Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Action on Pain Reg charity	Guideline			The common theme in each of these case studies is that if these proposals went ahead there is a high possibility that the medications would not be available. This cannot be right and we wonder what the committee can be thinking about. There is a moral issue here which seems to have got lost in the swathe of academia on the committee. We are also concerned that the committee is heavily weighted in favour of healthcare professionals yet no place for organisations such as Action on Pain who are well placed to give an objective view form the frontline without any hidden interests as we are totally independent. In conclusion we firmly believe that this guidance is not fit for purpose both in terms of the actions it proposes along with the rights of a patient to receive the best possible treatment. It lacks overall credibility proposing actions that cannot possibly be delivered. It is blindingly obvious that you cannot get skilled chronic pain professionals off the street. We therefore urge the committee to open their minds to the reality something here at Action on Pain we deal with on a daily basis. You stand to fail to deliver the reality which this situation demands to the detriment of chronic pain patients and your fellow chronic pain professionals..	Thank you for your comment. The composition of the committee was agreed to cover a range of different healthcare professionals who treat people with chronic pain, as well as lay members who have lived experience of chronic pain. Patient members are an integral part of the committee. All healthcare professionals on the committee are active in frontline pain management. We would refute your claim that the guidance does not support the patient's right to receive the best possible treatment. The evidence for all of the pharmacological management was reviewed. For the medicines we have recommended against, there is no evidence that they provide benefit to people with sciatica. Where there was uncertainty, research recommendations were made, and an additional research recommendation has been added since consideration of the stakeholder comments for the use of NSAIDs for sciatica. The recommendations for other management options in the guideline still remain, including non-pharmacological options. These recommendations therefore do focus on the treatment with the best evidence for benefit.

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Action on Pain Reg charity	Guideline	General	General	Established in 1998 Action on Pain is a national charity providing support and advice for people affected by chronic pain. Painline-our dedicated helpline has handled over 16000o calls and we have issued over 1000000 of our informative booklets. We have an. enviable reputation for telling it as it by promoting the positive side of living with chronic pain. We neither seek or accept funding from any government or pharmaceutical company enabling us to be totally independent and impartial in what we do. Run entirely by volunteers Action on Pain has an absolute wealth of experience and insight in to the needs of people affected by chronic pain. Turning to the guideline document which we have read in some detail enabling us to give a balanced view. Let us make it clear from the outset that we have serious concerns as to what is proposed along with the negative impact not only for patients but also for healthcare professionals working in NHS pain management teams. Whilst we have long been advocates of self-management we are also wise enough to realise that this is not an option open to many people affected by chronic pain. They often present with long standing complex problems which can see them attend the pain clinic as a last resort after many months/years of being passed around the NHS. To many the pain clinic is the "last chance saloon" so it is critical that clinicians have a wide range of treatments available to be able to responds to the INDIVIDUAL needs of the patient.	Thank you for your comments. The update of this guideline focussed on the pharmacological management of sciatica only. The evidence for this topic was reviewed and recommendations for use of medicines for sciatica were drafted based on this evidence. Evidence reviews for pharmacological management for low back pain, non-pharmacological management, and assessment of low back pain and sciatica were not updated and the recommendations from the 2016 guideline remain. There is also NICE guidance for other specific causes of chronic pain (for example osteoarthritis) and a guideline for chronic pain is currently in development. We acknowledge concerns that management of sciatica is complex and individual case histories may indicate benefit for some individuals, however the evidence review follows best practice in systematic reviews to give a robust evidence base for the benefit of the medicines reviewed for all people with sciatica. Evidence for all of the medicines considered is limited for people with sciatica. The evidence that does exist showed very limited evidence of benefit and some evidence of harms. Taking this evidence

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				In our opinion the proposed guidance fails to give sufficient weight to these particular needs which is cause for concern. There appears to be scant regard for the benefits that a highly skilled pain management team can bring to bear. Let us how turn to a question of resources. It cannot be denied that every NHS pain clinic suffers from long waiting lists. We have multiple examples of waiting times for a first appointment of up to a year, a follow up appointment up to 48 weeks, an URGENT physiotherapist appointment 6-9 months. With both an ageing and increasing population this is not going to go away. So let us change to the world of self-management that forms the backbone of these proposals. The obvious question that is absent from this document is where are the resources going to come from? Can you identify where in the NHs there is spare capacity or indeed the expertise needed to deliver these proposals? Simply put the answer is there is not. Your average GP has limited knowledge of complex pain issues and neither the time to deal with them. Your average physiotherapist does not possess am MSc in pain management with already upwards of a two year wait for a psychology appointment where is the extra in put going to come from? This document totally fails to address these issues. Let us now look at the role of the specialist pain consultant who deals with complex chronic pain patients on a daily basis. Currently they have a whole range of treatment	into account, the committee agreed it appropriate to recommend against the use of the majority of medicines considered rather than recommending treatments which may offer no benefit and could have negative effects. Where the evidence or committee experience was uncertain regarding potential benefit, research recommendations were made. This includes opioids for acute sciatica and antidepressants. All committee members submitted declarations of interest. Any with perceived conflicts relating to the pharmacological management of sciatica withdrew from recommendation discussions. The declaration of interests register is available on the guideline webpage on the NICE website.

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				options that this guidance document will almost emasculate. Whilst not always the option medications have an important role to play which should not be taken away. We go back to the essential point hat each patient has their INDIVIDUAL needs which common sense says cannot be compromised by a lack of suitable treatments. It beggars believe that this guidance document fails to recognise this given the consist of the committee instead seeking to implement proposals that will have a negative impact on chronic pain patients The use of medication is always a controversial subject generating much debate and we note that past comments from some of the committee members struggle to give a balanced view particularly in respect of opioids. Having visited the USA to look at the opioid issues over there it is very clear to us that the use of them has to be in a structured and controlled manner with regular reviews of the patient by the prescriber. We would suggest that this applies to all medications yet currently it appears that this is not always the case. Does this therefore give a compromised view of their usage. We suggest it does. To take away the options of using various medications to ease the suffering of a chronic pain patient cannot be right. Neither can it be right to take away the ability of pain consultants to prescribe them. We note with considerable concern the lack of insight by the committee in this instance.	

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				Case histories are always relevant to this process so we include three all with the permission of the patient although in an anonymous capacity. 1) Peter,58, damaged his back whilst at work leading to many years searching for a cure. Eventually he was prescribed opioids carefully regulated and monitored by his pain consultant. They had a profound impact on him seeing a return to work as well as enjoying his hobbies. Six years on he is still taking the opioids with no detrimental effect. He has regular reviews with his GP. Last year he called our helpline having seen a tv programme about opioids which in his words "put the fear of Christ up him" as it painted an unbalanced view on opioids. We advised him to chat with his GP who thankfully had the insight to reassure him that his treatment would continue. Such concern should not be the case . 2) Sally,37, called our helpline to tell us how grateful she was for the treatment she received at her local pain clinic. They understood her treating her as an individual. NSaids were prescribed along with some motivational advice both of which had a real positive impact on her. Her family life has improved, her self esteem is back, she feels a new woman.	

