Life at a premium: considering an end-of-life premium in Value Based Reimbursement

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Abstract
The increasingly explicit use of health technology assessment continues to generate substantial public and academic policy debates. The debates are about puzzling issues whose correct resolution is not immediately obvious and the very explicitness of HTA’s use pinpoints the issues and locates those likely to gain or lose from the solutions. The application of an end-of-life premium is one of a number of proposed ‘values’ for affecting who wins and who loses from HTA and reimbursement processes. In this chapter we review the literature on value premiums generally and the end of life premium specifically, before describing a conceptual framework for coherent use of value premiums in reimbursement decision process and how an end-of-life premium might work.

Key words: Health Technology Assessment, End-of-life.

JEL classification: I10, I12, I14, I18

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1 Introduction

The increasingly explicit use of health technology assessment (HTA) continues to generate substantial public and academic policy debates1 (1-11). The reasons are twofold. First, the debates are about puzzling issues whose correct resolution is not immediately obvious though they can radically change the implications of HTAs. Second, the very explicitness of HTA’s use pinpoints the issues and locates those likely to gain or lose from the solutions, thus making external examination and critique of current approaches both easier and more policy-relevant. Stakeholders have different interests (stakes) in the decision making processes, the methods of analysis, the evidence considered and the values, both social and private, upon which outcomes, depend. One specific issue, which raises a host of concerns, is whether it is proper to treat the benefits of treatment for patients close to the ends of their lives relatively favourably. This might be done by, for example, weighting their benefits more heavily, or their costs more lightly than those accruing to other patient groups; or by using differential discount (interest) rates, or by applying an ‘easier’ threshold condition for the technology in question to be approved. Our analysis concludes that the correct treatment of such matters has implications for both the methods of analysis, especially the treatment of opportunity cost, and the design of the decision-making procedures employed, especially regarding the characteristics of those consulted and those who directly participate in it.

It is clear that at the heart of many of these issues lie questions of value and, hence, of value judgments. Values are typically revealed in many ways and with varying degrees of completeness. The most obvious expression of a value attaching to a good or service is monetary: its price. In a well-functioning market (not typical of health care markets) a price represents both the minimum that the marginal supplier is willing to receive in order to provide a little more of that good or service and the maximum that the marginal consumer is willing to pay for a little more of it. This is the ‘willingness-to-pay/accept’ approach to valuation. It can be distorted in many highly significant ways, as when suppliers have monopolistic powers, consumers are poorly informed about the benefits and risks, their agents (health professionals) have conflicts of interest (for example by being paid for low quality care), or the beneficiaries include people other

than the immediate patients (for example, family, friends, informal carers and the general caring public). The individual willingness to pay approach is unsuited to public decision making not only on grounds such as these but also because those who may benefit from the care do not typically bear any of the cost. Instead the cost is distributed across the entire system. More resources for those near the end of life means less for others – usually anonymous people, unknown alike to the beneficiaries and to those who minister professionally to them.

In the publicly financed system, ‘value’ in HTA is typically measured as a ‘real’ outcome using a metric that corresponds to a (socially defined) notion of ‘health’ or ‘health gain’. Delivering this gain will invariably require monetary expenditures from the budget but these expenditures represent neither the value (private or social) of the benefit nor the value of what is sacrificed to gain it (i.e. health gain forgone by others). The value of what is both forgone and what is gained is expressed instead directly in terms of the health metric, generally in terms of Quality-Adjusted life-Years (QALYs) or Disability-Adjusted Life-Years (DALYs). Value Based Reimbursement is the challenge of defining the value of health gain in terms of what the provider (the public agency) is willing to pay. This problem has been at the centre of debates in health technology assessments and funding decisions from the outset. In HTA, therefore, a significant part of the value of a health technology is the value of the health that it produces or the value of the health displaced as the use of other technologies has to fall.

