

Developing and using an ethical framework in practice. The South Central Ethical Framework: A case study

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In this case study I will describe the South Central Ethical Framework, touching on how it was developed, how it is used in practice and give a flavour of its content. This is an example of an approach, taken on a collaborative basis by the PCT's in South Central, to give local priorities committees a common framework for decision-making. There are other frameworks and approaches operating in the NHS which may be equally effective, examples can be found on NPC's sharing practice website.

The "Framework" is used as an over-arching mechanism for developing treatment-specific commissioning policies within the South Central PCTs. It serves to advise PCTs in prioritising treatments.

Over 150 such policies now exist, dealing with matters ranging from cosmetic surgery and hearing aids, to hyperbaric oxygen therapy and [trans-catheter aortic valve implantation for aortic stenosis](#). They assist commissioners and clinicians respond to health care need in ways that treats patients fairly, equally and consistently.

The Framework is a collaborative enterprise and the product of an understanding between the PCTs of five counties. The framework has been adopted by:

- the nine PCTs of the South Central Region,
- the South Central Specialised Services Commissioning Group, and
- the Central South Coast and Thames Valley Cancer Networks

This means it has a sense of "legitimacy" and there is some "ownership" of the Framework. This is important for PCTs setting up new systems, perhaps based on others that already exist. It is sensible to exploit the experience of others. But senior members of the PCT must be engaged in understanding and introducing the system within their own organisations and be prepared to liaise with neighbouring PCTs in doing so.

Note, however, that although the framework is consistent, individual PCTs remain responsible for their own areas and are still entitled to *apply* the Framework differently. In other words, one would usually hope for consistency between PCTs applying the framework unless there are good reasons to the contrary, but those reasons may exist and, if so, reasonable differences between PCTs are perfectly legitimate.

I will now describe some key extracts from the framework which give a feel for what it seeks to achieve. As you consider this approach to priority setting, please pause to consider whether it might have assisted the

challenges you have dealt with in your own PCTs. Apply the principles we outline to the facts of the cases you have dealt with to test whether the process works.

First, the introduction to the document explains its purpose.

Primary Care Trusts are under a statutory duty to promote the health of the local community. They are also under a duty not to exceed their annual financial allocation. These legal requirements mean that, from time to time, difficult choices have to be made. The Priorities Committees help PCTs choose how to allocate their resources to promote the health of the local community. Individual cases are considered by each respective PCT.

The purpose of the ethical framework is to support and underpin the decision making processes of constituent organisations and their Priorities Committees and to support consistent commissioning policy through:

- Providing a coherent structure for discussion, ensuring all important aspects of each issue are considered
- Promoting fairness and consistency in decision making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity
- Providing a means of expressing the reasons behind the decisions made.
- Reducing risk of judicial review by implementation of robust decision-making processes that are based on evidence of clinical and cost effectiveness and an ethical framework

So, what criteria are used to give the Framework practical affect? The Framework incorporates the principles developed by the courts in the judicial review cases and the *NHS Constitution*, and aims to express the criteria in clear and non-technical terms accessible to everyone.

The major principles are largely self-explanatory and we will now discuss each of them and the rationale behind their development.

The first extract emphasises the need to have a balance of *clinical* expertise contributing to the work of the priorities committee. This is for two reasons. First, decision-making will usually involve evidence which clinicians are best placed to comment upon. For example the expertise may come from the Local Medical Committee, GPs, nurses, hospital doctors and clinical directors.

Their expertise may be relevant at two stages. Specialists in a particular field will be in a good position to submit evidence to the committee on the evidence from clinical trials, how effective is the treatment, do patients like it, how does it compare to other treatment, do they have personal experience of using the treatment? This evidence may be made available to the committee in a written report and, if needs be, in person by inviting clinicians to give oral evidence to the committee.

Clearly, in respect of the decision itself, it would not be fair to have clinicians deciding matters in which they have interests. For the purposes of the decision, the committee should be composed of people without special interests in a particular case.

