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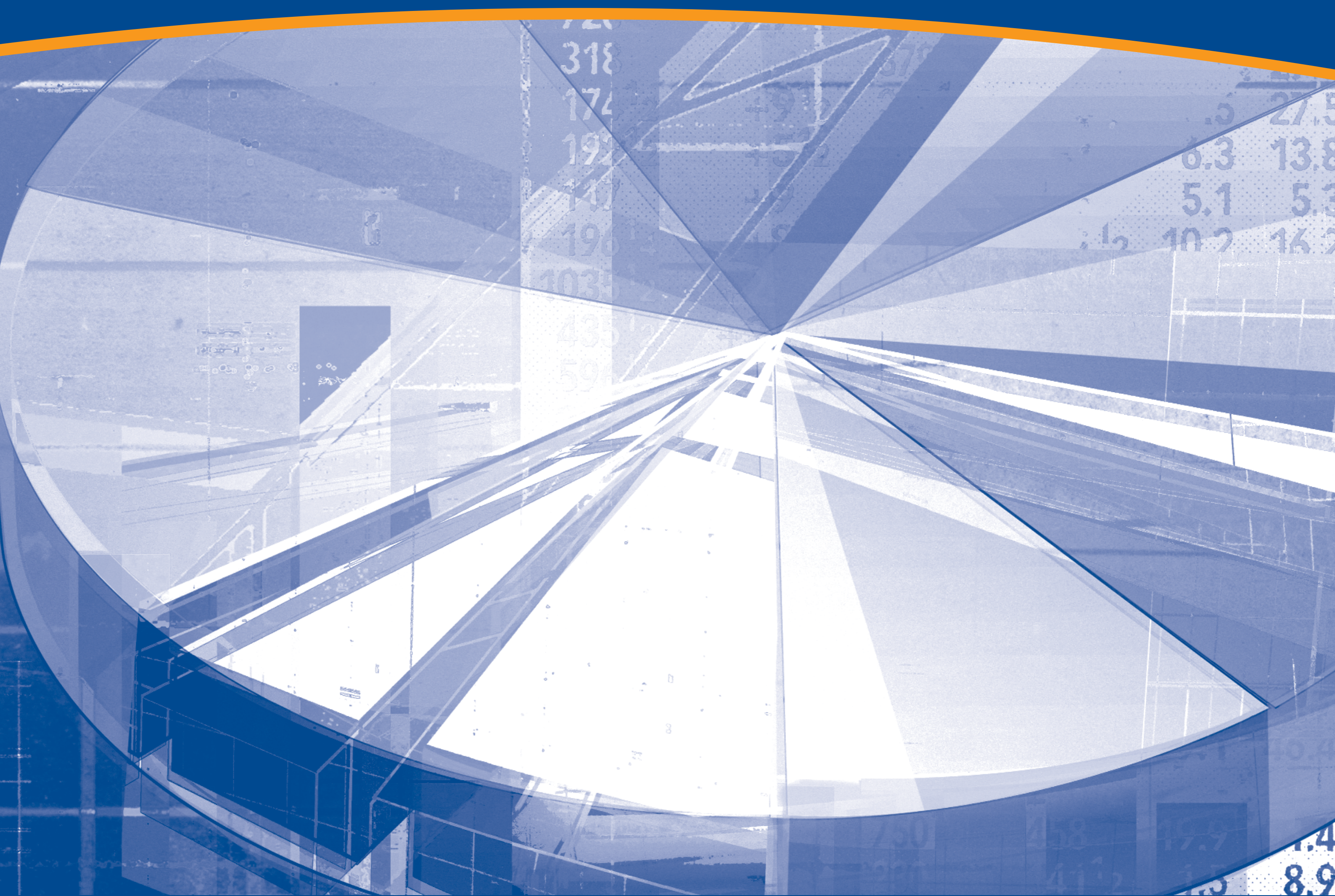
Priority setting: legal considerations



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Registered Charity no. 1090329
Published by the NHS Confederation

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ISBN 978-1-85947-150-0
BOK 59601

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Introduction

Judicial review continues to grow in significance, with public authorities of all types now regulating themselves so as to comply with it. Twenty years ago, the courts often deferred to the expertise of public authority decision makers but today things are different. Public authorities may have to account for their actions at judicial review and can be required to revisit their decisions.

