

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

need to be considered on their merits, even though there may be a general policy not to fund a specific intervention, to ensure that an exception is made, where the public body's duty to respect the human rights of the individual so require. The Equality Act 2006 brings together the rights and duties formerly embraced by different legislation such as race, disability and equal opportunity⁴¹. Its main impact is likely to be the duty on health bodies to monitor their compliance – extending the race equality monitoring to gender, religious belief and sexual orientation.

A blanket ban for a treatment of uncertain effectiveness (surgery for transsexualism) is illegal⁴². Whilst the court accepted that such surgery would have a lower priority, it can never be rational to refuse to fund any such cases. Each case must be considered on its merits and the greater the effect of the decision on the individual, the greater consideration is required by the decision maker. Exceptional Treatment policy cannot be discriminatory, excluding some groups. The Appeal Court said in the above case that PCTs must have a policy to take decisions about treatment priorities between different groups⁴³. This should include the ability to assess the nature and seriousness of illnesses, determination of effectiveness of treatments and a means of comparing the needs of different people.

The implication of the equality legislation and A14 is:

- *Tip 8: Ensure adequate recording and monitoring of characteristics of individual applicants for special funding for exceptional treatments or interventions out of area treatments (age, sex, race, religion, disability, and where appropriate sexual orientation)*
- *Tip 9: Avoid blanket bans of funding specific treatments*
- *Tip 10: Ensure that a corporate framework exists in which there is a policy describing priority groups for funding with a process for exceptions to be considered and that the policy is consistently implemented.*

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 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*

benefits perceived by the service user, in the light of poor evidence of clinical effectiveness.

(Procedural propriety).

- *Tip 36: Ensure that the decision is non discriminatory. What group in any particular case the courts will consider as the comparator for measuring discrimination is uncertain. But it is worth considering how fair PCT decisions are by comparing funding of new treatments across groups applying for exceptional treatments, as well as more widely in terms of accessing service.*
(Equality)

The recent *Herceptin* case⁷⁵ illustrates how an English court dealt with a case of uncertain clinical effectiveness. A woman with early stage breast cancer had surgery, some poorly tolerated chemotherapy and radiotherapy and fell into a group of patients who might benefit from the new drug Herceptin. The PCT declined to fund it, on the basis that their policy was not to fund unlicensed drugs and no case of exceptionality had been made out for the applicant.

The Appeal Court found the PCT had acted irrationally, in refusing to fund the drug for a case of early breast cancer. It was not on the basis of the clinical effectiveness arguments of not wishing to fund an "off licence drug", still pending licensing by the European Medicines Agency and being assessed by NICE, nor on cost grounds (about £26,000) but on the legitimacy of the process by which the decision was made. The PCT had not established what exceptional circumstances would qualify for funding and therefore be at risk of either randomly discriminating between applicants on the basis of personal characteristics or effectively having a blanket ban, both illegal.

Ironically the perverse decision of the PCT to submit that financial circumstances played no part in the decision making removed their most likely defence of their decision not to fund. The court is much less likely to challenge a decision if it was a resource allocation one, with higher priorities for funding.

The statement by the PCT was probably influenced by the unfortunate statement in the speech by the Secretary of State for Health on 25th October 2005, reported as encouraging use of Herceptin, subsequently issued in a bulletin, that *"PCTs should not refuse to fund Herceptin solely on grounds of its cost"*. The bulletin had the legal status of guidance and thus there was no requirement to alter local policies as a result.

- *Tip 37: Ensure that they can envisage what exceptional circumstances might qualify for funding, where possible by establishing criteria, but always with a consistent non discriminatory approach, which establishes relevant considerations for exceptionality.*
- *Tip 38: Realise that there is no merit in asserting that prioritising resource allocation plays no part in funding exceptional treatments, and the courts will respect allocation decisions, as long as the process is fair, transparent and rational, and not unduly swayed by popular opinion or political exhortation.*

3 Ethical duties of PCTs

3.1 Ethical principles

The most accessible discussion of application of ethics to resource allocation can be found in the UK ethics network⁷⁶. The Four Principles⁷⁷ widely used in medical ethics, briefly described below, can be applied in resource allocation:

Autonomy: respecting the decision-making capacities of individual people, to make their own reasoned informed choices.

Beneficence: considering the balance between the benefits of an intervention against its risks and costs and choosing the one with greater benefit to the individual patient.

Non maleficence: avoiding the causation of harm and ensuring any is proportionate to the benefits of treatment.

Justice: distributing benefits equitably, risks and costs fairly; so that patients in similar positions should be treated in a similar manner; Non discrimination on grounds of age, sex, race, disability, employment

These principles are in tension with each other: A balance must be struck between in the resource allocation decision, between respect for the individual patient or service user, getting the best quality at lowest risk, and also benefiting the whole population by appropriate policies and interventions, including a fair distribution of resources.

The ethical principles relate coherently but not symmetrically with legal principles. Beneficence and non maleficence are guiding principles in proportionality considerations, justice in equity considerations and autonomy is considered in procedural fairness. But the outlook of the public body is not the same as the individual, the public body giving a higher priority to justice than the individual. Note the very existence of the decision making powers of the public body reduces patient autonomy. Legally the application of proportionality potentially will embrace the balance of all these principles.

3.2 Ethics of refusing funding

In a decision to fund or not an exceptional treatment, funding might be refused because the balance of benefit and risk (beneficence and non maleficence) makes the capacity to benefit too small. But there may be different attitudes to risk by the patient from his professional carers (autonomy). Equally the decision will depend at any one time both on the available resources and on the previous decisions in a given group, to avoid discrimination (justice). That is not to say that once a decision

not to fund a drug for a condition has been taken that decision has to be consistently followed, for we have seen that a blanket ban is illegal. Each decision must consider the circumstances of its case.

3.3 Ethics of agreeing to exceptional funding

The PCT might decide to fund on the basis of the balance between funding an intervention for one individual with high chance of benefit, compared with the lost opportunity cost of benefiting the population in some other way (justice). Such a decision is not precedent setting in that all future decisions of funding the drug for a condition must be followed. The decisions of the PCT build up a case history in which the principles and reasons for decisions should be consistent and not arbitrary, but subsequent decisions cannot be made on grounds of discrimination against a particular group. Those that take a more utilitarian approach to maximise welfare, will look to tools such as Quality of Life Years (QALYs) as a means of quantifying and comparing the cost effectiveness of various interventions. This is now routinely used in PCT Priorities panels.

3.4 Responsiveness to service users — age and chronic disease

Groups of service users may have views or needs about access to treatments, which are relevant to the decisions. Those with chronic disease — and particularly the terminally ill and those with multiple sclerosis are disadvantaged in QALY assessment, as their score is lower, because of their reduced quality of life. Similarly some consider QALYs ageist. Arguably here recognition of a degree of discrimination in the use of QALY score needs to influence the decision to meet the justice principle.

3.5 Responsiveness to needs of population

The PCT is responsible for the healthcare needs of the whole population and thus their needs are a relevant comparison with those, for whom applications for funding are received by Priorities Panels. In a multi-ethnic population, more resource may be needed to enable some groups to access the service that will give benefit. Thus questions might be raised about how the new intervention will reach all who need it.

For those living in socio-economic deprivation, non- medical factors may play a key part in the cause of ill health. But tackling social determinants of ill health and reducing health inequalities is often expensive and requires long term funding. Should an area with a higher than average mortality from coronary heart disease commit proportionately more of its funding to the disadvantaged groups? It is clear that the strong justice arguments for benefit to the population need to be represented in the decision making process as well.

An example of the leading work of Tony Hope in the Oxford Ethox Centre is the debate in the ethics literature about *The rule of rescue*⁷⁸. This is by no means academic and goes to the heart of the question of what the principles and values

underpin exceptional treatment decisions by PCTs. If there is an identifiable person whose life is at high risk, applying for funding of an exceptional treatment, which has some chance of saving that person's life (for example *Herceptin* for early stage breast cancer), when should that funding decision take priority over investing in a preventive intervention which will change the chance of death in a large number of people by a small amount (for example extension of Statin prescribing). The cost per life year saved for the immediate individual intervention is greater than the preventive one. If we assume that cost of either new intervention is beyond currently budgeted expenditure, should a PCT agree to fund the more expensive "rescue intervention"? Professor Hope argues not, on the basis that those who could benefit from the preventive intervention have not been given the opportunity to choose to forgo their treatment, in order to enable identifiable patients to undergo more expensive treatment.

3.6 Responsiveness to political pressures and populism

The irreconcilability of different claims may entice PCTs to be less transparent about their decisions and their impact. This "avoids noise for the government". But whereas such tactical considerations sensibly dictate timing and style of announcement, the tendency not to be explicit is rightly criticised by ethicists and policy advisors⁷⁹, on the grounds that it weakens public accountability. As we shall see, it also increases vulnerability to legal challenge. What this and other research reinforces is that the iterative nature of priority setting requires a process of decision making that takes into account new information and changing circumstances in the budget year.

We have seen in recent months in the UK the power of the media to influence rationing decisions, and in the case of *Herceptin*, inappropriately urged by the Secretary of State. The duty to make the decision rests with the PCT in the context of its own needs and resources. A populist campaign to change that decision does not make it a better one. Indeed, as we have seen in discussing the ethical issues above, the silent victims are those who probably unknowingly suffer the opportunity cost of not receiving the most appropriate and timely treatment, that they might otherwise have had, due to deferment of investment. Funding decisions unduly influenced by popular opinion are inequitable and legally challengeable as an imbalance of considerations (see also below on balancing interests)⁸⁰.

The principle lesson for PCTs is that:

- *Tip 39: A PCT that has clearly adopted a coherent policy for determining priorities is better placed to resist political or media pressure and avoid policy making on the hoof.*

4 Establishing fair decision making processes

4.1 Lessons from literature on implementation

There is little evidence in the literature of decision makers systematically reflecting on evidence, in priority setting. A study in Alberta, Canada⁸¹ showed that the barriers to this were crisis orientated management, time constraints, a lack of skills and difficulties in seeing how to apply literature in practice. Cost effectiveness research answers precise clinical and cost questions, but does not provide information on the wider context that is needed by decision makers⁸². King's Fund research has shown that investigating the cost effectiveness of interventions does not address its impact on the performance of organisations, which fund or provide them⁸³. A wider contextual approach to information needs is required, that is appropriate for managers, and this must be more than a refinement of cost effectiveness research.

Ethicists are critical of NICE's own ethical decision making framework, claiming they misapplied the Accountability for Reasonableness Framework in the way they accepted their Citizen's Council's verdicts⁸⁴. The simple acceptance of NICE priorities or those of a public consultation will not satisfy ethical demands. Patient groups are critical of NICE decision making and so it would seem sensible for a patient representative to be involved in the exceptional treatment rationing decisions, if any trust and legitimacy is to be developed in the PCT process⁸⁵. In a survey in Lincolnshire⁸⁶, it was found that PCTs failed to make the rationale for decision making explicit and accessible, laying them more open to legal challenge. Ham and Coulter judge that the experience in those systems that have adopted a systematic approach to rationing, is that strengthening both the information base to support decisions and the institutional framework in which decisions are taken are both necessary, involving experts and users⁸⁷.

4.2 The need for financial explicitness

The *Herceptin* case showed the unsustainability of the argument that an exceptional treatment decision is made purely on clinical grounds. It may be good politics to claim that a reason not to fund (or indeed to fund) is uninfluenced by financial considerations, but it is not legal. PCTs have strict legal duties of financial management that have to be considered at the time of individual commissioning decisions.

The Audit Commission in its review of organisations that had failed in their financial duties⁸⁸ in PCTs "a marked absence of explicit financial analysis underpinning key commissioning decisions". It recommended that PCTs should publish the financial rationale underpinning all significant changes in commissioning policy and all commissioning decisions involving the investment of significant new resources, alongside any consideration of social or clinical issues.

Even though funding a new drug in one exceptional case may not have a huge financial impact, there may be impacts for the threshold at which the PCT agrees to fund such treatments and so it would be important to consider the likely pattern of need in the community and its effect on the current and subsequent financial years.

- *Tip 40: All exceptional treatments are commissioning decisions. There clearly needs to be an on-going process of sharing financial planning and budget management with all who make commissioning decisions.*

4.3 The Accountability for Reasonableness framework

The most readily used approach to the process of ethical decision making in rationing is *Accountability for Reasonableness*⁸⁹ (A4R). This is designed for populations, but also can be used for individuals or groups, especially where the decisions affect other groups in a significant way. Daniels and Sabin suggest that for such decisions to be ethical they must satisfy four criteria. Some suggestions of what that means in practice are made beneath each:

- **The rationale for decisions should appeal to reasons and principles accepted as relevant by people seeking a mutually justifiable solution**

Tip 41: Have appropriate internal and external stakeholders — including lay - been engaged in setting criteria for decision making?

Tip 42: Is the rationale for the decision explicitly recorded, with the way in which the conflicting arguments were handled?

Tip 43: Have the mission, values and strategic direction of PCT been explicitly linked to the rationing criteria?

Tip 44: Has adequate data and intelligence been brought to the decision making table?

Tip 45: Has information about relative needs and financial situation of the PCT been considered in making the decision?

- **Decisions and their rationales must be publicly accessible**

Tip 46: Is there a formal communication plan?

Tip 47: Is the rationale communicated as well as the decision?

Tip 48: Does the rationale communicated include reference to capacity to benefit, and affordability?

Tip 49: Whether or not funding is approved, does the PCT have the ability to describe the impact on other services or groups of funding the exceptional treatment on other services or groups with needs?

- **There is a mechanism for challenge and dispute resolution**

Tip 50: Is an objective Appeal process formally approved and established?

Tip 51: Is it consistent with the values and criteria of the original decision making body?

Tip 52: Does the Appeal process have all the information that the original decision making body had?

Tip 53: Do the PCT processes permit reconsideration of a decision in the light of new information within the budget year (such as NICE approval, increasing capacity of individual to benefit, or generation of new evidence that was not originally available)

- **There is some formal regulation of the process**

Tip 54: Is the formal process widely understood and seen to be monitored, to ensure compliance?

Tip 55: Is there strong executive leadership to enforce fairness in application of process and to prevent gaming by some stakeholders?

Tip 56: Is there adequate accountability for the process, so that the results of monitoring and review of the process can be considered and changes made in its operation?

