

## Introduction

The appearance of Evidence Based Medicine (EBM) in the 1990's (Sackett et al., 1996) 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 (UK), 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 (NICE, 2016). 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 (NICE, 2016).

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 reviews of evidence, or consensus of expert opinions (Deng et al., 2016). Health care professionals often consider several different guidelines in informing their clinical decision making, with some proponents considering NICE clinical guidelines as the benchmark of best management (Streeter and Brewster, 2015). There are, however, concerns that injustice, prejudice and rationing are implicit in the guidelines (Harris, 2005). 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 Alzheimers disease (Hunt, 2007) and neuroblastomas in children (Bernstein, 2016) Others argue that the pre-digested evidence and ready-made guidelines deskill clinicians (Hutchison and Rogers, 2012).

Clinical Guideline 140 (CG140), 'Opioids in palliative care: safe and effective prescribing of strong opioids for pain in palliative care of adults' (NICE 2012), was published in 2012 and reviewed in 2016. This paper 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 (NICE, 2009). A Guideline Development Group is responsible for each guideline and structure their appraisal of evidence using tools such as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. 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 (NICE,

2017). However, there appears to remain an ongoing greater respect for methods belonging higher in the hierarchy, such as systematic reviews of randomised controlled trials (Hutchison and Rogers, 2012).

### **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 (Moens et al., 2014). The World Health Organisation (WHO) considers pain management a global priority and promotes a three-step guide to providing effective pain relief in adults, with strong opioids, such as Morphine at step three (WHO, n.d.). CG140 is published by NICE to promote safe effective prescribing of these strong opioids for pain, cognisant of the barriers to prescribing, such as, legislative, patient and prescriber (Nguyen et al., 2013; Flemming, 2010). It, however, contains no definition of pain, the central concept of the guideline.

### **The philosophical foundations of research**

There are two main ways, or ontologies, in which the world can be viewed. In one way, an objective reality exists, independent of people or situations. Research is able to discover this reality with 'better' research leading to a closer reflection of what that reality is. This view describes the ontology labelled 'positivism' (Bryman, 2012). In the second view, the idea of a single true reality is rejected and replaced with the idea of multiple realities co-existing at the same time, possibly in the same **situation. These realities are**

created or constructed by people, both the researcher and the researched. This is line with constructivism and interpretivism (Ellingson, 2009). NICE provides no declaration of its paradigmatic framework; however, this paper argues that NICE publications are founded on a positivist paradigm (Wilmot 2011).

### **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 (Best, 2007). Scientific positivist approaches are useful in researching the pathophysiology of pain, however there are challenges measuring its subjective nature. Pain may be interpreted as a message, full of meaning and significance, such as from a deity. It may also be viewed as a meaningless organic symptom to be avoided, a challenge to be surmounted, or relating to guilt or shame (Renqvist, 2015). Irrespective of how it is interpreted, pain remains a personalised, idiosyncratic phenomenon, difficult for positivist research to access and measure (Morris, 1991). 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 heterogenous, non-validated methods of pain assessment (Haugen, 2010). 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 (Kaasa et al., 2011).

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 (NICE, 2012, Appendix E). For example, the literature search for review question 2: 'What is the most effective first-line opioid treatment in patients with advanced and progressive disease who require strong opioids?' identified twenty-five empirical quantitative studies. The respective evidence table recorded that pain intensity was measured through 100mm visual analogue scales (n=9), 4-point Likert scales (n=6), or was not recorded (n=10) (NICE, 2012. Appendix E). 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 (Morrissey, 2011). There exists more holistic or descriptive pain scales, such as the Brief Pain Inventory, however these are absent from the included evidence. The included study by Arkininstall et al. (1989) did use the McGill-Melzack Pain Questionnaire however used only the sub-index 'Present Pain Intensity'.

