

PCT decision making in Priorities Panels

**A review of the literature and management of
decision making processes in resource allocation
for commissioning treatments:**

Recommendations for PCTs and SHA

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Executive Summary

The context for PCT decision making on resource allocation is complex. There are legal, ethical and managerial considerations. There is some direction on priorities nationally, but the processes need to be developed locally. The research for this report examined the law, ethics, health economics measures and studied some examples in practice. The recommendations draw on theory and practice. Fundamental is the establishment of a local decision making framework, together with the provision of a specialist regional service to support PCTs. Reference to Recommendations (section 6) offers cross references to the relevant findings, evidence and tips in the report.

- PCT boards should adopt the recommended ethical decision making framework, with clearly defined principles, considerations, criteria and required information, reflecting both ethical principles and legal duties, applying to all commissioning. It should be adopted and adapted for local usage (section 6.1).
- There should be established a Regional Priorities Forum, which should facilitate consensus in adopting a region wide decision making framework, also applying to specialist commissioning, supported by a Regional Priorities Research Team, which would provide to PCTs a common core technical and information service on prioritisation and exceptional treatments (section 6.2).
- PCT should have a Priorities Panel, which embraces Exceptional and Out of Area Treatments and is accountable to an executive Commissioning Group or to the Board, which delegates financial responsibility to the Panel, to enable decisions to better reflect population need and impact on resources and a properly constitution of Appeal Panel, which takes into account legal requirements (section 6.3).
- Officer role definition is needed to balance conflicting interests. A case manager should be the patient advocate with a key role in ensuring timeliness, a scientific officer should advocate effectiveness, a finance officer efficiency and cost implications and a public health officer health gain and community health needs (section 6.4).
- Appropriate training of staff involved in resource allocation decision making, especially chairs of committees is essential. The needs are likely to include the decision making framework, law, ethics, health economics, scientific assessment. Technical staff also may require training in presentation to lay audiences (section 6.5).
- Corporate governance should include review of the decision making processes using a validated tool and board leadership should ensure adoption, fair implementation and compliance with policy and the decision making framework (section 6.5).

PCT Exceptional Treatments Policy

A review of processes for decision making

1 Introduction

1.1 Background

A London PCT originally commissioned this work to answer the question,

"How should the PCT make decisions about Exceptional Treatments?"

These are treatments which fall outside the normal service level agreements between PCTs and provider organisations and arise because the treatment is not mainstream NHS treatment, is often exceptionally expensive and is usually a new drug treatment, which has not yet been fully approved for routine use in the NHS. The PCT wished to know whether its processes were appropriate and also whether all was being done to ensure the appropriateness of the decisions it made, especially when a refusal of funding was agreed. It was recognised at the outset that this was a challenging problem, as PCTs were required to ration their resources without national guidance. It was soon appreciated that this piece of consultancy, although commissioned by one PCT, was applicable to all, as the problem of rationing or priority setting is a shared one. This report was written for a wider audience. The report seeks to illuminate a way forward for PCTs, rather than resolve problems inherent in the structures, policies and funding of the NHS. In the long term, the solutions are likely to require national initiative.

1.2 Methods

1. Consultation with the literature: Using the search criteria of "Decision making for Exceptional Treatments" no articles were found. A selection was made from a wider search of "ethical decision making in health services", "commissioning priorities in NHS" and "cost effectiveness of new drugs".
2. Reference to legal authority on public law duties
3. Consultation with the leading UK academic on the subject of NHS rationing, resources and ethics and consulted his books.
4. I met and discussed the issues and the views of local stakeholders about how the process works currently in one PCT.
5. I sat on a number of PCT "Priorities Panel" meetings.
6. Brainstorming with some PCT public health staff
7. Consultation with other public health staff in the sector.
8. I contacted several PCTs across the country, which were known to have given the processes some thought and requested documentation of their policies, processes and committees
9. Analysis of the research and recommendations followed and they are presented here with practical tips being bulleted in the text

1.3 The national context

There is no national framework for deciding how to ration resources to be spent on new technologies, although certain national priorities are set. New drugs have to be licensed by the Medicines and Healthcare Products Regulatory Authority (MHRA) before they can be prescribed and they are only licensed for use in a particular clinical context. Doctors can legally prescribe drugs once they are licensed - and under certain specific situations even when they are not. But the NHS usually only agrees to fund the prescriptions after the National Institute of Clinical Excellence for England & Wales (NICE) has advised them as suitable for use in the NHS, based on their cost effectiveness. This body was established to promote good practice but also to contribute to the process of improving effective use of resources by a process of prioritisation or rationing.

