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NICE's Discounting Review: Clear Thinking on Rational Revision Meets Obstacle of Industrial Interests

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Abstract

The National Institute of Health and Care Excellence (NICE) recently published a review of discounting practice and theory as part of a consultation on its current methods guidelines. The review examines the case for revision or retention of current methods. The changes considered include eliminating favourable rates in certain special cases and the reduction of the base-case rate for costs and health effects from 3.5 to 1.5%. The review also notes the potential need to reduce the cost-effectiveness threshold to accommodate a discount rate reduction, explaining that an agreement between the UK government and the pharmaceutical industry proscribes changing NICE's threshold range until the end of 2023. We believe NICE should be commended for a useful overview of the existing literature and relevant issues. We firmly endorse NICE's view that favourable discount rates are not a good way to apply a preference for certain interventions. Similarly, we support the option of reducing the discount rate to 1.5%, which better accords with real government borrowing costs. We suggest further work to clarify the appropriate theoretical basis for the NICE's social discount rate and the sensitivity of the threshold to changes in discounting. The prospects of a necessary discount rate reduction appear to depend on whether a threshold reduction can be achieved within NICE's current range or if the range itself must be revised downwards. NICE has usefully informed the debate around discount rates. Ultimately, the path to a methodologically consistent and evidence-based revision of discounting depends on whether NICE needs to adjust the threshold too and if it is free to do so.

1 Introduction

The National Institute for Health and Care Excellence (NICE) is holding a consultation on its health economic evaluation guidelines on discounting [1]. In preparation, it has published a review of both the discounting methods employed by NICE and the relevant academic literature

Key Points for Decision Makers

NICE is reviewing its discounting guidelines and has mooted a discount rate reduction from 3.5 to 1.5%, which we believe justified given the real cost of government borrowing.

The implications of a revision should be considered for other interventions such as screening and vaccination, even if they lie outside of NICE's remit, as appraisal methods should be consistent across all interventions.

While any necessary accompanying reduction to the cost-effectiveness threshold is precluded by a current government agreement with industry, NICE could use the considerable flexibility within its £20,000–£30,000 per QALY threshold range to accommodate reform without formally adjusting the threshold.

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[2]. The consultation and supporting review are welcome and demonstrate NICE's openness to methods revision and to views and expertise outside the organisation. This commentary examines NICE's review and what it reveals about the likelihood of any revision to discounting guidelines.

The purpose of this commentary is both to explain why we think NICE has done well in preparing for this consultation and to outline what remaining issues need to be considered further, both by NICE and by the cost-effectiveness analysis (CEA) methods research community. In addition, we wish to draw attention to the potential obstacle to sensible revision of methods guidelines posed by the latest in a series of agreements between the UK government and the pharmaceutical industry.

We have structured this commentary in four parts. In the first we address useful insights presented by NICE's review of discounting methods that merit highlighting and endorsing. Secondly, we describe what relevant issues were not addressed in the NICE review. Thirdly, we examine the constraints on necessary discounting reform placed by existing commitments not to revise NICE's cost-effectiveness thresholds range and some of the resulting practical policy concerns. Finally, the discussion section rounds up some of the broader themes from our perspective.

2 Analysis

2.1 Relevant Observations Deserving Emphasis and Expansion

There are a number of helpful observations made by NICE in its review that we wish to highlight. In some cases we expand on points that we feel NICE could have considered further.

NICE's review makes clear there are implications for the appropriate cost-effectiveness threshold if discount rates are revised. It includes evidence suggesting a reduction in discount rates is warranted and notes that the incremental cost-effectiveness ratios (ICERs) of many health-care technologies would be expected to fall if discount rates were reduced. A logical consequence is that the cost-effectiveness threshold must also be reduced in order for a rational allocation of resources to be maintained. How great the fall in ICERs and the threshold would be is an empirical question and depends in part on whether current allocations and prices are maintained or not. Nevertheless, it is helpful that NICE clearly recognises the relationship between discounting and the threshold and the implications this has for the prospects of a revision of discounting.

NICE's review also includes a preliminary empirical analysis of the sensitivity of ICERs in response to alternative

candidate discount rates. This is helpful in informing decision makers of the implications of discounting revision. NICE should be commended for providing this sensitivity analysis and, while the review clearly qualifies the results as being on the basis of a small sample of studies, we think NICE should consider extending this analysis to investigate a broader range of interventions more representative of the balance of NHS spending. In particular, we think the present analysis has not considered the implications of revision outside of therapeutic drugs. Vaccination, screening, public health and some surgical interventions can all be particularly sensitive to discounting. The resource implications of changes in eligibility within such interventions, both in terms of budget impact and service capacity, could be considerable and deserve consideration. Even if certain intervention types lie outside NICE's remit, it is logical that a common discount rate and threshold apply to all. Therefore, NICE should consider the full implications.