### **Controversies of CG140: Biases**

NICE makes provision for certain biases in the critical appraisal of the included individual studies; such as, considering whether participants were suitably randomised and how drop-outs were accounted for 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, the exclusion of older participants or those with co-morbidities from clinical research (Kelly et al., 2015). Most of the studies accepted as evidence for the NICE guidelines on managing older persons with low back pain excluded those over 70 years old, and very few reported how the effectiveness of therapies differed by age (Schild von Spannenberg et al., 2013)

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 focusing on patentable treatments such as drugs or drug delivery technologies (Rogers & Ballantyne, 2009). Furthermore, published industry-sponsored research produces more pro-industry outcomes compared to publicly funded research (Bhandari et al., 2004). To counter this bias, NICE recommends an evaluation of the funding sources of research through its inclusion in the generic evidence tables (NICE, 2009). However, this item is absent from the evidence tables employed in CG140 (NICE, 2012, Appendix E) and as such, there is no record that the source of funding was considered in the critical appraisal of evidence. One of the papers accepted as evidence was Davies et al. (2011) who researched nasal fentanyl delivered by a new patented drug delivery system (Watts and Smith, 2009). The authors declared financial ties with the researched product in the original research paper, however the Guideline Development Group made no mention of this bias, either in the GRADE profile summary (NICE, 2012, table 13, page 51) or the respective evidence table (NICE, 2012, Appendix E, table 5, page 55).

## **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?' (NICE, 2012a, p. 11). 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 (Bryman, 2012). These methods, such as focus group or in-depth interviews are commonly founded on constructivism, in which the perspectives of the research participants are regarded as equally valid and real, even if conflicting. 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. An alternative, more open, question would be preferable; such as, 'how do patients with advanced and progressive disease who require strong opioids, or their carers, *perceive* opioid treatment?'. This would better facilitate the inclusion of data on the perspective of the patient and their family, rather than that of the health care professional. Examples of such data and their usefulness are discussed later in the article.

## **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 (Goldenberg, 2014). Rather than being free of values and prejudices, this gap 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 (Goldenberg, 2006). These values influence, not only, how policy makers, researchers and clinicians interpret data, but also how data is created; which topics are researched, the choice of research questions, the selection of methods and the level of integration of the patients in research (Kelly et al., 2015).

Patient-centred care is central to EBM (Sackett et al., 1996). For it to be practiced, the health care professional needs to journey to the patient's world and understand their feelings, thoughts and 'lifeworld' experiences (Svenaeus, 2003: p.415). We suggest that research approaches aligned to constructionism are inherently complementary to this approach. The rejection of an objective reality, and the possibility of multiple co-existing realities validates individual patients' views as being insightful and important. 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.

G140 could be enriched by this genre of research; encouraging individuality, broadening the evidence base and challenging the objectives of the guidelines (Greenhalgh et al., 2015):

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. (Kotzee et al., 2016)
2. Evidence base: The patient's lifeworld, their understanding and experience of illness are valid and important sources of evidence (Goldenberg, 2006).
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 (Goldenberg, 2006). Patients do not consider a reduction of their pain on a numerical rating scale as helpful. They are interested in whether their pain is sufficiently controlled so that they can perform their desired activities and maintain their relationships (Gibbons et al., 2013). This is suggested as a topic for further research in the NICE guidelines 173: Neuropathic pain – pharmacological management (NICE, 2013. Pg. 131)

## Synthesis of research

Integrative reviews allow both quantitative and qualitative research to be synthesised to give a better understanding of the researched topic. The integration of data from qualitative methods can go some way of making guidelines more patient-centred, while being clinically and cost-effective. 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. There are now established approaches for the systematic review of qualitative studies, and the synthesis of qualitative and quantitative research in integrative reviews \_REF NEEDED\_. However, the integration of qualitative research into the production of guidelines has been slower (Munoz-Plaza et al., 2016; Utens et al., 2016). In the present structure of CG140, such findings are limited to the section on information and communication. An alternative approach is the mapping of qualitative data onto guidelines' recommendations (Flemming, 2010). An example of how a sample of findings from qualitative data cited in this article could map onto a recommendation from CG140 is presented in table 1.

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.'
(Fleming, 2010)	Patients perceive unstable pain as a sign of deteriorating clinical situation, and impending death.
(Fleming,	Patients perceive any increased dose of morphine as leading to sedation

2010)	and a hastened death. This fear is heightened with the use of syringe drivers.
(Gibbons et al., 2013)	Patient's desire their pain to be controlled so that they can keep their usual activities and social relationships. They may prefer pain management and methods of administration which can best maintain their mobility and independence.

**Table 1: Sample integrative table relating to CG140**

**Conclusion**

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

**Declaration of Conflicting Interests**

The Authors declare that there is no conflict of interest

DF is a medical doctor practicing palliative care in West Africa. He is carrying out a mixed-methods case study as part of his research towards a PhD in palliative care in Mauritania.

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