

**NATIONAL INSTITUTE FOR HEALTH AND
CARE EXCELLENCE**

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Low back pain and sciatica

Date of quality standards advisory committee post-consultation meeting:

26 April 2017

2 Introduction

The draft quality standard for Low back pain and sciatica was made available on the NICE website for a 4-week public consultation period between 9 March and 7 April 2017. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 22 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?
2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?
3. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the [NICE local practice collection](#) on the NICE website. Examples of using NICE quality standards can also be submitted.
4. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement specific questions:

1. For draft quality statement 2: In cases where serious underlying pathology is suspected, it may be appropriate for primary care services to refer people with low back pain for imaging. Do you think this statement has the potential to inappropriately reduce these referrals? If so, how could this be avoided?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- General support for this quality standard reflecting the key areas for quality improvement including risk stratification and self-management.
- General concern raised on statements for:-
 - their over-simplification and the appropriateness of combining treatments for low back pain with or without sciatica and chronic compared to acute back pain based on significant management differences. This could lead to significant confusion for commissioners and patients, treatment delays and increase disability
 - only 2 out of 6 statements relate to positive actions- risk stratification and support for self-management
 - the number of 'do not do' statements. This could be seen as negative and will increase visits to A&E or the out of hours service. Suggestion to offer alternatives rather than state what not to do.

Consultation comments on data collection

- Data coding on different low back conditions was reported as varied.
- Local systems are in place in primary care with risk stratification tools currently present in some clinical computer systems.
- Local general practice datasets are crucial to measuring drug treatment.
- Linking GP and hospital service data may be challenging.
- Statement 1 - STarTBack could be used to audit healthcare resource use.

- Statements 4 and 5- As these medications are commonly prescribed for a wide range of conditions other than back pain this may be hard to measure accurately as it is reliant on data quality.
- Statement 5 - Query raised on how chronic low back pain can be measured using computerised clinical systems.
- Statement 6 - Pain clinic services could collect local data.
- An app for patients is needed collect outcome data.

Consultation comments on resource impact

- Supported as achievable with suitable resources.
- Funding rapid access back pain physiotherapy services will improve clinical care by promoting non-drug treatments.
- There will be initial local investment but potential long-term cost savings as a result of more effective management using risk stratification.
- Increasing primary care consultation time is needed for implementing risk stratification with the additional services required.
- Education is required to support GPs and other front line healthcare practitioners to use a risk stratification tool in routine clinical practice.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Primary care services have an approach to risk stratification for young people and adults presenting with a new episode of low back pain with or without sciatica.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- General support for risk stratification approach being important for early detection of serious conditions with the following suggested inclusions:
 - red flag screening tools
 - x-rays

- patient reported outcomes such as sufficient and appropriate intensive support
- to be used in all referrals to secondary care.
- Concern raised on:
 - stratification based solely on pathology, anatomy or psychology
 - the benefit of spinal stabilisation exercises.
- The Classification Based Cognitive Functional Therapy was supported as an alternative approach.
- Include Hospital Occupational Health Services as a service provider.

5.2 *Draft statement 2*

Young people and adults with low back pain with or without sciatica are not referred by primary care services for imaging.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- General support for imaging only being requested by specialists who can appropriately interpret the results in their setting.
- Concerns raised on:-
 - the scope which may lead to poor outcomes for patients with significant and potential disabling disc disease
 - altering management which may lead to missed diagnoses such as metastatic disease, spondyloarthropathies and osteoporotic fractures
 - healthcare settings and access as many expert triage services are provided in primary care therefore imaging referrals from these services would be primary care. Also the community care musculoskeletal team may need to request imaging to streamline the availability for information at specialist level referral
 - restricting radiological access to secondary care may be appropriate to request x-rays in primary care but not MRIs. A definition of

imaging is therefore needed on this with significant red flag back pain requiring an x-ray within 24 hours.

Consultation question [5]

Stakeholders made the following comments in relation to consultation question 5:

- Supported as clinical judgement will be used so if serious pathology is suspected and patients will still be referred for investigations
- Concerns raised on:-
 - serious underlying pathology being missed. There needs to be emphasis on assessment of low back pain and sciatica and alternative diagnoses- [NICE NG59 recommendation 1.1.1.](#)

5.3 Draft statement 3

Young people and adults with low back pain with or without sciatica are supported to self-manage their condition.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Supported as a central part of overall strategy and management plan
- Concern raised on the scope leading to poor outcomes for patients with significant and potential disabling disc disease
- Suggestion to specify the type of support needed:-
 - a stepped care approach
 - pain management course
 - appropriated psychologically based rehabilitation programmes
 - appropriate evidence-based exercise programmes
 - Public Health information programmes
 - involvement by Spinal Specialist Triage practitioners.
- Include Hospital Occupational Health Services as a service provider.

5.4 *Draft statement 4*

Young people and adults are not offered anticonvulsants, antidepressants or paracetamol alone to treat low back pain.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Support for addressing inappropriate prescribing in people with low back pain.
- Concerns raised on not offering these medications as:-
 - there are elements of neuropathic pain which may be appropriate for considered
 - paracetamol alone may be appropriate for people with NSAIDs contra-indications
 - appropriate analgesia in the acute phase is needed
 - this is not very helpful in advising GPs on pharmacological strategies
 - having the potential to drive up the use of NSAIDs and benzodiazepines which may lead to adverse effects of NSAIDs and increased benzodiazepine addiction.
- The healthcare setting focus was queried- primary or secondary care or both?
- CCG pharmacists could audit and highlight inappropriate prescriptions of these medications.

5.5 *Draft statement 5*

Young people and adults are not offered opioids to treat chronic low back pain.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- Supported to avoid opioids for long term pain.
- Concerns raised on not offering opioids as :-
 - short term use in the acute phase may be appropriate whilst the patient awaits definitive interventions
 - this is not very helpful in advising GPs on pharmacological strategies

- a definition of chronic low back pain is needed.

5.6 Draft statement 6

Young people and adults are not treated with spinal injections for low back pain.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

- Supported as being achievable with education of those involved with the referral processes.
- Concerns raised on:-
 - this statement is incorrect and contradicts NICE guideline NG59 recommendation 1.3.5 which will lead to misinterpretation.
 - the potential to drive up the use of NSAIDs and benzodiazepines which may lead to adverse effects of NSAIDs and increased benzodiazepine addiction.
- Suggestion to include:
 - a better definition of the injections which is supported by NICE guidance is needed as these are all very different
 - secondary care providers in the audience descriptors.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Self-management programmes- physical or psychological
- Manual and psychological therapies (such as spinal manipulation, osteopathy, chiropractic, massage and CBT)
- Emergency medicine
- Public awareness education campaign- referral process and spinal degeneration.
- Schools, colleges and universities
- Physical and emotional/ mental wellbeing

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- Poor quality of care- Missed diagnoses of serious pathology, delays in diagnoses of treatable disease and unintended over-prescribing of medications with potentially serious adverse effects such as NSAIDs and benzodiazepine
- Patient accessible information sources.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments ¹
General			
1	Faculty of Pain Medicine of the Royal College of Anaesthetists	General	Is NICE aware that the consultation questions are inhibitory of views that the FPM, or other professional group, involved in the care of these individuals might wish to make to enable best patient care? The questions are designed around implementation and not their inherent quality.
2	Faculty of Pain Medicine of the Royal College of Anaesthetists	General	The mixing of acute/chronic LBP/Sciatica is a flawed approach to a complex problem which will lead to significant confusion, therapeutic delays and has the potential to increase disability and the overall economic burden to society of these conditions.
3	Faculty of Pain Medicine of the Royal College of Anaesthetists	General	It would be preferable to have a separate Quality Standard for chronic low back pain and a second for sciatica with or without back pain.
4	Faculty of Pain Medicine of the Royal College of Anaesthetists	General	The National Back Pain Pathway that helps facilitate delivery of the NICE guidance should be referenced.
5	Faculty of Pain Medicine of the Royal College of Anaesthetists	General	There are far too many “nots” in the statements. This will lead to comments such as “well what am I to offer?”. How about something better like “An approach that considers medical, psychological and social factors to develop a management plan should be used”.
6	Faculty of Pain Medicine of the Royal College of Anaesthetists	General	The merging of "non specific low back pain and sciatica" may confuse users/commissioners/patients (as this term is amalgamated from 2008 NICE Guidance 88 and 2016 NICE Guidance 53). I understand that the term was used while <u>preparing</u> the 2016 guidance, but the actual 2016 publication refers to "Low Back Pain and Sciatica". It should be clarified what the authors actually mean here and which guidance they draw their Quality standards from.