Another issue addressed in NICE's review is the application of favourable discount rates in special cases, referred to as 'non-reference case discounting'. The first such special case was mifamurtide for the treatment of osteosarcoma in children and young people [3], but this has subsequently been formalised to apply to interventions that provide substantial health effects that are sustained over a long period of time [4]. NICE's review recognises that non-reference case discounting presents problems. These relate to inconsistencies around the eligibility criteria that give rise to equity concerns between patients that do and do not qualify for apparently arbitrary reasons [2, 3]. Moreover, NICE's review clearly indicates that applying favourable discount rates is not a good way of reflecting a social preference for some interventions over others. We very strongly endorse this clear statement by NICE. The suggestion within the NICE review that any preferences should be applied through explicit modifiers is sensible and we are hopeful it will be followed. The application of explicit modifiers both for the health gain of an intervention and any relevant component of the opportunity cost of health foregone to derive net health benefit is the most complete and coherent approach to incorporating specific preferences [5, 6]. Moreover, the approach of using explicit modifiers is the most suitable for an evidence-based quantification of any such preferences.

Related to the consideration around non-reference case discounting, we note NICE clearly recognises that the particular sensitivity to discounting of certain interventions is not a valid argument for applying more favourable rates to some interventions than to others. Such a statement is welcome as it signals NICE is aware of spurious arguments in favour of inequitable application of special discount rates based on favourable outcomes rather than any underlying principles. Such clarity is welcome given that special

pleading appears to have influenced NICE in the past regarding non-reference case discounting [3].

We note that NICE's review does not appear to give serious consideration to hyperbolic discounting or other declining discount rates. The implication of the review is that such approaches are impractical due to the potential for time inconsistency. We consider the pragmatism shown by NICE in this regard appropriate. However, we feel NICE could have gone further to explore the differences between descriptively valid models of discounting for individual behaviour and what is rational for a social planner to adopt in decision analysis. There appear to be good reasons not to reflect human heuristics in policy making [6]. Separately, while there might be theoretical merit in considering discounting uncertainty probabilistically, we feel this would present challenges for the practical application of decision rules, so NICE's omission of such forms of discounting seems justified.

2.2 Points for Further Examination

2.2.1 Appropriate Basis for the Discount Rate

An issue not handled particularly clearly in the published literature is whether government borrowing costs or the social rate of time preference (SRTP) is the most appropriate determinant of the social discount rates for public resource allocation. This is reflected in NICE's review. While NICE's current guidance references SRTP as estimated by HM Treasury in the Green Book [2, 7], the theoretical literature cited by NICE's review makes reference to the government borrowing cost as the basis for discount rates (prior to additional adjustments for growth in the cost-effectiveness threshold or change in the consumption value of health over time) [8, 9]. Accordingly, it is not clear what basis NICE considers most relevant.

Uncertainty of what is the most appropriate basis for the social discount rate is reflected by a lack of consensus among economists on the topic [10]. Our view is that government borrowing costs are the most relevant source and this reflects published guidance supporting the recent Canadian discount rate revision from 5% for costs and health effects to 1.5% [11, 12]. The reasoning for such a position is that while an SRTP may be derived for any given outcome, if markets permit the trading of outcomes across time and prices to remain constant, then rational resource allocation should be made according to the cost of moving resources between periods, rather than the SRTP. In the context of public decision making, this cost is the real cost of public borrowing.

It is important that NICE resolves what it holds to be the appropriate basis for the social discount rate. The SRTP is an estimate of society's time preference for outcomes in different periods. The Green Book derived it from the Ramsey

equation and presents an estimate of 3.5% [7]. This is substantially higher than the real borrowing cost faced by the UK government, which has been below 1% for the past decade and currently stands at less than zero [13]. Accordingly, this is a substantive and meaningful question for NICE to clarify its position on.

NICE's review indicates that NICE itself raises questions regarding the relevance of the discounting recommendations of the Green Book. Paragraph 19 raises a number of important differences between the analytic approach assumed within the Green Book and those employed by NICE [2]. We think caution regarding the Green Book's recommendation is warranted, not only because of the irrelevance of the SRTP but also because of the weakness of evidence supporting the parameters in the Ramsey equation and questionable assumptions made by the Treasury regarding the valuation of health and how it might change over time.

Basing the social discount rate on borrowing costs rather than the SRTP provides direction for further research. While the components of the Ramsey equation are difficult to determine, the real cost of borrowing is comparatively easily observed. Nevertheless, there still are issues to resolve regarding an appropriate single discount rate to apply in the medium to long term, as bond yields vary with maturity dates and real borrowing costs will change over the business cycle. While these questions probably lie beyond the scope of what the NICE review could have been expected to consider, they do represent targets for future research and further consideration by NICE.

