Making Difficult Choices
Ethical Commissioning Guidance to General Practitioners

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Executive Summary

This guidance is for general practitioners, and particularly GPs who will have a role as commissioners in clinical commissioning groups in England. Ethics and commissioning are big subjects. This document focuses on the following questions:

- When resources are limited, and when the consequences of our decisions affect the lives of many thousands of people, how can we decide which treatments and services to pick?
- How ought GPs and others in future clinical commissioning groups (CCGs) go about making these difficult decisions?
- How can we address potential conflicts of interest that arise for GPs involved in commissioning?

GPs have always made resource allocation decisions. For example, we routinely make judgements about whether a referral should be offered. Such decisions are a matter of clinical judgement, but they are also about whether the benefits justify the cost, as we are of the costs involved and the needs of others patients. As doctors, we are also familiar with medical ethics. The four principles of respect for autonomy, beneficence, non-maleficence and justice are helpful in clinical practice, and may be a useful way to begin thinking about ethical commissioning.

When we are making decisions that will impact the health of a population, we need to justify our decisions not just on grounds of cost-effectiveness and efficacy but also in terms of justice. For example, if we change the threshold for funding cataract surgery, will this have a disproportionate effect on the elderly or people of Indian descent?

We aim to offer a framework for considering questions like this, and for making and justifying difficult choices. However, there are no widely-accepted “right answers” to the difficult ethical questions we address in this guidance.

Allocating Resources Ethically

In this guidance, we propose that commissioners should aim to use limited resources to:

- Do as much good as possible;
- Whilst being fair.

Doing as much good as possible means maximising health (and any other justifiable) benefit. One proposed means of measuring health benefit is quality-adjusted life years (QALYs). Sometimes it may be justifiable to do less overall good in order to be fair (e.g. when targeting resources at a deprived group). When considering what is fair, in this guidance we argue that commissioners can apply two fundamental principles of human dignity:

- every person’s life has intrinsic value and is worthy of equal concern; and
- autonomy: each of us has responsibility for the governance of our own life.

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1 “treatment” and “care” are used interchangeably in this document.
2 With “good” being health and any other justifiable benefit
3 where one QALY is a year of good health (see sections 2.2 and 2.3)
4 other than young children, and adults lacking competence
We illustrate in the guidance how these aims and principles could be applied using scenarios.

**GPs as commissioners**

The future structure of the NHS is still subject to change. However, it is clear that GPs, working within clinical commissioning groups, will have a leading role in allocating scarce resources to healthcare. In the guidance, we argue that:

- resource allocation inevitably involves rationing, that rationing is not new, is ethically justifiable, and that GPs and others have a responsibility to explain to patients why fair resource allocation is a necessary part of any healthcare system;
- whilst many doctors will be concerned that they continue to represent their patients’ interests, the role of commissioner can be reconciled with the role of GP;
- in order to increase the democratic legitimacy of their decision-making processes, CCGs should have fair and open processes to consult and engage the public on resource allocation, and collaborate with health and well being boards and others;
- to avoid legal challenge, CCGs should develop and publish policies for priority setting which treat patients fairly and consistently, and have procedures for considering "exceptional" cases;
- ethical commissioning relies on cost-effectiveness and efficiency, and CCGs should rely on evidence to judge the effectiveness of interventions, and work together where there are economies of scale.

**Potential conflicts of interest for GPs as commissioners**

A conflict of interest exists when a commissioner’s judgement could be, or could be perceived to be, influenced or impaired by their other concerns or obligations e.g. as a provider of services.

Clinical commissioning groups should:

- Have a clear statement of the conduct expected of those involved in its governance (based on the Nolan principles for public life);
- Ensure that all individuals involved in decision-making are required to declare their interests when joining the governing body;
- Maintain a register of these interests which is updated regularly;
- Have clear procedures for handling conflicts of interests in meetings;
- Ensure that procurement and contracting procedures comply with the law and good practice.

Conflicts can be avoided and managed by:

- Doing business properly;
- Being proactive not reactive;
- Being balanced and proportionate.

In trying to decide whether or not something might be seen by others as a conflict, imagine explaining the situation to an investigative reporter (the “Paxman test”). If in doubt – disclose. Scenarios are provided in the guidance.
1 Introduction

1.1 Purpose of this guidance

The purpose of this document is to provide a framework for making and justifying ethical decisions that are likely to arise when commissioning healthcare services.

1.2 Target audience for this guidance

The guidance is aimed primarily at general practitioners, and particularly those becoming involved in clinical commissioning groups in England. It also may be helpful to other people, including non-GP members of clinical commissioning groups and local medical committees.

1.3 Scope of this guidance

This guidance considers how finite resources ought to be allocated to healthcare, and how those decisions ought to be made in the NHS where general practitioners are commissioners. When general practitioners become commissioners, some additional ethical dilemmas arise: how ought we to carry out our role as doctors when we, or our general practitioner colleagues that we have elected, are accountable for commissioning decisions? How ought we to ensure that our decisions are not affected by self-interest, and that we are seen to make decisions that are unaffected by self-interest? Some of these difficult questions have no “right” answers; the purpose of this guidance is to provide advice to help general practitioners make these difficult decisions.

Ethics demands that we make the best possible use of resources, and thus that care provision is efficient and effective. This guidance focuses on what care ought to be commissioned, rather than how that care ought to be provided.

1.4 Structure of this guidance

Five further sections follow this introduction:

- Section 2 considers the problem of allocating resources to healthcare from an ethical perspective from the standpoint of any commissioning organisation
- Section 3 applies this thinking to clinical commissioning groups, and the role of GPs, in the new NHS;
- Section 4 considers conflicts of interest;
- Section 5 outlines the legal context for commissioning; and
- Section 6 illustrates how the ethical aims, principles and procedures could be applied to problem scenarios that might arise for clinical commissioning groups.
2 Ethical resource allocation

2.1 The need to address challenging ethical questions

Healthcare commissioning includes resource allocation. To ensure that good value for money is achieved, services have to be procured and monitored appropriately, and there is an ethical dimension to this. When funds available for healthcare are limited, challenging ethical questions arise when trying to decide what services and treatments should be commissioned, and potentially, which patients should receive these services. These dilemmas are heightened when people are living longer, expectations of health services are increasing, and budgets are reducing.

Difficult choices arise such as:

- Should we fund treatment for things which are not life threatening or seriously harmful such as snoring in the absence of sleep apnoea?
- Should we fund fertility services rather than lower the threshold for hip replacements?
- Should we fund treatments which the public want but where the evidence is poor, such as homeopathy?
- Should we fund interventions that might prolong life but are very expensive, such as some cancer medication?
- Should we fund health education such as smoking cessation, healthy eating, and sexual health?

Further consideration of these questions reveals additional, more fundamental, dilemmas, such as:

- What is the aim of health services?
- Is there a duty to save lives that “trumps” all other claims on resources?
- How ought we to value the lives of the unborn, the young and the elderly?
- What rights do we have to interfere with the decisions made by adults on how to lead their lives?

These are very difficult and contentious ethical issues – so difficult that commissioners might prefer to ignore them. But without policies that implicitly or explicitly address questions like these, it will be extremely difficult to make consistent decisions, or to withstand legal or public challenge on how tax-payers’ resources have been spent. There is an enormous wealth of philosophical and bioethical literature addressing these difficult questions, revealing many illuminating but often conflicting answers (see below). This ethical commissioning guidance does not attempt to provide you with a “correct” set of answers to these fundamental life-and-death dilemmas. Rather, it seeks to steer you towards a path where you can establish ethically-justifiable resource allocation policies.
2.2 Learning from others

2.2.1 Resource allocation in theory

There is widespread acceptance in the academic literature that rationing is necessary for the fair allocation of resources, whether it be in a single-payer system like the NHS, or an insurance market like the USA (where policies inevitably set fixed limits on medical cover). The disagreement arises on how to ration.