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				3) Bob,70, is a tough,no nonsense man who was critically injured many years ago leaving him with long term injuries and high pain levels. Very positive in his approach he went to pain management courses which certainly helped him. Yet all through his journey he had needed medication to help him get through. A sensible man he has three levels of pain medication which he manages himself with regular reviews from the pain team and his GP. Over the past couple of years his pain levels have increased so he sits on a long waiting list for a dorsal column stimulator. His pain consultant prescribed an opioid which he is sensible enough to take only when he needs to. In his words "it keeps me going when things get tough, take it away from me what else is there for me" Nothing. .	
Advanced Practice Physiotherapy Network	Pharmacology	General	1.216	Our members fully understand the 'risk' associated with the gabapentinoids not only to the patient but also associated with abuse of these medications and therefore the reason they were reclassified. The decision to completely remove these drugs from the management of sciatica based on two conflicting studies is something our members do not support. To completely take these drugs away from the formulary for sciatica may leave many patients with acute pain in difficulty.	Thank you for your comment. The committee considered the evidence from all of the studies (meta-analysed where possible) alongside the quality of that evidence and their own clinical expertise when making the recommendations. For gabapentinoids there was evidence from 3 studies compared to placebo. There were 2 conflicting results for pain reduction, evidence from 2 studies demonstrated no difference compared to placebo – this evidence was rated as high quality and included 408 participants.

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				The risk on the overall health economy is of: Increased emergency department attendances due to uncontrolled acute radicular pain. Increased demand for steroid injections (epidurals and root blocks) due to uncontrolled acute radicular pain, causing pressure on services offering this. Increased surgical intervention for uncontrolled acute radicular pain, in both the NHS and private sector. As the evidence tells us this increases the risk of recurrence more than conservative management. Could there not be some room in the guidelines for a 'judicious prescription' (of short term) gabapentoids in those that have no response to amitriptyline. Perhaps the advice could be to use infrequently or with caution in acute radicular pain only with regular review and short term use only. These drugs should be given in conjunction with evidence based treatment such as exercise, lifestyle and health promotion advice.	Evidence from another study using a different pain measure demonstrated a benefit, however this was rated as moderate quality and included only 43 participants. The committee considered all of these factors alongside the other outcomes (quality of life, function, psychological distress and adverse events) when drafting the recommendations. We do not agree that recommending against the use of medicines that do not have proven efficacy will negatively impact on the health economy. The evidence does not support recommending these even for a short trial. The recommendations for other treatment options in the guideline still stand.
British Society for Rheumatology	Guideline	General	General	BSR is supportive of the guidance as it stands.	Thank you for your comment.
Connect Health Ltd	Guideline	General	General	The recommendations are reasonable, and evidence based. We are fully supportive of the updated guidance and feel it will be welcomed within clinical practice.	Thank you for your comment.

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Faculty of Pain Medicine	Evidence review	006	025-031	The 2019 surveillance review is mentioned as one of the reasons for review of this guidance. https://www.nice.org.uk/guidance/cg173/resources/2019-exceptional-surveillance-of-neuropathic-pain-in-adults-pharmacological-management-in-nonspecialist-settings-nice-guideline-cg173-7014450925/chapter/Surveillance-decision?tab=evidence The surveillance decision states: "We noted that for sciatica, a common type of neuropathic pain, evidence for gabapentin and pregabalin appears to be insufficient, and topic experts were concerned about using these drugs in this condition. Therefore, we decided that an update to the guideline should focus on treating sciatica, particularly whether gabapentin and pregabalin are suitable treatments for this condition." This would suggest a foregone conclusion from the outset of the review. We are faced with a mechanism of assessment: absence of evidence is reason to stop prescribing, however weak the negative evidence actually is.	The surveillance review informed the decision by NICE to update the guideline. It is not a foregone conclusion of the guideline however. Following the surveillance review the guideline update was commissioned to the National Guideline Centre (NGC) working with an independent committee. The technical team at the NGC undertook a thorough update of the evidence for all pharmacological management options for sciatica (as agreed in the review protocol). Evidence was presented to the committee who drafted and agreed recommendations. This was all done independently to the team who undertook the surveillance review, and recommendations drafted are based on all of the evidence reviewed together with the committee's expertise. The committee consider the quality of evidence also taking into account the risk of harms. In the case of gabapentinoids the limited evidence did not show a benefit but there were harms. This, considered alongside the committee's expert knowledge of harms associated with these medicines, and the MHRA safety update highlighting the risk of abuse and dependence with gabapentin and pregabalin that followed their reclassification as Schedule 3 controlled drugs, led the committee to agree that

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					recommending against their use for sciatica was appropriate.
Faculty of Pain Medicine	Guideline	007-008	021-008	The FPM has significant concerns with the content of this draft guideline. It is far too restrictive. We would be very happy to support recommendations which support doctors in addressing the issues of regular assessment of patients' medications, supporting maintenance on any analgesic or co-analgesic if there is clear holistic benefit, but this does not allow that.	Thank you for your comments. We have responded to each below but would like to note that these recommendations are based on a review of the evidence following processes set out in the NICE guideline manual. Positive recommendations are made when the committee is confident that the benefits clearly outweigh the harms for most people.
Faculty of Pain Medicine	Guideline & Evidence review	General	General	The FPM has very deep concerns regarding the impact and the implications of this review. For severe and long-term pain NICE is indicating that no other therapies beyond paracetamol, codeine, physiotherapy and coping skills (whether by psychology or a PMP) are to be available on the NHS. This will create a scenario of considerable suffering with no ability to assess the potential individual options from pharmaceuticals. There is a significant problem with the published analysis of trials, in that to-date, even well designed trials, often resort to simple averages and confidence intervals when assessing the outcome. Where drugs have limited, but significant individual value such information is lost in this simplistic analysis of the data. An underlying assumption of economic benefit fails with the long-term suffering and societal costs that could have been helped with medications that have a low NNT. Without the ability to trial, there is a significant risk of cost-burdens to society that the drug costs for the individual, or for their use	Thank you for your comments. This update focussed on the pharmacological management of sciatica only. All other recommendations have been retained from the 2016 iteration of the guideline and still apply. The recommendations follow a review of the available evidence. The process followed and criteria for making recommendations are consistent with those set out in the NICE guidelines manual. Specific methods for the systematic reviews are detailed in the methods chapter for this guideline and follow best practice methodology. We do not agree that recommending against the use of drugs for sciatica that do not have demonstrable benefit but do have known harms would lead to cost burdens to society.

