Clinical guidelines for low back pain. A critical review of consensus and inconsistencies across three major guidelines.

Corresponding author: Neil E O'Connell PhD, Health Economics Research Group, Institute of Environment, Health and Societies, Department of Clinical Sciences, Brunel University London, Kingston Lane, Uxbridge, UB8 3PH, United Kingdom

Email: neil.oconnell@brunel.ac.uk,

Tel: +44 1895 268814

Chad Cook PhD, PT, MBA Professor, Department of Orthopaedics, Duke University, 2200 W. Main St. Ste B230, Durham, NC, USA, 27705. Phone 1-919-684 8905 Fax 1-919 684 1846 chad.cook@duke.edu

Benedict Martin Wand BAppSc, GradDip, MAppSc, PhD, School of Physiotherapy, The University of Notre Dame Australia, Fremantle, Australia

Email: benedict.wand@nd.edu.au

Tel: +61 8 94330203

Stephen P Ward MBBS FRCA FFPMRCA, Department of pain Medicine, Brighton and Sussex University Hospitals NHS Trust, Eastern Rd, Brighton BN2 5BE, United Kingdom

Email: <a href="mailto:stephen.ward@bsuh.nhs.uk">stephen.ward@bsuh.nhs.uk</a>

Tel: +44 1444 441881

#### **Abstract**

Given the scale and cost of the problem of low back pain, it is imperative that healthcare professionals involved in the care of people with low back pain have access to up-to-date, evidenced based information to assist them in treatment decision making. Clinical guidelines exist to promote consistent best practice, to reduce unwarranted variation and the use of low value interventions in patient care. Recent decades have seen the publication of a number of such guidelines. In this narrative review we consider three selected international interdisciplinary guidelines for the management of low back pain. Guideline development methods, consistent recommendations and inconsistencies between these guidelines are critically discussed.

# **Keywords**

Low back pain, Clinical Guidelines, Evidence based practice, implementation.

#### Introduction

Low back pain (LBP) is the leading cause of disability worldwide. This is now as apparent in low-income countries as it is in the more affluent and developed countries across the globe. Disappointingly, despite a significant increase in back pain expenditure over the last decade, the levels of disability associated with back pain over the same period have remained virtually unchanged [1]. As well as the healthcare resource and economic burden that back pain and related disability present, a recent survey of nearly 200,000 people across 43 countries shows that people with back pain are at least twice as likely to have one of five mental health conditions (depression, anxiety, stress, psychosis and sleep deprivation) compared to those without back pain [2].

Given the scale of the problem, it is imperative that healthcare professionals involved in the care of people with LBP have access to up-to-date, evidenced based information to assist them in treatment decision making. Over the last few decades, a myriad of treatment options for back pain have emerged and with this, an ever expanding repository of clinical trial data and scientific publications. The results of this global research effort into the causes and treatment of back pain are often conflicting and of variable quality. This heterogeneity in the data and its sheer scale means that for the individual clinician in the pursuit of best clinical practice, making sense of the literature can be difficult and bewildering.

In an effort to assimilate and formally evaluate this information, an increasing number of clinical practice guidelines (CPGs) have been produced by countries across the world. Since the publication of the first low back pain clinical practice guideline by the Quebec Task Force in 1987 [3], more than a dozen 'national' multidisciplinary low back pain guidelines that were sponsored by professional societies, government agencies, and healthcare payers within their parent countries have emerged [4]. Each of the low back pain guidelines are created by an expert panel through consensus.

In this chapter, we compare three clinical guidelines for the management of low back pain. We outline where they agree on what comprises best practice for low back pain. We also consider inconsistencies in recommendations between these guidelines and some of the possible reasons for these; discuss the challenge faced in implementing the recommendations of guidelines and consider controversies and future directions for clinical guidelines in low back pain.

We have selected three major recent well-recognized, multidisciplinary back pain guidelines. The three guidelines include:

2016 NICE Guideline on Low Back Pain and Sciatica NG59 – United Kingdom [5]

2015 Evidence-Informed Primary Care Management of Low Back Pain – Canada [6]

2007/2009/2017 Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society – USA [8-10]

These three guidelines were chosen either because they were judged as high quality guidelines in a recent systematic review of clinical guidelines for back pain [4] or because at the time of writing they represented the most up to date clinical guidelines available. We will illustrate the differences and similarities between the guidelines in terms of development and their recommendations, and the challenges faced by guideline implementation.

#### What is a Clinical Practice Guideline?

Clinical practice guidelines have been defined as "...systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [11] and

"statements that include recommendations, intended to optimise patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" [12]

Clinical guidelines make an important contribution to effective dissemination and implementation science; CPGs provide the recommended information within the knowledge integration process [13]. The overarching goal of dissemination and implementation science is to ensure that advances in health science become standards for care in all populations and all health care settings. By recommending effective and evidence based interventions and discouraging interventions lacking in scientific support, clinical guidelines seek to optimise quality of care whilst reducing waste and the potential harm associated with ineffective or unsafe interventions. By adhering to guideline recommended practice, it is hoped that clinicians and patients can be reassured that best current practice, supported by the best available evidence, is being delivered. Clinical guidelines can reduce variations in practice, provide a rational basis for referral and act as a mechanism of quality control. Importantly, clinical guidelines can also identify areas of scientific uncertainty and make recommendations for future research.

Clinical guidelines for the same condition across the world should in principle be broadly similar. Guideline development groups have access to the same scientific data and evidence base after all. Conflicting guideline recommendations do however emerge. Some expected and reasonable sources of variation might be related to differences in the local economic and healthcare infrastructure in the country in which the guideline is developed. However, other less desirable sources of divergent recommendations may include variations in review methodology, subjective differences in the interpretation of benefits and harms, the local political landscape and, potentially, the constitution of the guideline committee, with the risk that recommendations might unduly reflect the work of those within the committee [14].

