

Introduction

In the UK, Clinical Ethics Committees (CECs) have until recently focussed very much on individual patient care and many have not specifically considered issues of resources. However, as they become more established in acute trusts and develop in primary care trusts (PCTs) they will be more likely to consider issues that have resource implications, as some already have done.

The distribution of limited healthcare resources, be they money, time, equipment, staff, or organs for transplantation, requires setting of priorities. This is so throughout the health service, both at the level of individual patient care (should a patient be prescribed a particular drug?), and at the level of populations (should a PCT spend more on renal dialysis services than prevention of heart disease?).

Questions of allocation of resources involve a range of ethical considerations including fairness, respect for individual autonomy, responding to individual need and benefiting the whole population.

Difficult choices have to be made where pressing claims are made upon a limited budget. For example, should preference be given to:

- Those who are young and have a longer expected time of survival / good health with treatment?
- Those who are parents with dependent children?
- Treating a greater number of patients rather than fewer patients with a greater need?
- Treatment that prolongs life or treatment that improves the quality of life?
- Established treatments rather than experimental treatments?

Issues of resource allocation and priority setting are likely to present to clinical ethics committees in both acute trusts and PCTs. As a generalisation, committees in acute trusts are more likely to consider issues involving individual patient treatment, whereas CECs in PCTs will consider issues around strategic priority setting. There will be much in common between the two settings, both in terms of issues, and of the principles and values underlying the decisions.

On these pages we explain some of the ethical theories that underpin thinking on resource allocation and consider their application to practical problems. We also look at some topical legal issues. We have listed relevant professional guidance and have suggested some reading material so you can examine these issues in more depth.

This section does not provide a comprehensive overview of the issues around resource allocation, and does not make recommendations about what an ethics committee should do. It highlights issues that a committee may wish to consider and provides some ethical and legal frameworks for approaching the subject.

Ethical Considerations

Maximising Welfare / Benefit

In many ethical dilemmas in health care, for example informed consent, confidentiality or end of life decisions, the focus is on the individual patient. However, in considering how to make the best use of limited health care resources, the focus of the decision shifts from the individual patient to

a group of patients or potential patients, which may be the national population, a local community, or users of a specific service in an a hospital. One ethical theory that lends itself to community or population level decisions is utilitarianism. For a utilitarian, the ethically correct action will be that which results in the maximum overall benefit.

Thus, in making decisions about health care this theory requires consideration of the benefit to be gained from the various competing options in terms of the improvement in health for an individual and also the number of individuals who could benefit. In the context of the allocation of limited healthcare resources a key issue is the cost of the benefit achieved by the healthcare intervention. This approach would tend to favour resources being allocated to less expensive treatments or services that provide the greatest benefit. This may be a treatment that produces a large benefit for a small number of people or a small benefit for a large group of patients.

A criticism of this theory is that it fails to take into account the 'need' for healthcare intervention and relies rather on cost effectiveness. For example, it may favour preventative treatment such as cholesterol lowering agents to prevent future deaths from heart disease compared to renal dialysis for end stage renal disease.

The practical application of utilitarian theory in allocation of health care resources can be seen in the use of Quality Adjusted Life Years (QALYs) as a means of quantifying the net benefit from health care interventions to allow comparison of different interventions.

QALYS

QALY stands for **Quality Adjusted Life Year**.

Alan Williams has described the thinking behind the development of QALYs thus:

"The essence of a QALY is that it takes a year of healthy life expectancy to be worth 1, but regards a year of unhealthy life expectancy as worth less than 1. Its precise value is lower the worse the quality of life of the unhealthy person (which is what the 'quality adjusted' bit is all about)."

A. Williams, 'The Value of QALYs', Health and Social Service Journal July (1985), 3.

Health care interventions are measured both by the number of extra years of life, and by the increased quality of life, that they can achieve. Thus an intervention that provides 10 years of extra life at full health would have a QALY value of 10, and an intervention that improves quality of life from 0.5 to 0.8 for a person with a predicted further life expectancy of 30 years, would have a QALY value of 9. $[0.3 (0.8-0.5) \text{ multiplied by } 30]$. Once the QALY value of a health care intervention is calculated and its cost is known it is then possible to calculate the **cost** per QALY of each intervention and provide a direct comparison between interventions. The general idea is that a high priority health care activity is one where the cost per QALY is as low as it can be.

Some examples of Cost per QALY calculations:

Hospital dialysis for end-stage renal disease for patients aged 55 – 64 years (compared with no treatment) £45, 000

Coronary artery bypass graft for patients with mild angina (compared with medical management) £26,000

Breast cancer screening programme	£6,800
Cervical cancer screening (women aged 20-59 years)	£200

Medical Ethics and Law, the core curriculum. T. Hope, J. Savulescu and J. Hendrick, (Churchill Livingstone) 2003 Chapter 13 (table 13.2).

Several objections have been made against QALYs. These include:

1. Many healthcare interventions are not the subject of a QALY assessment and direct comparisons between the cost-effectiveness of different treatments is not possible.
2. QALYs are based on population-level information. They do not take into account the personal response of individuals to their illness and their views of their need for treatment.
3. QALYs are ageist. Ageism is unfair discrimination against a person on the grounds of their age. Some would consider QALYs ageist under this definition because providing treatment for younger people is likely to give a better QALY calculation. Individuals who have a greater span of life ahead of them, typically a younger person, would gain more from treatment on the basis of their predicted life expectancy in comparison with an older person who would have fewer years to benefit from a particular healthcare treatment. So a one-off life-saving intervention performed on a one-year old with a life expectancy of 80 years has a better QALY rating than the same intervention performed on a 70 year old. This would not apply to all treatments. If the treatment needs to be continued indefinitely then the cost per QALY calculation may not favour the younger person because the cost would be greater the longer the patient continued to live.