One category of NICE approved interventions is technology appraisals, which since 1993 have had the legal status of directions and must be implemented within three months. Other guidelines are discretionary but often form part of national policy to be implemented and performance managed and inspected against national standards, which include NICE recommendations.

However the NHS bodies to which the guidance is issued have fixed budgets. Compliance with NICE guidance is estimated at over £800 million, with drug costs rising faster than NHS investment, or potential efficiency savings. Thus it is inevitable within the system, that PCTs will find themselves unable to balance their budgets if they fund all NICE approved drugs. The Audit Commission Report in September 2005¹ found that only 25% of NHS bodies surveyed were implementing NICE appraisals of drugs and treatments within the required three months. A third of trust said that NICE had issued guidelines that they were unable to fund in 2002/03, 85% reporting funding was insufficient.

Observers have criticised NICE guidance as not helping decisions between competing technologies² and suggested that NICE has misunderstood how its ethical decision making framework fits into prioritisation decisions³. Health bodies are subject to the media interest in new treatments, pressures of patient choice and requirements to invest in new technologies by NICE, that has the comfort of making those requirements outside the budgetary regime of the NHS.

PCTs are also increasingly being asked to fund drugs, which had been licensed but not yet received NICE approval. Pressure on NICE to increase the speed of its assessments built up in 2005 after the Cancer Charity BACUP reported 23 new drugs were awaiting appraisal, at a time when the government had reduced the funding of NICE⁴. It reached its peak when the Secretary of State made a controversial public statement about the funding of *Herceptin*⁵, which at the time had not received NICE approval for use in early stage breast cancer.

This paper was being researched at the time of the challenge by Mrs Rogers of the refusal of PCT 5 PCT to fund her treatment with *Herceptin*, which was upheld by the Appeal Court on April 12th 2006⁶. This was on the grounds of the illegality of the PCT processes of decision making. There was further publicity about "failure" of the draft guidance of NICE in April, advising against use of *Exubera*, an insulin inhaler

on the NHS, until further assessment of its cost effectiveness had been completed. The drug had already been given approval by the European licensing body and both doctors and patients wished to use it in the UK. On May 23rd a woman was refused funding for *Rituximab*, a drug for non Hodgkins lymphoma, by a PCT which was £20 m in debt . PCTs are receiving applications for funding drugs for the wet form of age related macular degeneration, which causes blindness.

We may well see a legal challenge to decisions not to fund this and other drugs awaiting NICE assessment. Thus PCTs have no comfort zone in being immune to challenge a decision to decline funding on the grounds of pending NICE assessment.

Thus this research must consider how PCTs are to honour:

- a) DH requirements on financial management and legal duties to maintain financial balance.
- b) The expectation and duties to provide a comprehensive service
- c) The legal duty to deliver or commission high quality and clinically effective services
- d) The legal duties in the way that decisions are made
- e) Ethical principles in refusing to fund what clinicians and patients request
- f) Ethical principles in funding a request, at the cost of making another's need a lower priority

These they will need to do in the context of the need to be responsive to the competing needs of their service users, the population, political pressures and to high publicity demands.

2 Legal Duties of PCTs

2.1 Legal duties

The framework of legal duties is laid down in statute, although those covering the NHS are complex and scattered across many Acts of Parliament, some many years old. Much law in the NHS is made as secondary legislation, that is a statutory instrument issued as a directive from the Secretary of State to organisations. The legal system has a common law tradition, which means that the law is developed in many areas in an iterative way as the legislation is interpreted by cases. Finally the law is influenced by the jurisprudence of the European Court of Justice and increasingly by the *Human Rights Act*, which has made more accessible the rights of the European Convention on Human Rights and jurisprudence of the European Court of Human Rights in Strasbourg.

