


A philosophical critique of the UK's National Institute for Health and Care Excellence guideline 'Palliative care for adults: strong opioids for pain relief'

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Abstract

The National Institute for Health and Care Excellence (NICE) promotes evidence-based medicine throughout contemporary health care. Its guidelines are employed in the United Kingdom and elsewhere, influencing the type and quality of health care provided. NICE considers a range of evidence in the process of creating guidelines; however, the research accepted as evidence greatly relies on positivist methodologies. At times, it is unnecessarily restricted to quantitative methods of data collection. Using the Clinical Guideline 140, opioids in palliative care, as an example, it is demonstrated that the research accepted as evidence is unable to provide answers to complex problems. In addition, several inherent biases are discussed, such as age inequality and pharmaceutical company influence. In order to provide coherent and useful guidelines relevant to complex problems in a real world setting, NICE must move away from focusing on data from randomised controlled trials. Its epistemological foundation must be questioned, paving the way for alternative research paradigms to be considered as evidence and thereby enriching subsequent guidelines.

Keywords

Pain management, palliative care, evidence-based medicine, clinical guidelines, opioids

Introduction

The appearance of evidence-based medicine (EBM) in the 1990s¹ heralded a transformation in health care practice. The growing evidence base from clinical trials, published in peer-reviewed medical journals, replaced unproven personal ideas and subjective experience as the foundation of health-related decisions. In the United Kingdom, one response to this shift was the formation in 1999 of the National Institute for Clinical Excellence (NICE). Its aim was to make EBM tools and skills available to the UK's National Health Service (NHS) in order to permit clinically and cost-effective health care.² NICE produces clinical guidelines covering disease management and the effectiveness of interventions. In 2013, the name was changed to National Institute for Health and Care

Excellence to reflect an extended remit covering the concepts of health promotion and social care.²

In health care, clinical guidelines are produced by multiple organisations at local, regional, national and international levels. They are recommendations to improve patient care, based on either systematic

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reviews of evidence or consensus of expert opinions.³ Health care professionals often consider several different guidelines to inform their clinical decision making, with some proponents considering NICE clinical guidelines as the benchmark of best management.⁴ There are, however, concerns that injustice, prejudice and rationing are implicit in the guidelines.⁵ For example, advocates for certain patient-populations have previously considered NICE guidelines to be the UK government's justification for withholding expensive treatments, such as in Alzheimer's disease⁶ and neuroblastomas in children.⁷ Others argue that the pre-digested evidence and ready-made guidelines deskill clinicians.⁸

Clinical Guideline 140 (CG140), 'Opioids in palliative care: safe and effective prescribing of strong opioids for pain in palliative care of adults',⁹ was published in 2012 and updated in 2016. This article will use this guideline as a basis for exploring the positivist, empirical paradigms of EBM and NICE. It will argue that these are insufficient foundations for dealing with the complexities of pain and the decisions relating to better managing it. Finally, the advantages of broadening the paradigmatic approach to CG140, and other NICE guidelines, will be discussed.

Evidence

NICE clinical guidelines are developed using standard processes, with explanations of how decisions and recommendations are made.¹⁰ A Guideline Development Group is responsible for writing each guideline and it employs tools, such as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to appraise the available evidence. NICE introduced the GRADE system to encourage a fairer and more rigorous weighting of the evidence. It replaced the hierarchy of evidence, which involved scoring evidence on a scale of trustworthiness, or alternatively as expert opinion. Qualitative research and integrative reviews, encompassing both qualitative and quantitative data, have been recognised as credible sources of evidence by NICE.¹¹ However, there appears to remain an ongoing greater respect for methods considered as higher in the hierarchy, such as systematic reviews of randomised controlled trials.⁸

The philosophical foundations of research

There are two classical ways, or ontologies, in which the world can be viewed. One approach suggests an objective reality exists, independent of people or social situations. Research is able to discover this reality with a direct relationship between the quality and quantity

of research, and the accuracy of how that reality is captured. This view describes the ontology labelled 'positivism'.¹² In the second approach, the idea of a single true reality is rejected and posits multiple realities co-existing at the same time, possibly in the same situation, a constructivist ontology. Everyone creates or constructs their own realities, including both the researcher and the researched. A constructivist ontology.¹³ NICE provides no declaration of its paradigmatic framework; however, this article argues that NICE publications are largely located in a positivist paradigm.¹⁴

Clinical guideline: opioids in palliative care

Pain is a common problem in populations with life-limiting illnesses, with over 50% of these patients experiencing pain.¹⁵ The World Health Organisation (WHO) considers pain management a global priority and it promotes a three-step guide to providing effective pain relief in adults, with strong opioids, such as morphine at step three.¹⁶ CG140 is published by NICE to promote safe effective prescribing of these strong opioids for pain, cognisant of the legislative, patient and prescriber barriers to prescribing.^{17,18} It, however, contains no definition of pain which is the central concept of the guideline.

