EBM Analysis

NICE rapid guidelines: exploring political influence on guidelines

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Abstract

The National Institute for Health and Care Excellence (NICE) has been presented as politically independent, asserting it is free from industry influence and conflicts of interest so that its decisions may be led by evidence and science. We consider the ways in which soft political factors operate in guideline development processes at NICE such that guidelines are not truly led by science. We suggest that while NICE procedures explicitly incorporate scientific principles and mechanisms, including independent committees and quality assurance, these fail to operate as scientific practices because, for example, decisions may only be challenged through the courts, which regard NICE as a scientific authority. We then examine what the NICE rapid guideline procedure for COVID-19 reveals about the practical reality of claims about the scientific integrity of NICE guidelines. Changes to guideline development processes during the COVID-19 emergency demonstrated how easy it is to undermine the scientific integrity of NICE's decision-making. The cancellation of the guideline programme and publication of a rapid guideline process specifically to address the COVID-19 pandemic removed scientific checks and balances, including independent committees, stakeholder consultation and quality assurance, demonstrating that the relationship between NICE and the UK government is more complex than a scientific principles truism. We suggest that NICE is not (and indeed cannot be) truly independent of government in practice, nor can it be truly led by science, in part because of its relationship to the state, which it is simultaneously constituted by and constitutive of.

Background

Plans for a new National Institute for Clinical Excellence, later rebranded the National Institute for Health and Care Excellence (NICE) were first set out in the New Labour government's 1998 white paper 'A First Class Service'[1]. The stated purpose of the new organisation was to address the so-called postcode lottery, with "unacceptable variations in the quality of care available to different NHS patients in different parts of the country". The emphasis in government narrative was on improving health at the population level by "drawing on best available clinical evidence…to maximise health gain for the population". NICE would "advise on best practice in the use of existing treatment options, appraise new health interventions, and advise the NHS on how they can be implemented and how best these might fit alongside existing treatments". These statements suggest that at the outset, NICE was intended to have the authority to deliberate on matters of science and evidence; and to advise, rather than be instructed by, other health care organisations. NICE would be

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led by science, generate knowledge and be free from political interference or advocacy from drug companies[2]. The argument we pursue in this paper is that if this independence existed at the outset, this function seems to have diminished over time and, moreover, it has been significantly undermined during the COVID-19 pandemic. The analysis that follows considers how various soft political factors may operate and how they undermine scientific integrity.

How does 'political independence' work?

NICE was established in 1999 as a type of Arm's Length Body (ALB), at one remove from government, sponsored by the Department of Health. Early political opposition to NICE focused on its potential to operate as a rationing device, thus the status of ALB would appear to remove government from unpopular decisions and enable rationing to take place under claims of scientific legitimacy rather than economic need or political drivers. Claims about NICE's role in rationing were proven wrong over its first few years during which it approved the majority of treatments it assessed and in so doing increased NHS treatment costs[3]; yet concerns about NICE's role in rationing remain part of the ongoing political rhetoric around the NHS.

Whether to increase the deniability of rationing claims or for other political purposes, the political independence of NICE was made more explicit in the 2012 Health and Social Care Act which "specifically prohibits the Secretary of State from directing [NICE] about matters relating to the substance of NICE's advice, guidance or recommendations." In 2013 NICE was thus re-established as a Non-Departmental Public Body (NDPB) meaning that any changes to NICE's powers or governance could now only be approved by parliament rather than by ministers alone, seemingly increasing its independence from government. A NDPB is defined as "a body which has a role in the processes of national government, but is not a government department, or part of one, and which accordingly operates to a greater or lesser extent at arm's length from ministers", meaning that "the day-today decisions they make are independent as they are removed from ministers and Civil Servants."[4] This revision to the relationship can be regarded as a move towards a more explicit form of meta-governance, whereby government mechanisms are enacted through a range of quasi-autonomous bureaucratic devices. This can be seen, for example, in the way that NHS England operates through intermittent mandates issued by the Department of Health and Social Care (DHSC) setting out priorities for the coming year or years[5]. There has been a process of obfuscation across these mandates, from a set of clearly stated objectives in 2013 towards a much less specific set of expectations in later mandates[6]. A lack of

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specificity in the governing agreements of ALBs renders the possibility of remote governance through distal networks more possible, working to make the DHSC less accountable.