In the NHS, this is important in deciding which services the NHS can afford to commission and also with respect to individual funding requests. Reasonable priority setting should be central to primary care trust (PCT) corporate governance. Key individuals within PCTs should have some knowledge of judicial review to act as advisors, as well as maintaining good relationships with solicitors who specialise in this field. This is a complex and developing area of law and this report is not a comprehensive guide; PCTs must always refer specific issues to their own legal team.

This report will consider the following:

- what is judicial review
- the duties of the Secretary of State for Health and PCTs
- the role of the National Institute for Health and Clinical Excellence
- prescribing rights in primary care
- European Union law and human rights law.

It also covers judicial review proceedings and provides some tips on working with lawyers.

Is litigation always a bad thing?

Litigation is not pleasant. It can cause anxiety, stir up hostility, add to the pressures of work and it is expensive. But this is not necessarily a good reason to avoid it at any cost. If every PCT conceded every claim for fear of litigation, reasonable priority setting would be impossible. Those patients who did not litigate would always be last on the waiting list.

The benefit of litigation is that it can resolve unsettled issues so that reliable, legal arrangements become accepted practice and regulate practice in future. This is preferable for everyone. PCTs might consider entering a cost-sharing agreement so that cases in which there are significant legal doubts can be tested without causing disproportionate costs to one PCT alone.

What is judicial review?

Judicial review is a mechanism for scrutinising the lawfulness of public authority decision making. It gives the courts power to examine whether a public authority has exercised its powers lawfully and reasonably within the parameters of the statutory authority conferred on it. Judicial review does not normally involve claims for damages.

The two most likely reasons for legal action against PCTs are:

- major changes to services
- refusal to fund treatments for individual patients.

A successful challenge in judicial review does not normally secure the claimant access to the treatment in question. Instead, the original PCT decision is nullified and referred back to the trust to be taken again in the light of the court's observations. In such a case, although it is still possible for the PCT to reaffirm its original decision, many concede the claim. Of course, rational and responsible priority setting will be undermined if PCTs concede every challenge and fund low-priority treatments.

What are the grounds for judicial review?

There are three grounds for judicial review, namely that the decision taken was one or more of the following:

- illegal
- irrational
- procedurally improper.

1. Illegality

A claim that a decision is *illegal* contends that the PCT has acted outside its statutory powers. This can be difficult to determine because words in statutes are sometimes ambiguous. In these cases, the words may confer *discretion* on the public authority as to how they should be interpreted. An example of an illegal action would be for a PCT to ignore a 'direction' from the Secretary of State to fund a treatment (see the section on NICE, page 8).

The principle of illegality also now includes the Human Rights Act 1998 (see page 10.)

2. Irrationality

A claim that a decision is *irrational* contends that the decision maker has considered irrelevant factors, excluded relevant ones or given unreasonable weight to particular factors. *Irrationality* is considered on page 5 in the discussion of *R v NW Lancashire HA*.

The courts respect the *discretion* of decision makers to reach their own conclusions, provided they are reasonable. The court does not look for a 'correct' solution, or one with which the court agrees. But it must be within a range of reasonable solutions.

Recently, the courts have become more intense in their scrutiny of PCT decisions. Whereas until the mid-1990s they tended to accept without question the rationality of health authority decision making, today judicial review is more rigorous. This means that a PCT must demonstrate that it has properly considered all the relevant factors and come to a reasonable conclusion. This usually means granting access to PCT documents and minutes of meetings.

3. Procedural impropriety
A claim that a decision is procedurally defective may contend that the PCT has misunderstood a statutory *procedural duty*. Examples would be a failure under section 11 of the Health and Social Care Act 2001 to consult patients and the public about service changes, or coming to a firm conclusion before consultation is complete.

But procedural impropriety may also apply to decisions relating to the PCT's individual funding request panels. If a decision of the panel will affect someone's interests, that individual is entitled to know what factors are being considered, have the opportunity to make representations in writing and be reassured that the panel is independent.