A distinction that may be useful is to understand the difference between private law and public law. The former govern the relationship between individuals and thus a patient suing a doctor for medical negligence (or in practice the employing authority through Crown Immunity) is in the law of tort. The remedies here in theory (in practice they are increasingly difficult to access) include damages. Public law concerns the conduct of public bodies and their duties to individuals. Here the action of challenge is usually judicial review and the remedies are declarations of illegality, a demand to review a decision or an order to do or refrain from doing something. The decisions about exceptional treatments are therefore governed by public law. The advent of the Human Rights Act has now raised the possibility of there being additional challenge in the English court of breaching an individual's human rights. In the health field, a public body must make decisions, which are mindful especially of the individual's right to life (Article 2), the right not to be subjected to inhumane or degrading treatment (Article 3), the right to liberty (Article 5) and the right to respect for privacy and family life (Article 8). There is now the possibility that the remedy of damages can be available under certain circumstances for breaches of fundamental human rights.

Thus health law is not something that is simply looked up in a book, but a fascinating and dynamic area, where there will be some gaps, some uncertainties, and importantly where old cases are not necessarily a good predictor of current and future law. It is impractical and unnecessary for PCTs to take legal advice on every significant decision, but it is important that the decision makers understand the basic principles of the relevant law and that the PCT has established a sound framework for making decisions, so that decision makers can understand what risks they are taking, what precautions are wise and when advice is needed. The sections that follow are a brief overview of some relevant areas of law, with some practical advice about the implications. The cases are referenced in the bibliography and for further reading the leading academic authority is Christopher Newdick⁹.

2.2 Financial duties

PCTs like all **NHS** provider organisations have statutory financial duties. The board of a PCT has a duty to ensure that business is conducted in accordance with law, and that public money is safeguarded and properly accounted, and used efficiently and effectively. Its chairman and non-executive directors are responsible for monitoring the executive, and are held to account by the Secretary of State in discharging this responsibility. The Chief Executive (CEO) is the accountable officer responsible for financial management. There are also specific duties of the audit committee in internal control and risk management. There is a duty upon each member of the board to ensure proper financial governance and reporting systems. Auditors also review whether the statement on internal control has been presented in accordance with relevant requirements; and have a responsibility to assess whether there are proper arrangements to secure economy, efficiency and effectiveness in the use of resources.

There is a statutory duty for NHS organisations to break even: A PCT must ensure that its expenditure in year, attributable to its functions, does not exceed its income¹⁰, and if it does the Secretary of State has intervention powers and can suspend officers". The current accounting requirement, laid down by the Department of Health, is the resource accounting and budgeting (RAB) regime¹². If a PCT reports a deficit in one year, its income is reduced by that amount the following year. In addition to affecting the following year's income, the PCT's in-year deficit is added to the balance sheet and carried forward to future years to give a cumulative figure. This is used to assess whether the PCT has achieved its statutory duty to 'break even taking one year with another'. The combination of a carried forward cumulative deficit and a reduction in income the following year is often known as a double deficit.

- *Tip1: The relevance of this to decisions about funding exceptional treatments is to understand the statutory duty to control expenditure and further to appreciate that decisions on funding any individual treatment will probably vary depending on the financial position — in particular whether the PCT has a double deficit, at the time of the decision.*

2.3 The duty to provide services

The Secretary of State has a duty to promote a comprehensive health service, including treatment and prevention and to provide premises and services "to the extent that he considers necessary to meet all reasonable requirements"¹³. The duty to provide is delegated to organisations in the NHS for most services. The duty to provide treatment or prevention to meet all reasonable requirements is not absolute¹⁴.

This duty has to be provided in the main without charges to patients¹⁵. It is interesting to reflect whether this was the key factor in North Dorset PCT changing its plan to only fund one cochlear implant for a deaf child, instead of two, when the clinical opinion was that two was the appropriate treatment¹⁶. This is especially since the provision of the second at the same time would only incur marginal increase in

cost. On the other hand providing only one cycle of IVF treatment has been established as legal.

- *Tip 2: If a PCT agrees to provide a treatment, providing part and requiring co-payment runs a higher risk of being found illegal than not providing a new treatment at all for good resource allocation reasons.*

Many directives are issued from the Department of Health, which have stipulated various aspects of service delivery and development, and by creating national service frameworks and performance targets, have given priority to some services over others. When a low priority service creates a problem of access, or an attempt is made to stop a service or there is a demand to start a new one, the question may arise as to what constitutes the duty to provide the service. Especially if no fresh directive or guidance is issued, then the health body deciding the matter may be vulnerable to challenge in law. The challenges in various cases have shaped the law and helped define the extent of this duty. The next section outlines the nature of these challenges.

