Assessment of public opinion regarding the ethics of NICE CDF, HST, and end-of-life criteria for drug reimbursement

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Introduction

In the UK, the National Health Service must decide how to spend a fixed budget to best reflect the health requirements and moral maxims of the population.

For a new treatment to be reimbursed it must pass a test to show that it is cost-effective, with an ICER ≤ £30,000 per QALY. However, recent healthcare policy has changed so that some conditions must meet less strict criteria.

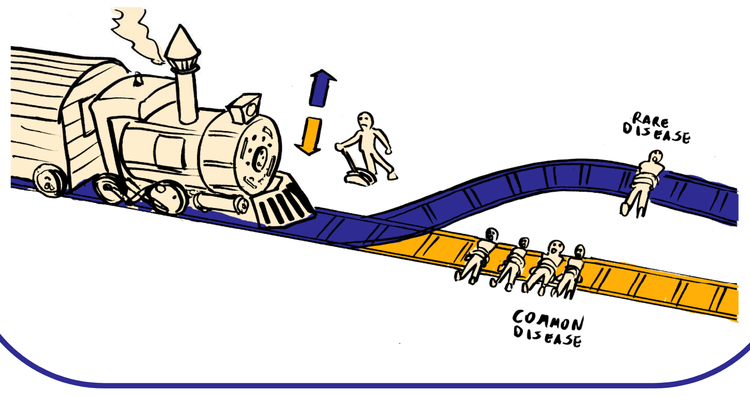
- The highly specialised technology (HST) appraisal for ultra orphan treatments (disease affects < 1:50,000) will automatically reimburse therapies costing up to £100,000 per QALY; while end-of-life (EoL) criteria allows ICERs ≤ £50,000 per QALY, and the cancer drugs fund (CDF) accepts drugs with a higher degree of uncertainty as to their cost-effectiveness.
- The reasons for implementing the EoL and CDF reflect that treating the associated diseases has additional value to society not captured by QALYs. For example, EoL treatments might allow people to put their affairs in order[1], while QALY gains from severe diseases such as cancer may be of more importance[2].
- Implementing HST reflects two opposing ethical theories shown in Table 1.

Table 1: Utilitarianism vs Egalitarianism

Utilitarianism	Egalitarianism
The greatest good for the greatest number of people, regardless of any other consideration.	Every individual has a right to treatment. No individual should be abandoned.

- Developing treatments for rare diseases can be expensive, and the cost must be divided by smaller patient numbers, making it difficult to make them cost-effective[3]. The payers must therefore decide whether to abandon these individuals in favour of utility, or sacrifice lives in favour of equity, as shown in Figure 1.

Figure 1: Trolley dilemma for rare diseases



Aims

Hadorn (1991) observed that many people believe community values should play an important role in setting healthcare policy[4]. The aim of this research was to assess whether the recent shifts in favour of cancer, EoL, and rare disease treatments are merited in the opinions of the electorate, and to identify any differences between different clusters of society.

Methods

We conducted a global review of all published research, assessing public opinion toward the ethics of drug reimbursement.

The databases searched included: PubMed, Embase, ISPOR, OHE, EconLit, NICE, and HTAi.

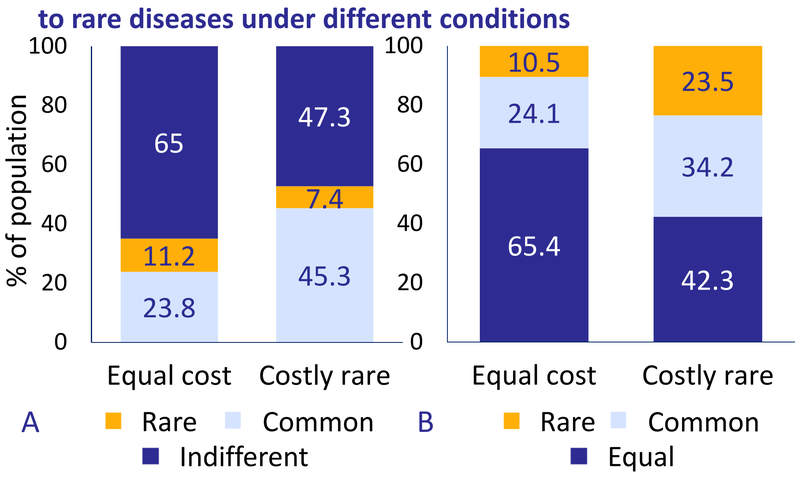
The search terms combined "ethic*" or "util*" with "health care", "end-of-life", "NICE", "CDF", "HST", "orphan", or "HTA".

Results

Eighteen studies were identified discussing ethical considerations related to funding rare diseases, cancer, and EoL. Four of these studies contained original data on community values, which are discussed below.

- Twenty out of 27 members of the NICE-commissioned Citizens Council (74%) thought that it was sometimes or always necessary to pay premium prices to treat rare diseases[5].
- In a survey of 1,547 people by Desser et al. (2010), respondents were asked how they would allocate funds between a rare and common disease when choosing between (Figure 2A) and allocating more to one disease than the other (Figure 2B)[6].