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				in identifying 'positive responders' would have saved, in addition to the significant suffering that results. We recognise the importance of considerable caution and care with any medications that have tolerance, dependence, withdrawal and abuse potential, and we are clear that guidance on a clear evaluation of benefit, and of a time limited approach to stopping medications that have not achieved significant benefit is a safer, more humane and appropriate response to current concerns rather than a blanket ban on individual assessment, for options of low NNT, but very significant individual benefit.	
Faculty of Pain Medicine	Guideline & Evidence review	General	General	By increasing the focus on each area within the guidance, without clear reference to the overall aim of improved support and outcome for patients, this review fails to recognise the limited role that medications have in reducing suffering in a large cohort of low back pain and sciatic sufferers, who will usually already have failed to gain benefit from other therapies (e.g. Pain Management Programmes, Psychology, Physiotherapy, injections), which may have better NNTs and NNH's, but still fail to help large numbers of sufferers.	This update focussed on the pharmacological management of sciatica only. The recommendations already included in the guideline for low back pain and sciatica still apply. Algorithms detailing all of the different treatment options have also been included in the full guideline on pages 14 – 18 of the assessment and non-invasive section of the guideline.
Homerton University Hospital	Evidence review	010	013 014 015 016	This evidence was excluded however; the studies included on gabapentinoids were on mixed populations of just lower back pain and those with neuropathic leg pain. This is therefore contradictory.	Thank you for your comment. We can confirm that all studies included for gabapentinoids were specifically in people with sciatica. One study (Baron et al. 2010) included people who may have low back pain as well as sciatica, but as part of the inclusion criteria for the trial, confirmation was required that sciatica pain was the main symptom and treatment focussed on

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16/07/2020 to 30/07/2020

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					sciatica. These studies are all consistent with the inclusion criteria set out in the methods chapter and review protocol.
Homerton University Hospital	Evidence review	10	19	The studies chosen for this evidence review for the use of gabapentinoids appear only a very small select number (5) and it is unclear why a larger body of evidence hasn't been used. Many studies are of poor quality. It is very difficult to make any conclusions based on this research. One study on pregabalin vs placebo reviewed a change of ≥30% was significant (Baron et al. 2010). It is difficult to use such percentages as meaningful across the board. A change in pain score equal to 1.65 for the NRS and 16.55 for the VAS is sufficient for patients to report a change worth mentioning (Bahreni et al. 2020). However, of our patients with very persistent neuropathic pain or somatic pain, often getting a 'much better' response from purely medication is a futile pursuit, and is not a realistic expectation of medication. Using percentage changes is therefore complex. If a meaningful change for an individual patient is not gained with medication, it should be titrated down and stopped. Furthermore, pregabalin had positive effects on most of the outcome measures used including those for depression and anxiety as well as sleep disturbance and sleep quality compared to placebo in the single-blind phase (Baron et al. 2010). The lack of difference between placebo and pregabalin in the double blind phase could be due to the	Thank you for your comment. A thorough search of all available evidence published in peer reviewed journals was carried out. No other studies specifically focussing on gabapentinoids for sciatica were identified that were relevant to the review protocol. The intention within the systematic review is to meta-analyse the evidence where possible to lead to a pooled estimate of effect across studies. This would also increase the weight of the evidence when the individual studies are small. As part of this, each study is critically appraised and the evidence for each outcome is quality assessed to give a quality rating. This assessment is considered by the committee alongside the results. In the case of gabapentinoids a meta-analysis was only possible for a couple of outcomes due to the heterogeneous nature of outcome selection and reporting across studies. However, where this was not possible, the outcome is still quality assessed in the same way, and the size of the body of evidence is also taken into account in decision making. The outcomes extracted and analysed in this review are those relevant to the review protocol. These were determined a priori as the key outcomes for decision

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16/07/2020 to 30/07/2020

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				length of the double blind phase and that placebo patients received pregabalin for the first week. In addition, patients who didn't respond in the single blinded phase were removed from the study, but some patients take longer to respond to medications than others, and therefore this may have also contributed to the lack of difference in the double blind phase. Unfortunately, patients were also taking concomitant medications including opioids, plus prohibited medications in a small number of cases, which could have influenced the results. It should also be noted this study was on chronic radicular pain and not acute. It is much harder the get a response with medication in persistent neuropathic pain compared with acute. There was an issue with lack of reporting of confidence intervals (CIs) for some of the statistics used and therefore clinical significance couldn't be established. Other times the CIs were included. Quoting p-values without CIs is not considered good practice. Ko et al. 2016 study included in this evidence compared 20 patients on oral steroids and 20 on pregabalin or gabapentin. This is severely underpowered. The authors concluded the steroid group did better but reviewing the data there is very similar improvements in both groups. Plus considering the long term side effects of steroids, it would not be worth the risks for most patients. Again no confidence intervals were quoted which makes reviewing clinical significance more difficult. It is likely the results can	making. Statistical significance is not used as the basis for decision making. The committee take a number of factors into account when making a recommendation. They judge each result according to pre-specified minimal important differences (described in the methods chapter and defined in the summary GRADE tables in the evidence review). These values are those agreed as being the minimal change to demonstrate a clinically important difference. The confidence intervals around the effect estimate are calculated for each and these are considered within the imprecision rating as part of the quality assessment. We do not use the conclusions of the individual studies themselves, but instead use these values and our own analysis and quality assessment to interpret the results with the expertise of the committee. We do not exclude studies based on their sample size. This is because that may be added to by inclusion in a meta-analysis, and irrespective of that it is considered within the risk of bias rating and subsequent quality assessment. It was agreed when setting the protocol that acute and chronic sciatica would be considered together unless heterogeneity in the evidence suggested a difference in treatment effect according to this. Where the committee agreed different considerations

