

ETHICAL AND OTHER CONSIDERATIONS INFORMING BEST PRACTICE ON HIGH COST TREATMENTS

On 18th November 2008, the Specialised Healthcare Alliance¹ held a conference on high cost treatments. This looked at the pressures on the NHS in its provision of such treatments and the consequences for patients. Presentations and discussion covered the ethical and clinical concerns around patient care, the links with research and development and the potential criteria that can be used to inform decision making.

The conference followed an Early Day Motion on rare and complex medical conditions and an associated Parliamentary debate (Westminster Hall 14th October 2008). EDM 2005 of 9th July 2008 attracted cross party support and stated:

That this House acknowledges that while the cost of treating people with rare and complex medical conditions represents a tiny fraction of NHS expenditure, the relative specific costs of such treatment can be high; recognises the great strength of the NHS in pooling financial risk for the benefit of such individuals; encourages interested parties to work together in developing an ethical framework to inform decisions on funding; and calls upon the Government to ensure that the National Institute for Health and Clinical Excellence reflects the Secretary of State's directions regarding clinical need and innovation in assessing high cost treatments.

Against that background and informed by the results of the conference and subsequent consultation with members, the Alliance has put together the following framework to inform best practice.

Overarching values

In a taxpayer funded system, difficult decisions will always need to be taken between different forms of public expenditure (eg healthcare versus defence) and between different types of healthcare (eg prevention versus treatment). The balance between competing priorities is struck by government and put before the electorate.

On a day to day basis, decisions about healthcare spending rest with public servants. The primary mechanism for informing decisions is clinical and cost effectiveness, which assists in distributing health resources in the fairest way within society as a whole. The assumptions underlying

¹ The Specialised Healthcare Alliance is a coalition of 43 patient organisations supported by nine corporate members which campaigns on behalf of people with rare and complex medical conditions requiring specialised care. More information can be found at www.shca.info.

calculations of clinical and cost effectiveness are, however, somewhat arbitrary. For example, wider social benefits arising from treatment such as employment are excluded, while the weighting placed on, say, mobility versus continence is open to dispute. In addition, what is theoretically right for society in terms of allocating resources may not accord with what society perceives as right for an individual with identifiable needs. The values underpinning these difficult decisions therefore rest with parliament.

In a representative democracy, parliament is informed but not necessarily bound by public opinion. Opinion testing exercises, most notably NICE's Citizens' Council, show strong but not unconditional levels of support for those in greatest clinical need, even when the cost of treatment is high.

Specific criteria

In a society disposed to help those in clinical need there is significant agreement about which factors should be taken into account in reaching decisions, though the exact terminology may vary. In particular:

1. **urgency** – how urgent is the need? This is often related to conditions which are immediately life-threatening. It is, however, difficult to draw distinctions where, for example, the absence of treatment will lead to a rapid deterioration in an individual's quality of life but with a delayed impact on mortality;
2. **gravity** – how severe is the need? Although there is a degree of overlap with urgency, the primary emphasis here is on quality of life and the extent to which this is adversely affected in the absence of treatment. In extreme cases, quality of life is so poor that people may prefer to be dead;
3. **benefit** – what is the impact of treatment? This throws up complex considerations including the potential benefits and harm arising from treatment. A treatment which cures or significantly ameliorates a life-threatening or severely debilitating condition could expect to be more favourably assessed than one which has a marginal impact or side-effects of comparable severity to the underlying condition. The full benefit of superior treatment decisions for long term conditions may only become apparent in the longer term;
4. **alternatives** – what options are available? If they are available, it clearly makes sense to use alternative therapies offering equivalent clinical benefits at lower cost.

Other considerations

There may be other considerations which should be taken into account in reaching a decision. For example, a person's familial situation might invest extra months of life with additional importance. Innovation which

has potentially wider significance may be worthy of greater financial support. The cost of a treatment will vary up or down depending on the market size relative to inelastic development costs. Clinical and other circumstances can also change over time, requiring flexibility.

Procedural issues

Particular importance attaches to good procedural practice given the sensitive nature of most decisions affecting high cost treatments. Key elements include:

- patient and public involvement – so that decision-makers look beyond bureaucratic precepts to reflect society's values;
- transparency – so that it is clear for all to see who is reaching decisions and on what basis;
- timeliness – so that individuals are spared prolonged uncertainty and the prospects of successful treatment maximised.

Conclusion

The Specialised Healthcare Alliance commends these principles to those involved in funding-related decisions for high cost treatments at all levels within the NHS and to those in parliament and elsewhere who have an interest in ensuring that the right balance is struck between the best interests of society and society's wish to help individuals in greatest clinical need.

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