as a whole.</p>
10 - MTEP	<p>Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the</p>	<p>GAE will cost considerably less than the current system of these patients having an unmet care need, being managed for chronic pain. GAE is performed as a day case procedure in interventional radiology. GAE uses standard embolization equipment, found in all</p>

	procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	interventional radiology departments, and as such no specialist equipment is required to perform the procedure.
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 is no standard of care for patients with mild to moderate knee OA failing conservative treatment. As a result, these patients place a large demand on the NHS and other auxiliary support services, as they transition into chronic pain. Offering GAE to these patients has the potential for significant cost savings. The staffing, and equipment required for GAE are currently available in interventional radiology units in the UK.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	GAE for OA can be performed in interventional radiology departments in the UK with expertise in embolization.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Whilst GAE for haemarthrosis is performed by interventional radiologists in the NHS, GAE for OA is not widely practiced. Centres wishing to perform GAE for OA will need to have experience of embolization with microcatheters, will require specific training, and should have a proctor for the first few cases.

Safety and efficacy of the procedure/technology

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p>	<p>As with any angiographic procedure, there are the risks associated with an arterial puncture (bleeding, infection, pain, vessel injury, nerve injury). The most common complication from GAE is skin discoloration over the area embolised as a result of non-target embolization to the overlying skin. In a recent systematic review of GAE, the complications from the studies reviewed revealed the following adverse events (6)</p> <ul style="list-style-type: none"> • Minor adverse events such as erythema in the region of embolization (21/186, 11%), • Puncture-site hematoma (18/186, 10%), • Paraesthesia (2/186, 1%)
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	Anecdotal adverse events (known from experience) Theoretical adverse events	<ul style="list-style-type: none"> Fever (1/186, 0.5%) <p>In our own experience (1), we had 12% of patients with a small patch of skin discolouration over the embolised territory. All cases resolved to normal within two weeks without specific treatment.</p>
15	Please list the key efficacy outcomes for this procedure/technology?	The Western Ontario and McMaster University Osteoarthritis Index score (WOMAC) and Knee Injury and Osteoarthritis Outcome Score (KOOS) are the two patient-reported scoring systems used in the GAE literature. These are validated questionnaires designed to quantify the severity of OA symptoms. They are used throughout the orthopaedic literature to assess symptom change to treatments for knee OA such as total knee replacement surgery(7).
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	GAE for OA remains a new indication. There is emerging literature, that reveals a good safety profile. There is potential efficacy in cohort studies at early follow up, however there is a lack of controlled data. There is a sham RCT that is complete and currently under peer-review. The results of this study were presented at the Society of Interventional Radiology, USA 2020 (8).
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The data on GAE for OA is limited at present. There is a need for controlled studies to establish efficacy.
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).	Provided as a separate attachment
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	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.	<ol style="list-style-type: none"> 1. The GENESIS study will continue to follow patients to 2-years. 2. There is a cohort study led by Sid Padia (USA) that is complete and awaiting publication. The results were presented at SIR 2020(8) 3. There is a sham RCT study led by Ari Isaacson (USA) that is complete and awaiting publication. The results were presented at SIR 2020 (8)

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)?	An estimated 50,000
22	Are there any issues with the usability or practical aspects of the procedure/technology?	There is a learning curve when performing GAE for knee OA, so training and supervision for the first few cases would be good practice.

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?	Not to my knowledge
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Controlled studies are required to confirm efficacy. A UK-wide registry of GAE for mild to moderate knee OA would be useful to capture real world prospective data.
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - 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: 	<p>Beneficial outcome measures:</p> <p>KOOS/WOMAC/Visual analogue scores pre and at 4 weeks, 6months, 1 year post GAE. These outcome measures will assess efficacy of the technique.</p> <p>MRI imaging of the treated knee pre and at 6-month follow up to assess radiological response to GAE and any complications.</p> <p>Adverse outcome measures:</p> <p>Skin non-target embolization is the most common early complication. Patients could be contacted within the first two weeks to record the incidence of this complication.</p>

Further comments

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

1. Little MW, Gibson M, Briggs J, Speirs A, Yoong P, Ariyanayagam T, et al. Genicular artery embolization in patients with osteoarthritis of the Knee (GENESIS) Using Permanent Microspheres: Interim Analysis. *Cardiovasc Intervent Radiol*. 2021 Jan 20;
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3. Okuno Y, Korchi AM, Shinjo T, Kato S. Transcatheter arterial embolization as a treatment for medial knee pain in patients with mild to moderate osteoarthritis. *Cardiovasc Intervent Radiol*. 2015 Apr;38(2):336–43.
4. Ashraf S, Mapp PI, Walsh DA. Contributions of angiogenesis to inflammation, joint damage, and pain in a rat model of osteoarthritis. *Arthritis Rheum*. 2011 Sep;63(9):2700–10.
5. Dieppe P, Lim K, Lohmander S. Who should have knee joint replacement surgery for osteoarthritis? *Int J Rheum Dis*. 2011 May;14(2):175–80.
6. Casadaban LC, Mandell JC, Epelboym Y. Genicular Artery Embolization for Osteoarthritis Related Knee Pain: A Systematic Review and Qualitative Analysis of Clinical Outcomes. *Cardiovasc Intervent Radiol*. 2021 Jan;44(1):1–9.
7. Roos EM, Toksvig-Larsen S. Knee injury and Osteoarthritis Outcome Score (KOOS) - validation and comparison to the WOMAC in total knee replacement. *Health Qual Life Outcomes*. 2003 May 25;1:17.
8. 2020 Scientific Abstracts and Reviewers. *Journal of Vascular and Interventional Radiology*. 2020 Mar 1;31(3, Supplement):S1–3.

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
<i>Non-financial professional</i>	I am PI for the GENESIS study, which was funded by Merit Medical	2018	present
<i>Direct - financial</i>	I am a consultant for: Boston Scientific Merit Medical Guerbet Cranmed	2018	present
Choose an item.			

X 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:	<input type="text" value="Mark W. Little"/>
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Dated:

4/3/2021