

## Analysis

# The Dobson–Rawlins pact and the National Institute for Health and Care Excellence: impact of political independence on scientific and legal accountability

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This analysis considers whether the independence of the National Institute for Health and Care Excellence (NICE), while safeguarding guidelines from commercial lobbying, may render NICE legally and scientifically unaccountable. The analysis examines the role of judicial reviews and stakeholder consultations in place of peer review in light of current debates concerning the depression guideline.

## Declaration of interest

None.

## Keywords

Clinical governance; depressive disorders; ethics; psychiatry and law; statistical methodology.

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Originally established in 1999, the National Institute for Health and Care Excellence (NICE) was re-established in 2013 as a non-departmental public body. Although accountable to the Department for Health and Social Care, NICE is operationally independent of government. The secretary of state may intervene ‘if NICE fails to discharge its functions’<sup>1</sup> but, in practice, NICE was instituted such that neither ministers nor enraged pharmaceutical company chiefs could interfere with decisions. When NICE made its first controversial decision not to recommend Relenza in 1999, Frank Dobson backed NICE, ignoring raucous threats from GlaxoWellcome to move their business abroad.<sup>2</sup> Dobson is quoted as saying to Rawlins (chairman of NICE): ‘I think we’d have had to back you regardless, whether you were right or wrong. Fortunately, you were right.’<sup>2</sup> This early precedent set the stage for how ‘political independence’ would work. The 2012 Health and Social Care Act ‘specifically prohibits the Secretary of State from directing the institute about matters relating to the substance of NICE’s advice, guidance or recommendations.’<sup>2</sup> Although it seems appropriate to safeguard NICE guidelines from pharmaceutical company lobbying, we consider whether political independence may render NICE insufficiently accountable, legally and scientifically. The 2018 stakeholder consultation on the draft depression guideline is considered an example of how accountability operates in the context of a field in which there are multiple divergent expert opinions.

## The duty of the court

NICE procedures were formed to comply with English administrative law. The principles that apply are general: to act lawfully, fairly and rationally. Rawlins notes that ‘the totality of published NICE guidance now totals over 1100 items but only four have been considered at judicial review and the courts have quashed none.’<sup>2</sup> In fact, as discussed later, the courts have upheld one judicial review challenge on appeal. Nevertheless, Rawlins suggests that this lack of challenge is ‘testimony to the institute’s assiduous approach to meeting its legal obligations’. Although this is possible, it is unlikely to be a satisfactory explanation. There are many reasons why judicial review proceedings are not pursued that are unrelated to the legal quality of decision taking. These reasons include lack of

awareness that judicial review is available, high costs of litigation and lack of access to appropriate legal advice.<sup>3</sup> Of judicial reviews that reach a hearing, around 50% are successful.<sup>4</sup>

The first judicial review concerning NICE was brought by a pharmaceutical company challenging the decision not to recommend their Alzheimer’s drug. One basis of this claim was that NICE’s decision was irrational. On this, the judge ruled:

‘[t]he court has no part to play in adjudicating between the rival merits of the arguments of the experts, of whom there are many who take a view different from the Claimant’s experts.’<sup>5</sup>

Similarly, in a later judicial review concerning recommended treatments for myalgic encephalomyelitis, the judge quoted English case law from 1984:

‘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.’<sup>6</sup>

Therefore, although the legal duty to act rationally may apply in matters of scientific judgement, NICE appears largely free from legal accountability because courts tend to defer to experts; parliament has given NICE authority to decide among the various scientific arguments.

In judicial reviews against NICE, claims have tended to concern specific recommendations, often relating to a single drug. In contrast, during the 2018 stakeholder consultation on the draft depression guideline, 14 professional and patient organisations jointly expressed methodological concerns relating to the way the guideline had been constructed in its entirety.<sup>7</sup> The methodological points raised do not represent commercial interests, indeed – if heeded – they could potentially reduce commercial influence on the guideline. The six methodological points were: long-term trial outcomes should be examined; service-user experience research should be reviewed; quality-of-life outcomes should be taken into account;

subcategories of depression should be in line with European and American bodies; partial recovery should be taken into account for severe depression; and network meta-analysis should be abandoned, following the Canadian guideline body, because it is 'associated with serious and unique risks' with 'no formal expert consensus yet established on its appropriateness for this type of review'.<sup>7</sup> In their formal response,<sup>8</sup> the Guideline Committee stated that none of these points would be addressed in a third revision due for publication in February 2020, largely on the grounds that the Guideline Committee's opinion differs.

