Commentary

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National Institute for Health and Care Excellence, social values and healthcare priority setting

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On 1 April 2019, the National Institute for Health and Care Excellence will be 20 years old. This is an anniversary worth noting, if for no other reason than how remarkable it is for a National Health Service quango (quasi-autonomous non-governmental organisation) to be still standing two decades after its inception. There are more reasons for marking and celebrating the National Institute for Health and Care Excellence's 20-year run. In the intervening years, the Institute has done much to advance the health of the UK population. It has achieved an international reputation for robust and fair healthcare prioritisation that is widely viewed as setting the global standard. The National Institute for Health and Care Excellence built this reputation not only through the rigorous development and application of scientific methods to guide its work but also through its efforts to articulate the underpinning social and ethical values that provide its decisions with robust justification. The National Institute for Health and Care Excellence's reputation also rests on its commitment to transparency, accountability and inclusiveness in facilitating public and patient input in its deliberations.

From the start, the National Institute for Health and Care Excellence developed a distinctive approach to its work. The Institute took a robust view on the need to provide evidence for the value of healthcare interventions. In a publicly funded but cash-limited system, citizens (and politicians) needed to be assured that the National Health Service would only fund interventions that provided good value for money. Yet, the National Institute for Health and Care Excellence went beyond these generalities to specify how value for money would be assessed. The National Institute for Health and Care Excellence considered whether the opportunity costs of investing in new interventions could be justified by the health

gains they could offer. A threshold was set – a range of £20,000 to £30,000 per additional quality-adjusted life-year – above which a new intervention would not normally be considered a 'good buy' for the National Health Service and rejected because its adoption would likely displace more health than it offered. As a way of publicly justifying its decision-making processes, the National Institute for Health and Care Excellence developed a statement of what it termed its 'Social Value Judgements' in 2005.[1] This document was updated in 2008, in response to the National Institute for Health and Care Excellence acquiring responsibilities for public health. Both editions focused on value for money as a foundational consideration for ensuring fairness to National Health Service patients in the context of limited resources. As a testimony to Social Value Judgements' importance, the document was cited in the first judicial review of a National Institute for Health and Care Excellence decision:

> The key principle underlying NICE's approach to appraisals is that the NHS's limited resources should be targeted on those treatments which provide best value for money. The principle is to be found at paragraph 4.1 of NICE's ''Social Value Judgments – principles for the development of NICE Guidelines''. (8 December 2005)[2]

Although the Social Value Judgements clearly conveyed the National Institute for Health and Care Excellence's commitment to securing value for money, they also recognised the critical importance of other social and ethical values. Reducing health inequalities, preventing discrimination and addressing disabled people's needs figured prominently in both Social Value Judgement documents. So, when the National Institute for Health and Care Excellence announced in November 2018 that it was updating Social Value Judgements, there was considerable interest in whether any changes would ensue – perhaps reflecting the increasing personalisation of medicine or how the National Institute for Health and Care Excellence was adapting to the addition of social care to its remit, within a global environment of healthcare austerity, scepticism of expertise and, of course, Brexit (the UK referendum decision to leave the European Union).[3]

Against this backdrop, the current consultation document, '*The principles that guide the development of NICE guidance and standards*' is puzzling. This short document is not just a revision of principles but implies a wholly different approach to the application of the social and ethical values thought to be relevant to the National Institute for Health and Care Excellence's work. It is pitched entirely on the procedural principles that govern how the National Institute for Health and Care Excellence works. While important, these are no substitute for the underlying substantive social and ethical values that the National Institute for Health and Care Excellence is committed to help secure. Table 1 highlights the key values of the existing and proposed versions of Social Value Judgements. The absence of any specific commitments or reference to substantive social or ethical values in the proposed version is remarkable.

Both the 2005 and 2008 versions of Social Value Judgements begin with a discussion of the substantive bioethical and procedural operating principles which govern the National Institute for Health and Care Excellence decision-making. This is absent in the proposed revision. Substantive values present in the earlier versions – notably fairness, equality and respect for autonomy – have now dropped out altogether.