¹PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

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ID	Stakeholder	Statement number	Comments ¹
7	National Council for Osteopathic Research	General	It would be prudent to use the term healthcare professionals when not talking about physicians, or manual therapists when describing manual therapy interventions. This would cover all potential practitioners that might be involved in the care pathway, such as physiotherapists, osteopaths, chiropractors, psychologists and specialist nurses.
8	NHS England Specialised Pain Services Clinical reference Group	General	The members of the CRG have had concerns raised with regards the quality statements combining the treatment of low back pain without sciatica and sciatica +/- low back pain. Whilst there is an agreement with the statements with regards LBP without sciatica this cannot be extrapolated equally to sciatica +/- LBP. Patients with acute or acute on chronic sciatica require access to appropriate evidence based management techniques as described within the NICE guidelines and the concern is the quality standards will be inappropriately extrapolated to prevent this. It may be better placed to simply have the standards for low back pain alone and create separate standards for sciatica.
9	NHS England	General	I welcome all the “do not do” statements. I would suggest one addition: - to specify the red flag symptoms that should prompt rapid referral for a specialist opinion.
10	Public Health England	General	Psychological/ cognitive therapy services are not available across all areas
11	Public Health England	General	STarTback should be embedded as a mainstream stratified care and evidence based cost effective approach.
12	United Kingdom Spinal Societies Board	General	Noted and supported
13	Primary Care Rheumatology Society	General	Also add Hospital Occupational Health Service repeat appointments Patient SELF Reported outcomes should be collected so conforming to Steven’s “Five Years Forward”. There is now available a patient app which measures outcomes produced by Inhealth Care. This app is being used in the North of England Regional Back Pain Pathway.
14	Primary Care Rheumatology Society	General	Refusal of CCGs and NHS to reimburse funding for (ineffective) treatment
15	Primary Care Rheumatology Society	General	Add: NHS professionals do not advise patients of inappropriate treatment which has been assessed by NICE to be not cost-effective.
16	Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust	General	The guidelines ignore the complexity of people and chronic back pain. In doing so they could harm individual patients, especially those at risk of chronicity and increase the healthcare burden due to iatrogenic disability.

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ID	Stakeholder	Statement number	Comments ¹
			<p>There is sense in the statements but they are oversimplistic and they will not help clinicians and patients with managing patients who do not manage back pain well.</p> <p>There is a significant danger in the current funding crisis that commissioners will use the guidelines to withdraw treatments and that care will suffer in the short term while evidence is produced. (Supporting evidence – the recent history of NICE guidelines and RFL. RFL funding was withdrawn and patients suffered until evidence could be produced)</p>
17	British Society for Rheumatology & Royal College of Physicians	General	<p>The wording is confusing. In clinical medicine, there is a big difference in managing someone with sciatica compared to low back pain alone (need for MRI; urgency of referral for spinal injections (e.g. caudal epidurals need to be provided within 6 months of symptom onset otherwise they are not effective) or neurosurgical decompression; role of anti-neuropathic agents) and this does not come across in the wording of the document. Similarly, there is a big difference in managing someone with chronic low back pain compared to acute low back pain (e.g. making a diagnosis) and this does not come across in the document. A better title might be ‘Non-red flag low back pain in Primary Care for over 16s NICE Quality Standard’</p>
Questions			
18	Arthritis Research UK Primary Care Centre	Question 1	<p>It is unfortunate that only two of the six standards relate to positive actions (risk stratification, support for self-management). Overall, however, we think the standards reflect the key areas for quality improvement, are sensible, achievable and auditable.</p>
19	Faculty of Pain Medicine of the Royal College of Anaesthetists	Question 1	<p>No. These draft statements do not accurately reflect safe clinical practice or the current NICE guidelines.</p>
20	Royal College of General Practitioners	Question 1	<ul style="list-style-type: none"> · It does reflect the key areas for quality improvement. The quality statement regarding use of risk assessment tools such as STarT Back Musculoskeletal Screening Tool looks reasonable. However it is difficult to locate online. Please provide a source link in documentation, to ensure GPs can engage with this standard. · This relies on coding, coding is variable, therefore appraising this standard will be inexact and misleading
21	United Kingdom Spinal Societies Board	Question 1	<p>Yes</p>
22	British Society for Rheumatology & Royal College of Physicians	Question 2	<p>Local systems may not in place to capture all of the data required to meet all of the Quality Statements included</p>

ID	Stakeholder	Statement number	Comments ¹
23	Faculty of Pain Medicine of the Royal College of Anaesthetists	Question 2	No. The confusion between significantly different aspects of this group of conditions (i.e. LBP vs radicular and acute vs chronic pain) will likely lead to significant inaccuracies in the data collection.
24	Royal College of General Practitioners	Question 2	<ul style="list-style-type: none"> · Local systems are in place in primary care. Risk stratification tools are currently present in some clinical computer systems but they are often ignored due to the time taken to complete them and the lack of services to follow them through. Investment is required to increase consultation time in primary care so that the tools may be used and to put in place the additional services required. · There is a difficulty in definition concerning quality statement 5. The NICE guideline deliberately avoids the terms acute, sub-acute and chronic but it is re-introduced here. What is the definition of chronic and how will this be measured using Computerised clinical systems? · the opportunity cost is likely to be large, and should be done with caution.
25	Arthritis Research UK Primary Care Centre	Question 2	<p>Local databanks should in theory be able to do this, for example, Ollie Hart's Sheffield system has referral to services by GPs linked to completion of the STaRTBack Tool, and it should be possible to link this with GP and hospital service data. The unit at Keele have also done this, for example, we have developed an electronic template that is compatible with GP electronic systems (e.g. EMIS). The template fires when a GP's enter a back pain related read code, advises regarding best practice management of low back pain and the STaRTBack tool pops up and is easily completed. The tool is then automatically scored. If the patient is low risk, the template advised the GP how to manage the patient and there is a link to a patient handout about back pain (including exercises) which is housed on a national website. If the patient is medium or high risk it can automatically pre-populate an electronic referral to physiotherapy and has space for additional information, This referral can then be sent to physiotherapy electronically. This template is now freely available nationally (e.g. national EMIS). This use of this template fits within GPs existing consultation times and work flows and supports a number of the quality statements (not imaging, reductions/changes in prescribing, use of a stratified care tool, provisions of a combined physical and psychological treatment, supporting patient self-management).</p> <p>Use of local general practice datasets are going to be crucial to measuring the use of pharmaceuticals and should in theory be available or, if not, it should be feasible to put this in place. The key weakness in local data systems is likely to be in services fronted by other health care professionals (e.g., physiotherapists) and in linkage between GP and hospital services. For example, the linkage between GP data on back pain consultations and radiology</p>

