THE ENGLISH NATIONAL HEALTH SERVICE AND THE 'TRANSPARENCY TURN' IN REGULATION OF HEALTHCARE RATIONING

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Introduction

In October 2010, NHS Warwickshire, a Primary Care Trust (PCT) which is responsible for commissioning health services for a local population of more than half a million people in the English Midlands, issued a press release in which it specified those clinical procedures which were to be prioritised over the forthcoming winter period, divided into three categories.1 Those in the ‘Fast’ category, which comprised cancer-related referrals, fracture-related referrals, urgent trauma cases and other procedures where a delay would cause deterioration in the patient’s long-term health, were to be undertaken as normal, with a shorter expected wait time in many cases. Those in the ‘Slow’ category were to be deferred until April 2011 except where, following a process of review, it was concluded that treatment should proceed immediately for clinical reasons. Procedures listed in this category included routine elective hip, knee and shoulder surgery, IVF treatment (unless already commenced), referrals for back pain management, oral surgery and orthodontic procedures. Additionally, a third ‘Stop’ category designated a number of procedures which would no longer be funded at all by NHS Warwickshire, save for in exceptional circumstances. These included acupuncture, correction of male pattern baldness, hair transplantation, oral vaccines for seasonal rhinitis, penile implants and tattoo removal.

The media took a predictable interest in this policy,2 reporting that similar measures were being adopted elsewhere in the face both of anticipated annual seasonal pressures and the requirement to make one-off efficiency savings of £15-£20 billion between 2011 and 2014.3 However, the position taken by NHS Warwickshire is arguably not especially newsworthy in the context of the English National Health Service (NHS). Explicit rationing by delay, in the form of the waiting list, has a venerable history, although the pre-publication of specified procedures which are subject to deferral for at least six months is a somewhat unusual step. Furthermore, since at least the early 1990s, when the purchaser-provider split emerged as a consequence of the creation of an ‘internal market’ in the NHS, explicit limitation of the ‘menu’ of treatments and procedures which are locally available has been a characteristic of the Service.4 However, the most notable and controversial form of explicit rationing by denial in the NHS in recent years has occurred as a consequence of local implementation of the health technology appraisal guidance produced at national level by the National Institute for Health and Clinical Excellence (NICE), which is discussed further below.

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As a manifestation of explicit rationing, the Warwickshire statement is therefore part of a wider historical pattern of increased visibility of allocative decision-making in the NHS, albeit that relatively high levels of expenditure on the Service during the Blair and Brown governments tended to obscure the need to make hard choices in healthcare, with the exception of those relating to expensive new health technologies. Of course, it is important not to overstate the case here. Klein has helpfully reminded us that certain forms of rationing are less overt than others.\(^5\) In particular, rationing by dilution, which might consist of a reduction in the number and/or quality of nursing staff, the number of diagnostic tests ordered, or the amount of time spent by doctors with patients, is highly prevalent but largely invisible, except in instances where major systemic failure eventuates. Furthermore, given a tendency to internalise resource constraints, it is difficult to discern the point at which a physician’s judgment as to the inefficacy of a particular treatment for a given patient shades into a financially-driven decision that finite local funds might be better expended in other ways. Nonetheless, there has been a general trend in the English NHS, as has been the case in other health systems worldwide, towards explicit rationing, especially in the context of decisions on access and availability above and beyond the ‘micro’ level of the physician-patient relationship.

This article seeks to examine how far such greater visibility in this socially important and morally controversial realm of public policy is paralleled by obligations of transparency, whether in hard or soft law form, which are imposed upon those charged with making allocative decisions in healthcare. The word ‘paralleled’ is deliberately chosen to obviate the need to engage with the difficult issue of the extent to which behavioural change (whether at an individual or an organisational level) can be shaped by law in either its hard or soft variant. I have argued elsewhere that law (and, especially, adjudication by courts) possesses the capacity to act as a facilitator of decision-making which is procedurally just in the healthcare context, albeit that this is not a role which is usually assigned to it by those working in, and writing upon, this field.\(^6\) Here, my goal is the more modest one of delineating the steps which have been taken by courts, key allocative decision-makers (namely, NICE) and latterly, government. These steps serve together to contribute to the creation of an environment in which transparency in NHS rationing is now more generally the norm than it was fifteen years ago. However, as a precursor to this discussion, I shall attempt briefly to analyse the value of transparency in administrative decision-making with particular reference to that which entails the allocation of scarce healthcare resources.

