'What counts is what works': NICE's new role and approach in developing evidence-based guidelines for social care

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Abstract

The past 15 years have seen what has been described as a 'post-ideological approach to public service reform' where evidence takes centre-stage and where 'what counts is what works'. The National Institute for Health and Care Excellence (NICE) embodies this ethos, using a robust methodology where evidence is systematically reviewed and guidelines with clear recommendations are developed for clinicians and public health professionals. The Health and Social Care Act 2012 extended the remit of NICE to develop guidelines for social care from April 2013, and in doing so has provoked debate within the sector on the available evidence-base for social care, the quality and applicability of research and evidence, the dangers of imposing a 'medical model' onto social care, and the challenges of implementing guidelines. This paper will outline the approach NICE has taken to address these valid concerns to develop and refine an effective and tailored methodology in order to generate guidelines and recommendations that are suitable for social care. This includes what NICE considers to be 'evidence' in social care, and the options and role of the Guideline Development Group when there is little or no evidence and consensus, or further expertise is required. It will also explore how recommendations are developed, the link between guidelines and professional opinion and the implementation of the guidelines on publication.

Introduction

The use of evidence to inform policy and practice is not a new phenomenon in the United Kingdom. The relationship between social research and social policy was shaped over the 19th and 20th centuries, evidenced strongly in the 1960s, but giving way to the doctrine of conviction politics in the 1980s and 1990s which arguably marginalised the use of research in policy making (Nutley, Davies & Walter, 2002). The election of the New Labour Government in 1997 revived the focus on evidence, research and policy, with the promise of a modernising agenda based on a third-way ideology and the mantra that 'what counts is what works'. The paper *Modernising Government* (Cabinet Office, 1999) affirmed that policy development as a process should encompass the key feature of being evidence-based. Since the mid-nineties, the UK has seen a range of think-tanks and organisations exert influence over policy development with the purpose of getting research and evidence into practice in a range of areas including justice, education, health and social care. Examples of the latter include the Centre for Evidence-based Social Services at the University of Exeter, and the 'Research on the Outcomes of Social Care for Adults' initiative at the University of Salford, and in 1999 the Government emphasised that rather than just '*using* research evidence', there was a desire for social work practice to be '*grounded* in evidence-based knowledge' (Department of Health, 1999).

In 2012, the Health and Social Care Act extended the remit of the National Institute for Health and Clinical Excellence (NICE) to publish quality standards for social care, to be developed using evidence-based guidance. Earl Howe stated that 'the *Care and Support White Paper* set out our plans to drive up the quality of care. NICE's new quality standards on social care will be a key driver of this. They will help define what good care and support looks like for commissioners and care providers as well as people using services' (Howe, 2012). Following this, NICE's name was changed to the National Institute for Health and Care Excellence to reflect this new remit.

This new remit has provoked debate within the social care sector. Since its creation in 1999, NICE has been a predominately health-focused organisation producing 'technology appraisals' assessing pharmaceuticals, surgical procedures, medical devices and screening technologies, as well as clinical guidelines and public health guidelines. The applicability of the evidence and methodologies developed for use in health care to the social sciences has been met with some scepticism and concern by early stakeholders of the NICE social care programme; the main concern being that a restrictive medical model as perceived, in use for clinical guidelines, would be applied unthinkingly. In practice, NICE also has considerable experience in public health where similar issues exist as for social care with regards to the evidence. This learning was considered in the development of the social care methods manual which is used to develop social care guidelines; however, this paper contrasts the perceived 'medical model' alone with the methods for social care.

This paper will consider the challenges for evidence-based social care, outlining the steps that NICE has taken to not only ensure that the process and methodology employed in developing social care guidelines has taken into account the differences between social care and clinical care, but also learns from the experience of guidance development in a diverse range of health topics, including that of public health. The paper will particularly focus on the range and quality of evidence available, the ongoing debate on the 'hierarchy of evidence' and the process by which the Guideline Development Groups assess the evidence and make recommendations. Finally the paper will briefly consider the challenges for effective implementation of social care guidelines.

