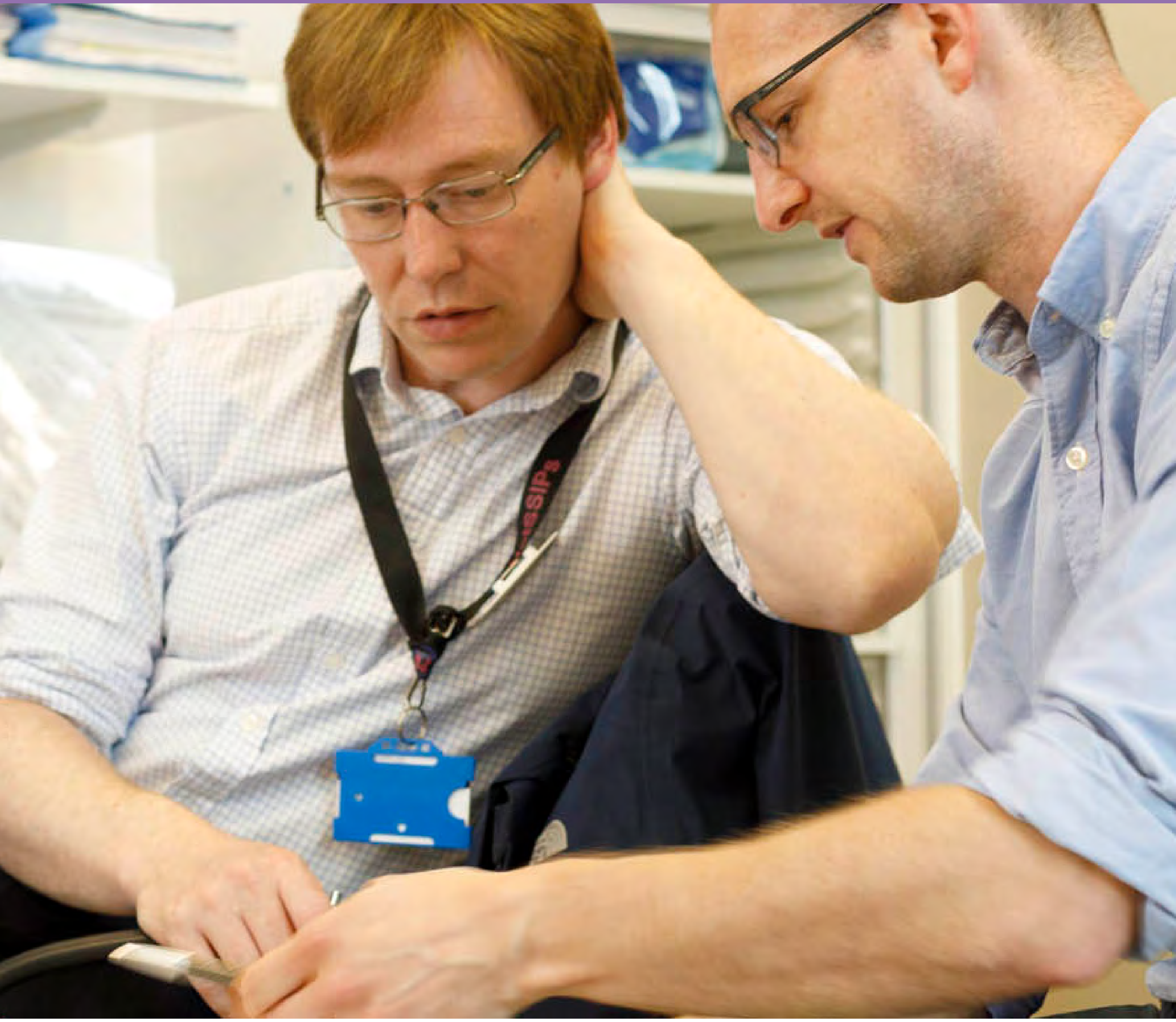
Practical Pain Management in Specialist Care:

How to help people with chronic pain when population based national guidance fails to help

Promoting individualised care for people with complex pain



FACULTY OF
PAIN MEDICINE
of the Royal College of Anaesthetists

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Introduction

Chronic pain is a WHO recognised disease which remains a significant problem both for the individuals affected and society as a whole. The impact of chronic pain has been defined previously by the FPM[1]. Chronic pain leads to significant disability, depression and has adverse social consequences. There are enormous economic costs in health care and through loss of work.