‘Value’ in HTA, as in other regions of public policy, also has wider connotations. For example, a further reason for valuing a technology may be because it makes a contribution to reducing avoidable inequalities in the health of the population. Yet another dimension of value may be the reduced exposure to financial risk of heavy out of pocket expenditures through inclusion of a technology in the insured package (private or public). Other elements may be the contribution made to uniformity in terms of access and a sense of common ‘solidarity’. None of these elements of ‘value’ lends itself easily to financial measurement but it is not, fortunately, usually necessary for them to be valued in monetary terms. What is necessary is for them to be recognised as expressions of public or social value judgments (with implications for governance and procedure) and for decision makers to be able to take due account of each in a reasonable way in reaching a conclusion about the inclusion of a technology in the insured package. The only point at which a monetized expression of value is necessary
is in the so-called ‘threshold’ cost per QALY, which is set so far as possible at a level
such that no technology inside the insured package has a cost per QALY higher than
the threshold and no technology not in the package has one that is lower. That principle
assumes that population health maximization is a primary policy objective (though
clearly in the light of the foregoing not the only one) and debate about how best to
estimate this threshold has been another abiding discussion point since the 1980s.

Arguments for an end-of-life (EOL) premium, especially in the context of late stage
cancer therapies, have been advanced in a number of jurisdictions2 (12-13). However,
the grounds for premiums are rarely made clear by the small groups who effectively
make the decisions, are certainly not evidence-based (in the sense of being informed by
unbiased evidence concerning the views the general public) and are essentially ad hoc.
The role, implicit and explicit, of self-interested technology makers, professional users
and organized patient groups (often funded by manufacturers) is doubtless significant
(though there is deplorably little firm evidence to corroborate this conjecture). Most
importantly of all, the notion that allowing benefits for this group means denying
benefits to other groups tends to be ignored: research asking for people’s expressed
values rarely confronts experimental subjects with the ‘price’ of forgone care for
others; and in the real world those most likely to be denied care as a consequence of
resource deployment to this group are never present in consultations or in person within
the decision making process. Methodological guidance issued to advisory committees
and research groups rarely mentions the true opportunity cost and never outlines
methods for estimating it empirically.

The ‘real’ as distinct from the monetary costs are incurred at two policy levels. The first
is in decisions about the budget. In private insurance systems the test is essentially a
market test of the revenue stream that is judged to be supportable from premiums.
Regardless of the risk aversion of the public, higher premiums involve less disposable
income available for other purchases and these forgone purchases, potentially including
health care, are the opportunity costs and they are implicitly revealed through the
public’s willingness to pay for different insurance packages. In social insurance and tax
funded systems of health care the test is one made by politicians and relates to the
setting of budgets for the various categories of public expenditure: more on health care

2 NICE Appraising Life extending, end of life treatments. NICE July 2009 http://www.nice.org.uk/guidance/gid-
tag387/resources/appraising-life-extending-end-of-life-treatments-paper2 (accessed 23rd September 2014)
means less on education, transport or defence. (At even higher levels, there is the choice between public expenditure as a whole against private consumption as a whole). The second policy level, given a decision about the health care budget, concerns the health benefits package to be made available and those who are entitled to receive care. A fully universal system is one in which all have equal entitlements and the range of services is comprehensive – but nonetheless budget constrained. It is this second level of decision-making with which we are concerned here.

Is it possible to develop a theoretically coherent, procedurally transparent and inter-decision consistent value framework to inform reimbursement decisions? In this chapter we describe the landscape in which the debates for such a framework are taking place, and critically evaluate the claims made by different groups for different value premiums from a conceptual and empirical perspective. We then review a theoretical framework for Value Based Reimbursement decisions given a health care budget, and use this framework to explore how value premiums could be incorporated into the reimbursement/listing process. In the final section we consider the implementation of an EOL premium in such a framework and consider the likely impact of doing so on (a) access to health care and (b) the health of individuals approaching the end of their lives.

