COST-EFFECTIVENESS AND SOCIAL VALUES

RECOMMENDATIONS FOR REVISING NICE'S *SOCIAL VALUE JUDGEMENTS*

An Open Letter to the National Institute for Health and Care Excellence.

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The authors and contributors belong to the 'KCL/UCL Social Values and Health Priority Setting Group' which has been meeting regularly since October 2012 to study the role of social values in health care priority setting. They come from different academic disciplines as well as the world of policy. Their individual views on NICE's principles of appraisal – for example the weight to be given to end of life considerations - differ considerably. However, all work on the assumption that justifiable approaches in this area can be identified in an impartial way, even where there is reasonable disagreement about which might be the best approach.

This letter is in response to a request from Professor Sarah Garner Associate Director of R&D at NICE for the group to consider the issues to be addressed when updating the 2008 edition of *Social Value Judgements document.*

EXECUTIVE SUMMARY

NICE's document *Social Value Judgements* specifies the role of social values like fairness, non-discrimination and justice, alongside cost-effectiveness, in developing its appraisals. NICE is currently revising the 2008 edition of *Social Value Judgements*, and this open letter offers an independent evaluation of key elements of that document. We make a series of recommendations as to how *Social Value Judgements* might be improved in the next edition, identifying a number of issues that will require further attention including:

- The accurate description of NICE's method
- The rationale for NICE's cost-effectiveness threshold
- End of life as a special case
- Social equality
- Good professional practice as a social value
- Innovation

Our recommendations are:

- **Recommendation 1**: NICE should eliminate all references to claims that its primary task is to maximize health gain in *Social Value Judgements*. Instead it should state that it aims to impose a presumption that all assessed interventions should meet a cost-effectiveness threshold, unless there are important countervailing considerations to the contrary.
- **Recommendation 2:** NICE should cease to link its principles to any particular ethical framework, such as Beauchamp and Childress's Four Principles Approach.
- **Recommendation 3:** NICE should amend *Social Value Judgements* so as to include a rationale for the methods for arriving at the value of the ICER threshold that it uses.
- **Recommendation 4:** In the light of the complications associated with the operation of the end-of-life criteria, NICE should record the cases in which the operation of those criteria has proved problematic.
- **Recommendation 5:** In the operation of end-of-life criteria, there should be an explicit statement that the extra weight this implies may need to be constrained by considerations of the opportunity costs that such a weighting necessarily involves.

- **Recommendation 6:** Decisions about interventions should take into account considerations beyond those that accrue to individuals. *Social Value Judgements* should make it clear that relations of fairness and equality among individuals are also important.
- **Recommendation 7:** If NICE departs from standard Treasury discounting in making appraisals, *Social Value Judgements* should explicitly state the grounds on which this is done. An alternative approach would be to specify the groups, for example children, where special exceptions are made.
- **Recommendation 8:** *Social Value Judgements* should explicitly recognise that not all social values can be expressed in terms of the outcomes that an intervention produces. For example, NICE may need to explore the merits of including 'good professional practice' as one social value that can, under the proper circumstances, overturn the general priority given to cost-effectiveness.
- **Recommendation 9:** *Social Value Judgements* should state explicitly that innovation will only be considered as a modifier of normal cost-effectiveness considerations when it produces measurable improvements in the patient's experience that is otherwise not captured in the QALY. However, it should also explicitly rule out using innovation to overturn cost-effectiveness considerations when the sole claim is that of benefit to producers.
- **Recommendation 10:** NICE should review regularly appraisals to assess whether its social values are being applied consistently, and whether the presumption of cost-effectiveness is being overturned in a way that is justifiable by reference to those values.

I. INTRODUCTION

Social Value Judgements specifies the role of social values like fairness, non-discrimination and justice, alongside cost-effectiveness, in the development of its appraisals. [1] In light of NICE's current efforts to revise *Social Value Judgements*,[2] this letter offers an independent evaluation of the 2008 second edition of *Social Value Judgements*. It makes a series of recommendations as to how NICE's statement of its practical reasoning might be improved in the next iteration.