4.4 Balancing interests: empowering stakeholders

A study of the process of priority setting in an acute hospital setting, using A4R, showed that the strong influence of executive power limited the inclusiveness and the balance of stakeholders' views⁹⁰. The authors recommend adding a fifth condition of a fair process, namely an "empowerment condition". There was concern about the wide variation in individuals' preparedness to contribute, especially when there were knowledge gaps, and a culture in which some voices were louder than others. At stake was the issue of ensuring all relevant considerations were taken into account and irrelevant ones were not, a category for challenge by judicial review, on the grounds of illegality in English administrative law⁹¹. With this in mind the criterion might be:

- **There should be an effective opportunity for all appropriate stakeholders to independently submit their relevant considerations**

Tip 57: Have all relevant considerations been brought to the panel?

Tip 58: Have the views of the key stakeholders all been represented fairly (eg consultation, equal voice, fair hearing)?

Tip 59: Is the system of voting without pressure to follow a particular line, (eg no compulsion to vote, benefits of secret ballot especially in presence of

executives and line managers, support and time for contributors to gain information and knowledge before they decide)?

Tip 60: Are there any irrelevant considerations that should be discounted before the decision is taken?

4.5 The need for PCT to have a corporate ethical policy

The debate above about the rule of rescue highlighted the need for decision-making processes to properly represent the needs of the population. It raised the question of legitimacy and accountability for decisions. If the PCT wishes to fund a range of exceptional treatments, which are more expensive than population interventions with as good effectiveness that are needed, it should explicitly make clear that overall more lives would be lost and gain consent to that policy. If it does not, then it must make clear the reasons and support its officers in making unpopular decisions which might refuse funding of some new interventions for a limited range of people. What it should not do is to act as if there is no conflict of prioritisation. These are matters of board level policy, which should be agreed, after advice from a suitably constituted Ethics Committee or Priorities Panel, and frame the decision-making processes of its commissioners and priorities panels.

- *Tip 61: Corporate agreement on values and ethical principles that should guide resource allocation decisions, before the decisions are taken, is an important element of good governance.*

4.6 Cost effectiveness thresholds

Agreeing priorities is not an exact science, especially when the principles and considerations may be in conflict. How does one compare extending community palliative care so that more people can have terminal care at home with introducing a new smoking cessation intervention or an expensive new insulin inhaler for diabetics?

Health economists approach the question of relative benefits by devising generic scales to measure benefit, of which the best known is the Quality Adjusted Life Year or QALY. It measures quality of life and length of time it is enjoyed. Thus cost per QALY is a cost effectiveness measure that enables different interventions with different outcomes to be compared. The ethical problems with the scale have already been mentioned as for example those who are old and have chronic disease will score less well. Should those who need treatment such as diabetics receive priority over those who would merely benefit from an intervention, such as, for example, smokers receiving smoking abstinence advice? Thus there may be other considerations than cost per QALY that would be needed to take fair decisions.

But as a measure of cost effectiveness the QALY offers a means of determining how total health care resources should be spent. Theoretically if PCTs only commissioned care, which met a certain QALY threshold, then it would be possible to manage the NHS budget without overspend and in a fair manner. Indeed it has

been argued that the use of cost effectiveness thresholds is the only objective fair way of rationing.

NICE has made clear that there is no single incremental cost effectiveness ratio (ICER) above which new technologies are automatically rejected. But its publications make clear that an intervention is more likely to be favourably viewed if it was under a cost per QALY of £30,000. The choice of threshold involves ethical as well as economy issues and although it will make transparent and equitable the rationale for rationing decisions, such an approach would need to command stakeholder and public support.

These issues were discussed at a conference, which report is useful further reading⁹². NICE reports it uses a flexible approach in which under an ICER cost effectiveness of £20K cost effectiveness is the main determinant, and above that other factors such as innovative technology, features of condition and population and societal value play a bigger part in shaping their recommendations. Above £30K arguments need to be increasingly strong to support funding the intervention. The impact of NICE has been well summarised by Newdick⁹³.

- *Tip 62: Some PCTs have gone down the road of considering an incremental cost effectiveness threshold as a criterion for funding. The importance of doing this within a justified ethical context and with local stakeholder and public support must be stressed. PCTs will also need to consider how explicit or implicit their use of such thresholds is to be.*

5 Lessons from local organisations

A number of locations have been chosen on the basis of available intelligence about well developed systems and processes of decision making. Officers of these PCTs have generously shared documentation about their processes to share learning and intelligence. Drafts have been edited after comments by contributing officers. Many of these organisations are currently going through reorganisations. All found the issue challenging and did not want to attract publicity in a field that was highly litigious. The comments that follow are limited by only being based on the documentation for all but one PCT, which the author visited. A number of the documents were still in development and therefore this can be said to be a snapshot of findings in mid 2006. For all these reasons, the PCTs are anonymous. Two of the PCTs are London organisations.

5.1 A Regional Group — PCTs 1 and 2

5.1.1 The ethical framework

A number of PCTs have built processes using the early publications of three fundamental values or components in an ethical decision making framework⁹⁴. In one such group, there is an ethical framework, which is used by six PCTs, a common Priorities Team, Cancer Network and Local Specialist Commissioning Group. The key components are:

1. *Effectiveness* of treatment (beneficence and maleficence) — that is the extent to which the intervention achieves the intended effect - and value of a particular treatment - how valuable that effect is for that individual, - ie the capacity to benefit, relative to the value of other treatments. If a treatment is ineffective it should not be funded.
2. *Equity* - people in similar situations should be treated similarly, without discrimination. This also embraces the fair allocation of resources based on need. The forum balances this by firstly considering the cost-effectiveness of the intervention e.g. using QALYs; and secondly if the intervention is less cost effective than interventions normally funded, considers whether there are nevertheless any reasons for funding it⁹⁵. Examples might be life saving or improving poor quality of life of chronically disabled.
3. *Patient choice* - patients can choose between treatments of similar efficiency. Also this enables patients to value outcomes which might not be those chosen by the health professions

It is noteworthy how the ethical framework mirrors part of the legal one. The first component reflects the legal requirement for proportionality, but only in relation to individual need. The second is a statutory requirement and equality is itself a ground for judicial review. It also took into account resource allocation for the community, which is an essential part of proportionate decisions. The introduction of

patient choice is based more on ethical than legal considerations, but it can be seen to be a reflection of unreasonableness that refusal of available choice at no extra cost would seem to be irrational and perhaps a way of identifying legitimate expectations. It might permit some consideration of giving a fair hearing. It also chimes with current NHS policy.

This group of PCTs has not specifically listed a fair procedure or acting within powers, but legality appears to be handled as a result of initial processing of applications. This may be considered appropriate, as these may not be viewed as fundamental ethical values, but operational criteria. Other PCTs have included procedural fairness as an ethical value in its own right, in view of the importance legally of due process and procedural propriety and of ethically of respecting a degree of patient autonomy.

Note also that not all PCTs consider efficiency as a value. Its absence as a specific criterion might be thought important with increasing competitiveness of providers, although its consideration may be included in the other principles.

This group of PCTs have their own the Priorities Fora and Case Review Committees for their decision making processes. How this operates will now be studied in one of the participating PCTs, based on published materials.

5.1.2 PCT 1 Case Review Committee

A Case Review Committee deals with referrals for individual patients for treatments that are possible exceptions to previously agreed policy, or not covered by contracts. If a GP or consultant believes that a patient is exceptional, their case will be referred to the relevant PCT and then, if deemed a possible exception on to the Case Review Committee. This is a Committee of GPs, Managers and Public Health Representatives who represent all the Primary Care Trusts in the Region. In particularly difficult cases, the Case Review Committee may seek the advice of the County Priorities Forum, but it is the Case Review Committee who will be responsible for advising the PCT on an appropriate decision.

5.1.3 The County Priority Setting Forum (CPSF)

There is a Priority Setting Forum for the county, hosted by one Primary Care Trust, on behalf of all, which provides an advisory service to the PCT Commissioning Board to help them make difficult decisions on prioritisation. This covers services and exceptional treatments. It makes recommendations about which drugs and treatments should be low priority and which should be high priority.

The functions of The Priorities Forum can be summarised as follows:

1. To consider locally identified innovations
2. To consider potential disinvestments
3. To produce and review lavender statements (services of low priority)
4. To develop and use criteria for prioritisation, to be used as part of an annual prioritisation process to feed into the Service and Financial Framework
5. To advise on local implementation of NICE guidance

6. To give advice on selected, complex individual cases as requested by the Case Review Committee

The decisions of the Forum are available publicly on the internet.

5.1.4 The Regional Priorities Team

The Regional Priorities Team produce evidence based policies and literature searches to inform the Priorities meetings in three counties to decrease postcode prescribing.

5.1.5 PCT 1 Commissioning Board (P1CB)

This is the decision making body. It agrees the services that will be commissioned and holds the purse strings. From the minutes of meetings of the CPSF it is clear that the arrangement, despite being approved in judicial review, is not a totally happy one. Members of the CPSF have voiced concern that the P1CB accepts the decisions that are made for disinvestment more readily than those which require investment. There was also concern whether the P1CB operated its decisions on the basis of the Ethical Decision Making Framework. This raises an important principle of the need for the same framework to cover all groups that were making decisions. There is an Appeal mechanism from individual funding decisions.

5.1.6 PCT 2

Here a representative of the Commissioning Board makes decisions at Priorities meetings and the PCTs own Priorities Panel has access to its own limited budget.

5.1.7 Conclusions from Regional arrangements

In a review of the framework shared by an officer, the following areas were highlighted — equity, evidence of clinical and cost effectiveness, cost of treatment, individual need for health care, needs of the community and national standards. As the framework has developed, the focus is to be more conscious of cost and allocation decisions that affect the community. The addition of Efficiency as a principle would therefore be appropriate

The local process met the adapted *Accountability for Reasonableness* framework (4.3 above) in having rational basis for decisions, public accessibility, a mechanism for challenge and some regulation — but there may be scope for more leadership to ensure compliance and fairness in application of framework by the Commissioning Board. But the framework may not have fully captured the aspirations of Sabin's empowerment condition or my proposal for including the legal requirement for relevant considerations to be met (see 4.4 above). Substitution of Patient Choice by Responsiveness may be a solution.

The ethical framework has been found by several PCTs to be key to the decision making process and echo the view that use of measurements such as QALYs are only decision aids⁹⁶. For example whether or not to consider outcomes valued by

patients, which did not reflect cost effectiveness measures can only be robustly taken if the way in which patient autonomy and choice are reflected in the ethical framework. My conclusions about the framework for this region are:

- *Tip 63: An ethical decision making framework is the most important element of a robust decision making process*
- *Tip 64: Measures of cost effectiveness are an important decision aid but cannot themselves be solely determinative of the decision*
- *Tip 65: The values or principles of Effectiveness, Equity and Patient Choice have stood the test of time and have a sound legal and ethical basis, but they may not be sufficient. It would be preferable to embrace both Efficiency as a principle and the wider procedural propriety issues than simply Patient Choice. Efficiency is widely recognised as a commissioning principle in its own right. One option for developing Patient Choice would be to combine two other recognised commissioning principles – those of User Responsiveness and Relevance. These could operate by requiring "Responsiveness" to all appropriate stakeholders, including the applicant, to ensure all relevant considerations are included.*
- *Tip 66: The model of using their ethical decision making framework to steer the work of a Priorities Forum that oversees the commissioning of services and treatments has merit, as it achieves greater equity by applying the same principles to all commissioning.*

The processes in this region appear to have created some separation of expert advisory decisions being taken within an ethical decision making framework, from executive resource allocation decisions, taken in a different environment. It is essential that the advisory, financial decision-making and Appeal groups operate under the same ethical and legal framework for all their decisions. It is easier to ensure consistency if there is delegation of financial powers to the group considering the information and most used to the complex balancing exercises in decision making, which appears to be the case in PCT2.

- *Tip 67: If the advice and decision making about allocation of resources are split between groups or bodies, it is essential that the same ethical and legal framework needs to cover all decision-making.*
- *Tip 68: Where possible, those given the power to agree priorities in allocation of resources within an ethical framework should also be given the power of committing those resources*

The arrangement of sharing specialist advisory services based on agreed policy, across PCTs appears to have worked well.

- *Tip 69: There is real value in sharing expertise, especially the technical assessments, across PCTs as far as possible, whilst retaining to each PCT the decision making on each case.*

5.2 PCT 3

5.2.1 The decision making framework

The main "principles" underpinning the funding decisions show:

1. An emphasis is on ensuring adherence to evidence base and clinical cost effectiveness
2. Balancing the rights of the individual (and any overriding individual health care needs) with those of the rights of the population
3. Consistency, using a criterion based structured decision making process
4. Transparency. The operational requirements of clear documentation and effective communication would seem to go some way to address the public accessibility criterion of A4R (4.3 above)

The first three would seem to meet the rationality criterion of A4R. In comparison with the Regional group approach, the first principle corresponds with *Effectiveness* and the second roughly with *Equity*, although the need to avoid discrimination is not explicit.

Though autonomy is represented in the second statement above, there is no explicit mention of a *Patient Choice* or *Responsiveness* principle. The strong commitment to cost effectiveness, beneficence and avoiding maleficence would seem to be more dominant values than that of patient autonomy. This might lead to decisions excluding interventions, which are valued by patients more than doctors and in general be disempowering for sufferers. Thus for example perhaps complementary therapies or access to counsellors might be excluded more readily in this inner city PCT. This observation is not to argue one way or the other, but to stress the importance of an ethical framework, which establishes the values and principles that should guide decision making. The PCT has decided by adopting this set of principles that when there is a conflict between autonomy and beneficence, evidence of the latter is limited to arguments of clinical effectiveness. There is a body of academic opinion that doubts the value of meta-analyses in selecting effective treatments and believes that "evidence based medicine" has elevated epidemiological information above other evidence that might be relevant to an individual treatment decision⁹⁷. If a PCT wishes to create space for a shared view of patient and clinician of the benefit of a specific treatment for an individual, despite the lack of epidemiological evidence, and consider wider definitions of beneficence, the inclusion of patient choice and responsiveness would be advisable.