Controversies of CG140: pain

Pain is a subjective, socially constructed phenomenon, embedded in the cultural context, which can best be described through our interpretation of it.¹⁹ Scientific positivist approaches are useful in researching the pathophysiology of pain; however, there are challenges measuring its subjective nature. Pain may be perceived as relating to a persons' guilt or shame, or may be interpreted as a message, full of meaning and significance. It may also be viewed as a meaningless organic symptom to be avoided or a challenge to be surmounted.²⁰ Irrespective of how it is interpreted, pain remains a personalised, idiosyncratic phenomenon, difficult for positivist research to access and measure.²¹ Researchers employ reductionist methodologies to measure pain, although there is no consensus on the classification of pain in cancer-related clinical trials with extensive use of heterogeneous, non-validated methods of pain assessment.²² The Cancer Pain Assessment and Classification System recommends that there should be at least four domains to pain assessment: pain intensity, pain mechanism, breakthrough pain and psychological distress.²³

The critical appraisal of studies in CG140 includes no mention of how pain is defined, and limited

consideration of its measurement. Pain intensity and, occasionally, breakthrough pain are the only related outcomes recorded in the evidence tables.²⁴ For example, the literature search for the second review question: ‘What is the most effective first-line opioid treatment in patients with advanced and progressive disease who require strong opioids?’ identified 25 empirical quantitative studies. The respective evidence table recorded that pain intensity was measured through 100 mm visual analogue scales (n=9), 4-point Likert scales (n=6), or was not recorded (n=10).²⁴ The broad concept of pain is reduced to a single numerical score, ready for statistical analysis. The social, psychological and spiritual elements of the experience of pain are ignored.²⁵ There exists more holistic or descriptive pain scales, such as the Brief Pain Inventory; however, these are absent from the included evidence. In the included study by Arkininstall et al.,²⁶ the authors compared a sustained release morphine tablet with immediate release solution. They employed the McGill-Melzack Pain Questionnaire to measure pain however used only the sub-index ‘Present Pain Intensity’. This study was potentially biased as it was supported by a grant from the pharmaceutical company who produced the branded sustained release morphine tablet.

Controversies of CG140: biases

The critical appraisal of individual studies by NICE includes the consideration of certain possible biases, for example the method of randomisation of participants and the accounting for drop-outs in the statistical analysis. This approach is employed in an attempt to provide a just solution for a target population. It is important and appropriate; however, it is limited to the level of the individual studies. It does not question whether there are higher-level biases which prevent the selected evidence base from providing a just solution. For example, older participants and those with comorbidities are more likely to be excluded from clinical research.²⁷ In the NICE guideline on managing older persons with low back pain, most of the studies accepted as evidence excluded those over 70 years old, and very few reported how the effectiveness of therapies differed by age.²⁸

The funding of clinical trials by pharmaceutical companies is a further example of injustice within clinical research. Industry-influenced research agendas have resulted in much of the current clinical research being focused on patentable treatments such as drugs and drug delivery technologies.²⁹ Furthermore, published industry-sponsored research produces more pro-industry outcomes compared to publicly funded research.³⁰ To counter this bias, NICE recommends an evaluation

of the funding sources of research through their inclusion in the generic evidence tables.¹⁰ However, this item is absent from the evidence tables employed in CG140²⁴ and as such, there is no record that the source of funding was considered in the critical appraisal of evidence. This is evident in the paper by Arkininstall et al.²⁶ mentioned above, and Davies et al.³¹ who declared financial ties with the pharmaceutical company producing fentanyl delivered nasally by a patented drug delivery system, the focus of their research.³² The Guideline Development Group made no mention of these potential biases, either in the GRADE profile summaries⁹ or in the respective evidence tables.²⁴

Controversies of CG140: is the positivist foundation appropriate for the subject matter?

The construction of the CG140’s review questions highlights the value-driven assumptions and the ontological foundation. The following review question illustrates this, ‘What information do patients with advanced and progressive disease who require strong opioids, or their carers, need to consent to opioid treatment, and monitor the effectiveness and side effects of the opioid?’⁹ This question is defined as ‘qualitative’ and therefore, evidence was restricted to qualitative studies. Qualitative research methods are an appropriate choice to understand participants’ feelings and fears at a deeper level. These methods, such as focus group discussions and in-depth interviews, are commonly based in a constructivist approach, in which the perspectives of the research participants are regarded as equally valid and real, even if conflicting.¹² However, the review question is phrased in a closed way which implies that there exists a single answer, true for all patients and their families. This is in line with the underlying positivist framework, which we argue is not in harmony with the ethos behind much of qualitative research. It would be preferable to use an alternative, more open question, such as ‘how do patients with advanced and progressive disease requiring strong opioids, or their carers, *perceive* opioid treatment?’. This would better facilitate the inclusion of data from the perspective of the patient and their family, rather than that of the health care professional. Examples of such data and their suitability are discussed below.