# Approaches to guideline development

Clinical guidelines should be based on a systematic review of the available evidence developed by a panel of multidisciplinary experts. The review(s) should focus on the strength and quality of the evidence and result in a set of recommendations. This should involve both the evidence and value judgments regarding benefits and harms of alternative care options, addressing how patients with a particular condition ought to be managed, everything else being equal.

There are usually five steps in the initial development of a clinical practice guideline [15].

- 1. Identifying and refining the subject area.
- 2. Convening and running a guideline development group.

- 3. Assessing the evidence about the clinical question or condition, on the basis of systematic reviews.
- 4. Translating the evidence into a recommendation within a clinical practice guideline.
- 5. External review of the guideline.

Whilst these steps represent the broad principles of guideline development there are variations in the processes and methodologies of different guideline groups and centres across the world. To illustrate some of the methodological variations in low back pain clinical practice guideline development, a summary of the processes adopted by NICE, the American Pain Society and American College of Physicians, and the Canadian 'Towards Optimised Practice' program is presented below:

#### NICE Guideline on Low Back Pain and Sciatica (NG59) 2016

The National Institute of Health and Care Excellence is a state funded organisation in the United Kingdom whose stated goal is to improve outcomes for people using the NHS and other public health and social care services. One key aspect to this is the development of clinical guidelines. The remit for all NICE guidelines comes from NHS England and published guidelines are usually reviewed for update every two years (with a guaranteed review at least every 4 years from the date of publication). NG59 was commissioned in response to the review of the 2009 NICE low back pain guidance (CG88) in 2012.

NICE commissioned the National Clinical Guideline Centre (NCGC) to develop the guideline and the NCGC produced a draft scope. The draft scope was reviewed by stakeholder groups and a final scope agreed. Review questions were agreed by the multidisciplinary Guideline Development Group (GDG). The GDG comprised 12 healthcare professionals from a range of backgrounds and two lay members. Conflicts of interest were declared at the start of the process and at the beginning of each of the 25 GDG meetings.

The population covered by the guideline included people over the age of 16 years with low back pain and/or sciatica. The duration of symptoms were not specified. Back pain prevention, persistent back pain following surgery and back pain during pregnancy were excluded. The NCGC technical team performed the literature searches and prepared the systematic reviews of the evidence and the economic analyses. Randomised controlled trials were given primacy but uncontrolled cohort studies were reviewed where there was insufficient evidence from randomised trials. Existing systematic reviews were identified primarily to ensure adequate capture of the relevant data. Twenty-two *de novo* systematic reviews were performed by the technical team. The GDG discussed these systematic evidence reviews along with expert testimony (from within the guideline development group or from invited expert witnesses with particular specialist expertise not represented in the guideline development group) and from this developed draft recommendations.

The methods used by NICE to conduct evidence reviews are transparent and explicit [16]. Where possible, data were meta-analysed and the quality of the body of evidence underpinning comparisons was assessed in terms of quality using GRADE methodology [17]. The strength of each recommendation is reflected in the wording (eg. 'offer' implies a strong recommendation whereas 'consider' reflects a weaker recommendation, usually on the basis of the strength of the

underpinning evidence). Consideration was given to the strength of the evidence, the relative benefits and risks, cost effectiveness and, importantly, the patient perspective.

The draft guideline was submitted to the public for stakeholder consultation and revised where appropriate in light of stakeholder comments. The revised guideline was submitted to NICE for internal peer review and sign off by the NICE executive. Once ratified by the NICE executive, the guideline was published.

# 2007/2009/2017 Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society

This guideline was initiated by the American Pain Society (APS). The first stage, published in October 2007 [7], focused on initial (primary care) evaluation and management of low back pain, and was conducted in partnership with the American College of Physicians (ACP). The second stage, published in May 2009, focused on use of conservative management [8], interdisciplinary rehabilitation [14] surgery and interventional therapies for low back pain [9]. An updated version focusing on non-invasive pharmacologic and non-pharmacologic treatment was published in February of 2017 [10]. A challenge to using the 2007/2009/2017 documents is that although the information was created by the same guidelines group, the method of dissemination varies depending on the paper accessed. That said, there are seven papers that collectively introduce the ACP guidelines [7-10, 18-20].

In the 2017 guidelines, the targeted population includes adults (≥18 years of age) with acute, subacute and chronic low back pain, radicular low back pain, or symptomatic spinal stenosis. In the original guidelines (2007-2009), the target population included adults (age >18 years) with acute and chronic low back pain not associated with major trauma. Children or adolescents with low back pain; pregnant women; and patients with low back pain from sources outside the back (non-spinal low back pain), fibromyalgia or other myofascial pain syndromes, and thoracic or cervical back pain were not included.

For the 2017 update, The Agency for Healthcare Research and Quality's (AHRQ) Pacific Northwest Evidence-Based Practice Centre completed all evidence reviews. Key questions included 'what are the comparative benefits and harms of different pharmacologic therapies for acute or chronic non-radicular low back pain, radicular back pain or spinal stenosis' and 'what are the comparative benefits and harms of different non-pharmacologic therapies for acute or chronic non-radicular low back pain, radicular back pain or spinal stenosis'? The review researched databases from 2008 through April 2015, and then updated the search through November of 2016. The previously published 2007 APC guidelines were used to detail any studies published prior to 2007. The authors incorporated published controlled clinical trials and systematic reviews. The majority of the 2017 ACP low back pain guidelines are similar to those reported in 2007. The most notable differences include a lack of endorsement of paracetamol (acetaminophen) and tricyclic antidepressants in the 2017 guidelines; a contrast from the 2007 guidelines.