The following are listed as decision making "criteria":

1. Frequency of condition
2. Evidence of clinical effectiveness of treatment
3. Nature, extent and significance of health gain
4. Possible adverse effects of treatment
5. Availability and clinical effectiveness of alternative approaches to care, which are comparable and more cost effective

6. National guidance (and its evidence base) (NICE)
7. Evidence of cost effectiveness
8. Cost of intervention including long term
9. Human Rights Act considerations
10. Balance of duty to individual, patient subgroup and towards its population
11. Financial considerations including available resources
12. Any overriding clinical need of the patient
13. Other relevant healthcare issues

5.2.2 Treatments Outside Service Level Agreements (TOSLA) Panel

There is a Treatments Outside Service Level Agreements Panel (TOSLA). Its role was originally advisory but newly adopted proposals establish it with delegated financial power. Its aims are to:

1. Make decisions on behalf of the PCT on funding individual treatment requests on the merits of each case
2. To set a framework for making decisions on funding individual treatment requests.
3. Provide data to inform PCT about future inclusions and exclusions in service level agreements (six monthly).

It is accountable through the commissioning director to the PCT board. Its membership includes a coordinator, secretary, pharmaceutical advisor, member of Professional Executive Committee, public health specialist, commissioner, non executive member and a clinical governance representative, with advisory expert consultants as required.

It has a useful task list in which roles of members of the panel in processing an application are laid out chronologically. This includes consideration of support from NHS professional, local registration with GP, non coverage by a service level agreement, requirements for further information. The application form lays much emphasis on grading strength of evidence of effectiveness with references. The brief of evidence used by the panel is prepared in accordance with written technical guidelines⁹⁸, which are part of the PCT TOSLA policy/terms of reference

It has specific term of reference to avoid conflicts of interest, which requires declaration of interests of members or advisors and another addressing confidentiality requirements.

5.2.3 The Appeals Panel

A separate Appeals Panel is constituted where there is a disagreement over the original panel decision, rather than a change of evidence or patient circumstances. The Appeals Panel is chaired by a non-executive and includes a non-executive member, Professional Executive committee member, Chief Executive (or other corporate director) and a Public Health consultant. It only receives written information but invites the responsible clinician to be present. It reviews whether the

decision followed an appropriate process, considered relevant information, kept to its terms of reference and made a fair and reasonable decision.

Its role is to uphold the decision or ask the TOSLA panel to reconsider the case. It can also substitute its own decision, which is discussed below under PCT 4. It has written requirements about informing the patient. This clearly meets the mechanism of challenge criterion of A4R (see above 4.3)

5.2.4 Managed Entry of New Drugs

There is a proforma for proactively considering entry of new drugs, which collates information and clinical views and assesses priority for future funding.

5.2.5 Conclusions from PCT 4

The following observations may be useful:

- *Tip 70: The exclusion of a Patient Choice or Responsiveness principle should only be taken explicitly, mindful of the lower value thereby being placed on patient autonomy.*
- *Tip 71: The blurring of the distinction between principles (eg Effectiveness), Criteria (eg a specific cost effectiveness threshold) and Information required (eg possible adverse effects) is common in the PCTs reviewed. It reduces clarity and obscures the attempts to ensure decisions do comply with policy and are consistent.*
- *Tip 72: The proforma for grading levels of levels of clinical effectiveness may be useful to copy*
- *Tip 73: The inclusion of a clinical governance representative and a set of criteria which focus on outcomes of local provider are valuable ways of focusing on quality in practice and not just basing decisions on theoretical evidence from literature.*
- *Tip 74: The inclusion of specific requirements for handling conflicts of interest is essential*
- *Tip 75: The need to observe confidentiality in handling applications is commendable. Design and maintenance of the process of decision making should be within the regular purview of the Caldicott Guardian. The need to meet the public accessibility requirement of A4R (4.3 above) is in tension with this, but may be met by the periodic reports to the Board, providing accountability and transparency.*
- *Tip 76: The Managed Entry of New Drugs proforma may be useful*
- *Tip 77: The operation of the Appeals Panel with a NED Chair, access to the information put before the original panel, the presence of lead clinician, the*

patient notification requirement and facility to remit the decision back to the panel are appropriate and meet legal procedural propriety requirements. It is questionable for there to be a power to substitute its own decision (see below).

- *Tip 78: The monitoring of the process and enforcing compliance (formal regulation criterion of A4R 4.3 above) is less clearly described in this and other PCTs and could beneficially be considered by others seeking to establish new processes.*

5.3 PCT 4

5.3.1 Framework for decision making

The policy is to base the decision on the following "criteria", which are formulated in the request form

1. Quality of Clinical Care
 - a. clinical effectiveness
 - b. competency of provider
2. Quality of Life — impact on individual
3. Health Gain — health outcomes of individual
4. View of Stakeholders — patient, GP, specialist
5. Equity
 - a. Precedence for funding
 - b. Is it effectively a new service development
 - c. Does it fit patient selection criteria esp NICE guidance
 - d. Priority in relation to opportunity costs and alternative spend on other needs of whole population
 - e. Exceptional circumstances to treat differently from others with similar condition
6. Value for Money
 - a. Availability under existing contract
 - b. Availability of less expensive alternative interventions
 - c. Availability of less expensive alternative providers
7. Human Rights
 - a. Would declining funding be classed as an interference with rights under Human Rights Act
 - b. Is PCT pursuing a legitimate aim?
 - c. Is the request/decision proportionate?
8. Affordability

The list is similar to PCT 3, but with inclusion of stakeholder views. Note the way that proportionality is included in 7, but it is a consideration also in 1, 2, 3, 4 and 5. Equity features in 5 and cost in 5 and 6. Some procedural propriety is reflected in 4 and legality partly addressed in 7.

The headings have a degree of overlap. They choose to focus on a mix of principles and relevant considerations. Consideration of the Effectiveness principle can be seen in 1. Note too the inclusion of a specific consideration addressing an Efficiency principle, missed by other PCTs (Value for Money - 6). The equity principle is listed itself (5). Responsiveness and Patient Choice is expressed in 4. There may be benefit in more clearly identifying the values or principles that have to be used in balancing the considerations and criteria on which decisions are made.

5.3.2 Commissioning Panel

This PCT has established a Commissioning Panel with delegated powers for making financial decisions. It includes the Director of Finance, Director of Public Health, Director of Primary Care, clinical and prescribing members, a continuing care manager, a commissioning manager and non executive member of the board. Its purpose is:

1. To provide advice to trusts/GPs on how to respond to requests for exceptional treatments
2. To act as a panel to consider funding for exceptional treatments
3. To consider proposals for clinical treatments which would normally be considered of low priority.

All requests that are not continuation of existing policies or unavoidable admission, which has already occurred (eg hyperbaric oxygen for a diving accident) are authorised by a manager. Other requests are referred to a special subgroup, which completes a template for the panel's decision.

5.3.3 Sub groups of Commissioning Panel

A subgroup has membership of a commissioning manager, Director of Finance, Director of Public Health and Prescribing Advisor and receives the request from the patient or clinician and conducts their assessment and analysis and completes the request form with advice.

Complex cases are processed by another PCT on behalf of several and these are sent to an advisory complex cases Commissioning Panel, which has the same membership as the normal subgroup with additional co-opted experts.

The completed template is then sent to the Commissioning Panel, which has delegated powers for financial decision making.

5.3.4 Appeals Panel

An Appeals Panel comprises Chief Executive, independent non executive director and Professional Executive Committee member and only considers written

evidence. In hearing an appeal, the Panel will consider the validity of the original decision making process, relevant considerations and criteria applied and also whether there is any new information. The Panel "must be seen" to consider and weigh relevant evidence, give proper weight to claims of applicant compared with other groups competing for resources, act in good faith and ensure reasonableness.

This last requirement might obscure the clarity as to whether the appeal panel reviews the process of the former panel or also takes new decisions on funding. The benefit of the latter is that a more speedy decision could be taken. The disadvantage is that new group of three, none a public health consultant and all unfamiliar with much of the detailed information and less familiar with the use of the ethical decision making framework and perhaps prior decisions, is less well placed to *make* the final decision. Its independent constitution is to enable it to have an independent unbiased view on the adequacy of the process. There is the danger that decisions over time will not be consistent.

5.3.5 Conclusions from PCT 4

Three reflections may be of value:

- *Tip 79: It is possible to manage the business and risk by delegating financial powers to the commissioning panel for exceptional treatments*
- *Tip 80: It is preferable for the independent Appeal Panel to be chaired by a NED, checking the exercise of power of the executive and for the Appeal Panel to review cases.*
- *Tip 81: It is probably likely to establish greater consistency in decision making for the Appeal Panel not to have the power to substitute its decisions. It should normally refer back the decision of the original panel, having reviewed their decision making process, with instructions about the new consideration or amendment to process. This would require a fast track facility for panel meetings, but ensure a robust and consistent decision making process.*

5.4 PCT 5

5.4.1 Ethical framework and Clinical Priorities Policy

The ethical framework describes PCT aims as to:

1. Consider all relevant evidence
2. Consider opinions of relevant clinicians
3. Give proper consideration to the views of the patient or group and accord proper weight to their needs against other groups competing for scarce resources
4. Consider only material factors (relevant considerations)
5. Act in utmost good faith

6. Make decisions that are in every sense reasonable

In the text of the policy it is confirmed that the ethical framework also is non discriminatory and the health needs consider capacity to benefit.

The ethical framework is described as concerning:

1. Evidence of clinical and cost effectiveness — but outcome measures considered by patients and doctors will be given greatest importance
2. The needs of patients — especially life saving which will be the highest priority, and also the right to choose wherever possible
3. The needs of the community — this will include decision on preventive care and public health interventions.

Then additionally there is guidance to presenters to the forum about the areas they should address, which include:

1. Details of drug/technology
2. NICE guidance
3. Current practice
4. Proposal for consideration
5. National Priorities
6. Local priorities
7. Evidence of Effectiveness
8. Cost Effectiveness
9. Equity
10. Patient Choice
11. Implications for not using this treatment
12. Audit process for NICE guidance
13. Financial impact — a detailed proforma about costs, savings, consultation, impact over several years to enable financial planning

Whilst not as explicit as the framework in the Regional group, the principles of Effectiveness, Equity and Patient Choice can be seen within the policy.

5.4.2 Clinical Advisory Forum

Policy is devised by a Clinical Advisory Forum with local NHS health economy stakeholder representation. This large group is tasked with a similar role to the County Priorities Forum, but also making explicit the task of engaging stakeholders in understanding ethical, economic and clinical issues and taking and supporting prioritisation decisions.

The group is a subcommittee, accountable to the Professional Executive Committee, which is unusual. Note that the PCT and not the PEC has legal responsibility for resource allocation decisions. However the PEC agrees investment priorities and refers policies on the decision making processes to the PCT Board.

5.4.3 Clinical Priorities Committee

Exceptional treatments are considered by the PCT Clinical Priorities Committee, which is a subcommittee of the PCT board. Its membership is chaired by a non executive director (NED), and includes two lay representatives who are NEDs, the Chair of the Professional Executive Committee, Director of Public Health, Director of Commissioning and Director of Finance. There is a protocol for referral with roles for members.

The policy of the committee is to normally only fund treatments with at least a moderate level of cost effectiveness (good quality observational control or case studies). Communications are with the referring clinician. There is an urgent decision process under which the committee acts virtually with delegated power to some members with the agreement by the Chair.

There is a clear flow chart of handling cases. The proforma for application for funding an exceptional treatment requests evidence that the intervention will result in health improvement, on the assumption that usually a policy not to commission a service or therapy usually indicates a lack of evidence of effectiveness or limited benefit compared with adverse effects. This is somewhat akin to PCT 3, where there were also strong presumptions about the dominance of cost effectiveness criteria. Proof of Exceptionality is required (although no definition is given).

5.4.4 The Appeal Panel

The Appeal mechanism is well detailed and similar to other PCTs. It has the ability to refer back to the Clinical Priorities Panel if there is new information. There is the further capacity to refer disputes of fact for independent assessment, which is a valuable mechanism if the Appeal Panel is to have the power to substitute its own decision. Here it does so by recommending a decision to the PCT Board in a Part II meeting.

5.4.5 Conclusions from PCT 5

In view of the recent Rogers case, the PCT 5 processes are undergoing review with a particular emphasis on patient involvement in the processes and developing a policy on what is meant by exceptionality. These are still in development. This brief overview is entirely a personal judgment, based only on documentation.

It does show that the systems are well developed and appear to comply with many of the prompts in the A4R framework (see 4.3 above). As has been discussed above, it is clear from reading the Rogers case, that had the policy been followed in the decision making process, legal liability would not be found. However local managers felt that deviation was required due to the particular context surrounding the introduction of the use of Herceptin. Observations include:

- *Tip 82: Whatever policy and process are adopted, it has to be understood and implemented in a consistent manner.*
- *Tip 83: For an ethical framework to be followed, the guiding principles and balancing of considerations have to be known and understood by all decision*

makers. Clarity is important about the ethical principles and criteria for decision making, which are different from required information to process an application.

- *Tip 84: Professional Executive Committees may not be the most appropriate committee to which Local Priorities Fora should be accountable, but this would be up to local determination, depending on relationships between the Board and PEC and delegated authorities. The PCT Board or a Commissioning subcommittee of the board may be more appropriate, as the board has wider commissioning responsibilities and carries the legal duties.*
- *Tip 85: The adoption of an urgent fast track procedure has merit but also carries risk if a non member of the decision making panel is a new member of the delegated decision making group (some other districts have included the Chief Executive). The urgent procedure should be by virtual consultation with the membership and a smaller balanced subgroup of the original panel.*
- *Tip 86: The additional facility for the Appeal Panel to refer to an independent assessor to resolve a dispute of facts is a useful extra mechanism to ensure the robustness of decision making.*
- *Tip 87: The strong lay representation on the Clinical Priorities Committee is commendable and it is interesting that that was no bar to difficult non funding decisions*

5.5 PCT 6

5.5.1 Some features

PCT 6 has adopted Low Priority Procedures Policy with a long list of specified procedures, to gain greater commissioning leverage over trusts that were continuing to conduct procedures on the low priority list. Its process for considering exceptional treatments is considered by a panel, whose membership includes a medical ethicist. All members of the panel have had ethical decision making training.

