

CITY & HACKNEY ETHICAL FRAMEWORK
City & Hackney Teaching PCT (CHTPCT)
Homerton University Hospital NHS Foundation Trust (HUH)
CHTPCT/HUH Joint Prescribing & Medicines Management Group (JPG)

Background

This framework is based on the *Thames Valley Ethical Framework* produced by the Thames Valley NHS Trusts and the National Prescribing Centre document – “Supporting rational local decision-making about medicines (and treatments)”.

The *NHS Constitution* is a declaration of rights that are underpinned in law. It confirms that patients have the right to expect local decisions about the funding of medicines and treatments to be made rationally following a proper consideration of the evidence.

NPC- Supporting rational local decision-making about medicines (and treatments)

The CHTPCT/HUH Joint Prescribing & Medicines Management Group (JPG) is a group of representatives of the two main NHS organisations covered by this framework and includes lay members as well as clinicians and managers. The JPG acts as the Area Prescribing Committee for the City and Hackney health economy. One of the main functions of the JPG is to advise the local NHS as to the health care interventions and policies that should be given high or low priority.

PCTs have the statutory responsibility to commission care including medicines, for their populations, within available resources. The funding of medicines should not be viewed in isolation from the funding of other health services, although it is difficult to do this in practice. Decisions on whether to fund medicines should be taken in the context of the PCTs available resources to ensure that care is fairly allocated to all patients and, where appropriate, measured against the PCT’s other service development priorities, National Institute of Health and Clinical Excellence (NICE) guidance and national priorities. This inevitably means that, from time to time, hard choices have to be made. This document aims to outline the ethical framework the group will follow to ensure the decisions made are consistent and transparent – in particular where there is no NICE guidance available for a treatment or where the drug is not on the NICE agenda. The JPG helps CHTPCT to choose how to allocate its resources to promote the health of the local community.

One of the key aims of the JPG is to reduce the need for Individual Funding requests (IFRs) within City and Hackney by reducing the ‘post-code lottery’ by pro-actively co-ordinating funding decisions. However, the IFR process remains open for patients requiring treatment with a drug that has been rejected for wider use by the network or by the JPG. These IFR requests should be made

via the local hospital pharmacy and dealt with by the relevant PCT. As such the process for IFR funding is not covered in any great detail in this document.

Following *Improving access to medicines for NHS patients*, the DH published *Guidance for NHS patients who wish to pay for additional private care*. The JPG recognises the fact that when the NHS has made a decision not to fund a medicine or treatment, patients who wish to pay privately for that medicine or treatment can do so alongside their NHS care.

Purpose of the Ethical Framework

The purpose of this framework is to:

- Provide a coherent structure for discussion, ensuring all important aspects of each issue are considered;
- Promote fairness and consistency in decision making from meeting to meeting and with regard to different clinical topics;
- Provide a means of expressing the reasons behind the decisions made.

Many decisions will involve the exercise of judgement and discretion and there will be room for disagreement both within and outwith the JPG. Although there are no objective or infallible measures by which such decisions can be based, this Framework enables decisions to be made within a consistent setting which respects the needs of individuals and the community.

The JPG recognises that their discretion may be affected by National Service Frameworks, National Institute for Health and Clinical Excellence(NICE) technology appraisal guidance and Secretary of State Directions to the NHS.

Equity

The JPG believes that people have equal rights of 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 JPG 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.

Health care should be allocated justly and fairly on the basis of need and capacity to benefit, so as to maximise the welfare of patients within the budget available. The JPG will assess health needs according to patients' capacity to benefit from health care. There are 2 principles that must be recognised by all clinicians in both organisations:

- In the absence of evidence of health need, treatment will not generally be given solely because a patient requests it, and
- A treatment that has been shown to be of very little benefit will not be provided simply because it is the only treatment available.

These principles must be observed because it is necessary to ensure that resources are used to provide the greatest health benefit.

The JPG adopts the following general approach:

“The NHS... must provide health care within the money we have available. In order to manage our budget we give the highest priority to those treatments that are known to be most cost effective at improving health and a much lower priority to those treatments for which the cost is high or the evidence for health improvement is low.”

(Taken from Berkshire PCT's Patient Information Leaflet)

The Ethical Framework is particularly concerned with the following:

1. EVIDENCE OF CLINICAL AND COST EFFECTIVENESS

The JPG will seek to obtain the best available evidence of both clinical and cost effectiveness. It will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients. It will not normally recommend treatment that is shown to be ineffective.