2.4 Judicial review

As the PCT is a public body, it cannot be sued for its decisions in the same way as an individual whose action or inaction causes damage. It is challenged by way of judicial review, which focuses on the decision making process and the proper use of powers of the organisation, rather than the merits of the decision. The traditional grounds are illegality, irrationality and procedural impropriety¹⁸. The unreasonableness ground (irrationality) - called *Wednesbury* after its eponymous case, was "so unreasonable that no reasonable authority could have reached that decision"¹⁸. But changes in the society and the bench led to the threshold being lowered where fundamental rights were at stake¹⁹. The incorporation of the *European Convention on Human Rights* into English law by the *Human Rights Act*²⁰ requires all public bodies, including the courts, to act compatibly with the Convention and has further hastened the broadening of the grounds for judicial review, with proportionality being used in the **NHS** and irrationality no longer being sufficient²¹. Under the influence of the Strasbourg jurisprudence, the courts have adopted proportionality ("*a fair balance between protection for individual rights and the interests of the community*"²²) as a ground²³. Some authorities now add the grounds of *equality*²⁴ and *legitimate expectations*²⁵. In this section I will briefly consider the classical grounds for judicial review in order to understand past cases and the nature of more recent developments.

First the ground of *illegality*: Essentially this is about whether a PCT is acting within its powers. It is important for a PCT making decisions about whether to fund provision of a service or treatment, to understand whether or not it has discretion to decide and this is well described by Newdick²⁶. When the Secretary of State issues a circular, it is only a direction intended to invoke the statutory obligation to implement²⁷ where it unambiguously mandated action. Thus the strongly worded circular urging making *Beta Interferon* available for multiple sclerosis sufferers²⁸ was only guidance and if PCTs interpreted it as binding on them, their decisions could be challenged as acting illegally, by fettering its discretion²⁹. Under the same principle, a PCT would be entitled to remove a GP from their list who prescribed items on the

black list or inappropriately on the grey list³⁰ as that GP was acting illegally, and could be challenged under judicial review for not doing so.

- *Tip 3: The implication of this for PCTs is to determine what should be provided and what need not be provided on the NHS. There is no universal list of approved interventions, but rather a combination of a few mandated items and other exclusions based on prescribing lists or common practice. Most applications for Exceptional Treatments will be new drugs or fall in the category of "might be funded" and be on no list. It is important to check when care packages are being considered what is the duty of the local authority and not the PCT to fund.*

Secondly we turn to the challenge of *unreasonableness*: The historic tendency of the English courts is to adopt a high degree of judicial deference to those who make resource allocation decisions reached its peak with decisions in the 80's. In *Walker* the court did not require a hospital, which had not fully staffed its neonatal ward, to perform a heart operation on a new born child³¹ and even when the need was life threatening, in *Collier*³², the court would not judge the allocation of resources.

An important pre Human Rights Act case is *Child B*³³. A decision was made not to allocate resources (£75,000 in 1995) for a treatment, which many considered still experimental. It had about a 10% chance of saving the life of a child with fatal leukaemia. The court held that it was not for it to decide between conflicting medical opinions or to decide how the limited budget should be allocated. The Director of Public Health (DPH) of the challenged authority stated that the treatment could not be justified on therapeutic grounds and pointed out that the Department of Health (DH) required the ethical use of resources and the proper evaluation of new treatments before transfer to NHS service funding. In effect the Appeal Court chose the medical opinion of the DPH and must have been swayed by his arguments of ethical decision making and lack of clinical effectiveness. The claim of not judging conflicting evidence is no longer tenable, post *Bolitho*³⁴, *Bristol*³⁵ and the *Human Rights Act*. Now such a case would be subject to consideration of the principle of proportionality (see below).

- *Tip 4: The post Human Rights Act environment in which funding decisions for specific treatments are now judged is discussed further below. But for now the implication I wish to draw is the need to ensure decisions not to fund are made on the basis of explicit good evidence, and where there is conflict, it must include proper consideration of clinical effectiveness arguments*

Thirdly, the ground of *procedural impropriety*:

Procedural propriety is the provision by the common law, where a statute is silent, of basic minimum standards of fairness in procedure, called the rules of natural justice. The old cases — none of which are in the health field - focus on an entitlement to a fair hearing³⁶ with a limited duty to give sufficient information to enable the applicant to make representations³⁷.