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

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16/07/2020 to 30/07/2020

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				be dismissed based on the numbers of participants involved. Mathieson et al. 2017 reviewed pregabalin vs placebo in a mix of acute and chronic sciatica. They used pregabalin for up to 8 weeks. Titrating doses in 8 weeks is rapid compared with clinical practice and could have led to many more side effects than it would have done if this titration had been much slower. It is common in clinical practice to not see a change when using gabapentinoids for up to 8 weeks if slower titrations are used, so this study was not over a long enough period and this may have been why there was no significant difference. However the confidence intervals quoted were in the minus numbers as well, and therefore if there is doubt that this lower level represents clinical significance, then the result of the trial is not definitive and it is likely that the sample size wasn't large enough to find a true clinical difference (Guyatt et al., 1995; Jiroutek & Turner 2016). So whilst a power calculation was given and numbers appeared to be sufficient, the CIs suggest this may not the case. Mixing acute and chronic is not ideal either given the introduction of heterogeneity to the population and adds to the complexity of interpreting these results. Yildrim et al. 2003 was again an underpowered study but did show a statistically significant improvement placebo of gabapentin over placebo. Again an 8 week trial was used and titration to higher doses of gabapentin over such a	needed to be applied, this was reflected in the recommendations (for example the research recommendation for opioids for acute sciatica). We have included an RCT authored by Mathieson et al. (reported in 3 papers dates 2013, 2016 and 2017). Our search also identified a systematic review by the same author dated 2019 which we think is the one you are referring to. The references of this review were checked for any relevant to this update, but the review itself was excluded. The recommendations are written based on the evidence reviewed following the above process. On this basis the evidence does not suggest recommending a trial period with these medicines. Alongside the lack of evidence of benefit, we do not agree that the risk of abuse of gabapentinoids can be ignored. The classification of gabapentin and pregabalin as Schedule 3 controlled drugs highlights this.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
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				short length of time is likely to have induced more side effects than a slow titration. It would be possible that patients did not respond to gabapentin because the study was not over a long enough period. The reference is quoted in the table as 2013, but in the reference list as 2003. A systematic review which included combination therapy was also included in the evidence (Matheison et al. 2018). This can be useful if a patient has mixed nociceptive and neuropathic pain, commonly seen in clinical practice. However, 20 studies were on lower back pain only. It is clear that gabapentinoids should not be used for lower back pain without evidence of neuropathic pain. 6 further studies included those with lower back pain with or without leg pain. Again this is not really reviewing the patients most suitable for gabapentinoids potentially. The vast majority of studies were either on NSAIDS or opiates +/- paracetamol. There was one study comparing pregabalin and no other studies on gabapentinoids, therefore this study is not applicable to the use of gabapentinoids. Consequently, we believe that putting a closed statement of 'should not be offered' with regards to gabapentinoids is difficult based on the research quoted. As mentioned above, pain relief is a human right (Brennan et al. 2019), and whilst evidence is lacking in high quality trials of the advantages of pregabalin or gabapentin over other medications for pain, there is also a lack of evidence that	

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				many patients abuse these medications. For example a systematic review by Bonnet & Scherbaum (2017); ''*We did not find convincing evidence of a vigorous addictive power of gabapentinoids which is primarily suggested from their limited rewarding properties…..*'', In everyday clinical practice we rarely see patients abusing these medications, with much of the data on abuse coming from certain populations such as those with previous substance misuse, those on methadone programmes, those combining gabapentinoids with opiates and the prison population (Bonnet & Scherbaum, 2017; Bonnet et al. 2018; Lancia et al. 2020). Therefore we would suggest that these medications are on a trial basis and withdrawn if not effective, they should only be instigated in patients who present with neuropathic pain, and stepped down every 6-12 months to review efficacy and whether they still need to be prescribed (as per NHS Scotland guidelines). Screening for previous substance misuse, concomitant opiate use etc. should be undertaken at initial consultation. If there is any doubt about the use or abuse of these medications, or there is a suspicion of divergence, therapeutic drug monitoring could be instigated, and clarity regarding how compliant a patient is with taking medications and whether they are taking other non-prescribed medications could be established. This would be	

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16/07/2020 to 30/07/2020

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				preferable than denying medication to those in need, with no former history of substance misuse or divergence of medication. Brennan, F. Lohman, D. & Gwyther, L. (2019). Access to Pain Management as a Human Right. American Journal of Public Health, 109, 61–65. doi:10.2105/ AJPH.2018.304743 Bonnet, O. Richter, E. Isbruch, K. & Scherbaum, N. (2018). On the addictive power of gabapentinoids: A mini review. Psychiatria Danubina, 30 (2) 142-149. doi.org/10.24869/psyd.2018.142 Bonnet, O. & Scherbaum, N. (2017). How addictive are gabapentin and pregabalin? A systematic review. Eur Neuropsychopharmacol, 27(12), 1185-1215. doi.org/10.1016/j.euroneuro.2017.08.430 Lancia et al. (2020) Pregabalin Abuse in Combination With Other Drugs: Monitoring Among Methadone Patients. Frontiers in Psychiatry Volume 10 | Article 1022. NHS Scotland Effective Prescribing and Therapeutics Branch. Chronic pain prescribing strategy: gabapentinoid prescribing, https://www.therapeutics.scot.nhs.uk/ pain/ (accessed 27.7.2020).	

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Homerton University Hospital	Guideline	007	022	We are concerned that by not being able to at least trial gabapentinoids, patients will suffer unduly. There is no doubt that chronic non-cancer pain is a complex issue, requiring multidisciplinary input which goes far beyond the prescription of pain relief. At no point should clinicians be relying on medication alone to treat acute or chronic pain. However, for those patients who are severely affected by pain, off work, not sleeping, and not able to function; pain medication is often a necessary part of their care e.g. in acute sciatica presentations. Taking the acute/sub-acute sciatica example; this will force many patients down the route of spinal injections or even operative treatments, because pain is not able to be controlled in any other way. This will not only potentially be detrimental to the patient in the longer term and have higher risks, but also dramatically increase the costs of management of these patients. It is clear that neuropathic pain medications should be reserved for those with evidence of neuropathic pain. Screening tools such as S-LANNS, DNP4 and PainDetect are by no means fool-proof but can be helpful to review this (Bennett 2005; Bouhassira, D. et al. 2005; Berthelot et al. 2019) and make a decision regarding appropriate medication. These are not mentioned in this document. Furthermore, quantitative sensory testing may help in quantify the presence of centrally driven pain (Georgopoulos et al. 2019) and again aid decision making regarding prescribing. Combining these measures can also	Thank you for your comment. We would like to clarify that this update focusses only on pharmacological management of sciatica, not chronic non-cancer pain more broadly nor other types of neuropathic pain. The NICE neuropathic pain guideline (CG173) still stands, with the removal of the sciatica population. The pre-existing recommendations for pharmacological management of low back pain still stand in this guideline. We have undertaken a review of the evidence for all of the pharmacological options for sciatica listed in the protocol, and do not have evidence to support a recommendation for a trial of gabapentinoids. The evidence for gabapentinoids for sciatica was limited, but did not show a benefit, but harms were demonstrated. We do not agree that this will necessarily force more people down the route of invasive treatments as we have no evidence to suggest that the use of these medicines would reduce symptoms. For a couple of the medicines considered where the evidence was uncertain (opioids for acute sciatica and antidepressants) the committee agreed that further research was warranted to determine whether these could be of benefit. Alternatively the other non-pharmacological treatment options within the guideline can also be considered.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				be helpful in distinguishing specific neuropathic subtypes of pain (Spahr et al. 2017). We believe that the main issue with these guidelines is the mixing of low back pain and those with sciatica/radicular pain. These are two different subgroups of back pain, often requiring different management. There can be a degree of overlap in some patients however there is often a dominant feature of one or the other. If acute sciatica is not managed well, patients often go on to develop chronic problems and this is much more difficult to manage. We would propose that if a trial of gabapentinoids is started, patients should be followed up on a regular basis to review the effectiveness of these medications, and ensure that these are withdrawn, if there is evidence of lack of efficacy or significant side effects. In clinical practice, if patients find medications beneficial, we advise a trial reduction every 6-12 months by one stepped dose, to ensure the medication is still effective and that there is a need to continue with the medication, at that particular dose (as per NHS Scotland guidelines). Often patients can reduce their dose over time. It is important to explain all other pain management strategies available to the patient, to help them decide what is best for them. The use of multidisciplinary teams should be emphasized, so as not to be reliant on medical models of management such as prescribing.	We agree that low back pain and sciatica / radicular pain are two different subgroups. This guideline stratifies the populations into 3 categories of 1) sciatica, 2) low back pain and 3) mixed low back pain and sciatica. This is explained in the methods chapter on page 6. This updated focussed only on populations where sciatica was the primary symptom. Both acute and chronic sciatica were considered within the reviews. Where evidence suggested different approaches, this has been reflected in the recommendations (for example the research recommendation for opioids for acute sciatica). We agree that all available treatment options should be considered and that an individualised approach tailored to the person's needs should be adopted. Recommendations included in NICE's guideline on Patient experience in adult NHS services includes recommendations to this effect and should be considered alongside all of NICE's guidelines for specific conditions. All of the relevant treatment options are detailed in the updated algorithm on page 17 of the full guideline as well as in the short NICE guideline. We have cross-referred to the NICE guideline for safe prescribing and withdrawal management which will cover some of the suggestions you highlight in your final point. However the lack of evidence for