II. NICE'S DECISION PROCEDURE

This section summarises our understanding of NICE's methods by way of background to the subsequent discussion.

The starting point of an appraisal is an assessment of a given technology's cost-effectiveness. This contains the following elements:[3]

- Evaluation of effectiveness: NICE identifies the benefits arising from a health care intervention. The benefit is defined as the (mean) average improvement in the health status of individuals receiving an intervention. Health benefit is measured by reference to both an extension of life and an improvement in the quality of life, and is represented as a 'quality-adjusted life-year' (QALY). Because QALY gains arise from different interventions to treat different diseases, NICE uses wherever possible a measure of effect (the QALY) that is not specific to that intervention or disease. In this way comparisons can be made of the benefit to be expected from different interventions. QALY gains across different individuals are also compared to one another.
- Evaluation of cost: In the case of technology appraisals, costs are total NHS and personal social service costs. For medicines and devices, costs are given by the published list price. In recent years there has been some modification of this arrangement as "patient access schemes" and are negotiated between Industry and the Department of Health. However, they are usually initiated when draft guidance from NICE suggests that the intervention is not cost-effective.
- Evaluation of cost-effectiveness: NICE evaluates an intervention by reference to its 'incremental cost-effectiveness ratio' (ICER). NICE defines the ICER as 'the ratio of the

difference in the mean costs of an intervention compared to the next best alternative (which could be no action or treatment) to the differences in the mean health outcomes'.[4] NICE does not commit itself to an explicit maximum value of an ICER above which it does not recommend an intervention.[5] However, based on its decisions to date, commentators have inferred that its QALY threshold maximum is between £20,000 and £30,000.[6]

Against this background, NICE has adopted a set of 'social values' as considerations that may justify recommending a technology whose ICER puts it over that threshold. Departure from an ICER of over £20,000 per QALY gained is considered acceptable on the basis of five considerations (described in its *Guide to the Methods of Technology Appraisal* as 'modifiers'):

i) the degree of certainty around the ICER;
ii) the extent to which the assessment of the change in health-related quality of life has been captured adequately;
iii) the innovative nature of the technology;
iv) whether the technology meets the criteria for special consideration as a 'life-extending treatment at the end of life';
v) aspects that relate to non-health objectives of the NHS.[7]

Together, NICE takes modifiers i) – v) sometimes to warrant a departure from the ICER of £20,000 cost per QALY, where Appraisal Committees need to make an increasingly stronger case for supporting the intervention as an effective use of NHS resources with specific reference to the factors considered above as the ICER climbs over £20,000.[8]

As well as the values specified as grounds for weighting QALYs, NICE also uses those social and ethical values outlined in *Social Value Judgements*, including special consideration of the needs of disabled people, special consideration of the relief of stigma, reducing health inequalities (especially by benefiting the most disadvantaged), amongst others.[9] Again, these are taken to justify varying the cost-effectiveness threshold.

III. DESCRIBING NICE's METHOD

NICE is often described, both by itself and by others, as seeking to maximise QALY gain from health care expenditure.[10] Moreover, in *Social Value Judgements* NICE states that a maximizing approach is one way of understanding health care justice, and that this is one approach incorporated into its work.[11]

However, the description of NICE's decision procedure in Section II is not based on the principle of maximizing QALY gain. In making appraisals NICE does not create a cost per QALY rank-order, and then recommend interventions with the lowest cost per QALY, working its way through the league table until a global budget is exhausted.[12] Rather, it conducts pair-wise cost-effectiveness comparisons. The threshold is the point at which the health benefits gained through the purchase of the technology under appraisal are likely to be greater than those forgone through any implicit disinvestment thereby incurred.[13]

The cost-effectiveness threshold is therefore a filter. Rather than describe NICE as maximising benefit, its process is best thought of as establishing a rebuttable presumption that a minimum level of cost-effectiveness should be met by an intervention. A cost per QALY of *less* than the threshold amount will nearly always be sufficient to guarantee that the medical technology is approved. However, not all interventions above the threshold will be rejected. The test of a cost-effectiveness threshold can be rebutted in light of relevant considerations of the type set out in *Social Value Judgements.* Given that this is the decision process, NICE should cease to describe its own work in terms of maximizing health gain.

