

## Local decision-making judicial review script

### What it is; what it is not; when it is used and how it works

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It is a regrettable but inevitable part of the NHS today that staff who make difficult decisions face the constant threat of legal action against them. “I’ll sue you” and “I’ll take you to Judicial Review” are used almost interchangeably by the public, often with little understanding of what the terms mean.

Over the course of this presentation I hope to take you on a legal journey; to explain something of the procedures involved and describe what is meant by Judicial Review in the context of Individual Funding Request decisions, known as IFRs. Listeners who are not familiar with IFRs, and/or the overall commissioning context in which they fit, may wish to find out more by reviewing the National Prescribing Centre’s good practice Handbook to support rational decision-making about medicines and treatments, and by listening to the Legal and Ethical aspects of local decision making presentation.

This area of law is known as Administrative Law and court cases follow a process called Judicial Review. However it may be worth bearing in mind that most claims for Judicial Review fail. In 2005 there were 5,382 applications issued in the High Court for Judicial Review. These cases included challenges to all aspects of government action including planning, immigration and social care cases as well as challenges to medical treatment decisions. 87% of cases were refused permission by the Judges and so were dismissed. Even amongst the 13% which were granted permission, of those that were continued to be contested by the public body only 118 were successful. That means that overall one in 45 issued Judicial Review cases were successful at court, or just over 2%.

Judicial Reviews involving NHS bodies are very rare but, where they do happen, they need to be taken seriously. They have effects not only for the patient who brings the case but also on all other patients in a similar position. Some of the few successful applications for Judicial Review have been against PCTs over decisions not to fund medicines but equally other challenges in this area have been dismissed by the courts.

So what is Judicial Review? Well, in broad terms there are three types of cases that come before the courts in the UK. Criminal cases are where the state, usually through the Crown Prosecution Service after a police investigation, brings a case against someone who has broken the criminal law. At its most trivial it can be a parking offence and at its most serious murder and terrorist offences. If the case is proved, the Defendant is punished for breaking the criminal law by a fine or prison sentence.

The second type of case is a “private law” claim. This type of litigation involves a broad range of actions where one party alleges that another has breached his civil rights. It could be a breach of a contract or an

action for damages arising out of a road traffic accident. Clinical negligence claims, where a patient claims the NHS staff have acted negligently and caused them loss, fall into this category. These are claims where the main objective is usually to secure a sum of money – usually damages – to compensate a person or company for losses that person should not have suffered, or to secure an injunction to stop a continuing legal wrong.

Judicial Review cases are an entirely different type of court case. They are cases where the High Court makes a decision whether a government body has acted within its public law duties or not. Judicial Review cases can only be brought against government bodies, not against individuals or companies, however large.

This area of law is known as administrative law or public law. The primary purpose of public law is “to keep the powers of government within their legal bounds, so as to protect the citizen against their abuse”<sup>1</sup>.

Judicial Review is thus one of the mechanisms employed to hold public bodies accountable.

So what are the grounds upon which an application can be made for Judicial Review?

There are four main grounds for judicial review:

1. The PCT either did something that it was not entitled to do or failed to do something that it was bound to do;
2. The PCT came to a decision which no other reasonable PCT could have reached;
3. The PCT acted unfairly because it did not follow proper procedures
4. The PCT breached the patient’s human rights.

I will now address each of these in turn:

The first, and most obvious ground, that a public body either did something that it was not entitled to do or failed to do something that it was bound to do. All NHS bodies are – to use a lawyers’ phrase – “creatures of statute”. The powers of a Primary Care Trust are limited by an Act of Parliament and by Regulations. An NHS body can only act in accordance with its statutory powers and acts unlawfully if it tries to do something beyond its defined powers.

Let me take an example which obviously would never happen in practice. The Board of Directors of a PCT may be moved to tears by people dying in sub-Saharan Africa due to lack of medical facilities. As private individuals they could contribute to Oxfam but they are not legally permitted to use the PCT funds to subsidise a hospital in Eritrea or Ethiopia, whatever the needs of the population in that country and how ever strongly they feel about the need for medical services in Africa. The PCT directors are charged with using taxpayer provided funds solely for the purposes laid down the in the National Health Service Act 2006. Using money for any other purpose, however worthy, would be beyond the powers of the PCT. It would – in legal language – be “ultra vires” which means beyond the lawful powers of the public body. This is a clear

example but there is another example which is closer to call in the Quiz which accompanies this presentation.