There are conflicting views about whether QALY calculations are ageist. Most supporters of QALYs argue that QALYs are not ageist because the age of the patients is not taken directly into account. An urgent life-saving treatment for an 80 year old, who was then expected to live 5 years would have the same priority, under the QALY method, as a 40 year old whose life-expectancy was 5 years (because of some underlying, untreatable illness). Michael Lockwood argues that QALYs "are not ageist enough". He thinks the 40 year old should have greater priority than the 80 year old (in the above example) on the basis of a 'fair innings' argument, that is, the older person has already had the advantage of a long life and that treatment should be preferentially given to a younger person.

(Lockwood M, "Quality of life and resource allocation", in Philosophy and Medical Welfare, edited by J. M. Bell and S. Mendus, Cambridge: Cambridge University Press 1988).

4. Patients who suffer a disability unconnected with the medical condition requiring treatment would be disadvantaged; John Harris calls this 'double jeopardy'. Those who have a disability would be considered to have a lower quality of life and therefore would benefit less from treatment for an independent separate condition than those who, with treatment could be returned to full health. (Harris J. "QALYfying the Value of Life" Journal of Medical Ethics, Vol 13, Issue 3 117-123, Harris, J. Double Jeopardy and the Veil of Ignorance - A Reply. Journal of Medical Ethics 21:151-157).

Example:

A PCT has to decide on whether to allocate resources to neonatal intensive care services or to increase provision of coronary artery bypass grafts.

A QALY assessment will look at the relative **cost** of the different treatments and the change in **quality** of life and life **expectancy** that will result if the treatment is provided. Neonatal intensive care and coronary artery bypass grafts will both save lives. Some patients who require neonatal intensive care will go on to have healthy lives (QALY value of 1 for each year of life) while others may have diminished quality of life. Patients having coronary artery bypass grafts may not be completely healthy following treatment and will therefore not achieve a QALY value of 1 for each year of life. As heart disease is more common in the elderly, the average life expectancy for patients having coronary artery bypass grafts is likely to be less than that for patients requiring neonatal intensive care. Assuming for the sake of this example that the cost of neonatal intensive care and the cost of coronary artery bypass grafts are the same, then even though some babies will not survive intensive care, the potential life expectancy of the survivors will tend to weigh in favour of this intervention, and against the intervention that is aimed at an older age group.

Equity and Distributive Justice

A possible criticism of the utilitarian or QALY based approach to resource allocation is that it does not provide an equitable or fair way of distributing resources.

Aristotle, explaining his view of distributive justice, says, in effect, that equals should be treated equally, and unequals treated unequally in proportion to the relevant inequalities. This is known as Aristotle's "formal principle of equality". Its value lies in its implicit demand that we spell out the criteria we are using when we call people equal or unequal. Aristotle's own criteria were based on merit; modern criteria may (or may not) be based more on need. (Nichomachean Ethics 1131a-1131b. See for example the edition of Crisp R, Cambridge, CUP, 2000 pp 85-87). The utilitarian or QALY based approach could be said to treat unequals equally, in that it does not take account of differences in need for health care but focuses entirely on the benefit gained from an intervention. Some individuals or groups of patients will have poorer health than others, or more serious diseases, and will have a greater need of health care. If degree of need is a main criterion, a just distribution of health care resources may require that these individuals or groups have more resources, even if the benefit gained by treatment is small compared to that achieved by a different treatment in patients who are less sick.

One ethical theory that considers equity, or fairness, rather than overall benefit is John Rawls' 'Theory of Justice' (Rawls J. A Theory of Justice, The Belknap Press, 1971, revised edition 1999). Norman Daniels has applied this theory to the context of health care. For Rawls, a just system of distribution of 'goods' within a society is one in which those members of society who are worst off will be better off under this system than any other. Thus, in the context of health care we should allocate resources to ensure that those in poorest health, or greatest need, are as well off, in terms of health, as they can be.

Assessing and addressing inequity

Reducing health inequalities is seen as an important aim of the National Health Service. But there are different ways of looking at inequality, and some inequalities may be easier to address than others. Which inequalities are inequitable, that is, unfair? The concern about 'post code prescribing' relates to inequality of access to treatment across different parts of the country for all those with the same condition, for example access to fertility treatment for all women who meet specific criteria. Other types of inequality arise when comparing access to treatments for different conditions. How does one compare the need for hip replacement with the need for smoking cessation clinics, or the need for a new cancer therapy with the need for a treatment for multiple sclerosis? Even within the context of a specific medical condition, some patients may have a greater need for treatment because of more severe disease. Thus providing equal treatment without some assessment of health status or healthcare need is not always a just or equitable approach in health care.

Considering the social determinants of health

Non-medical factors may produce inequalities between individuals or groups with the same medical conditions such that more resources are required to achieve the same benefit in health. For example, greater resources per person may be needed to improve mortality and morbidity from diabetes or ischaemic heart disease in groups with a high degree of social deprivation than in affluent middle class patients. Is it equitable (fair) to provide greater resources for the more disadvantaged group.

'The veil of ignorance'

In trying to make decisions about allocation of resources in the context of different needs, it may be helpful to use the concept of the 'veil of ignorance' put forward by John Rawls in his Theory of Justice. Faced with a range of possible societies (or possible methods of healthcare resource allocation) you must decide which society you would wish to live in given that you would not know your position in that society, whether you would be old or young, rich or poor sick or healthy. Rawls would argue that a rational person would choose the society (or to allocate resources) so that the most disadvantaged were as well off as they could be.