There is an additional reason to avoid stating that NICE is maximising health gain. A maximizing viewpoint is associated with utilitarianism. To commit NICE to operating on utilitarian principles would be to make its decision making vulnerable to the standard objection to utilitarianism, namely that it produces injustice by violating the 'separateness of persons', sacrificing the interests of the few to the many.[14] Within its current procedures, NICE can avoid this charge without conceding the right of anyone to a claim to whatever resources are necessary to prolong or improve his or her life. Principle 5 of *Social Value Judgements* ('Although NICE accepts that individual NHS users will expect to receive treatments to which their condition will respond, this should not impose a requirement on NICE's advisory bodies to recommend interventions that are not effective, or are not cost effective enough to provide the best value to users of the NHS as a whole.') can be justified in terms of the general interest that everyone has in maintaining a financially viable health service.[15]

This recommendation is consistent with NICE's statement in *Social Value Judgements*, that those 'developing clinical guidelines, technology appraisals or public health guidance must take into account the relative costs and benefits of interventions (their "cost-effectiveness") when deciding whether or not to recommend them'.[16] The importance of this principle is also enshrined in the NHS Constitution, which states that 'The NHS is committed to providing best value for taxpayers' money and the most effective, fair and sustainable use of finite resources'.[17] Neither statement implies a maximizing strategy.

So, in the revision of *Social Value Judgements* NICE should eliminate all references to claims that its primary task is to maximize health gain.

Recommendation 1: NICE should eliminate all references to claims that its primary task is to maximize health gain in *Social Value Judgements*. Instead it should state that it aims to impose a presumption that all assessed interventions should meet a cost-effectiveness threshold, unless there are important countervailing considerations to the contrary.

As well as removing any reference to its work as an attempt to maximize health gain, NICE should eschew committing itself to particular ethical theories, since every ethical theory is controversial and so will not support public justification. For example, *Social Value Judgements* links NICE's methods to Beauchamp and Childress's 'Four Principles Approach' to bioethics.[18] However, it would be enough for NICE simply to affirm that its method recognizes the importance of consequences as well as constraints on crudely maximizing the good, and thus reflects the views of most reasonable people. We also question whether there is any merit in adopting the 'Four Principles' approach. These principles have been developed for contexts much wider than resource allocation – for example the securing of consent to treatment – and it is questionable to claim that principles like 'autonomy' are 'culturally neutral', as *Social Value Judgements* suggests.

Recommendation 2: NICE should cease to link its principles to any particular ethical framework, such as Beauchamp and Childress's Four Principles Approach.

IV. FURTHER ISSUES

There is a good case for saying that NICE's general method of setting a presumption to prioritize cost-effectiveness is reasonable.[19] But to say that the method is reasonable is not to say that it cannot be improved. In this section, we discuss a selection of issues (evidence cited in this section is summarised in Appendix 1).

a. Is NICE's cost-effectiveness threshold defensible?

The reasonableness of NICE's cost effectiveness depends not just on its absolute level, but on the rationale given for this level. *Social Value Judgements* remains silent about the rationale for the £20,000 to £30,000 level (and why it should be a range rather than a single number). However, other sources make clear that the rationale for the threshold is the mean cost of producing a QALY elsewhere in the healthcare system.[20] If £20,000 to £30,000 reflects the mean cost of producing a QALY, then the threshold looks reasonable. Within a fixed budget system, funding a new treatment means that some activities currently being undertaken will be forgone. If a new treatment is funded that costs more per QALY than the threshold, then funding the new treatment will displace activities that would have created more QALYs. Unless there are reasons, some of which we discuss later, for thinking that the treatment should be funded despite its displacing a greater health benefit elsewhere, it should not be funded.