I. The Nature and Value of Transparency

As Fisher has observed, transparency is a concept that is in vogue in a wide variety of spheres of contemporary public life.\(^7\) It is, however, a somewhat elusive value to comprehend, although a useful working definition is that it “entails ensuring that conduct is as open and accessible as possible, allowing comprehension and involvement of interested parties”.\(^8\) In English public law, which has traditionally operated in the shadow of a highly secretive state, the value has gained recent impetus by way of enactment of the Freedom of

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Information Act 2000, which confers a general right of access to information held by public authorities (albeit subject to a number of exemptions). The legislation does not, however, specify why this right has been conferred. This is perhaps unsurprising, as transparency may serve a broad variety of normative ends, such as the exposure of mistakes, promotion of public reason, building of trust, enhancement of accountability or facilitation of choice.\(^9\)

However, one distinction between the rationales for transparency which may be drawn from the literature is that between instrumental and non-instrumental goals. From the former perspective, transparency is valuable because it improves decision-making. For example, access to evidence and criteria which inform policy choices facilitates participation, allowing others to comment upon and challenge the proposal and the information and assumptions which underpin it, and to introduce new evidence and views which may lead to a better outcome being reached. Additionally, transparency would seem to be a prerequisite of democratic accountability, a principle which is valuable not only because it exposes mistakes to public scrutiny, but also because it stimulates more attentive and rigorous decision-making:

The central prerequisite for genuine accountability is clearly openness, a transparency which needs to embrace all decision-making from policy setting, through implementation to monitoring. A commitment to openness is of prime importance in order to counteract any tendency to control or distort information which might in turn prevent issues being the subject of proper debate and reduce capacity for reasoned choices to be made about priorities and resource distribution. [...] The same commitment also implies an obligation on the part of decision-makers to give explanations and justifications for their activities. The articulation of reasons for action or inaction is beneficial to accountability in several ways. It not only assists the development of standards and principles, but encourages more care and deliberation on the purposes of action by decision-makers and also provides a basis for criticism and facilitates challenge to decisions which appear arbitrary.\(^10\)

On a non-instrumental reading, transparency (and, especially, the provision of reasons for decisions) is important because of its connection to human dignity: the individual is treated as an autonomous subject rather than the undifferentiated object of administrative decision-making. This is especially significant where the decision in question significantly impacts upon the individual’s interests. Transparency also enhances trust. If procedures and decisions, and the evidence and other decisional criteria for them, are made publicly accessible, both affected individuals and the general public can better understand why a certain choice has been made. They are therefore more likely to accept it, even if they themselves might have chosen differently. In fact, this rationale for transparency exhibits an instrumental dimension, as well as having non-instrumental value. Acceptance of a decision-maker, its decisional processes, and the choices which it makes connects to legitimacy, defined by Habermas as a “political order’s worthiness to be recognised“.\(^11\) As Freedman has noted, legitimacy is fundamental to effective decision-making:

Institutional legitimacy is an indispensable condition for institutional effectiveness. By endowing institutional decisions with an inherent capacity to attract obedience and respect, legitimacy permits an

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institution to achieve its goals without the regular necessity of threatening the use of force and creating renewed episodes of public resentment. [...] substantial, persisting challenges to the legitimacy of governmental institutions must be regarded with concern, for such challenges threaten to impair the capacity of government to meet its administrative responsibilities effectively.12

The legitimacy rationale for transparency has been viewed as especially pertinent in the context of healthcare rationing. Most notably, the work of Norman Daniels (together with James Sabin) has sought to find a means of addressing the ‘legitimacy problem’ – defined as “under what conditions do decision-makers have the moral authority to set the limits they impose?”13 – through adherence to a model of procedural justice, ‘accountability for reasonableness’. Transparency is an important component of this model: indeed, Daniels has characterised it as “requiring transparency for all aspects of the [decision-making] process, including the rationales for the priorities adopted”.14 It takes the form of the ‘publicity’ condition, which requires that “decisions regarding both direct and indirect limits to meeting health needs and their rationales must be publicly accessible”.15 It is contended that this form of openness is important because it enhances consistency, obliges a decision-maker to become more focused in its deliberations, and facilitates understanding, and thus enhances systemic legitimacy.16 Even more broadly, Daniels argues that:

Not allowing health plan members or citizens to understand how and why limits are being set deprives them of an opportunity to participate in a fundamental form of social governance – the allocation and rationing of services so important for a fundamental human good. Transparency has the potential for enhancing the democratic process by helping our society learn how to allocate health care resources thoughtfully and fairly.17

In sum, as Fisher reminds us,18 powerful arguments exist for giving effect to transparency, especially in the context of the rationing of healthcare. I turn now to examine the means and extent to which recent developments have sought to reinforce observance of the principle in the environment of allocative decision-making in the English NHS.