In previous judicial reviews, courts have found in favour of NICE where the consultation process has been run in accordance with stated procedures and where NICE has provided a clear rationale for disagreeing with other scientific experts. This suggests that normally, even where differing scientific interpretations of evidence exist in relation to specific trials of specific treatments, NICE is protected from scientific challenge as long as its own stated procedures are followed properly. It remains to be tested whether this would still be the case if a judicial review were brought forward in which the divergent scientific opinions concerned the whole methodological approach and were expressed by a range of non-commercial stakeholders.

In terms of governance, NICE is accountable to the secretary of state and not to parliament directly, although the secretary of state is accountable to parliament.<sup>1</sup> Although 31 parliamentarians wrote jointly to NICE supporting stakeholder concerns about the depression guideline,<sup>9</sup> there is no direct imperative for NICE to take this into account. Whereas this may provide an appropriate form of defence from lobbying and commercial interests, in a case in which stakeholders' concerns are not commercially driven and represent legitimate scientific debate in a controversial field, the principles that might have driven the Dobson–Rawlins pact have the potential to operate perversely.

### Sewage works

We now consider the extent to which NICE is accountable from a scientific perspective, irrespective of parliament or the courts. Although never a perfect system since its introduction by English scientific societies in the nineteenth century,<sup>10</sup> scientific peer review is regarded as a central component of scientific credibility. One of its early advocates saw it as a way to prevent the 'veritable sewage thrown into the pure stream of science'.<sup>10</sup>

NICE employs stakeholder consultations for this function:

'Consultation with stakeholders is an integral part of the guideline development process. Comments received from registered stakeholders are a vital part of the quality-assurance and peer-review processes and it is important that they are addressed appropriately.'<sup>11</sup>

Any organisation may respond as a stakeholder, including pharmaceutical companies and those with financial links to them. The period allowed for consultation (normally 6 weeks) along with timelines for revision and final publication are not long enough for guideline committees to address methodological concerns raised at this stage; with the result that stakeholder consultations tend to manage stakeholder feedback in a superficial manner. There is no imperative for NICE to take on board stakeholder comments and NICE reserves the right not to publish or respond to comments that are too long. Relative to scientific publishing, this form of peer-review process could be described as 'light touch', particularly as commercial companies may represent their interests via consultations on a par with any other stakeholder.

There is nevertheless a greater degree of transparency in this process than with other guidelines. For example, the British Association for Psychopharmacology guideline for depression describes a similar process of inviting stakeholders to provide feedback on a draft.<sup>12</sup> It is also published in a peer-reviewed journal and so presumably had to address reviewer feedback. Yet none of this is transparent in the way that NICE publishes extensive documentation relating to consultations online.

Moreover, because NICE combines its public body 'duty to consult' with scientific peer review, further legal duties extend from the consultation exercise. Public consultations are expected to follow a set of principles referred to as the 'Gunning principles'. The Gunning principles were propounded by Mr Stephen Sedley QC and adopted by Mr Justice Hodgson in *R v Brent London Borough Council, ex parte Gunning* [1985] 84 LGR 168 at 169; they were subsequently approved by Simon Brown LJ in *R v Devon County Council, ex parte Baker* [1995] 1 All E.R. 73 at 91g-j; and by the Court of Appeal in *R v North and East Devon Health Authority, ex parte Coughlan* [2001] QB 213 at [108]. These principles have been understood to include that the public body should 'have an open mind during a consultation and not already have made the decision' (e.g. NHS Involvement, 2019).<sup>13</sup> In arguing that long-term outcomes of trials should be included in the depression guideline analysis, stakeholders noted in May 2018:

'Follow up data of 1–2 years have been omitted in the draft depression guideline. The Guideline Committee state that there are insufficient studies with long term follow up data to conduct such analyses. If this is the case then it is inappropriate for the guideline to make any firm recommendations for specific treatments based on (albeit large amounts of) short-term outcome data. Large amounts of poor evidence must not be used in place of small amounts of good evidence.'<sup>7</sup>

The Guideline Committee's formal response in October 2018 stated:

'Unfortunately, there is limited available data on long-term follow up and as a result the committee agreed prior to the examination of any evidence that this could not be the primary outcome for comparing treatment efficacy. But we used long term data where possible. (...) if the committee had not made recommendations for interventions which only report short-term data, there would have been very few recommendations in the guideline, which would have severely limited its clinical utility.'<sup>8</sup>

It is possible that a rational mind (in the legal sense) might consider this response to fall short of addressing the specific point about small amounts of good evidence outweighing large amounts of inadequate evidence. It also includes an inaccuracy in that no follow-up data were used in the analysis. The result is that the best possible evidence has potentially been left out of the guideline. Rather than demonstrating an open mind, the Guideline Committee restated their position before the consultation. Similar examples occur in response to each of the six methodological concerns, suggesting that decisions had already been made before consultation. Thus the scale and transparency of the stakeholder consultation exercise could leave NICE open to greater accountability than a closed peer-review process and, in this sense, the means of holding NICE to account scientifically could paradoxically be via its legal duties as a public body.