Another detail is the presence of a public health consultant to prepare and present cases at the Appeal Panel, but for that person not to be a member of the panel, to maintain its independence. That could be very useful to assist the panel in understanding the appropriate information, but all the information to consider the decision should be submitted in writing and the public health expert should understand the role is not to be an advocate, but to facilitate understanding of technical information.

5.5.2 Conclusions from PCT 6

- *Tip 88: Inclusion of a medical ethicist on decision making panels and training of members in ethical decision making is commendable*

- *Tip 89: The inclusion of a public health expert to present cases and facilitate understanding of technical information submitted to the Appeal Panel, whilst not being a member, is a useful compromise to help achieve robust decision making.*

5.6 PCT 7

5.6.1 PCT 7 Exceptional Treatments Policy

This PCT was studied in more depth with visits and discussions with staff. The PCT adopted a policy in January 2006. The need for further change in processes has been recognized and been postponed to consider the findings of this review. The policy outlines the decision making process and the process for developing commissioning policies. There are the customary processes for determining that the application is appropriate to the PCT and is an exceptional case. But there is no specific point at which consideration of the powers of the PCT to purchase the intervention or to decline to use its discretion. An algorithm determines whether a request is dealt with on an individual basis or as part of policy development, the latter being chosen for non-urgent cases to develop a policy before decisions on an individual case are needed.

The PCT invited me to attend the Priorities Panel meetings and talk with officers. In practice it was challenging to prepare the policy if the case was relatively urgent so that the panel sometimes received individual applications and only accompanying *draft* policy to guide the decision. The imperative to develop individual drug policies prior to individual decisions was a notable example of good practice, which not all other PCTs had yet developed.

The policy lists information required to make the decision:

1. The nature of the patients condition
2. The nature of the intervention or care
3. The cost of the intervention or care
4. Whether there are or likely to be others with similar needs
5. The clinical urgency of the decision
6. Confirmation that the treatment is not available on the NHS
7. Evidence of safety and of the intervention being considered by a provider Drug and Therapeutics Committee (DTC)
8. The expected benefits of the requested treatment, set against the expected outcome
9. A treatment plan, showing how long treatment required and when it would be stopped as no longer effective.
10. Whether relevant NICE guidance has been considered
11. Whether the treatment proposed is likely to be covered by NICE guidance or guidelines in the future
12. Scientific and normative evidence about effectiveness

This information is all relevant. In particular it is sensible that urgency, DTC minutes and the termination of treatment are requested. It is not clear that there would be adequate information to determine value for money, as in PCT 4, unless costs of alternative providers are considered. Similarly the considerations for quality of care in the local provider in PCT 4 and the involvement of a clinical governance lead in PCT 3 may be initiatives to model, in order to ensure sufficient commissioning leverage over quality of care.

5.6.2 PCT 7 Exceptional Treatments Panel

The panel is chaired by a non-executive director and includes the Director of Public Health/Medical Director, one other director (in practice procurement and Finance), a Professional Executive Committee GP and a Procurement and Finance representative. Additionally a member of the Public Health Directorate who provides the overview summary is in attendance, but not part of the decision-making Panel. The panel can be drawn from a pool of potential members.

The Panel considers the information collected as part of the general policy set out above, but sensibly retains discretion to seek further professional advice if required. This specifically identifies a capacity to act to ensure all relevant considerations are made. The panel is established as a decision making panel. Accountability is to the Commissioning Working Group.

The "principles" which guide the decision-making and the Panel must take into account are these:

- a) The clinical needs of that patient/group of patients
- b) The evidence of the effectiveness of the intervention and the extent to which it might meet the needs of the patient/patients
- c) Whether the needs can be met by alternative interventions
- d) The broad balance between benefits and costs
- e) The impact of the provision of this treatment on the PCTs resources
- f) The impact of providing similar treatment to other Haringey residents with similar needs
- g) The impact on other services /treatments for which money is then not available

The panel is also required to have commitment to non-discrimination on grounds of personal characteristics, including age, except where effectiveness of treatment is dependent upon one or more of these factors. Thus an equity principle is being honoured. It is not clear why this requirement is separate from the list of "principles" and considerations above, that must be taken into account.

Additionally there is a communication requirement and a facility for email/conference call for urgent panel decisions.

The above list is well chosen. If implementable they would appear to conform with the rationality criterion of A4R (see 4.3 above). But it should be noted that the panel does not receive information on the impact on other services for which money is not available (g) nor any systematic information on resources (e) with the result that

larger cost decisions are remitted to the Commissioning Group. From June 2006, the Panel had an agreed threshold within which to operate (max £30K individual cost / £1.50K 'cumulative' cost).

This threshold might be challenged as appearing arbitrary, as it is difficult to see how it enables proportionate decisions and it is not clear how (e) and (g) are properly considered. The fact that the decision making power of the panel is limited by a threshold of allocations which it can make and the ad hoc sharing of decision making with the Commissioning Group weakens compliance with the formal regulation criterion of A4R.

The Panel is tasked to make decisions on principles of resource availability and comparative population need, but is not currently equipped to do this, unlike its parent body. Ensuring how the subcommittees reach their decisions in relation to the overall decision- making framework is important.

The fact that there is a 6 monthly reporting requirement, reviewing panel decisions, to the Clinical Governance Committee is a good demonstration of a degree of formal regulation. But it must be questioned whether this is sufficient. It is likely the clinical governance committee will have interest and expertise in the content rather than the process of decision-making. The appropriate reporting should be to the wider group to which it is accountable, the Commissioning Working Group, which in turn brings the report to the Board. Inclusion of the Clinical Governance Committee and public health group in distribution of reports, for information and consultation would be sensible.

The compliance with A4R public accessibility criterion is more challenging for exceptional treatments panels, as anonymity is required and would depend on public access to the reports just discussed. But an anonymised report of decision-making and decisions should be possible.

There is no specific attention focused on the impact of the *Human Rights Act*. The benefit of promoting compliance with the *Human Rights Act* as a consideration as in PCT 3 and PCT 4 is that it is a crucial part of the decision making process. But it is not a distinct head such as cost effectiveness since it pervades the way the decision is made, taking into account the principles, criteria and considerations.

Whilst there is no formal ethical decision making framework, the principles of effectiveness and equity can be seen to be prominently working. The principle of Patient Choice or Responsiveness is less clear. This is further discussed in the London paragraph below.

From my attendance at the panel some further observations can be made: The public health member of the panel often found herself in the position of being an advocate for the patient to receive funding, partly as she possessed great technical expertise. But, at times, this conflicted with her role representing the interests of the population. Secondly all PCTs to which I spoke were faced with the challenge of ensuring the time taken for approval of an individual case was not inappropriately long. This PCT had arrangements which enabled virtual committee meetings and executive action to expedite decisions. Thirdly the voice of the commissioner in the

sense of local priorities was not always heard and that may reflect the separation of the panel's decisions from the main commissioning group, but the need remains for the allocation decisions to be taken in that wider context. The importance of balancing the interests of different stakeholders was discussed above (4.4). This may be achieved by clarifying roles of officers, each to represent different interests.

One further observation is how hard it is to bridge gaps of knowledge between the expert members of the group and the lay members. It is difficult to ensure that concepts such as cost effectiveness thresholds, QALYs, absolute benefit risks, and numbers needed to treat are understood by all. Some may be less comfortable with ethical principles such as equity and their relevance to the decisions of the panel. A panel cannot take robust and fair decisions without all members understanding what they have to consider and its relevance to a criterion or principle. It is commendable that drafters of the terms of reference of the panel inserted a requirement that the learning and development plans of members include consideration of the ethical aspects of resource allocation. Implementing and sustaining this is crucial.

5.6.3 PCT 7 Appeals Panel

The panel is convened by the Chief Executive and comprises the PCT Chair, a Director representative from another PCT and a PCT Director who was not involved in the original panel, one with a medical background. The Appeals Panel considers the original reports and the process undertaken. It is tasked to review whether:

1. There was a fair process
2. The relevant principles were followed (see 5.6.2, a-g),
3. Relevant considerations were not taken or irrelevant considerations were taken into account
4. The decision was one that no reasonable PCT would have made

This quartet of considerations defining the remit of the Appeal Panel was similar to other PCTs in the same region, suggesting some informal sharing. These considerations are clearly legal requirements based on the classical grounds for judicial review, but are not complete. There is merit in more specifically requiring that the rules of natural justice are applied to the handling of both the application and Appeal, particularly ensuring a fair hearing (2.4 and 2.5.4). The issues mentioned with PCTs 1 and 2 of ensuring that the PCT was acting within its legal powers and not fettering its discretion (2.4) and timeliness (2.6) might be included. Some might also add a check that if it is claimed that the PCT made any promise to a specific group, which is not being honoured, that it has not established a legally binding substantive legitimate expectation (2.4). The most important updating is to review that the decision was one which took into account the *Human Rights Act* (2.5) and ensured it was guided by the principles of proportionality (2.5.6) and non discrimination (2.5.2 and that the decision is reviewed to ensure that policy is clear and applied appropriately (2.7).

This PCT has a communication requirement, but it needs to stipulate the findings of both the panel and the Appeal Panel are sent not only to the lead clinician but also to the patient, with reasons for the decision (2.5.4). The merits of the panel normally

having specifically only the power to approve or remit the decision to the original panel have been discussed above (see 5.3.4).

The possible benefits of having a public health specialist present but not voting, to facilitate understanding of information and ensure all relevant considerations were made have also been discussed, with the proviso that the chair ensures the role is facilitatory (PCT 6). The invitation to the lead clinician to attend the appeal (PCT 3) is not legally necessary but meets an A4R criterion. Perhaps more important is the duty to ensure that the patient has the opportunity to tell the PCT why it should allocate resources to him or her and this can be met by inviting a written submission (see 2.5.4). The facility to access an independent assessor purely for resolution of factual disputes seems a useful facility (PCT 5).

5.6.4 PCT 7 Out of Area Treatments Panel

PCT 7 considers non pharmaceutical interventions separately from exceptional treatments in an Out of Area Treatments Panel. The panel is differently constituted with accountability to the Professional Executive Committee and these aims:

1. To provide support and advice to GPs on commissioning and accessing secondary care
2. To encourage referrals within local NHS service agreements
3. To decide whether a referral should be funded
4. To debate local referral issues and advise appropriately
5. To encourage development of good services locally

There are certain challenges in having two separate panels for considering exceptional treatments and risks of challenge to process if the criteria are not identical. The PCT has a plan to bring together the commissioning of individual treatments in one panel. That will raise the question of whether to preserve accountability to the Professional Executive Committee, as PCT 5, or to a Commissioning group on which PEC is represented, with accountability to the board.

5.6.5 PCT 7 Commissioning Working Group

This group is chaired by the Professional Executive Chair and comprises the Chief Executive, Director of Procurement and Finance, Director of Public Health, Director of Primary Care & Commissioning, a public health doctor and four practice based commissioning leads. It is accountable to the Board. Its role is:

1. To approve budgets and contractual agreements
2. To monitor performance against budgets and recommend in year action
3. To consider relative expenditure between different categories of care and at different stages of the patient pathway
4. To review benchmarks of commissioning against other organisations
5. To recommend prioritisation of decisions on expenditure on clinical services to ensure financial balance
6. To review capacity and service planning of local trusts and fit with PCT commissioning decisions
7. To review and approve practice based commissioning budgets

It is clear from the above that, in contrast to the Priorities Panel, this group has both the expertise and the information required to make decisions on allocation which take into account two of the key principles of the allocation decision (5.6.2), namely:

- e) The impact of the provision of this treatment on the PCTs resources
- g) The impact on other services /treatments for which money is then not available

It can make judgments on the first because of its budget purview (roles 1, 2, 5 and 7). It can make judgments on the second because of its prioritisation role (roles 3 and 5). There are membership links but no formal provision of information through these officers to the Panel which would set the context for robust decision making of e) and g). Further the limited financial delegation of powers has not matched the bestowed unlimited decision making powers.

Conclusions from PCT 7

The Exceptional Treatments Policy and Panel had excellent criteria and developed thinking on handling cost control, which have formed the basis for the recommendations in this report. It has involved primary care practitioners and chosen to bring together the PEC overview of practice referral and drug prescribing with the exceptional treatments provided in secondary care. In doing so the role of the PEC and the need to unify principles and ethical decision making need consideration. It has similar experiences to other PCTs especially PCT 1, consequent on splitting of resource allocation by a commissioning group, from a technical advisory panel. Implementation may be more effective with changes that integrate the structure. Drawing on the features of other PCTs, the following are suggestions or lessons for all:

- *Tip 90: The adequacy of information about relative cost of providers may need reviewing to ensure value for money considerations can be made*
- *Tip 91: The imperative to develop individual drug policies before individual decisions were taken is commendable, but resource intensive. Reports on these policies and panel decisions usefully go to the clinical governance committee. The example of PCT 3 of involving the clinical governance lead in collation of clinical quality data on providers may also be worthy of consideration*
- *Tip 92: There is merit in modelling on PCT 3's requirement for declarations of conflicts of interest in order to ensure probity. Information would be needed from both potential professional and corporate providers, as well as allocation decision makers.*
- *Tip 93: Panels tasked to make decisions on principles of resource availability and comparative population need must be equipped to do so. Ensuring how*

the subcommittees reach their decisions in relation to the overall decision making framework is important.

