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# Conflicting perspectives during guidelines development are an important source of implementation failure

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## ABSTRACT

In recent years many countries have created national bodies that provide evidence-based guidance and policy relating to the commissioning and provision of healthcare services. However, such guidance often fails to be consistently implemented. The differing perspectives from which guidance is developed is suggested as a significant contributor to these failures. A societal perspective is, necessarily, taken by policy makers, while patients and their healthcare professionals are primarily concerned with an individual perspective. This is particularly likely to impair implementation where national policy objectives, such as cost effectiveness, equity, or the promotion of innovation, are embodied in the guidance, while patients and healthcare professionals may consider it appropriate to over-ride these, based upon individual circumstances and preferences. This paper examines these conflicts with reference to guidance issued by the National Institute of Health and Care Excellence in England. Conflicts are identified between the objectives, values, and preferences of those who develop and those who implement such guidance, with consequent difficulties in providing helpful personalised recommendations. The implications of this for the development and implementation of guidance are discussed and recommendations are made regarding the ways in which such guidance is framed and disseminated.

## 1. Introduction

Recent years have seen rapid increases in the volume and accessibility of healthcare research outputs and rapid development of methods for evidence synthesis [1]. Evidence-based healthcare was initially seen as evaluating evidence [2] to inform individual decision-making [3]. Moving from individual decision making, to policy recommendations, requires value judgements. Grading systems for recommendations differentiate between the strength of evidence and that of recommendations [4,5], including judgements about outcomes such as resource implications [6].

There is mounting evidence of failed implementation of many guidelines, such as those produced by the National Institute for Health and Care Excellence (NICE) in England [7–12] and similar bodies in other countries [13–19]. This paper considers the conflicting perspectives from which guidance may be developed as a reason for such failure, based upon experience of NICE guidance, and discusses the implications for the preparation, dissemination, and implementation of evidence-based guidance.

## 2. Differing perspectives

The perspective from which guidelines are developed may have significant implications for the objectives of the guidance, the values

inherent in the guidance, and the ways in which guidelines may be personalised to suit individual circumstances.

### 2.1. *Conflicting objectives*

In publicly funded or insurance-based healthcare systems, patients and healthcare professionals seek the most effective healthcare, irrespective of cost or other societal objectives. Those developing guidance must consider societal objectives, such value-for-money and addressing health inequalities. Guidance from a single agency may differ in objectives. NICE interventional procedures guidance focusses on safety and efficacy [20], technology appraisals mainly target cost effectiveness [21], highly specialised technology (HST) guidance promotes innovation for rare conditions [22], while clinical guidelines aim to support shared decision making [23], although the criteria for recommendations include cost effectiveness [24].

Such conflicting objectives may impede implementation. NICE recommended endovenous treatment for symptomatic varicose veins as both clinically effective and cost effective [25]. However, access varies [11] and local guidance may prioritise financial objectives and directly contradict national guidance [26].

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## 2.2. Conflicting values and preferences

With multiple, potentially conflicting objectives, trade-offs are required that consider their relative importance. The £20,000 per quality adjusted life year (QALY) threshold used by NICE [27] makes explicit the trade-off between cost and effectiveness. For objectives, such as equity and innovation, no explicit thresholds are set, although these may be implicit in decisions. In HST, NICE sets a £100,000 per QALY threshold and weights QALY's up to three times under certain circumstances. For example, for Givosivan [28] NICE estimated 18.6 QALY benefit at 1.8 weighting. Commercial details are confidential, but assuming discounts reduced the price to £100,000 per QALY, each patient treated would cost about £3 M above the standard threshold, equivalent to 150 QALY's foregone elsewhere in the NHS.

Healthcare outcomes and processes have many attributes, measures of quality-of-life are multi-dimensional, and recommendations are often binary choices that weigh up many potential risks and benefits. The QALY combines health outcomes in a single metric representing both the quality and length of life. Different methods to measure utility (single quality-of-life weightings) produce conflicting results [29]. Individuals vary in the importance they attach to aspects such as mobility, pain, and social functioning [30], and many attributes are not captured. Patients value less invasive processes of care [31], would forgo QALY benefits for local treatment [32], and have time preferences that may differ from standard discount rates [33].

## 2.3. Lack of personalisation

Much research assumes consistent treatment effects, and may be planned to maximise demonstrated benefits [34] by excluding those such as older people, who may respond differently [35]. Individuals' risks and benefits may differ between treatment modalities, such as comparing more or less invasive procedures, which must balance early complications and mortality against longer-term benefits.