Determining morally relevant reasons for treating people differently

In considering equitable distribution of health care resources, care must be taken to ensure that any differences between individuals or groups that are used to justify different treatment are morally relevant differences. Thus, differences in race, sex or income are not seen as morally relevant. More controversial issues include whether factors such as personal responsibility for health and the presence of dependents are morally relevant in decisions about priority - setting in health care.

The influence of targets on resource allocation decisions

The recent introduction of targets into the NHS, with penalties for trusts that do not meet those targets, and rewards for those that do, may have an effect on decisions around resource allocation and priority setting. If failure to meet a target would result in fewer resources for future patient care, then it could be argued that maximum overall benefit will be achieved by always meeting targets. However, depending on how targets are set, the focus on achieving targets may result in patients with conditions not the subject of targets being treated unfairly.

Patient Autonomy

To what extent should a patient's wishes regarding the choice of the course of treatment be respected?

Respect for patient autonomy is a fundamental ethical principle that has assumed greater prominence in the healthcare setting over recent years. The emphasis on informed consent to treatment and shared decision-making within health care highlights the importance of this ethical principle. However, in considering how to allocate scarce health care resources for the whole community, or for all patients with a particular condition, respect for the autonomy of a specific individual may conflict with other values such as equity or the need to benefit the whole community or group, or with the autonomous choices of other individuals. Does respecting a person's autonomy to make decisions about their treatment mean that they should be able to choose an expensive treatment over a cheaper treatment? If the consequence of complying with such a choice is that treatment will be unavailable to other patients because of the limited available resources this may not be fair.

A balance needs to be struck between respect for individual autonomy, benefiting the whole population and fair distribution of limited resources.

Process of Decision Making

The lack of agreement on basic theory underpinning resource allocation has led to a focus on the **process** of decision-making. One example of an ethical approach to the process of resource allocation decision-making is that of Daniels and Sabin. (Daniels N. Sabin JE., Limits to health care: fair procedures, democratic deliberation and the legitimacy problem for insurers, *Philosophy and Public Affairs*, 1997; 26: 303- 350.) This approach is known as accountability for reasonableness. It focuses particularly on macro-level decision-making; that is decisions about treatments and services for populations, such as those made by a PCT. However, the rationale for a process of accountability would be just as relevant for decisions affecting individual patients. Acknowledging the competing ethical principles involved, Daniels and Sabin suggest that for such decisions to be ethical they must satisfy four criteria:

1. *Publicity* - Decisions and their rationales must be publicly accessible.
2. *Reasonableness* -The rationales for decisions should appeal to reasons and principles that are accepted as relevant by people who are disposed to finding terms of cooperation that are mutually justifiable.
3. *Appeals* - There is a mechanism for challenge and dispute resolution.
4. *Enforcement* - There is either voluntary or public regulation of the process.

A summary by Daniels appeared in Daniels, N. (2000) "Accountability for reasonableness", *British Medical Journal* 321, 1300-1301.

Priority Forums

Clinical ethics committees may be asked for advice on resource allocation issues at the level of individual patient care or in relation to setting priorities within an acute trust. In the UK, decisions about distributing resources for larger communities and populations lie within the remit of PCTs or health authorities. Many PCTs either have, or are considering developing, a committee or forum to advise on commissioning priorities for the PCT. Some of these priorities forums were originally developed within area health authorities prior to the reorganisation of the NHS in 2003. PCTs also have committees or panels that consider requests for individual patient treatments that fall outside the broad range of services routinely commissioned by the PCT. Some priorities forums have developed an ethical framework to inform their decision-making. The use of such a framework helps to achieve consistency and transparency of decision-making.

An example of a priorities forum that has developed an ethical framework is the forum first established within Oxfordshire Area Health Authority, and now hosted by Oxfordshire PCTs.

The ethical framework of the Oxfordshire Priorities Forum is structured around three main components:

- **effectiveness** of treatment - the extent to which the healthcare intervention achieves the desired effect - and **value** of a particular treatment - a judgement on how valuable that effect is for the relevant individual, relative to the value of other treatments

- **equity** - people in similar situations should be treated similarly. There should be no discrimination on grounds of employment status, family circumstances, lifestyle, learning disability, age, race, sex etc.
- **patient choice** - patients can choose between treatments of similar efficiency.

T.Hope, N. Hicks, D.J.M. Reynolds, R. Crisp, S. Griffiths, *Rationing and the health authority*, *British Medical Journal*, Oct 17, 1998.

The need for health authorities (or PCTs) to have a framework within which to make decisions about treatment priorities was recognised by the Court of Appeal in 1999.

R v North West Lancashire HA ex p A, D and G (1999) 53 BMLR 148, [2000] 1 WLR 977

The Court of Appeal said that a decision regarding the provision of treatment must be taken within a proper framework. Although it is appropriate for a Health Authority to have a policy for establishing certain priorities in funding different treatments, in establishing priorities - comparing the respective needs of patients suffering from different illnesses and determining the respective strengths of their claims to treatment - it is vital for the Health Authority to:
 accurately assess the nature and seriousness of each type of illness
 determine the effectiveness of various forms of treatment for it, AND
 give proper effect to that assessment and that determination in the formulation and individual application of its policy

Professional Guidelines

Any professional guidance will set the benchmark for ethical thinking on a particular topic. In general there is little professional guidance for health professionals in making decisions about allocation of resources. Guidance issued by the GMC identifies that a doctor should consider the needs of his patients individually, whilst also taking into account that treatment for a particular patient may impact on the availability of treatment for his other patients.

General Medical Council (GMC)

The GMC states that while the duty of a doctor is to his or her individual patient, there is also a duty to other patients and the wider community.