There are two main approaches to resource allocation proposed and pursued in the academic literature:

- utility-maximising rationale like QALYs, which can provide absolute but arguably unfair answers to the difficult questions arising in resource allocation, and
- fair processes such as “accountability for reasonableness”, which propose no solutions other than processes by which policy makers can reach and justify their own conclusions.

In the 1980s and 90s, economists (Williams, 1985, pp. 43-66, Brock, 1993) elaborated the concept of quality-adjusted life years (QALYs) as a measure of the utility, expressed in healthy years of life, to be gained from healthcare. A healthy year of life is worth one QALY, and a year of life at 70% of full health is worth 0.7 QALYs. At its simplest (and there are many variants, interpretations and applications), the QALY was proposed as a means to assess which healthcare treatments yield the greatest benefit, and thus how to allocate scarce resources.

There have been many objections to QALYs from bioethicists, philosophers and others, leading to much debate (Mooney, 1989, Cubbon, 1992). One major criticism is that they systematically discriminate against the elderly. Furthermore, when considering life-saving treatment, QALYs discriminate against disabled people (who have less health to gain under QALY ratings), and against those with a short life expectancy. More generally, many philosophers and bioethicists reject approaches like QALYs that aim to maximise utility, and some have concluded that it is not possible to agree a fair and publicly-acceptable rationale for allocating healthcare resources (Holm, 1998). They argue that there is too much disagreement on the numerous ethical questions that arise when making these difficult life-and-death decisions. Indeed the disagreement is not only on how to distribute resources fairly, but more fundamentally over what a healthcare system should aim to achieve. For example, is it maximising good-quality life years, as QALYs suggest? Is it life-saving first, and restoring bodily functioning second? Does it include preventing future ill-health and death?

Because of this lack of consensus, writers like Daniels (a philosopher) and Sabin (a clinician) propose that the only reliable guidance that can be given to policy-makers is that they use fair, transparent and accountable processes to develop and justify their resource allocation decisions (Daniels and Sabin, 2008). Many philosophers and bioethicists have supported, and worked to develop and refine, the “accountability for reasonableness” fair processes proposed by Daniels and Sabin (Martin et al., 2002, Daniels and Sabin, 2008).
2.2.2 Resource allocation in practice

In the UK, QALYs have been, and still are, used by bodies such as the National Institute for Health and Clinical Excellence to make resource allocation decisions on new medications and other technologies. NICE also deploys elements of the fair processes proposed by Daniels and Sabin. Primary care trusts have varied in their approaches, with few publishing explicit policies on rationale to allocate resources.

A number of countries, including Norway, Denmark, New Zealand and Israel have attempted to engage the public in explicit priority setting for healthcare. In general, these countries have favoured fair processes over utility-maximising approaches like QALYs. A notable exception is Oregon, USA where a QALY-like approach in the early 1990s led to controversial conclusions (e.g. prioritising pills for headaches for the many, over life-saving operations for the few) before it was changed in favour of an approach rooted in public consultation.

A very readable overview and analysis of this international experience has been provided by Sabik and Lie (Sabik and Lie, 2008).

2.3 Ethical resource allocation: aims and principles

2.3.1 Two aims: doing good and being fair

If health economists and bioethicists disagree about how to allocate health resources efficiently and ethically, what should commissioning bodies do? "Doing as much good as possible" will be a self-evident goal for most of us. Economists have applied it to create theories of utility maximisation, the strand of thinking on which QALYs are based. Why would we not seek to do as much good as possible with limited resources? The only good ethical reason is where being fair means doing less good overall so that benefits are distributed more justly. Therefore, an ethically-justifiable approach to resource allocation is:

- to maximise the good that can be realised from the limited resources available,
- whilst constraining the maximisation of good where necessary for reasons of fairness.

To do as much good as possible with a limited budget, services must be effective in delivering the outcomes required, and efficient. To achieve this, decisions should be based on evidence. Thus, bodies commissioning care have an ethical responsibility to monitor and ensure effective and efficient care provision.

Distributive justice (or being fair) in commissioning may mean that we do less good overall. For example, it may cost twice as much per user to advertise and run a smoking cessation clinic in a social housing estate than it does to run a similar clinic with GP-referred patients within a local health clinic. However, the commissioning body might justify that it is fair to run both types of clinic because transport problems would otherwise deter people on the housing estate from participating. However, as John Broome, the economist-turned-philosopher argues, fairness need not be an absolute constraint (Broome, 1988, pp. 64):
“Fairness and maximising will normally pull in different directions, and they need to be balanced against each other. Neither is overriding. It will almost certainly be right to sacrifice some good in total for the sake of fairness. And it will almost certainly be right to tolerate some unfairness for the sake of the greater good.”

Such trade-offs necessarily involve making value judgements. Value judgements are necessary too to assess what is good and fair. Clearly, virtually everyone would agree that improving a person’s health status is good, and the more improved it is, and the longer it is improved, the better. That is the thinking behind QALYs. They are a very useful tool for comparing the benefits of one intervention with another if the information (such as the expected health gain in years) is available. QALYs can also be modified to take account of the judgement that many of us would accept that an intervention that saves ten lives now is worth more than one that saves ten lives in fifteen years time.

But do QALYs capture our concept of the “good” we seek to achieve? That concept could be extended to take account of benefits to people other than the patient. For example, it could take into account the value to carers of medication that eases the demands made by people suffering from dementia. We could recognise the benefits to a whole family where one family member ceases to be dependent on alcohol. “Good” could also recognise the economic benefits to us all if a person returns to work quickly. We might also wish to value certain types of information as good in themselves (e.g. the results of a test for Huntington’s disease) even though it may bring no direct health gain. Equally, doing as much good as possible could mean considering the wider implications of resourcing decisions. For example, decisions could take account of the potential environmental impact of commissioned services and the knock-on effect on health(Costello et al., 2009), and encourage ethical trading.

There is no widely-accepted ethical consensus on this; ethical justifications could be constructed for many different interpretations of “good”.

Identifying what fairness means in practice is perhaps even more difficult. When resources are finite, difficult choices have to be made about which people, or types of people, are winners and losers. For example, even if QALY scores are in favour, would it be fair to fund fifty people to have knee operations and so lead healthier lives, rather than pay for expensive medication in order to significantly increase the chance of saving a single life?

This document can offer no definite answers to such a question. However, the principles that follow, and scenarios in section 6, can help guide such choices.

2.3.2 Two principles of human dignity

Norman Daniels, a leading international writer on the ethics of healthcare resource allocation, advised(Daniels and Sabin, 2008):

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As supported by the British Medical Association; see http://www.bma.org.uk/international/international_development/fairtrade/
“Resource allocation decisions in health care are rife with moral disagreements and a fair, deliberative process is necessary to establish the legitimacy and fairness of such decisions”.

They propose that commissioning bodies adopt fair processes to determine their own principles for priority-setting in healthcare. These fair processes are useful (see section 3.1.5 below) but the lack of ethical principles is not helpful to commissioning bodies.

We suggest here two principles that commissioning bodies could consider adopting. In his book *Is Democracy Possible Here?*, Ronald Dworkin attempts to bridge the gap in American politics by offering two fundamental principles of human dignity that he believes would be accepted by almost all Americans. From this common ground, he builds ethically justifiable conclusions about a range of contentious moral and political issues.

The two principles are:
1. every person’s life has intrinsic value and is worthy of equal concern, and it matters how every life proceeds; and
2. each of us has a personal responsibility for the governance of our own life.

These two fundamental ethical principles are chosen here for a number of reasons. Firstly, they that can be used as a basis to address many of the fundamental ethical dilemmas that arise in commissioning. Secondly, they should be widely acceptable to, and consistent with the values of, the vast majority of citizens in the United Kingdom. They can unite people who might hold different belief systems. For example, both humanists and Christians would accept principle 1, even though they have different reasons to accept it, and may disagree about when human life begins. Thirdly, the two principles are relatively simple, and easily understood.

