Debate & Analysis

Commissioning ethically and legally:

the more things change, the more they stay the same

GPs are at the centre of profound organisational change to the NHS. However, there are some things that will not change, namely the ethics and law of NHS rationing. The resources that any society has are limited and must be allocated between the different calls on them. This allocation could happen secretly, but an explicit method is ethically superior and legally necessary. We discuss the duties imposed by ethics and law.

MANAGING THE PROBLEM OF DEMAND AND SUPPLY

Demand for care is increasing as the supply of resources declines. Clinical commissioning groups (CCGs) must deal with all the pressures this brings. CCGs must introduce reasonable priority setting systems. They are not popular: they generate appeals, are poorly understood, and leave many patients unhappy. There is an urgent need for CCGs to understand the processes and procedures involved.

GPs must distinguish their 'Hippocratic' commitment to individual patients, from their duty to the community as a whole to manage finite resources competently. Conflicts are avoided principally by establishing a system which separates the commissioning decision-making process from the doctor–patient relationship.

FOUNDING ETHICAL PRINCIPLES

Patients should be treated equally, fairly, and consistently. On the one hand, the NHS is required to use its resources in the best way: treatments with the same outcome should be equally available to patients who need it (equality of outcome). On the other hand, the NHS should ensure that people are given an equal opportunity to be as healthy as they can.

Equality of outcome and equality of opportunity are important in the fair allocation of healthcare resources but often pull in different directions and people generally may differ about what is just in a particular case.[1] However, there are a finite range of factors that should be taken into account when making decisions of this kind:

- *Cost.* If the cost of an individual treatment is ignored and resources are distributed on a first come, first served basis, then funds will be exhausted before the end of the year. This is unfair to those who need treatment later.
- *Opportunity costs.* A decision to fund treatment A must take into account the fact that funding A may mean not funding B, C, or D. Resource allocation decisions should be made in the context of a fixed budget where the value of options can be compared.[2]
- *Clinical effectiveness.* As the central aim of a health system is to benefit patients, allocation decisions should consider the effectiveness of the treatments it provides. Resources should not be used to fund treatments that do not work.
- *Cost-effectiveness.* 'Value for money' matters in a health system because it optimises the benefit to the population given the resources available.
- *Need.* Considerations of 'need' give higher priority to those suffering the most ill health. This focuses attention on the individual patient's health requirements without regard to cost.
- *Ability to benefit.* Decisions should take account of patients that are particularly able to benefit from treatment or of the health service's ability to meet particular needs.
- *Procedural fairness.* These interacting factors must be weighed and balanced within a consistent system. Procedures and mechanisms must exist to implement them in a practical way. The idea is to promote procedural fairness.

NHS RESOURCE ALLOCATION AND THE NHS CONSTITUTION

Each of these factors can be the source of reasonable disagreement between stakeholders. Procedural fairness requires a balanced consideration of the range of relevant reasons. The search is not for 'correct' answers, but for decisions that can withstand close scrutiny. This is reflected in the NHS Constitution and new statutory regulations:

'You [the patient] *have the right to expect local decisions on funding of other drugs and* [...] *treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment* [...]*, they will explain that decision to you.'*[3]

'... each [CCG] *must have in place arrangements for making decisions and adopting policies on whether a particular healthcare intervention is to be made available for patients for whom* [it] *has responsibility ...* [and] *must compile information in writing describing the arrangements it has made ...'*[3]

Most NHS priority setting involves procedural rights and so requires proper procedures to be in place. Failure to do so exposes decision makers to serious risk of judicial review.[4] The courts have introduced a number of basic principles which apply to whoever is responsible for commissioning:

- CCGs should use a consistent mechanism for allocating resources. Call it an ethical framework. They must be able to demonstrate that all the relevant factors (such as those mentioned above) have been considered. The framework should be applied fairly and consistently. CCGs should collaborate together to share expertise.
- CCGs may differ in the way they perform these functions. The exact weighting of priorities may differ, but it makes no sense to have significant variation between CCGs. It is better to learn from the experience of others, and to demonstrate that decisions are inconsistent with practice elsewhere.
- CCGs are not obliged to fund a treatment just because a doctor recommends it. But if they decide not to fund it, they must tell the patient why. The new regulations require the CCG to 'provide that person with the reasons for that decision in

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writing.'[3] This may mean explaining the ethical framework, how it has generated a specific policy, and how it has been applied to the patients' particular circumstances.

- Blanket bans on treatment are subject to close scrutiny. Policy and procedure must accommodate claims that a patient has circumstances which make their case different from others. However the number of patients considered to be exceptions to a policy must be extremely small. Once 'exceptional' numbers accumulate, a new policy is required to respond in a fair and consistent way.

These ethical and legal considerations, as they apply to resource allocation in the NHS, resemble Daniels and Sabin's 'accountability for reasonableness' model.[5] There are four principles that constitute the fair process approach:

1. *Publicity.* Decisions and their rationales must be made publicly accessible.
2. *Relevance.* The justification for decisions should be reasonable, that is, accepted as relevant by fair-minded people committed to cooperation.
3. *Revision and appeal.* There must be mechanisms for challenge and dispute resolution regarding decisions and opportunities for revision in the light of new evidence.
4. *Regulative.* There is either voluntary or public regulation of the process to ensure that conditions 1–3 are met.[5]

The emphasis is on a fair process, governing how decisions are made rather than a specific guarantee of treatment. The relevant ethical considerations in this model are like those discussed above and are to be balanced against each other in each case.

From these four principles, we can extract a number of sub-principles necessary to assist the decision-making process required of CCGs.

- *Expertise.* The process should make use of a range of expertise in considering the evidence and reasons for decisions, based on both clinical and non-clinical experience.
- *Representation.* The process should include representation from a full range of stakeholders and the public. This ensures that decisions are relevant, practical, and publicly accountable.
- *Provision for exceptions.* The appeal principle guarantees that the system is flexible and can accommodate differences between individuals by dealing with exceptional cases.

PRESCRIBING DUTIES IN PRIMARY CARE

Since 1948, GPs have had a duty to prescribe on the basis of patient need. The current regulations provide that:

'... a prescriber shall order any drugs, medicines and appliances which are needed for the treatment of any patient who is receiving treatment under the contract by issuing to that patient a prescription form.'[6]

The only restriction on this principle is if parliament places treatments on the 'black', or 'grey' list of drugs, use of which is (respectively) banned, or restricted within the NHS.

For treatments outside the GP's legitimate experience, treatment and prescribing takes place in the hospital context where the GMS and PMS regulations do not apply. But what happens when CCGs need to reduce GP spending? Incentive payments (for example, from QOF, or QIPP) are intended to improve clinical practice. However, they cannot be used to contradict the GMS/PMS regulations. Incentives should never distort judgments about patients' needs. The Department of Health states that:

'Health professionals should base their prescribing decisions on individual assessments of their patients' clinical circumstances, for example, patients whose clinical history suggests they need a particular treatment should continue to receive it ... Payments or any other inducements to good practice must not reward prescribers or their practices simply for blanket prescribing of particular named medicines (that is, without consideration of the individual circumstances of patients).'[7]

Inevitably, these regulations mean that priority setting is easier in secondary care than primary care. Priority setting in primary care is more about persuasion than coercion.

CONCLUSION

The decision-making system described above is modelled on a process used in South Central Strategic Health Authority until April 2013 and is ethically and legally robust.[8] By instituting a fair and accountable process for making decisions about how resources are allocated, GP consortia can manage their clinical obligations with their wider obligations to manage the NHS budget. It ensures fairness, transparency, and consistency, without which decisions of this nature will be severely criticised.

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