Members of the Clinical Guidelines Committee were physicians trained in internal medicine and its subspecialties and included clinical experts and experts in evidence synthesis and guideline development. The committee performed quality assessment for randomized trials using a form

created by the Cochrane Back Review Group and the AHRQ, and evaluated systematic reviews using AMSTAR. Although patient preferences were considered, no patient representation was reported. Evidence was trichotomized as high quality, moderate quality, or low quality.

# 2015 Evidence-Informed Primary Care Management of Low Back Pain - Canada

This guideline is the 3<sup>rd</sup> edition of the Alberta Clinical Practice Guideline (CPG) for the Evidence-Informed Primary Care Management of Low Back Pain [6], which was produced as part of the second phase of the Alberta Health Technology Assessment (HTA) Ambassador Program.

The guideline was developed by a steering committee and an update committee. The update committee comprised a multidisciplinary group of primary care practitioners – most of whom were members of the group that developed the first edition of the guideline in 2009. Both the steering and update committees were supported by a research team.

The target population included adults with low back pain of any duration. Pregnant women were excluded. The focus was diagnosis and conservative non-surgical treatment of low back pain for use in primary healthcare settings. The guideline covers the diagnosis and treatment of radicular pain and a number of invasive interventions and injection procedures despite the proposed focus on primary care management but excluded in-patient interventions, such as surgical treatments.

Uniquely, the first edition of the guideline was developed by adapting existing good quality international and national guidelines on the management of low back pain. So-called 'seed guidelines' were identified and critically appraised and used to formulate the recommendations. These guidelines included some non-randomised study designs. Subsequent updates have identified more recent seed guidelines and recently published systematic reviews of new interventions that were considered important but were not included in the first edition of the guideline, but no new reviews of original studies were conducted as part of the development process.

Each recommendation from the CPG was sourced from one or multiple seed guidelines and the recommendations were categorized into three groups: *do, do not do* (not recommended), and *do not know*. The strength and quality of the underlying empirical evidence was not formally assessed however and could not be defined by terms such as good, fair, poor, insufficient, or conflicting. It is not clear whether patient or stakeholder comment was invited.

# Consistent recommendations across the three guidelines

In many areas the guidelines essentially speak with a single voice and produce broadly similar recommendations. In this section we will outline these key similarities in terms of diagnosis and management.

#### **Diagnosis**

The primary target of all three guidelines is acute and chronic low back pain. The NICE and Canadian guidelines defined non-specific low back pain as pain in the low back that has no identifiable cause and no clear association with a specific, serious underlying anatomical impairment or disease process. The updated US guidelines only differentiated low back pain as radicular, non-radicular, or symptomatic spinal stenosis. The Canadian and NICE guidelines excluded conditions such as

inflammatory systemic diseases (e.g. ankylosing spondylitis), structural spinal dysfunction (e.g. spondylosis, spondylolisthesis and scoliosis) and fractures associated with metabolic bone disease. While the US and Canadian guidelines separated studies and subsequent recommendations by the duration of symptoms (acute versus chronic), the NICE guidance broadly did not.

#### **Diagnostic Assessments**

All three guidelines recommended consideration of potential alternative diagnoses such as specific spinal pathologies, although it is worth noting that it was necessary to review two affiliated sister publications [18,19] to fully understand the screening processes that were used in the US based guidelines. Even if one includes the additional publications, then it remains evident that none of the guidelines provide notable detail on the best methods for screening. This reflects a broader inconsistency in the specific details for red flag screening advocated across guidelines for LBP [21]. The lack of consistent and detailed guidance in this area may be due, in part, to the limited diagnostic utility of red flag screening questions. Evidence suggests that tools used to screen for Red Flags lack the appropriate sensitivity (and subsequent negative likelihood ratio) to rule out the condition [22]. When combined with the very low prevalence, the change in post-test probability of the condition is minimal; a notable shortcoming in both CPGs and clinical practice.

The NICE and Canadian guidelines and the 2007 APC guidelines do not support the use of early, routine, imaging. Imaging is recommended only if it is likely to change the management of the patient or where there is justifiable suspicion of specific disease. The guidelines vary on the level of specific detail offered with regards suspicion of specific disease. While in the NICE guidance a suspicion of red flags essentially takes patients out of the NICE back pain pathway, the Canadian guideline specifies a list of specific indications for MRI including major or progressive neurologic deficit, suspected cauda equina syndrome, progressive severe pain and debility despite non-interventional therapy, severe or incapacitating back or leg pain, clinical or radiological suspicion of neoplasm or infection.. They recommend CT scanning where MRI is contraindicated, to detect or characterise primary bone tumours, or following trauma to rule out or characterise fractures. The updated US guidelines make no mention of the use of imaging within its primary or sister publications. Routine advanced imaging was not recommended by any guideline. Electro-diagnostic testing was not supported by the older US guideline and Canadian guidelines and not considered in the NICE guideline.

#### **Patient Management**

#### **Education and advice**

Advice to stay active and return to normal activities as soon as possible is a core recommendation across these guidelines. The NICE and Canadian guidelines go further, specifically recommending early return to work. The older US and Canadian guidelines specifically advise against bed rest as a treatment option. All advocate education toward an "expected" course of LBP, in which the probability of a rapid improvement in symptoms is high, potentially to reduce the risk of fear/catastrophizing and to moderate expectations.