Note that the second principle is not directly applicable to adults and children lacking the capacity to make autonomous decisions.

2.3.3 Beauchamp and Childress Principles

Many readers will be familiar with the four ethical principles developed by Beauchamp and Childress (Beauchamp and Childress, 2001, pp. 57-224):

- Respect for autonomy: respecting decision-making by autonomous persons, and enabling individuals to make reasoned informed choices;
- Beneficence: balancing benefits of treatment against the risks and costs, healthcare professionals acting in a way that benefits the patient;
- Non-maleficence: avoiding unnecessary harm to patients;
- Justice: distributing benefits, risks and costs fairly, patients in similar positions should be treated in a similar manner.

These principles are more relevant to clinical practice than resource allocation decisions but there are clear parallels to the two aims and two principles above.

6 See section 4 scenarios and the discussion of the rescue principle below.

7 In England, the law requires that others make decisions in their best interests.
Autonomy is captured by the second principle of human dignity – it is about people taking responsibility for decision-making in their own lives. The first aim (in 2.3.1 above) proposes maximising good (broadly equivalent to beneficence). Justice is a fundamental principle in resource allocation which is why the aim of maximising good is constrained by concerns of fairness, and the first principle of human dignity recognises the need to treat everyone with equal concern. Non-maleficence is less relevant to resource allocation, and more relevant when making clinical judgements about individual patients (although those making resource allocation decisions would also wish to avoid doing harm).

2.3.4 Balancing the two principles for reactive care

These two principles can be used to help us make difficult choices between treatments for patients seeking and needing care. Consider the case mentioned earlier: should we buy expensive medication that gives somebody with terminal cancer a chance of a few extra months of life? Some philosophers have suggested that there is a “rule of rescue” that compels us to fund such treatment to save lives despite the cost (Jonsen, 1986).

However, the rule of rescue is inconsistent with two principles above. The first principle of human dignity requires commissioners to have equal concern for all human lives, regardless of gender, race, disability etc.; the intrinsic value of human life means that every person ought to be treated with dignity. The second principle of self-determination implies that each person has to seek value in their own lives, and recognises that different things will add value to different people’s lives. Health is just one of those good things.

In his book *Sovereign Virtue*, Dworkin imagines how much a prudent person would choose to spend on health rather than other good things, and what kind of healthcare insurance cover they would purchase and what they would not purchase. Dworkin applies this thinking to an agency making commissioning decisions (Dworkin, 2002, pp. 317):

"An agency might well decide that while prudent people would … insure against serious medical risks at all stages of their lives by providing tested and reasonably effectively treatment should they need it, they would forego heroic treatment of improbable value if they needed it in return for more certain benefits like education, housing, and economic security."

Dworkin argues that justice requires us to consider how individuals would prioritise health spending against other good things. On this basis, he argues it is not just, as the rescue principle would suggest, to spend disproportionate sums of money to give someone the chance of a few extra days or weeks of life. His prudent insurer model balances the maximisation of good with fairness. He argues it is egalitarian but non-paternalistic (Dworkin, 2002, pp. 319).

2.3.5 Balancing the principles for pro-active care

Where competent adults are in need and seeking care, then law and ethics demand that they consent to treatment, and principle 2 above (self-determination) is particularly important. But is paternalism ethically justifiable in public health, where
commissioners actively target certain groups or individuals in order to prevent future ill-health? Can it be ever be ethical to commission interventions even when autonomous patients do not want them?

A rigorous ethical analysis of these questions, entitled Public Health: Ethical Issues was carried out by a distinguished list of bioethicists, public health specialists and clinicians for the Nuffield Council on Bioethics and published in 2007. It is recommended reading (both a full report and short guide are available online).

The authors develop a “stewardship model”, setting out goals and constraints for public health (where different circumstances may require a different balance between the two principles of equality and self-determination outlined above)(Nuffield Council on Bioethics, 2007, pp. 26):

“Concerning goals, public health programmes should:

- aim to reduce the risks of ill health that people might impose on each other;
- aim to reduce causes of ill health by regulations that ensure environmental conditions that sustain good health, such as the provision of clean air and water, safe food and decent housing;
- pay special attention to the health of children and other vulnerable people;
- promote health not only by providing information and advice, but also with programmes to help people to overcome addictions and other unhealthy behaviours;
- aim to ensure that it is easy for people to lead a healthy life, for example by providing convenient and safe opportunities for exercise;
- ensure that people have appropriate access to medical services; and
- aim to reduce unfair health inequalities.

In terms of constraints, such programmes should:

- not attempt to coerce adults to lead healthy lives;
- minimise interventions that are introduced without the individual consent of those affected, or without procedural justice arrangements (such as democratic decision-making procedures) which provide adequate mandate; and
- seek to minimise interventions that are perceived as unduly intrusive and in conflict with important personal values.”

The report includes a helpful “intervention ladder” (below) and provides examples of circumstances where different levels of intervention could be justified. The levels range from regulating to eliminate choice (e.g. compulsory isolation of patients with infectious diseases) through to providing information (e.g. on the benefits of eating five portions of fruit and vegetables per day) or doing nothing. These are choices about whether to participate in a public health programme rather than, for example, a patient’s choice of health care provider.
Case studies with specific advice on ethically-justifiable intervention are developed for public health programmes on:

- infectious diseases;
- obesity;
- alcohol and tobacco; and
- fluoridation of water.

The National Institute for Health and Clinical Excellence has adopted the stewardship model (Nuffield Council on Bioethics, 2010), and the UK government’s 2010 white paper Healthy Lives, Healthy People cites the intervention ladder (Department of Health, 2010, pp. 29-30). This model can be helpful to commissioners when assessing whether to fund programmes to encourage and help autonomous individuals give up smoking, or justifying the imposition of public health restrictions on a population, whilst at the same time withholding payment for treatments requested by individual patients.

### 2.4 Requirements of democracy

What gives governments, or commissioning bodies given authority by governments, the right to decide who gets treated? That question – of political legitimacy – is “the oldest question of political philosophy” according to Dworkin. His answer is that governments must respect the two principles of human dignity. When making law and policy they must show equal concern to all citizens and respect citizens’ personal responsibility for their own lives.
Daniels, Dworkin (Dworkin, 2002, pp. 25-66, Daniels and Sabin, 2007) and others recognise that expert committees alone should not determine policy in a democracy. Commissioners, like general practitioners, can not be seen in any straightforward way to represent patients. The opportunity for meaningful public participation is necessary in a democracy, and many writers have explored different ways to engage citizens in deliberation (Fishkin and Laslett, 2003, , Fischer, 2000, , Dworkin, 2006). However, this does not imply majority rule(Roper, 1989, pp. 63) (Dworkin, 2006, pp. 131-147) (Seidenfeld, 1992, pp. 1528-9).

Thus in a democracy like the UK, a commissioning body making what can be life-and-death decisions for others, requires legitimacy. This legitimacy is derived from:

- Authority to act, delegated by a democratically-elected government;
- Engaging the public in the decision-making process;
- In its actions, taking account of, and showing respect for:
  - The cultures, values, needs and interests of citizens,
  - The equal importance of all citizens, and respect for citizens’ personal responsibility for their own lives.

### 2.5 Fair processes for making decisions

For Daniels and Sabin, legitimacy relies on fair processes for setting priorities in healthcare resource allocation. Their “accountability for reasonableness” framework provides four conditions that must be met by commissioners:

- Publicity: rationing decisions made, and their rationale, must be made public;
- Relevance: the rationale on which decisions are made must be reasonable (i.e. based on evidence and relevant reasons), taking account of how the organisation provides value for money and meets varied health care needs;
- Revision and appeals: there must be a mechanism for individuals to challenge and dispute decisions, and for the organisation to learn and revise its policies;
- Regulation: there must be either external or self-imposed mechanisms for enforcing the first three conditions above.

