Appendix 6c
Interventional Treatments for Back Pain Task and Finish Group meeting, 25 April 2018
Notes of key discussion points

Task and Finish Group members

Attendees:		
Nikesh Dattani (Chair)	GP and Clinical Lead Barnet CCG	NCL
Folake Davies	GP Bromley/Bexley CCG	SEL
Sohini Kar	GP and Clinical Lead Hounslow CCG	NWL
Nicola Williams	GP and Clinical Lead Wandsworth CCG	SWL
Tim Bull	Consultant Spinal Surgeon	NCL
Adam Royffe	Extended Scope Physiotherapist	NCL
Patrick McGowan	Consultant in Pain Medicine	NCL
Denise James	Patient representative	SEL
Apologies		
Matthew Crocker	Clinical Lead	SWL

Also in attendance:

Jane Halpin	Director	Deloitte
Nikita Patel	Senior Consultant	Deloitte
Danny Batten	Acting Director of Transformation and Delivery (NEL)	NHSE (London)
Mandip Korotana	Programme Manager	Healthy London Partnership
Kunle Awosanya	Project Manager	Healthy London Partnership

1. Welcome from Nikesh Dattani, Chair of the Task and Finish Group

The Chair welcomed members and outlined the purpose of the meeting. The Chair confirmed:

- the meeting was quorate
- there were no conflicts of interest

2. Presentation of the evidence review from Jane Halpin and Nikita Patel

Colleagues from Deloitte presented the draft guidance review which had been circulated in advance to Task and Finish Group members based on the search strategy agreed by members. The aim of the guidance review is to present the available guidance to the Task and Finish group in order to support informed decision making regarding a London policy. There is currently significant variation across London, some CCGs have no policies whilst others do.

The guidance review has sought to collate relevant evidence, so far as it is available, from named sources, for the following interventions:

- Epidurals / nerve root blocks
- Spinal injections
- Spinal fusion
- Spinal decompression
- Sacro-iliac joint injections
- Radio frequency denervation
- Disc replacement
- Spinal cord stimulation
- Acupuncture

Deloitte colleagues confirmed that in order to cover the breadth of these procedures, the review has focused on guidance from three specific sources: NICE guidance, the recent (March 2018) Lancet review paper on back pain interventions, and NHSE National Low Back and Radicular Pain Pathway 2017.

Deloitte colleagues confirmed that this evidence review is draft, and will be updated following this Task and Finish Group meeting and comments from members.

3. Discussion on the evidence: is it robust and of high quality?

The key discussion points were as follows:

- The inclusion and exclusion criteria were discussed and it was confirmed that malignancy and radiology (diagnostic tests) are excluded from this policy
- It was acknowledged that radicular pain and lower back pain are two issues and follow different pathways. However, as they both relate to the back and may share similar causation, it was agreed that they should be covered in the London policy. This is in line with NHSE National Back Pain Pathway, where these two issues are covered in one policy whilst there are two pathways.
- It was agreed that the selected guidelines are reputable sources
- It was acknowledged that NICE advises clinicians to refer to best practice where no guidance is available.

The Chair confirmed that members were satisfied with the quality of the guidance review and were happy to proceed with drafting a London policy.

4. Drafting the London policy

The group reviewed each procedure in turn to draft a London policy and agreed the following **clinical criteria**:

<u>Epidural injections:</u>

- For patients over 16 years

- For lumbar spinal pain associated with radicular pain which is consistent with MRI findings (disc level) where this has been undertaken. Where primary care and MSK services do not have access to MRI, patients should be referred to a service that can offer MRI.
- For pain persisting for over 12 weeks of appropriate conservative management, although earlier intervention can be considered if there are motor symptoms.
- If referral is earlier than 12 weeks, then the following should apply:
    - Patient has no sign of improvement despite appropriate analgesia, manual treatment, conventional therapy and advice
    - Patient has symptoms that are moderate to severe and affecting daily life
    - The condition is likely to have impact with an epidural injection, concordant with clinical diagnosis
    - MRI (unless contraindicated) shows change consistent with the nerve root level affected by radicular pain
- A maximum of 3 epidural injections followed by physiotherapy, if response rates are as follows, for the pathology being treated:
    - 30% response rate after the first injection
    - 50% response rate after the second injection
    - 50% response rate after the third injection
- After 3 injections, re-approval is required. It is recognised that a small proportion of patients may benefit from one or more further courses of epidural injections, following the response rates as above. For example, this may apply to older patients whose pain may be managed by courses of epidural injections and who are unsuitable for or unwilling to have surgical treatments. Deloitte to review GIRFT data to understand current pattern of frequency of epidurals over a given period (to try and codify "current practice" more clearly).