#### **Pharmacological options**

In terms of pharmaceutical interventions all guidelines recommend the use of non-steroidal antiinflammatory drugs (NSAIDs) for acute and chronic low back pain. The guidelines are consistent in advocating a cautious approach to the use of opioids for acute low back pain. The new US guidance states that strong opioids are associated with small short-term improvements in pain , whereas the Canadian guidance statess that "short acting" opioid be used rarely, and only in severe cases. The NICE guidance recommends that a weak opioid, with or without paracetamol (acetaminophen) be considered only where NSAIDS are contraindicated, not tolerated or found to be ineffective. The updated US, NICE and Canadian guidelines recommended against long-term management of LBP using opioids. All three either recommend against or suggest only cautious use of antidepressants

#### Non-pharmacological, non-invasive management

All of the guidelines recommend some variation of exercise as therapy and none of the guidelines were able to specify whether any approach to exercise therapy is superior. As such, they recommend various forms. The NICE guidance places exercise therapy at the centre of conservative back pain treatment to a greater extent. In that guidance, a small number of other non-pharmacological interventions are recommended to consider, such as manual therapy or psychological interventions, however they are only recommended as part of a treatment package that includes exercise therapy and then not as essential components. Manual therapies are also recommended in the US and Canadian guidelines, though for acute back pain specifically and without the caveat of being offered alongside exercise therapy. Guidelines are consistent in recommending against the use of spinal traction.

Multi-modal care options, in which more than one type of intervention are incorporated into a treatment package, that include self-management principles and psychological approaches in the management of pain-related symptoms are also recommended across guidelines. The Canadian and newer US guidelines recommend multidisciplinary pain management programmes for chronic LBP, and the NICE guideline recommends to consider combined psychological and physical rehabilitation where a patient presents with significant psychological obstacles to recovery or where previous treatments have not been effective.

#### **Non-Conservative Interventions**

There is agreement between the NICE and Canadian guidelines that surgery should only be considered when conservative interventions have not shown improvement or resolution to normal functional status and both do not recommend any surgical interventions for low back pain. The older US guidelines provided much greater detail on management using surgical and injection-based approaches, as two separate papers were provided as supplements to the primary guidelines. All three guidelines recommended surgery for non-resolving radicular symptoms. The Canadian and older US guidelines do not specify the type of surgery, the NICE guidance recommends to consider spinal decompression surgery. Beyond this consensus there is little consistency across the guidelines for these types of interventions.

#### **Clinical pathways**

Both the NICE and the Canadian guidelines provide some guidance on referral pathways from primary care. The Canadian guideline recommends referral to a musculoskeletal specialist where patients are not returning to function at a reassessment 1-6 weeks following the initial contact. The NICE guidance recommends using a risk stratification tool to inform shared decision making about whether a patient can be managed with simpler and less intensive support, for example, reassurance, advice to keep active and guidance on self-management or referral to a range of

possible rehabilitation options including group or individual exercise with or without manual or psychological therapies or to a "combined physical and psychological" rehabilitation programme. Inherent to both approaches is the implication that not all patients presenting in primary care require specialist musculoskeletal intervention, given the favourable prognosis for many cases of low back pain.

# **Inconsistencies between guidelines**

While there are clear commonalities across these guidelines there are numerous examples where their recommendations diverge. There are many potential reasons for these inconsistencies.

Guideline development groups in low back pain are required to generate recommendations in the face of substantial uncertainty. Where the evidence of benefit is marginal or inconsistent across studies and study quality is mixed, as is often the case across interventions for low back pain, there is a large capacity for interpretive differences between different guideline development groups. These differences are likely to reflect the local clinical culture and the views of individuals comprising the guideline group. In the absence of evidence, guideline groups need to make pragmatic recommendations based on their expertise. These again will reflect local differences in culture and healthcare delivery.

#### **Interpretive differences**

Such differences are apparent in recommendations for interventional and surgical procedures for low back pain. While the NICE guidance recommends against the use of spinal injection therapies for low back pain, facet joint injections, prolotherapy or intradiscal injections are recommended in the older US guideline, and prolotherapy in the Canadian guideline, both with the caveat that they should be offered in "carefully selected patients". In terms of surgery, while the older US guidance recommends both spinal fusion and the use of interspinous spacers, the Canadian and NICE guidance make no positive recommendations for any surgical procedure for low back pain. Conversely while the NICE guidance recommends considering radiofrequency denervation of the medial branch nerve for selected patients, both the US and Canadian guidelines concluded that there was insufficient evidence to support a recommendation. Similarly based on a very limited evidence base, the NICE guidance recommended against the use of TENS, back belts and corsets, whereas the older US and Canadian groups recommended against their use as a sole treatment, given the uncertainty.

The willingness of guideline groups to make recommendations driven by expertise and opinion likely varies across groups and possibly differs across different interventions. Arguably this can be seen in the range of pharmacological and interventional options recommended across guidelines. Compared to the NICE guidance, the new US and Canadian guidance recommend a broader range of drug options including short-term opioids, specific serotonin reuptake inhibitors (SSRIs), anticonvulsants and herbal remedies and the Canadian guidelines advocate the use of TCAs and acetaminophen. For many of these the evidence base is either limited or not promising. On that basis NICE only recommend to consider the use of NSAIDs, and if NSAIDs are ineffective, contraindicated or not tolerated then consider a weak opioid, with or without paracetamol for acute back pain. While this latter recommendation is based on very limited evidence it arose out of recognition of the need for

an alternative treatment option for people with severe acute back pain where an NSAID could not be used.