Evidence-based social care

The term 'evidence-based' has become something of a buzzword in light of the reliance placed on research and evidence in the last 15 years. Indeed, some have sought to re-invent the term as 'evidence-informed', 'evidence-led' and even 'evidence-searched' (Knaapen, 2013) in recognition of the breadth and possibly misleading nature of the term 'evidence-based'. However, for the purposes of this paper evidence-based social care is described as the 'conscientious, explicit and judicious use of current best evidence in making decisions regarding the welfare of service-users and carers' (Sackett *et al.*, 1996). The principle underpinning this is that decisions are made based on the best available evidence and consider what interventions are likely to work in different circumstances, and organisations including the Social Care Institute for Excellence (SCIE) and the College of Occupational Therapists (COT) currently develop such guidelines using NICE-accredited methodologies.

Practitioners such as Geraldine MacDonald and Brian Sheldon have long been proponents of the evidence-based approach to deal with issues and variations in practice. MacDonald observes that the value in an evidence-based approach is that it is not reliant 'purely on ideological assumptions and subjective views about the basis of decision making' (MacDonald, 1999).

However, it is fair to say that in both social care and medicine, decisions may be taken with consideration given to subjective values and knowledge of external factors such as the financial and political landscape, as well as being inherently affected by the limitations of practitioner knowledge, or as Daniel Kahneman would describe it, the belief that 'what you see is all there is' (Kahneman, 2011). Whilst this paper does not intend to explore the behavioural science concept of system one/system two thinking in relation to the processes behind social care decision making, it will explore a little later the necessary part that practitioner opinion and judgment has to play when developing social care guidelines as well as the relationship between professional judgement and guideline implementation.

Perhaps one of the most convincing arguments for evidence-based guidelines is that there has been a fiscal squeeze in recent years on public services resulting in the reduction and even termination of social care services and provision. Falling staff numbers, departmental

restructures and a desire to ensure that quality is not compromised means that the promise of evidence-based approaches are even more salient than ever before (Webb, 2001). Whilst NICE has been clear that social care guidelines are not being developed with the primary purpose of cost-savings, the review questions that will be considered on the referred topics will look at what is effective and what is cost-effective; and also bear cost-saving in mind as guidelines are developed.

Developing evidence-based guidelines: what counts as evidence?

One of the concerns expressed regarding NICE's new role was that the approach to evidence would have a significantly clinical bias, and not without cause. NICE's experience in the development of technology appraisals and clinical guidelines has been perceived as being over-reliant on experimental research such as Randomised Controlled Trials (RCTs). This is a valid concern as NICE has historically referenced a 'hierarchy of evidence' which puts systematic reviews, randomised controlled trials and double blind clinical trials, which are traditionally scientific forms of evidence, at the top of the hierarchy. This hierarchy which puts these types of evidence at the top is based on the methodological design and its internal validity, that is to say whether it is replicable, rather than its external validity, which is to say whether it is ultimately valid and useful (Cartwright, 2007). The social work sector is therefore rightly concerned at the applicability of a model where this type of evidence would be demanded to develop social care guidelines; particularly since there is little confidence that large amounts of this kind of research exists, or would even work, for many areas of social care. However, it is worth noting that even in clinical guideline development at NICE, this simplistic hierarchical model has been superseded by a more considered and sophisticated approach to assessing the quality of the evidence.

It is notable that this concern regarding the availability of this type of evidence, i.e. 'scientific', is not unique to social care but also extends to medicine. In 2007, the 'Program in Evidence-Based Care' in Canada, which produces clinical guidelines for cancer, held a symposium focusing on the challenges of providing evidence-based advice where the evidence is lacking, of poor quality, immature or incomplete (Knaapen, 2013). Therefore it is not just in the social care sector where there is concern over the definition of 'evidence', as the hierarchy has generated criticism from clinicians for undervaluing many different kinds of knowledge and has been described as the source of evidence-based medicine's 'questionable epistemic practices' (Goldenberg, 2009, p.171).