For example, comparing open surgery, endovascular aneurysm repair (EVAR), or watchful waiting for abdominal aortic aneurysms, NICE guidelines [36] suggested that to minimise harm and save resources "practice needs to be rebalanced towards open surgical repair...". This guidance was controversial [37] and does not appear to have influenced practice, with continuing high rates of EVAR and marked geographical variation in practice [38]. This failure may relate to the individual anatomical, physiological, and demographic features, and personal preferences on the part of the clinician and/or the patient, that heavily influence treatment decisions [39].

When cost effectiveness analysis takes a long time-horizon, treatments with lasting benefits appear less cost effective in those with limited life-expectancy. This was partially recognised in NICE policies that prioritise end-of-life cancer treatments [40] and more recent NICE methods take account of 'proportional QALY shortfall' in modifying acceptable thresholds [41].

Where costly treatments are more cost effective in specific subgroups, guidance identifying restricted indications may be appropriate. However, this creates challenges, both in terms of equity and implementation. A review suggests that complexity and inadequate monitoring of restrictive NICE recommendations may impede implementation of some guidance [12]. For example, research showed that only 12% of patients had documented evidence of meeting criteria relating to weight loss, BMI, and age, set by NICE to determine eligibility for the use of Orlistat [12].

## 3. Discussion

In developing guidance, national bodies, such as NICE, take account of societal objectives, such as providing value-for-money and addressing health inequalities. Potentially conflicting societal and political objectives require value judgements and trade-offs. Although one can argue

**Table 1**

Differences between the requirements for guidance that takes a societal or an individual perspective.

Perspective	Societal	Individual
<b>Guidance objectives</b>	Cost effectiveness / value for money Equity Innovation	Clinical effectiveness Inform shared decision-making
<b>Target audiences</b>	Purchasers, commissioners, insurers, service providers, professional bodies	Patients and healthcare professionals
<b>Evidence requirements</b>	Evidence synthesis • Randomised controlled trials • Systematic reviews • Economic modelling Resource implications Budgetary impact	Evidence synthesis • Risk models • Personalised decision aids Local facilities and outcomes Information on treatment processes
<b>Sources of values and preferences</b>	Utility tariffs Population surveys Multi-disciplinary committees Public consultation	Individual patients and their healthcare professionals
<b>Personalisation</b>	Differential guidance for identifiable subgroups taking account of: • complexity • potential for discrimination • practicality of implementation	Individualised risks and benefits tailored to specific patient characteristics and the availability and outcomes of local services
<b>Recommendation requirements</b>	Clear, easy to implement and to monitor and/or enforce	Detailed information on options and potential consequences to inform shared decision making
<b>Levers for implementation</b>	Commissioning arrangements Referral mechanisms Financial incentives Professional standards	Dissemination and education Decision support tools

over the source, balance and legitimacy of such values [42] a societal perspective is appropriate for such guidance.

Patient choice and autonomy frequently compete with this societal perspective. NICE claims, particularly in respect to clinical guidelines, that these support shared decision making [23]. This creates significant conflict, as the societal perspective may be at odds with the individual perspective in many respects, including evidence requirements, sources of values, target audience and levers for implementation (Table 1).

Ultimately, the balance between numerous desirable societal and individual outcomes is not a question of evidence, to which there is a calculable answer, but requires moral and ethical value-judgements [42]. To support shared decision making, information needs to be tailored to individual situations, local circumstances, and personal preferences, quantifying the risks and benefits in specific circumstances, and describing the processes involved. This may benefit from decision support tools reflecting individual characteristics and personal preferences [43]. Guidelines that specifically take a patient-centred approach [44] and seek to incorporate patient preferences [45], may help in this process. However, the perception that economic considerations are the rationale for recommendations may result in distrust of the guidance or decision aids [46]. Furthermore, decision making in the presence of multiple competing risks and benefits is a complex process [47,48], and respecting the autonomy of patients and healthcare professionals may, in itself, be seen as an important objective [49].