As things stand, the £20,000 to £30,000 threshold has not been altered in NICE's lifetime. Moreover, the most thorough estimate available suggests that even at this level it may be too high.[21] This means that it is important to ask whether – even assuming that the threshold was set at the right level when NICE began - it is now set at the right level.

Recommendation 3: NICE should amend *Social Value Judgements* so as to include a rationale for the methods for arriving at the value of the ICER threshold that it uses.

b. End of Life as a Special Case?

It has been argued that those at death's door deserve more consideration than those for whom the extension of life is more remote, because a range of important considerations arise at the end of life (e.g. the need to order one's affairs, the importance to a society of paying special attention to the needs of the dying, the fact that today's exceptional treatment may become tomorrow's routine therapy). In response to these considerations, NICE introduced its end-of-life

criteria, according to which special provision could be made provided that the intervention offered an extension of life for those with a prognosis of less than 24 months, the extension of life on average was greater than 3 months and the treatment population size was small at less than 7000. The effect of these provisions is to allow the funding of treatments with a considerably higher ICER value than £30,000. For example, sunitinib, a treatment for renal cell carcinoma and the first product ultimately assessed under the end-of-life criteria, was originally appraised as having an ICER of between £49,300 and £54,366.[22]

However, there are complications with the criteria as they stand, since they do not capture pure end-of-life considerations. Consider the small patient population criterion. One can argue that, if the condition warrants special treatment, then this should be so no matter how many people suffer it. Conversely, in practice, there can be treatment drift, so that a product licensed for a small patient group might later be applied to a larger group. This is what happened to sunitinib (though to a group that was itself small) and there were similar issues in the case of trastuzumab.[23] There can also be questions about how rigidly to apply the criteria. This problem arose in the case of lapatinib, where the manufacturer questioned the application of the 3 months test.[24]

At one point, during its review of the burden of illness, NICE proposed that no separate consideration ought to be given to end of life, once the burden of illness was taken into account. Its own worked examples showed that those who suffer the greatest proportional loss of QALYs were those struck by terminal illnesses where death follows quickly from diagnosis, most typically cancer deaths. Since these are the cases to which the end-of-life criteria have applied, it would have been reasonable to bring these criteria within the scope of the burden of disease framework. However, as NICE has now rejected the burden of illness approach, the end-of-life criteria still apply. Given the problems of operating these criteria cited above, good practice would suggest keeping the application of the criteria under review, and if the costs of end-of-life treatments rise, making clear explicitly the opportunity costs that is involved.

Recommendation 4: In the light of the complications associated with the operation of the end-of-life criteria, NICE should record the cases in which the operation of those criteria has proved problematic.

Recommendation 5: In the operation of end-of-life criteria, there should be an explicit statement that the extra weight this implies may need to be constrained by considerations of the opportunity costs that such a weighting necessarily involves.

c. The Concern for Social Equality.

The intellectual approach on which the NICE standard operating procedure draws is individualistic in the sense that the unit of benefit is individuals and the QALY benefit to individuals is simply added. Health gains among individuals are viewed as separable. A gain added to one person is treated in itself without any consideration of the implications for the overall distribution of health status. There are well-known reasons why this approach cannot adequately take into account the fairness of distributions considered in terms of a profile of benefits. Thus, if smoking cessation programmes are responded to more positively by the better educated, this may widen social health inequalities, though the cost-effectiveness test could be met with flying colours.

Principle 3 of *Social Value Judgements* say that decisions about interventions should not be based on the evidence of their costs and benefits alone, but also on the need to distribute health resources in the fairest way within society as a whole. This is presented as a supplement to the standard operating procedure. But in fact, it is a qualification of it.

Recommendation 6: Decisions about interventions should take into account considerations beyond those that accrue to individuals. *Social Value Judgements* should make it clear that relations of fairness and equality among individuals are also important.

d. Discounting Future Gains.