In the context of NHS England, meta-governance refers to the idea that creating organisations “at arms’ length” from government is a way of obfuscating ministerial responsibility for difficult or unpopular political decisions. Translating this to NICE, decisions about access to healthcare, for example, can be made remotely from ministers and political motive obscured by claims of the need for availability to be determined by science not politics. As such, similar to analyses of the role of NHS England, we propose that the accountability mechanisms in place for NICE also function based on a form of meta-governance characterised by distal responsibility. Similar to the NHS England ‘mandate’, a Framework Agreement[7] sets out the legal relations between NICE and DHSC. This functions as a mechanism through which Government is able to hold NICE to account. The Secretary of State and the DHSC are “responsible to parliament for the system overall” and a Senior Departmental Sponsor liaises between NICE and the Secretary of State. This creates a number of layers in the chain of accountability, none of which relate to accountability for actual treatment approval decisions which must be made independently of the DHSC, and by extension, parliament.

In practice, accountability for the overall functioning of NICE is to parliament. This is split off from accountability for decisions made about approving or refusing treatments. This would suggest that the primary determinant of treatment approvals or refusals is a non-specific and undefined body of current best international scientific evidence, raising questions about who decides what is ‘current’ and ‘best’. This ostensibly makes NICE responsible for all decisions, and conversely, means government is not held responsible when certain treatments are not made available in the NHS. Appearing to ration healthcare is a difficult position for any parliamentary politician to openly embrace, but at the same time, it is a necessary, indeed vital, component of the social and political organisation of population healthcare. In order to counter allegations of undue political influence, it is important for sitting Governments that the political independence and scientific integrity of NICE is explicitly assured and demonstrated, so that decisions appear to be evidence-based rather than politically driven.

The recent response to COVID-19 suggests that rather than NDPBs all operating at an equivalent level in terms of relationship to Government, a hierarchy between NDPBs may have evolved over time, further obfuscating the political factors driving decisions concerning

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availability of treatments in the NHS. During the COVID-19 pandemic, a level 4 national emergency was declared. At the start of the UK lockdown, NHS England and NHS Improvement requested that NICE postpone their approved guideline programme and instead prioritise a programme of rapid guidelines to support the NHS response to the emergency[8]. In this context, it would seem that NICE was subject to a hierarchy of decision making via NHS England, the latter acting as the distal network implementing government agenda through other NDPBs. We explore the implications of the COVID-19 rapid guidelines later on; first, we consider the extent to which scientific principles operated in NICE guideline development prior to the pandemic.

Independent decisions led by science?

Limited attention has been paid to the role of various less visible influences on scientific decision-making processes within NICE. In emphasising 'political independence', the implication is that as long as NICE can demonstrate independence from government ministers, then it is being led by science – that NICE adheres to principles of empirical science, and that this obviates the need to be accountable in any other way for its decisions. Implicit here is that all science is objective and empirical and beyond any undue or improper influence by vested interests. NICE documentation acknowledges that there are uncertainties in science and since 2005 has attempted to weave 'Social Value Judgements' into its ways of working, including moral principles, distributive and procedural justice[9]. Nevertheless, NICE has committed to making decisions led primarily by science; and that while value judgements have a role, these are openly acknowledged and free from political motivation.