2 Policy challenges in Value Based Reimbursement

With hindsight, Value Based Reimbursement appears to be the inevitable destination of a journey that started with the development of health technology assessment in the 1970s (15-17). Value Based Reimbursement is guided by the principle that the monetary price paid for a new technology should be set to ensure that its incremental value in terms of health gain is positive; that is any additional cost in terms of the resources and consequential health it displaces for the new technology should be less than (and certainly not greater than) the value of the incremental health it produces (14). The guide price for this is the threshold, indicating the social willingness to pay

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3 NICE Methods of Technology Appraisal Consultation. NICE May 2014

4 Haute Autorité de Sante Pricing and reimbursement of drugs and HTA policies in France. HAS March 2014

5 IQWIG General methods for the assessment of the relation of benefits to costs. IQWIG November 2009
for an additional QALY or a lost DALY. When decisions are made under the assumption of a fixed budget, this condition ensures that the adoption of a new technology increases the overall health that is produced by the expenditure of that budget. When the budget is not fixed, but guided by some private willingness to pay for health, this condition ensures that the technology meets that private willingness to pay criterion.

QALYs combine life expectancy and health related quality of life in a single measure by weighting the time lived using weights for health related quality of life experienced in each time period. Whilst weights can be derived in many ways, increasingly they are preference based health-related quality of life measures such as the EQ-5D, SF-6D or Health Utilities Index (18-20). These instruments consist of psychometrically validated health state descriptive systems together with a utility algorithm that provides a utility weight for each health state in the descriptive system. The utility algorithm is normally constructed using statistical analyses of population health state preference survey data (21). However, there have been many critiques of this approach. Some have focused on the inadequacy of the descriptive systems used to capture health (22-23), others on the methods for deriving the utility weights (24); others have argued that the valued effects of health care are more than the impact on health and are modified by numerous other factors, such as the availability of alternative treatments, disease prognosis and impact of the condition on economic activity (25). Even more fundamentally, yet others have argued that the weights ought to be seen less as expressions of the strength of preferences of the lay population and rather as statements of public policy made on a population’s behalf by people judged to be unbiased, competent, sufficiently well-informed and accountable. Their judgments might be informed by the opinions of the public but need not follow them slavishly (26-29).

The response of policy makers and HTA institutions to these criticisms has tended towards acknowledgement of the limitations while nonetheless retaining the standard QALY-based evaluation. This seems a reasonable approach pending the resolution of the issues. Members of decision making panels are charged with taking account of the disputed issues as well as other problems such as the limitations of the quantitative analysis and bridging the gap between the ‘health-centric’ perspective of most evaluations and political concern for a broader set of social values to be taken into
account\textsuperscript{4, 5, 6}. In line with this approach, the processes of HTA have developed to create more formal opportunities for the communication of different values to decision makers. Patients, clinicians, advocacy groups and manufacturers are encouraged and often supported to provide their views on the value of a technology to the decision makers through written submissions, in-person presentations, consultations on proposed decisions and appeal processes (30).

Academics have produced a steady stream of commentaries, policy documents and empirical studies. In a recent scoping literature review Paulden and colleagues identified 19 additional value arguments that have been advanced for consideration in HTA in the context of rare diseases. They also proposed that the value arguments could be usefully sorted into four distinct categories: disease-related; technology-related; population related and socio-economic related factors (31). [Table 1].

Table 1: Typology of Value Arguments proposed for Health Technology Assessment processes