<u>Spinal injections (therapeutic)</u>

- In line with the evidence review, spinal injections won't be funded except for diagnostic purposes .
- Tim highlighted some new evidence on intr-discal ozone injections which he will circulate to the group.

<u>Spinal fusion</u>

- There is no role this surgery for non-radicular back pain.
- Any exceptions can go through IFR.

<u>Spinal decompression</u>

- For spinal stenosis: referral for decompression (for one or more spinal levels) can be considered after more than a year of continuing symptoms unresponsive to appropriate conservative and non-surgical treatment; management has not improved pain or symptoms from radicular pain; and there are concordant MRI findings (or alternative imaging where MRI is contra-indicated).
- Discectomy can be considered for continuing severe acute sciatica over 12 weeks duration where pain is not manageable and MRI (or alternate imaging if this is contra-indicated) shows concordant disc herniation

<u>Sacro-iliac joint injections</u>

- The evidence review had not highlighted information for sacro-iliac pain interventions, but the chair highlighted that other CCGs (for example, West Suffolk) had formulated polices on this – and asked that their evidence was identified and if possible used to consider policy development
- The nature of polices in place elsewhere suggested access only where patient is part of MSK service, has complied with conservative management including physiotherapy; where pain has persisted for over 12 weeks and the MDT/pain specialist has assessed that the pain originates from the sacro joint and causes at least a moderate impact on daily living.

Radio frequency denervation

- For lumbar and thoracic back pain
- MRI (or alternate imaging if this is contraindicated) has excluded other structural lesions
- There is a positive response to a diagnostic medial branch block.
- Pain is persistent
- Patient is over 16 years
- Conservative management including multidisciplinary input and physiotherapy has failed
- Treatment of 1 diagnostic block and 1 therapeutic injection. If further treatment is required, then this should go through IFR.

Disc replacement; Spinal cord stimulation; and Acupuncture

- Should not be routinely funded, access via IFR.
- Patrick knew of some specific evidence regarding radiofrequency neuromodulation for dorsal roots – and will circulate this to the group for consideration.

The discussions on the **presentation and implementation of the policy** were as follows:

- The policy was only for lumbar, lower back pain and radicular pain.
- There should be a line in the policy on exclusions
- It would be useful to include or refer GPs to guidance on lower back pain and the importance of MSK and physiotherapy services
- It was highlighted that it is often the MSK team that refers to secondary care rather than the GP and this should be clear in the policy
- We need to be mindful that there are areas where there is no access to MRI
- The policy needs to reference to patient's wishes i.e. they want a procedure or operation and are also fit enough to undergo such a procedure
- The policy needs to re-state the risk factors of back pain and what is part of successful management of back pain e.g. a healthy lifestyle, weight management, smoking cessation; and where relevant, the factors that may reduce the likelihood of successful treatment outcomes (e.g. smoking and spinal fusion surgery).

5. Review of draft policy (statements above) against the ethical framework application sheet

The statements and process were reviewed against the key principles and considerations of the ethical framework. The following comments were made:

- A detailed equality impact assessment will be carried out by individual CCGs

- As London's population is very diverse, information in a range of community languages will need to be available
- There are risks with every procedure and the thresholds are in place to manage these risk, using the latest available evidence, to support procedures that have the lowest risk and highest outcome
- The guidelines reviewed (NICE, Lancet, NHSE) include evidence drawn from across the world
- Health promotion and lifestyle factors should be included in the policy as they impact on back pain and on the success of some procedures

6. Next steps

The Chair thanked the Group and outlined next steps:

- A post pack with an updated policy and evidence review will be circulated within a week for comment.
- Tim Bull will send evidence on ozone therapy by 27 April.
- Patrick McGowan will send evidence on radio frequency treatment by 27 April.
- The next meeting on 16 May is to review and ratify the London policy.