In order to consider decisions of any sort to have been led by science, we should have a view on what constitutes scientific practice. We propose that the concept of a state appointed scientific authority (albeit one purportedly operating at arm's-length from government with a range of checks and balances) is potentially incongruent with the scientific method which values questioning and challenge above adherence to the views of the most powerful agents. For most of the scientific community, questioning and challenge comes in the form of peer review, serial rejections, rebuttals and so forth. NICE guidelines are not subject to these pre-publishing hurdles and so, in their place, there is a manual, setting out the process for developing guidelines including quality assurance procedures[10].

Certain scientific checks and balances exist within NICE procedures in respect of health technology appraisals (HTAs) for which there is an independent evidence review process. It

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has been argued that the rigour of these processes has been diluted by new procedures such as fast track appraisal[11]. Moreover, while there is a formal appeals process, appeals have most often been brought by manufacturers, less than half of these have succeeded and of those that did, only a third related to 'unreasonable evidence'[12]. Our current analysis focuses on guidelines rather than HTAs, the latter having historically been more rigorous because they lead directly to policy whereas guidelines are advisory only. Focusing on guideline development, we argue that there are a range of means by which political factors influence decision making.

Within NICE guideline development, a key aspect of scientific integrity is the role of guideline committees made up of independent experts, appointed through an open application process. Whilst committees enhance scientific integrity, they also provide an additional layer of distal responsibility, separating DHSC yet further from decisions about treatment availability. Further, NICE maintains soft forms of control over committee functions by employing technical advisors and systematic reviewers who collate evidence and advise committees on the interpretation of evidence. Committees are also required to follow the NICE guideline manual, which sets out a relatively singular position on evidence synthesis and hierarchies of evidence.

NICE guidelines are also subject to judicial review, seemingly improving scientific integrity. Yet, in spite of considerable scientific criticism over a range of different guidelines as well as numerous challenges on scientific grounds from drug industry and patient lobbies, published NICE guidelines have only been subject to a handful of judicial reviews[13], most of which were overturned. One was eventually won in the Court of Appeal but the grounds for most court decisions in favour of NICE's scientific judgements have rested on the position that judges cannot override scientific judgements made by a scientific authority in favour of a claimant who has a different view of the science (see Box 1).

Box 1: High Court Decisions

"Where the existence or non-existence of a fact is left to the judgment and discretion of a public body and that fact involves a broad spectrum ranging from the obvious to the debatable to the just conceivable, it is the duty of the court to leave the decision of that fact to the body to whom Parliament has entrusted the decision making power save in a case where it is obvious that the public body, consciously or unconsciously, are acting perversely."

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In this sense, the reliance on science creates a paradox whereby claims to scientific knowledge trump all other claims to other forms of knowledge. This implies that whilst a court may in theory overturn a decision by NICE which was clearly influenced by government ministers, it would not in practice overturn a decision on grounds of scientific contestation. In practice, NICE has been delegated by parliament to evaluate evidence and make decisions; yet its decisions seem unquestionable by virtue of NICE having been "entrusted" by parliament.

The NICE guideline manual makes explicit the way in which the quality assurance process incorporates and operationalises scientific principles such as managing bias and conflicts of interest, approaches to critical appraisal of research, peer review and quality assurance. In terms of accountability, stakeholder consultation on guidelines is set out as a core feature of quality assurance, almost as an alternative form of peer review. Yet the process of stakeholder consultation is comparatively light touch. For example, relevant stakeholders might be companies that manufacture medicines for profit who may comment on all consultation documents; indeed in some cases industry representatives may even be committee members[10]. The scheduled period for stakeholder consultation and timelines for revision and final publication of each guideline are very short for a document as complex as a guideline and mean that guideline committees could not reasonably take any serious methodological challenges into account. Unlike peer review, there is no imperative for the committee to address all stakeholder comments and the committee may, according to the manual, choose not to publish or respond to longer comments[10]. This makes it difficult for stakeholders to have anything other than minor impact on relatively superficial issues rather than having any serious impact on fundamental epistemological issues. In effect, stakeholder consultations provide a proofreading function rather than scientific scrutiny. There is no requirement for revised guidelines to be checked a second time by stakeholders. Examples have been offered of how this process has led to serious methodological issues being brushed aside by NICE responses to consultations[13].