<table>
<thead>
<tr>
<th>Disease-related</th>
<th>Technology-Related</th>
<th>Population-related</th>
<th>Socio-economic related</th>
<th>Opportunity cost considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence</td>
<td>Effectiveness of treatment</td>
<td>Identifiability of beneficiaries</td>
<td>Socio-economic policy objectives</td>
<td>Price of treatment</td>
</tr>
<tr>
<td>Severity</td>
<td>Magnitude of Benefit</td>
<td>Impact of treatment on the distribution of population health</td>
<td>Industrial and commercial policy objectives</td>
<td>Cost Effectiveness of treatment</td>
</tr>
<tr>
<td>Life-threatening/chronically debilitating</td>
<td>Safety of treatment</td>
<td>Societal Impact of treatment</td>
<td>Legal considerations</td>
<td>Budget Impact of treatment</td>
</tr>
<tr>
<td>Availability of treatment alternatives</td>
<td>Innovative nature of treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feasibility of diagnosis</td>
<td>Feasibility of delivering treatment</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

With so many candidate value arguments - in addition to the complexities already inherent in the form of poor, contested or absent evidence, imperfect models of health and cost consequences for periods outside the trial evidence base, political constraints, the post-decision behaviour of clinicians and patients - the policy challenge becomes clear. It is highly unlikely that decision makers can consistently, transparently and reproducibly balance so many competing factors given the established limits of human mental processing capacity (32). Such limitations in human processing capacity are one of the reasons why HTA processes have utilized decision theoretic models to synthesise large quantities of information from disparate sources (33). Hence it is unsurprising to

\[\text{NICE Guide to the Methods of health technology appraisal. NICE London 2013} \]
\[\text{http://www.nice.org.uk/article/PMG9/chapter/1-Introduction} \text{ (accessed 23 September 2014)}\]
observe the emergence of calls to use multi-criteria decision analysis (MCDA) as a tool for use in HTA (25, 34-35).

As the scope of value arguments proposed has expanded, some authors have sought empirical information on what weight different populations would attach to some of them. Researchers at the University of Sheffield and the Office of Health Economics have examined, amongst other things, whether the general population attach a special value to therapies that extend life at the end of life, and report conflicting results (36-37). Linley and Hughes undertook a large survey of the UK population and found that respondents did not support an EOL premium, a special status for children or socio-economically disadvantaged populations, treatments for rare diseases or cancer therapies. In contrast, they found support for paying a premium for treatments aimed at severe disease, unmet need and for innovative technologies (38). It is noteworthy that this is consistent with the qualitative work undertaken by the NICE Citizen’s Council (39).

Desser and colleagues undertook two separate surveys; one of the Norwegian General Population, the second of Norwegian Physicians. Both examined whether a special value should be attached to the rarity of the treated condition. The authors report that neither study found a clear preference for paying a premium for treatments based upon the rarity of the condition, but there was some indication for a generalized preference for equal access to care (40-41). A separate study from the same research group, published in the BMJ also found no preference for a premium for orphan diseases (42).

Two recent studies in Canada, one using Discrete Choice Experiments, the other a Citizens’ Jury examined population preferences for health care resource allocation around expensive drugs for rare diseases (43-44). Neither study reported substantial support for a value premium based upon the prevalence of the condition but there was support for a value premium based upon the severity of the condition and the magnitude of benefit. Neither the Canadian nor the Norwegian studies asked the respondents to consider proximity to the end of life.

Whilst there has been extensive discussion concerning the value of health gains, the empirical literature is not large. There is some consistency around value being driven by the effectiveness of a technology and the severity of the condition it treats. The empirical evidence for other proposed value arguments is either absent or conflicting,
and overall the evidence base for value premium could hardly be described as mature. The reported studies vary according to the methods, the populations surveyed and the value arguments that were investigated. A number of the value arguments identified in the Paulden scoping review do not appear to have been subjected to empirical investigation. As a result, the current literature plays a greater role in complicating the decision problem faced by decision makers than it does in offering solutions.

We return later to the consideration of the implications of this complexity.
3 Somebody else’s health care: value based choices for limited health care budgets

Applying the simple decision rule “select technologies and their optimal use so as to maximize population health” is, needless to say, made immeasurably more complex given the foregoing issues (both those that are resolved in principle but difficult to assess empirically and those that remain unresolved in principle). It is nonetheless helpful to assume them away in order to see the logical implications of such a decision rule. A useful model of this process, was described by Culyer and colleagues, in the context of the United Kingdom National Institute for Health and Care Excellence’s use of a cost-effectiveness threshold (8, 45).