- *Tip 94: Priorities Panels should formally report regular summaries of its decisions in an anonymised form with public access, to their parent committee, preferably being seen at Board Level.*
- *Tip 95: All PCTs should incorporate the duty to consider Human Rights Act in the terms of its resource allocation advisors, bodies and decision makers*
- *Tip 96: There is a need to consider how interests of different stakeholders can be balanced without internal conflicts between claims, in the way the allocation decisions are made*
- *Tip 97: All who take allocation decisions should have adequate knowledge and understanding of ethical and technical matters, and terms of reference such as in this PCT that require appropriate training of members are commendable. Papers brought to Priorities Panels should also be suitable for their readership.*
- *Tip 98: Terms of reference and powers and duties of the Appeal Panel of all PCTs need to be regularly reviewed and updated to reflect the requirement that the Appeal Panel ensures that the PCT has acted within the law, which is constantly changing. Legality, the Human Rights Act, proportionality, non discrimination, implementation of policy, and the procedural requirements based on the rules of natural justice are all relevant.*
- *Tip 99: PCTs may wish to consider limiting the power of the Appeal Panel to substitute decisions, steps to ensure the duty to give reasons is fully met, and for members to understand the information before them*
- *Tip 100: The priority setting and resource allocation functions for individual treatment or referral decisions should ideally be handled together in one Exceptional Treatments Panel, which can develop and apply one coherent set of principles within the decision making framework.*
- *Tip 101: The expertise and intelligence of Commissioning Groups with respect to budget allocation and relative needs should be made available to those in panels who make exceptional treatment funding decisions.*
- *Tip 102: Especially if a Commissioning Group is to take resource allocation decisions on exceptional treatments, it is essential that it operates under the same decision making framework as any Exceptional Treatments Panel*

5.7 London

5.7.1 North Central London consensus on ethical decision making

There has been some work across five PCTs in North London seeking consensus on a framework for decisions on priority setting⁹⁹. General agreement is reported amongst PCTs about the principles of priority setting. These include clinical effectiveness, cost effectiveness and equity, as mediated by capacity to benefit. Ethical principles are discussed and clearly underpin all the commissioning principles. The inclusion of quality as a separate heading from the theoretical principle of clinical effectiveness focuses attention on the practical delivery of care locally. It should probably be a key consideration and might generate a criterion for applying the fundamental principles. Patient Choice and Responsiveness are not been discussed in this draft.

Some priority setting guidance including consideration such as following NICE Technology Appraisals, being evidence based, being transparent, ethical and managerially robust (meaning due process). There is a useful section on probity, which has received less attention in the PCTs studied — selflessness, integrity, objectivity, accountability, openness, honesty and leadership.

The paper makes clear an intention to develop the ideas. This is a complex collection of principles and considerations, currently with a number of overlapping considerations in this draft. It is very useful as it demonstrates an emerging consensus across organisations and it helps to link the principles with the actual decision making process on the ground.

- *Tip 103: There is interest in one sector of a universal ethical decision making framework and it seems to be feasible in the short term, to grow from the field consensus in establishing a common framework, even if PCTs subsequently adopt some differences in policy.*

5.7.2 Other Pan PCT commissioning groups

There are other commissioning agencies which also have to set priorities. In NCL there is the Cancer Network. A London Cancer Networks New Drugs Group has been established to research the evidence for new drugs and make consensus recommendations. There are also the London Specialist Commissioning Groups (SCG) and Supra-Specialised Commissioning Groups. A recent national review of the Specialised Commissioning function has just been published¹⁰⁰. One of the recommendations of this report is that there should be a simplified system with one SCG per SHA area. Another is that each SCG should have an annual prioritisation process, with stakeholder consultation, which dovetails in with priorities for non specialised services. There is also a horizon scanning recommendation that information on new interventions be made available routinely to SCGs.

There is not specific reference in the document to an ethical decision making framework, although the principles of establishing the SCG included reduction of

inequalities. The SCG might benefit from the thinking on ethical decision-making and priority setting within local panels. These developments point to the need for a Region wide approach to Priority Setting, of which Exceptional Treatments is only a part. My recommendations will address this.

- *Tip 104: There would be great value in establishing an ethical decision making framework across the whole of a region, and applying it to all commissioning decisions.*
- *Tip 105: It would be efficient and foster equity and improve the quality of decision making if the PCT 1 and 2 model of centralising a range of expert functions in priority setting were followed. This could operate at a Regional level with a unique range of expertise, available as a service to PCTs..*

6 Recommendations

These recommendations are made with section references and tips throughout the text. Reference should also be made to the corresponding appendices, which offer a summary or specific details for implementation.

6.1 An Ethical decision making framework

Recommendation 1: PCT boards should adopt an ethical decision making framework, with clearly defined principles, considerations, criteria and required information, reflecting ethical principles and legal duties, and implemented through its forms, protocols and processes

The following is offered as a draft for discussion, based on literature and experience (*Tip 63*): A summary appears in Appendix 1 (7.1)

The framework:

PCT(s) will establish corporate governance arrangements, which commit their organisations to (*Tip 61*):

1. Honour as far as possible these **ethical principles** (section 3.1) and ensure awareness of them and an appropriate balance between them in structure and governance of the organisation.

- 1) Patient autonomy**
- 2) Beneficence**
- 3) Non maleficence**
- 4) Justice**

2. Recognise the **legal duties** as public bodies (section 2) to ensure that the decisions and actions withstand judicial review with respect to:

- 1) Meeting statutory duties**
- 2) Legality (acting within powers)**
- 3) Reasonableness**
- 4) Proportionality**
- 5) Procedural Propriety**
- 6) Legitimate expectations**
- 7) Equality/non discrimination**

3. Adopt as the **commissioning principles for resource allocation decisions** (sections 5.1.1, 5.1.7) and ensure appropriate balance between them in decision-making:

- 1) **Effectiveness**
- 2) **Efficiency**
- 3) **Equity**
- 4) **Responsiveness**

4. Ensure that in seeking to achieve a balance between the ethical principles and to meet the legal duties of public bodies, in making resource allocation decisions, the following **considerations** will be taken into account:

- 1) **Legality of funding decision**
- 2) **Clinical needs of patient, nature of intervention and individual clinician's treatment plan**
- 3) **Scientific evidence of clinical effectiveness of proposed intervention and where in doubt, normative practice**
- 4) **Cost effectiveness and value for money if alternative providers**
- 5) **Benefits and risks of intervention to the individual patient and capacity to benefit**
- 6) **Impact of provision of this treatment on PCT resources**
- 7) **Consistency in decision making and impact of providing similar treatment to other PCT residents with similar needs**
- 8) **Impact of funding decision on health of population**
- 9) **Impact of funding decision on other services/treatments for which money is not then available**
- 10) **Patient views**
- 11) **Potential human rights considerations and proportionality**
- 12) **Procedural propriety in decision making, transparency and probity**

5. Assist priority setting policy by adopting the following **criteria are adopted**

[Here insert specific criteria which weight, include or exclude an application, e.g. incremental cost effectiveness thresholds, categorisation into low or high priority commissioning (e.g. Croydon Priorities list ¹⁰¹), established policy for a specific drug, approval/non approval by London Cancer Network or Drug & Therapeutics Committee etc. These are PCT policy decisions and this section will vary from one PCT to another, depending on exceptional treatment applications and the extent to which the PCT wishes to specify precise criteria for decisions. The framework is operational without any criteria, but in effect the precedence of decision-making begins to establish criteria implicitly.]

6. The required information for PCTs to consider an individual application for funding for each of the considerations in 4 might include:

- 1) Is PCT acting within its powers? Is intervention one that should be provided on NHS rather than eg local authority, is PCT fettering its discretion eg by treating NICE guidelines as mandatory or not funding a mandatory intervention (NICE technology appraisal guidance)?
- 2) Nature of illness, current condition of patient, proposed intervention, previous treatments, clinical urgency, anticipated time treatment and treatment plan
- 3) Clinical effectiveness of proposed treatment, Literature review and research evidence of grade of effectiveness, where evidence is incomplete normative evidence of effectiveness and on capacity to benefit, Application of NICE guidance, anticipated NICE guidance
- 4) Assessment of cost effectiveness, QALY or ICER calculations, alternative treatments of comparable cost.
- 5) Anticipated benefits and risks for individual patient, possible adverse effects of treatment, Patient safety and clinical governance of provider, Drug & Therapeutics Committee and network group approval, monitoring treatment
- 6) Cost of assessment, intervention, follow up; cash flow forecasts, Budget trends, virement policy, Double deficit position; whether treatment available anywhere else and cost of alternative providers
- 7) Other PCT funding of trust, Precedence of previous similar funding applications, whether legitimate expectation, frequency of condition, cost implications for funding all group, exceptional circumstances if funding individual and not rest of group, potential to provide as new service
- 8) Assessment of health gain, extent that it meets national priorities eg NSFs or local priorities e.g. in Annual Public Health Report or to meet Local Delivery Plan Target, underestimates of QALY
- 9) Low Priority list, Opportunity cost to others, unmet need from Annual Public Health Report, local needs assessments, Local Commissioning Priority plans, and budget spends; adequacy of preventive spend in area of intervention
- 10) Patient understanding, attitude to risk, impact on quality of life, individual's own view of exceptionality, current changes in health and disability
- 11) Whether intervention interferes with a human right; whether it is a fundamental right, whether an alternative less damaging intervention is possible, whether interference is justified, proportionality of decision in relation to balance of harm and potential benefit to individual and to others, whether raises issues of discrimination against certain groups
- 12) Patient consent, extent patient informed of choices, opportunity for patient or representative to make the case for funding, All relevant considerations (e.g. stakeholder views) and no irrelevant ones included in information supplied; communications with applicant and patient, declaration of conflicts of interest, research projects and funding; Timeliness of application handling, Patient informed of decisions and right to appeal; Minutes of meetings and records of relevant discussions outside meetings.

The above list is not comprehensive, but is a suggested list of appropriate information required under each category of the list of considerations. Each PCT should assemble their own list and build it into operational protocols for the

appropriate staff and ensure the Exceptional Circumstances Submission Form reflects these information needs.

7.1.2 The wider adoption of the framework

Recommendation 2: The decision making framework should be adapted for local usage

This framework is an outline seeking to gain clarity as most PCTs have found it challenging to distinguish principles, considerations, criteria and required information. (*Tip 71, 83*). In this attempt to do so, it is intended to assist in understanding how ethical principles and the law may be applied in the implementation of policy and operation of committees. Thus the relevance of a principle or consideration can be seen. The framework can be expanded for discussion and sharing, using the material in this report and adapted by stakeholders to improve its relevance. There is scope for local determination of policy, which might be represented in the criteria section. For example it would be possible to specify the relative importance of cost effectiveness criteria.

Recommendation 3: The decision making framework should apply to all commissioning

The framework should apply not only to Exceptional treatments, but also to Out of Area Treatments, approval of individual packages of care, practice based commissioning, service level agreements and all commissioning decisions (*Tip 66*). The principles and considerations should be generic, but the specific criteria and then the information required will vary between a service level agreement and an individual treatment. Variations in criteria for different types of commissioning may be developed and if necessary specific new considerations added.

Thus the framework needs to be cascaded appropriately through each PCT and appropriate committees with support for staff to understand and implement it. In particular the Commissioning groups and fora should be familiar with and apply the same decision making framework as Exceptional Treatments Panels.

Recommendation 4: The decision making framework is adopted from the ground in groups of PCTs incrementally

Given the degree of consensus in NCL, and the fact that such a framework is guidance, it would be sensible to explore the potential for individual PCTs to adopt with neighbouring PCTs a common framework as a guide to their own governance arrangements and operation of their own panels (*Tip 103*). This can be done without creating a sectoral group. Consensus should be sought both between public health directors but also critically in order to ensure a lay voice and corporate commitment by discussion between non-executive directors. Similar consensus can be reached in other groups of PCTs, and in that way incremental adoption and learning is spread across a Region, without requiring a regional directive.

6.2 Regional structures

Recommendation 5: A Regional Priorities Forum should be established

The experience of areas with regional arrangements should be used to bring together people from across Regions to share approaches to priority setting and the development and use of decision making frameworks. This would most usefully be done by establishing a Regional Wide Priorities Forum with its first task to share and develop local frameworks and systems (Tip 66).

It could sit in the SHA or be established by the SHA and lead PCTs as an independent agency. It should include representation from the different types of stakeholder eg finance director, primary and secondary care clinicians, public health, PCT and specialist commissioners, mental health trusts, lay voices, together with specific expertise such as that of an ethicist. Depending on adopted priorities there would be the opportunity to have representation from specific disability or disease groups. A representative of the Regional Cancer Networks should be included especially since there will be learning from their operative new drugs model. Given the size of Regions it is possible that NICE might agree to be represented. The Forum should be educational, supportive and developmental and advise on policy, generated by a specialist team.

Recommendation 6: SHAs should seek to ensure a coherent approach to priority setting is adopted across different types of commissioning, including specialist commissioning, across the region (Tip 104)

This should be a priority for the new SHAs, linking the sharing of approaches to priority setting with the Regional Cancer Networks New Drugs Groups, and the specialist commissioning work, with the aim of developing a common ethical framework. This does not mean that different PCTs could not have different criteria, but there would be value in having a common set of principles and considerations for good governance. If that is not possible, it would be useful to make explicit the differences in values, principles or approaches in the Region and for commissioners to consider the implications of this.

Recommendation 7: The Priority. Setting Forum should be supported by a Regional Priorities Research Team, which would provide to PCTs a common core service (Tips 66, 105)

Each SHA should establish an agency, with a mix of expertise, drawn largely from current NHS employees within the Region, to act as part time consultants in such areas as development of commissioning, organisational development, quality assurance, management of clinical underperformance, strategic service development and project management. This agency should include expertise such as an ethicist, an academic lawyer, a health economist, a commissioning expert, public health, information specialist, a medicines manager, a pharmaceutical and

biomedical scientist, an epidemiologist, critical appraisers, who as part of their work, could comprise a specialist priorities research team.

A service level agreement between the Forum and the agency should establish specialist work that the team should do for PCTs. It is suggested the work of the team should normally go to the Forum for advice and/or policy agreement, but that the Forum will be too big to generate and discuss the details of all the work.