# **Date of publication**

More recent guidelines (newer US and NICE) reflect a more up to date reflection of the evidence base and there are examples where this is enough to drive a change of policy. A good example of this is the use of paracetamol (acetaminophen) for back pain. This staple first line analgesic has a long history in low back pain management, borne largely from tradition and experience, but the publication in 2015 of a large high quality multicentre trial [23] demonstrated no benefit of paracetamol over placebo for low back pain in primary care. This trial now dominates the evidence base for this intervention but sits within a broader body of evidence [24,25] demonstrating a lack of efficacy. On this basis the NICE guidance recommends against the use of paracetamol but the older US and Canadian guidance predate these substantial additions to the evidence base and subsequently recommend paracetamol in acute and chronic low back pain. At The updated ACP guideline for non-invasive treatment, published at the time of writing this review [10], is now consistent with the NICE guidance in recommending against paracetamol (acetaminophen) for back pain.

#### **Efficacy versus effectiveness**

The importance of efficacy as well as effectiveness in guiding the decision of guideline groups may also vary. Acupuncture recommendations vary substantially across the guidelines. The older and newer US guideline recommends acupuncture for both acute and chronic low back pain, the Canadian guideline recommends it as an adjunct treatment in chronic low back pain whereas the NICE guidance suggests "do not use" acupuncture for low back pain. Positive recommendations for acupuncture are based on comparisons with usual care or no treatment (effectiveness). In contrast the NICE group prioritised evidence of effects over sham acupuncture (efficacy) in making their decision and concluded that there were not meaningful effects over sham acupuncture. This variability across guidelines speaks to a wider controversy regarding whether it is appropriate and ethical to offer, or withhold, known placebos for the treatment of a range of conditions [26], though a detailed discussion of that issue is beyond the scope of this article.

#### Size of treatment effects.

In some cases the use of predetermined thresholds for clinical importance to guide decisions may have an important influence. The use of these thresholds shifts attention away from statistical significance towards the possible size of beneficial treatment effects. The NICE guidance utilised a minimally important difference (MID) for between group change in pain of ≥1 point on a 0-10 pain scale and similar thresholds for other critical outcomes. These thresholds had a substantial impact on the number of observed comparisons for which results were considered positive and in part will have driven the frequently more conservative recommendations of the NICE guidance. A key example if this is opioids. Opioids are recommended in the 2007 US guideline for chronic low back pain but are not recommended in the NICE guidance. The analysis in the NICE guideline demonstrated a statistically significant effect of opioids over placebo but both the point estimate of the treatment effect and the upper limit of the 95% confidence interval fell beneath the MID. This lack of an important effect, coupled with concerns regarding the known risks of these drugs [27] helped to drive a "do not use" recommendation for chronic low back pain. The updated US guidance

takes a more cautious view of opioid use, suggesting that opioids should be the last treatment option considered and only in patients for whom other therapies have failed. This modified recommendation appears to be driven more by recognition of the potential harms.

### **Scope of guidelines**

Finally inconsistencies might arise on the basis of the scope of the guidelines. An example of this is found in the recommendation in the Canadian and older US guideline of herbal treatments such as Harpogophytum procumbens extracts (Devil's claw), Combo Salix daphnoides (Willow bark), and capsicum futescens. These agents were not reviewed in the NICE guideline development process.

The reasons underpinning inconsistencies across guidelines are likely multifactorial and represent the date of the literature search, the influence of methodological approaches, the culture of the guideline development group and broader healthcare system, but, perhaps most strongly, the uncertain nature of the evidence of potential clinical benefits for many common interventions.

# The challenge of implementation

The challenge of implementing back pain guidelines in clinical practice is substantial. Indeed recognition of issues relating to implementation within clinical guidelines is included in the AGREE II quality assessment tool [28]. It is important to recognise that clinical guidelines are just one component in a more complex process of moving research into clinical practice [13] Strategies are needed to successfully bring guidelines into clinical practice but the potential barriers to implementation need to be understood. Glasgow et al. [13] emphasise the need for research that includes the study of interventions designed to increase implementation of evidence based recommendations, the evaluation of the effectiveness and cost–effectiveness under "real world" conditions and in diverse populations and ongoing surveillance of population health outcomes.

In a broad review of barriers to clinical guideline implementation, Fischer et al. [29] categorised them into three themes. Personal factors relate to clinicians' knowledge of and familiarity with the guideline, their attitudes to the guidance provided and agreement (or lack thereof) with the guideline recommendations. Guideline factors relate to the plausibility of the recommendations of the guideline, its credibility, and accessibility. External factors relate to constraints within the local organisation and resourcing of care that may restrict the capacity for changing practice.

In a systematic review and meta-synthesis of barriers to primary care clinicians' adherence to low back pain guidelines, Slade et al. [30] found that time constraints and the sheer volume of guidelines clinicians are faced with represented barriers to implantation. The specific issue of spinal imaging emerged as a prominent issue. While guidelines universally recommend against the routine imaging of low back pain, clinicians rationalised the use of imaging as a way to negotiate potential conflicts arising from patients' lack of acceptance of a non-structural diagnosis; to help to explain symptoms and attempt to reduce anxiety through offering an "unambiguous explanation". Any evidence to suggest that this is a successful strategy is lacking. Clinicians felt that guidelines constrained clinical practice; that their own use of popular practices often superseded guideline recommendations and that clinicians demonstrated a lack of knowledge of both the content of guidelines and the methodology underpinning them. Such views were also apparent in a recent qualitative study conducted in the UK [31] which focused on an earlier NICE guideline for the management of

persistent low back pain. Clinicians did not universally accept the evidence based practice paradigm, felt that guidelines did not resonate with their personal experience and believed that the guideline imposed rigid treatment pathways that constrained practice. This, in addition to organisational constraints, led to the guideline having only a peripheral influence on clinical decision making.