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Making generalised statements of 'not offering' a medication, does not reflect the complex nature of persistent pain and the nuance that each individual patient brings with them – there is no panacea when treating a condition as complex as pain, and equally there should be no panacea in deciding that large parts of the general population who suffer with neuropathic pain but never had a substance misuse problem, should be prevented from accessing valuable medication that can improve their quality of life. If there is any doubt about the use or abuse of these medications, or there is a suspicion of divergence, therapeutic drug monitoring could be instigated, and clarity regarding how compliant a patient is with taking medications and whether they are taking other non-prescribed medications could be established. This would be preferable than denying medication to those in need, with no former history of substance misuse or divergence of medication. Berthelot, J. et al. (2019) Are painDETECT scores in musculoskeletal disorders associated with duration of daily pain and time elapsed since current pain onset? Pain Reports, 4, e739. Bennett et al. (2005). The S-LANSS score for identifying pain of predominantly neuropathic origin: validation for use	beneficial effect from gabapentinoids for sciatica remains in this case and does not support a positive recommendation even if appropriate monitoring for abuse of the drugs were in place.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				in clinical and postal research. Journal of Pain, 6(3):149-58. doi: 10.1016/j.jpain.2004.11.007. Bouhassira, D. et al. (2005) Comparison of pain syndromes associated with nervous or somatic lesions and development of a new neuropathic pain diagnostic questionnaire (DN4). PAIN 2005;114:29–36. Georgopoulos, V. et al. (2019). Quantitative sensory testing and predicting outcomes for musculoskeletal pain, disability, and negative affect: a systematic review and meta-analysis. Pain, 160(9):1920-1932. NHS Scotland Effective Prescribing and Therapeutics Branch. Chronic pain prescribing strategy: gabapentinoid prescribing, https://www.therapeutics.scot.nhs.uk/ pain/ (accessed 27.7.2020). Spahr et al. (2017). Distinguishing between nociceptive and neuropathic components in chronic low back pain using behavioural evaluation and sensory examination. Musculoskeletal Science & Practice, 27, 40-48.	
Homerton University Hospital	Guideline	007	024	Can this be clarified in terms of weak opiates such as Codeine vs stronger opiates such as morphine sulphate? For an older patient with significant osteoarthritis, codeine can be helpful in moderation. This is obviously not to be escalated, but many patients require more than paracetamol for OA pain. NSAIDS are not commonly	Thank you for your comment. The search for evidence included all opioids (both weak and strong). No evidence was identified for the use of either for