Equally if a PCT failed to do something that it was legally duty bound to do, it would act in an ultra vires manner. So, for example, the PCT has a legal duty to fund a medicine approved by a NICE technology appraisal for a clinically appropriate patient. If there is a legal duty then the PCT has no choice. The PCT must find resources to fund the drug for that patient and is not allowed to complain that it has spent the money on other priorities.

This type of unlawful action is not a breach of the criminal law, so no one will go to prison. Equally a breach of a public law duty does not generally result in a damages claim for anyone. This action is unlawful in the sense of being a breach of the NHS body's public law duties. The actions of the public body can only be struck down in a Judicial Review case in the High Court.

There is a key difference for those running public bodies in law between “duties” and “powers”. If a PCT is under a legal duty to take a certain steps – such as funding a medicine approved by a NICE technology appraisal– it has no choice. That drug must be funded. But if the drug is not subject to a NICE Technology appraisal assessment but is clinically appropriate for a patient, the PCT has a power to commission the treatment but is not under a legal duty to do so.

This brings us to an important word in the legal dictionary in this area – discretion. If an NHS body has a power to do something, it has a discretion to exercise to decide if it will use the power or not.

All NHS bodies are under an absolute legal duty to break even financially. “Thou shalt not overspend” could be a motto written on the wall of every NHS employee. Staying in financial balance during and at the end of the financial year is one of the few absolute legal duties imposed on the NHS. The decision to provide treatment in almost every case is a matter of discretion but the duty not to overspend is one that the NHS cannot get away with.

But surely NHS bodies owe a duty of care to the patients and their needs come first? It's not quite that simple. This is a complex area but, in general terms the legal position is as follows. Individual clinicians who treat patients owe a legal duty of care to their patients. NHS bodies as a whole owe a duty to arrange the provision of staffing and their support services in a reasonably effective manner to facilitate the delivery of proper medical services. But NHS bodies and in particular, NHS commissioning bodies, do not owe a general duty of care to every potential patient who could call on them for medical services. This means that, as commissioners, NHS bodies do not owe a legal duty to act in the best interests of every patient.

The relationship between commissioning bodies, generally PCTs, and NHS patients is that NHS bodies owe a duty to consider the patient's request for reasonable investment in their medical care and to provide a fair

and reasonable response to the patient's needs, rationing available NHS resources between this patient and all the other patients who the PCT is required to serve.

This means that, when acting as a commissioner, NHS bodies are not bound to act in the best interests of every individual patient. Indeed, it would be quite impossible to do so because if NHS bodies were required to provide every treatment that was in the best interests of every individual patient, the NHS would very quickly run out of money and so would breach the duty to break even.

Coming back to Judicial Review – the legal analysis is straightforward if the NHS body did something the NHS body had no power to do, or failed to do something it was legally obliged to do (i.e. the first ground for Judicial Review). But most of the time Judicial Reviews are concerned with decisions that PCTs take where they have power to do something but choose – that is the exercise of a discretion – not to do it .

For example, a patient wishes to be prescribed a high cost cancer drug which is not covered by NICE Technology Appraisal Guidance. The PCT has power to approve the drug but has no absolute legal duty to fund the drug. The PCT decides, in the exercise of its discretion, not to fund the drug because it is not convinced the drug works and would prefer to spend the money on mental health or smoking cessation services which the PCT decides will deliver more health gain for the population as a whole.

In this case the patient cannot say the refusal to fund the drug was beyond the powers of the PCT – if the PCT has a choice to make then it can lawfully say “Yes” or “No”.

So how can the decision be challenged in a Judicial Review?

The answer is that the exercise of a PCT's discretion can only be attacked on what lawyers call “*Wednesbury* reasonable” grounds. This is the second ground for judicial review.

In the *Wednesbury* case and later cases the courts have explained that the Judges would only intervene to correct a bad administrative decision on grounds of its unreasonableness if the decision was, - quote - “So outrageous in its defiance of logic or accepted moral standards that no sensible person who had applied his mind to the question to be decided could have arrived at it”.