### Court of Appeal

In 2010, as noted earlier, the Court of Appeal quashed a decision by NICE.<sup>14</sup> Evidence concerning a drug's efficacy had been rejected by

NICE but accepted by another international body (the European Medicines Agency). Although NICE gave general reasons for their decision, the Court ruled that NICE should have given specific reasons as to why its decision differed from that of the European Medicines Agency.<sup>10</sup> This decision draws on a core principle that legally rational decisions should be supported by reasons. NICE recognises this duty in their manual:

‘Each comment must be acknowledged and answered as directly, fully and with as much information as possible... If no changes have been made, it should be clear from the response why not.’<sup>11</sup>

The duty to give reasons is normally only applicable in specific cases, e.g. concerning personal liberty, fairness or where a decision appears inexplicable.<sup>15</sup> Arguably, this duty exists in the context that concerns us here for a number of reasons, including that the guideline will affect a very large number of individuals with depression and their families, that NICE acknowledge a duty to give reasons in their manual and because the Guideline Committee should explain when their decisions deviate from internationally recognised approaches. Specifically, stakeholders referred to NICE sub-categories of treatment-resistant and chronic depression deviating from the ICD and the DSM which group ‘persistent’ forms of depression together; they also referred to reliance on network meta-analysis techniques as deviating from the approach of the Canadian Agency for Drugs and Technologies in Health.


## Conclusion

The Dobson–Rawlins pact appears to have been seeking to protect NICE from commercial lobbying, either directly or via parliamentarians, which many would agree is a laudable principle. Yet it might be considered undesirable should this level of protection extend to handing over to NICE the status of ultimate scientific authority, particularly in fields where not only the findings of evidence are routinely contested across the professional and scientific spectrum, but so are the methodologies and underpinning conceptualisations of the condition of interest.

Although successful judicial-review challenges to NICE decisions are rare, they are not unknown and judicial review remains a possible route for those seeking to question NICE. NICE is subject to English law and is required to adhere to a high level of transparency in terms of its duties as a public body; this undoubtedly exceeds accountability within closed peer-review systems. Yet there are aspects of the English legal and parliamentary system which impede scientific accountability by virtue of the fact that courts tend to defer to the expert appointed by parliament. Considering the precedent set by the one successful challenge to NICE, it may be argued that NICE has a legal duty to explain why its approach and conclusions differ to those of a body of equivalent standing outside of the UK. This is particularly important where, as here, expert opinions of UK professionals support the approach taken by these expert bodies. What began as a strategy to defend National Health Service (NHS) care from global commercial interests may instead have become a barrier to healthy scientific process and subsequently good care for millions of UK citizens who need or will need NHS support for depression. Perhaps in recognition of this, NICE have recently taken the unusual step of inviting concerned stakeholders to a ‘workshop’, pending the third revision, to discuss methodological concerns; the impact of this on the final guideline will not be known until the guideline is published in 2020.

Recent critiques of guideline development processes outside of the UK have argued that there has been an excess of professional

and commercial conflicts of interest. From a North American perspective, for example, ‘Hundreds and thousands of designated guideline coauthors share in the society-wide power game across a large portfolio of guidelines and statements that improve, fine tune, or manipulate disease definition and management... This creates a massive, clan-like, group self-citation network’.<sup>16</sup> It has been suggested that ‘clinical practice guidelines should be multidisciplinary in composition, independent of the governing bodies of medical specialty societies and strive to reduce fee-for-service conflicts of interest’.<sup>17</sup> NICE guidelines should in theory be less susceptible to these afflictions, but may have inadvertently become closed to methodological disputation with the same consequences where, for example, methodological choices such as prioritising short-term outcomes over long-term ones shine a better light on some treatments compared with others. A counterbalance to these conflicts of interest could be to strengthen citizen participation throughout the whole guideline development process<sup>18</sup> and to improve engagement with the full range of non-commercial stakeholders much earlier on in the process.

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