The intellectual background to NICE's decision making is in part drawn from principles of public investment appraisal. Such an approach assumes that a public decision maker has to spend a certain sum of money for a range of possible returns. In evaluating alternative returns, the approach discounts future costs and benefits, in order to bring different projects, each with a different incidence of costs and benefits over time, to a common net present value, thus making them comparable. The approach is set out clearly in the Treasury *Green Book*.[25]

Where the difference in time horizon between costs and benefits is not that great, no problems emerge with this approach. However, there has been one case of appraisal where the logic of discounting has caused problems, namely mifamurtide for the treatment of osteosarcoma among the young.[26] Because the majority of treatment costs are incurred in the first year, whereas the benefits are added to an already potentially long (around 60 years) survival time, estimating the ICER is affected by the discount rate as applied to the benefits. As a result of applying the standard Treasury discount rate (3.5%) the ICER value was relative high (£56,700 per QALY) whereas with a

rate of 1.5% it was only £36,000 per QALY. Although to date this type of case has been relatively rare, it is not difficult to see how it might occur more frequently in the future, for example in respect of products developed to ameliorate dementia to be taken by those having undergone a predictive test in their forties.

The ethics of discounting is controversial. Some argue that in the case of health we should not discount health utility in the same way as we discount the cost of producing that utility.[27] If this argument is valid, then it suggests that in not adopting standard Treasury discounting rules NICE has refined its decision making framework in a way that suits the special case of health expenditure. However, it would be useful to have an explicit statement to this effect in the revised version of *Social Value Judgements*.

Recommendation 7: If NICE departs from standard Treasury discounting in making appraisals, *Social Value Judgements* should explicitly state the grounds on which this is done. An alternative approach would be to specify the groups, for example children, where special exceptions are made.

e. Good professional practice.

A strict adherence to the standard NICE decision-making framework commits one to taking the QALY alone as the unit of benefit, presuming that it captures all that is valuable in an intervention. However, reliance on QALY values alone cannot capture the social value of interventions that may not show up in significant QALY differences, for example 'dignity' or conformity to the standards of good professional care. This narrowing of the standards of value emerged in the case of lucentis.[28] The original appraisal was premised on the assumption that, since patients who go blind in just one eye adapt to their disability, it would be cost-effective to allow patients to go blind in a weaker eye before lucentis could be administered. On this basis the funding of the intervention would be cost-effective. However, such a protocol would be inconsistent with good quality care and competent treating physicians would arguably be deficient in respect of their professional duties if they so acted. Eventually, in that case, the conflict of values was resolved within the QALY framework by claiming that there would be a loss of QALYs resulting from the unnecessary anxiety in those being treated. However, one could argue that, rather than adjusting the QALY values, it would have been better to have admitted the conflict with good professional practice and to say that the latter outweighed the result that one obtained from the original ICER estimate.

Recommendation 8: *Social Value Judgements* should explicitly recognise that not all social values can be expressed in terms of the outcomes that an intervention produces. For example, NICE may need to explore the merits of including 'good professional practice' as one social value that can, under the proper circumstances, overturn the general priority given to cost-effectiveness.

f. Innovation.

In principle, it can be argued that anything that is of value arising from innovation should be captured by the QALY gain. If the innovation leads to an improvement in QALYs for reasonable cost, then it should be approved; if it does not lead to such improvement, then it should not be approved. However, this is to suppose that all that is of value in an intervention is contained in the QALYs flowing to individuals. Yet there may possibly be other features of pharmaceutical development that are not measurable in this way. For example, there may be features of the way in which a drug is administered that do not affect the QALY value, but which are important in terms of more general quality of life considerations. This was argued in respect of abiraterone for prostate cancer and fingolimod for multiple sclerosis, where the fact that the drugs were administered orally was taken to be a significant innovation. A different sort of consideration arising from innovation concerned ipilimumab for advanced melanoma, where it was argued that there had been few advances in the treatment of advanced melanoma, and that the treatment options for patients were limited simply to their being enrolled in clinical trials.