II. Transparency in Rationing Case Law: Judicial Review of Administrative Action in the English Courts

As the preceding discussion indicates, transparency takes a variety of forms and there may be a number of justifications for its pursuit. However, if we examine the approach to transparency taken by the English courts when called to adjudicate upon a public law challenge to the rationing of access to healthcare, we may detect two broad readings of its meaning and the means

15 Idem, p. 118.
16 For an endorsement of the legitimacy rationale which is not explicitly grounded in the ‘accountability for reasonableness’ framework, see: I. Dhalla & A. Laupacis, ‘Moving from opacity to transparency in pharmaceutical policy’, Canadian Medical Association Journal 2008-178, p. 428.
17 Daniels 2008, supra note 13, p. 123.
18 Fisher 2011, supra note 7, p. 280.
for its realisation. First, there is transparency as to outcomes, in the form of imposition of a requirement to provide reasons for the choices which are made. Secondly, transparency connects to participation in so far as provision of information as to the models or criteria which are deployed in allocative decision-making enables a disappointed claimant to have some input into the process. Interestingly, these approaches tend to differ according to the identity of the litigant who initiates the challenge.

Traditionally, English law imposes no general obligation upon administrative decision-makers to give reasons for the choices which they make. In recent years, however, this principle has been eroded to such a degree that it has been said that “what were once seen as exceptions to a rule may now be becoming examples of the norm, and the cases where reasons are not required may be taking on the appearance of exceptions”. Decisions which entail the allocation of scarce healthcare resources are no exception to this general trend. As with case law in other areas of public administration, it is possible to identify differing judicial rationales for the imposition of an explanatory obligation upon the public agency.

The main 'trigger' for reason-giving in cases in which a disappointed patient challenges a rationing choice is the importance of the interest – the health of the individual – which is at issue in the case. Here, therefore, the English courts engage with a non-instrumental reading of the value of transparency which is connected to notions of human dignity and which may be seen as underpinned by the notion that healthcare possesses a special moral importance. This approach has its origins in the judgment of Laws J in the High Court in R v Cambridge Health Authority, ex parte B albeit that this was subsequently overturned by the Court of Appeal. This case involved a decision not to fund expensive experimental treatment for a ten-year-old child suffering from acute myeloid leukaemia. His Lordship pointed to the impact which the health authority's choice had had upon the child's right to life as protected by the European Convention on Human Rights, which he described as occupying “the most precious place” amongst all human rights. He considered that any violation of such a right necessitated a full explanation of priorities on the part of the authority, which had acted unlawfully in failing to provide this:

Merely to point to the fact that resources are finite tells one nothing about the wisdom, or, what is relevant for my purposes, the legality of a decision to withhold funding in a particular case. [...] Where the question is whether the life of a ten year-old child might be saved, by however slim a chance, the responsible authority must in my judgment do more than toll the bell of tight resources. They must explain the priorities which have led them to decline to fund the treatment. They have not adequately done so here.

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20 Stefan v General Medical Council [2000] HRLR 1, p. 10 (Lord Clyde).
21 On this, see the work of Daniels, especially Just Health Care, Cambridge: Cambridge University Press 1985; further Daniels 2008 supra note 13, Chapter 2.
24 The case was decided prior to the incorporation of the Convention in English domestic law by the Human Rights Act 1998. Nonetheless, the judge held that fundamental rights, "broadly those occupying a central place in the European Convention on Human Rights" should be regarded not merely as moral and political aspirations but rather as part of the substance of English common law: (1995) 25 BMLR 5, p. 12.
A similar stance was adopted by Buxton LJ in *R v North West Lancashire Health Authority, ex parte A, D and G*, a case in which the health authority adopted a policy broadly comparable to that implemented by NHS Warwickshire and outlined in the introduction of this article. It had explicitly allotted low priority for funding for treatment of gender identity dysphoria by way of gender reassignment surgery, in part because it evaluated the procedure as only marginally appropriate for public funding and also because it was unconvinced as to the effectiveness of this form of treatment. The judge stated that:

> [T]he more important the interest of the citizen that the decision affects, the greater will be the degree of consideration that is required of the decision-maker. A decision that, as is the evidence in this case, seriously affects the citizen’s health will require substantial consideration, and be subject to careful scrutiny by the court as to its rationality.  