The National Institute for Health and Care Excellence's rationale for this dramatic change is that all the values relevant to the National Institute for Health and Care Excellence are available in other documents. These documents include the National Institute for Health and Care Excellence Charter, its process and methods manuals, and legal and establishment materials – in total, many hundreds of pages whose content is, for the most part, highly technical. The National Institute for Health and Care Excellence's social and ethical values may be implicit in these documents, but they are by no means explicit, and they certainly require interpretation. The National Institute for Health and Care Excellence also claims, questionably, that its values are '*after almost 2 decades, well understood and accepted*'.[3]

This change raises two questions. First, what is lost when substantive ethical and social values, like those endorsed in both prior Social Value Judgements, are no longer explicitly put forward as guiding principles for the National Institute for Health and Care Excellence? Second, what is the impetus for and objective of this dramatic change – could it be heralding a shift in the way the National Institute for Health and Care Excellence thinks or works?

Considering the first question, the main casualties of this new approach are likely to be accountability, transparency, consistency, and public, political and professional understanding of the reasons for the National Institute for Health and Care Excellence's decisions. The move away from substantive ethical values towards procedural principles enables the detail of decision-making procedures and the content of recommendations to remain almost entirely unspecified. Patients who are being denied treatment on the basis of the National Institute for Health and

Table 1. Comparison of social values in 3 editions of principles underpinning NICE Guidance.

2005 Social Value Judgements document	2008 Social Value Judgements document	Proposed 2019 Social Value Judgements (closest parallel)
Principles of bioethics: Respect for autonomy Non-maleficence Beneficence Distributive justice (understood as procedural justice: publicity; relevance; challenge and revision; regulation) Also discussed is the need for 'broad accountability for reasonableness' in the National Health Service because it is constructed on the principle of social solidarity – UK citizens are the 'ultimate providers' and therefore must be engaged in the broad principles by which National Health Service priorities are set	*Principles of bioethics*: Respect for autonomy Non-maleficence Beneficence Distributive justice (understood as procedural justice/accountability for reasonableness: publicity; relevance; challenge and revision; regulation). *N.B. The consultation version of this doc was more explicit in highlighting the importance of distributive justice in addressing fairness issues owing to tensions between bioethics principles*	
Applying principles through process: Legal requirements underpinning National Institute for Health and Care Excellence guidance Procedural principles: Methodological robustness Inclusiveness Transparency Independence Appeals Review Implementation 1. The fundamental principles that underpin the processes by which National Institute for Health and Care Excellence guidance is developed should be maintained for current, and applied to future, forms of guidance	*Fundamental operating principles*: Respect for legal obligations and promoting equality, eliminating unlawful discrimination and actively considering the implications of its guidance for human rights Procedural principles: Scientific rigour Inclusiveness Transparency Independence Challenge Review Support for implementation Timeliness	
		1. Prepare guidance and standards on topics that reflect national priorities for the population's health and care
Cost-effectiveness and setting priorities: 2. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations 3. National Institute for Health and Care Excellence guidance should not support the use of interventions for which evidence of clinical effectiveness is either absent or too weak for reasonable conclusions to be reached 4. In the economic evaluation of particular interventions, cost–utility analysis is necessary but should not be the sole basis for decisions on cost-effectiveness	*Evidence-based decision-making*: 1. The National Institute for Health and Care Excellence should not recommend an intervention if there is no evidence, or not enough evidence, on which to make a decision 2. Those developing guidelines must take account of the relative costs and benefits of interventions 3. Decisions about whether to recommend interventions should not be based on evidence of their relative costs and benefits alone 4. The National Institute for Health and Care Excellence usually expresses cost-	2. Use evidence that is relevant, reliable and robust 3. Set out the frameworks for interpreting the evidence in our process and methods manuals, and review them regularly 4. Use independent advisory committees to develop recommendations 5. Take into account the advice and experience of people using the services, health and social care professionals,

(continued)

Table 1. Continued.