ID	Stakeholder	Statement number	Comments ¹
			<p>department data may be non-existent. The quality of hospital data in many places is currently problematic. Data is often not collected, if it is, the quality and robustness of the data is frequently poor and obtaining access to it is challenging for both services and commissioner. It is likely to be increasingly feasible to overcome these challenges in light of the growing emphasis on IT and connected health and the increasing commissioning of joined-up musculoskeletal providers, where services are expected to deliver the relevant data as part of the contractual arrangements. So in summary, whilst it is potentially challenging and there is much local variation, it should be feasible to resolve these issues so that relevant data can be gathered</p>
26	United Kingdom Spinal Societies Board	Question 2	<p>This varies considerably by area. It is anticipated that this is a role that the proposed and evolving Specialised Spinal Triage practitioner (see National Back and Radicular Pain pathway (NBRPP)) network could assist with .</p>
27	Primary Care Rheumatology Society	Question 2	<p>There is an app for patients to use to collect outcome data. Other audits could be done on STart back score and query do low scores need to be seen in the first place. Importantly Fitnotes are easily auditable</p>
28	Arthritis Research UK Primary Care Centre	Question 3	<p>Some of the people who have contributed to this response are part of the West Midlands Academic Health Science Network (AHSN) (Integrated Care Theme) implementation team and form the IMPACT Accelerator Unit within the Arthritis Research UK Primary Care Centre, Research Institute of Primary Care and Health Sciences, Keele University. The team includes a Knowledge Mobilisation Fellow, a NICE Fellow alumni and a current NICE Fellow. As a team, we have identified barriers and enablers to implementation of risk stratification (STaRTBack) and the appropriate matched treatments and have developed a range of resources to support implementation of stratified care.</p> <p>We have:</p> <ol style="list-style-type: none"> 1) Designed and tested an electronic template to assist GPs in using the STaRTBack tool in routine clinical practice and in referring to physiotherapy services appropriately ('help to do the right thing'). The electronic template is now freely available nationally (e.g.. EMIS GP electronic systems). 2) Co-created, with PPIE, bespoke patient information housed on a national website and freely available (Patent.info.uk). 3) Co-created a high quality freely available DVD for patients. 4) Developed and delivered training to equip physiotherapists to delivering the matched treatments (including a combined physical and psychological approach). 5) Developed a range of resources for commissioners, managers and clinicians to support implementation (e.g. audit tools, business cases, practice based support methodology and resources, DVD of a best practice consultation).

ID	Stakeholder	Statement number	Comments ¹
			<p>6) Developed a website with a range of information and resources on it to support implementation of a stratified care approach (https://www.keele.ac.uk/sbst/).</p> <p>As a result of this work:</p> <ol style="list-style-type: none"> 1) We have embedded the electronic STarTBack template on thirty Staffordshire and Stoke on Trent GPs clinical systems. 2) Are supporting 16 Clinical Commissioning Groups in the West Midlands and 25 North West Coast provider Trusts to support implementation of STaRTBack. 3) Have trained over 200 physiotherapist in delivering the matched treatments (including combined physical and psychological treatment). 4) Engaged twelve AHSN's around the country in implementing STaRTBack. 5) Over 2378 patients in the West Midlands have benefited from the implementation of the STaRTBack approach (WM Academic Health Sciences Network (AHSN) Annual Report) 6) STaRTBack has become an integral part of the NHS England Pathfinder Project as well as many regions Service Transformation plans (e.g. Staffordshire and Stoke-on-Trent NHS Partnership Trust) <ol style="list-style-type: none"> 1) STaRTBack is part of research and implementation projects around the world (e.g., America, Canada, New Zealand, Ireland, Denmark, Hong Kong, Germany, Australia and South Africa). 2) The team are working with PPIE and a team of Researchers and Implementers in Seattle USA to develop additional patient education materials and resources.
29	British Society for Rheumatology & Royal College of Physicians	Question 3	No examples given. NICE Guidance 59 is confusing with respect to the management of acute and chronic low back with or without sciatica
30	Faculty of Pain Medicine of the Royal College of Anaesthetists	Question 3	No. N/A as the statements are flawed.
31	Royal College of General Practitioners	Question 3	<ul style="list-style-type: none"> · See question 2 · No
32	Primary Care Rheumatology Society	Question 3	Example: North of England Low back pain and sciatica pathway including ongoing collection of data for assessment of safety, clinical effectiveness and cost effectiveness. For further information please refer to national back pathway

ID	Stakeholder	Statement number	Comments ¹
			for the initial results, implementation plans etc. http://www.ukssb.com/pages/improving-Spinal-Care-Project/National-Backpain-Pathway.html
33	United Kingdom Spinal Societies Board	Question 3	Could examples please be provided
34	British Society for Rheumatology & Royal College of Physicians	Question 4	Statements are likely achievable given current resources but may not be desirable
35	Faculty of Pain Medicine of the Royal College of Anaesthetists	Question 4	<p>No. As noted the unfocused nature of the statements and their contradiction of NICE guidelines make safe clinical practice unlikely, with CCGs misinterpreting the statements as simple short cut to the NICE guidelines and developing serious errors in their application.</p> <p>The idea of considering back pain in isolation is flawed. There are many overlapping conditions that mandate the use of central analgesics in many and opioids in a small number of patients. There is a lack of prominence of spinal injections like MBB which can be used. This is likely to mislead. The reader is not readily directed to parallel pathways of radicular pain which do require injections for pain which does ultimately arise from the spine. Sacroiliac back pain is also not specifically excluded.</p> <p>There is a serious risk that these measures evolve into measures of incomplete and therefore bad practice because a narrow view is taken.</p>
36	Royal College of General Practitioners	Question 4	<ul style="list-style-type: none"> · See question 2 · Clinical care would likely be most improved by funding rapid access back pain service from physio to avoid medicalisation promote non drug treatments.
37	Primary Care Rheumatology Society	Question 4	Requires education, team-working using the wider MSK and primary care team including small amounts of psychotherapy support (best to involve one small regional team covering at least 3 or more CCGs). It also requires re-education of secondary care and triaging of imaging requests. Requires CCG pharmacists questioning why prescriptions of anti-convulsants, opioids and similar drugs are being prescribed to patients with back pain especially chronic pain. Requires education and interaction with local occupational health departments especially NHS ones who typically have a more imaging based and treatment heavy approach to low back pain and sciatica

ID	Stakeholder	Statement number	Comments ¹
38	Arthritis Research UK Primary Care Centre	Question 4	<p>We are concerned about the potential for the standards to be implemented for the following reasons.</p> <p>a) Whilst use of the risk stratification tool such as the STarTBack tool in primary care is feasible, resources are likely to be required to support GPs and other front line practitioner to embed these within their usual workflows. Our implementation team has experience of the considerable challenges in supporting busy GPs to use a risk stratification tool in routine clinical practice.</p> <p>b) Risk stratification will only work if the relevant linked therapy (matched treatments) are available. For example, the matched treatment for the high risk subgroup of low back pain patients in STaRTBack is provision of combined physical and psychological therapy. Training of physiotherapist will be required in order to equip them to deliver this. Whilst this will require initial investment in many localities, there are potential cost savings in the long-term as a result of more effective management of this subgroup of patients. There should also be cost saving associated with the rest of the quality statements relating to lower radiography, lower long-term opioid problems and fewer hospital referrals for unnecessary treatments. There is a shortage nationally of clinical psychologists.</p> <p>c) The other resource investment that is likely to be needed is in supporting and training clinicians in how to avoid X-ray referrals and unnecessary treatments. The quality standards are unlikely on their own to be sufficient, educational materials for clinicians are required in order for clinicians to x-rays less, prescribe less and support patients to self -manage. Education materials for patients is also required in order to inform them, help manage expectations and support self-management. This will need initial investment but will result in cost savings from effectively managing the low risk subgroup of low back pain patients in primary care and from lower x-ray and prescription costs and from avoiding unnecessary referrals.</p> <p>Opportunities for disinvestment are difficult to identify, however, it is possible that there may be disinvestment in injections. STarTBack has already achieved savings in key areas identified in NHS QIPP plans, e.g., X-rays, medication, secondary care referrals, this all represents the invest to save case and potential opportunities for disinvestment. Overall, the use of a risk stratification tool, matched treatments and standards to streamline appropriate care should lead to efficiency savings in the longer-term.</p>
39	United Kingdom Spinal Societies Board	Question 4	It should be achievable given suitable resource . What does “given net resources “ mean .