On this basis, he held that the existence of a strong body of medical evidence in support of the effectiveness of the treatment placed a burden upon the authority to justify its contrary opinion, and in so far as it continued to de-prioritise such surgery relative to other procedures, it should “indicate, at least in broad terms, the reasons for [its] choice.”

A further illustration of the salience of non-instrumental rationales for transparency in healthcare allocation is afforded by *R (on the application of Rogers) v Swindon Primary Care Trust and Secretary of State for Health*, in which (save for situations of exceptionality) the Trust had refused to provide funding for the breast cancer drug Herceptin, which had neither been appraised by NICE nor licensed for use by the European Medicines Agency (EMA). Here, the Court of Appeal endorsed a statement of Sir Thomas Bingham MR in another context that “the more substantial is the interference with human rights, the more the court will require by way of justification before it is satisfied that the decision is reasonable”. Although *Rogers* was not pleaded under the Human Rights Act 1998, the court accepted that the ‘life or death’ nature of the case warranted the subjecting of the PCT’s decision to intensive judicial scrutiny, obliging the provision of a full explanation of the clinical factors which led to the withholding of funding for treatment. A similar view was subsequently taken in *R (on the application of Ross) v West Sussex Primary Care Trust*, although in that instance it was acknowledged that the PCT could not not be criticised for its failure to give reasons.

By contrast, where a decision which has the consequence of limiting access to medical treatments or interventions is challenged by a pharmaceutical company, the judicial rationale for insisting upon transparency in decision-making processes tends to rest upon instrumental bases. In particular, the court is concerned to ensure that the company is provided with sufficient information to enable it to controvert any mistaken assumptions or unlawful actions on the part of the decision-maker, including by way of introduction of conflicting and correcting evidence. One illustration of this is afforded by the litigation concerning the decision, taken at ministerial level, to make Viagra unavailable on the NHS except in specified (and limited) clinical

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circumstances. Although the government’s initial decision had been successfully challenged by the drug manufacturer on the ground that there had been failure to provide a statement of reasons based on objective and verifiable criteria for the decision, which was contrary to Directive 89/105/EEC (the ‘Transparency Directive’), a policy of continued restricted availability was upheld on review. Here, the Court of Appeal determined that the Directive required only a “fairly modest” degree of transparency. Of interest, however, was the court’s explanation of why the Directive obliged information to be provided to the manufacturer. Buxton LJ indicated that measures which restricted availability of products on grounds of public health needed to be open to verification by manufacturers so that they could be satisfied that such measures did not amount to ‘disguised’ quantitative restrictions upon imports which might be unlawful under European Union law.

The notion that transparency is of value because it enables verification and possible disputation of the criteria upon which a decision has been reached is most clearly illustrated by a series of challenges to economic models employed by NICE in appraisal of the cost-effectiveness of new medical technologies. In R (on the application of Eisai Limited) v NICE, the Court of Appeal ruled that failure to disclose a fully executable economic model to the manufacturer amounted to procedural unfairness. In the absence of such disclosure, it was impossible to assess the reliability of the model and to make informed representations on the matter to NICE. Similarly, in R (on the application of Servier Laboratories Limited) v NICE, where the economic model had not been disclosed at all to the manufacturer given the existence of an undertaking of confidentiality, the judge held that the Institute was under a duty (which it had failed properly to discharge) to press for removal of such undertaking so that consultees might “make further submissions or representations in response to that disclosure”. By contrast, in a third case, R (on the application of Bristol-Myers Squibb Pharmaceuticals Limited) v NICE, the challenge to the failure to disclose the model was unsuccessful, but the reasoning deployed by the judge was similar to that in the preceding two cases. Again, the focus was upon the company’s capacity to make informed and effective representations to NICE in response to the latter’s calculations and conclusions on the cost-effectiveness of the treatment, based upon the economic model.