There is a societal and humanitarian need for pain management to support those in pain and distress. Sufferers and patients' advocates often refer to chronic pain as the 'invisible disability', a term which emphasises under-recognition, its impact on individuals and underinvestment in provision of appropriate, supportive, timely services.

As chronic pain is a complex phenomenon with many interacting component parts so too is its management which is multimodal with pain management strategies matched closely to the needs of the patient. For those working in pain specialist medicine, it is well-recognised that the outcomes of interventions are not individual but mutually and critically interdependent. Emphasis must be on "whole packages" of care.

This publication considers the value and limitations of a conventional population-determined evidence based medicine approach in delivering care for an individual with pain, steering a path towards more pragmatic patient-centred care to best meet health-care needs.

As NICE have recently clarified in their guidance on the use of Cannabis based medicinal products for severe treatment resistant epilepsy, population-wide recommendations should not be interpreted by healthcare professionals as meaning that they are prevented from the use of treatments that are clinically appropriate in an individual case[2].

"The fact that NICE made no such population-wide recommendation should not however be interpreted by healthcare professionals as meaning that they are prevented from considering the use of unlicensed cannabis-based medicinal products where that is clinically appropriate in an individual case. Patients in this population can be prescribed cannabis-based medicinal products if the healthcare professional considers that that would be appropriate on a balance of benefit and risk, and in consultation with the patient, and their families and carers or guardian."

The advice explicitly means that individual-based care may supersede a population-based recommendation in some circumstances. It is long recognised in pain specialist practice that care must be individualised for people with complex pain. This is also recognised in the GMC's *Good Medical Practice* guidance: [3]

> **we must "treat patients as individuals"**
>
> **we must "protect and promote the health of patients and the public"**

This document serves to empower professionals, people with chronic pain and commissioners to make the best decisions for an individual patient with chronic pain. It acknowledges that the level of population based determination of efficacy of some pain management strategies is modest but the societal cost of not attempting to offer treatment to individuals with pain is enormous, when it is clear a subgroup of patients are likely to respond to treatment even if that treatment is not applicable to all patients in pain.

Specifically, there is risk that sole reliance on NICE (or other population based) guidance to determine which treatments to offer alone will lead to a needless increase in suffering of specific groups of patients.

This document sets out the FPM position and gives general principles to follow. Specific details on the pragmatic use of treatments such as medicines, injections and self-management strategies is planned to follow in later documents. The FPM emphasises that it does not support or wish to be seen to support treatments without evidence or credible rationale and at all times, the safety of the patient must be paramount and the consent process meticulous.

In the future, the FPM will further focus on pragmatic pathways of care, a strategy with which the British Pain Society is a partner in full support.

Best care

Core Standards for Pain Management Services (CSPMS)[4] is a collaborative multidisciplinary publication providing a robust reference source for the planning and delivery of Pain Management Services in the United Kingdom[4]. Care should be designed around the following principles:

- Effective triage
- Appropriate evidence based pathways
- Effective patient and professional educationIdentification and provision of the right care for patients with complex pain
- Assessment: Measurement of meaningful health and social care outcomes

Managing chronic pain well can transform a person's function and quality of life. This document focuses on people with complex chronic pain. Pain as a complex phenomena is defined in the Appendix, from existing FPM publications. The key message is one of person-centred, individualised care.

