Northern Treatment
Advisory Group

An Ethical Framework for the Northern (NHS) Treatment Advisory Group (Version 5, June 2014)

The purpose of this ethical framework is to:

Provide a consistent and equitable structure for discussion and consideration of treatment appraisals, leading to consistent treatment recommendations which are free of prejudice

Promote good practice with respect to patient safety of healthcare interventions and cost-effectiveness

Ensure that the rationale applied to treatment recommendations is open and can be scrutinised by interested parties (patients, commissioners, clinicians, commercial parties, etc.). It is important to note however that all NTAG recommendations are advisory to CCGs.

This ethical framework is considered to be complementary to the obligations described in the NHS Constitution and the statutory requirements for English primary care organisations. **If a conflict of interpretation or interest arises then any statutory requirements or the NHS constitution will take precedence over this ethical framework.**

Treatment appraisals and recommendations

The work of the group is primarily in conducting robust, inclusive, objective, fair and unbiased appraisals of treatments for which a specific demand for NHS patients has been highlighted or where there is a reasonable expectation that such demand will exist. Treatment appraisal includes in-meeting discussions from which a consensus recommendation is derived.

The outputs of the group are primarily treatment recommendations which are directed to those with the relevant commissioning responsibilities, and appraisal reports associated with each recommendation.

The group will publish its appraisal reports and recommendations on the internet to enable scrutiny by interested parties.

Evidence sources

The group will consider the nature of the sources of evidence. Data that has been published following a peer review process is preferred to data that has been published without peer review which is preferred to data that has not been published. Sources of published data include websites and other shared digital media. Examples of published peer reviewed data include: articles in the established medical press, for example in medical or other clinical journals and systematic reviews published via a respected indexing service such as the Cochrane Library.

Quality of evidence

In considering a treatment appraisal the group will first and foremost apply the principles of evidence based healthcare to both clinical and non-clinical sources of evidence. Evidence based medicine has been defined as 'the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients'.

The group will therefore apply this definition at a *population level* in order to achieve the application of evidence based healthcare.

Of crucial importance is determining 'current best evidence'. In this respect the group will apply the hierarchy implicit in the levels of evidence defined by the Oxford Centre for Evidence Based Medicine (2011).

Where sources of evidence are considered to be of equal or uncertain quality the group will consider (in no particular order):

- Relevance, i.e. whether comparator groups and interventions are relevant to current or expected local practice
- Confidence intervals around mean treatment effects
- Overall numbers of patients

The group will consider any potential sources of bias in the evidence, for example in the design and conduct of studies and from their funding sources or source of publication.

Relevance of evidence

The group will explicitly consider whether the populations in which clinical evidence has been derived are representative of the population in which the treatment may be applied.

Treatment efficacy

The group will consider the likely mean treatment effect across the defined patient population and not treatment effects in individual patients. The group may seek to identify patient sub-groups in which there is a reliable expectation for a greater mean treatment effect compared with the whole parent patient population. **The group will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and will not recommend a 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. Individual patient satisfaction or clinician preference will not be taken as evidence of clinical effectiveness.

Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of short duration with surrogate outcomes. These will be outlined in the treatment appraisal report. Evidence may be available from other sources and this will also be considered.

Patient safety

In considering effectiveness, or efficacy, the group must be mindful of both the desired and undesired effects of a treatment i.e. not just the intended benefit of a treatment but also adverse effects or 'side effects'. When making a judgement on the overall effectiveness of a treatment this judgement will, by default, include consideration of both the desired and undesired effects and their merits relative to each other and relative to no treatment. This will permit acceptance of a higher burden of adverse effects in conditions which carry a

higher burden of disease under treatment with the relevant comparator. The group must always ensure there is reasonable expectation that the benefits of a treatment will outweigh the risks of harm across the intended patient population.

Cost analysis

The group will take into account cost-effectiveness analyses of healthcare interventions (where available) to assess which yield the greatest benefits relative to the cost of providing them. We 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 group will be mindful at all times of the finite budget constraints in which the NHS operates. In this respect, the group will acknowledge that with every service development or additional treatment provision there is an opportunity cost reflecting the healthcare which is being sacrificed if resources had been allocated differently. The group will at all times seek to minimise the opportunity cost and in this way facilitate optimal health service efficiency across the Northern region.

The group will also have regard to the opportunity cost, such that all current, future, known and unknown patients of will be considered. In addition to considering the cost-effectiveness of a treatment, the group will also have regard to the overall affordability. That is, even if on an individual basis a treatment is considered to be cost-effective the group must consider the affordability as a factor of the overall expected patient population over the defined time horizon.