A full account of accountability for reasonableness, which is an approach that has been developed over many years and tested in a number of countries, can be found in Setting Limits Fairly - Can we Learn to Share Medical Resources?(Daniels and Sabin, 2007) A short summary was published in the BMJ(Daniels and Sabin, 2008)

We will suggest how the “accountability for reasonableness” framework could be applied by future clinical commissioning groups in England in section 3.

### 2.5.1 Enabling public participation to secure legitimacy

The “accountability for reasonableness” processes of Daniels and Sabin necessarily involve the public in priority-setting decision-making process. Dworkin too stresses the importance of public participation in decision-making because healthcare “rationing should reflect not just technical cost-benefit calculation but also the public's sense of priorities”(Dworkin, 2002, pp. 317).
They propose that members of the public have “seats at the table” where decisions are made. When commissioning bodies have few elected public representatives, the legitimacy of decision-making is more likely to be challenged, and the need to gauge public opinion and allow public participation in decision making is greater. Groups representing specific interests (e.g. those affected by diabetes) should have a channel through which they can express their claim on resources. But commissioners also need to try to understand whether their value judgements reflect public values.

Economists trying to solve the complex problem of resource allocation in healthcare place significant emphasis on public surveys of preferences (Dolan et al., 2005). They imply that because, for example, a majority of those surveyed would give priority to people who have children, that commissioners should adopt this policy and discriminate against those without child dependents. But surveying on complex ethical issues concerned with healthcare resource allocation is not like surveying public preferences for chocolate bars. People surveyed may be poorly informed of, or have had no opportunity to deliberate on, the complicated policy question. Surveys may not provide a reliable means for assessing public values (Ubel and Loewenstein, 1996, pp. 1053).

The danger of relying on a simple public survey of uninformed respondents to inform policy was illustrated in the results of a recent process. Selected members of the public were consulted on whether health spending should be fully protected from government cuts. When surveyed beforehand, 79% of the 24 members of the citizens’ jury were in favour, but after three days of deliberation where the citizens had the opportunity to hear and discuss expert evidence, only 9% wanted to rule out cuts in health spending (Stratton, Tuesday 10 August 2010).

A citizens’ jury (like that established by the National Institute for Health and Clinical Excellence)\(^8\) is an example of an appropriate mechanism for identifying public values, and enabling public participation. Commissioners ought to be aware that however carefully selected, the members of such a group contribute in an individual capacity, cannot fully represent the full range of public opinion, and are not acting as formal representatives of the public.

3 Ethical healthcare commissioning in the new NHS

3.1 Introduction

The structure of the NHS in England is changing. At the time of writing, the Health and Social Care Bill 2011 is progressing through Parliament, and so organisational structures and responsibilities are subject to change. This guidance is based on the proposals contained in the government’s response to the NHS Future Forum, available at:


Commissioning responsibilities in England are to be distributed between:

- The Secretary of State, who retains the responsibility to promote a comprehensive health service;
- The NHS Commissioning Board, which will oversee commissioning arrangements;
- NICE, renamed as the National Institute for Health and Care Excellence, now with a remit extended to social care, and which continues to evaluate and recommend the drugs and treatments to which patients should be entitled;
- clinical commissioning groups (CCGs), which have the primary responsibility to commission care for a local population;
- health and wellbeing boards, which will assess local health and care needs and develop a strategy to address them, providing a strategic framework for the plans of CCGs; and
- Clinical senates and networks, which will not be statutory bodies but which, amongst other things, will provide expert advice to, and assess the plans of, CCGs.

Every CCG will have a governing body with decision-making powers and responsibilities, and it is proposed that it will comprise general practitioners plus at least one nurse, one secondary care clinician, and one lay member. This ethical guidance document is aimed at general practitioners, and especially those on the governing body of a CCG. Therefore, the remainder of section 3 considers the role of the CCG and its relationship to other bodies, and describes briefly how general practitioners could apply the framework for ethical commissioning set out in section 2.

3.2 Ethical commissioning by clinical commissioning groups

The CCGs ought to use their allocated resources to do as much good as possible, whilst being fair (see section 2.3.1). CCG members must weigh up competing demands for resources, and consider the impact of their decisions on affected groups within the local population. There will be winners and losers, and especially careful consideration will be required where the losers are likely to include many people who are already disadvantaged within society, and perhaps as a result less able to take control of their own health. Prioritising such people could be ethically justifiable even where that means doing less aggregate good overall.
CCGs ought to be explicit about the good they are trying to achieve, articulating and publishing their aims. These aims are likely to include maximising health benefit, but may also include other goals (see section 2.3.1). Measures such as quality-adjusted life years (QALYs) may be useful tools in assessing health benefit, although commissioners ought to satisfy themselves that their decisions are fair and not rely solely on utility maximising formulae like QALYs.

When considering whether their resource allocation decisions are fair, CCGs may find useful the two ethical principles discussed in section 2.3.2:

1. that every person’s life has intrinsic value and is worthy of equal concern, and that
2. each of us has a personal responsibility for the governance of our own life.

CCGs are not elected bodies and yet they will make decisions about shared resources that affect the lives of everyone. Thus they have an ethical duty to elicit the views of the public, elected public representatives, and institutions created through democratic processes. They should publish their policies, and have fair processes for dealing with individual claims. This will add significantly to the legitimacy of CCG decision-making.

CCGs have a legal and ethical responsibility to make good use of public resources, and thus to plan, enable and monitor commissioned services that are effective and efficient.

### 3.3 GPs working as commissioners and doctors in a clinical commissioning group

Do GPs have a legitimate role as commissioners? Is our role not as a doctor, and our first concern the care of the patient?

Doctors are committed to treating their patients. Their concern is for the care of their individual patient, and for pursuing the best interests of that patient. Commissioning, on the other hand, is about the general good of a population, potentially at the expense of individual patients registered with the GP. There have been warnings that this poses a conflict of interest which threatens the patient-doctor relationship (Cassidy, 2011), and this is a genuine concern for some doctors.

However, patient care is not a doctor’s only concern; (s)he has other competing duties (Sokol). Commissioning is about planning and enabling the care of patients in a population. General practitioners (whether principals or sessional doctors) have a broad and deep understanding of the needs of patients, and are well-placed to play a leading role in commissioning healthcare. Allocating resources and setting limits on healthcare is inevitable in any healthcare system (whether funded publicly or privately through insurance). It is not something that doctors, whether commissioners or not, can ignore or disown. Doctors, commissioners, and politicians all have a role to play in explaining to the public that difficult choices have to be made, and that those choices may affect each and every one of us. If patients understand that rationing is inevitable, and that doctors can help to make rationing as fair as possible, then the doctor/patient relationship should not be adversely affected.
An important practical question is whether GPs have enough time to carry out properly the role of commissioner as well as doctor. Before seeking and agreeing to become commissioners, it is essential that GPs understand and do not underestimate the demands of that role, and ensure they can make available sufficient time. It is a new role for GPs and there will be much to learn. Whilst training should become available, GP commissioners will also depend on the skills of managers and others.

CCGs will make judgements about whether care would be better provided in primary care or in other settings, and on which organisations should provide that care. This poses ethical dilemmas of a different kind for GPs within CCGs who could be seen to be commissioning services for their own financial or other gain. These issues are to be addressed in the Health and Social Care Bill. Section 4 offers guidance to GPs on managing potential conflicts of interest.

3.4 Clinical commissioning groups working together

To be ethical, commissioning has to be effective and efficient. There will be much scope for CCGs to learn from each other and to work together for mutual benefit. In particular, working together will be important where it brings economies of scale.

There are significant costs, and significant potential economies of scale, in communicating with, and encouraging participation from, and the public. The fair processes for resource allocation advocated in this guidance have significant resource implications, and it would be very costly if done independently by each of the three hundred or more CCGs. Collaboration amongst CCGs, potentially in conjunction with health and wellbeing boards and clinical senates, would be efficient.