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				indicated in elderly patients due to co-morbidities. Some patients do not respond well to tablets due to significant side effects and in others codeine is ineffective in those who lack the liver enzyme required to convert it to the active drug, morphine. Therefore very low dose buprenorphine patches can also be of use in this population, but again as long as they are not escalated to stronger patches. These patients are attempting to maintain independence and mobility, and therefore it is important to review the benefit vs side effects of medication in this group, plus the harmful effects of a sedentary lifestyle on their health. It is also important to consider pain relief is a basic human right (Brennan et al. 2019), with much of the data on abuse coming from certain populations such as those with previous substance misuse, those on methadone programmes, those combining gabapentinoids with opiates and the prison population (Bonnet & Scherbaum, 2017; Bonnet et al. 2018; Lancia et al. 2020). Elderly patients suffering intractable pain due to severe inoperative OA should be allowed to choose what is best for them, especially in the case of a weak opiate such as codeine and low level buprenorphine patches. Brennan, F. Lohman, D. & Gwyther, L. (2019). Access to Pain Management as a Human Right. American Journal of Public Health, 109, 61–65. doi:10.2105/ AJPH.2018.304743	sciatica and therefore the recommendation applies to both. A recommendation already existed within the guideline for weak opioids for low back pain, this recommendation still stands. Please also note these recommendations are not for people with osteoarthritis, which is covered in another NICE guideline, currently being updated. The recommendations included in this update consider whether or not there is evidence that these medicines lead to pain relief. Where there is not, and there is evidence of harm, the committee agree it is appropriate to recommend against their use so that more beneficial treatment options can be considered.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Bonnet, O. Richter, E. Isbruch, K. & Scherbaum, N. (2018). On the addictive power of gabapentinoids: A mini review. Psychiatria Danubina, 30 (2) 142-149. doi.org/10.24869/psyd.2018.142 Bonnet, O. & Scherbaum, N. (2017). How addictive are gabapentin and pregabalin? A systematic review. Eur Neuropsychopharmacol, 27(12), 1185-1215. doi.org/10.1016/j.euroneuro.2017.08.430 Lancia et al. (2020) Pregabalin Abuse in Combination With Other Drugs: Monitoring Among Methadone Patients. Frontiers in Psychiatry Volume 10 | Article 1022.	
Homerton University Hospital	Guideline	007	025	We agree that patients already on medications should be warned of their side effects, but don't believe this goes far enough in terms of how to then manage the patient. They should not be taken off their medication suddenly which is what is happening in current GP practice. Patients are then presenting in A&E due to withdrawal effects. It would be helpful to suggest that slow titration down with appropriate support is required to manage these patients within the guideline and not just in the link to other work. Psychological support is especially helpful in our experience and again the multidisciplinary team approach. Many departments do not have a true MDT approach and consider a consultant with a nurse as an MDT. We would strongly recommend including psychologists and OTs as well as physiotherapists alongside this. It is also worth	Thank you for your comment. The recommendation makes clear the decision to discontinue drugs is a shared one. If a decision is made to stop, we agree people should not be taken off their medication suddenly. The guideline committee were aware when drafting the recommendations that there is a NICE guideline being developed on medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management. A link has been provided to the guideline page where recommendations will be included regarding withdrawal management. The evidence for withdrawal management was not considered within this update and therefore more specific recommendations are not included here.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				outlining our experience that patients who are referred to a pain management clinic once their medications are withdrawn are understandably upset and are therefore less likely to be open to looking at alternative strategies of living with pain.	
Homerton University Hospital	Guideline	008	1, 2,3	Discussing withdrawal is one thing (see line on page 7, line 25), but it is important to explain that reducing and titrating down medication should be controlled slowly and with ongoing support. There have been many cases in our local area of GPs withdrawing medication suddenly and patients having to attend A&E, losing faith in medical professionals and becoming desperate to get medication. This can lead patients down the route of street drugs. It is also worth outlining our experience that patients who are referred to a pain management clinic once their medications are withdrawn are understandably upset and are therefore less likely to be open to looking at alternative strategies of living with pain. Furthermore, the idea that this should be a shared decision emphasized and if patients wish to continue with some form of gabapentinoids and safe doses of opiates, they should be allowed to do so under Montgomery consent (i.e. the doctor cannot overrule the patient if they are competent and understand the risks associated with their treatment), as long as this is not causing dangerous side effects, the doses are acceptable, and there is no evidence of behaviour consistent with addiction or dependence. We understand that NICE are developing guidelines on this, but	Thank you for your comment. Please see our response to your comment above regarding why detailed withdrawal recommendations have not been included within this guideline. We do agree that this should be a shared decision, and the recommendation relating to the problems associated with withdrawal highlights that this is if a shared decision is made to stop these medicines, after a discussion with the patient. Further detail of the committee's discussion of the importance of shared decision making has been added to the discussion of the evidence in the evidence review.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				believe there should be expanded information given in this guideline to mention that some patients find their opiates and gabapentinoids helpful, and risks should be weighed with benefit, consent considered at all times and shared decisions made with patients, rather than just being told they have to come off and taken off suddenly. This is especially important in those patients who have been on their medications for a number of years without titration upwards or evidence of addiction/dependence. Plus psychological support is especially helpful in our experience when reviewing titration off of medication. Many departments do not have a true MDT approach and consider a consultant with a nurse as an MDT. We would strongly recommend including psychologists and occupational therapists as well as physiotherapists alongside this. We have found that most patients will share how they may get suboptimal pain relief from medication but are understandably reluctant to come off of them if they have no other strategies in place; this often changes when they are supported by a full MDT and start to develop other practical skills and strategies first or alongside any plan. This comes back to this being a shared decision making process with patients at the centre of this.	
Homerton University Hospital	Guideline	008	004	We believe this doesn't go far enough. Many thousands of patients end up in A&E for NSAID related bleeding every year. Those with diabetes and hypertension have risks to their kidneys. NSAIDS are harmful for quite a few of our population and many patients end up on them for years.	Thank you for your comment. The evidence review for NSAIDs revealed very limited evidence. Whilst this did not show a benefit, the committee agreed that there was insufficient evidence to recommend against their use. We have however added a