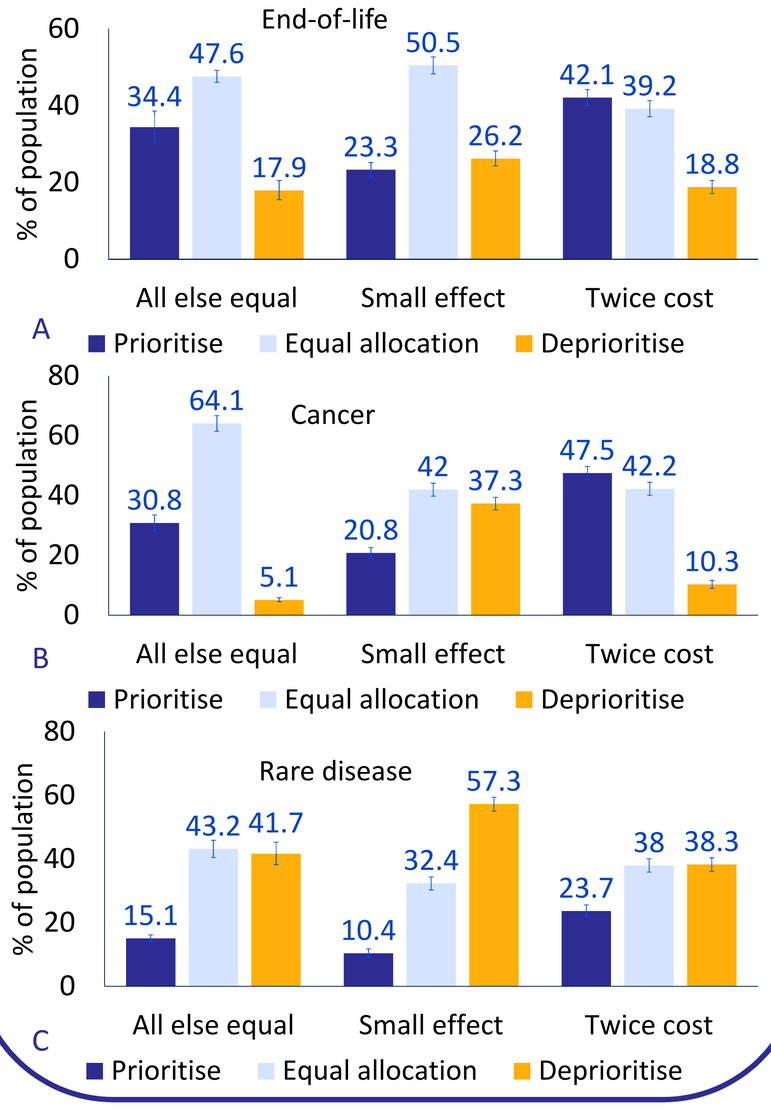
Figure 2: Percentage of respondents allocating resources to rare diseases under different conditions



Participants had to choose one disease to fund in A, and choose how to distribute funding in B.

- The results suggest that most respondents do not specifically value rarity, splitting funding when the diseases are of equal cost. However, when the rare disease is more costly, 65.8% of respondents favoured giving equal or more than equal funding to the rare disease, sacrificing some utility for equity.
- In another study, 4,118 respondents answered questions testing how they would allocate resources to end-of-life (Figure 3A), rare disease (Figure 3B), and cancer (Figure 3C) treatments when all else was equal, the drugs only had small effect, or were twice as costly[7].

Figure 3: Percentage of respondents allocating resources to cancer, end-of-life, and rare disease treatments



Results

- The results suggest that when costs were equal people favoured equal allocation for cancer, EoL, and rare diseases with their alternatives, suggesting no added social value.
- However, when the treatments became twice as costly, most people favoured prioritising cancer and EoL, with a significant increase in prioritising of rare diseases. In all cases, the majority sacrificed maximum utility to fund the more expensive disease, suggesting a disposition toward equity.
- Ubel et al. (1996) asked whether 568 respondents would prefer a cheap/bad test distributed to everyone (equity) or a more expensive/good test distributed to half the population, when the latter would save more lives (utility). Fifty six percent of the general public, 53% of medical ethicists, and 41% of medical decision makers favoured the cheap test, in effect valuing equity over utility[8]. The reasons they gave are shown in Table 2.

Table 2: Respondent explanation for choice of test (%)

Explanation*	Cheap test	Costly test
Fairness	66	16
Improved survival	3	73
Political appearance	5	0
Small survival difference	3	0
Highlight need for funding	0	2
Other	16	15

* Some participants failed to respond or gave more than one explanation.

- Notably, the responses of medical decision makers differed significantly from the general population. However, those with fewer years of education were significantly more likely to favour equity.
- Importantly, valuing equity is not the only explanation for allocating more resources to expensive treatments.
- It could stem from the misconception that more expensive drugs are more valuable, or from a feeling of entitlement that the government should fund all drugs no matter how expensive.
- The rationale for equity is particularly difficult to explain when simplified to the core principles of the trolley dilemma shown in figure 1, where facing a second trolley with new people on the track, the equitable controller saves the man on the right, merely because on the previous occasion he saved the four on the left.
- However, the crude application of the utilitarian approach favouring step-by-step improvements to common diseases is a potential barrier to innovative research which might yield longer-term benefits[9].

Conclusions

- Community values do not support policies reducing utility in favour of benefits not captured by QALYs for cancer and EoL treatments, and thus show little support for CDF and EoL criteria.
- Community values support policies favouring equity over utility. As treatments for rare diseases are necessarily more costly, this supports the recent introduction of the HST programme by NICE.
- However, how much utility should be sacrificed for equity, and whether community values should be heeded, are still open questions, especially when considering that medical decision makers showed preference for utility.

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