It could be argued that consultation with the public has to be with the local population for which the CCG is responsible, and only that population, because that population requires a clear, distinct voice. However, it is impracticable to consult the population as a whole, and any group will never be truly representative. Collaboration will enable CCGs to justify the expense of implementing proper processes. Furthermore, CCGs will not be bound by the outcome of such processes, but can interpret and apply the results making use of information about the specific needs of their own local population.

Furthermore, in an NHS funded by general taxation, and where CCGs are unelected bodies, it could be argued that patients should have similar entitlements to care wherever they live in England. The media and individual members of the public may have cause to speak out against "postcode lotteries". This strengthens the case for CCGs to collaborate when they consult the public and make resource allocation policy.

3.5 Clinical commissioning groups working with health and wellbeing boards and others

It is proposed that health and wellbeing boards will have a statutory responsibility to assess health and care needs of a population, and to produce a strategy to address those needs. The new boards provide an important opportunity to improve the
integration of health and social care. They will be set up within local authorities, and their membership will include elected councillors, increasing their legitimacy.

Working with health and wellbeing boards is expected to be a legal requirement for CCGs, and will add legitimacy to the operations of the CCG. It will be particularly important where CCGs seek to develop public health programmes.

CCGs will also be required to work with healthcare providers, the NHS Commissioning Board, clinical senates and networks, NICE (which becomes the National Institute for Health and Care Excellence). From an ethical perspective, working with other statutory bodies adds to the legitimacy of CCGs, and can improve the effectiveness and efficiency of the NHS as a whole.

3.6 Clinical commissioning groups working with patients and the public

Section 2.5 explains why ethical resource allocation relies on effective public participation. It highlights the potential risks in relying on surveys where members of the public may be poorly informed about a complex ethical policy problem like how to fairly allocate resources to healthcare. A forum (like for example a citizens’ jury) is needed where selected participants can be properly informed of, and can deliberate on, difficult issues. Such meetings can inform CCG decisions, but CCGs are the accountable body for commissioning.

As part of ethical commissioning, CCGs are encouraged to collaborate (see section 3.4 above) and develop processes to:

- Publish their resource allocation policies, and explain the rationale behind their decisions, and how these address health care needs and provide value for money;
- Consult the public to better understand how demands for healthcare resources can be prioritised;
- Provide mechanisms so that individuals can appeal where decisions made adversely affect their health; and
- Allow their policies to be revised and improved.

Practices can now receive funding to improve patient participation[^9], and it may be possible to co-ordinate their activities with those of the CCG.

[^9]: A GMS incentive payment equivalent to £1.10 per registered patient is available to practices. See: [http://www.bma.org.uk/employmentandcontracts/independent_contractors/general_medical_services_contract/gmscontractagreement2011.jsp](http://www.bma.org.uk/employmentandcontracts/independent_contractors/general_medical_services_contract/gmscontractagreement2011.jsp)
4 Potential conflicts of interest for general practitioners

Amongst the many issues that clinical commissioning groups will need to get to grips with as they become statutory bodies and take on financial and contractual responsibilities, is how they will manage real and perceived conflicts of interest facing the individuals involved in the governance and decision-making. There has been growing concern about this issue of healthcare professionals; it has become increasingly prominent in public debate of the government's proposals for health reform.

4.1 What are conflicts of interest and do they matter?

A conflict of interest can occur when an individual’s ability to exercise judgement in one role is impaired by their obligation in another because of the existence of competing interest(s). For members of a clinical commissioning group, a conflict of interest would exist when their duties as a commissioner could be, or could be perceived to be, influenced or impaired by their other concerns and obligations. It could arise because they are an owner, director or shareholder in an organisation doing business with the NHS, or because they are a professional or member of a special interest group, or because of their relationship to a close family member.

Such concerns may be financial but could also relate to personal commitments (qualifications to friends, colleagues, peers), special interests (for example, in a particular treatment or condition due to an individual’s own experience or that of a family member), other non-financial objectives (status or kudos), or professional loyalties or duties.

There is nothing inherently wrong in having conflicts of interest, and seeking to avoid or eliminate them entirely is unlikely to be possible or desirable for clinical commissioning groups. But if they are not managed effectively, and GPs and their colleagues are seen perceived to be misusing their new commissioning powers, the consequences will be serious. It could undermine providers and regulators’ confidence in the probity and fairness of commissioning decisions, damage patients’ confidence in the independence of healthcare professionals and ultimately destabilise public confidence in the system as a whole.

However the issue is not entirely new or unique and with good planning and governance, commissioners should be able to avoid these risks.

In trying to decide whether or not something might be seen by others as a conflict, imagine explaining the situation to an investigative reporter (the “Paxman test”). If in doubt – disclose.

4.1.1 Existing standards, policies and guidance

The General Medical Council's good medical practice guidance already requires medical practitioners to be mindful of, and when necessary to declare, conflicts of
interest. "If in doubt, disclose" is likely to be a good rule of thumb of healthcare professionals as they exercise their new commissioning responsibilities.

However, CCGs should not simply rely on individual professional judgement, and must ensure that policies and processes for identifying, managing and reviewing conflicts of interest are embedded in their structures from the outset.

CCGs will be able to draw on existing policies and procedures used to manage conflicts of interest in other parts the NHS, wider public sector and other industries, as well as the recent experience of PCTs and practice-based commissioning groups. They can apply the same basic policies, procedures and standards used by NHS trusts and other public bodies to manage conflicts of interest, which include:

- Having a clear statement of conduct expected of those involved in its governance (potentially based on the Nolan principles\(^\text{10}\), and reflecting any requirements that are set out in the clinical commissioning groups authorisation process);
- ensuring that all individuals involved in decision-making are required to declare their interests in joining the governing body;
- maintaining a register office interests, which is updated regularly;
- ensuring that specific conflicts of interest relevance of the agenda of a particular meeting are disclosed again at the beginning of that meeting and recorded, and that decisions are taken transparently and according to a clear policy as to whether conditional participation, partial exclusion or total exclusion from the decision-making is required; and
- ensuring procurement contract procedures comply with the law and practice.

4.1.2 Principles for managing conflicts of interest

Further guidance on the constitution and governance of commissioning consortia is expected from Department of Health, but commissioners will still need to understand, interpret and apply guidelines to their organisation. The following principles may help CCGs.

Conflicts can be avoided and managed by:

- **Doing business properly**
  If clinical commissioning groups get their needs assessments, consultation mechanisms, commissioning strategies and procurement procedures right from the outset, then conflicts of interest become much easier to identify, avoid or deal with, and should withstand scrutiny.

- **Being proactive not reactive**
  Substantial conflicts of interest can be avoided by being clear and transparent on what is acceptable before individuals are even elected or selected to join a CCG; by inducting team members properly and ensuring they understand their obligations to declare conflicts of interest; and by agreeing in advance how a range of different situations and scenarios can be handled, rather than waiting until they arise. Conflicts of interest should be considered and declared not only on appointment but before each decision making meeting.

- **Assuming that individuals may not always be sensitive to conflicts of interest**
  Most individuals involved in commissioning will seek to do the right thing for the right reasons, but they may not always do it the right way due to lack of awareness.

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\(^\text{10}\) See: [www.public-standards.gov.uk/Library/Seven_principles.doc](http://www.public-standards.gov.uk/Library/Seven_principles.doc)
of rules and procedures, insufficient information about a particular situation, or lack of insight into the nature of the conflict. Rules should assume people will volunteer information about conflicts themselves and absent themselves from decision-making where they exist, but there should also be prompts and checks to reinforce this.

- **Being balanced and proportionate**
  Rules should be clear and robust but not overly prescriptive and restrictive. Their intention should be to identify and manage conflicts of interest not eliminate them, and their effect should be to protect and empower people by ensuring decision making is efficient as well as transparent and fair, but not constrain people by making it overly complex or slow.