Pathways

Pain treatments are delivered and must be considered within broad well-accepted pathways of care. The value of an individual treatment should be considered as part of a package of care delivered within such a pathway. Removal of a cheap but safe treatment of apparent limited efficacy may be unhelpful and costly if its removal causes unintended consequences, for example creating greater flow of people with pain towards more expensive treatments with greater risk of harm. The FPM view is that there are real risks in pain practice if the value of an individual treatment is considered in isolation.

Care pathways need to be graded so individuals progress through a series of proportionate [graded] interventions based on individualised treatments. Such stepped care pathways benefit from triage and stratification to risk and complexity.

For example, it is recommended that pain rehabilitation interventions (such as Pain Management Programmes or PMPs) may be classified broadly into three groups. These are:

- Early care or pain management stratified to risk based on stress and disability
- More complex interventions such as Standard PMPs
- Intensive PMPs (including in-patient programmes) (4, 7.1 P100)

Effective care requires commissioning and health care provision at all three levels[5]. Early care is usually undertaken individually and may include combined psychology and physical interventions (CPP). This early care pathway is usually unhelpful for more complex patients that require more intensive interventions.

While PMPs are traditionally undertaken in groups, increasingly, PMPs are undertaken on an individual basis which has been shown to improve engagement and outcome in more complex or intractable patients.

Not recognising the differences between interventions may lead to expensive and perhaps futile overtreatment of individuals with a good prognosis, a poor match of treatment to complexity and omission of more specialised treatments required for complex patients.

Use and general limitations of conventional evidential approaches in Pain Medicine

Recently, both COCHRANE[5] and NICE[6] have come to very different conclusions about the value of a range of chronic pain treatments which we attribute to different methodological approaches and starting parameters. These include both medicines and psychological treatments designed to support people with chronic pain.

The FPM have previously highlighted that there are very significant and clearly demonstrable difficulties with the application and the use of this approach in complex pain situations.[1] This type of experimental method may be viewed to be unsound as a general rule in this context.[7,8] As an illustration the experimental approach relies on matching impactful confounding factors between groups. Yet many variables are not usually accounted for. For example, 'catastophisation' a usually uncontrolled psychological variable is important[9] and could be responsible for as much as 50% of variance in outcome from treatment. There are dozens of psychological and other confounding weaknesses in trials which risk losing individual treatment effects resulting ultimately in a nihilistic or parsimonious approach to pain practice. Table 1 lists some of the many, familiar, difficulties with this approach applied to people with complex pain.

Table 1

- Positivist strategies are philosophically inappropriate for complex phenomena e.g. pain
- Interpreting the evidence base for pain treatments is often hampered by heterogeneity of clinical populations and interventions and difficulty in capturing meaningful outcomes.
- Average effect sizes are often small, and an over reliance on restrictive methodology risks losing information that can greatly benefit some patients
- It is clear that nothing works well for most people, but for some interventions a small number of people may derive benefit.
- Lack of long-term trials
- Difficulties in controlling confounding factors in long term
- Lack of investment and hidden costs in powering trials for treatments with low level evidence and good experiential evidence
- Lack of evidence from one methodological approach (e.g. randomised double blind trials) is not evidence of lack of effect but treated as such.
- Analysis of the cost-effectiveness of a specific treatment on an individual treatment basis could prove costly to the NHS if pain pathways are not considered as a whole (see commissioning document)[1]

In addition, not all treatments can be tested through randomised trials and this is especially the case when assessing individualised, multidisciplinary care.

NICE also recommend some treatments being used only in the context of a clinical trial, yet the cost of bringing a new drug to market may be billions of pounds.[10] This, risks skewing pain practice development towards those well financed or studied treatments that may not be a central priority. Treatments or drugs which cannot be patented, risk being under researched and therefore unavailable to the practising pain clinician to prescribe. Cannabis is an example of a product which is both complex and difficult to assess via a randomised control trial due to its biological variability and the literature suggests that the synergy between the various pharmacologically active substances leads to efficacy but this varies from individual to individual.