From the patient perspective, a qualitative study of patients with osteoarthritis of the knee [32] found that poor comprehension of the disease process, negative experiences with drug therapies, poor communication by the health professional and disagreement with the recommendations of guidelines, presented key barriers to adherence. Within those disagreements an insistence on medical imaging and a fear that physiotherapy aggravates pain were important issues. The parallels with back pain care seem self-evident.

Fischer et al. [29] summarise what they refer to as central aspects for successful guideline implementation. These include dissemination (the supply of accessible information), education and training of health professionals, social interaction (in terms of outreach activities and marketing and the engagement of opinion leaders), decision support systems, standing orders and standardised documentation.

In a systematic review of the implementation interventions designed to improve clinical practice for the management of LBP -in low back pain Mesner et al. [33] found that a range of interventions had been applied but that single, one-off strategies were consistently unsuccessful and there was no consistent pattern with regards the differential effectiveness of the different types of implementation events utilised. Suman et al. [34] systematically reviewed the evidence of the effectiveness of multifaceted guideline implementation strategies for back and neck pain and did not find consistent benefits when they were compared to either usual or minimal intervention. Mesner et al. [33] concluded that frequency of messaging may be important as ongoing and regular interventions demonstrated greater success in changing practice and sustaining those changes, but advise caution on the basis of between study heterogeneity and risk of bias in the included literature.

The challenge of achieving lasting behavioural change in complex communities of clinicians is daunting, particularly it seems if that change requires de-adoption of current practices. While the need to go beyond the simple act of publishing guidelines is uncontroversial, the best way to achieve implementation is a question that remains to be answered. This is reflected in the apparent failure, to date, of the recent "Choosing Wisely" campaign to demonstrate any impact on the high rates of low back pain imaging in the absence of red flag indications in the US [35].

#### **Controversies and future directions**

We have seen how inconsistencies arise from uncertainty regarding the value of many interventions for low back pain. This uncertainty is likely the product of many factors including issues with the quality and size of many studies, diagnostic uncertainty, the largely unmet challenge of adequately targeting treatments to appropriate populations, and marginal or absent treatment effects. It is sobering that across all the interventions reviewed by the NICE group, no intervention was considered to have strong enough evidence to warrant a clear "offer" recommendation.

There are issues with regards where the burden of proof lies in this process. It is always controversial and challenging to recommend against the use of interventions that are already established in the market. Guideline groups may be reluctant to make strong recommendations against the continued use of interventions where there is little reliable evidence of effectiveness but also no clear evidence of ineffectiveness and harm. Such reluctance is likely driven both by the wish to avoid withholding treatments that may be of benefit, and by the agendas of professional groups and other stakeholders. But the costs associated with low back pain treatment have spiralled in recent decades and yet no major impact has been made in associated levels of disability. Logically this speaks to a problem of over treatment; to an expanding global clinical industry, sections of which may be supported only by the confounders of natural recovery, regression to the mean and internal study biases, rather than genuine clinical utility.

How the balance between benefits and harms of interventions are weighed is not clear across these guidelines. The primary source of evidence used in guidelines is that derived from RCTs of interventions, which generally lack adequate power to detect rare harms. None of the included guidelines described a systematic approach that included observational studies or regulatory data. Indeed the methodological challenges to systematically assessing treatment harms are considerable and the methodology for reviewing these data remains underdeveloped [36]. In the absence of such an approach, which would substantially increase the complexity of the guideline process and the workload of any review group, judgements regarding the risk of harms are likely made largely from the limited evidence found in trials and the expert opinion of the guideline group.

Popular emerging management concepts such as shared decision making receive little specific attention in guidelines. Shared Decision Making (SDM) is characterized as a process involving at least two participants (patient and health care provider), who interact together and share information to make decisions where both parties agree [37]. In the United States, SDM is endorsed by government agencies, yet to date there is limited literature to help evaluate this proposition and what is available does not appear supportive. In a recent RCT [38] people with nonspecific low back pain were randomised to receive either usual physiotherapy care or a physiotherapy care package that was developed through shared, informed decision making, and the results suggest that the shared decision making process was harmful. In an earlier study Eisenberg et al. [39] randomised acute LBP patients to receive either usual care or usual care plus the patients' choice of adjunctive acupuncture, massage or manipulation and found no meaningful benefit with the addition of the patient's chosen adjuvant therapy.

Guidelines often focus on the evidence for discreet interventions, but studying the process of care may be a path to improved outcomes and reduced costs and harms. The Canadian and NICE guidelines offer detail on suggested care pathways though these are largely determined by expertise rather than evidence. Observational evidence from the US suggests that the timing of care and the type of provider that a patient sees may influence downstream costs and utilization, specifically that early physical therapy was associated with reduced costs and healthcare utilisation [40, 41]. However in a recent randomised controlled trial of early physical therapy versus usual care no such beneficial effects were apparent, and no meaningful impact was observed on clinical outcomes [42]. Studying management processes and clinical pathways may yet yield improved outcomes, a strategy endorsed in stratified care processes [43]. This evidence base is in its relative infancy, but may be valuable to the scope of future guidelines.

Finally the role of population-level interventions is rarely within the scope of clinical guidance. Such interventions often aim to change behaviour in relation to a specific condition through mass marketing multi-media campaigns aimed at the general population and/or clinicians. The highest profile of these, delivered in Australia [44], successfully achieved lasting change in the attitudes and beliefs of physicians and the public and in the number of workers' compensation back claims and medical payments. Unfortunately, the results of other campaigns have failed to match this promise [45]. It remains an appealing idea that to successfully change practice may require the provision of accessible, appealing and convincing education to the public; that behaviour change might be positively driven through guiding patient demand as well as clinician behaviour.