Procedural impropriety also concerns whether PCTs have followed their own policies and procedures reasonably and consistently.

'If a decision will affect someone's interests, that individual is entitled to know what factors are being considered.'

Duties of the Secretary of State

The organisation of the NHS is governed by the National Health Service Act 2006. Section 1 of the Act requires that the Secretary of State for Health:

> *Must continue the promotion in England of a comprehensive health service designed to secure improvement (a) in the physical and mental health of the people of England, and (b) in the prevention, diagnosis and treatment of illness.*

This is not an absolute duty to 'provide' NHS treatment. Considering the nature of this duty, the Court of Appeal said in *R v North and East Devon Health Authority ex p Coughlan (1999)*[1]:

> *When exercising his judgment [the Secretary of State] has to bear in mind the comprehensive service which he is under a duty to promote... However, as long as he pays due regard to that duty, the fact that the service will not be comprehensive does not mean that he is necessarily contravening [the Act]… a comprehensive health service may never, for human, financial and other resource reasons, be achievable…*

Duties of PCTs

Healthcare resource allocation is not performed by the Secretary of State personally. This task, and the duty that goes with it, has been delegated to PCTs.[2] This is why judicial review litigation is normally conducted against PCTs, rather than the Secretary of State.

In addition to PCTs' duty to promote a comprehensive health service, Section 229 of the NHS Act 2006 states:

> *Each primary care trust must, in respect of each financial year, perform its functions so as to secure that its expenditure… does not exceed [its income].*

Sections 66–68 of the Act also give the Secretary of State power to remove from office those who fail in this duty. Board members, therefore, are under pressure to comply with ministerial instructions and not to exceed the budget that has been allocated to the PCT.

So, within their finite allocations, PCTs must decide how best to 'promote' a comprehensive healthcare service. The reality is that need and demand for healthcare exceeds the resources available to the NHS. As a result, hard choices have to be made between the competing claims of different patients. The law requires PCTs to exercise *reasonable discretion* in deciding how this is best done.

What is reasonable discretion? A helpful starting point is the case of *R v North West Lancashire Health Authority ex p A, D & G* (2000)[3], in which a refusal to fund transsexual surgery was overturned by the Court of Appeal. The court discussed some of the factors relevant to reasonable discretion.

1. Differences between PCTs

The court confirmed that:

> *The precise allocation and weighting of priorities is clearly a matter of judgment [for] each authority… Authorities might reasonably differ as to precisely where [a treatment] should be placed and as to the criteria for determining the appropriateness and need for treatment.*

Therefore, 'postcode variations' between PCTs are not unlawful of themselves. Equally, though, in a *national* health service wide variations are unattractive. PCTs should be aware of differences between neighbouring trusts and be able to explain why they are valid.

2. Need for a priorities framework

In relation to the priority-setting process, the court observed:

> *It makes sense to have a policy for the purpose – indeed, it might well be irrational not to have one…*

Each PCT should ensure it has a consistent priorities framework to guide the allocation of its resources. Throughout this series of priority-setting reports this is referred to as the *overarching policy document* on resource allocation. This policy should explain the principles of decision making in a way that can be easily understood by a lay readership.

Since the statutory duty belongs to the PCT, it cannot delegate this duty. It is, however, reasonable and useful for PCTs to collaborate in developing a framework intended to be consistent across a larger area.

Making choices between competing claims is a difficult and sensitive task because someone is generally dissatisfied and may be hostile to the outcome. For example, the court said in connection with transsexual surgery:

> *It makes sense that an authority would normally place treatment of transsexualism lower in its scale of priorities than, say, cancer or heart disease or kidney failure.*

However, if decisions like these are required, it is crucial that they can be justified against a framework that is transparent and treats patients equally, fairly and consistently.

The framework helps to manage the introduction of new treatments, the annual commissioning round and decisions about individual funding requests. (See the other reports in this series, where examples are given.)