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Again expanded information outlining the clinicians responsibility to inform the patient of risks (with OTC as well) and to provide PPI cover if the patient is on them for any longer than 5 days, to recommend limiting their use to flare-ups or in acute sciatica only, and for a maximum period (often 2 weeks), would be helpful.	recognition of the risk of harms to clarify this, alongside the limited evidence of benefit. The recommendations for NSAIDs for low back pain (not updated) also still stand in this guideline and highlight the considerations that are required regarding gastrointestinal, liver and cardio-renal toxicity, as well as the importance of gastro protective treatment and monitoring.
Royal College of General Practitioners	Guideline	007	021	The RCGP supports the changes to the guidance emphasising the limitations of using antiepileptics, gabapentinoids and benzodiazepines for sciatica	Thank you for your comment.
Royal College of General Practitioners	Guideline	009	008	We would encourage NICE to add a statement regarding the use of benzodiazepines in acute lower back pain. For example, "Benzodiazepines should not routinely be used for managing low back pain"	Thank you for your suggestion, however this update only covered pharmacological management of sciatica. The evidence for pharmacological management of low back pain was not updated and therefore this recommendation cannot be added.
Royal College of Nursing	General	General	General	The Royal College of Nursing (RCN) welcomes proposals to update the guidelines in line with the recent Medicines Health Regulatory Authority (MHRA) on pharmacological interventions. The RCN invited members with expertise in this area to review the documents on its behalf. The comments below reflect the views of our reviewers.	Thank you for your comments. We have responded to each below.
Royal College of Nursing	Guideline	006	018	Has there been an update regarding the evidence for not recommending acupuncture? Could this be amended to	This update focussed on the pharmacological management of sciatica only. The evidence for acupuncture was not reviewed as part of this update.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				suggest that acupuncture could be used however should be stopped if there is no improvement?	
Royal College of Nursing	Guideline	006	025	As above, this seems like a terrible shame to not recommend as it can be a very effective component of a pain management package for lower back pain. Could this be amended to suggest its use in combination with exercise and psychology?	This update focussed on the pharmacological management of sciatica only. The evidence for TENS was not reviewed as part of this update.
Royal College of Nursing	Guideline	007	022	This seems at odds with the NICE Guidelines for the management of neuropathic pain in non-specialist settings. Will the neuropathic pain guidelines be updated to reflect a consistent message?	All treatment recommendations for sciatica now sit within this guideline and the neuropathic pain guideline will be updated to clarify that the recommendations do not apply to people with sciatica.
Royal College of Nursing	Guideline	008	018	Are you recommending long term use of "weak opioids"? It is not clear if the terminology of weak opioids is appropriate given a dose of codeine is the equivalent to oral morphine. Should this read step 2 opioids? Perhaps a statement similar to that of NSAID's with regular review and continue for shortest period of time possible. Does this statement of "weak opioids" also cover Tramadol?	The recommendations for sciatica apply to all opioids. The recommendation you refer to is for low back pain and the evidence and recommendation was not part of this update. The recommendation is retained from the 2016 guideline and relates to acute low back pain only if an NSAID is contraindicated, not tolerated or has been ineffective, not long-term use. Recommendation 1.2.28 clarifies they are not recommended for chronic low back pain.
Royal College of Nursing	Guideline	009	002	The guideline states 'do not recommend opioids' however on the previous page recommends 'weak opioids'. It would be helpful to give more clarity in what is being classified as a 'weak opioid' and an 'opioid', Perhaps using the analgesic ladder as a guide maybe more appropriate.	The new recommendations added in this update apply for sciatica only and recommend against opioids. The recommendations for low back pain are retained from the 2016 guideline and detail the exception where weak opioids may be considered. A classification of what can be considered a weak versus a strong opioid is detailed in the BNF.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal College of Physicians (RCP)	Guideline	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our JSC for Clinical Pharmacology and Therapeutics and would like to make the following comments.	Thank you for your comments, we have responded below.
Royal College of Physicians (RCP)	Guideline	General	General	Our experts believe that this reads like an extensive "Do not offer…" list of interventions. Generally, most prescribers tend to take the positive aspects of NICE guidance on what particular item to prescribe. It is much more difficult for prescribers to take on board a long list of what not to prescribe. This is particularly true in acute hospital settings where patients may present with acute low back pain and be admitted for inpatient pain control. The guidance does not really provide much in the way of viable options for clinicians in this acute setting. Hence, adherence to this NICE guidance is likely to be poor. Clinicians feel that they must offer something to the patient to enable agreement on discharge from hospital. Unfortunately, this typically ends up being the scheduling of an Outpatient MRI scan plus a short course of opioid/ gabapentinoid/ benzodiazepine. There needs to be research into when and how the expectations of the prescriber and patient can be met in a situation where none of the pharmacological therapies are of any major benefit.	This update focussed on the pharmacological management of sciatica only. The review of the evidence demonstrated a lack of evidence of efficacy for many of the drugs considered, there was also evidence of harm. The recommendations from the 2016 iteration of the guideline for other treatment options still stand. The committee agreed that it is not appropriate to recommend medicines that are not demonstrated to be of benefit to people with sciatica. This would negatively impact on patients' quality of life, and would not improve their symptoms. We acknowledge the challenges of meeting expectations when there are few treatment options, and agree such research would be of interest, however any research recommendation included in this guideline must be specific to a research question we have reviewed. Research recommendations have been included for the use of antidepressants and NSAIDs (the latter added in response to stakeholder comments). We hope these may inform future updates of the guidelines. Non-pharmacological options already included in this guideline can also be considered as well as opioids for acute sciatica.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal College of Physicians and Surgeons of Glasgow (RCPSG)	Gudiance	General	General	The Royal College of Physicians and Surgeons of Glasgow although based in Glasgow represents Fellows and Members throughout the United Kingdom. While NICE has a remit for England, many of the recommendations are applicable to all devolved nations including Scotland. They should be considered by the relevant Ministers of the devolved governments. Low back Pain and Sciatica is an important condition in primary and secondary care and is responsible for a significant number of days off work for the UK population. Optimum treatment is important in an area where the evidence base is often lacking. Its management varies with each speciality and there is need for overall guidance based on science and minimising side effects. The promotion of drugs such as Gabapentin in the past for neuralgic pain with out considering side effects and dependency is noted. There needs to be a measured balance between potential benefits of any treatment and potential adverse effects. This guidance goes someway to achieving this aim.	Thank you for your comment.
Royal College of Physicians and Surgeons of Glasgow (RCPSG)	Guideline	004	006	One of our reviewers felt it would be of help to elaborate on what are concerning 'new or changed symptoms'	Thank you for your comment. This update focussed on the pharmacological management of sciatica only. All other evidence was not updated and recommendations have been retained from the 2016 guideline. Evidence for the assessment of low back pain and sciatica reflected in recommendation 1.1.1 was therefore not considered by this committee.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal College of Physicians and Surgeons of Glasgow (RCPSG)	Guideline	007	021	The College agrees with the review of drugs in sciatica. There is however no discussion of Tricyclic antidepressant which are frequently used in sciatica and have benefit limitations.	Thank you for your comment. The committee made a research recommendation for the use of antidepressants for sciatica. This is noted in the guideline in the box on page 7 and an explanation for this decision is given in the rationale on page 13. The committee's discussion of the evidence in the evidence review also provides further explanation.
Royal College of Physicians and Surgeons of Glasgow (RCPSG)	Guideline	008	004	NSAIDS can be useful in individuals despite low evidence. This needs re-phrasing. Neither are they addictive. Possible side effects need to be considered in relation to incidence in those without risk factors (low).	Thank you for your comment. The evidence review identified very limited evidence for NSAIDs, but of that, it was not supportive of a beneficial effect of NSAIDs. The committee considered this was insufficient to make a recommendation against their use. The recommendations for NSAIDs for low back pain (and the relevant considerations) were not updated and still stand.
Royal College of Physicians and Surgeons of Glasgow (RCPSG)	Guideline	013	021	Practically NSAIDS can be of use in Sciatica in some individuals. We recognise potential side effects as discussed above. However, they are widely ad effectively used. Rather than not recommend them the document should recognise their use and suggest further research.	Thank you for your comment. As detailed in response to your comment above, the potential for benefit was not reflected by the evidence. The committee did consider that healthcare professionals are experienced in the use of NSAIDs and recognising the risks and agreed to have a recommendation highlighting the lack of evidence in preference to recommending against their use for sciatica. However, on consideration of stakeholder comments, a research recommendation for the use of NSAIDs for sciatica has now been added to the guideline.
Royal College of Physicians and Surgeons of	Guideline	General	General	The College is in general agreement with the recommendations outlined in the document with clear guidance to avoid unnecessary potentially addictive	Thank you for your comment.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Glasgow (RCPSG)				medication in the management of Low Back Pain and Sciatica.	
The British Pain Society	Guideline	General	General	The BPS would like the addition of the comment that it is advised to trial an appropriate neuropathic drug following suitable assessment in a specialist pain clinic.	Thank you for your comment. There is no evidence to suggest that the effectiveness would differ according to the setting they are prescribed in. All of the included studies were in specialist settings and did not demonstrate a benefit.
The Chartered Society of Physiotherapy	Guideline	007 008	021 - 026 001 - 005	*The CSP supports the proposal to update the guidance as set out in the consultation. These changes will be relevant to physiotherapists in all settings managing people experiencing low back pain and sciatica, in particular our prescribing members who frequently are involved in the medicines management of low back pain."*	Thank you for your comment.
The National Hospital for Neurology and Neurosurgery	Guideline	007	022	This update defines sciatica as 'leg pain secondary to lumbosacral nerve root pathology'. This definition would therefore fall under a classification of neuropathic pain. NICE guidelines (CG173) currently recommend gabapentoids for neuropathic pain and as a consequence one would expect that they should also be used for all neuropathic pain including sciatica. Perhaps this recommendation could be expanded to read: "In the management of chronic sciatica, unless the patient is under the care of a pain management service, do not offer gabapentinoids, other antiepileptics, oral corticosteroids or benzodiazepines for managing sciatica. For acute sciatica, the above medication should only be	Thank you for your comment. When this guideline is published, the NICE neuropathic pain guideline will be updated to clarify that it does not include treatment recommendations for sciatica, and will cross refer to this guideline. The surveillance review of CG173 suggested that there was reason to believe different recommendations may apply for sciatica. We do not agree the suggested rewording is appropriate. There is no evidence to suggest any of the medicines considered are any more effective in different settings. All of the studies included in this review were in specialist settings, but did not demonstrate benefit.