However, there is an important second reason for inviting clinicians to assist the process of priority setting. They have personal responsibility for patients. Unless they are broadly sympathetic with the need for priority setting, it cannot really work and the inescapable challenge of balancing private and public interests will be frustrated. Every effort, therefore, must be made to engage clinicians at every stage of the process, for example, in creating an appropriate ethical framework, providing members to its committees and in deciding exceptional cases.

There is obviously a balance to be struck between managerial and clinical interests. Clinicians without expertise in managing large and complicated organisations may be at risk of mishandling the budget. And managers may be at risk of failing to understand clinical evidence and the views of patients and their carers. Representatives of both sides, together with lay representatives, are essential to the process.

With this in mind, the slide illustrates how the matter is dealt with in South Central.

1. EVIDENCE OF CLINICAL AND COST EFFECTIVENESS

The Committees will seek to obtain the best available evidence of clinical and cost effectiveness using robust and reproducible methods... The Committees will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment that is shown to be ineffective....The Committees will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community.

The second principle guarantees a fair, consistent and equitable process between patients. The difficulty of whether personal circumstances should be considered in requests for exceptional funding is discussed in the presentations in this e-learning series. The principle in the South Central Ethical Framework leans against the view that *personal* circumstances should be exceptional because it says “the committees will not discriminate on grounds of personal characteristics.” Equally, it does not always reject requests for pinnaplasty for children with prominent ears.

However, this exception on “social” grounds must be extremely limited otherwise there would be a risk for example, of carers being preferred to single people, or even of workers being preferred to those in retirement or people who were unemployed.

2. EQUITY

The Committees believe that people should have access to health care on the basis of need. There may also be times when some categories of care are given priority in order to address health inequalities in the community. However, the Committees will not discriminate on grounds of personal characteristics, such as age, gender, sexual orientation, gender identity, race, religion, lifestyle, social position, family or financial status, intelligence, disability, physical or cognitive functioning...

Principle 3 concerns Health Need and the Capacity to Benefit. In a sense, it expands the meaning of “equity” in principle 2. It does, however, have two consequences which may mean that treatment which a patient and their doctor request may not be funded. For example, what if a patient has been given the first and second line treatments for the condition, but it has failed, or they cannot tolerate it. The doctor requests an alternative treatment which is not normally commissioned within the PCT and for which there is no reliable evidence that it will assist the patient.

In an ideal world, “last chance” treatments of this nature would always be attempted, just in case they worked. But if the NHS routinely worked on such a basis, much highly effective treatment would have to be diverted from patients on well established care, in order to pay for care which was, in effect, experimental. Clearly, this would provoke serious complaints about equity.

The same may apply to treatment which is effective in a biological sense, because it alters the patient’s response at a biochemical level, but there is no evidence that it will improve their clinical outcome. Of course, results of this nature may be promising and justify entering the patient in a clinical trial. However until further evidence is available as to clinical *outcome*, it may be decided that the patient does not have the “capacity to benefit” from the treatment.

Principle 3 says:

3. HEALTH CARE NEED AND CAPACITY TO BENEFIT

Health care should be allocated justly and fairly according to need and capacity to benefit, such that the health of the population is maximised within the resources available. The Committees will consider the health needs of people and populations according to their capacity to benefit from health care interventions. So far as possible, it will respect the wishes of patients to choose between different clinically and cost effective treatment options, subject to the support of the clinical evidence. This approach leads to three important principles:

- In the absence of evidence of health need, treatment will not generally be given solely because a patient requests it.
- A treatment of little benefit will not be provided simply because it is the only treatment available.
- Treatment which effectively treats “life time” or long term chronic conditions will be considered equally to urgent and life prolonging treatments.

Inevitably, in any system constrained by finite resources, where demand is likely to exceed supply, the cost of treatment has to be considered. Principle 4 explains the concept of “Opportunity Costs.” One of the central concepts that we take for granted in the NHS is the principle of “solidarity;” that as a community, we are stronger by standing together. It is a feature of social welfare systems throughout Europe. Inescapably, however, it means that the more a treatment costs, the more its likely impact on other people has to be considered.