Prior to the Human Rights Act the implication for a PCT would be:

- *Tip 5: Is the procedure adopted to make the allocation decision fair, with sufficient information being given to the applicant to enable it to be challenged*

Fourthly the ground of *legitimate expectations*: Under certain situations (cases have mainly concerned residential care) where a specific promise has been made to a group, a substantive legitimate expectation may have been established, from which an organisation cannot legally resile, without an overriding public interest to do so ³⁸.

- *Tip 6: Thus a PCT should recognise that if it adopts an explicit policy to fund a new drug for a specified and group of named people, it may have created a legal obligation to provide it in the future. A policy which lays down criteria which would include the capacity of the group to benefit, but also other considerations such as other need and finance would still leave flexibility in decision making.*

Fifthly there is *equality*, which is essentially a requirement that there is not discrimination against one group and an example of this is the Canadian case below. *Proportionality* and *human rights challenges* are also more conveniently discussed below.

2.5 The impact of the Human Rights Act

2.5.1 Awareness and positive action

The Human Rights Act has ushered in a greater awareness of the needs of public bodies to consider the impacts of their decisions and decision making processes on individuals, as judged against universal standards of the European Convention for the Protection of Human Rights and Fundamental Freedoms (The Convention). In the context of this paper, it is only possible to sketch the briefest outline of the significance for access to health care. There is an NHS Toolkit ³⁹. The societal and legal changes discussed above have led to a change in the way that resource allocation challenges are handled by the courts, so that there is now a greater scrutiny and some challenges are succeeding. This is well discussed by Newdick ⁴⁰.

Article 1 requires public bodies to take positive action to secure Convention rights and thus simply refraining from action may be insufficient. The implication for health bodies is:

- *Tip 7: Ensure that staff are trained in awareness of the Human Rights Act and in particular the fact that there is a positive duty on PCTs to secure rights for its population, and that staff can access appropriate information and advice to assist in their decision making.*

2.5.2 Equality and Article 14

Article 14 is the requirement for non discrimination against groups because of their sex, race, religion, disability, disease etc. It is breached by blanket bans. All cases

2.5.3 Fundamental rights - Articles 2, 3 and 12

There are different types of rights, some fundamental and others qualified. Relevant fundamental rights are right to life (A2), right not to be subjected to inhuman or degrading treatment (A3) and the right to marry (A12).

It is most unlikely that many breaches of Article 2 or 3 will enable patients to access treatments that they would not have had prior to the passing of the HRA. It is speculation as to whether the baby denied an intense care bed in Collier would have been a breach of A2 or 3. What is certain is that the decision would now have been subject to more intense scrutiny as fundamental rights were at stake. Newdick considers Collier would be decided differently now, not on the basis of an A2/3 breach, but on the basis of the lack of evidence provided for the reasons for not treating the baby.

A study of LJ Laws' speech in the High Court, which required funding for Child B⁴⁴ (see above) before being overruled by the Appeal Court, is instructive. As the judge considered it raised human rights issues, it indicates how the court now, after passing of the Act, might consider A2 cases. He indicated the threat to her life required more than just an argument based on lack of resources. He drew attention to the lack of evidence before the court about what other cases might be prejudiced if the authority were to fund the case or where in the list of priorities a 10% chance of survival came. In other words where there is interference with a fundamental right, such as the right to life, more intense scrutiny will be required of the way the funding decision was made.

The impact of the Act has been considered in a research paper from the Nuffield Trust⁴⁵, which recommendations have been edited below. It is likely that the rights will continue to be used to challenge the non-provision of life prolonging treatment. To ensure compliance the PCT should:

- *Tip 11: Ensure awareness of Human Rights Act and its implications by staff involved in decisions to prolong life or to fund interventions to that effect.*
- *Tip 12: Ensure that the decision makers consider the implications of these fundamental rights in making funding decisions*
- *Tip 13: Avoid non funding of interventions where the risk of death is real and the intervention is likely to avert it, but where the evidence about costs and effectiveness points to the possibility of not funding, it is essential to present and consider evidence on relative need of others who might benefit from the funding and how the priority for scarce resources is agreed.*
- *Tip 14: Ensure there is procedural propriety in the way that the decision is made and any appeal handled*

- *Tip 15: Ensure that there is adequate documentation and transparency about the reasons for the decision, which will withstand more intense scrutiny.*

The right to marry has been unsuccessfully used to challenge the non-provision of various assisted conception interventions. The law is clear that the right is to found a family and not to give birth to a child.