In any period of time we take the budget available for service provision to be given, as determined variously by a parliamentary vote, forecast premium income or forecast hypothecated taxes and ‘contributions’. As we saw earlier the decision rule “select technologies and their optimal use so as to maximize population health” is equivalent to setting the threshold cost per QALY or incremental cost-effectiveness ratio (ICER) at a level such that no technology inside the insured package has a cost per QALY higher than the threshold and no technology not in the package has one that is lower. It is worth noting that Eckermann and Pekarsky observe that this model assumes that the current allocation of the budget across reimbursed technologies is optimal (46). For the purposes of our discussion here, if this assumption does not hold, then the consideration of who bears the opportunity cost would expand to include patients whose access to funded therapies was further delayed, as well as patients for whom technologies would cease to be funded. The central tenet of our observations would not be affected.

Let us assume that a health care system has solved the selection problem of the correct threshold (we examine later the situation where the threshold has been set too high or too low). All technologies that are provided have an ICER no higher than the threshold and there are no technologies not provided that have an ICER lower than the threshold.

Figure 1 illustrates the starting position. On the left hand side of the figure we see a portfolio of reimbursed technologies, ranked in the order of their efficiency – where efficiency is measured in terms of health produced per $1000 of expenditure (the
reciprocal of the cost-effectiveness ratio). After the eighth technology has been funded, the available budget is exhausted. On the right hand side of the figure we see four technologies that are not reimbursed. All four were previously not available but two of them have C-E ratios that are lower than the threshold. The question facing the decision maker is, which of any of these technologies should be funded?

Given the fixity of the budget, any new technology must produce at least as much health per extra dollar spent than any technology that it replaces; it is simple to see that technologies 11 and 12 should not be adopted. That is, the appropriate decision by an HTA decision maker who wishes to maximise population health is to refuse reimbursement to these technologies. However, this still leaves technologies 9, 10 and 11 as likely candidates for funding, since these are all produce health more efficiently than (so, have an incremental health per incremental dollar higher than) technology 8.

To see which technologies should be funded on efficiency grounds, we can order all 13 technologies in terms of their efficiency. This is shown on Figure 2. Within this diagram, 1-4 and technologies 9 and 10 are provided within the existing budget. Technologies 6, 7 and 8 are no longer funded; the new investment requires complementary disinvestment. The unfunded technologies (6-8, 11-13) are not selected because they yield health benefits less efficiently than each of those that were selected; in each case these treatments would yield health benefits but do not do so efficiently –
they are relatively cost-ineffective. To have invested in any of these would have reduced population health. The opportunity cost (of health foregone) would have exceeded the health benefits that they would have provided.

Note that whilst technology 11 was a likely candidate for funding (as it produces health more efficiently than technology 8), it is not funded when all treatments are taken into account. This is because as technologies 9 and 10 are added, the opportunity cost (of health foregone) increases and so the efficient criteria to obtain funding becomes more onerous. Whilst technology 11 would have met the old criteria, it does not meet the new.

The decision to fund new technologies, in the absence of an increase in the budget, certainly means that other people’s health care has been displaced. It also means that the health generated is greater than the health lost. But the gainers will not normally be the same people as the losers. The question therefore arises: do the displaced individuals, diseases and technologies have characteristics that may be deserving of a ‘value premium’, as outlined in Table 1, that may, after all, keep them in the insured bundle (or warrant an increase in the budget at the next opportunity).
It is very difficult for HTA decision makers to know which patients will bear the opportunity cost of the new technology – i.e. which patients will not be able to access previously available treatments or services. Suppose that all patients count equally in the sense that a QALY for each counts as of equal significance, so that decision makers are indifferent as to who gets an additional QALY. This is often expressed as the QALY=QALY=QALY rule. Under these circumstances, knowing the identity of the losers is of little importance – all that is required is that their losses of health are more than compensated by the increases in the health of the gainers. But now suppose that decision-makers regard the beneficiaries as being specially deserving by virtue of their closeness to death. Now not knowing the identity of the losers is problematic for it can no longer be assumed that none of them is also ‘close to death’. It cannot be safely assumed that the patients who bear the opportunity cost are ‘average patients’ with no special value characteristics. To assume this would imply that decision-makers use different frameworks to value the health gains of the identified beneficiaries of the technology being appraised and the health losses of the unidentified individuals who bear the opportunity cost. The patients may be individually unidentified but something may be known about their prevalence in the population as a whole.