The work might include:

1. Horizon scanning of new interventions, linking DH work with local information to enable service planning
2. Based on NICE work, scientific, legal literature and other literature and normative practice, offer PCTs recommendations, policies and strategies for dis-investment in ineffective or inefficient technologies, for agreement by the Forum
3. To produce recommendations for prioritisation, such as inclusions on low priority lists, for agreement by the Forum.
4. To develop options for criteria for individual PCTs to use in local exceptional treatment priorities and service level agreements, with particular advice about the ethical implications of different approaches.
5. To monitor progress in implementation of NICE recommendations and report to Forum and trusts
6. To collect data from across the Region about exceptional treatment decisions and analyse trends and precedents (*Tips 29, 36*).
7. To give specific advice to individual PCTs on exceptional treatment decisions with respect to specific considerations in the decision making framework (Recommendation 8):

Recommendation 8: A specialist Priorities Research team should be established at Regional level to provide a service for decision making about exceptional and out of area treatments, based on the areas for consideration (numbered) in the decision making framework (Recommendation 1) (Tip 69):

- Legality of funding intervention ie is it duty of NHS to provide? (1)
- Evidence of clinical and cost effectiveness of proposed intervention and normative views, especially where intervention new or of uncertain effectiveness (3)
- Evidence of specific risks and adverse effects to be considered and especially any specific patient qualifying criteria to ensure capacity to benefit for individual patient can be accurately assessed (5)
- Precedence of funding decisions in the Region and lessons from national cases that have received publicity or gone to court (7)
- Impact on health of population (8)
- Potential human rights considerations and proportionality and advice on ethical decision making (11)
- Advice on compliance with procedural propriety in decision making, transparency and probity in line with NHS standards, ethical considerations and legal recommendations (12)

The feasibility of incorporating the work of Regional Clinical Networks such as Cancer Network New Drugs Groups as a workstream of this team should be explored and this model may be helpful in establishing other work areas, linked to other networks. Note that this advice includes the technical scientific assessment and legal and ethical advice. It does not constitute advice on the decision that should be made, nor does it take away from the PCT the capacity to make any decision in the light of the circumstances of the case, the resource environment and the needs of the local population. But it does ensure that local decisions are based on a common set of data and intelligence and inefficient duplication of research effort is minimised.

6.3 PCT Committees

Recommendation 9: All commissioning of individual treatments or access of individuals to specific treatments should be managed from one PCT group, whether led by practices or PCT.

Exceptional drug treatments panels, medical devices and equipment review groups, Out of Area Treatment groups, practice based commissioning fora for individual treatments, and individual case commissioning panels should all be merged into one Priorities Panel for each PCT. There is no sense from either an efficiency point of view or from a commissioning viewpoint for any separation of different types of commissioning of individual treatments. The Individual Treatments Priorities Panel should have accountability to a Commissioning Group or the Executive Group of the PCT that leads commissioning, with accountability through to the Board. (*Tips 84, 94, 100*). Specific recommendations about its membership are considered below in Recommendation 14. The new group should include lay representation (*Tips 41, 87*) a lead for clinical governance (*Tip 73, 91*) and if possible an ethicist (*Tip 88*).

There should be specific requirements for declaration of conflicts of interest amongst members and applicant clinicians (*Tips 74, 92*). One member should specifically hold the remit of Caldicott guardianship and the terms of reference and operating guidelines should specify clearly how confidentiality is to be maintained (*Tips 23, 75*). This needs to be balanced by some transparency in decision making and public accountability (*Tips 46, 47, 48, 49, 54, 55*), which could be met by anonymised reporting to the board of decisions and their rationale (*Tips 56, 75, 94*).

In gathering the information, structuring the agenda and chairing the meetings, it should be ensured that all the considerations in the decision making framework have been appropriately considered (Recommendation 1, section 4). It is important that as part of the processes of the Panel that the PCT is assured that the patient is given an opportunity to say why the resources should be allocated to him or her (*Tip 17*) and that he or she is informed of the decision and the reasons for the decision (*Tips 16, 46, 47*) unless consented to have a representative. This might mean copying correspondence with the referring clinician directly to the patient or notifying the patient of the communication to the clinician. It is important that there is good documentation of the decision and its rationale with indexing of sources of evidence and previous decisions, especially the grounds found for exceptionality (*Tips 31, 37*).

Recommendation 10: Individual Treatments Priorities Panels should be well equipped to make decisions about comparative population need

PCTs legally must balance the needs of an individual with those of the community (*Tip 21*). Priorities Panels are often tasked to consider population need in reaching their decisions, but in practice it is difficult to implement, as there is no recognised systematic way of doing it. The decision making framework requires considering population health, health gain and lost opportunity cost of spending on an exceptional treatment (considerations 8 and 9 see Recommendation 1, section 4 above).

If there is separation of mainstream commissioning from individual treatments, as much of the relevant information and intelligence rests with the Commissioning Groups, local processes must make it available to Priorities Panels (*Tip 101*). There is a need to translate this into a means of ensuring decisions take this into account in a robust rather than ad hoc way (*Tip 21, 93*).

The presence of members of a public health department at panel meetings on the panel is key, as their expertise is needed. It is recommended that public health departments review their access to data and information about population health and needs and explore the feasibility of future reports of the Director of Public Health, rather than being a static annual report, becoming a live and developmental tool that can inform decision making throughout the year. The recommendation is that an electronic report of the health of the population and adequacy of commissioning plans to meet those needs is available, as an internal decision tool, with monthly updates. It should comprise a priority needs list in view of information received on demand, health status, effectiveness of commissioning, health care evaluation, exceptional treatment investments and cost saving plans in year. This will give a stronger more explicit voice to population needs, improve the robustness of the decisions made and reduce vulnerability to judicial review.

Recommendation 11: Individual Treatments Priorities Panels should be well equipped to consider resource availability in making decisions and these decisions should be better integrated with the Commissioning Groups or boards which make commissioning or resource allocation decisions. They themselves should use the decision-making framework to delegate financial powers and a budget to the Priorities Panel, with a specific process of handling decisions with a cost effectiveness threshold, when the budget is exhausted.

Most PCTs established Priorities Panels with accountability and responsibility to the PCT board, although one PCT used the PEC and another a Commissioning Group. The structure is a local decision, although unifying all commissioning decisions in one Commissioning Group accountable to the board seems attractive. What must be universal is a function fit for purpose, with accountability for priorities decisions ultimately coming to the board.

The decision-making framework requires that resource allocation and commissioning panels consider cost and the impact of the decision on budgets

(considerations 6 and 7 of framework, section 4, Recommendation 1 above). The mechanism of doing this needs improving so that ethical decision making on priorities and commissioning strategy is not divorced from resource allocation and service level agreements (*Tips 40, 67, 68, 79, 93*).

The Priorities Panel should be given a delegated annual budget. This budget should be set, as all other commissioning budgets, using the decision making framework (*Tips 67, 102*). To do this information should be brought, which determines resource allocation includes the demands on service level agreements and exceptional treatments from previous years and the anticipated demand on both, the exceptional treatments demand being calculated from the historic pattern, cases in the system and horizon scanning. As part of this exercise, specific interventions should be chosen to develop as a specific policy, on recommendation by the Priorities Panel, with view to developing new service level agreements. If the budget allocation has been rigorous and within the decision making framework, then the delegation of the budget meets the requirement of the Panel to consider the impact of its decisions, save the need for the Panel to look at the impact of its decisions on the options for other spend of its own budget on exceptional treatments.

There are two key provisos to this assumption:

1. The first is that the PCT financial cash flow situation does not significantly deteriorate in year.
2. The second is that the Priorities Panel budget remains in surplus.

If either of these conditions are *not* met, then the Priorities Panel will need to look more intensively at the impact of its decisions on resources. The PCT Board or Commissioning Group to which the Panel is accountable must ensure that the Priorities Panel is aware of the new context for allocation decisions, and a mechanism for doing this is discussed below.

At the same time, it is recommended that monthly budget management reports are made of those budgets, in which virement is possible, together with information about double deficit, cash flow targets and an assessment of the impact of decisions on the resources (*Tip 40*). As the public health report above, this should be an electronic report updated monthly and available as a decision making tool. As with the population health report, this information should be available to all resource allocation panels, including the Commissioning Group or PCT Board.

When the financial cash flow deteriorates in year or when the Priorities Panel budget is exhausted, the PCT cannot simply stop funding exceptional treatments, as we have seen that a blanket ban on applications is illegal (section 2.5.2). Then the decisions of the Panel will need to be made under the guidance of the Commissioning Group or board to which it is accountable, with an intensive look at the impact of decisions on resources. In order to prevent the divorce of the expertise and consistency in decision making that has been built up by the Panel, it would be preferable for the Panel not to simply cease making decisions and to advise its parent group. Nor is agreeing a limit on spend per case, which is pragmatic but not fair, as it is less clearly within the ethical decision making framework.

Rather the Commissioning Group or Board should adopt an incremental cost per QALY threshold for all commissioning decisions and the finance officer present a full

picture of the resource impact of decisions of the Panel (Recommendation 13 below). In severe financial situations, there might also be a joint meeting: the Panel meet in a Part II of the Commissioning Group or PCT board, for such a period as the financial problem lasts. Without such explicit processes the robustness of decisions will be less easily defensible against a human rights challenge, and will be less fair.

See Appendix 2 (7.2) for a draft template of Priorities Panel Terms of Reference

Recommendation 12: The constitution of Appeal Panels should be reviewed and updated to reflect current law and practice

The operation of Appeal panels should be regularly reviewed to ensure they are up to date (*Tips 16-20, and 98*) to meet legal requirements and honour ethical principles. It is important that all the information put before the original panel is before the Appeals Panel (*Tip 77*). The considerations that it must make in hearing an Appeal should be (sections 5.2.3, 5.3.4, 5.4.4, 5.5.1, 5.6.3):

- **Ensuring the Priorities Panel operated within the decision making framework applying its principles and in particular heard evidence to enable adequate hearing of the considerations** (s4, recommendation 1)
- **Ensuring that irrelevant considerations were not taken and that no relevant consideration was not heard**
- **Ensuring use of power is legal and not fettering discretion**
- **Excluding that a promise has been made that might amount to a substantive legitimate expectation**
- **Reviewing that the decision considered the Human Rights Act, and was guided by the principles of proportionality and non discrimination**
(note this replaces the test that the decision was not one which no reasonable PCT would make, as it is less onerous and all irrationality is likely to be disproportionate)
- **Assuring that policy was clear and applied appropriately**
- **Ensuring there was fair process, the rules of natural justice are applied to both the handling of the application and the Appeal, particularly with respect to a fair hearing and ensuring patient is fully informed**

The Appeal Panel should normally either approve the decision or refer back for decision of the original panel in the light of findings on Appeal, rather than substitute its own decision. This improves the consistency and robustness of decision making, but requires a flexible frequency of panel meetings (Recommendation 14) (*Tip 81*). The capacity to refer to an independent assessor for resolution of factual disputes may be useful (*Tip 86*).

The Appeals Panel should be chaired by a non executive director (*Tip 80*) and continue to be comprised of voting members, none of whom took part in the original decision (*Tip 20*). It should consider allowing presentation by a clinician representing the patient in order to ensure a fair hearing (*Tip 77*) and the presence of a non voting public health specialist as a source of advice to understand the information presented (*Tips 33, 89*).

A proposed template for the Terms of Reference of an Appeals Panel may be found in Appendix 3 (section 7.3).

6.4 Roles of PCT officers to balance stakeholder interests

Recommendation 13: The principal interests in relation to the decision should be independently represented by different officers, whose roles should focus on that interest and presenting it to the decision making panel, including a designated case manager.

The importance of a careful balancing of conflicting interests in decision making and ensuring independent submission is a key criterion of the *Accountability for Reasonableness framework* (section 4.4). The operation of an ethical decision making framework is the vehicle, which enables and a decision, which is legal, fair and accepted. The requirement that there are specific considerations and that the decision considers them and does not include irrelevant ones are all part of the process of balance (see Recommendation 1, section 4). But in practice the way that considerations are handled are subject to bias and subjective judgments are likely when there is an imbalance of input or executive influence. To address this it is proposed that the major potentially conflicting interests are separately represented in the way that the evidence is prepared and presented to the panel. There should be four separate officers with specific roles, whose focus should be on specific considerations from the decision making framework (Recommendation 1, section 4, numbered) (*Tip 96*);

- 1) *Patient's interests*: This interest majors on the commissioning principle of **responsiveness**, including patient choice and considers patient autonomy. It should be represented by a designated case manager, who collects the information, is the key communicator with the applicant, advises on timeliness and is the advocate for the application (Recommendation 14). It looks at considerations of patient views (10) and clinical needs of patient (2), which would include the applicant clinician's views and perhaps a normative view as well, which become especially important where there is no or weak scientific evidence of clinical effectiveness. Consistency in decision making (7), procedural propriety (12) and potential human rights claims (11). should also be areas the Case Manager considers. This officer is responsible for collection of information and proper documentation of decisions (*Tips 15, 22, 31, 42, 44*)
- 2) *Scientific interests*: This interest represents **effectiveness**, providing the evidence balancing beneficence and maleficence, and arguing on clinical effectiveness (3) and cost effectiveness grounds (4), and capacity to benefit (5). This role should be met by the person who is most familiar with the technical issues of assessing and measuring cost effectiveness. Whilst it is recognised that cost effectiveness thresholds are a means of balancing community interest and resource interests (below) we have seen that they are best regarded as a key decision making tool and not the definitive resolution of the balancing of interests (*Tip 64*).
- 3) *Community needs*: This interest focuses on the ethical principle of distributive justice and the commissioning principle of **equity**. This role is to consider

need rather than benefit; to apply the agreed commissioning priorities, and consider the impact of the decision in the light of those priorities and the needs and health of the population (8). Consideration should be given to other services/treatments for which money is not then available (9). This is a public health function, which is best exercised without the tensions of also representing the scientific arguments and clinical benefit. The role would include presenting priorities of unmet need in the community and identifying the extent of health gain and the implications for not funding alternatives. The role should also include commentary on the application of cost effectiveness thresholds, and any unjustness in QALY measures presented (*tips 13, 21*).

- 4) *Resource interests*: This role focuses on the commissioning principle of **efficiency**, looking at whether needs can be met by an alternative provider of the same treatment – value for money (6), and the feasibility of meeting the cost of providing similar treatment to other PCT residents with similar needs (7). It also critically considers the impact of provision of an exceptional treatment on PCT resources (6), which information is critical to the public health judgments about relative need and the overall panel decision (*Tips 40, 45*). Theoretically if a PCT were to commission entirely on the basis of incremental cost effectiveness thresholds, then cost effectiveness data would render unnecessary consideration of both the impact of provision on PCT resources (6), the impact of provision for others with a similar need (part of 7) and on other services for which money is not available (9). As it seems likely that such scientific purity of approach will not be possible or acceptable in the short term, this wide range of impact assessments is crucially important. Remember it is perfectly legal and ethical to decide differently on an individual funding decision in a double deficit situation from one of financial surplus.