Figure 1. An example of PCT collaboration in developing a priorities framework

The Thames Valley PCTs have agreed a *Thames Valley Ethical Framework.*[4] This provides a transparent template within which each PCT may assess, for example, the introduction of new treatments. The framework balances:

- evidence of clinical and cost effectiveness
- the cost of the treatment
- the individual need for care
- the needs of the community
- mandatory national standards (see Further reading).

Figure 1 provides an example of collaboration between PCTs. Of course, the discretion permitted to PCTs means that they may differ about similar cases, but the framework of analysis will be consistent.

Some PCTs have their own 'priorities committees', while others take advice from clinical networks. Neither are statutory bodies and they have no statutory functions of their own. Their role is to make robust recommendations to the PCT board. Provided they are authorised to take a broad overview of the local health economy and can assess the competing claims of its differing sectors, their recommendations should normally be respected. A PCT board is at liberty to reject the advice but if it does so too often without good reason, the committee will quickly cease to be useful.

Priorities committees must provide a fair balance of managerial and clinical interests. If the process becomes too 'corporate' and unable to weigh and balance the *clinical merits* of a case, it will be criticised for under-valuing, or ignoring, relevant aspects of the decision, and for being irrational. The need for proper balance between managers and clinicians should be dealt with in the committee's standing orders.

3. Absence of robust evidence of effectiveness

Many treatments do not have the benefit of evidence from randomised controlled trials, or are too new to have been fully evaluated. Also, it may be difficult to conduct robust trials because of small patient numbers or lack of sponsorship. However, this does not justify an outright ban on a treatment. A reasonable clinical case in favour of a treatment must be met by a reasonable case against if the PCT is deciding not to fund it. As the Court of Appeal said in the case of *A, D & G* above:

The mere fact that a body of medical opinion supports the procedure does not put the health authority under any legal obligation to provide the procedure… However, where such a body of opinion exists, it is… not open to a rational health authority simply to determine that the procedure has no proven clinical benefit while giving no indication of why it considers that is so.

4. Blanket bans

The court was uncomfortable with 'blanket bans' on treatment. Judicial review insists that the PCT must consider all the relevant circumstances, including the possibility that the patient has 'exceptional' needs. In particular, it said:

The more important the interests 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… seriously affects the citizen's health will require substantial consideration, and be subject to careful scrutiny by the court as to its rationality.

Therefore, the policy framework must contain a procedure by which patients may say: "I know my treatment is normally a low priority, but my circumstances are so exceptional that they deserve an exceptional response." This requires the existence of individual funding request panels capable of considering the clinical merits of such a claim. These panels are dealt with in more detail in the NHS Confederation publication in this series, *Priority setting: managing individual funding requests.*

For example, in *R (Otley) v Barking and Dagenham PCT* [5], the patient had colorectal cancer and argued that she had exceptional capacity to benefit from Avastin. The PCT rejected her argument but the court held that the decision was irrational for not considering all the relevant evidence. The court said that although the PCTs general policy was rational and sensible, its decision in this case was flawed because it had not properly considered a number of factors, including the fact that:

Ms Otley … was young by comparison with the cohort of patients suffering from this condition. Her reactions to other treatment, in particular to Irinotecan plus 5FU, had been adverse. Her specific clinical history suggested that her reaction to a combination of chemotherapy and Avastin had been of benefit to her. By comparison with other patients, she, unlike many of the subjects of the studies, had suffered no significant side-effects from a cocktail which included Avastin…

The matter was referred back to the PCT to be reconsidered.

PCTs are not bound to support all exceptional cases. However, if they refuse to support the treatment, they should clearly show why. For example, the evidence of clinical effectiveness may be too uncertain. There may be pressure to conduct a clinical trial, yet the costs of the trial may be prohibitive. Or, even if a trial is conducted, its results may still be inconclusive. Or the treatment, even if it is effective, may be so expensive as to be unaffordable in any case (at least without reducing access to other patients). In these cases, it may be reasonable to refuse funding.

The law is not yet clear as to the exact nature of 'exceptionality'. Indeed, their very nature makes it impossible to anticipate every exceptional case. In particular, can *personal* circumstances ever be 'exceptional' (for example, that the patient has young children and extending his or her life, even by months, is important)? Recent cases suggest that they may be. Further litigation will help clarify these issues.