Paulden and colleagues recently described the implications of considering the value characteristics of those bearing the opportunity cost in the same way as the identified beneficiaries (31). They identified two general principles for taking account of additional value arguments to modify a cost-effectiveness threshold:

First; the greater the weight that is applied to the value of health for the individuals given special consideration, and the greater the proportion of those individuals amongst the population bearing the opportunity cost, the lower the cost-effectiveness threshold should be for technologies that do not affect those individuals.

Second, when there are multiple special value arguments under consideration, if the bearers of the opportunity cost are assigned a greater cumulative weight than the beneficiaries of the technology, then the threshold should be lower compared to when everyone’s health is valued equally. Equally if the cumulative weight is greater for the beneficiaries of the technology than for those who bear the opportunity cost, then the threshold should be higher.
4 Implementing a coherent end-of-life (EOL) premium: mechanisms and implications

In the UK, NICE has operated an EOL premium since 2009. The amendment to the Institute’s methods guide identified three criteria that, if fulfilled, justified giving greater weight to QALYs acquired in the later stages of terminal disease. The criteria were:

- The treatment is indicated for patients with a short life expectancy, normally less than 24 months;
- There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional 3 months, compared to current NHS treatment; and
- The treatment is licensed or otherwise indicated, for small patient populations.

When these criteria were met, the Appraisal Committee were to consider “the magnitude of the additional weight that would need to be assigned to QALY benefits in this patient group for the cost-effectiveness of the technology to fall within the current threshold range”.

Despite its superficial attraction, there is a hidden minefield of ethical and political value judgments that warrant explicit identification and discussion. One is whether discriminating in favour of people with a short life expectancy is warranted when one considers that it is tantamount to discriminating against those with a longer expectation of life. The merit in valuing extensions in life expectancy over improvements in quality of life at the end of life is not self-evident. The use of arbitrary thresholds – the three month life extension and an expected life expectancy less than 24 months - to determine which technologies qualify invites questions about the rightness of these periods compared to others. The apparent unfairness to those who may fall just on the wrong side of these apparently arbitrary time lines seems not to have been openly debated. It is the latter apparent arbitrariness that we discuss in more detail here. Any EOL premium plainly requires a definition of “length of life” – but what ought it to be and by what means ought it to be determined?
Using NICE’s specification of the EOL premium, consider a treatment for a patient group with a 3 year life expectancy and very poor quality of life. A treatment that both improved their quality of life and extended life expectancy by 6 months would not qualify for the EOL premium. By contrast, a treatment that increased the life expectancy of patients with an already good quality of life and an 18 month life-expectancy by three months would qualify. The first group of patients has fewer remaining QALYs than the second, yet are disadvantaged even further by the EOL premium. Similarly, a treatment that provides an extra three months life expectancy of poor quality of life would qualify though a treatment that offers only two months extension but of good quality of life, would not. The arbitrary cut-offs introduce apparent injustice in the treatment of people that are consistent with neither common notions of horizontal and vertical justice nor with what we take to be the rationale of the appraisal process. The process by which NICE values health outcomes explicitly adjusts quantity of expected life by its quality. It is not obvious why quality of life is normally an essential component of the value of health care save for those with short expectations of life.