2.5.4 Intensive scrutiny of decision making — procedural propriety

This development of the law, in which the ground of procedural propriety is more tightly defined, has been developing in the common law, but hastened by the Human Rights Act. This is partly because A6 requires a fair hearing for determining civil rights and partly because it has been necessary to ensure proportionality of decision-making (see below). More recently a duty to give reasons has been established.

The process of making the decision must have certain characteristics. There must be a policy, which might be excluding the treatment except in exceptional circumstances; the PCT must apply it and the rules of natural justice must be used in considering exceptional cases. The patient must be given the reasons for the adverse decision, must be given a fair hearing to present his or her case and there must be an Appeal mechanism. In a case of a mental health patient unsuccessfully challenging her discharge placement⁴⁶, the court outlined the requirements for a health body:

- *Tip 16: The patient must be told of the decision and the precise reasons for the decision.*
- *Tip 17: The patient must have the opportunity to tell the Priorities Forum in writing why it should allocate its resources towards him/ her.*
- *Tip 18: The patient does not need to see the material going to the Forum beforehand*
- *Tip 19: The Priorities Forum is not a contested hearing and should not have rules of disclosure as if it was*
- *Tip 20: For an Appeal mechanism to be fair it must have a different membership than that of the original decision making group.*

2.5.5 Article 8

The most relevant qualified human right is respect for private and family life (A8), which may be interfered with by public bodies if the interference is legal and if it is

necessary in a democratic society, for example for the protection of health or rights and freedoms of others. There are cases which illuminate how this right is interpreted: For example, mental health is a crucial part of private life associated with moral integrity. A8 protects a right to identity and personal development, and the right to establish and develop relationships with other human beings and the outside world⁴⁷.

The right also extends to the disabled to participate in the life of the community and to have access to essential economic and social activities and to an appropriate range of recreational and cultural activities. But they explicitly do not include the right to a fair distribution of resources or fair treatment⁴⁸. The State is not required to take every positive step that might possibly promote the emotional well-being of some of its citizens⁴⁹.

A key case that was heard in the Strasbourg court and therefore established the boundaries of the law is *Sentges*⁵⁰. The patient suffered from Duchenne Muscular Dystrophy (DMD), a disease characterised by progressive muscle degeneration and loss of the ability to walk and hardly use his hands. He requested funding for a specially designed robotic arm to give him more autonomy, but his application was rejected, as Article 8 can only be relevant in exceptional cases where there is a special link between the situation complained of and the particular needs of his or her private life. The court went on to say that regard must be had to the fair balance that has to be struck between the competing interests of the individual and of the community as a whole and to the wide margin of appreciation enjoyed by member states in this respect, in determining the steps to be taken to ensure compliance, especially when it involves the assessment of the priorities in the context of the allocation of limited State resources. In other words A8 is not going to enable individuals to claim, by right, services or drugs, which the health body cannot afford to fund.

It has been pointed out that A8 creates positive duties for health bodies⁵¹. It can be breached by disclosure of confidential information about patients. The respect for confidentiality of medical records in the decision making process is of importance. A8 has also been successfully used to challenge the failure of public authorities to provide information to local people in a timely manner about risks to their homes and lives from possible environmental hazards (such as a chemical factory)⁵². Thus there are implications in terms of positive duties for public health and environmental health departments.

The lessons for PCTs from the case law include:

- *Tip 21: Ensure that the decision making process has a proper balance between the needs of the community and the individual, whose application is before it. That will require some systematic assessment of the needs of the community and their relative importance*
- *Tip 22: Ensure that applications for funding for non drug and non treatment interventions which improve communications and participation in the community of those with disabilities and mental illness are carefully*

considered and not dismissed out of hand

- *Tip 23: Ensure that applications for Exceptional treatments are handled with due respect for patient confidentiality*

2.5.6 Proportionality

The assessment of Judge Munby⁵³ is that the most important effect of the Convention has been the provision of new tools for the judiciary to fill gaps in the common law and the way in which we analyse the use of power and decisions of public bodies. The most evident of these is the substitution of the flexible Convention principle of 'proportionality' for the inappropriately high hurdle of the *Wednesbury* test of irrationality. It is now the case that where a 'victim'⁵⁴ seeks judicial review on the basis of a breach of a Convention right, any interference with rights must be proportionate to the intended legitimate aim or objective being pursued⁵⁵. This means that even if there is a legitimate reason for interfering with a particular right, the desired outcome must be sufficient to justify the level of interference proposed.