The one exception to the judicial trend to conceptualise transparency in purely instrumental terms in situations where the claimant is a pharmaceutical company is the Court of Appeal decision in the Servier Laboratories case. In this instance, the court referred to the “great importance” of NICE appraisals to the “commercial interests of drug manufacturers”, observing that a negative appraisal, or one which recommended the treatment only for restricted classes of patient, would be likely to lead to modest sales of the product. The court held that NICE’s failure to provide reasons for its rejection of a “piece of evidence which lay at the heart of assessment of a particular drug” rendered its decision unlawful on grounds of procedural impropriety. The rationale for this conclusion was not grounded in the

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32 R (on the application of Pfizer Limited) [2002] EWCA Civ 1566, para. 27 (Buxton LJ).
33 [2008] EWCA Civ 438.
35 That is, those invited by NICE to take part in the technology appraisal process, who are entitled to submit evidence, comment on appraisal documents and appeal the final determination.
37 [2010] EWCA Civ 346, para. 2 (Smith LJ).
inability of the company to challenge NICE’s assessment: rather, it was viewed as simply unfair, the court accepting the company’s argument that a short explanation for rejection of the evidence was “not too much to ask”. This approach therefore more closely resembles the dignitarian rationale for transparency advanced in cases such as *ex parte B*. However, instrumental justifications for transparency can still be detected in this case. In particular, provision of reasons is seen as valuable since this is more likely to ensure that care will be taken in decision-making and fatal flaws thereby avoided. In the absence of such reasons, a court may conclude (as did Smith LJ in this instance) that there must be doubts as to the rationality of the decision which is reached. Here, this was particularly the case as the data which NICE had rejected had been accepted by EMA, and while NICE was not bound by the decision reached by the former, it was expected that “some reason [would be] given for NICE reaching a view different from a body of similar standing”.

Two conclusions might be drawn from this account of the case law. First, it is quite apparent that English courts are willing to impose obligations of transparency upon bodies whose decisions have an impact upon the allocation of healthcare resources. This is a significant change from the position of some two decades ago, typified by the decision in *R v Central Birmingham Health Authority, ex parte Collier*, in which no such requirement was placed upon the authority, notwithstanding the judicial observation that:

> If I were the father of this child, I think that I would want to be given answers about the supply to, and use of, funds by this health authority. No doubt the health authority would welcome the opportunity to deal with such matters so that they could explain what they are doing and what their problems are.

Given that the environment in which rationing takes place is significantly altered from that which existed in the late 1980s – and, in particular, that awareness of the existence, scope, and processes of rationing is much greater as a consequence of a general shift towards explicitness – such a transformation in judicial attitudes is perhaps unsurprising.

Secondly, the precise rationale for requiring transparency varies in accordance with the context. Non-instrumental rationales are most salient in cases where the challenge is initiated by a disappointed patient. The moral rawness of the ‘tragic choices’ inherent in healthcare rationing is seen to necessitate some degree of openness as to the decision reached, out of respect for the individual’s dignity and autonomy. By contrast, where the litigant is a pharmaceutical company, the courts are more concerned to facilitate good decision-making by permitting the company fully to scrutinise and challenge the evidence and criteria which underpin a decision. Save for the *Servier Laboratories* appeal, in which the commercial interests of the manufacturer functioned as a ‘trigger’, the rationale for transparency in these cases does not rest upon a judicial perception of what the litigant deserves. Rather, it is connected to enhancement of the decision-making process by rendering it more efficient, or by expanding the range of information which is available so that a ‘better’ outcome is reached.
III. Transparency in the National Institute for Health and Clinical Excellence (NICE)

NICE has emerged as a major player in the NHS rationing arena since its establishment in April 1999. It undertakes a number of tasks of which, for the purpose of present analysis, the most significant is its technology appraisal function. This entails appraisal of the clinical and cost-effectiveness of (primarily new) health technologies and the issuing of recommendations for use on the NHS in England and Wales. Statutory directions oblige PCTs (and, in Wales, health boards) to provide funding for technologies which NICE recommends for use, normally within three months. The existence of this requirement means that, in effect, NICE determines the scope of coverage of the NHS as regards new technologies, albeit that clinicians retain discretion to depart from the guidance which it issues if they consider it appropriate to do so in the particular circumstances of the patient’s case. If the Institute refuses to recommend a technology or (as is more likely) restricts its recommendation to limited categories of patient, resource-constrained PCTs and health boards will, in practice, either totally deny access to it or will limit availability to those categories which NICE specifies.