PCTs should be sensitive to opportunity costs. Unlike clinicians whose primary duty is *Hippocratic* and owed to individuals, PCTs have a duty to promote a “comprehensive” health service throughout the community as a whole. If it were otherwise, there would be a danger of annual financial allocations being exhausted by the end of September. This would not only be unfair on those who presented themselves for treatment in October. It would be a serious dereliction of public duty.

Principle 4, therefore, reads:

4. COST OF TREATMENT AND OPPORTUNITY COSTS

Because each PCT is duty-bound not to exceed its budget, the cost of treatment must be considered. The cost of treatment is significant because investing in one area of health care inevitably diverts resources from other uses. This is known as opportunity costs and is defined as benefit foregone, or value of opportunities lost, that would accrue by investing the same resources in the best alternative way.

Principles 5 and 6 further explain how *public* interests have to be taken into account. They recognise that priority setting is often about making hard choices between competing demands. Sometimes, central government may issue policies which prioritise resources to some groups rather than others. For example, the Department of Health has long been concerned with health inequalities. Accordingly, it encourages health service resource allocators to consider health inequalities in setting priorities. The same is the case with the 18-week waiting time targets.

Principle 5, therefore, reads:

5. NEEDS OF THE COMMUNITY

... the Committees will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health (such as the guidance from NICE and National Service Frameworks). Others are produced locally. The Committees also support effective policies to promote preventive medicine which help stop people becoming ill in the first place.

Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, it may do little to improve the patient's condition, or to stop, or slow the progression of disease. Where it has been decided that a treatment has a low priority and cannot generally be supported, a patient's doctor may still seek to persuade the PCT that there are exceptional circumstances which mean that the patient should receive the treatment.

And principle 6, therefore, reads:

6. POLICY DRIVERS

The Department of Health issues guidance and directions to NHS organisations which may give priority to some categories of patient, or require treatment to be made available within a given period. These may affect the way in which health service resources are allocated by individual PCTs. The Committees operate with these factors in mind and recognise that their discretion may be affected by National Service Frameworks, NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance.

Last, principle 7 addresses Exceptional Need. The purpose of this principle is to respond to the wholly unusual case in which the patient has an exceptional response to treatment. As we have said, this is exceptional not just at a molecular, or biochemical level, but therapeutically in the sense that the treatment significantly improves their health status in a way that would not happen to patients generally.

Normally, the patient's doctors will be in the best position to present this sort of evidence. What treatment is recommended? What is the evidence on which the clinical opinion of an "exceptional" response is based? What are the risks and benefits expected from the treatment, both short and long-term? And what is the proposed cost of the treatment?

The approach to exceptional cases should be according to the same principles as are applied to other commissioning decisions. This means that cost limits are still relevant; even those with exceptional clinical circumstances may still find that the treatment proposed is simply too expensive in terms of the opportunity costs to other patients.

The numbers of patients in this category are tiny, not simply by virtue of the unusual clinical response in question. It is because the PCT is under a general duty to create a new policy-response once it becomes clear that a treatment is available for which there will be more than a hand-full of requests. If it failed to do so, and responded to (say) ten requests for the same treatment by referring each to an Individual Funding Request (IFR) process to test whether they were exceptional, then some might obtain the care whilst others might not. This would be inconsistent and inequitable. Similar requests should all be considered against the same framework.

Principle 7 says:

7. EXCEPTIONAL NEED

There will be no blanket bans on treatment since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Each case of this sort will be considered on its own merits in light of the clinical evidence. PCTs have procedures in place to consider such exceptional cases on their merits.

I hope that this has given you a flavour of how the South Central Ethical Framework was developed, its content and how it is used as a framework for decision-making. In the end, this process is not about “the right answer,” but nor is it about unjustified variations between PCTs which are not supported by sound reasons. It is about recognising the need for difficult choices and having a reliable and consistent way of balancing “community” interests with the needs of individual patients. The fabric of the NHS depends on a notion of solidarity that provides a guarantee of procedural fairness that all NHS patients will be treated with dignity and that the “the individual” will never be lost in the process.

This approach tries to balance the sometimes competing demands for finite NHS resources; and to do so in a way that treats patients fairly, equally, consistently and openly.

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