ID	Stakeholder	Statement number	Comments ¹
40	Arthritis Research UK Primary Care Centre	Question 5	<p>We think that most GPs will interpret and use the standard as supporting the idea that there is nothing to be gained by x-raying people with uncomplicated back pain even if they want it for 'reassurance'. Those GPs who have difficulty managing patient requests for imaging will be helped by being able to discuss the quality standard (not to X-ray) with patients. GPs may require training to support them in conversation with patients around this.</p> <p>The vast majority of GPs and physiotherapist know to look out for red flags and the guidelines are 'guidelines not tramlines' so clinical judgement will be used and patients will still be referred for investigations if sinister or serious pathology is suspected.</p>
41	British Society for Rheumatology & Royal College of Physicians	Question 5	<p>Statement 2 in its current form will lead to missed serious underlying pathology. There needs to be emphasis in the document with reference to NICE CG 59 statement 1.1</p> <p>"Think about alternative diagnoses when examining or reviewing people with low back pain, particularly if they develop new or changed symptoms. Exclude specific causes of low back pain, for example, cancer, infection, trauma or inflammatory disease such as spondyloarthritis."</p>
42	Faculty of Pain Medicine of the Royal College of Anaesthetists	Question 5	<p>Yes. Referral should be emphatically encouraged where serious underlying pathology is even remotely suspected.</p>
43	Faculty of Pain Medicine of the Royal College of Anaesthetists	Question 5	<p>Primary care should be allowed to order imaging in patients with red flags. The reality is that most services have some degree of waiting time (whether they are community spinal interface services/pain clinics/neurosurgery) and having to refer patients without a scan when malignant or otherwise sinister pathology is suspected, risks introducing unacceptable delays in treatment.</p>
44	Royal College of General Practitioners	Question 5	<ul style="list-style-type: none"> · Yes this could have an adverse effect particularly with respect to osteoporotic fractures and the introduction of bisphosphonates. The other "serious" pathological causes as presentation purely as back pain are rare in primary care. Due to the clinical complexity it is difficult to envisage a single measurable statement except to reduce the standard from 100 per cent to 95 per cent. · Statement 5 appears too strong. It is misleading and the measure incorrect. The guideline implies that weak opioids are sometimes appropriate: 1.2.20 Consider weak opioids (with or without paracetamol) for managing acute low back pain only if an NSAID is contraindicated, not tolerated or has been ineffective. There are a substantial number of people where a NSAID is not indicated or caution should be used. High volumes of NSAID use risk increased Acute Kidney Injury and gastrointestinal bleeding.

ID	Stakeholder	Statement number	Comments ¹
			<p>· As stated, binary 'must not do' are generally counter productive, unhelpful, and incorrect. Far better to say 'imaging is usually not needed and often causes more problems than it can solve; and then explain why i.e. most people have changes that are normal are not responsible for pain, and doesn't change management, however in people with previous cancer, or who are systematically unwell, or when you are considering ankylosing spondylitis, etc. then your management might include...</p>
45	Primary Care Rheumatology Society	Question 5	<p>There are two groups with serious underlying pathology 1/emergency red flags that go immediately to A&E 2/ less time specific red flags. Both these have been discussed in detail and a consensus to their management has been achieved http://www.ukssb.com/assets/PDFs/2017/February/National-Low-Back-and-Radicular-Pain-Pathway-2017_final.pdf pages 95-100</p>
46	Primary Care Rheumatology Society	Question 5	<p>Please refer to national back pain plan Red flags are discussed in detail and consensus to their management has been achieved http://www.ukssb.com/assets/PDFs/2017/February/National-Low-Back-and-Radicular-Pain-Pathway-2017_final.pdf pg 95-100</p>
47	United Kingdom Spinal Societies Board	Question 5	<p>This does have the potential to inappropriately reduce “red flag “referrals for imaging . There should be specific reference made to this as has already been included in the NBRPP document (see below) in which there is also an appendix with timelines for referral depending on the nature of the clinical presentation.</p> <ul style="list-style-type: none"> · Priority Spine imaging (Protocol led MRI whole spine unless contraindicated) <ul style="list-style-type: none"> o Past history of cancer *(new onset spinal pain) o Recent unexplained weight loss o Objectively unwell with spinal pain o Raised inflammatory markers (relative to range anticipated for age) Plasma viscosity , CRP , ESR (according to local practice) o Possible immunosuppression with new spinal pain (IVDU, HIV, Chemotherapy, Steroids). o Prolonged steroid use * o Known osteoporosis, with new severe spinal pain o Age <15, or >60 years new onset axial back pain <p>*Statistically significant red flags. Although the others listed may not be statistically significant these are the</p>

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			symptoms items which are commonly seen in serious pathology. The more of these present the greater the probability of serious underlying pathology.
48	Spine Intervention Society	Question 5	<p>It is important to stipulate that in cases where underlying pathology is suspected it may be appropriate for primary care services to refer people with low back pain for imaging. Imaging red flags exist and should be listed. For example: A young adult, a known heroin abuser, developed severe back pain. The primary care provider requested an MRI that revealed osteomyelitis. Intravenous antibiotics and surgery literally saved this person's life. If the proposed NICE quality standard were followed, this patient would not have survived.</p> <p>Also, indicate whether there will be a minimum period of self-care prior to allowing imaging.</p>
Additional area			
49	British Society for Rheumatology & Royal College of Physicians	Additional area	The draft consultation does not reflect the key areas for quality improvement and will perversely drive to poor quality of care (missed diagnoses of serious pathology; delays in diagnosis of treatable disease; unintended over-prescribing of medications with potentially serious adverse effects – e.g. NSAIDs and benzodiazepines).
50	Public Health England	Additional area	Agree with the statements: In addition to work place there may be other places in reference to young people such as schools/ colleges and universities. Also in reference to sports injury does there need to be consideration to support the physical and emotional/ mental wellbeing due to potential long-term effects and disability.
51	Public Health England	Additional area	Self-Management: Prevention, early detection and early intervention will have a big impact on self-management- Physical Activity / Obesity/ Mental wellbeing
52	Royal College of Emergency Medicine	Additional area	There is little relevant to emergency medicine in this quality standard.
53	Yoga for Healthy Lower Backs Institute	Additional area	<p>Combined physical / psychological programmes</p> <p>As ‘combined physical / psychological’ self-management programmes (as mentioned in the Guidelines) which are cost-effective are available (such as ‘Yoga for Healthy Lower Backs’), we feel these should be mentioned in the quality standards for improvement. Although we understand that intensive and/or costly programmes should be compared to other available programmes, before recommending these.</p>
54	Yoga for Healthy Lower Backs Institute	Additional area	<p>Manual and psychological therapies (spinal manipulation, osteopathy, chiropractic, massage, CBT) only offered alongside exercise.</p> <p>We would like to see this reflected in the quality standards.</p>