The duties of a doctor registered with the General Medical Council

“Patients must be able to trust doctors with their lives and well-being. To justify that trust we as a profession have a duty to maintain a good standard of practice and care and to show respect for human life. In particular as a doctor you must:

- make the care of your patient your first concern”

duties of a doctor GMC

However, there may be a conflict between the doctor's duty to a particular patient and his or her duty to other patients and the wider community.

The GMC document 'Priorities and Choices' directly addresses the issue of determining priorities in the context of limited resources.

Priorities and Choices, July 2000 paragraph 8

"In determining priorities between individuals for a limited resource, clinicians should have regard for the three duties of care [to protect life and health, to respect autonomy and to treat justly]. In many cases this assessment will give priority to the need to protect life and health, so that those whose healthcare needs are greatest or most urgent on clinical assessment will receive priority."

http://www.gmc-uk.org/guidance/library/priorities_choices.asp

The GMC recognises the particular difficulties that face clinicians who also have a managerial role within health care (for example medical and nursing directors or clinical members of PCT executives).

Management in Health Care - The Role of Doctors, May 1999, paragraph 7.

"Conflicts may arise when doctors are called upon to make decisions about the use of resources and about patients' care, when the needs of an individual patient and the needs of a population of patients cannot both be fully met. Dilemmas of this kind have no simple solution. When taking such decisions, doctors should take into account the priorities set by Government and the NHS and/or their employing or funding body. But they must also be clear about their own role. As clinicians, doctors must make the care of their patients their first concern, bearing in mind the effects of their decisions on the resources and choices available for other patients. As managers, doctors must allocate resources in the way that best serves the interests of a community or population of patients. In both roles, doctors should use evidence from research and audit to make the optimum use of the resources available".

Return to the

National Institute for Clinical Excellence (NICE)

<http://www.nice.org.uk>

The National Institute for Clinical Excellence (NICE) was set up as a Special Health Authority for England and Wales on 1 April 1999. It is part of the National Health Service (NHS) and its stated role is to

"provide patients, health professionals and the public with authoritative, robust and reliable guidance on current 'best practice'."

NICE guidance and funding implications

NICE sets out the obligations of health professionals to provide treatment which it has recommended to be provided. This is set out in 'A Guide to NICE' (page 6):

“Once NICE guidance is published, health professionals are expected to take it fully into account when exercising their clinical judgment. However, NICE guidance does not override the individual responsibility of health professionals to make appropriate decisions according to the circumstances of the individual patient in consultation with the patient and/or their guardian or carer.”

However there seems to be some contradiction about who is responsible for any increased funding implications of NICE recommendations. On one reading of A Guide to NICE the NHS is responsible through its technology appraisals:

“Since January 2002, the NHS has been obliged to provide funding and resources for medicines and treatments recommended by NICE through its technology appraisals work programme.”

On another reading the responsibility would fall to local NHS organisations e.g. PCTs:

"Local NHS organisations are expected to meet the costs of medicines and treatments recommended by NICE out of their general allocations".

The issue of funding NICE recommendations has received attention recently with the publication of NICE guidance on provision of infertility treatments.

NICE guidance recommends that the NHS funds up to three cycles of IVF treatment for those couples meeting specific criteria. However, NICE guidance will not yet be fully implemented and the Health Secretary has said that couples will only be offered 1 cycle of IVF treatment and there is no deadline for full implementation of the guidance. There is a question for PCTs about how they will implement this recommendation within their limited healthcare budget.

CG11: Fertility: assessment and treatment for people with fertility problems.

<http://www.nice.org.uk/pdf/CG011niceguideline.pdf>

This issue was considered in:

NICE, the draft fertility guideline and dodging the big question, J R McMillan, J. Med. Ethics, Dec 2003; 29: 313 - 314.

Legal Considerations

We consider below the legal implications of some topical issues relating to resource allocation in the National Health Service.

- Is there a right to medical treatment?
- Going abroad for treatment

Does the European Convention on Human Rights (incorporated into UK law by the Human Rights Act 1998) provide a right to medical treatment?

<http://www.dh.gov.uk/>

Article 2 states that there is a ‘right to life’. There is a positive obligation upon the State to ensure that this right is respected. Does this mean that there is a right to medical treatment? The positive obligation under Article 2 must be interpreted in a way that does not impose an impossible or disproportionate burden on the authorities. Therefore, although the State cannot be expected to fund every treatment, it must act reasonably in allocating resources.

The European Court in *Osman v UK* ((1998) 29 EHRR 245) said that there will be a range of policy decisions relating to the use of state resources which it will be up to the contracting states to assess on the basis of their aims and priorities, subject to these being compatible with the values of democratic societies and the fundamental rights guaranteed in the Convention.

Article 8 provides a right to respect for private and family life. This does not impose an obligation upon the State to provide medical treatment. Article 8(2) allows the state to restrict the right to respect for private and family life in the interests of the protection of health or morals, or the protection of the rights and freedoms of others. This requires a balance to be struck between the interests of the community and those of the individual.

A refusal to fund medical treatment because of the advanced age of the patient could be a breach of **Article 2** and **Article 14** (prohibition on discrimination). **Article 14** would also be relevant where resources are not allocated for treatment on the grounds of gender.

Treatment in EU Member States

E112 authorisation is a Department of Health scheme whereby prior authorisation can be obtained for a patient to receive treatment abroad where he/she would otherwise face 'undue delay'.

If approved, payment under the NHS would be made by the PCT.

Watts v Bedford PCT and the Department of Health [2004] EWCA Civ 166.

Mrs Watts suffered constant hip pain and had limited mobility. She was on an NHS waiting list for a hip replacement and given a waiting time of approximately one year. She applied to have the operation performed in France under E112 authorisation. The PCT refused, one of the reasons given was that as she would receive the operation within the normal waiting time she would not suffer undue delay.