It has been claimed that NICE is an exemplar of an institution “set up on the premise that it is transparent [...] and thus transparency is inherent in its modus operandi”.46 This is readily apparent from consideration of some of the key documentation which underpins the Institute’s work. In an annex to the Directions initially issued by the Secretary of State for Health to NICE in August 1999, it was provided that “the Institute will endeavour to conduct its business in an open and transparent manner”.47 Similarly, the Institute’s Guides to its two forms of technology appraisal each commence with a commitment to a “standard, open and transparent process [...] designed to achieve robust guidance for the NHS with appropriate contribution from stakeholders”,48 while its Guide to the Methods of Technology Appraisal notes that “it is essential that the evidence and analysis and their interpretation are of the highest standard and are transparent to scrutiny”.49 To this end, provisional and final decisions and the reasons for them are made publicly available (in formats written both for medical professionals and for those without specialist medical knowledge), most evidence is published, decision-making procedures are publicly accessible, meetings of the Institute’s board are held in public, and there are extensive opportunities for stakeholder involvement at various stages of the appraisal process.

NICE explains its commitment to transparency in its document on Social Value Judgements, which seeks to outline the ethical principles upon which it bases decision-making, particularly that which relates to the allocation of scarce resources. The document explicitly connects the value to procedural justice, and specifically to the ‘accountability for reasonableness’ framework. The Institute claims that transparency (alongside other procedural values, such as inclusiveness, independence, challenge, and review) “give[s] legitimacy to NICE guidance”.50 This somewhat immodest and optimistic claim has received some support from Daniels, who has praised the Institute for its adherence to

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47 Directions to the National Institute for Clinical Excellence (6 August 1999), Annex A, para. 2.
‘accountability for reasonableness’,\(^{51}\) although a degree of scepticism as to NICE’s compliance with the model has been expressed by other commentators, including the present author.

As regards the specific question of the Institute’s success in realising its promise of transparency, differing views may be identified. In the *Eisai* case, the Court of Appeal commended NICE for the “remarkable degree of disclosure and of transparency in the consultation process”,\(^{52}\) although paradoxically this proved to be problematic for the Institute as any small deficiency in this regard created a space for a ruling that it had acted in a procedurally improper manner when set against its own high standards.\(^{53}\) By contrast, the parliamentary Select Committee on Health has been critical of what it perceives as a lack of transparency. In its first inquiry into the work of the Institute, it commented that “NICE should improve the transparency of its processes by striving to make information on how and why its decisions are taken, and on members’ declarations of interests as readily and clearly available to lay stakeholders as possible”.\(^{54}\) Subsequently, in 2007 it cited with approval an opinion given in evidence that:

> [W]hen one says ‘no’ obviously one will be unpopular unless one says clearly why one is saying that. At times I believe that the reason why it says ‘no’ is not clearly stated. It is very easy for those who do not like the ‘no’ to marshal considerable forces in the press and elsewhere to attack that decision and many times the criticism is very unfair. A more clear description of why ‘no’ has been said would be helpful.\(^{55}\)

Arguably, NICE affords a good illustration of Fisher’s point that, whatever strenuous attempts are made to give effect to transparency, these may not be enough in themselves.\(^{56}\) By comparison with the vast majority of administrative agencies, it conducts its activities in a manner which is highly open and accessible, but there are always likely to be improvements which could be made to render its processes and decisions still more transparent, as the decisions in the *Eisai* and *Servier Laboratories* cases suggest. Nonetheless, its structure, processes and decisional output serve as a useful yardstick for other bodies whose work impacts upon the allocation of scarce healthcare resources in the NHS. Those bodies are under no obligation to implement procedures which are identical to those used by NICE, but the Institute undoubtedly serves as a model of good practice for those who are, or who aspire to be, committed to transparency.

### IV. Legislation and Quasi-legislation: the NHS Constitution

The most recent contribution to the ‘transparency turn’ identified in this article has come at the initiative of the government. On 21 January 2009, the *NHS Constitution for England* was issued.\(^{57}\) The document purports to be a statement of the principles and values of the NHS in England.\(^{58}\) It sets out a

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\(^{52}\) [2008] EWCA Civ 438, para. 66 (Richards LJ).

\(^{53}\) See also the *Servier Laboratories* case at first instance, especially [2009] EWHC 281 (Admin), paras. 121, 123.