2005 Social Value Judgements document	2008 Social Value Judgements document	Proposed 2019 Social Value Judgements (closest parallel)
5. National Institute for Health and Care Excellence guidance should explain, explicitly, reasons for recommending – as cost-effective – those interventions with an incremental cost-effectiveness ratio (ICER) in excess of £20,000 to £30,000 per quality-adjusted life-year 11. Although respect for autonomy, and individual choice, are important for the National Health Service and its users, they should not have the consequence of promoting the use of interventions that are not clinically and/or cost effective	effectiveness in terms of the incremental cost-effectiveness ratio 5. Although the National Institute for Health and Care Excellence accepts individuals who will expect to receive treatment to which their condition will respond, this should not impose a requirement on the National Institute for Health and Care Excellence to recommend non-effective/cost-effective interventions Orphan drugs are treated the same as others The rule of rescue is rejected	commissioners and providers 6. Base our recommendations on an assessment of population benefits and value for money
Responding to comments and criticism: 12. It is incumbent on the Institute and its advisory bodies to respond appropriately to the comments of stakeholders and consultees and, where necessary, to amend the guidance. The board is aware, however, that there may be occasions when attempts are made (directly or indirectly) to influence the decisions of its advisory bodies that are not in the broad public interest. The board requires the Institute, and members of its advisory bodies, to resist such pressures	*Responding to comments and criticism*: 6. The National Institute for Health and Care Excellence should consider and respond to comments it receives about its draft guidance	7. Give people interested in the topic area the opportunity to comment on and influence our recommendations
Social Value Judgements – service users: 6. Only recommend the use of a therapeutic or preventive measure for a particular age group when there is clear evidence of differences in the clinical effectiveness of the measure in different age groups 7. There is no case for the National Institute for Health and Care Excellence to distinguish between individuals on the basis of gender or sexual orientation unless these are indicators for the benefits or risks of interventions 8. No priority should be given based on individuals' income, social class or position in life, and individuals' social roles, at different ages, should not influence considerations of cost-effectiveness. Nevertheless, in developing its approach to public health guidance, the National Institute for Health and Care Excellence wishes its advisory bodies to promote preventative measures likely to reduce those health inequalities that are associated with socioeconomic status 9. Only recommend the use of an intervention for a particular racial (ethnic) group if there is clear evidence of differences between racial (ethnic) groups in the clinical effectiveness of the intervention	*Avoiding discrimination and promoting equality*: Only recommend an intervention for a particular racial (ethnic) group when there is clear evidence of differences in clinical effectiveness Take special care of the needs of disabled people In general, patients should not be denied National Health Service treatment simply because of age. But where certain conditions apply, age may be taken into account Avoid distinguishing between individuals on basis of gender or sexual orientation, unless there are indicators for benefits or risks Stigma may be taken into account when relief of stigma affects quality-of-life considerations Self-induced condition is not relevant to recommendation Recommendations should be independent of income, social class or position in life 7. Recommend an intervention is restricted when clear evidence of effectiveness or other reasons related to fairness in society as a whole	

(continued)

Table 1. Continued.

2005 Social Value Judgements document	2008 Social Value Judgements document	Proposed 2019 Social Value Judgements (closest parallel)
10. Avoid denying care to patients with conditions that are, or may be, self-inflicted (in part or in whole). If, however, self-inflicted cause(s) of the condition influence the clinical or cost effectiveness of the use of an intervention, it may be appropriate to take this into account 13. Priority for patients with conditions associated with social stigma should only be considered if the additional psychological burdens have not been adequately taken into account in the cost–utility analyses		
	Public health: List of considerations to be taken into account when recommending mandatory public health interventions Accept the Nuffield Council for Bioethics stewardship model	
	Reducing health inequalities: 8. When choosing topics, actively consider reducing health inequalities	
	Following the principles: Work should follow the principles of document, which fulfil requirements of A4R Responsibility to monitor	8. Lead work with partners to encourage and support adoption of recommendations 9. Assess the need to update publications in line with new evidence 10. Propose new research questions and data collection to resolve uncertainties in evidence

Care Excellence's decisions will particularly struggle to make sense of their situation, as will clinicians who need to explain such decisions to them. Equally, the National Institute for Health and Care Excellence's decisions are left open to a wide range of professional, financial, political and other interests without providing a basis for scrutinising them. For these reasons, the move towards procedural principles sends a worrying signal to other countries who are establishing priority-setting processes for Universal Health Coverage. Universal Health Coverage is about the values and principles that countries could embrace in expanding health benefits for their populations. With the proposed Social Value Judgements, the National Institute for Health and Care Excellence risks losing its status as a leading example from which others might learn how to combine procedural and substantive values in decision-making.