The normal NHS waiting time for the treatment had been used as a threshold, but the Court said that this could not be the sole determinant of what constitutes 'undue delay'. The fact that a waiting time is normal (in the UK) does not necessarily mean that it is reasonable. Other relevant factors that should be taken into account are: whether the patient is in pain, has had repeated delays in treatment or will suffer deterioration if treatment is delayed, in assessing whether there has been undue delay.

The original waiting time for Mrs Watts of one year would have amounted to undue delay despite the fact that this fell within NHS Target waiting times. However, she was reassessed about three months later and, because her condition had deteriorated she was reclassified as an urgent patient to be provided treatment within 3 to 4 months time, thus there was no undue delay

The attitude of the Courts to resource allocation

A patient who has been refused treatment may appeal to the court by way of judicial review. In reviewing the decision to refuse treatment the court does not look at the merits of the decision but rather whether it was taken lawfully, e.g. did the decision-maker have the power to make the decision, were the correct procedures followed, were relevant considerations taken into account

and was it reasonable and proportionate. The court would then decide whether the PCT has acted lawfully in refusing to fund treatment. Traditionally the courts have been reluctant to involve themselves in the allocation of resources as they consider that judges lack the expertise to make such decisions and that those charged with the duty, i.e. managers in Health Authorities (now PCTs) should be left to make the decision. The court does have the right to find that a decision is unlawful.

It is true that the NHS does have a statutory duty to provide medical treatment. But that is not and, because resources are finite, cannot be, a duty to provide all conceivable treatments in all circumstances. In *R v East Devon Health Authority ex p Coughlan*, [2000] 3 All ER 850, the Court of Appeal said that, in exercising judgments about resource allocation, the Secretary of State for Health (and therefore all bodies which took their powers from him) had "to bear in mind the comprehensive service which he is under a duty to promote....However, as long as he pays due regard to that duty, the fact that the service will not be comprehensive does not mean that he is necessarily contravening [his statutory duty]. The truth is that, while he has the duty to continue to provide a comprehensive free health service and he must never....disregard that duty, a comprehensive health service may never, for human, financial and other resource reasons, be achievable....In exercising his judgment the Secretary of State is entitled to take into account the resources available to him and the demands on those services. In *R v Secretary of State for Social Services and others ex p Hincks* (1980) 1 BMLR 93 the Court of Appeal held that s. 3(1) of the Health Act does not impose an absolute duty to provide the specified services. [He] is entitled to have regard to the resources made available to him under current government policy."

In *R v North West Lancashire Health Authority ex p A and others* [2000] 1 WLR 977, which concerned the legality of a refusal to fund gender reassignment surgery, the Court of Appeal said this about the general principles to be applied in making decisions about resource allocation:

"As illustrated in the *Cambridge Health Authority* and *Coughlan* cases, it is an unhappy but unavoidable feature of state funded health care that Regional Health Authorities have to establish certain priorities in funding different treatments from their finite resources. It is natural that each Authority, in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each Authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose - indeed, it might well be irrational not to have one - and it makes sense too that, in settling on such a policy, an Authority would normally place treatment of transsexualism lower in its scale of priorities than, say, cancer or heart disease or kidney failure. Authorities might reasonably differ as to precisely where in the scale transsexualism should be placed and as to the criteria for determining the appropriateness and need for treatment of it in individual cases.

It is proper for an Authority to adopt a general policy for the exercise of such an administrative discretion, to allow for exceptions from it in "exceptional circumstances" and to leave those circumstances undefined; see *In re Findlay* [1985] 1 AC 318, HL, per Lord Scarman at 335H-336F. In my view, a policy to place transsexualism low in an order of priorities of illnesses for treatment and to deny it treatment save in exceptional circumstances such as overriding clinical need is not in principle irrational, provided that the policy genuinely recognises the possibility of there being an overriding clinical need and requires each request for treatment to be considered on its individual merits".

R v Cambridge HA ex p B [1995] 2 All E.R. 129

A ten year old girl had non Hodgkin's lymphoma with common acute lymphoblastic leukaemia. She was receiving palliative care only. Her father had sought other medical opinions recommending other treatments. He wanted the Health Authority to fund a further course of chemotherapy and a bone marrow transplant. It refused on the grounds that the proposed treatment was unproven and that the cost was disproportionate to the likely benefit.

In the court of first instance Laws J. said that where a life was at stake then a health authority must 'do more than toll the bell of tight resources' and must explain the priorities that led them to decline to fund the treatment. He referred to the fundamental right to life and that the Health Authority should justify any limitation on that right if it refused to fund treatment.

However, the Court of Appeal did not invoke the right to life. The court said that in reviewing the decision of the Health Authority it must only look at the lawfulness of its decision and not the merits.

"Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make."

Has the law moved on? Now that the Human Rights Act 1998 is in force could an individual argue that a decision to refuse to fund treatment infringes his right to life? The English courts' reluctance to adjudicate in disputes about the allocation of resources is mirrored in the jurisprudence of the European Court of Human Rights at Strasbourg. Probably, in relation to resource allocation questions, the European Convention on Human Rights adds little to the position under purely domestic public law. If a decision about funding is made irrationally (for instance taking into account irrelevant factors or not taking into account obviously relevant factors), then the court is likely to interfere. But irrationality is hard to show. It is no easier simply because the argument is framed in terms of Article 2. Although Article 2 does give an absolute right to life, it does not follow that it confers an absolute right to have whatever is necessary to maintain life. The courts recognise that resources are limited. If person X could go to court saying: "It is a breach of my Article 2 right not to have this treatment", person Y could equally go to court saying: "My Article 2 right to have treatment has been breached because the resources needed were all used up on person X." The only way out of that sort of bickering is to resort, in Article 2 debates about resource allocation, to the old public law principles. And that is what the courts have done. If a decision not to fund treatment is based on factors that are relevant e.g. clinical effectiveness of treatment and is made as a result of an explicit and transparent process, then the refusal would probably be justifiable. Courts are likely to regard PCTs as acting reasonably if they refuse to fund treatment where the cost is high and the prospects of success or benefit are limited.