Any specification of an EOL premium defined in terms of maximum life expectancy and then applied to evaluations that otherwise consider quality as well as length of life, will necessarily lead to this type of incoherence. Any specification of a minimum life expectancy benefit is similarly flawed. Expanding the EOL definition to include the quality of life, for example by specifying a maximum remaining quality-adjusted life expectancy, will introduce the possibility that people with substantial disabilities but long life expectancy may qualify, though the policy could then scarcely be described as an “end of life” policy.

The opportunity cost of this weighting is, let us recall, forgone health for others, including those who have severe health problems and who may themselves have a short expectation of life. It is well established that the majority of health care resource consumption takes place in the last years of life. Indeed proximity to death is increasingly accepted as a better predictor of health care consumption than age (47). The EOL premium implicit in the current allocation of health care resources raises two further questions. The first regards the probability that the opportunity cost of new technology adoption is borne by people who would meet the criteria for the EOL
premium. Unless disinvestment decisions actively target other sub-groups in the population, it is credible that some portion of the impact will fall on such people.

Consider a reimbursement decision for an end of life therapy, which is expected to produce 1.8 QALYs for each treated patient. However the price of this highly effective therapy means that it will cost 2.1 QALYs through displaced health care elsewhere in the system. The application of an EOL premium that weighted EOL QALYs 20% higher than other QALYs values the new therapy as producing 2.16 EOL_QALYs – [1.8*1.2]. Initially, this suggests that the EOL means we should reimburse the new technology, as its outcomes are more highly valued than the health care it displaces. However, if 20% of the people whose health care is displaced also meet the EOL criteria, the expected value of the displaced health care increases to 2.184 EOL_QALYs [(2.1*0.8) + (0.2 * 2.1 * 1.2)]. When the EOL criteria is applied to both the beneficiaries and those whose care would be displaced, the new therapy is no longer good value.

Internal ethical coherence in the application of the value premium requires that only a minority portion of any premium should be taken into account; and as a result many fewer technologies are likely to clear a premium weighted cost-effectiveness threshold than its advocates expect.

Secondly, the application of an EOL premium entails the possible exacerbation of a pre-existing inequity. If there were strong evidence of the public having a preference for a premium price for technologies that extend life but only at the end of life, this favoured discrimination might be justified as ‘evidence based’; however, the empirical evidence for such a social value is uncertain at best and even if it were, it does not follow that public policy ought to follow that preference slavishly. There is at least as strong an evidence base for a social preference for preventive treatments rather than cure (48). It is hard to make a convincing argument that the application of an EOL premium is consistent with our understanding of social preferences.

Although the NICE methodological guidance Reference Case recommends that “the valuation of health-related quality of life … should be based on a valuation of public preferences from a representative sample of the UK population using a choice-based method. This valuation leads to the calculation of “utility values”. The idea that public values should be “based on” individuals’ preferences or, indeed, on preferences at all
opens the question of the extent to which technology appraisers have discretion in setting relative values on outcomes accruing to people with different characteristics. One might normally expect that people appointed to advisory committees like the NICE Appraisal Committees will have suitable characteristics not necessarily found in the general population: their preferences over health states, insofar as preferences are what matters, will arguably be better informed as to probable outcomes, they will be alert to exaggerated claims made on behalf of technologies and selection bias in the evidence presented to them. With usual clinical and patient representation, these committees will also have a combination of direct and vicarious experience of the conditions being treated before and after treatment. For such reasons, it may be expected that respecting public preferences (however revealed) will be done in a mature and impartial manner. In the matter of applying weights to particular groups, however, like those near the end of life, there is very little to guide decision makers by way of unbiased evidence as to “what the public thinks”. It seems highly likely that the evidence about “what the public thinks” is evidence gathered (often by journalists) with no regard to the fact that favouring one group necessarily involves disfavouring another.