#### **Conclusions**

In this narrative review we have selected and reviewed 3 major interdisciplinary clinical guidelines for LBP. As such our review does not represent a systematic review of current guidelines, but rather aims to use selected guidelines to inform a discussion of where they concur and diverge on what represents best practice. In addition at the time of writing the ACP published a new guideline for non-invasive treatment. We have discussed selected changes in that new guideline here but the focus of this review is on the earlier iteration of that guidance.

Clinical guidelines exist to promote consistent best practice in patient care, to reduce unwarranted variation in care and the use of low value interventions. There seems to be little controversy that routine imaging is not advisable, nor that ruling out alternative diagnoses and offering high quality education should represent the staple treatments for non-specific low back pain. Indeed ensuring the widespread, global implementation of this simple core message might go some way to improving the huge burden of back pain related disability and reducing the costs of low value clinical interventions. How that is actually achieved might be the great challenge of low back pain.

## **Practice points**

- Guidelines consistently recommend ruling out alternative diagnoses and then offering high quality education including the encouragement of an early return to activity.
- Guidelines consistently recommend against the routine use of imaging for non-specific low back pain.
- Guidelines consistently recommend physical exercise for non-specific low back pain.
- Guidelines consistently advocate a cautious approach to the use of opioids in non-specific low back pain.

# Research Agenda

• Further research into implementation strategies for guideline recommendations and optimal clinical pathways for low back pain may be useful to guide future clinical guidelines for LBP.

#### References

1. Vos T, Allen C, Arora M et al. Global, Regional, And National Incidence, Prevalence, And Years Lived With Disability For 310 Diseases And Injuries, 1990–2015: A Systematic Analysis For The Global Burden Of Disease Study 2015. <u>Lancet</u> 2016; **388**:1545-1602.

- 2. Stubbs B, Koyanagi A, Thompson T et al. The epidemiology of back pain and its relationship with depression, psychosis, anxiety, sleep disturbances, and stress sensitivity: Data from 43 low- and middle-income countries. <u>Gen Hosp Psychiat</u> 2016;**43**:63-70.
- 3. Spitzer W, LeBlanc FE, Dupuis M et al. Scientific approach to the assessment and management of activity-related spinal disorders. Spine 1987;**12**:1–58.
- 4. Wong JJ, Côté P, Sutton DA et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. Eur J Pain. 2016; in press
- 5. National Guideline Centre (UK) 'Low back pain and sciatica in over 16s: assessment and management'. Manchester: National Institute for Health and Care Excellence; 2016 <a href="https://www.nice.org.uk/guidance/ng59">https://www.nice.org.uk/guidance/ng59</a>
- 6. Toward Optimized Practice (TOP) Low Back Pain Working Group. 2015. Evidence-informed primary care management of low back pain: Clinical practice guideline. Edmonton, AB: Toward Optimized Practice. Available from: <a href="http://www.topalbertadoctors.org/cpgs/885801">http://www.topalbertadoctors.org/cpgs/885801</a>
- 7. Chou R, Qaseem A, Snow Vet al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. <u>Ann Intern Med</u> 2007;**147**:7:478-91.
- 8. Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine 2009a; 34:10:1078-93.
- 9. Chou R, Loeser JD, Owens DK et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine 2009b; **34**:10:1066-77.
- 10. Qaseem A, Wilt TJ, McLean RM, Forciea MA, Clinical Guidelines Committee of the American College of Physicians. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. 2017; in press
- 11. Field MJ, Lohr KN <u>Clinical practice guidelines: directions for a new program</u>. National Academy Press, Washington, DC. 1990.
- 12. Graham R , Mancher M, Miller Wolman D. <u>Clinical practice guidelines we can trust.</u> Institute of Medicine. National Academies Press, Washington DC. 2011.
- 13. Glasgow RE, Vinson C, Chambers D, Khoury MJ, Kaplan RM, Hunter C. National Institutes of Health approaches to dissemination and implementation science: current and future directions. Am J Public Health 2012; **102**: 1274–81.
- 14. Jones DJ, Barkun AN, Lu Y et al. International Consensus Upper Gastrointestinal Bleeding Conference Group. Conflicts of interest ethics: silencing expertise in the development of international clinical practice guidelines. <u>Ann Intern Med</u> 2012;**156**: 11:809-16

