

Judicial review, individual funding requests and exceptionalality

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The NHS is a state funded health service where demand has always and, despite increases in funding under successive governments, will always exceed the NHS's ability to deliver healthcare. New drugs arise at regular intervals which are claimed to be marginally or radically more effective than their predecessor but at vastly greater cost.

That means that doctors, medical managers and ultimately Trust Boards have to take some tough decisions. What is the approach of the courts? It may surprise some to know that 10 years ago the courts erected a large "Lawyers Keep Out" sign at the door of the medical rationing debate.

Any analysis must start with the principle that sections 1 and 3 of the National Health Service Act 2006 create a "target duty" in law. A specific legal duty is a duty which must be fulfilled. In contrast a target duty means "something to be aimed at" but not necessarily hit. Hence if – as is always the case - the funds are insufficient to fund everything, the NHS does not breach its duty by failing to fund that which it cannot afford.

This was established in a leading and tragic case back in 1995¹ which concerned child B – later revealed as Jamie Bowen - who wanted the Health Authority to fund novel and unproven but potentially life saving treatment for a 16 year with leukaemia, Lord Justice Bingham said:

¹ R v Cambridge Health Authority, ex p B [1995] 2 All ER 129, [1995] 1 WLR 898.

“I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay their nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like.

Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make. In my judgment, it is not something that a health authority such as this authority can be fairly criticised for not advancing before the court”

The court went on to make two important observations. First it said:

“Mr McIntyre [*counsel for the patient*] went so far as to say that if the authority has money in the bank which it has not spent, then they would be acting in plain breach of their statutory duty if they did not procure this treatment. I am bound to say that I regard that submission as manifestly incorrect. Unless the health authority had sufficient money to purchase everything which in the interests of patients it would wish to do, then that situation would never ever be reached. I venture to say that no real evidence is needed to satisfy the court that no health authority is in that position”

Thus the argument “you’ve got money in the bank – fund my treatment - does not work”.

Secondly Bingham LJ said:

“Furthermore it would be totally unrealistic to require the authority to come to the court with its accounts and seek to demonstrate that if this treatment were provided for B then there would be a patient, C, who would have to go without treatment. No

major authority could run its financial affairs in a way which would permit such a demonstration”

Hence PCTs do not need to go into vast detail about how deficits work and who will lose out if a treatment is funded.

The next step in the NHS resources series of cases was the *North West Lancashire Health Authority case*² which concerned funding for transsexual surgery. This was a judicial review where the Court quashed the Health Authority’s decision to refuse to fund extra-contractual referral to the Gender Identity Clinic at Charing Cross Hospital for diagnosis and funding for gender reassignment treatment, and the policy on which those refusals were based.

The Judge said:

“It is natural that each authority, in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose-indeed, it might well be irrational not to have one.. ”

He then said:

“In my view, a policy to place transsexualism low in an order of priorities of illnesses for treatment and to deny it treatment save in exceptional circumstances such as overriding clinical need is not, in principle, irrational provided that the policy genuinely recognises the possibility of there being an overriding clinical need and requires each request for treatment to be considered on its individual merits”

The health authority’s position was however undermined by two factors. First the evidence showed that it did not really consider that transsexualism was a medical

² R v North West Lancashire Health Authority, ex parte A [2000] 2 FCR 525

condition and thus the decision making process which had placed it in the lowest priority alongside non-medical conditions. This was held to be flawed. Secondly – and this is perhaps the most important aspect of the case – this categorisation was not saved by a caveat that there could be “exceptions to this policy on the basis of overriding clinical need”. However when pressed the health authority could not say how anyone could fulfil the criteria. The Judge said:

“..if a regional health authority devises a policy not to provide treatment save in cases of overriding clinical need, it makes a nonsense of the policy if, as a matter of its medical judgment, there is no effective treatment for it for which there could be an overriding clinical need”

This case is often mistakenly taken as authority for the proposition that it is unlawful or a NHS body rule out funding a condition or supplying a drug unless there is an “exceptional clinical need or exceptional circumstances” qualification. That is not a correct reading of the case. What the court said is if there is an “exceptional clinical need qualification” then there must be the possibility that someone would be treated as exceptional. However that does not mean there has to be such a term in your policy. In contrast Auld LJ said:

“it follows from the foregoing propositions that a health authority can, in the course of performing these functions, determine that it will provide no treatment at all for a particular condition, even if the condition is medically recognised as an illness requiring intervention that is categorised as medical and curative, rather than merely cosmetic or a matter of convenience or lifestyle”

The court did say that the more serious or life threatening the condition, the more the court will scrutinise the evidence but provided the NHS has behaved rationally it will not have behaved unlawfully. But it is very clear that NHS bodies are legally entitled to rule out specified treatments under their policy provided they have adopted a rational approach in deciding the policy in the first place. Whether they do rule out specific treatments for funding is obviously a matter for the individual PCT to decide.