One way of justifying these modifications of the standard decision making framework is to say that they are acceptable because they are elements of what the original QALY formulation was seeking to capture anyway. Arguably health policy is generally about enhancing the quality of life of patients. One way of capturing this is to formalise the idea in the measurement of QALYs but it would be wrong to infer that all that is valuable is captured in this way. Hence, making allowances for the way in which products are administered or the importance of communicating to patient groups that their needs have not been forgotten are legitimate considerations. By contrast, it would not be a legitimate consideration to claim that a product should be approved because the pharmaceutical sector was a successful part of the UK economy. That consideration is not part of what one would be trying to capture in quality of life measurements, and it is, in any case, too general a consideration, since it would not discriminate among products that were good value for money and those that were poor value. If there is an argument for the state supporting innovation in industry, there is no reason why the cost of that support should be attributed to the NHS budget.

Recommendation 9: *Social Value Judgements* should state explicitly that innovation will only be considered as a modifier of normal cost-effectiveness considerations when it produces measurable improvements in the patient's experience that is otherwise not captured in the QALY. However, it should also explicitly rule out using innovation to overturn cost-effectiveness considerations when the sole claim is that of benefit to producers.

g. NICE's Decision-Making Process

NICE's setting of a presumption to prioritize cost-effectiveness is bolstered by its strong commitment to a robust process by which decisions about individual health interventions are made. *Social Value Judgements* endorses the dominant conception of procedural justice in health and health care, namely accountability for reasonableness.[29] This approach is also consistent with the *NHS Constitution*, which emphasizes the importance of accountability.[30] While there is some academic discussion around accountability for reasonableness, fair and transparent decision-making processes are widely recognized as central for making decisions about which reasonable people might disagree. Healthcare resource allocation falls squarely into this area of reasonable disagreement, and so NICE's commitment to robust decision procedures lends significant support to the decisions it makes.

NICE has rightly added several important procedural requirements to the recognized 'accountability for reasonableness' framework that make it more robust.[31] For example, NICE recognizes the intrinsic value of inclusiveness, requiring inclusion of stakeholders as an element of good practice, whilst other versions of accountability for reasonableness regards stakeholder involvement purely instrumentally, as more likely to result in recognizing all relevant reasons. NICE also requires independence which is critical for managing conflicts of interest. Nonetheless there are potential improvements in NICE's decision-making process. For example, NICE could review its judgements on a regular basis across a sequence of decisions to examine whether social values are being consistently applied, particularly when the presumption of cost-effectiveness is overturned. Table 1 shows a simple model by which this might be done.

Recommendation 10: NICE should review regularly appraisals to assess whether its social values are being applied consistently, and whether the presumption of cost-effectiveness is being overturned in a way that is justifiable by reference to those values.

V. Conclusion and Recommendations

This letter has argued that the approach taken by NICE in *Social Value Judgements* is reasonable, but that more needs to be done to clarify the roles that social values do, and should, play in NICE's processes. Table 1 summarises the recommendations and the rationale that supports them in each case.

Table 1

Summary of Suggested Revisions to NICE *Social Value Judgements* 2008

Recommendations	**Rationale**
Recommendation 1: NICE should eliminate all references to claims that its primary task is to maximize health gain. Instead it should state that it aims to impose a presumption that all assessed interventions should meet a cost-effectiveness threshold, unless there are important countervailing considerations to the contrary. (See: Section 2.2 *SVJs*)	Since NICE does not work to a protocol of maximising health gain, section 2.2 is misleading. The section is also confusing, since it appears to say that there are two approaches to distributive justice, but then says that one of the approaches is 'at the expense of fairness'.
Recommendation 2: NICE should cease to link its principles to any particular ethical framework, such as Beauchamp and Childress's Four Principles Approach. (See: Section 2.1 *SVJs*)	The 'four principles' approach is not universally accepted in bioethics, and the principles are not 'culturally neutral'. Stating these principles in the document obscures the stance that NICE in fact takes. Section 2.1 should explain the rationale for the presumption of cost-effectiveness, in terms of the value of maintaining a system in which the potentially catastrophic consequences of ill health do not fall solely on individuals. This would be consistent with the statement at the top of p.18 that advisory bodies should use their judgement when considering cost-effectiveness analyses.
Recommendation 3: NICE should amend *Social Value Judgements* so as to include a rationale for the methods for arriving at the value of the ICER threshold that it uses. (See: Section 2.2 and 4.2 *SVJs*)	At present there is no rationale given for the particular value that is used in the ICER. This section should make clear that the value chosen is supposed to represent the opportunity cost of displaced treatments, though it is only adopted as a presumption.
Recommendation 4: In the light of the complications associated	Legitimate questions have been raised as to how rigidly to apply the criteria and why some