While goals such as reducing health inequalities are embedded in National Health Service legislation, to be meaningful and actually addressed, they must be enacted in the day-to-day functioning of the National Institute for Health and Care Excellence and other health and care organisations. Furthermore, although the historical divide between health and social care is becoming more blurred, this should not lead to an assumption that challenges in both areas are similar. Rather, analysis of the challenges and opportunities in the two areas working in a more integrated fashion is required. The National Institute for Health and Care Excellence has been responsible for developing social care guidance since 2013 but, according to the proposed Social Value

Judgements, this does not seem to have prompted reconsideration of the way it might function in the future, even though a National Institute for Health and Care Excellence Citizens Council discussion in 2013 suggested there could be some differences, in emphasis at least, in the areas of dignity and respect for autonomy.[4] Applying a consistent set of principles to both sectors together with clearly identified research priorities for the National Institute for Health Research (NIHR) would enhance both the way the National Institute for Health and Care Excellence approaches these interrelated decisions and the availability of empirical data, especially relating to outcome measurement, valuation, costing and inequity reduction.

Other flagships of the National Institute for Health and Care Excellence's methods, for example how 'evidence' is defined and assessed, are also given little attention. While its invocation of the use of 'relevant, reliable and robust evidence' seems uncontroversial, it says nothing about how the National Institute for Health and Care Excellence will approach the contestable nature of the interpretation of these attributes. Simply signposting interested parties to the technical and process manuals might be considered efficient, but it is analogous to inviting people to read the New Testament in order to identify key Christian values.

With regard to the second question – what is the impetus for and objective of this dramatic change in guiding principles for the National Institute for Health and Care Excellence? – the Institute is no longer the dominant provider of National Health Service guidance – National Health Service England is increasingly issuing clinical guidance either directly or in collaboration with the National Institute for Health and Care Excellence, for example, in the case of the Cancer Drugs Fund.[5] Public health guidance is now frequently developed by Public Health England. Within this crowded space, there are hints that the National Institute for Health and Care Excellence's methodology is changing to accommodate broader goals.[6] The previous emphasis on cost-effectiveness as a social and ethical value and the use of an explicit cost-effectiveness threshold are watered down to the somewhat inexact '*assessment of population benefits and value for money*' (Principle 6 in the new document). This vagueness may be mere drafting for a general audience or it could represent a drift towards greater managerial discretion and control. Specifically, this could reflect a weakening of the application of the threshold – either upwards to the benefit of industry or downwards for the sake of expenditure control. Both have consequences for the fair distribution of people's health.[7]

So what is the way forward? The National Institute for Health and Care Excellence has a responsibility not only to ensure that its social and ethical values are explicit and aligned with the goals of the National Health Service, public health and social care,[8,9] but how they are made a day-to-day reality. This new document does little to achieve this: it would be better to withdraw it and start work on a thorough revision of Social Value Judgements. Alternatively, the National Institute for Health and Care Excellence published a Charter in 2017[10] that has a short section on social and ethical values. This could be expanded.

As a group of observers and admirers of the National Institute for Health and Care Excellence, we are disappointed that the proposed Social Value Judgements document departs from many of the values that made the National Institute for Health and Care Excellence such an innovative and widely admired organisation. The National Institute for Health and Care Excellence and the National Health Service are currently under immense pressure, but now is not the time for retreat from substantive values. This is the time for the National Institute for Health and Care Excellence to reaffirm these values and seize again its global leadership role as an institution that brings accountability, transparency and legitimacy to decisions that are among the most ethically and politically challenging in any society.

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