This test involves balancing different interests — such as those of the individual applicant for exceptional treatment funding with those who await service improvement, which depends on the availability of new funding. Note that the action or decision has to be legal in the first place and that the potential interference with a Convention right needs to be identified prior to the decision. The proportionality test prevents arbitrary decisions and establishes a degree of rigour and objectivity into decision making processes. It requires former decisions and policy to be studied to determine justification for the interference with the right. Whereas the traditional legal doctrine of judicial review was that it examined the decision making process and not the content of the decision, it is clear that proportionality requires judges to examine some aspects of the merits of decisions^{5b}.

The application of proportionality to exceptional treatment cases can be considered in a hypothetical case of a treatment non-compliant client with multi drug resistant TB. She has failed to complete her treatment and is a public health risk in the community. It is proposed that she is detained in isolation for compulsory treatment. She declines and applies instead for funding for exceptional treatment by Directly Observed Therapy, which requires staff supervising all her treatment in the community, and which the PCT currently does not provide as a service.

Under section 37 the Public Health Act 1984, there are statutory powers of forcible removal to hospital of a patient suffering from infectious respiratory tuberculosis. The powers are subject to the conditions that proper precautions against spread of disease cannot be taken at home, that the infected person creates a risk to others, and that suitable hospital accommodation can be found. Section 38 provides powers of detention of the patient where there is thought to be no alternative suitable accommodation in which proper precautions can be taken to prevent the spread of disease. There are many aspects of these provisions that make them vulnerable to

challenge under the Convention on Human Rights, which are comprehensively discussed elsewhere⁵⁷.

But for our purposes, the use of such a power may result in an unnecessary deprivation of liberty and interference with family life. Article 5 of the Convention provides that everyone has the right to liberty. There is an exception to this provision if the deprivation of liberty is for the purpose of the prevention of the spread of infectious disease, but any deprivation of liberty will be challengeable', and compensation payable for detention, which is not justifiable on the basis of prevention of spread of disease⁵⁹. Any deprivation of liberty must be proportionate to the objective of disease prevention and the onus lies on the public authority to justify detention⁶⁰. Similarly the detention may breach the right to respect for private and family life (A8).

The onus is on the public authority to demonstrate that the exercise of the detention power is proportionate to the achievement of accepted exceptions and any possibility of a less restrictive alternative must be taken into account. Relevant might be the extent to which the usual facilities of home had been made available to the patient in hospital, access to family members, the extent to which the stay in hospital required acute sector services and the degree of risk to the community at the time of proposed detention.

Proportionality requires that the public authority exercising power shows that there are no other less restrictive means of achieving the same end. It is arguable in the case of detention under the Public Health Act that the WHO recommended Directly Observed Therapy (DOT) approach to treatment of TB is a less restrictive means, and should be tried first⁶¹, before any deprivation of liberty is justifiable. It has been said that DOT programmes are more demanding on resources⁶², but this will not in itself justify the use of detention powers. The PCT should gather the evidence for the Exceptional Treatments Panel and in fact should find that the resources argument is weak, now that decision analysis suggests that DOT policies are cost effective, compared with conventional therapy'. By ensuring prompt care, preventing relapses and reducing drug resistance, DOT programmes save money⁶⁴. Homeless patients have longer hospitalisation rates⁶⁵ and a high non compliance rates⁶⁶ and targeting the group to provide appropriate care is likely to be cost saving. Thus if the client's application for funding of "DOT" programme were refused and she were detained under the Public Health Act", a legal challenge of both decisions is likely to be successful as the actions taken are not proportionate because an effective and affordable alternative is available, which interferes less with Convention rights.

2.5.7 Summary of implications of HRA for PCTs

I conclude with implications for PCTs, some questions being adapted from a published practical guide⁶⁷:

- *Tip 24: Note the need to identify when a Convention right is threatened by allocation decisions — is the decision likely to adversely affect the quantity or quality of life, the private or family life of the applicant?*