In summary:

A **case manager** should be an advocate for the **patient**

A **scientific officer** should make the case for **effectiveness**

A **public health officer** presents **health gain and community health needs**

A **finance officer** presents the **efficiency and cost implications**

It is sensible that the same officers fulfil the same roles, where appropriate, on the Priorities Panel and the Commissioning Group. Ideally none of these should be voting members and all should report on every decision (subject to Recommendation 11 above). Other generic members should take the overview, seeking to balance each interest.

With respect to the Panel, if it is possible to have five other voting members, then the officers need not be voting members and a very healthy structure and process for balancing interests would have been achieved. These five might be, say, medical director, nurse director, lay ethicist (perhaps NED), commissioning manager and GP Commissioning lead.

Recommendation 14: The interests of the patient to have a timely decision should be assured by requiring a case manager responsible for determining timeliness in handling applications and appeals.

The system of provision of exceptional treatments legally has to be timely where the patient's health is deteriorating (*Tip 34*). A fast track procedure for the panel to consider cases by virtual meeting or by convening an urgent meeting should be used whenever timeliness is a critical issue. A case officer representing the interests of the applicant patient should, on advice of the applicant clinician, advise the chair of the Panel that there is a need for an urgent meeting. This should trigger one.

This facility can partly be met by having a reasonably frequent scheduled set of meetings pre arranged in the diary throughout the year. The urgent meeting should not include new members of the panel, even at CEO level, but should be available especially if the health of the patient is deteriorating or if an Appeal Hearing sends back a decision (*Tip 85*). Whether the meeting is real or virtual is a chair's decision in the light of the complexity of the decision and the extent of conflicts of interest. Such meetings must fully document the decision and its rationale. The decision not to hold an urgent meeting after application for one should also be documented.

6.5 Governance, Training and Leadership

Recommendation 15: The corporate governance framework of the PCT should include the systems and processes of Priority Setting and rationing, which should be subject to periodic review and audit, including benchmarking against the use of the adapted Accountability for Reasonableness Framework (section 4)

It is recommended that, as part of the routine governance requirements of the PCT, there should be regular audit of the resource allocation decision making processes, to inform the board's duty to maintain corporate values and ethics (*Tip 61*). It has already been advised that there should be an anonymised report of decisions of the Panel, reaching the Board and Clinical Governance Committee. The latter will particularly focus on the merits of the decisions in relation to need and quality of providers. What is also needed is that a review of systems and processes, which support decision making goes to the board.

This should be carried out using the adapted *Accountability for Reasonableness Framework* (section 4.3). This could be used across all commissioning decisions in the PCT as part of the evidence of fitness for purpose for commissioning in the core self assessment for the Healthcare Commission. It comprises a self assessment using five ethical criteria (suggested accompanying questions are *Tips 41-60* in the text). Many of the questions are prompts for enquiry and can only be answered subjectively, but the process of establishing dialogue with stakeholders around this framework would be a valuable way of reinforcing ethical principles, identifying problems and improving governance:

- **The rationale for decisions should appeal to reasons and principles accepted as relevant by people seeking a mutually justifiable solution**

Have appropriate internal and external stakeholders — including lay - been engaged in setting criteria for decision making?

Is the rationale for decisions explicitly recorded, with the way in which the conflicting arguments were handled?

Have the mission, values and strategic direction of PCT been explicitly linked to the rationing criteria?

Is adequate data/intelligence brought to the decision making table?

Has information about relative needs and financial situation of the PCT been considered in making decisions?

- **Decisions and their rationales must be publicly accessible**

Is there a formal communication plan?

Is the rationale communicated as well as the decision?

Does the rationale communicated include reference to capacity to benefit, and affordability?

Whether or not funding is approved, does the PCT have the ability to describe the impact on other services or groups of funding exceptional treatments on other services or groups with needs?

- **There is a mechanism for challenge and dispute resolution**

Is an objective Appeal process formally approved and established?

Is it consistent with the values and criteria of the original decision making body?

Does the Appeal process have all the information that the original decision making body had?

Do the PCT processes permit reconsideration of a decision in the light of new information within the budget year (such as NICE approval, increasing capacity of individual to benefit, or generation of new evidence that was not originally available)?

- **There is some formal regulation of the process**

Is the formal process widely understood and seen to be monitored to ensure compliance?

Is there strong executive leadership to enforce fairness in application of process and to prevent gaming by some stakeholders?

Is there adequate accountability for the process, so that the results of monitoring and review of the process can be considered and changes made in its operation?

- **There should be an effective opportunity for all appropriate stakeholders to independently submit their relevant considerations**

Have all relevant considerations been brought to the group or panel?

Have the views of the key stakeholders all been represented fairly (eg consultation, equal voice, fair hearing)?

Is the system of voting without pressure to follow a particular line, (eg no compulsion to vote, benefits of secret ballot especially in presence of executives and line managers, support and time for contributors to gain information and knowledge before they decide)?

Are irrelevant considerations discounted before decisions are made?

A summary of annual review requirements with the adapted A4R framework can be found in Appendix 6 (7.6).

Recommendation 16: All those involved in priority setting and allocation decisions should be appropriately trained so that there is sufficient common level of knowledge and skill, to understand the information presented and to make robust informed decisions

Training is essential for staff to understand ethical and legal principles and a new decision making framework and ensure that decision makers not only have sufficient knowledge, but also can use it appropriately (*Tips 7, 11, 12, 59, 88 and 97*). One way of stimulating this is to appoint as lay member an ethicist, perhaps as a non-executive director, who will offer some leadership and may have links to ethical training providers. PCTs 1, 3 and 6 have trained staff in ethical decision making and may share their experiences.

In addition to ethical decision making, there also needs to be training in aspects of law, health economics and public health skills, to ensure that all members of resource allocation committees and bodies understand the relevance of human rights, the basics of assessment of clinical and cost effectiveness and risk and the technical terms used.

It is particularly important that the chair is well informed and trained, as that role has to ensure that all stakeholders make informed and balanced decisions.

There is also merit in considering training for scientific staff in presentation of technical information to lay audiences.

Such training might be something that could be provided as part of a service level agreement with an agency including the Priorities Research Team (see Recommendation 7 above).

Recommendation 17: There needs to be corporate and professional leadership to promote the ethical decision making framework, to ensure fairness in application of policy and to prevent gaming or undue influence by any stakeholder.

The need for leadership is shown by the research on implementation of decision making systems (see sections 4.1, 4.3, 4.4). A specific role for the board is to ensure that there is fairness and no bias in the way that the decisions are made (*Tips 54, 55, 59, 60*). It is especially important to ensure that no irrelevant considerations influence decisions and that political and populist pressures do not lead to inappropriate decisions (section 4.4) (*Tip 30, Tip 38*). There must be independence for stakeholders to express their views without executive pressure (*Tip 59*).

Review of corporate systems by the board has been recommended (Recommendation 15), as has training initiatives for staff (Recommendation 16). A particularly important focus for the board is the appointment, training and support for chairs of resource allocation panels, who must be fully aware of the issues in this report and the requirements for procedural propriety.

The adoption of greater transparency and an ethical basis of decision making usually requires cultural change in the organisation, which requires priority and perseverance from chair and chief executive. This will considerably be assisted by the adoption of such an approach as a priority by the SHA.

7 Appendices

7.1 **Appendix 1:** An Ethical Decision Making Framework

SHAs should take a lead in the ensuring the development of adequate integrated governance in all PCTs and the Healthcare Commission in monitoring and assessing governance. This should include corporate governance arrangements, which commit their organisations to a systematic process for meeting their legal duties and an ethical decision making process which reflects PCT mission and values. (Tip 61). A recommended model follows:

PCTs should commit to:

1. Honour as far as possible these **ethical principles** (section 3.1) and ensure awareness of them and an appropriate balance between them in structure and governance of the organisation.

- 1) **Patient autonomy**
- 2) **Beneficence**
- 3) **Non maleficence**
- 4) **Justice**

2. Recognise the **legal duties** as public bodies (section 2) to ensure that the decisions and actions withstand judicial review with respect to:

- 8) **Meeting statutory duties**
- 9) **Legality (acting within powers)**
- 10) **Reasonableness**
- 11) **Proportionality**
- 12) **Procedural Propriety**
- 13) **Legitimate expectations**
- 14) **Equality/non discrimination**

3. Adopt as the **commissioning principles for resource allocation decisions** (sections 5.1.1, 5.1.7) and ensure appropriate balance between them in decision making

- 5) **Effectiveness**
- 6) **Efficiency**
- 7) **Equity**
- 8) **Responsiveness**

4. Ensure that in seeking to achieve a balance between the ethical principles and to meet the legal duties of public bodies, in making resource allocation decisions, the following **considerations** will be taken into account:

- 1) **Legality of funding decision**
- 2) **Clinical needs of patient, nature of intervention, including the individual clinician's treatment plan**
- 3) **Scientific evidence of clinical effectiveness of proposed intervention and where in doubt, normative practice**
- 4) **Cost effectiveness of intervention**
- 5) **Balance of risk and benefit for patient and the capacity to benefit**
- 6) **Impact of provision of this treatment on PCT resources and whether needs can be met by alternative provider**
- 7) **Consistency in decision making and impact of providing similar treatment to other PCT residents with similar needs**
- 8) **Impact of funding decision on health of population**
- 9) **Impact of funding decision on other services/treatments for which money is not then available**
- 10) **Patient views**
- 11) **Potential human rights considerations and proportionality**
- 12) **Procedural propriety in decision making, transparency and probity**

5. Assist priority setting policy by adopting the following **criteria are adopted**

Individual PCTs may wish to specify detailed criteria, such as low priority interventions or define cost effectiveness thresholds or adopt detailed policy for specific interventions. These will vary from one PCT to another and should reflect the principles and considerations adopted in the framework.

6. The **required information** must be collected

The required information for PCTs to consider an individual application for funding for each of the considerations should be defined, collected, analysed and brought to the decision making table. These categories are best defined by using the headings of the considerations (6.1.6). Some PCTs may wish to develop an algorithm or operational protocol or decision pathway in which there are critical steps for

appropriate staff gathering and using information. The design of the Exceptional Treatments Application Form should reflect these needs.

7. The balance of interests of stakeholders

Key to an ethical decision making framework is establishing a process for giving equal weight to different principles and interests. One way of securing this is to define roles of PCT officers around different interests. For ease of reference an extract of the recommendations in section 6.4 are reproduced here (numbers of the considerations in ethical decision-making framework are in brackets):

1. A Case Manager is advocate for Patient's interests:

This interest majors on the commissioning principle of **responsiveness**, including **patient choice** and considers **patient autonomy**. The Case Manager collects the information, is the key communicator with the applicant, advises on timeliness and is the advocate for the application (Recommendation 14). It looks at considerations of patient views (10), clinical needs of patient (2), Consistency in decision making (7), procedural propriety (12) and potential human rights claims (11). This officer is responsible for collection of information and proper documentation of decisions.

2. A Scientific Officer makes the case for effectiveness:

This officer presents the analysis of evidence for **effectiveness** of the intervention, providing the evidence **balancing beneficence and maleficence**, arguing the adequacy of **clinical** (3) **and cost effectiveness** grounds (4). He or she also takes a view on the balance of benefit and risk to this particular patient and considers **capacity to benefit** grounds (5).

3. A Public health officer presents health gain;

This interest focuses on the ethical principle of **distributive justice** and the commissioning principle of **equity**. This role is to consider community health need rather than individual benefit, to apply commissioning priorities, and consider the impact of the decision in the light of those priorities and the needs and health of the population (8). Consideration should be given to other services/treatments for which money is not then available (9). The role would include presenting priorities of unmet need in the community and identifying the extent of health gain and the implications for not funding alternatives. The role also includes commentary on the application of cost effectiveness thresholds, and any unjustness in QALY measures presented.

4. A Finance officer presents efficiency and cost implications:

This role focuses on the commissioning principle of **efficiency**, looking at whether needs can be met by providing alternative treatments cheaper (6) and the feasibility of meeting the cost of providing similar treatment to other PCT residents with similar needs (7). It also critically considers the impact of provision of an exceptional treatment on PCT resources (6), which information is critical to the public health judgments about relative need and the overall panel decision.

7.2 Appendix 2: Recommended functions at Regional Level

There would be economies of scale and opportunities to concentrate range of expertise to apply to commissioning decisions and processes if some functions were established at Regional (SHA) Level with a service agreement with PCTs. The decision-making and resource allocation would still rest firmly at PCT level, but much of the marshalling of evidence, policy guidance and advice on process could be provided uniformly across the region. An extract from recommendations in section 6.2 are reproduced here for ease of reference:

A Regional Priorities Forum should:

1. Oversee assembly of horizon scanning of new interventions, linking **DH** work with local information to enable service planning
2. Based on NICE work, scientific, legal literature and other literature and normative practice, develop consensus recommendations, policies and strategies for disinvestment in ineffective or inefficient technologies, for agreement by Forum, to be offered to PCTs
3. Produce recommendations for prioritisation, such as inclusions on low priority lists, for agreement by the Forum, for PCTs.
4. Develop options for criteria for individual PCTs to use in local exceptional treatment priorities and service level agreements, with particular advice about the ethical implications of different approaches.
5. Monitor progress in implementation of NICE recommendations and report to Forum and trusts
6. Collect data from across the Region about exceptional treatment decisions and analyse trends and precedents (*Tips 29, 36*).
7. Give specific advice to individual PCTs on exceptional treatment decisions with respect to specific considerations in the decision making framework

A Regional Research Team should research and provide advice on (ethical decision-making framework considerations in brackets):

1. Legality of funding intervention ie is it duty of NHS to provide (1)
2. Evidence of clinical effectiveness of proposed intervention especially where intervention new or of uncertain effectiveness (3), especially any specific patient qualifying criteria to ensure capacity to benefit (5)
3. Evidence of cost effectiveness and balance between cost and benefits (4)
4. Precedence of funding decisions in the Region and lessons from national cases that have received publicity or gone to court (7)
5. Impact on health of populations (8)
6. Potential human rights considerations and proportionality and advice on ethical decision making (11)
7. Advice on compliance with procedural propriety in decision making, transparency and probity in line with NHS standards, ethical considerations and legal recommendations (12)

7.3 **Appendix 3:** Draft template application form and case record

This ensures the appropriate information is collected to address the considerations

The application form that follows can be used in its present form by PCTs. It represents a comprehensive list of relevant information, which would inform all the considerations in the ethical decision making framework. It is constructed systematically so that each of the considerations heads the required information, so that at the panel meeting each consideration can be easily considered and not omitted. The form below is both an on going case record and application form, being completed initially by the applicant clinician and then subsequently by PCT officers. This hopefully reduces bureaucracy and keeps the relevant information in one place at any time.