### 4.2 Outstanding issues

While the primary responsibility for ensuring conflicts of interest are identified and managed appropriately will lie with CCGs, there are still issues which need to be addressed such as:

- How can the public be assured that CCGs are managing conflicts appropriately?
- How will non GP members be selected and how will their conflicts be managed?
- What will the rules be on issuing commissioning rewards and incentives to those involved with commissioning? The public do not wish to perceive that their GPs are being rewarded for not offering them care.
- Should clinicians be required to make explicit choices between pursuing commissioning and provider roles?
- How does competition and choice fit in with this? Whether or not commissioners seek to promote competition or integration with existing healthcare providers, they still run the risk of having a possible conflict.

### 4.3 Conclusions

The fact that clinicians running CCGs will sometimes have conflicts of interest does not in itself mean that they will take inappropriate decisions or undermine the credibility and independence of the governing body. Conflicts of interest are inevitable. In most cases it is possible to handle conflicts with integrity and probity by ensuring that they are identified, declared and managed in an open and transparent way.
5 The legal context for commissioning

Rationing may be justified ethically, but is it also lawful for commissioning bodies to deny healthcare to individual patients? The short answer is yes, it can be. Patients decide whether they wish to receive treatment, but it is for commissioners and individual doctors to offer treatment options according to need, and not for patients to demand any treatment they choose. A brief overview of relevant law (not legal advice) is given here.

Although this may change when the Health and Social Care Bill 2011 becomes law and is enacted, under the NHS Act 2006 section 1, the Secretary of State has a duty to promote a comprehensive health service, but has a duty to provide services to the extent he considers necessary to meet all reasonable requirements. As the judgement concluded in R v North and East Devon Health Authority ex p Coughlan [2001] “he has the duty to continue to promote a free health service...a comprehensive health service may never, for human, financial and other resource reasons, be achievable”.

Similarly, current law requires primary care trusts to decide what healthcare services to commission, but backed by policies and procedures. As lawyer Christopher Newdick explains:(Newdick, 2007, pp. 236)

“Primary care trusts (PCTs) require reasonable and lawful policies to control their expenditure. Inevitably, this means that some treatments may be regarded as low priority and difficult to obtain within the NHS; for example, cosmetic surgery, or expensive treatment where clinical effectiveness is marginal, or unknown. However, general policies of this nature must also include ‘exceptional case review’ procedures. Individuals should be entitled to argue that, the general policy notwithstanding, their treatment is likely to be of such exceptional benefit that it deserves to be funded by the NHS.”

However, as Newdick goes on to explain, only legitimate priority setting is acceptable, namely where PCTs’ duty to spend within their budget is balanced with their duty to promote the health of the entire community (now under the NHS Act 2006).

It is clear from R v North West Lancashire Health Authority, ex p A, D and G [1998] that PCT policies and procedures must be rational. Authorities must allow for exceptional individual cases, and where a decision seriously affects a citizen’s health, it will require substantial consideration. The judge explained:

“To deny treatment except 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 to be considered on its individual merits.”

However, having proper policies, and dealing with, exceptional cases is complex, as is ensuring that decisions and decision-making procedures are fair and consistent with the Human Rights Act and other legislation. Commissioning bodies may require legal advice. This is particularly true given the further complication of EU law, as Newdick explains(Newdick, 2007, pp. 244):
“The European Court of Justice (ECJ), however, has developed a different approach focusing simply on the need of individual patients. Ignoring the opportunity costs of diverting finite resources from Peter to treat Paula, it has said that if ‘normal’ treatment cannot be obtained at home without ‘undue delay’, it may be purchased in the EU abroad on the basis that the cost will be met by the ‘home’ health authority. Clearly, such a principle undermines the role of exceptional case review committees. If treatment considered normal elsewhere in the EU is unavailable in the NHS and it may be obtained irrespective of NHS funding constraints, then those willing and able to travel abroad will have greater access to expensive treatments than those who are too ill, old or disabled to travel. The economics of this ‘individualist’ approach are obvious. As the cost of funding NHS care in the EU increases, the funds remaining to those at home will diminish; it is they who will come to dominate the work of NHS exceptional case review committees in future. The ECJ has never explained or sought to justify the policy which underlies this divisive and unethical conclusion.”

Up until now, very few patients have sought refunds for treatment carried out overseas. Nevertheless, CCGs ought to be aware that if commissioning policy leads to “undue delay”, it may become more common for patients may seek treatment from outside England, and then claim reimbursement from their CCG.

Lastly, the Equality Act 2010 is currently being introduced (in stages). The British Medical Association has published initial guidance on the Act(British Medical Association, 2011). Public authorities will be required to publish an equality statement every four years and a statement of compliance annually. The new Act defines discrimination and makes illegal direct discrimination, although age discrimination can be justified by public authorities if it is “a proportionate means of achieving a legitimate aim.”(2010, pp. 19) The courts may or may not accept that CCGs withholding funding of treatment for older people with a short life expectancy in order maximise the health benefit from public funds is a proportionate means of achieving a legitimate aim.
6 Illustrating the guidance: scenarios

This section provides scenarios to illustrate and apply the ethical commissioning framework in earlier sections. It uses examples that may arise and prove contentious in real-life commissioning, and offers conclusions that draw on the reasoning from within the guidance. However, it is important to stress that there are no widely-accepted “right answers” to these difficult ethical issues; each CCG will reach their own conclusions on such questions.

1. Breast augmentation in a woman who is self harming and being teased.

Although, there is a local policy which says that cosmetic surgery of this sort takes a low priority, a 21 year old patient’s doctor writes to the CCG saying that his patient is an exception to the policy in that her small breasts and the reported teasing have caused her to make superficial cuts to her wrists. The GP says that these problems are likely to be solved by offering her a breast augmentation. The cost of such treatment is approximately £4000. Before reaching the board, the case passes through the CCG’s exceptions process in order to ensure that the claim is considered fairly and will not be subject to subsequent legal challenge.

Response to Scenario

The CCG Board considers the case. There is a general feeling that there might be a case to make an exception to the policy if the treatment would prevent self-harming and significantly reduce risk of suicide because of the significant good it would achieve by reducing harm, and raising self-esteem thus promoting autonomy and the young woman’s capability to lead a fulfilling life. Furthermore, the cost of treatment is relatively low, particularly taking into account the NHS costs saved from further self-harming. However, available evidence suggests that breast augmentation does not prevent self-harming or significantly increase self esteem. For this reason, the CCG (on the advice of its exception panel) decides to reject the funding request, and for a letter of explanation to be sent to the GP.

2. When to listen to active pressure group – e.g. Parkinson’s

The local Parkinson’s disease group is very active and attends every board meeting asking questions about Parkinson’s. They believe that the disease is inadequately managed in the area. It is not a priority mentioned in the Joint Strategic Needs Assessment. There is pressure to increase provision, with the local leader of the council starting to ask questions via the local newspapers prompted by the local interest group. Furthermore, the Parkinson’s group proposes to pump prime investment by providing a nursing team free of charge for 2 years on the understanding that the funding will continue from the NHS.

Response to scenario
In drawing up the Joint Strategic Needs Assessment, the CCG had spelt out their aims of maximising good subject to fairness, and their underlying ethical principles. They used these as explicit criteria when assessing and establishing the priorities for spending in the Joint Strategic Needs Assessment. As a result, the board feels that sufferers from Parkinson’s were treated fairly in the needs assessment relative to other groups. For these reasons, they are reluctant to make any promises about increased funding when the pump priming expires in two years. Members were also concerned about whether a nursing team funded by the charity would blend in as part of the team and whether or not they would be prepared to follow guidelines developed by the CCG. The board decides against any additional funding at this stage, but to investigate further the claims that local standards of provision are sub-standard. Given the level of local pressure and media attention, the chair of the CCG asks for a meeting to be set up with the council leader and a representative from the Parkinson’s disease charity in order to fully understand their concerns. It is agreed that after that meeting, the board will consider making a press release.