with the operation of the end-of-life criteria, NICE should record the cases in which the operation of those criteria has proved problematic.	requirements, for example 'small numbers', are applied. If the burden of disease approach is not to be adopted, then the existing criteria should be kept under review.
Recommendation 5: In the operation of the end-of-life criteria, there should be an explicit statement that the extra weight this implies needs to be constrained by considerations of the opportunity costs that such a weighting necessarily involves.	There are reasonable ethical arguments for having an extra weighting for end-of-life, but these need to be set in the context of NICE's existing Principle 5, which says that no individual can claim a disproportionate amount of resource.
Recommendation 6: Decisions about interventions should take into account considerations beyond those that accrue to individuals. *Social Value Judgements* should make it clear that relations of fairness and equality among individuals are also important. (See: Sections 4.2 and 8 *SVJs*).	At present the concern for health inequalities in *SVJs* sits uneasily with the individualistic approach via the ICER. NICE could clarify that it is using considerations about relations among individuals to guide its decision making.
Recommendation 7: If NICE departs from standard Treasury discounting in making appraisals, Social Value Judgements should explicitly state the grounds on which this is done. An alternative approach would be to specify the groups, for example children, where special exceptions are made.	The case of mifamurtide highlighted some difficulties with the application of standard Treasury discount rules. There are complex conceptual and philosophical issues involved in establishing a social discount rate. This recommendation is intended to make the complexity of the issues explicit.
Recommendation 8: Social Value Judgements should explicitly recognise that not all social values can be expressed in terms of the outcomes that an intervention produces. For example, NICE may need to explore the merits of including 'good professional practice' as one social value that can, under the proper circumstances, overturn the general priority given to cost-effectiveness.	Once NICE's general approach to cost-effectiveness is recognised as a rebuttable presumption, then broader considerations can be invoked. Normally good professional practice should be consistent with NICE recommendations, but in cases where they diverge, as was arguably true in the case of lucentis, modifiers should be allowed to overturn the presumption.

Recommendation 9: Social Value Judgements should state explicitly that innovation will only be considered as a modifier of normal cost-effectiveness considerations when it produces measurable improvements in the patient's experience that is otherwise not captured in the QALY. However, it should also explicitly rule out using innovation to overturn cost-effectiveness considerations when the sole claim is that of benefit to producers. (See: Section 4.2 *SVJs*).	There are cases where innovation leads to an improvement in the quality of patients' experience. However, there is no reason why the health budget should play a role in supporting industrial development for its own sake.
Recommendation 10: NICE should review regularly appraisals to assess whether its social values are being applied consistently, and whether the presumption of cost-effectiveness is being overturned in a way that is justifiable by reference to those values. (See: Section 9 *SVJs*).	Our review of NICE's decisions has shown that there have been important cases where the complexity of the social value judgements on which it relies has been significant. This recommendation is intended to suggest that the experience should be codified. Table 1 shows a simple model by which this might be done.