In considering the cost of treatment the group will include all directly associated obligatory healthcare requirements such as additional tests, investigations and diagnostics which are specific to the treatment being appraised. Discounting of healthcare costs and benefits will not be applied in standard analyses. Discounting may be applied in specific circumstances with extended time horizons and reliable supporting evidence.

With respect to a cost-effectiveness threshold, or limit, the group will apply the same that is used by the National Institute for Health and Clinical Excellence (NICE). Although NICE has not explicitly defined a threshold value, this has been empirically identified as about £20,000 per quality adjusted life year. Therefore the group will use a similar approach to NICE with treatments that they consider. Where cost-effectiveness data is not expressed as a cost per

QALY the group may consider the likelihood that a treatment will meet a particular threshold.

Regulatory treatment constraints

In accordance with guidance from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and various healthcare professional organisations, a licensed treatment is preferred to an unlicensed one and use of a treatment within its product license is preferred to use of a licensed product outside of its license (off-license use). However, in considering an off-license or unlicensed treatment the group will still have due regard to cost-effectiveness and will apply the same threshold as is applied when considering other treatments. The group will consider that it is preferable to recommend an unlicensed or off-license treatment that meets the predefined cost-effectiveness threshold than not to recommend any treatment at all, for example if the licensed alternative is considered to exceed the accepted cost-effectiveness threshold. In addition, the preference for licensed treatments does not absolutely preclude use of unlicensed or off-license treatments where such treatments may offer other benefits in terms of efficacy, cost-effectiveness, safety, or other relevant criteria.

Equality and diversity

The group will consider each individual within our populations to be of equal value. It will consider all treatments against the same criteria regardless of the size of the expected patient population. Therefore treatments for orphan or ultra-orphan diseases, as defined by the European Medicines Agency, will be judged against the same criteria as non-orphan treatments. When considering the size of study populations for orphan treatments the group will acknowledge that large trials are often not feasible. In addition, with smaller patient populations for any treatment there may be a bias towards favouring the treatment on the basis of affordability to the NHS Northern region.

The group will consider all treatments against the same criteria regardless of the expected age-profile or gender, mental, physical, racial, religious, sexual or socio-economic characteristics of the expected patient population. Treatments will be considered without ‘blame’ or culpability with respect to the medical need.

However higher priority may be allocated to interventions addressing health needs in subgroups of our population who currently have poorer than average health experience (e.g. higher morbidity or poorer rates of access to healthcare).

Access to treatments

A negative treatment recommendation does not mean that an individual patient has no recourse to access a treatment with NHS funding. With clinical support, the option for submission of an individual funding request will remain, although it is expected that those tasked with considering such requests will be aware of and duly consider recommendations from the group.

Research boundaries

The group may wish to support the routine collection of data for audit and retrospective research purposes. The group will be mindful of applications for treatments or service developments which may be better served as prospective clinical research with full ethical consideration.

Member conduct

Members are required to conduct themselves in accordance with all necessary laws and regulations which relate to operating within or on behalf of the NHS. Members may incur such obligations by virtue of their primary employment and additionally through membership of NTAG. The following is a non-exhaustive list of the regulations which may apply when conducting business within NTAG:

- Standards of Business Conduct for NHS Staff (HSG(93)5). Department of Health, January 1993
- Commercial sponsorship - Ethical standards for the NHS. Department of Health, November 2010
- The Bribery Act, 2010
- Members are required to act in accordance with the 'seven principles of public life' published by the Committee on Standards in Public Life (www.public-standards.gov.uk).
- NTAG Declarations of Interest Policy

References

Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. British Medical Journal 1996;312 :71

OCEBM Levels of Evidence Working Group*. "The Oxford 2011 Levels of Evidence". Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653

West Midlands Specialised Commissioning Team: www.wmsc.nhs.uk/uploaded_media/WM1%20-%20Ethical%20Framework%20pdf.pdf

NHS South Central: www.oxfordshire.nhs.uk/documents/SOUTHCENTRALETHICALFRAMEWORK.pdf

Central Lancashire PCT: www.centrallancashire.nhs.uk/Library/Documents/policies/Ethical%20Framework.pdf

Gloucester PCT: www.gloshospitals.nhs.uk/pdf/publications/innf_ethicalframe_0107.pdf

Hounslow PCT: www.hounslowpct.nhs.uk/Principlesanddecisionmakingframework.pdf.pdf

Manchester PCT: www.manchester.nhs.uk/document_uploads/Board%203%20Feb%202010/Prioritisation%20criteria%20v11%20FINAL.DOC