The National Institute for Health and Clinical Excellence (NICE)

So far, the discussion has focused on the decision-making powers of PCTs and the range of discretion available to them. However, there are a number of instances in which their discretion is more limited.

The Secretary of State may impose his, or her, will on the NHS by means of *Secretary of State's Directions* (Section 8, NHS Act 2006). A direction removes the right of a PCT to exercise its own discretion – it mandates what will happen. Directions often have the appearance of a statute but they may also come in the form of executive letters and circulars, provided the words 'direct' that a particular action is required.

Directions are important for PCT priority setting as a result of NICE's Technology Appraisal Guidance (TAGs). Since 2000, these have had the status of Secretary of State's Directions. The NICE Direction says:

> *A PCT shall, unless directed otherwise by the Secretary of State… apply such amounts of the sums paid to it… as may be required to ensure that a health intervention that is recommended by [NICE] in a Technology Appraisal Guidance is, from a date not later than three months from the date of the Technology Appraisal Guidance, normally available (a) to be prescribed for a patient on a prescription form for the purposes of his NHS treatment, or (b) to be prescribed or administered to any patient for the purposes of his NHS treatment.*[6]

Therefore, unless directed otherwise by the Secretary of State, PCTs 'shall' commission a treatment recommended by a TAG, 'normally' within three months of its publication. This mandate remains controversial. Some say that NICE does not take affordability into account and imposes considerable opportunity costs on PCTs, yet offers little guidance on which treatments should be reduced, or abandoned, to make way for new TAG recommendations. Whatever the merit of this concern, NICE TAGs have mandatory status in respect of PCT funding. It would be illegal (and give patients the right of action in judicial review) to fail comply with them.

The word 'normally' may cause confusion, but it should not be read to mean that PCTs with hard-pressed budgets cannot normally afford to commission new treatments. The word requires PCT planning to accommodate the cost of NICE TAGs. PCTs should only decide not to fund a NICE TAG recommendation in exceptional circumstances.

NICE also publishes *clinical guidelines* and guidance on *interventional procedures*. These are not mandatory. Nevertheless, they represent the view of an authoritative NHS body. PCTs are not duty-bound to adhere to them, but they must be prepared to demonstrate that they have given them proper consideration and have good reasons for not following them.

NICE's TAGs are binding on PCTs. But they remain guidance only with respect to clinicians. Even the best guidance has its limitations. So, as each TAG states, clinicians must decide whether a treatment subject to a TAG is suitable for their individual patients (or whether factors such as co-morbidity or incompatible drug regimens mean it is unsuitable).

Prescribing rights under the General Medical Services Regulations

The second area where PCTs' discretion is restricted concerns primary care and the General Medical Services (Contracts) Regulations 2004 (the GMS Regs).[7]

PCTs may exert a downward pressure on prescribing costs in primary care. This is done using indicative prescribing amounts assessed by PCTs as appropriate to each general practice. Thus Section 18 of the NHS and Community Care Act 1990 states:

> *The members of a practice shall seek to secure that, except with the consent of the PCT or for good cause, the orders for drugs, medicines and listed appliances given by them… in any financial year does not exceed the indicative amount notified for the practice…*

Note, however, that this does not make it wrong to exceed the amount for 'good cause', for example, an unexpected influx of new patients, or the availability of new and effective medicines.

Also, prescribers may be penalised if they prescribe excessively, for example, by prescribing drugs for their own financial advantage, or in unjustified doses[8] (see also GMS Regs, Schedule 6, para 46).

However, these downward pressures need to be balanced against a separate GMS duty of prescribers to respond to patient need. The Department of Health has described this duty as follows:

> *Patients will continue to be guaranteed the drugs, investigations and treatments they need… There will be no question of anyone being denied the drugs they need because the GP or primary care group have run out of cash. GPs' participation in a primary care group will not affect their ability to fulfil their terms-of-service obligation always to prescribe and refer in the best interest of their patients.*[9]

The reason for this statement may originate in the GMS duty that insists that prescribers shall provide 'necessary and appropriate' care and prescribe 'the medicines and appliances which are needed' for the treatment of their patients.[10] These duties were considered in the Viagra case (*R v Secretary of State, ex p Pfizer [1999]*[11]), in which the Secretary of State wrote to GPs saying that they should not prescribe the drug except in specified circumstances. The letter was challenged in judicial review as being illegal.