When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients' health status:

- Trials of longer duration with 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 also be available from other sources and this will also be considered;
- Patient reported evidence of significant clinical benefit is also relevant;
- Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness.

The JPG will also 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 Group will consider technical cost-benefit calculations (e.g. QALYs), but these will not by themselves be decisive.

The following may be used as a guide:

Ethical Values to help with Decision making

1. RESPECT FOR PEOPLE	<i>1.1 Responsiveness</i> To what extent does this intervention reflect the wishes or preferences of the public, the people at whom it is aimed or other stakeholders?
	<i>1.2 Accessibility</i> Will it be easy for the people who need this intervention to actually use it?
	<i>1.3 Appropriateness</i> Can we be sure that the intervention will be delivered to the right people, at the right time, in the right place, by the right personnel?
2. PRODUCING BENEFIT	<i>2.1 Size of the Problem</i> Roughly how many people in the population are directly affected?
	<i>2.2 Severity of the Problem</i> To what extent are people who suffer from the problem at risk of death or incapacity (physical or psychological) because of it?
	<i>2.3 Outcome of Intervention</i> How much improvement in quality and/or length of life is the intervention likely to produce?
	<i>2.4 Likelihood of Benefit</i> How likely is it that the improvement will happen? What is the number needed to treat (NNT)?
	<i>2.5 Evidence of Effectiveness</i> How strong is the evidence that this service or intervention actually works? What is the strength of the evidence?
3. NOT CAUSING HARM	<i>3.1 Risks</i> What chance is there that unintended harm could result to those who use the service or intervention or to others? What are the risks of not taking action in this area?
	<i>3.2 Quality</i> What certainty is there that accepted standards of good practice (if any exist) will be met?
4. JUSTICE	<i>4.1 Use of Resource</i> What will be the cost benefit (£ spent vs £ saved) cost effectiveness (£ per unit of health outcome) cost utility (£ per QALY) opportunity cost of using this drug (what could have done instead?)
	<i>4.2 Equity</i> How much of a contribution will this make to reducing the gap between the best off and the worst off?
	<i>4.3 In accordance with identified values & priorities</i> How closely does the use of this service or intervention correspond to existing national, regional or local priorities, policies or activity?

2. COST OF TREATMENT

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. A single episode of treatment for an individual patient may be very expensive, and this needs to be balanced against the cost of treating a large number of

patients with a drug that is low cost for an individual, but for which cumulative costs may be very high.

3. INDIVIDUAL NEED FOR HEALTH CARE

The JPG will consider the health needs of individual patients according to their capacity to benefit from health care. So far as possible, it will respect the rights of patients to choose between different treatment options, subject to the support of the clinical evidence. Urgent and life-saving treatment will be given a high priority, as will treatment which effectively treats “life time”, or chronic conditions such as arthritis, mental illness, or sensory impairment. When evidence of clinical effectiveness is equivocal, options for treatment will be given particular attention.

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

Requests for funding for exceptional circumstances for individual patients are considered by a difficult decisions panel:

- Requests are received by the Specialist Commissioning Directorate and are forwarded to a panel of PCT advisers for consideration;
- The panel includes the Director of Public Health, GP Commissioning adviser, and Head of Prescribing and Pharmacy;
- Each adviser considers the request and provides the Specialist Commissioning Directorate with their recommendation as to whether the PCT should approve the request;
- The request for funding is then formally considered by a formal Difficult Decisions Panel, taking into account the advice. Membership of the panel includes GPs and other clinicians, and it is chaired by a Non-Executive Director

4. NEEDS OF THE COMMUNITY

Public health is an important concern of the JPG and it 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 guidance from NICE and National Service Frameworks); others are produced locally in response to local priorities. The JPG 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 seek to persuade the PCT that there are exceptional

circumstances which mean that the patient should receive the treatment within procedures established by the PCT.

5. NATIONAL STANDARDS

The Department of Health issues guidance and directions to NHS bodies which may give priority to some categories of patient, or treatment. These may affect the way in which health service resources are allocated. The JPG operates with these factors in mind and recognises that the Group's discretion may be affected by National Service Frameworks, NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance.

Prepared by:
Jas Khambh
Pharmaceutical Adviser, CHTPCT

Approved for adoption by:
CHTPCT/Homerton Joint Prescribing & Medicines Management Group