That dictum applies today. So if an NHS body such as a PCT has a discretion, it can only act unlawfully in its final decision if the decision is one that no reasonable PCT could have reached.

The High Court is not a court of appeal on the merits of the decision. The court is not concerned with whether the PCT reached a decision with which the court agrees. The High Court Judge is not an NHS manager and the Judge is not faced with competing demands for medical treatment and the need to balance the PCT's books. That discretion is vested by law in the NHS manager and the Judges respect that. So attacking the reasonableness – the merits – of the final decision is very difficult to say the least.

And what about money? Is the PCT entitled to say that it took finance into consideration in making the decision on a requested treatment? The answer is not only is the PCT entitled to take money into account but, given the duty to break even, it is duty bound to do so. In 1995 the Court of Appeal considered the very difficult case of Re B, a 10 year old girl. In September 1990 she was first diagnosed as suffering from non-Hodgkins lymphoma with common acute lymphoblastic leukaemia. The child developed acute myeloid leukaemia and was treated for the second time with a course of chemotherapy. The Cambridge doctors felt they had come to the end of the road for B but doctors in London thought there was a slim chance of a benefit from a further course of chemotherapy which, if that was successful, would be followed by a second bone marrow transplant operation.

The Health Authority refused to fund the treatment on the grounds that the chances of success were so slim that the investment was not justified. That decision was challenged by way of Judicial Review. The Health Authority lost in the High Court but won in the Court of Appeal. Lord Bingham recognised 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”.

He said that to adopt that approach would “be shutting one's eyes to the real world ....”. The Judge said ““Difficult and agonizing 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”.

So the discretion given to NHS bodies as to how to exercise their discretion is wide and resource based decisions are acceptable to the courts.

So, on what grounds do decisions get challenged in the High Court? The fact that final decisions are so difficult to contest means that emphasis is often placed on how the decision was taken – procedural challenges. This is the third ground for judicial review.

All PCTs have policies and procedures which describe how they should take decisions. The PCT does not have a contract with members of the public because it is not that sort of relationship but in general terms the PCT has a duty to act in a “fair” way when it takes decisions. If the PCT has a policy, the legal duty of fairness generally requires that the PCT follow its own policy.

Public bodies such as PCTs have a wide discretion as to how to take decisions but once the PCT has nailed its colours to the mast in a policy which sets out how it is going to consider a decision, it may well be found to have acted unfairly when it does not to follow its own policy.

In a procedural challenge the patient does not challenge the final decision as such, but challenges the fairness of the procedure by which the decision was made. So the message is simple – if you have a

procedure “stick to it”. You may be at risk if you do not follow your normal processes when considering IFR Requests. This includes decisions taken outside of official meetings or fast tracked via email discussions.

But procedural fairness involves more than just sticking to the written procedure. Public bodies generally take decisions away from the public gaze and the only way that the public know what has happened is to look at the paper trail that is left behind. This is why the courts pay so much attention to the paperwork showing how a decision was taken and that all relevant factors were considered and that the decision was not based on a factor that was legally irrelevant.

But let me admit that this can be unfair. An IFR panel will consider maybe 10 applications at one session, with the members having read the papers the day before and debating each one in sequence, but maybe only taking 10 minutes over each decision. Even then the meeting is nearly 2 hours long.

Then, a few months later, the paperwork leading up to the decision will be considered in great detail over a 2 day case in the High Court. There is a danger that every word of the reports and minutes and the nuances attached to each word, will be considered by a team of top lawyers and a Judge, to look for inconsistencies or inaccuracies in the way the decision was taken.

There is, in reality, nothing the PCT can do to prevent its decisions being criticised – fairly or unfairly - but where there is a threat of Judicial Review it is important to make sure that the Court has a complete paper trail showing how the decision was taken from beginning to end. In practice there is a great deal PCTs can do to protect themselves. I would recommend that listeners work through the relevant review exercise on the website in order to identify steps that they can take to help develop a reliable paper trail.

Remember, in a case that might go to court, a judge may have to read all your paper work and will not necessarily be familiar with such cases or your processes. Bear this in mind as you produce overviews and summaries designed to show a lay person ‘this is our policy, this is the evidence in this case and these documents show we have followed our policy.’