- *Tip 25: It is important to identify the nature of the right being interfered with and whether it is fundamental or qualified and for the justification for the interference to be appropriate and proportionate*
- *Tip 26: When a decision interferes with a right in some way, it is important to identify a means of comparing that interference with the potential gain from interference*
- *Tip 27: Review whether the interference can be altered so that the severity of the impact of the decision on the individual applicant is minimised*
- *Tip 28: Ensure that the benefit that is expected from the interference is likely to accrue*
- *Tip 29: It is important to use previous decisions as a guide. Where relevant use guidance from professional bodies and identify how similar cases have been judged.*
- *Tip 30: Review what is a relevant consideration and what should not influence the decision. For example it is particularly important to use corporate policy and not allow populist opinion to unfairly sway a decision.*
- *Tip 31: The process requires good documentation and indexing of sources of evidence and of such prior decisions, as well as the reasons for the decision*
- *Tip 32: Ensure that the decision is free from discrimination against an individual or group. For example blanket decisions are illegal but so are covert decisions which exclude funding a treatment or group such as the aged without adequate assessment of individual circumstances*
- *Tip 33: As the decision making process itself is under greater scrutiny when human rights are at stake, is the decision being made sustainable from an objective view point? Non experts in the panel need to understand and support the reasoning.*

2.6 The statutory duty of quality — timeliness

PCTs, as all NHS trusts, have to comply with a statutory duty of quality⁶⁸ (SDQ). The implications of this have been thoroughly researched elsewhere⁶, but the importance for our purpose relates to the timeliness of provision of services, which are accessed via an Exceptional Treatments Panel. The common law, prior to the statutory duty being in force, has recognised that a provider of health care has a duty to provide a safe system of work, in a case in which liability was found for birth asphyxia, where there was an unsafe junior doctor on call system". Although this common law duty has not often been tested in the courts, its existence, quite separately from the required standard of an action in negligence, is indisputable.

In a sense both *Walker* and *Collier*, discussed above, are cases in which delays in treatment were challenged, where this primary liability could have been explored. Another case where the opportunity was also missed was *Hardaker*²¹, where there was a failure to deliver under a service level agreement for back up provision of specialised services for treatment of divers' decompression, resulting in permanent disability. Escaping liability in this case was possible partly because the police service owed no duty of care, an argument that will be less easy to sustain with SDQ and the current requirements of integrated governance across partnerships. But another argument given by the judge was that the claimant had failed to put forward evidence of a better system of providing care at no greater cost. This is reminiscent of *Knight*²², where a prison failed to prevent the suicide of a high

risk inmate, due in part due to appalling medical staffing, and the judge, finding no liability, remarked that no evidence had been brought about the appropriate staffing standard.

It is submitted that both these cases might well be held differently now, post *Human Rights Act*. But the particular lesson for PCTs is that the combination of SDQ, HRA and case law suggests that the system of provision of exceptional treatments itself needs to be safe and no better one possible at similar cost. If a medical accident occurs or a less good clinical outcome is achieved as a result of a defect in the systems of assessing or providing an exceptional treatment service, then without any need to prove negligence, liability may now be found. Thus PCTs and trusts require the process to have some timeliness in handling urgent requests and flexibility in considering more quickly those whose health is affected by continuing delay. It should be pointed out that this may cause some tension with acute trusts applying for funding, as they may share liability, despite not leading the process.

- *Tip 34: PCTs should ensure that the system of assessing and making decisions about exceptional treatments should be timely and flexible enough to respond more rapidly in cases where health of an applicant is deteriorating.*

2.7 Duties to provide individual treatments in human rights era

From the above discussion, it is clear that if all possible treatments are not to be funded, then a decision about any one is inevitably one about priority setting. How far will the courts go in questioning priority setting in the future with the developments of the law in the human rights era? The role of the courts in relation to rationing decisions is undergoing change and is the subject of debate.

A most interesting article on a recent refusal of the Supreme Court of Canada to require funding for an expensive treatment for autism is instructive of the likely direction of future challenges⁷³. The reasons for refusal were that the treatment was not sufficiently medical, it had uncertain cost effectiveness and that it was not discriminatory against those with mental disability, if the comparison was made with other emerging treatments. The academic review of this case and the trend of cases in both UK and Canada⁷⁴ is that the courts are more comfortable dealing with *perceptions* of the participants about the effectiveness of a new treatment, rather than engaging with a comprehensive explanation based on scientific evidence.

The argument is surely correct that in their concern not to be seen to second guess priorities of local health service managers, courts have thus far failed to be sufficiently robust in their role of overseeing the fairness and legitimacy of the process by which the decisions to ration are made, but that is the direction of travel, as cases are litigated.

The implications for PCTs are to:

- *Tip 35: Ensure that there are robust processes for decision making, including considering cost effectiveness, and explicitly explain the co-existence of*