Ethical challenges faced when there is a mismatch between guidelines, patient autonomy and clinical practice

This editorial reviews the ethical day-to-day challenges faced by pain specialists when managing each patient's unique requirements, in light of guidelines, clinical practice and interpretation of evidence relating to the assessment and management of chronic pain.

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The publication of the National Institute for Health and Care Excellence (2021a) guidelines NG193 on 'Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain' created a significant ripple of anxiety among the pain fraternity, both from a clinician and patient perspective.

The guidelines describe the biopsychosocial assessment of all chronic pain and then go on to discuss the management of chronic primary pain. National Institute for Health and Care Excellence (2021a) attribute their terminology to the International Classification of Diseases (World Health Organization, 2020) (ICD-11) and define chronic primary pain as 'pain that has no clear underlying condition or where the pain (or its impact) appears to be out of proportion to any observable injury or disease'. However, the full definition used in the ICD-11 classification (World Health Organization, 2021) is as follows:

> **'Chronic primary pain is chronic pain in one or more anatomical regions that is characterised by significant emotional distress (anxiety, anger/frustration or depressed mood) or functional disability (interference in daily life activities and reduced participation in social roles). Chronic primary pain is multifactorial: biological, psychological and social factors contribute to the pain syndrome. The diagnosis is appropriate independently of identified biological or psychological contributors unless another diagnosis would better account for the presenting symptoms.'**

Both the Faculty of Pain Medicine of the Royal College of Anaesthetists (Faculty of Pain Medicine, 2021) and the British Pain Society (2021) have issued statements expressing concern regarding the impact of these guidelines on patient care. This followed on from various negative stakeholder statements during the draft guidance consultation period (National Institute for Health and Care Excellence, 2020), including an analysis of scientific evidence pertaining to the management of chronic primary pain by the Cochrane Pain, Palliative care and Support Group (Cochrane, 2020). Concern has also been voiced by various patient groups.

The National Institute of Health and Care Excellence (2021b) has just published its strategy for 2021 to 2026, wherein its vision for the next 5 years is reflected in four key pillars that will underpin its transformation efforts. These include:

1. Rapid, robust and responsive technology evaluation
2. Dynamic, living guideline recommendations
3. Effective guidance uptake to maximise their impact
4. Provide leadership in data, research and science.

However, as the Cochrane (2020) group aptly put it, this area of practice in pain medicine is 'affected by challenges of clinical heterogeneity (in populations and interventions), diagnostic ambiguity, difficulty in capturing an elusive outcome (the experience of pain), heterogeneity in treatment response, the highly variable quality of relevant clinical studies and generally small average treatment effects'.

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Pain is multifactorial

The Faculty of Pain Medicine, as well as the British Pain Society and its Patient Voice Committee, remain concerned that the way in which ICD-11 classification has been interpreted does not reflect clinical practice or the current research base. The guidelines state that chronic primary pain has no clear underlying condition and that the mechanisms underlying it are only partially understood. This does not mean that this is a single entity, but rather a classification that allows patients who fulfil the ICD11 definition to be recognised and recorded as having chronic pain (World Health Organization, 2021). Further research is needed to develop to gain a better understanding of the underlying mechanisms and phenotypes. Chronic primary pain is multifactorial: biological, psychological and social factors contribute to the pain syndrome.

There is also a risk that patients diagnosed with chronic primary pain will ultimately go on to develop secondary pain without it being recognised or treated appropriately. The guidelines can also be misconstrued by commissioners and non-pain specialists to guide management of all chronic pain with the risk of secondary care services, in particular pain management programmes, being decommissioned and patients being taken off useful medications by their primary care doctors. Moreover, the guidance recommendation that acupuncture be used for the treatment of chronic primary pain suggests that all primary pain is musculoskeletal, which is clearly not the case. The recommendations in the guidelines of delivery of one course of five sessions of acupuncture is unlikely to be met because of a lack of resources, as acupuncture treatment has long been decommissioned both in primary and secondary care. It also begs the question: what happens if a patient's chronic primary pain improves with a course of acupuncture, only to return after a few weeks or months? How can a clinician ethically decline a further course of acupuncture? The guidelines raise other questions, including that of how can the demand for psychological therapy, as recommended by the guidelines, be met? How do we develop the clinician skills and resources in primary care to review the management of all these patients?

The very aim of these guidelines is to inform a care and support plan by setting out a comprehensive person-centred assessment of the causes and effects of pain and agreeing possible management strategies, including self-management. National Institute for Health and Care Excellence (2021a) recommend that clinicians put the emphasis on designing joined-up care around people's needs, rather than around organisational silos.

Balancing cost effectiveness and patient autonomy

Four ethical principles underline the setting of healthcare priorities (McMillan et al, 2006): justice, beneficence, non-maleficence and autonomy. National Institute for Health and Care Excellence (2021a) guidelines support optimum use of NHS funds by evaluating the clinical and cost effectiveness of treatments currently offered. However, when guidance understandably has to reflect priority setting with regards to costs, the principle of autonomy and patient choice can give a misleading impression that patients can demand the nature of treatment they wish to receive, which is clearly not the case.

Doctors practising in pain medicine have decades of experience in adopting cost-efficient, pragmatic approaches for people with complex pain. Their practice is also guided by the Core Standards for Pain Management Services (Faculty of Pain Medicine, 2015) – a collaborative multidisciplinary publication providing a robust reference source for the planning and delivery of pain management services in the UK.

People have the right to be able to make informed decisions about their care – however, National Institute for Health and Care Excellence (2021c) clearly states that the guidance should be taken into account when making decisions with patients.

The development of high-quality evidence-based guidance to support patient management is always welcomed. However, recognition of the need for a pragmatic approach where patients do not respond to the guideline recommendations is also required. The authors recognise that implementation science in setting guidelines is very complex, in particular where the evidence-based interventions being measured have both patient- and provider-facing elements (Huynh et al, 2018). The authors also recognise the additional complexity

Key points

- Guidelines have a beneficial role for both patients and health professionals, but more transparency is required regarding their limitations.
- The definition for chronic primary pain needs to be consistent internationally to avoid misinterpretation and allow research data to be comparable.
- Pain is heterogeneous both in clinical presentation and in treatment response – each patient is unique and this makes it challenging to interpret complex research data.
- Patients not fitting or responding to guidance need to be recognised and accounted for – the authors advocate a pragmatic approach.
- A national programme of care is required for the management of all chronic pain that works across community, primary and specialist levels of care.

arising from the need to implement the same guidance across multiple health organisations, each with their own unique set of characteristics and resources.

In line with National Institute for Health and Care Excellence's (2021b) own generic guidance, the authors wish to remind healthcare professionals that they are expected to take guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

The authors would welcome a more pragmatic approach by National Institute for Health and Care Excellence, particularly in a field of practice such as pain medicine, wherein each patient's journey is truly unique.

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