The court held the letter to be unlawful for contradicting the duties contained in the (similar) GMS regulations of 1992. It said that:

> *The doctor must give such treatment as he, exercising the professional judgment to be expected from a GP, considers necessary and appropriate.*

This is not to say that prescribers should always prescribe the latest, most expensive medicines. For example, it is still reasonable to prescribe a generic medicine if it has equal therapeutic benefit. On the other hand, the GMS Regs insist that the prescriber 'shall' prescribe what is 'needed' and this does not seem to permit the PCT to make savings at the cost of patient care. So, if a proportion of patients will not respond well to a generic medicine, the PCT is duty-bound by the GMS Regs to see that an alternative is available to be prescribed. (This may be why a practice has good cause to exceed its indicative budget.)[12]

This right to prescribe is subject to the statutory restrictions contained in the 'black' and 'grey' lists, which, respectively, prohibit and restrict access to certain drugs within the NHS.[13] Note, however, that PCTs cannot add a drug to these lists. Following the Viagra case, treatments for erectile dysfunction were added to the grey list and may not now be

freely prescribed. However, this is a decision for Parliament, not PCTs. Put another way, if it is sensible to limit access to medicines under the GMS Regs, then it is for Parliament to do so by means of the lists.

To this extent, supervising primary care prescribing is more difficult than controlling the costs of treatments in secondary care. This suggests that PCTs should do so by agreement and negotiation, but not by issuing their own black lists that penalise prescribers for doing what the regulations require. Otherwise, PCTs could be at risk of judicial review – in the same way as the Secretary of State in the Viagra case – for contradicting the GMS Regs.

European law

The third area in which it is difficult for PCTs to exercise regulatory discretion over NHS costs is in connection with EU law. The basic principle of EU law is to promote the freedom of movement of goods, services, labour and capital between the member states of the EU. The question is whether public health services are included within the principle protecting the freedom of movement of *services*.

The matter was first raised in respect of NHS care in 2006 in *Watts v Bedfordshire PCT*.[14] At the age of 77, Mrs Watts required bilateral hip replacements. She was put on a hospital waiting list and assured of treatment within the usual waiting period, at that time, of one year. She declined to wait so long and arranged to have her care at a hospital in France. Although, shortly before she left, the PCT offered her treatment within four months, she declined the offer, had her surgery and returned with a bill of £4,700 for the PCT. It refused to pay and the matter was taken to the European Court of Justice (ECJ) to consider whether the provision of NHS care was a 'service' subject to the rules on free movement.

The ECJ ruled that it was such a service. However, it was not freely available in exactly the same sense as private banking, or insurance services. The right to obtain care elsewhere in the EU at NHS expense was available only if the treatment was 'normal' in the sense that it had been sufficiently tried and tested by international medical science, and could not be provided without 'undue delay'.

Significantly, the existence of 'standard' waiting times could not displace the right of a patient to treatment if he or she had urgent need. The ECJ said:

> *Where the delay arising from such waiting lists appears to exceed in the individual case concerned*

an acceptable period having regard to an objective medical assessment of all the circumstances of the situation and the clinical needs of the person concerned, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, [or] an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated.

The ECJ's role is to advise domestic courts how to resolve the dispute, not to decide the merits of the case itself. So the matter was referred back to the Court of Appeal to be reconsidered in the light of this guidance. The PCT settled out of court before the need arose for further litigation.

Clearly, a widespread use of this freedom could destabilise patterns of resource allocation in the NHS. The problem is not so much in connection with 'undue delay' because the new NHS 18-week waiting list target will probably satisfy most cases. But what if treatment is not provided within a PCT because it is considered low priority? If such treatment were normally available in (say) France and Germany, would it be 'normal' treatment in EU law? Can patients simply obtain it in the EU and return with the bill? With respect, the European Court has not been conspicuous for its clarity in this area.