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			NICE guidelines, mentions only referring to these therapies if also combined with exercise. It is worth noting that patients often rely on repeat doses of this kind of therapy treatment, whereas empowering them to self-manage through well-structured programmes would be a better goal.
55	Primary Care Rheumatology Society	Additional area	Nothing about patient generated outcomes. Nothing about improved resilience and triaging of inappropriate face-to-face consultations with patient accessible info sources online, paper based or seeing local chemist instead of seeing a primary care professional face-to-face. Fitnotes should be auditable especially ones lasting greater than 8 weeks.
56	Primary Care Rheumatology Society	Additional area	Community and Public Health: There is a need for a public awareness education campaign to explain the latest evidence-base and the NICE back pain guidelines. The prevalence of low back pain with and without sciatica means that low back pain is a public health issue. There are many false perceptions about low back pain and sciatica in the community and this has been exacerbated by over medicalisation of the condition over many decades. The significant changes in the new NICE guidelines showing that much of the past treatment is inappropriate and damaging to patient outcomes means that people need to be educated about these changes. Research from the likes of the North of England Back Pain Pathway, Glasgow back Pain and Australia show the importance and effectiveness of public information campaigns in any new back pain pathway. This improves its bedding down into the health care system, improving compliance and helping build resilience of the general public to managing minor symptoms of low back pain themselves.
57	Yoga for Healthy Lower Backs Institute	Additional area	<p>Relating to your Question 1. Please add Exercise.</p> <p>We believe one of the key areas for quality improvement is to signpost, or ideally refer, to appropriate evidence-based exercise programmes. NICE’s press statement and summaries state in the first paragraph that exercise should be recommended as a ‘first step to managing low back pain’. In reality, it is not easy for patients to understand how to follow this advice by themselves, unless they are guided to a good starting-point. GPs need educating as to how to find appropriate programmes taught by professionals who understand the ‘biopsychosocial’ and mechanical aspects of low back pain.</p> <p>The ‘Yoga for Healthy Lower Backs’ 12-week course was used successfully in University of York / Arthritis Research UK randomised control trial and would offer a good example of such an available programme with its gently progressing fully-supervised programme.</p> <p>(N.B. ‘Yoga for Healthy Lower Backs’ is an identification name used in the research – design phase, published</p>

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			<p>heading in Annals of Internal Medicine journal paper, current programme name offered up by quality, regulated, experienced and governed Registered 'Yoga for Healthy Lower Backs' yoga teachers. www.yogaforbacks.co.uk) We feel perhaps that there could be a separate quality statement about exercise, as the evidence is there for this (otherwise, it seems important that 'appropriate exercise' should be mentioned within Statement 3).</p>
Statement 1			
58	British Society for Rheumatology & Royal College of Physicians	1	<p>We would welcome the use of risk stratification for the prediction of persistence of pain. However it is entirely inappropriate to apply such rehabilitation triage on a 'new episode of low back pain with or without sciatica' without excluding serious pathology first. No emphasis in the Quality Statements have been made on the risk stratification for red flag back pain and this must be addressed. The language in Statement 1 of 'Examples include OMPSQ and STarT Back' is inappropriate as patients recruited to the research endeavour to develop both of the questionnaire had serious pathology excluded. No mention of this is made in the NICE Quality Statements and this must be addressed, otherwise serious pathology will continue to be missed in Primary Care. Both the OMPSQ and STarT questionnaires are best positioned in the early rehabilitation phase for someone with a diagnosis of chronic low back pain NOT acute low back pain and we can not emphasise enough that a clear diagnosis using established red flag screening tools should be the very first level of risk stratification before further psychological profiling is used.</p> <p>This is the exclusion criteria from Hill et al' Lancet paper from STarT back: "We excluded patients with potentially serious disorders (eg, cauda equina compression, inflammatory arthritis, and malignancy), serious illness or comorbidity (including those undergoing treatment for a prevalent axis 1 or 2 mental health disorder according to the Diagnostic and Statistical Manual of Mental Disorders, fourth edition [DSM-IV] criteria), who had spinal surgery in the past 6 months, who were pregnant, who were receiving back treatments (except primary care), and who were unable or unwilling to attend".</p> <p>This is not reflected in the NICE Quality statements and needs to be.</p>
59	British Society for Rheumatology & Royal College of Physicians	1	<p>The diagnosis of Ankylosing Spondylitis is still significantly delayed. A recent audit published in the Rheumatology (Oxford) journal in 2016 (senior author Dr Karl Gaffney) demonstrated that it is more than 9 years from symptom onset until diagnosis. Multiple encounters with Primary Care teams occur during these 9 years, all of which afford opportunity to make and earlier diagnosis, allow earlier treatment and improve quality of life, productivity and</p>

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			<p>reduce costs to the UK of such a condition. This delay has not shortened for more than 30 years and needs to improve. NICE Quality standards do not mention such a diagnosis.</p> <p>Assessing patients for inflammatory back pain (2+ from the following morning stiffness of >30 minutes; improvement with exercise but not with rest; second half of the night awakening; alternating buttock pain) leads to a 70% sensitivity and 81% specificity of diagnosing patients with such a spondyloarthropathy (Arthritis Rheum, 46, 319)</p>
60	British Society for Rheumatology & Royal College of Physicians	1	The diagnosis of osteoporotic crush fractures of vertebrae are often missed and an estimated one-third are undiagnosed in Primary Care. This document does not emphasise such a diagnosis which should be made by X-ray in the appropriate individual and this needs to be taken into account.
61	International Neuromodulation Society	1	Yes, agree
62	National Council for Osteopathic Research	1	How will you know if the stratification approach works in practice? Perhaps introduce and patient reported outcome or audit subsequent health care resource use according to stratification to indicate whether stratification process is carried out?
63	Society of British Neurological Surgeons (SBNS)	1	Agree. The risk stratification must recognise the need for early detection of serious conditions.
64	United Kingdom Spinal Societies Board	1	Very much supported We suggest all referrals to secondary care should include a risk stratification score . (Possibly also a disability score (? Oswestry
65	Yoga for Healthy Lower Backs Institute	1	<p>Risk stratification.</p> <p>We welcome this move towards recognizing that low back pain patient outcomes are most often positively affected by a holistic approach to their condition, i.e. mind-body, physical-psychological. However, we feel that risk stratification is probably only worth doing, if the locality provision would be able to offer sufficient and appropriate intensive support.</p> <p>We know that long-term self-management mind-body programmes, such as the evidence-based ‘Yoga for Healthy Lower Backs’ course serves well as a first-line treatment within Primary Care for many of these people with ‘High’ and ‘Medium’ risk. This yoga programme would be a good option; it is available and it is not costly compared to physiotherapy and Secondary Care clinics (LH Chuang et al published paper, mentioned in the 2016 Guidelines). This</p>

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			<p>yoga programme puts the patients in control of positively affecting their health and well-being for the long-term. Care should be taken with the wording on NICE website for the patients, as we know that ‘normalizing’ and ‘demedicalizing’ low back pain is likely to improve outcomes. Our teachers, and GPs in one of our Steering Groups, see many patients ‘worried’ or ‘stuck’ inappropriately in Pain Clinics for inappropriately long periods of time. This is another reason to aim to get simple treatments and advice to the patient towards the beginning of the care pathway before their condition becomes chronic.</p> <p>We believe the above comments require consideration, as patient and referrer satisfaction and cost-savings can be made, e.g. Right Care approach.</p> <p>We believe that Commissioners should ensure cost-effective, evidence-based, self-management programmes are available as a first-line treatment for these Yellow Flag patients, otherwise patient and referrer confidence in the risk stratification tool will not be there.</p>
66	Primary Care Rheumatology Society	1	This could be achieved using SStart back. Personnel would need to be trained in its use and just as importantly people collecting the data would need training so that the data was acted upon.
67	Primary Care Rheumatology Society	1	There needs to be evidence of the use of SStart back as the current NICE standard (or an explanation of what was used alternatively backed with evidence-based explanation that this alternative is as least as good). The evidence should outline clearly how that information was used: as a minimum, to whom was the information communicated and what actions were triggered. If possible there should be something about the room within the approach for clinical judgement to inform the actions and communications. Importantly there should be something to state if and how the information was collated for audit and/or sharing.
68	Primary Care Rheumatology Society	1	Hospital Occupational Health Services need to be mentioned specifically as a service provider(This is because these services have open access to physiotherapy and easier access to imaging/surgical opinion so Occupational Health Services over medicalise and are not cost-effective even though they pay lip service to the NICE guidelines. The literature shows that medical staff are over treated and have poorer health outcomes with greater disability-adjusted life years(DALYS) than patients treated via their community GP and their local back pain pathway.
69	Primary Care Rheumatology Society	1	The OMPSQ is commonly used in Australia but not in the UK. To avoid confusion and promote consistency should NICE just recommend one tool?
70	Primary Care Rheumatology Society	1	Stratification based solely on pathology, anatomy, or psychology all are unproven despite many years of research (the wrong sub grouping argument does not hold up either as a defence) and as such should not really be