Interventional Treatments for Back Pain Task and Finish Group meeting, 16 May 2018
Notes of key discussion points

Task and Finish Group members

Attendees:		
Nikesh Dattani (Chair)	GP and Clinical Lead Barnet CCG	NCL
Folake Davies	GP Bromley/Bexley CCG	SEL
Sohini Kar	GP and Clinical Lead Hounslow CCG	NWL
Nicola Williams	GP and Clinical Lead Wandsworth CCG	SWL
Tim Bull	Consultant Spinal Surgeon	NCL
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Jane Halpin	Director	Deloitte
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Danny Batten	Acting Director of Transformation and Delivery (NEL)	NHSE (London)
Mandip Korotana	Programme Manager	Healthy London Partnership
Kunle Awosanya	Project Manager	Healthy London Partnership

7. Welcome from Nikesh Dattani, Chair of the Task and Finish Group

The Chair welcomed members and outlined the purpose of the meeting. The Chair confirmed:

- the meeting was quorate
- reconfirmed that there were no conflicts of interest
- noted the additional information sent by Patrick McGowan

8. Review of additional information received

It was noted that Patrick had recently emailed 2 papers to the Group – a BMJ article on evidence based medicine (Greenhalgh) and epidural lysis randomised control trial study paper (Gerdesmeyer).

For the Greenhalgh paper, there was discussion around evidence based medicine and how it works for patients. It was noted, that in practical terms, evidence was required to build policy across Trusts and Commissioners, however this can be difficult when evidence does not exist. There was a discussion about how the IFR process works and it was noted that there is variation in turnaround time and ease of use across the CCGs in London. The Gerdesmeyer paper was discussed in the epidural section on the policy below.

The challenge of managing patient expectations was discussed and the importance of having an evidence based policy to help clinicians across the NHS to have informed and often difficult discussions with the patients.

There was discussion about whether there was sufficient available evidence and how various research projects can get funding, although it was noted that this was out of the scope of this Task and Finish Group. The Group noted the dichotomy of dealing with the whole via a pan London policy versus the specific needs of an individual patient. The policy is about the majority of patients and commissioning criteria are not about disadvantaging the individual patients with exceptional cases. These patients can still receive funding through the IFR process. It was noted that CCGs undergo a continual policy review process and amend policies as new evidence, procedures and themes arise.

9. Review of the draft London policy

The draft policy was presented and the following **clinical criteria** were discussed:

Spinal fusion

There was a discussion about patients who have back pain, but no leg pain, and therefore don't fulfil the criteria for treatment, despite undergoing conservative treatment. There was a concern that these patients may not get the treatment they need. Following discussion, it was agreed that the number of such patients was very low, and in a majority of cases, patients often develop leg pain so would fit within the existing criteria. The low volume of patients this applies to can go through the IFR process. It was noted that many of these patients are referred to Stanmore, Guys and St Georges (tertiary specialist centres) and that specialised commissioning may apply to some of these procedures. Furthermore, these centres are more likely to be experienced with the IFR process.

It was confirmed that paediatrics is outside the policy.

Discectomy

There was a discussion of whether there an OR not AND in between the following two criteria statements due to concerns about delays to patient referral:

> *The patient has shown no sign of improvement despite conventional therapy for 3 months*
>
> *Patients have acute, severe and unremitting sciatica concordant with disc herniation demonstrated on MRI scan within 12 weeks (unless contraindicated).*

Following discussion, it was agreed that AND was appropriate, given the length of time before the patient sees a GP, has some treatment in primary care, has a MRI scan etc. It was further noted that this criteria was about treatment, not referral, which should be clear in the policy.

It was agreed that for consistency, 3 months should also be stated as 12 weeks throughout the policy.

Sacroiliac joint injections

At the last meeting, it was agreed to look at sacroiliac joint injections by reviewing the West Suffolk CCG policy and its references. There is limited evidence on injections for therapeutic use and it was agreed that injections for therapeutic use will not be routinely funded. It was noted that the West

Suffolk commissioning criteria did not seem to be specifically evidence based in terms of the references used. It was agreed that there should be a section in the policy for diagnostic injections.