This issue is now (in March 2008) before the European Commission for the purpose of a new directive on cross-border access to treatment within the EU.

Human rights law

Human rights law is more sympathetic to the difficult challenges of reasonable resource allocation. Under the Human Rights Act 1998, claims may be brought, for example, in respect of the right to life (Article 2), the right to freedom from degrading and inhuman treatment (Article 3), the right to private and family life (Article 8), and the right to found a family (Article 12) enshrined in the European Convention on Human Rights. These are important in connection with clinical relationships, especially compulsory detention under the Mental Health Act, but they have been less significant in connection with issues of resource allocation.

Space does not permit extensive consideration of this area. However, the European Court of Human Rights has said that sensitive matters of this nature are best left to the reasonable discretion of national authorities. In contrast to EU law, therefore, the European Convention on Human Rights acknowledges the opportunity costs of requiring the treatment of patient A without knowing whether whether a decision of this nature will adversely affect patients B, C and D. To this extent, except in extreme cases, the European Convention trusts local public bodies and courts to manage and control disputes in this area.

Judicial review proceedings

Figure 2. Three steps leading to judicial review

1. Correspondence prior to action
First, there is likely to be correspondence before formal proceedings commencing. Patients who have been adversely affected by a decision are entitled to know how and why it has been made. A candid and transparent explanation of PCT procedures may demonstrate that the decision was fair and reasonable. It may also enable misunderstandings to be put aside and, if necessary, new information to be considered.

2. Pre-action protocol
This is a stage at which the parties should search for a legal solution. Judicial review requires the claimant to identify the substance of the complaint and the documents that may be used, and explain why the authority is said to be wrong. New information may come to light that suggests that the original decision should be reconsidered.

3. Judicial review
If pre-action protocol fails, the matter may proceed to judicial review. The claimant has three months from the date the claim first arose to issue judicial review proceedings, unless there is good reason for a delay.

We consider the two stages of judicial review proceedings below.

Priority setting is a contentious area and judicial review is becoming increasingly common. What is the procedure and how should PCTs respond? It is important to contact solicitors as soon as there is a suggestion of legal action, both for their advice and because they may facilitate a solution.

There are two stages to a judicial review.

(a) Permission stage
This stage requires the claimant to obtain the permission of the court to proceed with the case. To do so, the claimant must serve on the defendant a Claim Form and detailed statement of the case, explaining the grounds for judicial review.

This gives the defendant notice of the commencement of proceedings.

The timetable for decisions about judicial review is short. If the defendant wishes to contest the claim, he must respond to the Administrative Court within 21 days with an Acknowledgement of Service and a summary of the defence. The defendant can also submit written argument that permission should be refused. At the hearing, if the judge refuses permission to proceed, the claimant can have the matter reconsidered at an oral hearing within seven days, which the defendant is entitled to attend and

present argument. If permission to proceed is granted, the matter is taken to a full hearing.

Both parties are under a duty of candour to disclose all the information connected with the case, including things that do not support their position. This is especially important for the public authority. (In any case, the Freedom of Information Act may compel disclosure of relevant documents).

(b) Hearing stage

The *hearing stage* could be within six months of permission being granted, and in an urgent case, much sooner. Judicial review is normally conducted on the papers alone. PCT officers will be required to give witness statements; they are not usually required to give oral evidence. Nevertheless, issues could arise during the hearing for which further instructions are required. For this reason, those familiar with the case should attend and assist if required.

If the defendant's decision is criticised and judicial review granted, the claimant will apply for a *remedy*. A frequent remedy is a *quashing order*, by which the court overturns the PCT's decision and refers it back to the PCT to be taken again. The court may also make a *declaration* (for example, declare that the PCT has acted unlawfully), the affect of which is very similar – that is to require the matter to be reconsidered. It is uncommon in NHS cases for the court to make a *mandatory* order requiring the PCT to do something specific because the courts are conscious that giving resources to Peter may mean taking them from Paula.