The form has been constructed from the study of several in current use by PCTs, with additional questions to ensure all the considerations are addressed. But this particular form has only been piloted for one application, and PCTs may wish to adapt the precise wording in the light of their experience. It can be regarded as a template for PCTs to check their current application and collection of intelligence procedures, and/or construct new forms and algorithms to handle applications.

The bold sections are those, which it is considered the applicant clinician should be asked to complete. If he or she is unable to complete the cost effectiveness section, it may fall to the scientific officer of the PCT to do so. There are four proposed officers, who are employees of the PCT, who contribute to completing the form (see text section 6.4 and Appendix 7.1). The others are the public health officer, the finance officer and the case manager. The latter takes charge of the process of the application and is responsible for the completion of the unfilled sections by either himself or herself or by a colleague. It may be that some sections are not possible to complete because of available information or lack of training of staff. For example, some PCTs might find it hard to complete the human rights considerations. In the interim, if such a section is left incomplete, that will need to be considered by the Chair of the panel and handled in the most appropriate way. For example it may be that the combined expertise of the panel can complete some sections at the meeting.

Many PCTs are finding it very difficult to handle the amount of work involved in these applications at present. The form is long, but should not generate more work for PCTs than at present. Firstly much of the information should be provided by the provider organisation (in bold). To make it efficient and save time in handling at PCT level, some parts of the information should be possible generate at a regional level to "cut and paste". These recommendations are discussed in section 6.2 and Appendix 2. Furthermore if the whole form is completed, it should make the administration for Panel meetings and the decision making process easier. The confidence which the PCT can gain from having a process, which balances all these considerations is that it is minimising risk of legal challenge and also building up commissioning expertise.

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7.4 **Appendix 4:** Template for Terms of Reference of Priorities Panel
[or group mandated to take decisions approving individual treatments]

1. The Priorities Panel is established to make decisions on resource allocation for individual or exceptional treatments or treatments out of area, which fall outside current service level agreements
2. The voting membership of the Panel shall be as follows:
 - i. A non-executive director with responsibility for corporate governance and ethical decision making, as chair. (Ideally an ethicist should be a **NED**).
 - ii. The medical director (or where appropriate the nurse director)
 - iii. Another non clinical director
 - iv. The director of Commissioning
 - v. A GP Commissioning lead/ PEC representative
3. A quorum shall be four, with the chair having a casting vote. Members should all be trained to understand the technical material and in ethical decision making. Deputies should only be allowed where the substitute has had the appropriate training and have been agreed by the Panel.
4. The following non voting members should attend and present to the panel:
 - i. A case manager, who should lead the process of handling each case and be an advocate for the applicant patient
 - ii. A scientific officer, who should present the scientific arguments for relative merits of applications
 - iii. A public health officer, who should present the impact of the decision on the health of the population
 - iv. A finance officer, who should present the impact of the decision on the use of resources of the PCT
5. Application to the Panel for funding of an individual treatment is normally made by a clinician in a provider unit on behalf of the patient on an agreed proforma, sent to the [Director of Commissioning]. A preliminary enquiry may be made before completion of the form to determine the appropriateness of referral to the [Priorities Panel].
6. The Commissioning Director will request the relevant [Case Manager], initially within [one week], to establish whether funding such an intervention would be legal. Considerations include whether the PCT is acting within its powers, whether the intervention is one that should be provided on the NHS rather than the Local Authority or not at all; whether the PCT could be fettering its discretion eg by treating NICE guidelines as mandatory, or not funding a mandatory intervention such as NICE technology appraisal guidance.

7. The [Case Manager] also should establish within [one week] whether the intervention is provided within an existing service level agreement or contract, whether one is available elsewhere on the NHS and where relevant cost of alternative providers.
8. Where the intervention is legal and discretionary and no appropriate service level agreement is available, the [Case Manager] should ensure that the proforma is properly completed and that any further information required information for the areas for consideration by the panel (see 6.1.6) is collected by the referring clinician and appropriate officers. The [Case Manager] should ensure at all times that:
 - i. The process is timely in light of the urgency of the decision needed, in consultation with the Chair of the Panel
 - ii. The process is documented with with care
9. The [Case Manager] is responsible ensuring the Panel consider *responsiveness* of their decision to the applicant and for advising the Panel information about:
 - i. Patient choice and his or her views about exceptionality
 - ii. Any specific needs of the patient group in the submission
 - iii. Consistency of decision making, drawing on past and other panel decisions
 - iv. Procedural propriety and human rights considerations.
10. The [Scientific Officer] is responsible for ensuring the Panel have information to consider *clinical effectiveness* of the intervention. The officer should collate information on
 - i. Capacity of the individual to benefit
 - ii. Cost effectiveness measures including a literature review on the clinical effectiveness of the intervention
 - iii. Normative professional view on appropriateness of the intervention, including patient safety, balancing beneficence and maleficence. This may be the opinion of a professional group such as a Drug & Therapeutics Committee or a professional body. Where there is uncertainty, consideration should be given to commissioning an independent normative clinical view of the application (with consultant and patient anonymised) any alternative treatments.
11. The [Public Health Officer] is responsible for ensuring the Panel have information to consider the *equity* of the decision and its impact of the decision on the health of the population. This role includes
 - i. Any commentary on the application of cost effectiveness thresholds such as QALY measurement in the elderly.
 - ii. Assessing how the decision fits alongside the health needs of the population and the agreed commissioning priorities
 - iii. Assessing the impact of the decision on other services and treatments that might not be affordable if the intervention is funded.
Much of this information may be presented as a monthly up date of public health needs, rather than customised to each applicant.

12. The [Finance Officer] is responsible for ensuring the Panel have the information to consider *efficiency and financial control* in their decision. The officer should collate:
- i. Any alternative cheaper treatments
 - ii. The feasibility of meeting the cost for other PCT residents with similar needs
 - iii. The cash flow forecasts and budget trends
 - iv. The overall impact of the financial decision on PCT resources in the light of current budget management, virement policy, financial control and double deficit
- Much of this information may apply equally to all cases before the Panel at any one meeting, as they are time sensitive.
13. The agenda and papers for the meetings of the panel will be presented to the Chair for approval by the [Case manager] at least [two weeks] before the meeting date and sent to members with [ten days] reading and preparation time.
14. The Chair of the Panel will ensure that the decision making framework is applied to the discussion and decisions of the panel, in particular ensuring a proper balance between interests and ensuring the following considerations have been covered:
- i. Legality of funding decision
 - ii. Clinical needs of patient for this intervention, the clinician's plan
 - iii. Scientific evidence of clinical and cost effectiveness of proposed intervention and the normative view
 - iv. Whether needs can be met by alternative means or interventions
 - v. Balance of risk and benefit for individual patient and capacity to benefit
 - vi. Impact of provision of this treatment on PCT resources
 - vii. Consistency in decision making and impact of providing similar treatment to other PCT residents with similar needs
 - viii. Impact of funding decision on health of population
 - ix. Impact of funding decision on other services/treatments for which money is not then available
 - x. Patient views
 - xi. Potential human rights considerations and proportionality
 - xii. Procedural propriety in decision making, transparency and probity
15. The [Case Manager] shall be responsible for informing the applicant (usually the patient's hospital consultant) of the decision of the Panel, providing reasons for the decision and explaining fully the right to appeal and the process of doing so. Unless the patient has consented to the applicant clinician receiving communications on his or her behalf from the Panel, a communication should also go directly to the patient, indicating that the details of the decision and right to appeal have been sent to the patient's

clinician.

16. The [Case Manager} shall record the decision and discussion of panel members accurately and the draft minutes of the meeting must be approved by Chair and presented to the next meeting for agreement. The [Case Manager] shall establish a process of recording decisions and their principle reasons, so that future meetings can have ready access to them.
17. The Clinical Governance lead shall review the decisions and take suitable reports to the Clinical Governance Committee for discussion about the contents of decisions with implications of developing clinical practice or standards and discussing differences.
18. The [Case Manager] shall prepare an [annual] report of the work of the Panel, the process of decision making and an anonymised summary of the decisions for the [Commissioning Group] and the Board to review the adequacy of the process against the ethical decision making framework. This should include a comparison of access to new drugs across client groups. The review should incorporate the use of an evaluation tool (Modified A4R in Appendix 4) and form part of a wider report for self assessment of governance and integrated governance standards monitored by the Healthcare Commission.

7.5 Appendix 5: Template for Terms of Reference for Appeals Panel

1. The Appeals Panel is established to hear Appeals against decisions of the PCT about individual or exceptional treatments, outside Service Level Agreements, made by [the Priorities Panel or Commissioning Group] or officers of the PCT.
2. The Chief Executive will establish an Appeals Panel comprising three voting members, none of whom took part in the original decision, and one of whom has a clinical background:
 - i. The PCT Chair or non executive director, as Chair
 - ii. A Director representative from another PCT
 - iii. A PCT Director who was not involved in the original panel
3. The Panel may also invite three non voting members to be present for part or all of the meeting:
 - i. A scientific or public health officer, whose role is simply to explain the terminology or technical reports.
 - ii. A clinician or other suitable representative of the appellant patient, who is invited to present the reasons that the decision is held to be wrong, in particular bringing the argument for exceptionality. Where there is any doubt whether a fair hearing has been given, the patient representative should be present.
 - iii. The [Case Manager or officer responsible for the process] of the application, who can clarify facts about the process and keep records of the findings of the Appeal Panel.
4. Any appeal against the Priorities Panel decision should be addressed in writing to the Chief Executive of the PCT.
5. The Chief Executive will ask [the Case Manager or the relevant manager responsible for the process] for a report of the whole process of handling the application, and documentation of the grounds and content of any decisions eg: whether to consider, whether to seek further advice, whether to fund. Copies of the application and all associated documentation considered by [the Priorities Panel] and the subsequent Appeal should be made available. These should be presented to the Chair of the Appeal Panel.
6. The Chair of the Appeal Panel should review the documentation and if further clarity is needed, gain further understanding from the Chair of the [Priorities Panel]. The Chair of the Appeals Panel should determine whether there is a relevant factual dispute and if so consider whether to refer to an independent assessor for resolution of factual disputes before convening the Appeal Panel.

7. The considerations that the Appeals Panel should make through review of the documentation, if necessary supplemented by answers to questions put to invited non voting members, are to ensure that:
 - i. The [Priorities Panel] operated within the decision making framework, applying its principles and in particular heard evidence to enable adequate hearing of the considerations.
 - ii. There is a fair process with the rules of natural justice being applied not only to the application, but also to the handling of the Appeal, particularly with respect to a fair hearing and ensuring patient is fully informed
 - iii. Irrelevant considerations were not taken and that no relevant consideration was not heard
 - iv. The use of power was legal and not fettering discretion
 - v. Any specific promise that has been made does not amount to a substantive legitimate expectation
 - vi. The decision took into account the Human Rights Act, ensured it was guided by the principles of proportionality and non discrimination
 - vii. Policy was clear and applied appropriately

8. The Chair of the Appeals Panel will inform the [Case Manager] of the Appeal Panel's decision and the Chair of the [Priorities Panel] and write to the applicant's clinician, giving specific grounds for the decision, under the headings of the considerations, which the Panel is required to follow.

9. The Appeal Panel should normally either approve the decision appealed against or refer back for decision of the original panel in the light of findings on Appeal, rather than substitute its own decision. The Chair of [the Priorities Panel] should be empowered to convene a rapid and if necessary virtual meeting to reconsider its decision in a timely manner.

7.6 Appendix 6: Annual review of decision making

Each PCT has to make an annual assessment of compliance with healthcare standards for the Healthcare Commission. This includes corporate governance and there is a developmental standard on integrated governance. This process is the most convenient for reviewing the governance arrangements for commissioning individual treatments and the decision making framework itself. A modified A4R tool may be used as an audit tool:

- **The rationale for decisions should appeal to reasons and principles accepted as relevant by people seeking a mutually justifiable solution**

Have appropriate internal and external stakeholders - including lay - been engaged in setting criteria for decision making?

Is the rationale for decisions explicitly recorded, with the way in which the conflicting arguments were handled?

Have the mission, values and strategic direction of PCT been explicitly linked to the rationing criteria?

Is adequate data/intelligence brought to the decision making table?

Has information about relative needs and financial situation of the PCT been considered in making decisions?

- **Decisions and their rationales must be publicly accessible**

Is there a formal communication plan?

Is the rationale communicated as well as the decision?

Does the rationale communicated include reference to capacity to benefit, and affordability?

Whether or not funding is approved, does the PCT have the ability to describe the impact on other services or groups of funding exceptional treatments on other services or groups with needs?

- **There is a mechanism for challenge and dispute resolution**

Is an objective Appeal process formally approved and established?

Is it consistent with the values and criteria of the original decision making body?

Does the Appeal process have all the information that the original decision making body had?

Do the PCT processes permit reconsideration of a decision in the light of new information within the budget year (such as NICE approval, increasing capacity of individual to benefit, or generation of new evidence that was not originally available)?

- **There is some formal regulation of the process**

Is the formal process widely understood and seen to be monitored to ensure compliance?

Is there strong executive leadership to enforce fairness in application of process and to prevent gaming by some stakeholders?

Is there adequate accountability for the process, so that the results of monitoring and review of the process can be considered and changes made in its operation?

- **There should be an effective opportunity for all appropriate stakeholders to independently submit their relevant considerations**

Have all relevant considerations been brought to the group or panel?

Have the views of the key stakeholders all been represented fairly (eg consultation, equal voice, fair hearing)?

Is the system of voting without pressure to follow a particular line, (eg no compulsion to vote, benefits of secret ballot especially in presence of executives and line managers, support and time for contributors to gain information and knowledge before they decide)?

Are irrelevant considerations discounted before decisions are made?

7.7 **Appendix 7:** Contributors

Below is a list of those who were kind enough to allow me to listen to their thoughts and experience or contributed in some way to this work. Any errors are mine and the views expressed and recommendations are also those of the author and not those who contributed.

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7.8 Appendix 8: References and Bibliography

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