Guidance based upon value-for-money must be relatively simple to implement and enforce and may be difficult to limit to subgroups, based upon cost effectiveness. Guidance based upon societal objectives must be generalisable and can only achieve its objectives if it can take precedence over personal choices, where these are in conflict. Those who

**Table 2**  
Recommendations for issues to be considered in developing guidance.

Recommendation	Rationale
Guidance should state the objective and the perspective from which it has been developed (societal or individual).	<i>This has significant implications for the methods of implementation and monitoring.</i>
Recommendations with different objectives and/or perspective should be separately documented.	<i>These are likely to be aimed at different target audiences and a lack of clarity leads to confusion or distrust which may prevent successful implementation.</i>
Recommendations with societal objectives, such as equity and value-for-money, should be implemented through commissioning or purchasing arrangements, professional standards, or regulatory mechanisms.	<i>Allowing freedom of choice for individual patients or their healthcare professionals is likely to result in decisions based upon individual rather than societal objectives.</i>
Healthcare professionals should not be placed in the position of enforcing recommendations that are based upon societal objectives, where these conflict with clinical effectiveness, patient choice, or individual preferences.	<i>A conflict of interest between the duty of a professional as patient advocate, and their role in meeting wider societal objectives, undermines their position as a trusted advisor.</i>
Recommendations that are limited to a subgroup of patients, need clear mechanisms to identify and monitor appropriate implementation.	<i>Without a clear mechanism for restricting use to eligible patient it is likely that implementation will be inconsistent and potentially inequitable.</i>
Where additional data collection is required to monitor adherence to guidance, this should be fit for purpose and collect sufficient data to identify all potentially eligible patients.	<i>Many current registries are procedure or treatment-based, and do not consider those who may have been eligible for treatment but have been inappropriately excluded, for example, due to failure of timely referral or defensive practice.</i>
Where guidance aims at supporting individuals in shared decision making, recommendations should explore factors that may be relevant to personalisation, such as individual risk factors, preferences, and disaggregated outcomes, using risk models and decision aids, as appropriate.	<i>Blanket recommendations, based upon average risks and benefits are likely to be of little value in informing shared decision making in complex situations.</i>
Where recommendations have a significant cost implication, these should be linked to potential funding mechanisms.	<i>Implementation may otherwise fail due to inability to free up the required funding.</i>

are most empowered, or have the greatest resources, may be best able to circumvent recommendations that conflict with their personal interests, thus increasing rather than reducing health inequalities [50].

The conflicting perspectives explored in this paper are not the only reasons for the failure of guideline implementation, and theoretical frameworks have been suggested to identify the underlying barriers to implementation and reasons for variation in practice [47,48]. Other influences may include perverse incentives, which may result from financial incentives [51], private practice [52], academic and commercial activities, such as seeding studies [53] and payments to clinicians for educational or research activities [54].

Finding resources for cost-effective service developments may require disinvestment decisions. NICE “do not do” recommendations, aimed at saving resources [55] are not related to specific investment decisions and, without additional measures to implement them, they may make little difference [56]. Another option is ringfenced funding for service developments, a precedent set by NICE with the cancer drugs fund and recently implemented innovative medicines fund, which has a ringfenced £680 M budget for new medicines [57].

#### 4. Policy recommendations

The potential conflict between societal and individual objectives and values has several implications for the way in which guidance is developed, presented, and implemented (Table 2). Guidance that confounds different perspectives with recommendations based upon both societal and individual perspectives, creates difficulties in

implementation. Transparent documentation of the perspective and objectives may clarify the nature and format of evidence requirements, and appropriate methods to promote adherence.

This paper focusses on the experience of guidance issued by NICE in England. However, all healthcare systems face the same tension between the escalating costs of healthcare, and the ever-increasing demands of the population for new and effective interventions. The vast, rapidly expanding, and globally accessible range of healthcare publications and media require evaluation and aggregation, to support professionals and patients in making complex healthcare decisions. Many stakeholders produce healthcare guidance and policy, claiming to follow the best evidence. However, with differing perspectives they are likely to make contradictory recommendations. Guidelines based upon individual or societal perspectives serve different purposes. The former may support shared decisions, patient autonomy, and should be adaptable to local circumstances and individual preferences. The latter must set the parameters and limitations within which such decisions are made.

The development of guidance is time consuming and costly and provides little benefit if it fails to be implemented. There is clearly value in gathering and evaluating all the clinical and economic evidence that can help to support healthcare decisions. However, it is important to acknowledge that the move from evidence synthesis, to developing guidance based upon this evidence, is not an objective scientific process, but requires value judgements that will be dependent upon the perspective that is taken. Unless those who commission, develop, publish, and implement such guidance consider the implications of this, it is likely that the potential of such guidance will fail to be realised.

#### Declaration of Competing Interest

Both authors declare funding from the NIHR Programme Development Grants Programme (NIHR202042). JM has previously chaired a National Institute of Health and Care Excellence (NICE) Guideline Development Group and been vice chair of the NICE Appraisals Committee.

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