Finally a brief word about Human Rights claims which are the final grounds for Judicial Review. The European Convention of Human Rights contains a delicate balance between the rights of individuals and the duties on state bodies. This is a technical area of law but, even though human rights arguments are often deployed in IFR cases, they rarely if ever make a difference to the final outcome. So if a PCT properly follows its own policies and properly pays attention to government guidance it is highly unlikely to breach anyone’s human rights.

Next, a word about how the courts look at the vexed issue of exceptionality. To put this in context it may be helpful to describe the legal framework within which these decisions emerge.

First, when considering whether to fund a treatment for an individual where the PCT policy is not to fund the treatment generally, there are generally four things that the PCT's IFR policy ought to ask the PCT to consider, namely:

- a) Does the patient have exceptional clinical circumstances;
- b) Is the requested treatment likely to be clinically effective;
- c) Is the requested treatment likely to be cost effective;
- d) Is the requested treatment likely to affect other patients, in which case the matter should be dealt with as a request for a change of policy and not as an individual case.

Exceptionality – or perhaps more accurately exceptional clinical circumstances - are therefore important because the gateway in the above reasoning process. It is the potential justification for allowing NHS money to be spent on an individual patient when the general policy of the PCT is not to commission the treatment in question. Proving exceptional clinical circumstances gets the patient's case onto the agenda. The other three issues should help decide whether the case should be funded and they should be considered separately, with only limited reference to exceptionality.

So how does this arise as a matter of law? Let me set out a few general principles which operate in this area:

1. It is a matter for the PCT how it allocates its resources, so long as it does so reasonably. This will involve “difficult and agonizing judgments as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients.”
2. In reaching these decisions, PCTs should consider the nature and seriousness of each type of illness, and the effectiveness of various forms of treatment. That is the job of the annual commissioning round.
3. Following the *B v Cambridge* decision discussed earlier, it is very difficult, if not impossible, to succeed in a legal challenge to a decision not to fund treatment on the grounds that it took into account financial restraints and the particular circumstances of the individual patient.
4. It can be lawful for a PCT to have a policy not to fund a reasonably priced and clinically effective treatment, unless the patient has exceptional circumstances. There may of course be some treatments which are either so expensive or so lacking in evidence of clinical effectiveness that it is impossible to envisage circumstances in which the PCT would be prepared to fund the treatment. That is not unlawful. The NHS is rightly wary about funding anything which relies on the placebo

effect alone and almost certainly would be within its rights not to fund a treatment that cost £1M per year for a patient, whatever the medical benefits. Exceptionality applies when deciding cases about reasonably priced and clinically effective treatments.

But if the PCT does have a policy to fund treatment in exceptional clinical circumstances, what does this mean in practice? What does the patient have to prove? However it must be possible for someone to show that they could be exceptional or the policy is, in reality, a blanket ban.

All patients have unique individual circumstances but few patients, however individual their circumstances, are exceptional. It may help to consider a school full of children who all take part in the school sports day. How many can properly be described as “exceptional” athletes so that, for example, they should be given the chance to train to reach the Olympics team? Winning your class 100m race – that is being best amongst 30 – is not enough. Being best in your year amongst say 200 pupils might be starting to get there but we would not describe every year winner as being exceptional. Being one of the top pupils the school has ever produced for the 100m for 14 year olds may well qualify a child as being an “exceptional” talent, and thus may get the child onto the national training programme. It’s a test of being in a tiny minority in comparison to the child’s peers. In this case the bar is very high and rightly so because only a few can have specialist coaching.

It’s much the same with medical investment. The general duty of the PCT – as a tax payer funded service which is contributed to by all - is to be as fair as possible in the allocation of resources between different patients in the same clinical circumstances. So there is a heavy presumption that a treatment should not be funded for a few which is refused for the many.

So a patient who is required to demonstrate exceptional clinical circumstances should do just that – demonstrate exceptionality as compared with other patients with the same condition and at the same stage of progression.