\(^{56}\) Fisher, *supra* note 7, pp. 281-82.

\(^{57}\) The document was reissued in March 2010.

\(^{58}\) Since health is a matter which is devolved to the regional governments in Wales, Scotland and Northern Ireland, the *Constitution* only applies in England. However, on 3 July 2008 governments
series of ‘pledges’, which the NHS is committed to achieve, ‘responsibilities’ which public, patients and staff owe to each other to ensure that the Service operates fairly and effectively and – most importantly for present purposes – ‘rights’ to which patients, public and staff are entitled. These rights emanate from a variety of sources, most predating the publication of the Constitution, and not all are directly legally enforceable in themselves. However, they are given indirect legal effect by way of a statutory obligation imposed upon most bodies within the English NHS, including those with key allocative responsibilities, to “have regard” to the provisions of the Constitution in performance of their functions. The consequence is that a failure to comply with the Constitution is likely to form the basis of legal challenge: for example, in the context of judicial review of administrative action, the rights will be regarded as relevant factors to be considered in the process of decision-making, and they appear likely to give rise to a legitimate expectation, frustration of which might be unlawful.

Two of the provisions of the Constitution are particularly germane to the discussion in the present article. First, there is a “right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence”, and that an explanation will be provided “if the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you”. This right, which is partly derived from administrative law principles such as those articulated in cases discussed earlier in this article, is said to be justified because “for […] local decision-making (ie on whether to fund a service or treatment), it is important that the process is rational, transparent and fair”. To this end, statutory Directions have been issued to PCTs in England which oblige them to provide, upon request, a written statement of reasons for a general policy on the availability (or otherwise) of a particular health care intervention, except where a statement of reasons for its policy has been published on its website. Trusts are also required to provide an individual whose request for funding for a particular intervention has been refused in accordance with the policy with a written statement of reasons, irrespective of whether the individual has issued a request.

Secondly, and more broadly, the Constitution contains a pledge by way of which “the NHS commits to make decisions in a clear and transparent way, so that patients and the public can understand how services are planned and delivered”. The Handbook which accompanies the Constitution conceives of this commitment primarily in terms of public involvement in local decisions on commissioning of healthcare, together with arrangements for consultation of local populations and partnership with local authorities. However, the

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59 Health Act 2009, s.2(2).  
60 For a case in which the Constitution was successfully used as the basis for a claim, see R (on the application of Booker) v NHS Oldham [2010] EWHC 2593 (Admin).  
61 Department of Health, The NHS Constitution for England, 2010, p. 9. The reference to “other drugs and treatments” connects this right to that which precedes it, which provides that “You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you”. It is therefore clear that, in situations where decisions are made on funding of technologies which have not (yet) received NICE approval, a similar evidence-based appraisal and process of reasoning is expected.  
63 Idem, p. 37.  
64 Department of Health, Directions to Primary Care Trusts and NHS Trusts concerning decisions about drugs and other treatments (12 March 2009), direction 3.  
65 Department of Health, supra note 62, p.9.  
66 See especially Local Government and Public Involvement in Health Act 2007.
inclusion of such a provision does appear to provide evidence of a general acceptance of the value of transparency in healthcare decision-making, including that on allocation of resources. Furthermore, were the issue to be litigated, a court might well take the view that the commitment was sufficiently concrete in content to give rise to an enforceable legitimate expectation in the rationing context.

As is generally the case with constitutional documents, relatively little detail is offered as to the precise meaning and appropriate modes of implementation of the provisions contained in the Constitution. It is, therefore, necessary to turn to soft law, in the form of guidance, to develop an understanding of how the obligations of transparency are expected to be given effect ‘at ground level’. Guiding Principles published by the Department of Health state that Trusts making decisions on those treatments which should be funded “should take reasonable steps to provide an explanation to the public on the need for PCT prioritisation due to local health outcome choices and finite budgets”, that they should “communicate clearly with stakeholders including the wider NHS, patients and public” and that “public access should be provided to decision-making policies, procedures and criteria”. Further good practice guidance provides checklists and frameworks to assist decision-makers in upholding these principles. The NHS Warwickshire policy discussed previously in this article may be seen as an attempt to implement such good practice guidance at a local level.