In exceptional cases, if the claimant can prove that a decision was in breach of a duty and caused damage, the court may award damages under either the Human Rights Act or common law.

Working with lawyers

The following points can help PCTs communicate effectively with lawyers.

- Build up a relationship with one or two lawyers to work with the PCT and assess its policies, structures and processes. Do not use them only when the PCT is in trouble.
- Select your legal team carefully – you need a firm specialising in the NHS.
- Legal advice is important – build the costs into the budget.
- Ensure that the legal team has an overview of priority setting.
- Ask lawyers to check key documents.
- Seek regular training sessions and legal updates.
- Ensure that nominated individuals have access to legal opinion; particularly the director of commissioning and the senior public health consultant involved in priority setting.
- When in doubt, seek legal advice rather than continue to operate in an area of uncertainty. The law is not always crystal clear, but it is helpful to know where the uncertainties lie.

Conclusion

Patients and the public should be engaged in the process of priority setting. Their involvement requires PCT policies and documents to be prepared in ways that are reasonable, accessible and transparent. In this way, the community may see and understand the need for choices in the NHS. The objective is to manage the risks of priority setting, and these risks are not just to the PCT; poor practice also puts at risk the community and individuals. Judicial review, therefore, is about reasonable systems for balancing the sometimes competing claims on finite resources. The law has developed rapidly but, within the limits we have discussed, still leaves much scope for reasonable discretion.

Key action points

Step 1: Agree key principles to underpin priority setting

- Ensure that the PCT board and other key members of the PCT have an understanding of the law in this area.
- Adopt a policy that legal training should be mandatory for key members of the PCT and arrange training as required. A one-day seminar is sufficient.
- Agree the principles and factors that will inform decision making and ensure that these are consistent with the law.

Step 2: Develop and establish priority-setting structures and processes

- Draw up a set of good practice guidance as shaped by the law, or ask your lawyers to do it for you.
- Make a contract with your lawyers to provide legal updates and make recommendations if changes to policies and processes are needed.
- Ensure that there is good documentation of all aspects of the decision-making process.
- Audit PCT decision making regularly.

Step 3: Consider how to approach key relationships

- Ensure that there is good access to legal advice and that designated individuals can obtain it with relative ease.
- Build up a long-term relationship with specialists in this field of law.

Step 4: Produce key policy documents

- Ensure that the PCT has a document that sets out the principles, policy and processes that it will adopt when priority setting. This should apply to all levels of decision making.

See *Priority setting: an overview* for a description of the steps.

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Acknowledgments

This series has emerged from the ESRC-funded series on managing scarcity in healthcare, run by Professor Cam Donaldson. It has been funded by a grant from the NHS Institute for Innovation and Improvement.

The author and the NHS Confederation would like to thank Dr Daphne Austin, consultant in public health for the West Midlands Specialised Commissioning Team, for her assistance with this report. Responsibility for errors and omissions are the author's alone.

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Department of Health, 1998.

10 *National Health Service (General Medical Services contracts) regulations. 2004*, Schedule 6, paras 15 and 39. HMSO SI 2004, No. 291.

11 R v Secretary of State for Health, ex p Pfizer [1999] *Lloyd's Rep Med* 289

12 *Revisions to the GMS Contract 2006/07. Delivering investment in general practice*, Schedule 8. BMA and NHS Confederation, 2006.

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14 R (Watts) v Bedfordshire PCT Case (2006) *ECJ*, C-372/04

Further reading

Newdick C. 2005: *Who should we treat – rights, rationing and resources in the NHS*. Oxford University Press. This book considers the managerial, political, clinical and legal pressures on NHS resource allocation.

The Treasury Solicitor. 2006: *The judge over your shoulder*, 4th edition. This book is a layman's guide to judicial review generally.
www.tsol.gov.uk/Publications/judge.pdf

Priority setting: legal considerations

This report is the fourth in a series of publications that aims to help organisations review their current priority-setting processes and, if needed, provide a reference document for PCTs who still have to develop a comprehensive priority-setting framework.

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ISBN 978-1-85947-150-0
BOK 59601

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