However provided there is some check on treatments for breakthroughs for potentially life threatening or saving treatments, adopting a policy to refuse to fund new developments and forcing them into the LDP process is in my view rational and thus potentially lawful.

As this talk is about the rational use of resources I must refer to and discard a recent case which was expressly said not to be about the rational use of resources. *R (on the application of Rogers) v Swindon NHS Primary Care Trust and another*³ – the Herceptin case. The background to this case is complex and took a highly unusual course in the way that it approached the treatment. The core problem was that the PCT's policy in that case said that the decision would:

“.. not be determined on cost grounds.”

Thus the court was unable to approach the matter on the basis of the rational allocation of resources even though the treatment was, at that stage, expensive, controversial and largely untested. The problems in that case were compounded because the PCT tried to say that, even though decisions would not be made on financial grounds, it would only fund exceptional cases when, as the medical evidence presented to the court (at that stage showed, it could not choose clinically between the different cases.

Thus the case came down to largely the same issue as the Lancashire case, namely “how can you have an exceptionality policy if no one can be shown to be exceptional”. The key part of the judgment says:

“Mr Havers [*for the PCT*] was naturally asked to give examples of personal circumstances which might justify funding one woman rather than another within the eligible group. He submitted that it was not necessary for the PCT to identify possible examples and relied upon the North West Lancashire Health Authority case. The only positive example he gave was that of a woman with a child with a life-limiting condition. For our part, we cannot see how that fact can possibly justify providing funding for that woman but not another when each falls within the eligible group and

³ [2006] All ER (D) 181

there are available funds for both. After all, once financial considerations are ruled out, and it has been decided not to rely on NICE without exception, then the only concern which the PCT can have must relate to the legitimate clinical needs of the patient. The non-medical personal situation of a particular patient cannot in these circumstances be relevant to the question whether Herceptin prescribed by the patient's clinician should be funded for the benefit of the patient. Where the clinical needs are equal, and resources are not an issue, discrimination between patients in the same eligible group cannot be justified on the basis of personal characteristics not based on healthcare" (*my emphasis*)

But if financial constraints are relevant then social factors are permissible the Court of Appeal said:

"It could properly involve a decision by a trust which was subject to financial constraints and which decided that it could not fund all the patients who applied for funding for Herceptin treatment, to make the difficult choice to fund treatment for a woman with, say, a disabled child and not for a woman in different personal circumstances"

I confess to having profound problems with this approach. It means that whether or not a patient gets NHS treatment could depend on factors other than their clinical prognosis. It has the potential to be highly discriminatory against those without children or other dependants and could be socially divisive. However the present state of the law is that if you have an individual treatment decision where there is an exceptionality requirement based on resource limits, you are entitled (but not obliged) to take social factors into account.

Before looking at exceptionality more closely, I must address the issue of the European Convention of Human Rights which was confidently predicted to cut through all logical and sensible rationing decisions. Since 1998 the European Convention of Human Rights has become part of the domestic law of the UK as a result of the Human Rights Act 1998. Included within the Convention is the Right to Life under Article 2 and the Right to respect for private and family life under Article 8.

However Hedley J in the Charlotte Wyatt case said as follows:

“In the course of argument the European Convention on Human Rights was referred to but no separate submissions were developed even though key rights are undoubtedly engaged. That was because although English domestic law has undoubtedly been significantly affected by the concept of Convention rights, it is recognised that in this case at least the convention now adds nothing to domestic law”

This was developed by Ouseley J in an important case in 2005, *R (on the application of D) and others v London Borough of Haringey and Conjoined cases*⁴. This case was about the failure of a PCT to provide as much respite care as another PCT had assessed the patient required.

The case is important for 2 reasons. First, it comprehensively looked at the interaction of the European Convention of Human Rights and the PCT’s statutory duties. Second, it made explicit statements about the extent to which a PCT is bound to provide services once there is an assessment by medical professionals of a medical need.