Conclusion

The NHS Constitution, although the brainchild of the Labour government of Gordon Brown, has been endorsed by the Conservative-Liberal Democrat coalition government. This would suggest that a commitment to transparency will remain fundamental to decision-making in the NHS for the foreseeable future. Yet the government has also announced proposals for reforms which appear to go against the grain of the principle of rational and transparent decision-making encapsulated in the Constitution, albeit that significant aspects of the detail of to these reforms remain, as yet, unclear.

Prominent amongst these is the proposal to remove the mandatory funding requirement which currently attaches to NICE guidance and to hand decision-making as to which new health technologies are to be funded to ‘consortia’ of general practitioners (GPs) operating at a local level, with the existing PCTs being abolished. The government argues that this will be beneficial to patients as it will:

[B]ring together responsibility for clinical decisions and for the financial consequences of these decisions. This will reinforce the crucial role that GPs already play in committing NHS resources through their daily clinical decisions and that it will increase efficiency, by enabling GPs to strip out activities that do not have appreciable benefits for patients’ health or healthcare.

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69 Department of Health, Equity and Excellence: Liberating the NHS, Cm 7881 (2010), para. 1.4.
70 Idem, para. 4.4.
Critics, however, have claimed that the policy risks resurrecting the ‘postcode lottery’ which NICE was originally established to address: that is, geographical inequities in access to and provision of treatments and care across the NHS.\(^71\)

It should be noted that this proposed reform is unlikely to lead to a return to a system of implicit rationing in which the resource considerations for denying or limiting access to treatment are concealed beneath a ‘veil’ of clinical judgment. It seems implausible that any such state of affairs could now be brought about: the British public is, by now, well aware that resource constraints necessitate the making of hard allocative choices in healthcare and, to coin a metaphor, the cat cannot be put back into the bag (not least, in light of the existence of the Freedom of Information Act 2000). The hope of the government is, presumably, that diffusing an even greater number of allocative decisions to local level will serve to defuse some of the controversy which has frequently attended the issuing of guidance by NICE at a national level. But it is quite possible that the outcome will be precisely the opposite: that is, that the instability which already exists as a consequence of explicit rationing will be exacerbated when patients, pressure groups and pharmaceutical companies become aware that drugs and treatments which are not funded in one locality are available a short distance away. Indeed, a senior general practitioner has already raised the spectre of ‘medication tourism’, envisaging a situation in which “busloads of sick people [are] traversing the country based upon rumours that another consortium is offering drugs that their local one isn’t”.\(^72\)

This is not to argue that local variations in population health needs may not necessitate different patterns of funding of healthcare treatments and services. Indeed, the Guiding Principles which flesh out the Constitution’s requirement for rational decision-making acknowledge that “natural variation will exist, and is appropriate, in order to meet the differing health care needs of local populations”. However, as the document also notes:

\[\text{[I]n the absence of a national framework, local priority decisions have led to variations in responses between PCTs and this, on occasions, has given rise to concern. The }\textit{NHS Constitution}\text{ [therefore] aims to address variations in the availability of medicines and treatments resulting from inconsistency in local decision-making processes.}\] \(^73\)

On this analysis, transparency will be more important than ever under the ‘enhanced localised’ form of rationing which is envisaged by the present government. The only realistic hope for generating the level of public understanding which appears imperative for any long-term systemic stability lies in the provision by GP consortia of clear, reasoned explanations as to why priorities for funding must differ from those of neighbours. These should be rooted in evidence both as to the clinical and cost-effectiveness of the treatments in question and, more broadly, in information as to the health needs of the particular locality. Ideally, such transparency should be underpinned by some degree of participation in priority-setting decisions, enabling affected stakeholders to introduce evidence and arguments which might impact upon the decisions taken by the consortia. Moreover, given that continued legal challenge to allocative decisions is inevitable, especially in light of the perceived ‘unfairness’ of geographical differentiation in access to

\(^{71}\) See, for example: ‘Nobbling NICE will lead to a new postcode lottery’, The Guardian, 4 November 2010.

\(^{72}\) L. Buckman (chair, British Medical Association General Practitioner Committee), quoted in: A. Jack, ‘Fears that curbing NICE will bring “chaos”’, Financial Times, 7 November 2010.

\(^{73}\) Department of Health NHS National Prescribing Centre 2009, supra note 68, p. 3.
treatment, it will be especially important that the courts remain vigilant and continue to articulate values of transparency, whether these are drawn from centuries-old common law notions of procedural fairness or from the principles enshrined much more recently in the *NHS Constitution*.

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