Diagnostic injections (facet joint, sacroiliac joint, medial branch block)
It was agreed that these would be routinely offered for patients under a specialist, where they have had pain for 12 weeks or longer. It was agreed to have similar wording to the West Suffolk policy of up to two injections, within a 2 week period, with the second injection only given if the first injection elicited a positive response of 80% improvement in pain, which should be clearly documented in the notes.

In summary, the group decided that the criteria should include patients under a specialist and with pain for 12 weeks or longer. Furthermore, up to two injections (one short acting and one long action) be used within a two week period.

Spinal injections (facet joint, medical branch blocks, intradiscal therapy, prolotherapy, trigger point, sacroiliac joint)
The group agreed that this section should be amended to include 'Therapeutic Spinal Injections'.

Radiofrequency Denervation
The policy should state MRI or SPECT. 80% improvement should also be clearly documented in the notes as this is important for audit processes.

Epidurals
It was agreed that there should be no timeframe for the 3 injections offered. It was noted that the policy had flagged older patients who may require re-approval for further injections, as previously agreed.

The Group discussed the Epidural Lysis paper circulated by Patrick McGowan. It was noted that this was a small randomised control trial with a cohort of only 90 patients. Given this, it was agreed that there is not a sufficient evidence base to routinely fund this procedure. Therefore the group agreed that epidural lysis will be added to the policy as not being routinely funded.

This led to a discussion on the **IFR process** as follows:

- The process varies across London.
- For back pain, IFRs are usually done by a specialist and most of these patients will be under specialist care.
- It usually takes 2 – 3 weeks to get the outcome, unless it is urgent, for which IFRs can be turned around in 48-72hours.
- SWL have a tick box system for prior approval. However, other CCGs do not require this prior to the procedure being carried out and they may carry out a retrospective audit.
- Information on the patient and GP is anonymised for the IFR process.
- A separate work stream in NHSE (London) is looking at how this process can be standardised across London.
- It was agreed that a sentence would be included in the commissioning criteria part of the policy that informs the clinician that they can apply for funding via the IFR process for procedures that are not routinely funded.

Other parts of the policy were discussed as follows:

- It was agreed that for patients with moderate or severe pain, referral for assessment should not be delayed and this needed to be clear in the 'advice for primary care section' of the policy. It was further clarified that this section should make clear that the commissioning criteria is for the treatment rather than assessment and that delays for assessment should not be delayed. Wording should be clear and in bold, referring to patients with uncontrollable pain that cannot be managed through conservative treatment
- It was agreed that the general guidance on lifestyle factors such as weight and smoking will be standardised in line with other London policies being developed.
- The issue of legal challenge to the policy was raised. It was assured that commissioners can choose want they fund, as long as they follow due process, so only the process can be challenged, not the policy. However, the policy does not stop patients from having procedures as those seeking treatment have access to treatment through the IFR process, if not funded by this policy.
- The IFR route should be pointed out clearly at the front of the policy.

10. Agreement on the London policy

The Chair summarised the key changes to the policy (as above) and Task and Finish Group members that they were group agreed that they were happy to agree the policy on this basis.

11. Review of draft policy against the ethical framework application sheet

The statements and process were reviewed against the key principles and considerations of the ethical framework. The group agreed that there were no changes made at the meeting that would change the ethical framework. However, the following points were noted:

- Patrick McGowan and other pain specialists were unable to attend the meeting today. However, the papers sent by Patrick were reviewed, and they also had been given the opportunity to comment over email. The studies sent were small and not a sufficient evidence base on which to change the policy.
- For patients with exceptional circumstances, the IFR route was open.
- An open policy risked patients having inappropriate or unnecessary treatments, and the policy should protect patients from this.
- It will be made clear in the policy that there should be no delays to referring patients with uncontrollable pain.
- This policy should be reviewed regularly.

12. Review of notes from the previous meeting

The notes were reviewed, with no further comments.

13. Next steps

- The final version of the policy will be circulated to members by the end of the week.
- Members should give final comment, if possible, in the next 2 working days.

- The final policy will then reviewed as part of the testing / soft launch phase where it will be sent to a range of stakeholders for feedback on language and ease of use.
- The policy will also be sent to Task and Finish Group as part of this phase, and they should send it on to key colleagues.