Appendix 1: The Use of Social Values to Overturn NICE's defeasible Cost-Effectiveness threshold

Technology Appraised	Description	Initial assessment of ICER	Additional values considered	Accepted or Rejected
Sunitinib[32]	Treatment for renal cell carcinoma	Between £49,300 and £54,366 per QALY gained	End-of-Life as a special case; Innovation	*Accepted* - if a patient has an ECOG performance status of 0 or 1 and there are no further treatment options recommended by NICE after first-line sunitinib treatment
Trastuzumab plus cisplatin and capecitabine or 5-fluorouracil[33]	Treatment for advanced and metastatic cancer.	For the whole population covered by the marketing authorisation - between £63,100 and £71,500 per QALY gained. For IHC3-positive subgroup - between £45,000 and £50,000 per QALY gained.	End-of-Life as a special case	*Rejected* for the whole population covered by the marketing authorisation. *Accepted* for HER2-positive, gastric cancer who have not received prior treatment for their metastatic disease and whose tumours are IHC3 positive
Lapatinib[34]	Treatment for advanced or metastatic breast cancer	For lapatinib plus capecitabine compared with vinorelbine monotherapy - £79,000 per QALY gained. For lapatinib plus capecitabine in comparison with trastuzumab monotherapy - £24,000 per QALY gained, (but this did not take into account the comparison of trastuzumab with capecitabine, for which the ICER was approximately £109,000 per QALY. For lapatinib plus capecitabine in comparison with all comparators - £61,000 per QALY gained.	End-of-Life as a special case; Orally administered treatment (Choice).	*Rejected*
Lucentis[35]	A treatment for Age-Related Macular Degeneration (AMD)	In cases where there were classic lesions - £15,638 per QALY gained when compared with the current practice of Photodynamic Therapy; £11,412 per QALY gained when compared with the best supportive care for non-classic lesions; £25,098 per QALY gained when compared with best supportive care for classic lesions.	Dread; That 'Something Ought to be Done';	*Approved* for treatment of the first eye that came to clinical attention with AMD.
Abiraterone	Treatment for Prostate cancer		Innovation; Orally administered treatment (Choice)	*Rejected* initially, but then *Accepted* with a patient-access scheme.

Fingolimod	Treatment for Multiple sclerosis		Innovation; Orally administered treatment (Choice)	*Rejected* initially, but then *Accepted* with patient-access scheme.
Ipilimumab	Treatment for Advanced Melanoma		Innovation; Few recent advances	*Approved*, despite being above threshold. Patient access scheme.
Mifamurtide[36]	Treatment of osteosarcoma among the young		Standard discount rate (3.5% on costs and benefits inappropriate.	*Approved*, despite being over the ICER threshold with discount rate.

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[10] E.g. Shah *et al.*, who suggest that 'The use of cost effectiveness analysis in NICE's technology appraisals reflects an underlying 'non-welfarist' or 'extra welfarist' normative position that the principal aim of the NHS is to maximise QALYs' (See Shah, K., Praet, C., Devlin, N., Sussex, J., Appleby, J., Parkin, D., (2012) 'Is the aim of the English health care system to maximize QALYs?' *J Health Serv Res Policy* 17(3): 157-163).

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[12] Such an approach was tried in the first round of the Oregon health care plan. See: Tengs TO, Meyer G, Siegel JE, Pliskin JS, Graham JD, and Weinstein MC (1996) 'Oregon's Medicaid ranking and cost-effectiveness: is there any relationship?' *Med Decis Making* 16(2): 99-107.

[13] Cf. Claxton, K. and Culyer, A. J., (2007) 'Rights, responsibilities and NICE: a rejoinder to Harris' *J Med Ethics*, 33: 462-464. Recent research has suggested that NICE's existing threshold may be too high, with the cost to QALY in the wider NHS being £12,936 per QALY gained – see Claxton K, Martin S, Soares M, Rice N, Spackman E, Hinde S, Devlin N, Smith PC, Sculpher M. (2013) *Methods for the estimation of the NICE cost effectiveness threshold* (Centre for Health Economics, University of York). https://www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP81_methods_estimation_NICE_costeffectiveness_threshold_(Nov2013).pdf. Accessed 07/04/14

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