Aside from the concern that there would be a paucity of 'gold standard' evidence if such a simplistic hierarchy were to be used, there was also the valid concern that outcomes in social care are more likely to be found in pre-test/post-test designs, ideas and opinion based studies which are usually associated with social sciences and can be found at the bottom of this hierarchy. An additional criticism of some clinical guidelines is that patient perspectives may not always be considered. NICE has always included consideration of the patient experience when drafting clinical guidelines (sometimes through a review of evidence on patient perspectives or experience, but always through involving patient and carer input at several stages). However, this may be even more important to consider in social care guidelines where service user experience may be the primary outcome.

Rigid adherence to a simple hierarchy of evidence without due consideration of service user experience could therefore limit and exclude valuable evidence, and would result in a clinical model being *imposed* on social care (Gould & Kendall, 2007). Reputationally and methodologically, this was exactly what NICE was determined to avoid. It was essential that published guidelines would not only be based on the best available evidence, but that they would continue to ensure public involvement, reflect service user and carer opinion and input, and that they are something that is ultimately useful and adds value for the sector. Therefore, in preparation for taking on the new social care remit, NICE acknowledged that the disciplines of

social work and medicine are very different, and that a broader consideration of a wider range of evidence and inputs to guideline development were essential.

Previous experience in the development of a joint health and social care dementia guideline with the Social Care Institute for Excellence (SCIE), had allowed NICE to enable 'practitioner, service user and carer involvement and consultation at the stages of defining topics, research questions, deciding on appropriateness of types of evidence and producing the summary review of evidence' (Gould & Kendall, 2007, p.486). It was acknowledged that in comparison with clinical topics, there was a notable absence of the more scientific studies that NICE have been traditionally familiar with and that the production of this guideline relied on systematic review and meta-analysis of qualitative data and a more pragmatic approach to the evidence. However, it remained faithful to the fundamental principles of systematic reviewing and resulted in the production of a guideline which was therefore transparent and replicable (Gould & Kendall, 2007).

Building on the learning from the publication of this guideline, NICE was clear when developing the new methods and processes manual for social care guideline development that in social care a greater variety of evidence may need to be considered. The Social Care Manual states specifically that NICE supports 'innovative and flexible approaches to searching. The use of iterative searching (sometimes referred to as emergent searching) in which the evidence base is not pre-defined is welcomed, as is the use of grey literature sources, such as charity and government department websites' (NICE, 2013). NICE has emphasised to all Guideline Development Groups (GDGs), and at every stakeholder workshop and public event relating to social care, that a robust search strategy would be devised and agreed with the GDG, and a wide range of evidence would be considered and systematically reviewed with recommendations being developed that reflect the strength and validity of the evidence used. Therefore concerns about a restrictive approach in terms of searching for evidence in the social care programme are largely unfounded. The types of evidence may be categorised in terms of their quality based on the methodology used, but searches for evidence are not limited to the perceived 'gold standard' in recognition of its limitations to social care practice and interventions.

Absence of evidence

There remains, however, the question of what if there is no research evidence, gold standard or otherwise, at all. Interventions that are easier to measure and are more replicable tend to receive the most attention, meaning that some types of practice will not be well represented in the research literature (Adams *et al.*, 2009, p.170). The absence of evidence has in fact been considered an achievement in itself by NICE, and as a guideline developer they have focused on the positives of establishing knowledge of the unknown. As part of NICE's work on cancer guidelines, they have helped set up a 'database of cancer uncertainties' (DoCU) which collects and advertises where there is an absence of evidence during guideline development as a prompt for further research. For NICE's social care guidelines where there may be many gaps in the evidence, the Guideline Development Group will be encouraged to select key research recommendations to include in the final guideline, and similarly encourage further research in these areas.

However, the gaps in evidence may not be because the evidence does not exist, but because it has not been found using standard information retrieval methods. For some review questions, other types of information are required such as ongoing research in a field, new services or interventions, abstracts of studies, data on adverse effects, economic models and reports of the experiences of service users, carers or social care practitioners or other professionals. Similarly, where service guidance is being developed, this may rely on statistics which vary between localities and regions, as well as evidence on service configurations and models to generate a baseline assessment (NICE, 2013).