COVID-19 rapid guidelines

As noted earlier, NICE was asked to reprioritise all guideline programmes which had been set out in its annual programme at the point that the UK declared a public health emergency

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in 2020. In turn, NICE released documentation describing a new programme of 'rapid guidelines'[14] in which both independent committees and the process of systematic review were removed, substantially weakening claims about scientific integrity and independent decision making. Rapid guidelines would repurpose existing reviews sourced from previous NICE guidelines, the World Health Organisation, Public Health England, the Medicines and Healthcare Regulatory Authority or professional bodies. These contributing organisations are a mixture of government, international advisory bodies, industry or professionally led bodies and therefore not politically nor scientifically 'independent' in the sense NICE is purported to be. Furthermore, there were no independently appointed guideline committees and the manual for creating rapid guidelines omitted all elements of stakeholder consultation and risk of bias assessment. This means that any previous concerns regarding accountability, supposedly assuaged by committee independence and stakeholder consultation were not addressed in these new processes. The quality control process for approving rapid guidelines involved "a pragmatic accuracy check" and the guidelines would be reviewed by NHS England prior to publication. This was a new role for NHS England in the guideline authorisation process, confirming the emergence of a governance hierarchy among NDPBs. Whilst appearing to present a necessarily expedient approach to an emergency, the elements omitted were all vital tenets of ensuring appropriate scientific method and quality assurance.

The rapid guideline approach was updated in July 2020 in the form of a more detailed interim process for emergency situations[15]. This replaced, in diluted forms, some elements of scientific integrity such as an independent advisory expert panel but without open recruitment. Stakeholder consultation was reintroduced but limited to half a day or up to a week. The sources of evidence that might be consulted were expanded but retained the potential to repurpose WHO or MHRA guidelines or advice. NHS England would no longer be part of quality control but both NHS England and the DHSC retained a role in determining topic selection for emergency guideline development.

Whether or not there may have been ways to better manage the balance of expediency versus quality between March and July 2020, the fact that expediency at the request of another NDPB was able to take precedence over scientific scrutiny, raises important questions about the legal and political framework under which these sudden changes were implemented and what they might reveal about how the role and function of NICE has evolved. It is also open to question whether the more permanent emergency process put forward in July 2020 is an adequate way to balance these concerns. Given NICE was

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established primarily as a science-led organisation to end unwarranted variation in treatment whilst avoiding industry influence, the explicit removal of some or all scientific checks and balances in an emergency situation suggests that the central reliance of NICE on claims to scientific legitimacy is not in fact central at all. Rather it is the first feature to be removed in the interests of expediency as though scientific processes were unnecessary bureaucracy.

This begs the question that if NICE is no longer able to make claims to scientific integrity, then on what basis is it accountable for its decisions? Political drivers could now, without any new legal agreement, prior discussion in parliament or amendment to the Framework Agreement, directly influence the scope and content of rapid guidelines, for example by enabling the direct repurposing of guidance or policy written by them. NHS England could also have ultimate oversight, bypassing DHSC and therefore the Framework Agreement. This inverts the original assertion that NICE would be a politically independent body led by science which would advise other health bodies rather than take advice or direction from any other organisation. The rapidity with which this commitment was dropped by NICE, in addition to suggesting that scientific and political independence were only superficially written into the institutional fabric of NICE (such as the Framework Agreement, Charter and principles), also highlights questions around the implications and consequences of the UK government's overall commitment to their COVID-19 response being "driven by science". Science is, by its very nature, never particularly rapid and therefore no political response to a novel situation can be led by science; it can only be led by politicians informed by incomplete speculative hypotheses from multiple sources with an inevitably wide range of built-in biases and conflicts of interest. In essence, NICE cannot be truly led by science, in part because of its relationship to the state, however obscure that relationship has been made.

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