The Judge rejected the argument that ECHR arguments added anything to this debate saying:

“[*The European Human Rights cases*] embody a wide margin for the judgment of statutory bodies charged with the allocation of resources to competing priorities, many of which could be said to engage art 8(1)”

That is very valuable ammunition against those who claim that there are unspecified “human rights” arguments that mean that resource based rationing decisions must be set aside.

⁴ [R \(on the application of D and another\) v Haringey London Borough Council R \(on the application of D\) v Haringey Primary Care Trust - \[2005\] All ER \(D\) 256 \(Oct\)](#)

Secondly, the case looked at how a PCT should deal with an assessment – in this case by another health service body – that said Mum should have 20 hours respite care when it has decided it could only allocate 10. The Judge said:

“If HPCT is providing the resources, it is entitled to decide how they should be used. Even if it had in reality delegated the task of making a judgment to IPCT it is still entitled to reach its own view later and to be judged by that later and different view. The Claimants cannot say that HPCT is bound in law by the IPCT view to provide what emerged”

So in general I think we can be reasonably confident that European Human Rights arguments are not going to upset the applecart.

So if ECHR arguments are largely irrelevant, what does an exceptional case mean? Let's start with the dictionaries. Exceptional means “far beyond what is usual in magnitude” or degree and “surpassing what is common or usual or expected”. Which raises the question “what are we comparing it with?”.

The answer, as is clear from a long series of cases, is that the relevant cohort to which the comparison is to be made is the cohort of patients with the relevant condition, not people walking around in the High Street.

Thus for a case to be exceptional the circumstances must be exceptional within the group of patients suffering from that condition. There are largely 2 ways in which this can be established:

- The clinical outcome for that patient may be exceptional – they may not tolerate the usual and cheaper treatment, there may be evidence they would do far better than the average on the treatment or even – and this is controversial – they may have already funded the drug privately and been able to show exceptional clinical outcomes.

- They may have exceptional social factors. But things like “having dependant children or being a full time carer” cannot be exceptional because that is not “far beyond what is usual”.

However it is, of course, for individual PCTs to say what factors are and are not permitted as part of your individual funding policy.

So what’s new on the horizon? The case of *R (on the application of Watts) v Bedford Primary Care Trust*⁵ potentially presented perhaps the most serious legal challenge to the NHS. Mrs Watts wanted a hip replacement and was told it would be several months before this could be provided on the NHS. She regarded that wait as unacceptable and went abroad. She then sought to charge the NHS for the treatment in France on the basis of EU law – that is the rules of the European free market not the ECHR.

Her case has had a long and tortuous history – somewhat of a feature of EU cases – and is due to come back to the Court of Appeal in London next month. The judgment of the European Court is hard to interpret but, having read and re-read it and the other cases supporting it, I suggest that it has the following consequences.

First, it is about the waiting times for treatment which would be available in the NHS, not about treatment abroad for treatment which was denied to an NHS patient. The difference is crucial. The European Court has not, in my view, said anything that suggests that the scope of publicly funded treatment which can be obtained via Europe is greater than that which is obtained at home. The key regulation – article 22 of regulation 1408/71 – is about those who

“satisfy the conditions of the legislation of the competent state for entitlement to benefits” to get treatment abroad “

where patients cannot be given the such treatment

⁵ <http://www.bailii.org/eu/cases/EUECJ/2006/C37204.html>

“within the time normally necessary for obtaining the treatment in question”.

There are various places in the judgment which recognise that it is for national governments to set NHS budgets and allocate treatment, and there is little directly in this case which will change that.

It is thus about a free EU market in state supplied services and is difficult to read as giving a right to increase the quantity of those tax paid services. That would infringe article 152 which allows individual countries freedom to decide how much funding they provide to their own social security systems.

However where, as for example in IVF treatment, waiting periods are used to manage budgets and constrain demand, the case may be applicable. In such cases the patient will have the right to go abroad to seek treatment if the waiting period is excessive. And what is excessive must be judged by the clinical features of the case for that patient, not just the “usual NHS waiting time” for such treatment.

But – the astute might say – if a patient can go to France for IVF treatment and require the NHS to pay, why not go to a private provider in the UK. The court accepted (and did not question) that:

“the NHS is not obliged to authorise and assume the cost of hospital treatment provided to patients in private non-NHS hospitals in England and Wales”

The logic of that position is due to be tested in a case which will hit the courts later this year. That case has been stayed by the Courts whilst Watts is decided.

Is a refusal of funding a breach of the duty of care?