3. Funding of pre-implantation genetic diagnosis

The CCG has noticed that the cost of funding pre-implantation genetic testing (PGD) has grown markedly over recent years. The Board asks for a paper assessing whether funding should continue for couples who are both carriers of cystic fibrosis, and who wish to have PGD rather than prenatal testing (costing approximately £1,000) and a potential termination of pregnancy if the foetus is found to be affected with cystic fibrosis (which is a 25% probability). The CCG currently funds all such cases for two treatment cycles, regardless of whether either parent already has a healthy child. The paper explains that the cost of PGD is £8,000 per cycle and that there is a 30% chance of the treatment leading to the birth of an unaffected child. With up to two cycles funded, a couple has a 51% chance of coming out of the PGD treatment process with an unaffected child. Cystic fibrosis severely affects a person’s quality of life, although it can be picked up early as part of national screening, and with treatment, life expectancy is now over 30. The report explains that there is no national guidance to cover this, and that PGD is funded in some areas and not others. Some authorities currently funding PGD do not fund couples who already have a healthy child.

Response to scenario

The Board discusses the policy at length. Members are split on whether to continue funding PGD for couples who are both carriers of cystic fibrosis. A majority of members agree to the following conclusions:
that when valuing the health benefit derived from PGD, the expected healthy life years of an unborn child should not be taken into account because that child does not yet exist;

any additional health benefit from PGD to the couple could be taken into account, but it is difficult to be confident that any quantifiable health benefit will result;

the potential significant future cost to the NHS of a carrier couple giving birth to, and bringing up, a child with cystic fibrosis (of which there is a 25% chance) should be taken into account;

the 75% chance of a healthy child being born through natural conception (with the added option of pre-natal diagnosis), and the 51% chance of a healthy child being born through PGD, are both relevant considerations;

given the above conclusions, and using quality-adjusted life years to assess these health benefits, the cost per QALY does not justify CCG funding (given other funding priorities);

in terms of equity, a couple who are both carriers of cystic fibrosis and have no healthy children are disadvantaged, but not to such an extent that it changes the conclusion reached about funding;

the issues are so difficult and contentious that the question and the initial conclusions of the CCG board, should be referred to the citizens’ council for deliberation before any change is made to the current policy.

4. Continuing funding for a charitable organisation which offers a refuge for battered women

The primary care trust has been part funding a local refuge for many years. The refuge is valued in the community and has been a spending commitment for successive health commissioning organisations. Money is tight for the CCG and they have to review all of their spending. The Council is providing 20% funding for the centre but cannot provide any additional funding.

Response to scenario

All members of the CCG recognised the importance of the centre, and the good done by the refuge, and that it ought to be funded for reasons of justice given that it was vital to the interests of a vulnerable and disadvantaged group. Nevertheless, a majority of members on the board felt that such a service fell outside the scope of the CCG’s commissioning responsibilities, and the CCG’s published aims (the
most relevant of which is “maximising health benefit through commissioned health services”). Some members voiced their concern that without a refuge, the health of affected women and their children would suffer, and that lives would be put at risk. In order to give the centre the opportunity to find alternative sources of funding, the board agreed on an intention to maintain funding for the coming year, provide half of that funding for the following year, and then to stop any further funding. However, given the potential impact of stopping funding, it was agreed that the chair would consult with the local health and well-being board before any decision was announced.

5. The CCG has been reviewing its policy on primary hip and knee replacement. A paper has been put to the board recommending that patients should only be offered surgery if:

- there is severe functional impairment or pain; and;
- they have a BMI of under 35; and
- they do not smoke.

The paper recognised health benefits (measured in QALYs) per pound spent on primary hip and knee replacement were relatively high. It justified its recommendation on grounds that that the risk of complications or other poor outcomes from surgery for smokers and obese patients were higher (by a margin of 15% and 20%\(^\text{11}\) respectively). The document further argued that both smokers and obese patients were making lifestyle choices that damaged their health, and that changing their lifestyle to give up smoking and/or lose weight would have wider benefits to their health. It proposed that patients who changed their lifestyle so that they met the criteria should become eligible for surgery (taking advantage if they wished of available smoking cessation and weight loss programmes).

**Response to scenario**

*The minutes from the board meeting read:*

“After long deliberation and debate, the Board reached the conclusion that the current guidelines allowing joint replacement surgery regardless of weight or smoking status should remain for the present time. In reaching its decision, the board took account of the following factors:

- A primary aim of the CCG is to maximise health benefit with available resources, and given the relatively small decrease in health benefits associated with smokers and obese patients, primary joint replacement for such patients still represents good value for money despite the clinical risks;
• The other primary aim of the CCG is to be fair in the distribution of resources, and denying treatment from patients who smoked or were obese would be unfair in this case because:

  o Although expecting autonomous people to face up to the costs and consequences of their informed decisions is ethically justifiable, the NHS is a service that is available free at the point of delivery to all, regardless of status;

  o It is the responsibility of each person to decide how much to eat and whether to smoke, and whilst the CCG ought to encourage healthy living, it was not ethically justifiable for the CCG to coerce people into giving up smoking or losing weight.

• The Board were concerned that smoking and obesity were the only criteria considered in the report, whereas other relevant factors such as age were not assessed.

The Board noted that if the effect of smoking or obesity on expected health benefits had been significantly greater, so that health benefits per pound were below that which could be achieved from other health programmes not currently funded, the Board’s decision may have been different. However, given that such a decision to deny treatment could be contentious and seen to discriminate against specific groups, the area citizen’s council would be consulted."

6. Near to the financial year end, a paper is presented to the CCG identifying that there is some available funding. It reminds the board of two potential areas of spend that in recent months they had put on hold because they were unsure of funding. There are enough funds to pay for the first year costs of one of the two proposals but not both. The proposals are:

A. Palliative care facility: A local hospice has an available ward and wishes to open a small centre of four short-stay beds for terminal care or for symptom control, designed to allow those in the later stages of degenerative illnesses to be cared for out of a hospital setting. This facility will enable symptoms to be more effectively managed by a specialised palliative care team, improve the quality and personal dignity of the last days or weeks of these patients’ lives, and will free up beds in an overstretched geriatric unit in the local hospital.

B. The parents of a 5-year old child with Hurler Syndrome, a rare degenerative genetic disorder, have asked their clinical geneticist to prescribe a costly new medication. The clinical trials and early use of the

12 See http://en.wikipedia.org/wiki/Hurler_syndrome#Treatment
drug in the USA show positive results, although there has been no evaluation within the UK by the National Institute for Health and Clinical Excellence (and nor is one likely in the near future). Without the drug, the child can be expected to live until aged 10, with pain relief but a poor and worsening quality of life. With the drug, a small improvement in quality of life can be expected, and early results suggest that life expectancy will increase to around aged 14.

**Response to scenario**

The board decides not to fund the medication for Hurler Syndrome (B. above), and to provide first year funding for the palliative care facility (A. above) with further funding to be reviewed in six months when commitments for the following year are clearer. The minutes from the meeting explain their reasoning:

“The quality of life of the tragic case of the child with Hurler Syndrome would not be greatly improved by the new drug, and so the additional years of life would not bring much health benefit to the child. A poor quality of life would be extended. The additional benefits are difficult to assess given the relative lack of information about the new drug. The board also recognised that they had previously refused funding for previous interventions for other conditions which had equivalent or somewhat greater health benefits, and in funding this treatment they would not be maximising the good that can come from the available resources.

The effect of funding the palliative care facility will be to significantly improve the quality of the end of life of dying patients. It respects the dignity of people whose lives are of equal importance and worthy of equal concern. In freeing up beds in the local hospital, it will allow people who currently may be receiving inadequate care because of pressure on geriatric beds, to be treated in hospital, adding to the quality of, and potentially extending, their lives.