The lack of financing in research may mean that treatment opportunities are missed through restricted medicine development, lack of refinement of evidence in older medicines or trials being financed only for narrow indications coupled to reluctance to accept the generalisability of research findings. In addition, funding for research into psychological, physical and self-help interventions is very limited and, when combined, in a multimodal package is very challenging to undertake and likely only feasible in ways that would lead to exclusion by NICE.

Guideline confusion – the disconnect between clinical practice and national guidance

The result of such differing approaches to guideline development has been to sow confusion amongst clinicians and commissioning bodies, and a growing variance between guidelines and clinical practice.

In a recent survey of Faculty of Pain Medicine members, over 60% of respondents disagreed with the current NICE guidance on the assessment of chronic pain, and over 80% disagreed with the guidance on management of chronic primary pain [NG193]. Fewer than 15% of those surveyed used the diagnosis of 'Chronic Primary Pain' in clinical practice, with over 85% disagreeing with the inclusion of distinct diagnoses such as CRPS in this 'umbrella' term.[11]

This highlights the methodological and practical flaws of using a classification system that has been adopted by NICE and yet is neither clinically established nor in current clinical use. As a result, there is widespread clinical concern that some patients will be denied therapeutic options that they may find helpful, and suffer as a result. NICE have emphasised that their recommendations remain guidelines and not tramlines, and where there is insufficient evidence (based on their methodology) that healthcare professionals are not prevented from using interventions that are clinically appropriate in an individual case. Despite this, in practice, their guidelines have been transformed into rigid frameworks which allow little clinical discretion especially when it is accepted their methodology is flawed for determining individual clinical outcome.

In the application of NICE guidance to chronic pain, we further highlight the following fundamental flaws:

1. **The lack of trials using the WHO diagnosis of chronic primary pain[12] leads to severely limited evidence availability**
2. **Lack of codification systems**
3. **The lack of objective tests for pain diagnosis and therefore wide inter clinical variability as to what diagnosis is given**

Consequences of current trends

The aim of pain treatment is to improve the long term quality of life, reduce distress and disability.

Delivery of the treatment of complex health conditions such as chronic pain in 'silos' with a reliance on simplistic population-based single modality evidence risks rendering treatment ineffective and wasting considerable resource. There may be delays in accessing the right care by the right professionals at the right time. As time passes, declining potential for functional rehabilitation to be successful likely contributes to dependency on addictive pain medications [CD26].[10]

Costs will rise further as quality of life for this group diminishes with the well-recognised consequences of increased heath care consumption: more appearances at both the GP surgery and overstretched Emergency Departments as well as high social costs [CD16] [CD19].[10]

Way forward

While guidelines such as those produced by NICE play a vital role in helping to inform the clinical decision-making process, we conclude there is a need to augment these guidelines to help clinicians decide what best to do in an individual case. While care for an individual with chronic pain may be informed by NICE guidance, it is unlikely to end with only NICE guidance if we wish to offer meaningful benefit to some patients. Such practical guidance would seek to include an individualised approach to trial and assessment of a treatment to allow the efficient use of resources.

Management of pain requires an atmosphere of trust and cooperation between pain specialists and those who commission care, with careful impact modelling on rebound costs from decision making around limiting treatments and new evidential frameworks to determine the reliability of experiential, pragmatic evidence.

Appendix

Factors that influence complexity in chronic pain (the 'Complexity Model')[1, 13]

- Psychiatric and psychological comorbidities including catastrophisation
- Medical comorbidities
- Multiple chronic pain problems/triggers
- Physical conditioning and number of past surgeries
- Risk for medication abuse and diversion
- Polypharmacy
- Sleep disorders
- Body mass index
- Goal setting
- Tobacco smoking
- Coping and social support
- History of head trauma
- Educational level and employment status

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FACULTY OF
PAIN MEDICINE
of the Royal College of Anaesthetists

www.fpm.ac.uk
@FacultyPainMed
contact@fpm.ac.uk
0207 092 1682

Churchill House
35 Red Lion Square
London WC1R 4SG