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			mentioned in this document. The Classification Based Cognitive Functional Therapy approach accepts the multifactorial nature of people living with back pain and is showing some promise in trials so may be acknowledged.
71	Primary Care Rheumatology Society	1	There is no evidence for spinal stabilisation exercises to be better than other activities so best not to mention as these terms (Spinal manipulation and spinal stabilisation) may inappropriately increase the use of these examples.
72	5 Boroughs Partnership NHS Foundation Trust	1	No comments regarding this quality standard
73	NHS England Specialised Pain Services Clinical reference Group	1	No comment
Statement 2			
74	5 Boroughs Partnership NHS Foundation Trust	2	Whilst we agree with the statement many expert triage services are provided in primary care and therefore imaging referrals from these services would be classed as primary care. Therefore further clarification is required on this statement
75	British Society for Rheumatology & Royal College of Physicians	2	“Imaging does not often change the initial management”. There is agreement with this statement, but in those patients in whom it does alter management, this can be life changing. Recent examples, all of which have occurred in several services that have fed back are: missed metastatic disease, missed spondyloarthropathies, missed osteoporotic fractures. What is the acceptable rate of ‘missed diagnoses’ that will be cost-effective? This needs to be quantified and accepted as a ‘service standard’ which can then be used to benchmark services as to ‘Diagnostic effectiveness’.
76	British Society for Rheumatology & Royal College of Physicians	2	Imaging should be defined. For obvious red flag back pain, an X-ray that can be obtained within 24 hours is essential in managing that patient effectively. It will be inappropriate to restrict Radiological access to secondary care. MRI scans should be restricted to services that can view the images with expertise to interpret them. This may be appropriate to have in Primary Care.
77	Faculty of Pain Medicine of the Royal College of Anaesthetists	2	Statements 2 and 3 are far too broad and likely lead to poor outcomes for patients with significant and potentially disabling disc disease.
78	International Neuromodulation Society	2	Yes, imaging only requested by those that can interpret the results in the context. However Community care MSK may need to request imaging to streamline the availability for information at specialist level referral

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79	NHS England Specialised Pain Services Clinical reference Group	2	Whilst it is important for imaging to be appropriately used by those able to best interpret outputs it must be recognised that the growing number of community musculoskeletal services should have the ability to consider ordering imaging to ensure correct onward specialist referral.
80	Public Health England	2	'Should' instead of 'May'
81	Public Health England	2	Recommend referral for imaging in cases where serious underlying pathology is suspected.
82	Society of British Neurological Surgeons (SBNS)	2	The imaging should be performed and prioritised based on clinical information. It is essential that serious causes of back pain such as cancer and infection are detected quickly. These patients do not always have other clinical features indicating serious disease.
83	United Kingdom Spinal Societies Board	2	<p>See National Back and Radicular Pain Pathway (NBRPP) Red flag section The group below are justifiable exclusions</p> <ul style="list-style-type: none"> • Priority Spine imaging (Protocol led MRI whole spine unless contraindicated) <ul style="list-style-type: none"> o Past history of cancer *(new onset spinal pain) o Recent unexplained weight loss o Objectively unwell with spinal pain o Raised inflammatory markers (relative to range anticipated for age) Plasma viscosity , CRP , ESR (according to local practice) o Possible immunosuppression with new spinal pain (IVDU, HIV, Chemotherapy, Steroids). o Prolonged steroid use * o Known osteoporosis, with new severe spinal pain o Age <15, or >60 years new onset axial back pain <p>*Statistically significant red flags. Although the others listed may not be statistically significant these are the symptoms items which are commonly seen in serious pathology. The more of these present the greater the probability of serious underlying pathology</p>
84	Yoga for Healthy Lower Backs Institute	2	<p>Relating to your Question 5.</p> <p>We welcome the move towards weighting the back pain care pathway towards being more appropriate for the 95+% of those who will be unlikely to benefit from investigations, imaging or invasive treatments. It is important to make sure that patients are not made to become anxious/ depressed/ worried about their condition, so if there is a</p>

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			change to the standard, the wording should be considered very carefully (in order to prevent worsening patient outcomes, through inference of serious pathology). Education for health professionals and especially patients about how spinal degeneration (including disc bulges) are normal, but is not necessarily causative of pain/ symptoms seems to be an important issue.
85	Primary Care Rheumatology Society	2	This is achievable with education of those involved in the referral process so includes the patient so need Public health information Campaigns("A scan will not make you better but moving will" Australia) This will build resilience and reduce people attending primary care unnecessarily.
86	Primary Care Rheumatology Society	2	Add as a definite provider Hospital Occupational Health Services
87	Primary Care Rheumatology Society	2	Must mention specifically Hospital Occupational Health Services
88	Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust	2	The argument against this is the same as for Statement 6. A young person with longstanding back pain (not radiating dermatomally to legs) can get obsessed with investigation. GPs Xray some which reassures them (cheap, very small risk) but others are convinced that an MRI is required. I don't want them sending to me if they are coping otherwise. The risk is low and they can be warned that it may show other things that are irrelevant to their pain. This can be a saving – patients continue to seek medical help and psychologically move into a position where their backpain escalates.
Statement 3			
89	Arthritis Research UK Primary Care Centre	3	Provision of patient information and other self -management support should be universally available in different languages and across the clinical pathway. Self-management options in the community are dependent upon availability in that region and CCG funding streams.
90	Faculty of Pain Medicine of the Royal College of Anaesthetists	3	Statements 2 and 3 are far too broad and likely lead to poor outcomes for patients with significant and potentially disabling disc disease.
91	Faculty of Pain Medicine of the Royal College of Anaesthetists	3	Statement 3 is vague. It could say "supported to self-manage using a stepped care approach" or "self-management support should encompass psychologically based rehabilitation programmes where needed".

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92	International Neuromodulation Society	3	Yes, as a central part of overall strategy
93	National Council for Osteopathic Research	3	Self-management advice implies telling people what to do and or giving them information. We know this alone does not prompt behaviour change, especially necessary for those with long term low back pain. Measuring what you tell people, vs measuring receipt of information vs actioning advice are very difficult and different. The numerator becomes a tick box exercise that will not indicate quality. Commissioning of self-management programmes and or pain management course might be more indicative. Introduction of patient reported outcomes?
94	NHS England Specialised Pain Services Clinical reference Group	3	This is important as part of an overarching management plan.
95	Society of British Neurological Surgeons	3	Agree
96	United Kingdom Spinal Societies Board	3	Supported . This would be an anticipated role for the Spinal Specialist Triage practitioners.
97	Yoga for Healthy Lower Backs Institute	3	<p>Relating to your Question 1. Please add Exercise.</p> <p>We believe one of the key areas for quality improvement is to signpost, or ideally refer, to appropriate evidence-based exercise programmes. NICE’s press statement and summaries state in the first paragraph that exercise should be recommended as a ‘first step to managing low back pain’. In reality, it is not easy for patients to understand how to follow this advice by themselves, unless they are guided to a good starting-point. GPs need educating as to how to find appropriate programmes taught by professionals who understand the ‘biopsychosocial’ and mechanical aspects of low back pain.</p> <p>The ‘Yoga for Healthy Lower Backs’ 12-week course was used successfully in University of York / Arthritis Research UK randomised control trial and would offer a good example of such an available programme with its gently progressing fully-supervised programme.</p> <p>(N.B. ‘Yoga for Healthy Lower Backs’ is an identification name used in the research – design phase, published heading in Annals of Internal Medicine journal paper, current programme name offered up by quality, regulated, experienced and governed Registered ‘Yoga for Healthy Lower Backs’ yoga teachers. www.yogaforbacks.co.uk)</p>