The place for alternative philosophies

Pain is a complex subjective phenomenon; however, there is no acknowledgement within CG140 of the

limitations of quantitative measurements of health, which reduce rich descriptions to a single numerical score. This reductionist approach to knowledge creation is framed within the concept of value-free interpretation of research findings. This is a flawed concept as there is an unbridgeable chasm between evidence and theory, labelled the Gap Argument.³³ This gap is not free of values and prejudices, rather it is filled with cultural, social and political values, and it is this value-laden environment that functions as a lens through which knowledge is created.³⁴ These values influence, not only, how policy makers, researchers and clinicians interpret data, but also how data are created: which topics are researched, the choice of research questions, the selection of methods and the level of integration of the patients in research.²⁷

Patient-centred care is central to EBM.¹ For it to be practiced, the health care professional needs to journey to the patient's world and understand their feelings, thoughts and experiences.³⁵ We suggest that research approaches aligned to constructivism are inherently complementary to this approach. The rejection of an objective reality and the acceptance of multiple co-existing realities denotes the importance of individual patients' views. Patient-centred care is acknowledged in the section on patient information and communication. It is not, however, carried over to the other sections, which maintain a symptom or disease-centred approach. This genre of research could enrich CG140, through increasing the individuality, broadening the evidence base and challenging the objectives of the guidelines:³⁶

1. *Individuality versus generic population.* NICE guidelines are designed to be applied at an individual patient level; however, this purpose can be over-shadowed by the population-based evidence. The individual prescriber should be encouraged to consider the best fit for the patient in front of them, rather than the right response.³⁷
2. *Evidence base.* The patient's lifeworld, their understanding and experience of illness are valid and important sources of evidence.³⁴
3. *Goal.* The central tenet of CG140 is the provision of pain relief in an empirical biomedical context; however, the patient-centred goal of management is the reintegration of the patient into their own lifeworld.³⁴ Patients do not consider a reduction of their pain on a numerical rating scale as helpful. Rather, they are interested in whether their pain is sufficiently controlled so that they can perform their desired activities and maintain their relationships.³⁸

Synthesis of research

The reliance of CG140 upon scientific data to improve skills and practice reflects the predominance of 'techne', the technical skill in arts and crafts. 'Techne' is one of several intellectual virtues described by Aristotle, traditionally ascribed to medicine.³⁹ The complementary virtue of 'phronesis' or practical wisdom is little represented in CG140. This genre of knowledge is learned through practical life-experience, and not through the understanding of theory.³⁵ This virtue, like intuition, is complex and not easily measured or quantified. However, these challenges do not negate its importance, as it is naïve to accept that being able to measure something equates to understanding it. For CG140 to be most useful and applicable to its readers, it requires elements of phronesis to complement the already present techne.⁴⁰ One approach to this is through the use of integrative reviews, which allow both quantitative and qualitative research to be synthesised to give a better understanding of the researched topic. Qualitative research should not be relegated to the 'qualitative' question, rather its integration with quantitative data can facilitate a better understanding of the wider subject area, making guidelines more patient-centred, while still being clinically and cost-effective. There are several approaches for the systematic review of qualitative studies and the integrative review of qualitative and quantitative studies.⁴¹ However, the integration of qualitative research into the production of guidelines has been slower.^{42,43} For example, such findings are limited to the section on information and communication in the present structure of CG140. An alternative approach is the mapping of qualitative data onto guidelines' recommendations.¹⁸ An example of such is provided in Table 1, with qualitative data cited in this article mapped to the recommendation 1.1.13 of CG140, which relates to the initiation of subcutaneous opioids.

Conclusion

This article argues that the positivist framework adopted by CG140 is inappropriate for the subject matter. It does not, however, suggest that quantitative research is without value. Rather, it highlights some of its weaknesses, unacknowledged within CG140, and how it can be complemented with research from alternative philosophies. Much of CG140's reductionist approach to pain management results in disease-centred health care and does not give credence to the experience of the patient. It is important that health care professionals do not ignore how pain is experienced and what it means to an individual patient. We argue that more space for intuition and

Table 1. Example of how qualitative data can be mapped to guideline recommendations.

	Findings relating to initiating subcutaneous opioids
Author	Recommendation 1.1.13: 'Consider initiating subcutaneous opioids with the lowest acquisition cost for patients in whom oral opioids are not suitable and analgesic requirements are unstable, supported by specialist advice where needed'
Flemming ¹⁸	Patients may perceive unstable pain as a sign of worsening health, disease progression and impending death
Flemming ¹⁸	Patients and families may fear that any increased dose of morphine will lead to sedation and a hastened death, especially when given through a syringe-drivers
Gibbins et al. ³⁸	Patients want their pain to be controlled to allow them to keep up their usual activities and social relationships. They may prefer choices of pain management and administration which can best maintain their mobility and independence

alternative philosophical approaches would lead to improved patient-centred care, in line with the objectives of EBM.

Conflict of interest


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