In these situations, a 'call for evidence' may be made to all registered stakeholders specifying the question being addressed and detailing the type of evidence being sought. For example, the structured framework being used and study design for questions of effectiveness. For service guidance, reports, datasets and survey data may also be requested from a variety of organisations to clarify the baseline position. Furthermore, 'expert witnesses' can be requested to attend and give testimony to the GDG on specific review questions where there are gaps in the evidence.

In order to produce the best guideline and recommendations possible, it is important to look to as many available sources as possible for the information to answer the review questions for the guideline. An absence of strong evidence, or any evidence, presents a significant challenge. There has been criticism that a 'weak' recommendation is oxymoronic by nature, and that an absence of certainty and confidence in the evidence should preclude any kind of recommendation being made at all (Knaapen, 2013, p.686). However, a guideline developer in the Netherlands has pre-empted this in their process manual by stating:

> *Evidence-based means that a systematic search of evidence from literature has taken place and was reported on transparently… if there was insufficient evidence – and this happens frequently – an answer still needs to be provided for the key question. Then the opinion of – and consensus between – the various experts will be decisive. We still call the method 'evidence-based': where possible, we have based our recommendations on evidence and made it explicit that the selected search methods did not provide any evidence.*
> (EBRO, 2007, p.4)

NICE takes a similar approach and includes an 'evidence to recommendations' section in its guidelines demonstrating how the final recommendations track back to the available evidence and how they were formed. However, the evidence first requires review and discussion by the Guideline Development Group.

The Guideline Development Group (GDG)

One of the strengths of the NICE methodology is the way evidence is systematically reviewed, synthesised, presented, discussed and formed into action-oriented recommendations by the Guideline Development Group (GDG).

The GDG are an advisory committee to the NICE Board and are made up of a constituency of approximately 15 individuals from different disciplines relevant to the topic. These can include professionals and practitioners across health and social care, commissioners, academics and for social care topics a minimum of 4 service user and carer members. The group is chaired by either an experienced chairperson with support from a topic expert, or an expert chair with prior experience of the subject.

The primary role of the GDG is to agree what the topic specific review questions should be which will generate the evidence searches to answer those questions. The evidence searches are then carried out by the information specialists at the NICE Collaborating Centre for Social Care and the relevant studies are then assessed against pre-defined criteria. Each included study is then assessed for quality and validity, summarised in the form of evidence tables and presented to the GDG with a narrative summary of what has been found and concluding with an evidence statement. This evidence statement briefly summarises for the GDG the number of studies and participants, the quality of the evidence overall and any significance in the findings. An absence of evidence, or lack of sufficient evidence, can still generate an evidence statement which can then guide the GDG to consider other means of making a recommendation (NICE, 2013).

An important aspect of the role of the practitioner members on the GDG is that they do not represent the views of their professional organisations, but rather are appointed to the group by

virtue of their expertise, skills and knowledge. Earlier in this paper, it was noted that subjective views of decision making, individual expertise and the reliance on limited practitioner knowledge are seen as running contrary to the evidence-based movement. However, what counts as evidence does not depend solely on published research, but also on how that evidence is then interpreted and the subsequent agreement of recommendations. This is done by the members of the GDG who mobilize a range of other knowledge, including their qualified opinions, experience and understanding of the context. This is applicable across all NICE guidelines in social care, public health and clinical practice.

Indeed much of the criticism of evidence-based guidelines in general has been amongst clinicians who claim that guidelines based predominately on evidence such as Randomised Controlled Trials were reducing their profession to 'cookbook medicine' (Sackett *et al*., 1996, p.71). Before NICE was established, one of the most quoted paragraphs ever published in the British Medical Journal acknowledged the increasing development of clinical guidelines, stating that 'the practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence… by individual clinical expertise, we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice' (Sackett *et al*., 1996, p.71). This statement is indicative that the authors believed that any separation of the science of medicine and the practice of it is in fact a false dichotomy, and that a combined approach is preferential. The appointment of a GDG with a range of perspectives, proficiencies and knowledge aims to do exactly the same in the production of guidelines aimed at social care; to bring together those with knowledge of the practice of social care to discuss and interpret the best available evidence on interventions and processes. In the absence of evidence, or where the quality of evidence is questionable; this is where the GDG and their interpretation of the evidence, or collective consensus on what should form the basis of a recommendation is invaluable by virtue of that very expertise.