Patients often seek to support an application for individual funding on the grounds that their personal circumstances are exceptional. This can include details about the extent to which other people rely on the patient or the degree to which the patient has contributed to society or is continuing to contribute to society. Most PCT policies appreciate that everyone’s life is different and such factors may seem to be of vital importance to patients in justifying investment for them in their individual case. However including non-clinical, social factors in any decision making raises at least three significant problems for any PCT.

The following factors may be relevant here:

- It is very difficult for a PCT to reach a view of the reliability of any material put before the PCT concerning non-clinical factors. Patients are in a vulnerable situation and how can a PCT know if the information that the patient is providing about non-clinical matters is true or not?
- The essence of an individual funding application is that the PCT is making funding available on a one-off basis to a patient where other patients with similar conditions would not get such funding. If non-clinical factors are included in the decision making process, the PCT may be concerned

whether it is being fair to other patients who are denied such treatment and whose social factors are unknown.

- PCTs should be committed to a policy of non-discrimination in the provision of medical treatment. If, for example, treatment were provided which had the effect of keeping someone in paid work this would tend to discriminate in favour of those of working age and against the retired. If a treatment was provided differentially to patients who were carers this would tend to favour treatment for women over men.

Most PCTs seek to commission treatment based on the clinically presenting condition of the patient alone. The requirement of fairness means that most PCTs, lawfully in my view, exclude the patient's non-clinical circumstances when looking at IFR applications.

Having looked at what judicial review is in the context of IFRs, and considered the grounds on which a judicial review may be brought, the final part of this lecture seeks to summarise – in very general terms – what actually happens in a Judicial Review claim. There are 4 stages:

- Pre-action protocol letters
- The issue of proceedings
- Permission, and
- The final hearing

There is a detailed court approved protocol which explains what parties should do before they ever get to court in a Judicial Review case. It involves an exchange of letters which requires the person who is bringing the action – called the Claimant – to explain the reasons why he or she feels the public body has acted unlawfully. Then the public body gets a chance to respond, it can either accept that it has messed up the process and agree to start again or correct the Claimant on the facts or the law, and defend its position. It is really important to take these letters seriously. PCTs should provide a full and prompt response to these letters because they form part of the basis on which the judge will decide whether to grant permission to proceed to a judicial review.

If the exchange of letters does not resolve the issues the Claimant starts a formal claim in the High Court – in London, Birmingham, Cardiff, Leeds or Manchester. The case is set out in the “Grounds” which explain the facts and why the Claimant says the public body has acted unlawfully. The public body – by now known as the Defendant – serves an Acknowledgement of Service containing Summary Grounds of Defence to explain its version of events and set out its defence to the claim.

Then a Judge looks at the papers and asks whether the Claimant has established an arguable case on the papers. If so permission is granted to proceed with the case. If not – and not is the answer in 87% of cases – permission is denied. The Claimant can have another go to get permission in front of the Judge in person to try to show that the judge on paper got it wrong, but that is rarely successful.

For the 13% of so of cases that get permission, the Defendant has 35 days to file written evidence and put in full Grounds of Defence. Then the case is listed for a final hearing for a decision by the Judge on the evidence.

It's very rare for anyone to give evidence in person in a Judicial Review. It's a review of the decision of the public body primarily on the paperwork that the public body provides, supported to a limited extent by written statements to explain the paperwork. However there is no dramatic cross examination and, in general the matters is looked at and judged from the Defendant's perspective. However, this really underlines the reasons of making sure the initial paperwork is absolutely spot on.

Judicial Review cases are tried by a Judge not a jury, and the judgement – like IFR decisions – has to give reasons.

I hope this talk has been useful in explaining what Judicial Review is and how it works. All public bodies should operate within the confines of public law duties and thus should be mindful that almost all decisions may be subject to Judicial Review. Most of the steps that I have outlined above to put yourself in a position to explain your decisions and thus defend any potential Judicial Review are organisational common sense and part of good corporate governance in any event. But I will end where I started. Please keep the risks in perspective. Successful Judicial Reviews against NHS bodies are as rare as hen's teeth.

The vast majority of threats of JR amount to nothing and fail, but if a threat of Judicial Review is made, it's important to take it seriously and ensure that you have some expert legal advice.

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## References

1. Wade H, Forsyth C, Administrative Law. Oxford University Press