Patients cannot use the direct legal duty of care owed by individual clinicians to claim a breach of that duty if NHS bodies fail to make the best and most expensive and most extensive treatment available. This has been established in many cases including R (on the application of K) v West London Mental Health Trust⁶. The court held in that case last year that a consultant psychiatrist could not escape the rigours

of resource allocation by pushing for expensive treatment (in the private sector) for a mental health patient who was leaving Broadmoor. The Trust were entitled to say that it may well be the best treatment but it could not be afforded.

The key point here is that the NHS organisation, which is the decision maker, does not owe the patient a direct duty but only a “target duty” to the patient whereas the doctor owes a direct duty of care. The patient cannot use the fact that the NHS employer is vicariously liable for any breach of duty by the individual doctor to bypass the target duty.

What should NHS professionals do if a Judicial Review challenge emerges?

If I say “seek expert legal advice” I sound a bit like Mandy Rice Davies in the Stephen Ward trial who famously answered a question by saying “well he would say that wouldn’t he”. But the most expert legal advice at the earliest stage is vital because of Legal Services Commission Funding issues.

Most cases come to court with public funding. That funding is only granted after an examination of the merits. Responding to the Claimant’s letter before action with a detailed analysis of the law and explanation as to why the case will fail – over 7 pages and with citations from the key cases if needed – is the best defence. That letter goes to the Legal Services Commission who, in our experience, are increasingly prepared to take these arguments seriously and refuse funding. And no LSC funding usually – but not always – means no case.

If a case is threatened or does start then:

- Collect all the papers at the earliest opportunity. The court will want to see the relevant policies, the case papers that went to the panel and the minutes of the key meetings. Most JR cases that succeed do so on process not on outcome.
- Get the key people to write down what they did and when and why.

⁶ 90 BMLR 214

- If there were key conversations, there should be attendance notes for the file and if not get both parties – independently to set down what was said.
- Thus the “time line” emerges and the rationale for the decision.
- If there is a resources based judgment then the Director of Finance will have to prepare a statement explaining the pressures. The PCT cannot just “toll the bell of tight resources” but it is not necessary to explain where every penny is spent.

That gives the chance to put your lawyers in the best possible position to defend any claim – recalling that many claims are made and very few succeed.

What are the minimum legal standards for policies?

I hope this review of the legal position shows that the courts have effectively declined to go behind any health rationing decisions that the NHS makes, provided (I would suggest) minimum standards of fairness are met. These minimum standards could be expressed as follows:

1. Save in an emergency, rationing decisions should be made in accordance with clear written policies, specifically adopted by a PCT and reviewed regularly.
2. Policies should be as specific as possible and set up the tests for the PCT to consider in order to decide which patients should and should not get specified treatment.
3. The procedures for individual cases should include consultation with clinicians, patients, parents (in the case of children) and affected family members.
4. You can have blanket bans. They are not unlawful.

5. If you do leave the exceptional case or exceptional clinical grounds exemption, make sure (a) you say its on resources grounds, and (b) you decide if social factors are in or out.

Should you admit that resources play a part in the decision making?

My experience is that there is a great reluctance amongst some clinicians (but less amongst public health professionals) to admit that treatment decisions are being taken on the basis of prioritisation or rationing – and I regard the words as interchangeable. Part of that reluctance is based on a concern that if a patient is refused a treatment because the clinicians do not consider that the cost/benefit analysis makes the treatment justifiable, they will instantly run to the courts.

Patients may, of course, run to the newspapers and shroud wave before the court of public opinion, but if the decision is properly made, it may be that there is a misunderstanding amongst the medical community as to the approach of the courts. Properly made rationing decisions ought to be much more legally defensible than decisions which are made – aside from resources – supposedly solely in the best interests of a child.

The worst possible position – as a lawyer – is to think that a decision is being made solely on the basis of the best interests of a patient but to find that in fact there is a strong but un-stated element of resource prioritisation which is driving the decisions.

So where does all this lead. I would suggest the following:

1. If a decision is solely being taken in a patient's best medical and overall interests, bear in mind it is the clinician's role to advise on treatment options and the patient's role to decide between those options – not select one which is not offered.
2. If there is a resources element in the offer, make sure that the decision is taken in a clear transparent way in accordance with established policies. These are decisions for the NHS, not patients.

3. Never pretend that a decision is on best interests grounds alone if it is a mixture of best interests and justifiable resource allocation.
4. If in doubt, seek legal advice. All Trusts ought to have lawyers who operate a 24 hour helpline service. If patients can get doctors out of bed at 4 in the morning, there is no reason why we lawyers should be allowed to sleep in.

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