Developing recommendations

The predominant feature of the NICE guidelines is the recommendations which are made based on the available evidence. The recommendations are developed by the GDG and describe the relative value placed on outcomes, benefits and harms, net benefits and resource use, and the overall quality of the evidence; as well as any other influences on the group in reaching their decision. The wording of these recommendations is crucial and the below table illustrates how the strength of the evidence translates to how recommendations are worded in the guidelines.

Strength of Evidence	Wording to Use
Where the recommendation expands upon something where there is a legal duty, or where the consequences of not following the recommendation would be significant.	Must or Must not
Where the GDG is confident that the action will do more good than harm and be cost-effective.	Should + verb *(strong)* 'offer', 'refer', 'advise', and 'discuss' are also used for strong recommendations
Where the GDG is confident that the action will do more good than harm for most people and will be cost-effective, but that other options may be similarly effective or that there are cheaper alternatives which may be slightly less effective.	Could + consider *(weak)*
Where there is no evidence or a significant lack of evidence – recommendations may focus only on the research value of particular interventions where this is feasible and where they have a likely prospect of being beneficial to service users.	Research recommendations in the form of a question.

Agreeing recommendations across a large group of people is challenging as there are many different approaches to making group decisions and a lot depends on the individual members of the group and the dynamic cultivated throughout development. In the majority of cases, the GDG reaches decisions through a process of informal consensus, although formal consensus methods such as the Delphi Technique (Linstone & Turoff, 2002) and formal voting methods may also be used. It is also important to note that recommendations can be based on the GDG's view of current cost-effective practice where no other evidence has been identified, and consensus techniques can be used to capture those opinions and record any areas of disagreement. The 'evidence to recommendations' section of the guideline is clear on how decisions have been made.

It is worth noting that not only do all NICE guidelines have the benefit of having been developed using the best available evidence by practitioners and experts in the field, but that both the scope and the draft guideline are also subject to stakeholder consultation. Therefore, the recommendations will have been refined based on stakeholder feedback. On publication the recommendations will clearly identify the audience, the population covered, the setting, what specifically should be done and, if relevant, a timeframe for doing so. Having gone through this full process the guideline is then ready for publication and implementation.

Implementation and professional judgement

The implementation of NICE guidelines for social care is a further challenge as the programme is still in its infancy, and the intended audience comes from a variety of backgrounds. Also, there is a need for NICE to tailor its messages and products to the social care sector as it is a new audience for NICE with a different language and a varied audience of practitioners, local authorities, commissioners and providers. Part of this implementation will be awareness raising, and emphasising the value of the guideline, assuring the sector that it has been produced in a robust and methodologically sound way. However, it will also rely on encouraging practitioners and professionals to use the guideline as a tool to enable effective decision making in conjunction with service users and to explore the options set out in the recommendations.

As regards the 'enforceability' of NICE guidelines, NICE guidelines for social care and clinical care are not legally binding, although strong links with social care regulators (CQC and Ofsted) will doubtless see recommendations strongly linked to inspection and regulation handbooks. Guidelines try and create consistency, to evidence best practice and to guide practitioners in their decisions. The development and use of guidelines provides an approach to social care based more on evidence and objective demonstration of 'what works' as opposed to an intuitive or subjective method. However as Woolf *et al.* (1999) highlight, guidelines need to be interpreted and applied in an appropriate manner and are just one option for improving the quality of care, that is, the guidelines cannot be applied in a vacuum with little regard to the service user narrative. The nature of guidelines is that they are formulated based on evidence derived from a sample population and therefore the recommendations or conclusions are not magic bullets. As the amusing analogy goes, 'just because the average UK dress size is 16, it does not mean all women should wear that size clothes' (Goodman, 1999, p.250); in other words, one size really doesn't fit all.