- 15. Shekelle PG, Woolf SH, Eccles M, Grimshaw J Developing guidelines. <u>BMJ</u> 1999; **318**: 7183: 593–596.
- 16. National Institute of Health and Care Excellence (2014) The guidelines manual. <a href="https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview">https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview</a> Accessed December 2016
- 17. Alonso-Coello P, Oxman AD, Moberg J et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines. <u>BMJ</u> 2016;**353**: i2089.
- 18. Chou R, Deyo R, Friedly J, Skelly A, Weimer M, Fu R, Dana T, Kraegel P, Griffin J, Grusing S. Systemic Pharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. Ann Intern Med 2017; in press
- 19. Chou R, Deyo R, Friedly J, Skelly A, Hashimoto R, Weimer M, Fu R, Dana T, Kraegel P, Griffin J, Grusing S, Brodt ED. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. Ann Intern Med 2017; in press
- 20. Qaseem A, Snow V, Owens DK, Shekelle P, Clinical Guidelines Committee of the American College of Physicians. The development of clinical practice guidelines and guidance statements of the American College of Physicians: summary of methods. Ann Intern Med. 2010;**153**:3:194-9
- 21. Verhagen AP, Downie A, Popal N, Maher C, Koes BW. Red flags presented in current low back pain guidelines: a review. Eur Spine J. 2016;**25**:9:2788-802
- 22. Downie A, Williams CM, Henschke N, Hancock MJ, Ostelo RW, de Vet HC, Macaskill P, Irwig L, van Tulder MW, Koes BW, Maher CG. Red flags to screen for malignancy and fracture in patients with low back pain. Br J Sports Med. 2014; **48**:20:1518
- 23. Williams CM, Maher CG, Latimer J et al. Efficacy of paracetamol for acute low-back pain: a double-blind, randomised controlled trial. <u>Lancet</u> 2014;**384**:9954:1586-96.
- 24. Machado GC, Maher CG, Ferreira PH et al. Efficacy and safety of paracetamol for spinal pain and osteoarthritis: systematic review and meta-analysis of randomised placebo controlled trials. <u>BMJ</u> 2015;**350**:h1225.
- 25. Saragiotto BT, Machado GC, Ferreira ML et al . Paracetamol for low back pain. <u>Cochrane Database Syst Rev</u> 2016;**6**:CD012230.
- 26. Miller FG, Colloca L. The legitimacy of placebo treatments in clinical practice: evidence and ethics. Am J Bioeth 2009;**9**:12:39-47.
- 27. Stannard CF .Opioids for chronic pain: promise and pitfalls. <u>Curr Opin Support Palliat Care</u>. 2011;**5**:2:150-7.
- 28. Brouwers MC, Kho ME, Browman GP et al. AGREE II: Advancing guideline development, reporting and evaluation in healthcare. <u>Can Med Assoc J</u> 2010; **182**: E839-842.

- 29. Fischer F, Lange, K, Klose K et al. Barriers and strategies in guideline implementation- A scoping review". Healthcare 2016; **4**: 36.
- 30. Slade SC, Kent P, Patel Set al. Barriers to primary care clinician adherence to clinical guidelines for the management of low back pain. A systematic review and metasynthesis of qualitative studies. <u>Clin</u> J Pain 2015; **32**:9:800-16.
- 31. Bishop FL, Dima AL, Ngui J et al. "Lovely pie in the sky plans": A qualitative study of clinicians' perspectives on guidelines for managing low back pain in primary care in England". Spine 2016; 40:23:1842-50
- 32. Spitaels D, Vankrunkelsven P, Desfosses J et al. Barriers for guideline adherence in knee osteoarthritis care: A qualitative study from the patients' perspective. <u>J Eval Clin Pract</u>. 2016; in press.
- 33. Mesner SA, Foster NE, French SD. Implementation interventions to improve the management of non-specific low back pain: a systematic review. BMC Musculoskelet Disord. 2016;**17**:258.
- 34. Suman A, Dikkers MF, Schaafsma FG et al. Effectiveness of multifaceted implementation strategies for the implementation of back and neck pain guidelines in health care: a systematic review. <u>Implement Sci</u> 2016;**11**:1:126.
- 35. Rosenberg A, Agiro A, Gottlieb M et al. Early Trends Among Seven Recommendations From the Choosing Wisely Campaign. JAMA Intern Med 2015;**175**:12:1913-20.
- 36. Chou R, Helfand M. Challenges in systematic reviews that assess treatment harms. Ann Intern Med. 2005;142:12 Pt 2:1090-9.
- 37. Emanuel EJ, Emanuel LL. Four Models of the Physician-Patient Relationship. <u>JAMA</u> 1992;**267**:16:2221–6.
- 38. Patel S, Ngunjiri A, Hee S et al. Primum non nocere: shared informed decision making in low back pain--a pilot cluster randomised trial. BMC Musculoskelet Disord 2014;**15**:282.
- 39. Eisenberg DM, Post DE, Davis RB et al. Addition of choice of complementary therapies to usual care for acute low back pain: a randomized controlled trial. Spine 2007;32:2:151-8
- 40. Childs JD, Fritz JM, Wu SS et al. Implications of early and guideline adherent physical therapy for low back pain on utilization and costs. <u>BMC Health Serv Res</u> 2015;**15**:150.
- 41. Fritz JM, Childs JD, Wainner RS, Flynn TW. Primary care referral of patients with low back pain to physical therapy: impact on future health care utilization and costs. <u>Spine</u> 2012;**37**:2114–21.
- 42. Fritz JM, Magel JS, McFadden M et al. Early physical therapy vs usual care in patients with recent-onset low back pain: a randomized clinical trial. <u>JAMA</u> 2015;**31**4:14:1459-67.
- 43. Hill JC, Whitehurst DG, Lewis M et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. <u>Lancet</u> 2011;378:9802:1560-71.

- 44. Buchbinder R, Jolley D, Wyatt M. Population based intervention to change back pain beliefs and disability: three part evaluation. <u>BMJ</u> 2001;**322**:7301:1516-1520
- 45. Buchbinder R, Gross DP, Werner EL, Hayden JA. Understanding the characteristics of effective mass media campaigns for back pain and methodological challenges in evaluating their effects. <u>Spine</u> 2008;**33**:1:74-80.

#### **Declarations of Interest**

NOC, BW and CC are qualified physiotherapists.

SW was the Chair of the recent NICE guideline development group for low back pain and sciatica and NOC was a member of that guideline development group.

SW is a consultant in pain medicine and practices in both the public and private healthcare sectors.

This work was undertaken in part by Neil O'Connell and Stephen Ward, member and chair respectively of the NICE guideline committee (NG59 Low back pain and sciatica in over 16s: assessment and management). The development of this guideline was funded by the National Institute for Health and Care Excellence. The views expressed within this publication are those of the authors and not necessarily those of NICE