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			We feel perhaps that there could be a separate quality statement about exercise, as the evidence is there for this (otherwise, it seems important that ‘appropriate exercise’ should be mentioned within Statement 3).
98	Yoga for Healthy Lower Backs Institute	3	<p>Supported self-management.</p> <p>We believe that this statement should encourage more specific advice, as the wording is currently rather vague, which might therefore lead to patients with back pain feeling disheartened, i.e. they most likely do not know ‘how’ to return to normal activities or ‘how’ to begin to exercise.</p> <p>The term ‘supported self-management’ is used often in this quality standard. It is certainly aspirational, but in reality patients need to be ‘fully-supported’ especially at the beginning of the back pain care pathway. Just giving ‘advice and information to manage their condition themselves’ might be insufficient, unless health professionals refer or signpost to appropriate evidence-based supportive programmes that enable patients to become self-sufficient through learning how to self-manage their condition.</p> <p>Leaflets can be useful, but are not always appropriate for everyone. There should be a variety available.</p> <p>Support groups might not be helpful, if the out-dated attitude of ‘having to live with constant pain’ is prevalent amongst group members, i.e. they might need education about up-to-date evidence.</p>
99	Yoga for Healthy Lower Backs Institute	3	<p>‘Evidence of local arrangements to ensure patients are supported to self-manage their condition.’</p> <p>Evidence-based self-management group exercise programmes should be developed.</p> <p>Where they are already available these should be usef. (e.g. ‘Yoga for Healthy Lower Backs’ programme, although this offers more than just the physical element of exercising, as it includes relaxation, breathing and postural awareness, mindfulness, etc.).</p>
100	Yoga for Healthy Lower Backs Institute	3	<p>You say ‘people are provided with advice and information, tailored to their needs and capabilities, to help them self-manage their low back pain with or without sciatica, at all steps of the treatment pathway.’ – we hope this will be reflected in the care pathway and in practical terms.</p> <p>We thoroughly recommend an amendment to the 2nd bullet point to the following: ‘enablement and encouragement to continue with normal activities, e.g. by signposting to appropriate exercise programmes’. We feel this is a more helpful statement.</p>
101	Primary Care Rheumatology Society	3	<p>This is achievable by education of the personnel involved in the referral process. A public health campaign both national and local will help. There needs to be investment in ensuing access to suitable material to help with this or create new material if required that has local relevance. The advice and information should have clear instructions on what to do if and when self-management may become insufficient.</p>

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102	Primary Care Rheumatology Society	3	Public Health info campaigns including via social media can provide much of this advice in a safe, timely and cost-effective manner, helping build resilience in the community to managing common minor ailments without the need to seek medical attention and risk over medicalising the condition.
103	Primary Care Rheumatology Society	3	Add Hospital Occupational Health Services as many appear to consider that self-management is not Treatment
104	Primary Care Rheumatology Society	3	Major problem is that Health and Safety Legislation is very out of date to current evidence so patients are receiving the wrong information when they return to work
105	5 Boroughs Partnership NHS Foundation Trust	3	No comments regarding this quality standard
Statement 4			
106	5 Boroughs Partnership NHS Foundation Trust	4	We agree with this statement except in the case of paracetamol where patients cannot be given concurrent NSAIDs due to contra-indications
107	Arthritis Research UK Primary Care Centre	4	The standards are not very helpful in advising GPs what to do with patients, particularly in relation to pharmacological strategies.
108	British Society for Rheumatology & Royal College of Physicians	4	It is confusing to have this statement restricted to 'low back pain' only and not sciatica when all of the other Quality Statements are concerning both low back and sciatica.
109	British Society for Rheumatology & Royal College of Physicians	4	It is confusing to not have clarity as to whether this Quality Statement refers to Primary Care or Secondary Care. All other statements refer to Primary Care
110	Faculty of Pain Medicine of the Royal College of Anaesthetists	4	Statement 4 and 5 are direct from NICE - but there is confusion here about the need for appropriate analgesia in the acute phase (esp. sciatica).
111	Faculty of Pain Medicine of the Royal College of Anaesthetists	4	It could be added that: anticonvulsants and antidepressants are appropriate for neuropathic pain associated with sciatica. As written there is a risk of under-treating that population.
112	International Neuromodulation Society	4	If there is neuropathic pain associated with the sciatica these will need to be prescribed by specialist care and continued by primary care

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113	NHS England Specialised Pain Services Clinical reference Group	4	If there are elements of neuropathic pain then these medications may be appropriate to be considered. It would be appropriate to mention this within the standards to avoid inappropriate extrapolation of the standards for financial expediency.
114	Society of British Neurological Surgeons (SBNS)	4	Agree
115	Primary Care Rheumatology Society	4	This would be achievable with Education of those involved in the referral process
116	Primary Care Rheumatology Society	4	CCG Pharmacists to audit and highlight prescriptions of these medications where it appears that they are being prescribed inappropriately for low back pain +/- sciatica
117	Primary Care Rheumatology Society	4	Add specifically Hospital Occupational Health Services and Chronic Pain Clinics.
118	Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust	4	Paracetamol on its own should be taken if it works (problem is it doesn't for many). If patients haven't tried it they should
119	British Society for Rheumatology & Royal College of Physicians	4	The effect of denying anti-neuropathic agents for patients with back pain will be to drive up the use of NSAIDs and benzodiazepines. This will have adverse consequences to the population with back pain as adverse effects of NSAIDs and addiction to benzodiazepines will increase. This will not be measured by the Quality Standards. This is unacceptable.
120	Primary Care Rheumatology Society	4	Add after dependency, increased risk of mortality
Statement 5			
121	British Society for Rheumatology & Royal College of Physicians	5	It is confusing to have 'chronic low back pain' whereas all other Quality Statements refer to acute low back pain. This needs to be clarified otherwise treatment for patients in acute back pain will be denied.

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122	British Society for Rheumatology & Royal College of Physicians	5	The effect of denying anti-neuropathic agents for patients with back pain will be to drive up the use of NSAIDs and benzodiazepines. This will have adverse consequences to the population with back pain as adverse effects of NSAIDs and addiction to benzodiazepines will increase. This will not be measured by the Quality Standards. This is unacceptable.
123	International Neuromodulation Society	5	Opioids will still need to be prescribed for acute episodes and some chronic cases
124	National Council for Osteopathic Research	5	An additional indicator of numbers reducing opioids for their low back pain.
125	NHS England Specialised Pain Services Clinical reference Group	5	There may be a place for the short term use of opioids in the acute (or acute on chronic) phase whilst the patient awaits definitive interventions.
126	Society of British Neurological Surgeons (SBNS)	5	Agree
127	United Kingdom Spinal Societies Board	5	Supported
128	Primary Care Rheumatology Society	5	Personnel need to be involved with Education for this to be achievable, and a Public Health campaign required. Highlight the risks of addiction and increased mortality risk as per National Institute of Health(NIH) in America re addiction and mortality as well as lack of clinical effectiveness.
129	Primary Care Rheumatology Society	5	CCG Pharmacists to audit and highlight prescriptions of these medications where it appears they are being prescribed inappropriately for low backpain +/- sciatica
130	Primary Care Rheumatology Society	5	Add specifically Hospital Occupational health services and Chronic Pain Clinics.
131	Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust	5	not to be offered opioids. Fine long term but I would hope that an intelligent patient would have tried over the counter cocodamol before getting to their GP (or neurofen plus if they are very clever) Yes avoid opioids in long term pain (I am sick of dealing with the results of treating health anxiety and depression with Fentanyl 75 patch instead of psychological support and exercise). This won't stop until the physio and pharmacist are first port of call for back pain not the GP in a 5 minute slot.