This interpretation could dispel any idea that NICE guideline recommendations are binding or could railroad social workers into using them against their professional judgement, much like the 'cookbook medicine' argument. There are many academic studies which argue that the use of judgement, intuition and lay knowledge is less preferable due to the limits of bounded rationality or the potential use of the representative heuristic which may result in bias and error (Rosen, 2003, p.199). However, in line with the commitment to person-centred care, NICE states in the introduction to all of its guidelines that whilst the primary audience (social care practitioners) are expected to take the guideline into account, this is not a substitute for professional judgement, as decisions are taken in conjunction with service users or carer(s)

having discussed the risks, benefits, values and preferences enabling them to make a fully informed decision.

Therefore the status of 'guideline' as well as this introduction section should assure social care practitioners that professional judgement remains a prevalent feature in decisions about social care. Bearing this in mind, the challenge for NICE going forward will be to engage effectively with the social care sector to demonstrate the strength of the evidence used and encourage practitioners to exercise their judgement in conjunction with the recommendations set out in the guidelines and have regard for them. This is particularly relevant as a recent judgement in *R (Elizabeth Rose) v Thanet Clinical Commissioning Group* (CCG) held that Thanet CCG had acted unlawfully by having a policy on fertility which contradicted a NICE guideline, because the CCG did not have confidence in the strength of the evidence. NICE guidelines are not legally binding, but the court ruled that Thanet CCG was still under an obligation in public law to *have regard* for the guideline. The fact that the CCG simply disagreed with it and created a policy which was contrary to the guideline was unlawful (Laird, 2014). Therefore, part of the argument that NICE will have to make is that guidelines are a useful tool to deliver fundamental standards of care by demonstrating the robust process by which they have been developed and by highlighting the range of evidence from which the recommendations have been formulated. In addition, implementation tools and tailored versions of the guidelines may be produced for different audiences, to better help the sector understand the key messages, as well as signposting them to resources which can help them get the research into practice, and potentially demonstrate this as an example of shared learning to the rest of the sector.

Conclusion

Evidence-based social care is a contentious issue, particularly when considering the quality and range of evidence that is available. This paper has discussed the challenges facing NICE in the development of guidelines for the social care sector, and has explored how NICE has responded to these challenges.

Firstly, the challenge of overcoming the assumption that NICE's experience in developing clinical guidelines will result in the rigid application of a 'medical model' on social care guidelines, whereby only 'gold standard' evidence such as Randomised Controlled Trials should be used and considered to be 'evidence'. It has been shown that this type of evidence is not always available even for clinical conditions, and experience from the development of early social care guidelines and public health guidelines is that a traditional medical hierarchy of research evidence would not be applicable to social care. To develop recommendations based only on available evidence in the form of systematic reviews and RCTs would be a significant challenge; and therefore a more inclusive methodology is required.

NICE has addressed this in the development of the social care guideline development manual, which includes more robust methodologies allowing the reviewers to take a broader view of evidence, using a range of search methods and putting out calls for evidence where this is required. The involvement of practitioners, professionals and service users and carers in the development of the guidelines also adds the dimension of expertise from those immersed in the sector. These methodologies are included in the new NICE Process and Methods Manual which came into effect on 1st January 2015 and harmonises guideline development across various guideline development centres within NICE and ensures that all guidelines are developed using substantially similar processes and methods.

By addressing these challenges of development, NICE is now well underway in the delivery of social care guidelines, with the first publications due in summer 2015. The next challenge is of implementing and disseminating the guidelines to the social care sector and encouraging their use in order to improve care and support and limit variation in practice where possible. In conjunction with practitioner-friendly tools and resources targeted at different audiences, and the capturing of shared learning; this will be how NICE's foray into social care will ensure that evidence truly gets into practice and that 'what counts is what works'.

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