



*Buckinghamshire Clinical Commissioning Group
Berkshire West Clinical Commissioning Group
East Berkshire Clinical Commissioning Group
Oxfordshire Clinical Commissioning Group*

THAMES VALLEY PRIORITIES COMMITTEE

ETHICAL FRAMEWORK

Background

A primary responsibility of the commissioners of NHS health care in England is to make decisions about which treatments and services should be funded for their designated populations. This includes making decisions about the continued funding of currently-commissioned treatments and services, as well as the introduction of new treatments and approaches to the delivery of care.

Commissioners are subject to a statutory duty not to exceed their annual financial allocation. Further, the NHS needs to make savings to narrow the substantial financial gap in order to continue to meet the demands for care and treatment^{1,2}. As the demand for NHS health care exceeds the financial resources available, commissioners are faced with difficult choices about which services to provide for their local populations.

The Priorities Committee has representatives of the NHS organisations across ten Thames Valley Clinical Commissioning Groups (CCGs) and includes lay members as well as clinicians and managers. The purpose of the Priorities Committee is to make recommendations, in the form of policies, to the local CCGs as to the services and health care interventions that should or should not be funded.

To help in this process, health care commissioners in the Thames Valley region have developed a decision-making tool - the 'Ethical Framework', to facilitate fairness and transparency in the priority-setting process.

The Ethical Framework was originally developed in 2004 by the NHS public health organisation *Priorities Support Unit* (now *Solutions for Public Health*) and the Berkshire PCTs. Since then, the Framework has been revised to take account of policy developments in the NHS and changes in the law, and has been adopted more widely.

¹Five year forward view (2014) <https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf>

²NHS long term plan (2019) <https://www.longtermplan.nhs.uk/>

The purpose of the Ethical Framework

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

- Providing a **coherent structure** for the consideration of health care treatments and services to ensure that all important aspects are discussed.
- Promoting **fairness and consistency** in decision making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity.
- Ensuring that the **principles and legal requirements of the NHS Constitution**³ the **Public Sector Equality Duty**⁴ and the requirement to involve the public when making significant changes to the provision of NHS healthcare⁵ are adhered to.
- Providing a transparent means of **expressing the reasons** behind the decisions made to patients, families, carers, clinicians and the public.
- Supporting and integrating with the development of CCG Commissioning Plans.

Formulating policy recommendations regarding health care priorities involves the exercise of judgment and discretion and there will be room for disagreement both within and outwith the Committee. Although there is no objective measure by which such decisions can be based, the Ethical Framework enables decisions to be made within a consistent setting which respects the needs of individuals and the community.

The following Ethical Framework consists of 8 principles or relevant considerations that will be taken into account in the development of each recommendation. It does not prejudice the weight that any one consideration is given nor does it require that all should be given equal weight.

1. EQUITY

The Committee believes 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 Committee will not discriminate, or limit access to NHS care, on grounds of personal characteristics including: age, race, religion, gender or

³ The NHS Constitution

<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx>

⁴ Equality Act 2010: guidance (June 2015 update) <https://www.gov.uk/guidance/equality-act-2010-guidance>

⁵ NHS England - Involving people in health and care guidance <https://www.england.nhs.uk/participation/involvementguidance/>

gender identity, sex or sexual orientation, lifestyle, social position, family or financial status, pregnancy, intelligence, disability, physical or cognitive functioning. However, in some circumstances, these factors may be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit from the treatment.

2. HEALTH CARE NEED AND CAPACITY TO BENEFIT

Health care should be allocated justly and fairly according to need and capacity to benefit. The Committee will consider the health needs of people and populations according to their capacity to benefit from health care interventions. As 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.

3. EVIDENCE OF CLINICAL EFFECTIVENESS

The Committees will seek to obtain the best available evidence of clinical effectiveness using robust and reproducible methods. Methods to assess clinical and cost effectiveness are well established. The key success factors are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way to support the work of the Committee. Choice of appropriate clinically and patient-defined outcomes need to be given careful consideration, and where possible quality of life measures should be considered.

The Committees will promote treatments and services for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment and services that cannot be shown to be effective. For example, is the product likely to save lives or significantly improve quality of life? How many patients are likely to benefit? How robust is the clinical evidence that the treatment or service is effective?

When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients' health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies. Evidence may be available from other

sources and this will also be considered. Patients' evidence of significant clinical benefit is relevant.

The Committee will also take particular account of patient safety. It will consider the reported adverse impacts of treatments and the licence status of medicines and the authorisation of medical devices and diagnostic technologies for NHS use.

4. EVIDENCE OF COST EFFECTIVENESS

The Committees will seek information about cost effectiveness in order to assess whether interventions represent value for money for the NHS. 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 Committee will consider studies that synthesise costs and effectiveness in the form of economic evaluations (e.g. quality adjusted life years, cost-utility, cost-benefit), as they enable the relationship between costs and outcomes of alternative healthcare interventions to be compared, however, these will not by themselves be decisive.

Evidence of cost effectiveness assists understanding whether the NHS can afford to pay for the treatment or service and includes evidence of the costs a new treatment or service may release.

5. COST OF TREATMENT AND OPPORTUNITY COSTS

Because each CCG is duty-bound not to exceed its budget, the cost of a treatment must be considered. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high. This is important because of the overall proportion of the total budget: funds invested in these areas will not be available for other health care interventions. The Committees will compare the cost of a new treatment to the existing care provided, and consider the cost of the treatment against its overall health benefit, both to the individual and the community. As well as cost information, the Committees will consider the numbers of people in their designation populations who might be treated.

6. NEEDS OF THE COMMUNITY

Public health is an important concern of the Committee and they 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 Health and Social Care Outcomes Framework). Others are produced locally. The Committee also supports 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 CCG that there are exceptional circumstances which mean that the patient should receive the treatment.

7. NATIONAL POLICY DIRECTIVES AND GUIDANCE

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 CCGs. The Committee operates with these factors in mind and recognise that their discretion may be affected by Health and Social Care Outcomes Frameworks⁶, NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance.

Locally, choices about the funding of health care treatments will be informed by the needs of each individual CCG and these will be described in their Local Delivery Plan.

8. SIGNIFICANT CLINICAL BENEFIT

There will be no blanket bans on treatments since there may be cases in which the clinician providing the care can demonstrate why an individual patient is likely to obtain significant clinical benefit at reasonable cost from an intervention which is not normally funded. CCGs will consider such cases according to the following general procedures:

The CCG through its Individual Funding Request (IFR) panel will consider whether the criteria in (1) or (2) have been satisfied;

(1) In cases in which NICE technology appraisal or local clinical commissioning policies⁷ do not recommend use of the intervention, treatment may be funded if:

- (a) the clinician can demonstrate persuasive evidence why the patient's clinical circumstances are significantly different to those of the population of patients for whom the recommendation has been made not to use the intervention, **and**
- (b) the clinician can demonstrate why the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients for whom the recommendation is not to fund it, **and**
- (c) the IFR panel are satisfied as to the reasonableness of the cost of funding the intervention.

⁶ <https://www.gov.uk/government/collections/health-and-social-care-outcomes-frameworks>

⁷ Local commissioning policies include local drug formularies

(2) In cases in which the intervention has not been subject to NICE technology appraisal or local clinical commissioning policies, treatment may be funded if:

(a) the clinician can demonstrate why the patient is likely to gain EITHER significantly more clinical benefit from the intervention than other similar patients OR for patients with rare conditions, an equivalent benefit to patients with comparable symptoms **and**

(b) the IFR panel are satisfied as to the reasonableness of the cost of funding the intervention.