Where decisions about allocation of resources have been made on the grounds (for example), of race, colour or creed, Article 14 of the ECHR is quick to strike them down, (although the public law principles of impartiality and irrationality would produce the same result). If a decision not to fund treatment is based on factors that are relevant e.g. clinical effectiveness of treatment and is made as a result of an explicit and transparent process, then the refusal would probably be lawful. Courts are likely to regard PCTs as acting reasonably if they refuse to fund treatment where the cost is high and where there is limited prospect of success or benefit of the treatment.

Issues that may present to a CEC or Priorities Forum

The issue of resource allocation is beginning to come to Clinical Ethics Committees for consideration.

Below we use hypothetical cases to illustrate the ethical principles a committee needs to consider in approaching requests for advice on issues of resource allocation.

Case One: Who should have the intensive care bed?

Most choices regarding resource allocation are made at a managerial level. However, clinicians are faced with difficult decisions about determining priorities within the limited resources available in their area. For example, what should you do if the intensive care unit is full and a patient that requires intensive care is admitted to the hospital?

Barry is a 32 year old man with meningitis and is brought into the A&E department of hospital A. He is unconscious with an extremely low blood pressure and evidence of renal failure. His condition is grave and without intensive care support he is almost certain to die. With intensive care support he may make a full recovery. Until this illness he has been fit and well. The Intensive Care Unit (ICU) in hospital A is full, with some patients critically ill and some in a relatively stable condition but for whom optimum care would still require the facilities of an ICU. There is evidence that moving a patient from an ICU early increases their chances of complications and may increase mortality. There is an available bed in an ICU in hospital B, which is fifty miles away. The intensive care consultant on call must decide if Barry should be moved to hospital B or if a patient already in ICU should be transferred to allow Barry to be admitted. The clinical ethics committee is asked to review the case retrospectively and advise on how such cases should be approached in the future.

Questions for the committee to consider

1. Does the clinical team, or the institution, which the CEC is advising owe an equal duty of care to both patients?
2. If each patient is owed the same duty of care, should the aim be to maximise the chance that both patients live, or minimise the chance that both patients die.
3. In contrast to 2, should the sickest patient be given any greater priority in receiving best possible care?
4. If the patient in ICU is owed a greater duty of care, is this **sufficient** to justify the decision not to admit the other patient, given the foreseeable probable outcome?
5. Is patient autonomy relevant in this situation?

Keep in mind that it is not possible to provide the best care to both patients

Discussion of the issues

The first step in considering such a dilemma is to establish the clinical facts and clarify the concepts used. This process may involve seeking expert opinion from sources outside the clinical team treating the patient and / or outside the Trust. This is an important part of the process of any ethical discussion, but is particularly important in issues of resource allocation when underlying ethical principles include terms such as benefit and need that may be open to interpretation. Thus

information such as what will be the benefit of a certain course of action, and to whom it will accrue, and the relative need of the individuals involved, is essential to inform the ethical debate.

Maximising benefit

One way of looking at the dilemma would be to consider the relative benefit of different courses of action. The benefit to Barry of being admitted to ICU is clear; he will die if he is not given intensive care. However, the actual benefit will depend on the likelihood of his surviving even with intensive care. If his chances of making a full recovery are 80% the potential benefit will be greater than if his chance of surviving, even with intensive care, is 10%. The effect of transferring Barry to another hospital on his likely survival would also be important. For a patient already in ICU in hospital A, there can be no benefit from moving them out of ICU and transferring them to another hospital. The assessment here would be of the possible risk of such a move and the likely effect on their long-term recovery. If the risk is small, and the risk of moving Barry is great, then a utilitarian calculation of the overall benefit may support the transfer of a stable patient in hospital A to provide a bed for Barry. However, a greater risk of transfer for patients already in ICU combined with only a small chance of benefit to Barry from admission (a high likelihood that he will not survive even with treatment) may give a different answer if the criterion for the decision is overall benefit.

Responding to need

Another way of looking at this dilemma is from the point of view of the relative need for intensive care treatment. Barry is in urgent need because without intensive care treatment he will die. One can argue that we have a moral responsibility to respond to such urgent need even if the chances of success are small and it involves a small risk of potential harm to others.

Respecting autonomy

Respecting a patient's autonomous wishes is an important ethical principle in health care. What weight should be given to the refusal of a patient, or their relatives, to agree to a transfer to another hospital to allow a very sick patient to have their bed? What about the autonomous wish of the patient in the casualty department to have appropriate care in the hospital to which they have been brought? In terms of acceding to patients' or relatives' wishes, the principle of autonomy is not particularly helpful in this situation.

Duty of care

Health professionals in an ICU have a duty of care to their patients and must act in their patients' best interests. Therefore it may be very difficult for them to make a decision that is not entirely in their patient's best interest. The question arises as to whether the intensive care team also has a duty of care to a patient who is currently physically elsewhere in the hospital but who is in need of intensive care treatment. A further question is whether the hospital management has an equal duty of care to both patients, and if so how does this fit with the clinician's duty of care?

Case two: Should a clinician prescribe a new treatment that is more expensive than the standard treatment?