Independent of the source of these values, elementary horizontal justice requires that a coherent EOL premium should apply to both the identified beneficiaries of the technology being appraised and to the individuals, as best they may be identified, bearing the opportunity cost of its adoption. Further, it would be desirable were it based upon some evidence of social support for the position. The problem of perverse decisions that comes from arbitrary cut-offs along continuous scales (such as life expectancy or quality of life) are unavoidable, but evidence of social support for the specific rationale, may at least meet some requirements of procedural justice.

Within the context of value based resource allocation decisions, coherence would dictate that both quality of life and quantity of life improvements – to patients who meet the EOL qualification criteria – are valued and valued at a premium. Hence NICE’s 3 conditions would be replaced by 1; the specification of the EOL status.

The example above, of NICE’s 2009 EOL amendment illustrates the difficulties of weighting schemes within CEA. These problems are most apparent when the weighting system to account for additional value arguments is made explicit. However, most jurisdictions do not have explicit EOL schemes. In these cases additional value
arguments relating to EOL care may be incorporated informally, as decision makers may use discretion to accept interventions at higher costs than would be justified by strict application of the cost-effectiveness threshold alone. The problems of explicit weighting schemes described above apply equally to such use of discretion. Indeed, since the implicit application of value premia through the application of discretion is less apparent than explicit weighting schemes this poses the additional difficulty of typically not being evident to observers. Accordingly, the inconsistencies and potential inefficiencies can be even less obvious and may remain unquestioned.

5 Conclusions

An EOL premium for health state values is one of many special value arguments that have been advanced to support the reimbursement of technologies that fail standard value for money assessment criteria. Along with rarity, innovation, the lack of alternative treatment and ‘discount rate blight’ – the United Kingdom has been amongst the most enthusiastic champions of its use. However, the evidence for social support for the many of these special value arguments is either negative or contradictory; not just in the UK, but in other jurisdictions as well. However, these evidentiary problems do not appear to weaken the advocates’ belief in the rightness of their beliefs; and hence the question of how an EOL premium should be implemented remains a live policy issue.

The first recommendation we would make is that no single value premium should be implemented in isolation. There are many arguments for special value status and these should be considered in their entirety as most individuals will qualify for one or more of them over the time horizon of most policy analyses (49). At a minimum, all value arguments that clear a shared evidence threshold should be considered. In the current evidence environment, that is likely to include the majority of the value arguments identified by Paulden and colleagues (31). An arbitrary adoption of a subset of value premia would open up decisions to challenge on the basis of inconsistent application of rationales to decisions affecting the same health care budget and/or failure to take account of relevant evidence. The feasibility of decision bodies being able to do this reproducibly and reliably without recourse to some formal valuation framework, such as a quantitative multi-criteria decision analysis, is dubious given the evidence on human capacity for processing information (32, 50).
Our second recommendation is that whichever value framework is constructed must be applied equally to the identifiable beneficiaries and those who would bear the opportunity cost of adopting new technologies. To do otherwise is to value individuals health differently solely on the basis of identifiability, leading to inequitable and inefficient reimbursement decisions, creating a systematic bias in favour of new interventions at the expense of existing care.

Third, whichever arbitrary definition of EOL is chosen should be validated against social preferences. The arbitrary and potentially perverse incentives that come from such a definition are unavoidable, but demonstrating social support may make them an acceptable price to pay for a pragmatically tractable decision making framework.

Fourth, assuming that the components of the conventional QALY are a subset of the value of a technology, the benefit of an EOL premium must apply to both improvements in health related quality of life and life expectancy. To do otherwise creates an unnecessary and unjustified inconsistency in the valuation framework used for end of life technologies and all other technologies.

Finally, whilst moving forward with values based upon the best available evidence and expert judgment is a reasonable initial strategy, substantive research to obtain robust evidence on the values of the population affected by the resource allocation decisions will be an urgent priority if decisions that depend on ‘special value’ arguments are to withstand the challenges that will come from any system that complies with the important principles of procedural justice.
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