Mid and South Essex Medicines Optimisation Committee (MSEMOC)

ETHICAL FRAMEWORK

Background

Mid and South Essex (MSE) Medicines Optimisation Committee is an over-arching local decision-making group for medicines related interventions, for MSE Clinical Commissioning Groups (CCGs), made up of healthcare professionals and a patient representative. Its purpose is to provide a strategic approach to medicines related interventions and clinical decision making, with due regard to clinical and cost-effectiveness in order to ensure patients have safe and consistent access to medicines in the context of care pathways which cross multiple providers.

Clinical Commissioning Groups 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.

Decisions and Recommendations from the MSE Medicines Optimisation Committee help commissioners choose how to allocate their resources to promote the health of the local community.

Purpose of the Ethical Framework

The Committee has developed this Ethical Framework to enable it to make fair and consistent decisions which treat patients equally. The purpose of the ethical framework is to support and underpin the medicines related decision making processes of the 5 CCGs, to enable consistent commissioning policy by:

- 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
- 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 outside the Committee. Although there is no objective or infallible 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 Committee recognises that its discretion may be affected by National Service Frameworks, National Institute for Health and Care Excellence (NICE) technology appraisal guidance and Secretary of State Directions to the NHS.

The Ethical Framework considerations

Seven broad issues need to be considered as a part of the Ethical framework before making investment/disinvestment decisions for medicines.

1. Impact on health inequalities (Equity and Equality)

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 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. 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. Clinical Effectiveness

The Committee will recommend treatments for which there is good evidence of clinical effectiveness in improving the health status of patients. It will not normally recommend treatments that are shown to be ineffective. Issues such as safety and drug licensing will also be carefully considered. 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 also be available from other sources and this will also be considered. Patients' evidence of significant clinical benefit is also relevant.

3. Cost Effectiveness

Because each CCG 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. The concept derives from the notion of scarcity of resources. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high.

The Committee will also compare the cost of a new treatment pathway 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. They will consider technical cost-benefit calculations (e.g. QALYs), but these will not by themselves be decisive.

4. Impact on overall health in Mid and South Essex CCGs (Needs of the community and population)

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 Committee 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 rights 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 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.*

5. Alignment to current CCG strategies and Department of Health policies (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 CCGs. 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. 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 Operational Plan The MSEMOC will seek to ensure that there is equitable access to medicines for all patients living in Mid and South Essex foot print.

6. Implementability

The Committee will consider all factors and issues associated with implementing any initiative. This includes consideration of how easy it will be to implement the initiative and achieve the benefits as well as considering the issues that may impact the ability to successfully implement an initiative.

7. Current benchmarking performance (Policy Drivers)

The Committee will consider decisions made by other neighbouring CCGs and other appropriate decision making bodies e.g. Scottish Medicines Consortium, All Wales Medicines Strategy Group.

The Human Rights Act has been considered in the formation of this ethical framework

The Committee 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 **and** the evidence for health improvement is low."

Priority for NHS funding of therapies

The strength of evidence available to support the clinical indications claimed for the use of new or new uses of existing therapies available to the NHS, can vary widely. Furthermore, the cost of such therapies compared with existing alternatives is often high, raising questions about the cost effectiveness and affordability of such treatments, which will need to compete for limited NHS resources with other existing therapies and services. The following assessment categories will be used by MSEMOC to be applied to the evidence available to support the use of new treatments, assessed in the context of the acquisition cost and likely overall cost effectiveness to the NHS. Ethical framework agreed across Mid and South Essex will be used to inform this process.

Mid and South Essex Health and Care Partnership

NHS

Proposed assessment categories for therapies

A. Development where cost effectiveness is based on firm clinical evidence and is so great compared with current costs of medical care that they ought to be made available at the expense of something else if necessary. - **HIGH PRIORITY**
This recommendation will have cost implications and will therefore require JCC or individual CCG Board approval.

B. Developments appear to be BENEFICIAL but COST-EFFECTIVENESS compared to other treatments and service developments, may be less certain in the light of the quality of evidence. - **MEDIUM PRIORITY**
Treatments allocated a medium priority cannot be recommended unless real savings to fund the treatments are identified upfront with a delivery plan included in the business case. Such recommendations will need JCC or individual CCG Board approval.

C. Developments where benefits have either not been demonstrated or are demonstrated only by weak evidence and cannot be justified in competition with other priorities. - **LOW PRIORITY**

D. Developments where work is in progress but benefits are not yet proven. - **LOW PRIORITY**

Any other categories will be at the discretion of the MSEMOC members and would need to be consulted with CCGs.

Prescribing Recommendation Classification

Based on the priority designation and taking account of the full ethical framework considerations, the level of risk identified by the qualitative risk assessment tool the committee will agree a prescribing recommendation classification of either green, yellow, amber, red or black.

Green	Recommended for prescribing and treatment considered to be suitable for initiation in Primary, Community or Secondary care and continuation in Primary Care.
Yellow Continuing Care (CC)	Recommended for prescribing but only considered suitable for initiation by specialists in Secondary and Tertiary care with prescribing (and monitoring, where applicable) continued by GPs and Primary Care Clinicians. Shared care is not required but the GP and Primary Care Clinician must be supplied with sufficient information on the prescribed medication
Amber Shared Care (SC)	Recommended for prescribing but only considered suitable for initial prescribing by specialists in Secondary and Tertiary care with prescribing continued by GPs and Primary Care Clinicians in conjunction with a Shared Care Agreement or relevant equivalent or (where appropriate) with patient specific information provided by the hospital specialist. The patient would normally be stabilised before prescribing responsibility is devolved. A shared care guideline is required detailing the prescribing clinicians' responsibility. These medicines require additional blood tests/ clinical monitoring for safe prescribing which are/is considered to be over and above the level of monitoring expected for safe medication prescribing under essential services. The difference between Amber SC and Yellow is that Amber drugs require more routine monitoring (at least every six months).

Red	Not recommended for prescribing in Primary Care. Prescribing responsibility remains with secondary or tertiary care because of clinical issues or because funding responsibility lies with NHS England, and/or in line with Clinical Commissioning Group's policies; prescribing (including requests to prescribe in primary care by secondary or tertiary care) will be subject to challenge .
Black	Not recommended for prescribing by either Secondary or Primary care; NOT a priority for funding, such a treatment should only be used in exceptional cases (having followed due process) and prescribing will be subject to challenge. Any Technology appraisals terminated by NICE will automatically be designated a "black" category

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