Dr Z is consultant at a specialist cancer unit. A new cancer treatment has recently become available for use in patients who have reached the end of conventional treatment for a particular type of cancer. Without further treatment less than 5% of patients will survive for 6 months. With the new treatment 40% of patients survive for six months and 5% are still alive at one year after treatment.

40% of patients survive for 6 months
If we treat 100 people we will gain 20 life years (40 multiplied by 0.5)
Cost of treating 100 patients is £500,000
Cost per life year gained is £25,000 (500,000 divided by 20)

5% of patients survive one year
If we treat 100 patients we will gain 5 life years
Cost of treating 100 patients is £500,000
Cost per life year gained is £100,000 (500,000 divided by 5)

Thus, the cost of one life year gained with this treatment is £25,000 if we use 6 month survival figures and £100,000 if we use one year survival figures.

Dr Z has a patient for whom he wishes to prescribe the new treatment. Alice is a 27 year old mother of two young children. Dr Z argues that an extra 6 to 12 months of life will make a huge difference to Alice and her children, and it is possible that within those 12 months further advances in treatment may be made. Furthermore, if she is one of the 5% of patients who survive for one year, she may go on to survive for much longer as there is little experience of this drug in the longer term. The Trust managers are concerned that they will not be able to meet the total cost of treating all patients who may benefit from this drug without cutting other services or treatments. They ask the clinical ethics committee to consider the ethical implications of this request for treatment.

This issue could come to a CEC of an acute trust where a clinician is asking the acute trust to fund such treatment.

If the acute trust says that it cannot afford the treatment, then the issue could go to the local PCT as a request for further funding to the acute trust.

Questions for the Committee to consider

1. If this treatment were funded, how many other patients would have a claim on this drug?
2. Is the cost per life year gained greater than that normally funded by the Trust? If so, from which budget should the funding come? From the envelope of resources for cancer care, or from other services? In which case, is this fair?
3. Does the fact that this patient has dependent children affect the decision? If it does, and if it provides a reason for giving greater priority, does this have implications for allocation decisions elsewhere in the Trust?
4. Does the increase in probability of extended life, and the predicted extent of extended life, justify paying more for a treatment than the Trust can normally afford? Are there other examples within the Trust of expensive interventions being used because of a chance of saving someone's life?

Discussion of the issues

Maximising benefit

A utilitarian approach to this dilemma would be to consider the cost effectiveness of the new treatment compared to other treatments currently provided by the cancer unit and by the trust as a whole. Money used to fund the new treatment would need to come from other treatments or services, assuming that the trust was fully committed financially. Therefore, to maximise benefit to

all patients across the Trust it is necessary to have a threshold for cost effectiveness of treatments or services that the Trust will fund. This allows different treatments or services to be compared directly on cost effectiveness terms and ensure that resources are used efficiently. Inefficient use of resources will reduce the overall benefit that can be achieved. If the Trust had a threshold of £20,000 per QALY or per life year extended, then the new treatment proposed by Dr Z would not fulfil the cost effectiveness criterion. One problem with only considering the cost effectiveness of the new drug is that other treatments already available may be less cost effective.

Responding to need

Are there reasons other than cost effectiveness to fund this new treatment? A persuasive argument would be the pressing need of Alice for treatment, without which she will die very soon. Even if the treatment only extends her life by six months that is a significant length of time for someone who is otherwise likely to die in a few weeks. In comparison, other treatments that are funded within the trust may not extend life but simply improve the quality of life for those having treatment. Is extending life always more important than improving the quality of life?

Fairness and morally relevant differences

If it were not possible to provide funding for every patient who might benefit from this treatment, could Dr Z argue that the fact that Alice has two small children who would benefit from having their mother around for even a short amount of time, gives her a stronger case than others without children for receiving treatment? This raises the question of whether having children is a morally relevant difference and justifies 'unequal' treatment. What if, rather than having dependent children, Alice is the main carer for her elderly mother?

Autonomy:

How much account should be taken of Alice's views of what treatment she wants? Respecting patient autonomy is important but the wishes of individual patients must also be balanced against the interests of others. In the context of limited resources, as we saw in case one, the principle of individual autonomy is not particularly helpful.

Case three: Prevention or treatment?

Decisions about setting priorities for treatments and services on a larger scale raise difficult ethical issues for PCTs. A PCT may seek advice on the ethical issues arising from these 'macro-level' decisions from a priorities forum, or a PCT may develop their own ethics committee to inform these decisions.

Metroville PCT has a sum of recurring money that has been ring-fenced for use in the area of ischaemic heart disease. The PCT has two proposals for developing services in this area and must decide which proposal to fund.

Proposal 1 is from the local acute trust and is for an increase in angiography and angioplasty services. The proposal cites evidence from research studies to show that reducing waiting times for angioplasty will save lives and is a cost effective use of resources.

Proposal 2 is from the local diabetes group and is for a project that will focus on the small Asian community within the population. This community has a high prevalence of diabetes and ischaemic heart disease and traditionally has tended to use health care services only when they are acutely ill rather than attending for regular care of their chronic diseases. The proposal is to

provide a specialist diabetes nurse and health advocate for this population and an educational programme for the whole community focusing on prevention of diabetic complications and promotion of life-style changes to reduce the incidence of new cases of diabetes. There is no research evidence for this intervention but there is some anecdotal evidence from other areas that this approach has some success.

The PCT must choose one of these proposals.