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				prescribed for a short period and the risks fully explained to the patient [2020]" Further, it is our opinion that guidelines on the management of neuropathic pain should now consider parenteral treatments options (e.g. IV lidocaine and Ketamine) and topical treatments (e.g. Qutenza) even if the reference is a call for further research. Patient feedback: "Do the guidelines need to be strengthened at all to say that more than 'discussion' might be needed to get people off opioids? Strong emphasis needs to be put on the importance of a very carefully designed tapering schedule by the patient and clinician to avoid the hideous withdrawal symptoms. They may need specialist support. We are also nervous that care won't be personalised to the individual, but that is inherent in guidelines."	We will pass your comment about parenteral treatments for neuropathic pain to the NICE surveillance team which monitors guidelines to ensure that they are up to date.. We agree that the points raised in the patient feedback are important to consider. The guideline committee were aware of the NICE guideline for safe prescribing and withdrawal management in development which will consider issues such as information required by patients and withdrawal strategies. The NICE guideline for patient experience in adult NHS services also highlights the importance of an individualised approach.
UK Spine Societies Board	Pharmacology	General	1.216	There is anecdotal evidence gabapentinoids are useful drugs for short term pain control in patients with neuropathic pain, it appears the decision has been made to remove this drug based on two contradictory studies. A paucity of evidence is perhaps not sufficient to withdraw a group of drugs completely. The real need here is for further research to determine the groups of patients with sciatica who would respond to one type of drug or the other.	Thank you for your comment. This decision has not been made on 2 contradictory studies. A thorough review of the evidence was undertaken. The committee considered the evidence from all of the studies (meta-analysed where possible) alongside the quality of that evidence and their own clinical expertise when making the recommendations. For gabapentinoids there was evidence from 3 studies compared to placebo. There were 2 conflicting results for pain reduction, evidence from 2 studies

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The national back pain clinical network agrees that long term use of gabapentinoids is not recommended and the use for non-radicular pain should not be recommended. A complete ban on use of this drug for sciatica may push a significant number of patients to have either an epidural steroid injection or surgery. There is also a fear that a large number of patients with unrelenting sciatica will start appearing in the emergency departments because they will be unable to cope with the sciatic pain. Would it be prudent to change the wording to allow a short term course supervised by a specialist (in accordance with the national low back pain pathway) and educate patients on the potential side effects and also to explain the importance of gradually weaning off when stopping the drug. This may need to differ depending on the local area there is a risk of illegal sales of the drug. NICE recommends the different types of pain medication that SHOULDN'T be used, there is little in the recommendations regarding things that we can do apart from Epidural and surgery? Many patients are unable to tolerate NSAIDS or amitriptyline and using weaker opiates don't often help with neuropathic pain. Is there scope in the guidance to cover health promotion with evidence to support the importance of this in discal pathology?	demonstrated no difference compared to placebo – this evidence was rated as high quality and included 408 participants. Evidence from another study using a different pain measure demonstrated a benefit, however this was rated as moderate quality and included only 43 participants. The committee considered all of these factors alongside the other outcomes which in most cases was not conflicting (quality of life, function, psychological distress and adverse events). The committee agreed it is not appropriate to recommend a drug when there is no proven evidence of benefit, but there are known harms. The other non-pharmacological treatment options recommended in this guideline still apply. These include group exercise, manual therapy as part of a treatment package with exercise with or without psychological therapy, or vice versa for psychological therapies plus exercise, with or without manual therapy. If these are ineffective and pain persists, the option of a combined physical and psychological programme, incorporating a cognitive behavioural approach can also be considered. We therefore do not agree that recommending against some pharmacological treatments where the harms outweigh the benefits for most people would necessarily increase the number of people receiving invasive treatment options. Opioids can be

Low back pain and sciatica in over 16s: targeted review of pharmacological interventions

Consultation on draft guideline - Stakeholder comments table
16/07/2020 to 30/07/2020

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					considered for acute sciatica, as well as the non-pharmacological treatments listed above.
Warwick CTU	Guideline	008	001	Recommendation 1.2.19. This recommendation is currently imprecise and potentially misleading. As currently written it could be interpreted that the discussion about the problems associated with withdrawal might come after the shared decision. Our view is that this discussion is part of the decision making process. Of course we note that a shared decision could also be made to continue these drugs. If this recommendation is retained we suggest rewording to reflect these concerns. For example, *'When making a shared decision to stop, or continue, opioids, gabapentinoids, or benzodiazepines for sciatica discuss the problems associated with withdrawal with the person.''* We have also been unable to find any material within the evidence review to support this recommendation. This does not appear to us to be explicitly within the scope for this update. We suggest that addressing withdrawal of such drugs is too broad to be considered specifically for sciatica. We suggest that this recommendation is not included here, as it is out of scope and not supported by evidence. It may be better to direct the reader to the forthcoming NICE guidance on 'Safe prescribing and	Thank you for your comment. We do not agree that the recommendation should be reworded as suggested. The wording already implies continuing is one of the options that could be made as a result of discussion and shared decision making. We have however reworded the recommendation to clarify that discussing problems associated with withdrawal should be part of the discussion. Further detail of the committee's discussion of the importance of shared decision making has also been added to the discussion of the evidence in the evidence review. This recommendation was made by expert consensus opinion, this has been added to the rationale and the discussion of the evidence to clarify. We agree it is important to cross refer to the guideline in development for safe prescribing and withdrawal management, and have done so, however it was agreed important to highlight this important issue here with a recommendation as well. Specific detail on how to withdraw has not been provided as that is within the remit of the safe prescribing guideline. The technical team involved in developing the guideline are cognisant of the importance of consistency between the guidelines.

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				withdrawal management of prescribed drugs associated with dependence and withdrawal'. We anticipate that the development of this guidance will have considered the issues in detail. For the record we are not disagreeing with the advice which, as re-written, we would support. Rather this is a concern about process, and avoiding the risk that NICE may have two guidelines that are not consistent when addressing very similar points.	Recommendations have been drafted to ensure this is maintained.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

Registered stakeholders