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			So making this statement is negative and not supportive of staff or patients in the first line and will only increase visits to A&E or the out of hours service.
132	Arthritis Research UK Primary Care Centre	5	The standards are not very helpful in advising GPs what to do with patients, particularly in relation to pharmacological strategies.
133	Faculty of Pain Medicine of the Royal College of Anaesthetists	5	Statement 4 and 5 are direct from NICE - but there is confusion here about the need for appropriate analgesia in the acute phase (esp. sciatica).
134	5 Boroughs Partnership NHS Foundation Trust	5	No comments regarding this quality standard
Statement 6			
135	British Society for Rheumatology & Royal College of Physicians	6	This statement is contradictory to NICE guideline NG59 and needs to be modified to clarify the role of epidurals as most patients, commissioners and healthcare practitioners would view an epidural to be a spinal injection: Epidurals 1.3.5 Consider epidural injections of local anaesthetic and steroid in people with acute and severe sciatica.
136	Faculty of Pain Medicine of the Royal College of Anaesthetists	6	Statement 6 is simply wrong and directly contradicts NICE on RF, and has the potential to mislead regarding acute radicular symptoms and epidural injections.
137	Faculty of Pain Medicine of the Royal College of Anaesthetists	6	The spinal injection statement needs to clarify where spinal injections are considered as part of specialist care.
138	Faculty of Pain Medicine of the Royal College of Anaesthetists	6	Statement 6 should include a caveat to allow median branch blocks and denervation if the pain is thought to be from the facet joints.
139	International Neuromodulation Society	6	Medial branch local anaesthesia, steroid epidurals and transforaminal steroid epidurals are still meant to be available at specialist level

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			This statement will cause confusion to commissioners who will interpret it as NO SPINAL injections to be commissioned whatsoever
140	NHS England Specialised Pain Services Clinical reference Group	6	The wording of the standard is confusing and needs better definition of the injections supported by the NICE guidance (e.g. Radiofrequency denervation, Lumbar medial branch blocks, Epidurals and nerve root blocks are all very different and should not be grouped as spinal injections for risk of confusion and decommissioning). The current configuration would allow for possible wilful misinterpretation by commissioners and the removal of ALL injections.
141	Society of British Neurological Surgeons (SBNS)	6	Should it read as Facet Injections rather than Spinal as the latter can include Epidurals?
142	United Kingdom Spinal Societies Board	6	The local data collection needs to include secondary care providers and in particular Pain Clinic services .
143	Primary Care Rheumatology Society	6	This would be achievable with education of those involved with the referral processes
144	Primary Care Rheumatology Society	6	Add Hospital Occupational Health Services and Chronic Pain Clinics
145	Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust	6	<p>No injections. Although RFL is in the detail, not the statement.</p> <p>This is likely to make my job difficult. I agree almost all injections don't work or last less than 6 weeks (I audit mine regularly).</p> <p>I do injections that I am not impressed with (med branch blocks included) because patients want them, usually because the referrer has implied we can cure them with them.</p> <p>Some work longterm, many work for 3 months, many don't (I audit regularly). However, it can be useful to get patients to do physio, attend psychology etc. It also moves them on psychologically to a place where they can accept other treatments.</p>
146	Spine Intervention Society	6	Based on the brief (separate attachment), NICE differentiates between "spinal injections" and "epidural steroid injections". Those definitions are as follows:

ID	Stakeholder	Statement number	Comments ¹
			<ul style="list-style-type: none"> • "Spinal injections are variations of injected agents which aim to either reduce inflammation in tissue or induce inflammation to stimulate healthy tissue regrowth. These include facet joint injections, medial branch blocks, intradiscal therapy and prolotherapy." • "Epidural injections involve an injection into the epidural space within the spine, using either corticosteroids or anti-TNF agents for their anti-inflammatory and immunosuppressant properties." <p>The quality standard defines spinal injections much more broadly as inclusive of epidural injections, and only allows for medial branch blocks as diagnostic tools to determine appropriateness of radiofrequency neurotomy:</p> <ul style="list-style-type: none"> • "These are variations of injected agents which aim to either reduce inflammation in tissue or induce inflammation to stimulate healthy tissue regrowth, or reduce firing of nerve fibres that may be contributing to pain. They include steroid spinal injections, intradiscal therapy, prolotherapy and trigger point injections. However, medial branch block injections can be used as a diagnostic tool to establish if the person would respond to radiofrequency denervation." • "Facet joint radiofrequency denervation for patients who do not respond to the care pathway and who have a positive response to diagnostic medial branch blocks." SIS would suggest changing this to "diagnostic <u>comparative</u> medial branch blocks". • Intra-articular facet joint injections could be considered when low back pain is caused by the lumbar zygapophysial joints' synovial cysts (aspirate/rupture). (References: Martha JF, Swaim B, Wang DA, Kim DH, Hill J, Bode R, et al. Outcome of percutaneous rupture of lumbar synovial cysts: a case series of 101 patients. Spine J. 2009;9(11):899-904. Allen TL, Tatli Y, Lutz GE. Fluoroscopic percutaneous lumbar zygapophyseal joint cyst rupture: a clinical outcome study. Spine J. 2009;9(5):387-95.) • <u>When RFN is not available</u>, intra-articular facet joint injections to treat facetogenic pain could be considered based on the results of two pragmatic (although imperfect) studies. (References: Ribeiro LH, Furtado RNV, Konai M, Andreo AB, Rosenfeld A, Natour J. The effect of facet joint injection versus systemic steroids in low back pain: a randomized controlled trial. Spine. 2013;38(23):1995–2002. Lakemeier S, Lind M, Schultz W, Fuchs-Winkelmann S, Timmesfeld N, Foelsch C, et al. A comparison of intraarticular lumbar facet joint steroid injections and lumbar facet joint radiofrequency denervation in the treatment of low back pain: a randomized, controlled, double-blind trial. Anesth Analg. 2013;117(1):228–35.)

ID	Stakeholder	Statement number	Comments ¹
			<ul style="list-style-type: none"> • “Epidural injections for neurogenic claudication in people who have central spinal stenosis.” Epidural steroid injections do provide short-term pain relief and functional improvement for patients with radicular pain due to neurogenic claudication and may be considered for palliative care in patients who have not responded to other treatment options and are not candidates for surgery. • “Epidural injections of local anaesthetic and steroid in people with acute and severe sciatica.” We suggest NICE consider changing this to, “Epidural injections of local anaesthetic and steroid in people with moderate or severe acute or chronic radicular pain” in order to better define the nature of pain and reflect studies supporting effectiveness of epidural steroid injections. <p>Until there is a clear definition of “spinal injections”, it is difficult to comment on the appropriateness of this quality standard; however, as currently worded, implementation will significantly limit treatment options for patients with back pain that has not improved following a reasonable period of self-management.</p>
147	Spine Intervention Society	6	The quality standard should <i>at the very least</i> be consistent in implementing the NICE Low Back Pain guidelines, which allow for epidural steroid injections for patients with acute and severe sciatica (NICE NG59 – Recommendation 1.3.5). Evidence strongly supports the effectiveness of epidural steroid injections in reducing pain and improving function in patients with moderate or severe acute or chronic radicular pain.
148	5 Boroughs Partnership NHS Foundation Trust	6	No comments regarding this quality standard

Registered stakeholders who submitted comments at consultation

- 5 Boroughs Partnership NHS Foundation Trust
- Arthritis Research UK Primary Care Centre
- Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust
- British Society for Rheumatology
- Department of Health

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- Faculty of Pain Medicine, Royal College of Anaesthetists
- International Neuromodulation Society
- National Council for Osteopathic Research
- NHS England
- NHS England Specialised Pain Services Clinical Reference Group
- Public Health England
- Primary Care Rheumatology Society
- Royal College of Emergency Medicine
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians
- Society of British Neurological Surgeons
- Spine Intervention Society
- United Kingdom Spinal Societies Board
- Yoga for Healthy Lower Backs Institute