7. The local allergy clinic is well supported by local GPs. It has become a national centre of excellence and is pioneering new ways of reintroducing children to things that they have an allergic reaction to so that they have the prospect of being able to eat e.g. peanuts and eggs again. The treatment is extensive and therefore expensive. The current CCG expenditure is approximately £600,000. At the same time, unscheduled care for the elderly is rising, putting additional strain on the hospital system and despite a cap in the payment to the hospital, is accounting for significant additional spending (and the associated problems related to avoidable admissions to hospital). A group has been looking at this and suggests that a £100k investment in a risk assessment computer system and a £200k investment in community matrons would address this issue and that it could be paid for by introducing strict referral guidelines for referral to the allergy clinic. Local parents groups are
furious about this suggestion, and no one seems to be speaking up for the elderly.

**Response to scenario**

The board members recognise the important pioneering work of the allergy centre, and a suggestion is made that research funding may be available to fund some of its activities. They assess that, in general, the health benefit to children suffering from these food allergies is relatively small (though benefits would accrue across a lifetime), whilst recognising that there may be exceptional cases that merit special treatment. Preventing falls and other causes of unscheduled admissions by the elderly provides significant health benefit to affected patients although for a shorter duration.

The board decide to agree to the proposals to address unscheduled care for the elderly, and to reduce funding for the allergy clinic. In considering whether this decision was fair, the board concluded that elderly people were a vulnerable, disadvantaged group, and unlike children suffering from allergies, they were identified as a priority in the Joint Strategic Needs Assessment. One of the board members agrees to meet with doctors from the allergy centre to explain the CCG’s decision before it is published.

8. Potential conflict of interest on diabetes project

The diabetes lead of a CCG has been working on a community diabetes project for two years and has a plan to reduce diabetes outpatients activity by 50% and to re-invest in primary care education, patient education, more specialist nurses and community consultant sessions. A cornerstone of this new service is a local enhanced service to be paid to practices for GP and nurse education to improve the prevention and identification of diabetes, and for providing enhanced diabetic care for their patients.

**Response to scenario**

Rather than benefiting a particular organisation, in this scenario all GP practices/primary care providers in the area could potentially benefit from the decisions being taken by primary-care based commissioners, at the expense of existing secondary care providers. The CCG may have to deal with the perception and challenge that the GP commissioners were favouring their “electorate”. However, it will not have engaged in any wrong-doing if it can demonstrate that it is possible and appropriate to reduce the number of people being referred to hospital for the management of diabetes and related complications, that it is likely to improve patient experience and outcomes overall, and that the service improvement required to achieve this relates specifically to general practices with registered lists of patients.

The CCG should have set out and communicated the case for change and the rationale for the proposed service model clearly and transparently before taking the final decision to proceed. When developing the diabetes commissioning strategy, the group should have consulted on, and then been absolutely clear about, who would have the opportunity to provide the service.
model and why, and this should have been consistent with an existing commissioning strategy and procurement framework. Other qualified providers should be given the opportunity to provide those elements of the new service model not specifically embedded in general practice (e.g. specialist nursing and community-based consultant sessions).

9. Potential conflict of interest on “free software”

Dr X is the chair of a local CCG. He is married to Dr Y. Dr Y is the clinical director for Health R Us, a company which has developed risk stratification software designed to enable primary care providers to identify vulnerable patients at risk of going into hospital and help them to put measures in place to address this. Health R Us has offered to supply the software to Dr X’s CCG free of charge for one year to help develop it. It will then be offered at a discounted price because of the work that the commissioning group would have done in developing it and acting as a demonstration site.

Response to scenario

There is no immediate financial gain to Drs X and Y from the decision to accept the software free of charge for a year. However, there is potential future gain to Dr Y (and therefore to her husband) as the clinical director of a company that could profit from a product that her husband’s commissioning group has helped to develop, and from a preferential position as an incumbent supplier to that CCG. Dr X should declare an interest and he should exclude also himself from any decision-making about this project.

Any decision subsequently taken by the rest of the group should depend on whether or not the product on offer would help them to achieve an existing, stated commissioning objective (i.e. – they should not accept it just because it is on offer), and whether or not the deal being offered was in line with the groups existing policies for partnership working/joint ventures/sponsorship etc.

If the CCG had a clear, prioritised commissioning strategy and policies for working with other organisations, from the outset, this decision should be fairly straight-forward. However, there is a question as to whether or not the group should accept this offer at all. Although it may meet an explicit commissioning objective, it may not be appropriate even then to simply accept the offer without, at least, some kind of analysis of whether other companies might be willing or able to offer the same or better. The concern is not necessarily about the personal relationships involved, but more generally about whether this is an acceptable way for a public body to do business.

10. Potential conflict of interest over new service tendering

Dr A is a member of a CCG with a long-standing interest in and commitment to improving health and social care services for older people. She has worked closely with local geriatrician Dr B for many years, including working as her clinical assistant in the past. They have developed a number of service improvement initiatives together during this time and consider themselves to be good personal friends.
Recently, they have been working on a scheme to reduce unscheduled admissions to hospital from nursing homes. It involves Dr B visiting nursing homes and doing regular ward rounds together with community staff. It has been trialled and has had a measure of success which has been independently verified by a service evaluation. They would now like to extend the pilot and the foundation trust that employs Dr B has suggested that a local tariff should be negotiated with the CCG for this ‘out-reach’ service. However, the commissioning group has decided instead to run a tender for an integrated community support and admission avoidance scheme, with the specification to be informed by the outcomes of the pilot.

Response to scenario

Due to her own involvement in the original pilot, association with the incumbent provider and allegiance to her friend and colleague, Dr A may be considered to have a conflict of interest when it comes to making decisions about the specification of this service and the award of the contract. She should probably not be involved in developing the tender, designing the criteria for selecting providers or in the final decision-making, even though she is a local expert. If the CCG has clear prompts and guidelines for its members, this should be obvious to Dr A, who should decide to exempt herself, but may feel frustrated by this. If the consortium was clear at the outset about its commissioning priorities and strategy and its procurement framework (setting out what kind of services would be tendered under what circumstances), its decision to tender for the service should not have come as a surprise to the trust, or to the individuals involved.

CCGs will need to ensure that they do not discourage providers, or their own members, from being innovative and entrepreneurial by being inconsistent or opaque in their commissioning decisions and activities.

11. Potential conflict of interest over primary care contracts

Dr S is a partner in a company that has recently taken over a number of single-handed practices and dramatically improved their performance in a short period of time. The company has a clear expansion strategy, and ambitions to operate nationally. Dr S is also a member of the governing body of a CCG. The CCG has had two practices allocated to it that do not wish to engage with its commissioning strategy. Their patients use the local hospital more than comparable practices, their quality outcome measures are poor, and local community healthcare professionals have raised concerns about patient safety. Poor management of the secondary care and prescribing budget in these practices is having a detrimental effect on the financial situation of the whole CCG. The CCG is meeting to decide whether or not to refer their concerns about the quality of primary care being delivered by these practices to the National Commissioning Board.
Response to scenario

Dr S is an expert in primary care improvement and turnaround, and her input to this decision would be valuable to the group. However, if she was instrumental in a decision which led to the NHS Commissioning Board withdrawing the primary care contract from these practices, she could be in a difficult position if her company then bid to take over the running of these practices. She could be accused by competitors as working with insider knowledge, or by the existing partners of the practices of taking a particularly hard-line approach to their performance management and referral in order to create opportunities for her own company.

The group would have to decide the level of involvement that Dr S should have in these discussions and whether or not she should be excluded from any decision-making. As Dr S’s company has a clear intention to expand its business and may be considered likely to bid for these contracts, Dr S should probably not be involved in the decision as to whether to refer the practices to the NHS Commissioning Board.

However, it is also possible that other GPs on the commissioning group might also have a potential conflict of interest here, because they could be equally interested in taking over a failing practice albeit not as part of a larger corporate enterprise. This highlights the importance of not making assumptions about who will have conflicts and why, but of having formal prompts and procedures that ensure everyone has to consider this.
References