Questions for a priorities forum to consider

1. Should the aim of the PCT be to provide the best value health care for the whole population by always funding the most cost effective treatments, or are there other considerations that would outweigh the cost effectiveness argument?
2. If overall value to the whole population is the most important consideration, how does the PCT compare the value of different interventions when different levels of evidence are available for each?
3. Is providing a service that is equally accessible to everyone in the population who could benefit from it (angioplasty and angiography) fairer than providing a service that will only benefit a specific section of the population who could benefit (diabetes intervention for minority ethnic group)?
4. Should the PCT put more resources into services for specific groups that are currently disadvantaged in health terms, compared to the general population, to redress the balance, even if these services are less cost effective than those usually funded by the PCT?
5. Should services that have an immediate impact in terms of saving lives always be preferred over those that may reduce the risk of future death (and thus save lives in the future)?

Discussion of the issues

As with individual clinical cases, the first step in considering such an issue is to obtain as much relevant information as possible about the two interventions, including the views of users of the services as well as providers.

Maximising benefit

An important consideration for a PCT is how to use its limited budget in an efficient manner in order to provide as much overall benefit as possible for the community it serves. A utilitarian perspective of maximising benefit will require an assessment of the evidence of how effective each intervention is and the cost of obtaining that benefit. QALY calculations, if available, would be useful in this context. However, not all health care interventions have robust research evidence, including economic data. Some interventions are difficult to assess in a randomised controlled trial, and some medical conditions are less attractive to researchers or funders of medical research. A lack of evidence about the effectiveness of an intervention is not the same as good evidence that the intervention is not effective. Making a decision that was informed only by evidence of cost effectiveness of the competing interventions would tend to favour interventions for which evidence was available and could lead to unfair treatment of patients with equal need. The priorities forum of Metroville PCT may wish to consider evidence of effectiveness for the diabetes intervention other than that from formal research studies to obtain a more balanced view of the likely overall benefit to its population.

Reducing inequity

A different approach to this difficult decision would be to consider what would be a just distribution of resources in the context of existing health inequalities within the population served by the PCT. If the Asian community was particularly disadvantaged in terms of its health compared to the population as a whole, then one could argue that targeting resources at this group will reduce inequality in health between it and the general population.

Responding to need

One argument for funding the increased angioplasty service could be that those patients who will benefit from this service are in more acute need than those who will benefit from the diabetes intervention. Even if more lives could be saved in the long term from a preventive service, there are identifiable individuals on the angioplasty waiting list who may die very soon if not treated. Is it more important morally to save the lives of identifiable patients in the short term or to save the lives of as yet unidentified patients in the long term?

Equal access to treatment

What if waiting times for angioplasty were longer in this PCT than in other areas of the country? If this were the case one could argue that this is unjust and that the resources should be used to redress this inequality. A similar argument could be made for the diabetes intervention. How do we balance the demand of equal access to a specific treatment for all who would benefit, and equal access to appropriate treatment for people with different conditions but equal need?

How much weight is given to the different principles and perspectives will affect the outcome of the decision. There is no ranking formula for this process. What is important is that members of the committee or forum consider carefully all relevant facts and values in deliberating the issue. As PCTs will be expected to justify their decisions to their population, a fair and transparent process that is followed for each decision will also be of great importance.

Useful Links for Patients

NHS Alliance

<http://www.nhsalliance.org>

National Institute of Clinical Excellence (NICE)

<http://www.nice.org.uk>

General Medical Council (GMC)

<http://www.gmc-uk.org/standards/default.htm>

Department of Health - Health Inequalities

<http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/HealthInequalities/fs/en>

Department of Health - Human Rights Issues

<http://www.dh.gov.uk>

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Glossary of Terms

Commissioning - the authority to purchase goods and services for patients from a range of different providers in the public, private or voluntary sector. For example a PCT may 'commission' palliative care services in its area.

Distributive Justice - A form of justice that applies to the distribution of goods or resources between individuals or within a society. One influential theory of distributive justice that has been used in the context of health care is that of John Rawls, who developed a theory of 'justice as fairness'. But it is not the only view on distributive justice.

Maximising Welfare - "the right and rational course of action in a situation where resources are insufficient to maximize the health of individuals is to maximize the health of the population or group as a whole" John Butler, *The Ethics of Health Care Rationing, Principles and Practices*, Cassell, 1999, page 135. (In this context "welfare" and "health" are being equated, but other writers use these terms in different ways).

National Institute of Clinical Excellence (NICE) - NICE is an independent organisation responsible for providing national guidance on treatments and in the NHS. It publishes clinical guidance based on evidence-based medicine on different healthcare interventions (<http://www.nice.org.uk/>)

Primary Care Trusts - a body with its own health care budget, established with the purpose of providing or arranging for the provision of health care within its particular area. There are more than 300 PCTs in England and Wales.

Priorities Forum - a group set up to assist a health authority or PCT in making decisions about individual treatments or in determining their relative priorities for commissioning. (Hope T, Hicks N, Reynolds DJM, Crisp R and Griffiths S, Rationing and the health authority. *BMJ*, 1998; **317**: 1067-1069)

QALY (Quality Adjusted Life Year) - "The essence of a QALY is that it takes a year of healthy life expectancy to be worth 1, but regards a year of unhealthy life expectancy as worth less than 1. Its precise value is lower the worse the quality of life of the unhealthy person (which is what the 'quality adjusted' bit is all about).
A. Williams, 'The Value of QALYs', *Health and Social Service Journal* July (1985), 3

'Undue Delay' - an unreasonable delay for NHS treatment, potentially justifying recompense for expenditure on treatment obtained from EU countries. ([Watts v Bedford PCT and the Department of Health \[2004\] EWCA Civ 166](#))

Utilitarianism - an ethical theory which states that the morally correct thing to do is that which secures overall maximum benefit. This would favour allocation of resources in a way that maximises the benefit to the whole community. Note that any form of utilitarianism needs a criterion, or some criteria, of what the "good" is.

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