2.2.2 Sensitivity of the Threshold to Changes in Discounting

As mentioned above, NICE's review includes a sensitivity analysis of ICERs with changes to discount rates. How the cost-effectiveness threshold should reflect such sensitivity will require further consideration. If NICE seeks to adjust the 'standard' threshold range it applies currently of £20,000–£30,000 per quality-adjusted life-year (QALY) to better accord with recent estimates of the opportunity cost of care foregone in the NHS of approximately £12,936/QALY [14, 15], then consideration needs to be given as to how a change in discount rates affects the estimates of the opportunity cost. Indeed, it is notable that Claxton et al.'s £12,936/QALY estimate is based on undiscounted outcomes. The same estimate using discounted outcomes is only very modestly higher at £13,142/QALY [15]. This difference is small relative to the sensitivity analysis presented within NICE's review that found a mean 9% reduction in ICERs when the discount rate is reduced from 3.5 to 1.5% [2]. That the opportunity cost estimate is so comparatively insensitive to discounting is therefore surprising and merits further investigation.

2.2.3 Differential Discounting

The NICE review suggests that differential discounting of costs and health effects is not likely to be adopted in a guideline revision. Despite this, there are some important points to observe. In considering differential discounting we note the review reflects the prevailing view in the literature that the postponing paradox is not relevant to decision making as it does not arise in practice. We would point to existing work not cited in the review explaining how a problem closely related to the paradox does arise under differential discounting in multi-cohort models, such as those commonly used in CEAs of vaccination and sometimes of cancer screening [16]. The inclusion of multiple future cohorts in such models systematically drives down ICERs, confusing comparisons against alternative uses of resources assessed only in present cohorts. We believe differential discounting will also have implications when using models of single aged cohorts to answer policy questions that relate to cross-sections of populations that vary in age. We believe further research is required to clarify how modelling should best correspond with policy questions in these cases. While these effects are not an argument against differential discounting in principle, they point to analytical problems in practice yet to be resolved.

The understanding within NICE's review of threshold growth and its implications for differential discounting merits some additional comment. Paragraph 89 articulates the view that the fungibility of health gain due to the fungibility of resources implies that costs and health effects should be "treated the same" within an economic analysis [2]. We interpret this as an argument for equal discounting. This, however, overlooks the insight of Claxton et al. that a changing supply-side threshold over time influences the rate at which costs and health effects are converted [8]. This, as the review recognises clearly elsewhere, provides the rationale for differential discounting. Similarly, the review cites Weinstein and Stason's consistency thesis as an argument in favour of equal discounting [2, 17]. This is an oft-repeated misinterpretation that overlooks Weinstein and Stason's assumption that the value of health remains constant and their alternative conclusion that differential discounting is justified if the value of health changes over time.

A more nuanced observation relates to what constitutes growth in the threshold. The current basis for differential discounting set out by Claxton et al. assumes that the cost-effectiveness threshold represents the opportunity cost of care foregone (a 'supply-side' estimate). There is increasing attention on empirically estimating the opportunity cost and a consequent realisation that the thresholds used in decision making (the 'policy threshold') are not equal to the opportunity cost [18]. There is evidence that the opportunity cost changes over time [15], but the UK policy threshold

has remained fixed in accordance with current and previous agreements with the pharmaceutical industry [19, 20]. This raises the question of whether a differential between the discount rate for costs and health effects should be determined by changes in the opportunity cost or the policy threshold. This has not been addressed by the literature to date and is an issue for future research.

2.2.4 Equity Concerns

NICE's review gives special consideration to equity concerns that might be affected by a revision of discounting guidelines. We welcome the attention paid to the equity considerations arising from the arbitrary eligibility criteria for non-reference case discounting. There is, however, a broader equity concern that we do not see explicitly addressed by NICE. The primary purpose of CEA is to balance the needs of candidate recipients of new healthcare interventions against those that bear the opportunity cost of care foregone. As noted earlier, we believe that current discount rates are too high, which means in principle some patients will not be provided interventions that would otherwise be judged cost effective. While this equity concern does not apply to any specific group based on gender, race, age or other such characteristic, we think this is an important issue of fairness that must be acknowledged and addressed.

2.3 Potential Obstacles to Reform

The NICE review identifies several factors likely to impede rational reform of discount rates. These issues are not matters of economic theory or evidence, but rather relate to the protection of special interests and institutional inertia. It is important that we have a clear-eyed assessment of these constraints in order to appraise the potential for improving CEA methods. Furthermore, we should seek an honest understanding of the magnitude of harm facilitated by allowing special interests to prevail and institutional inertia to persist.

NICE's review mentions a recent consultation by the UK Department for Health and Social Care on revisions to cost-effectiveness methods for vaccines conducted in 2018 and the subsequent response of the UK government [21, 22]. The methods revisions proposed (but ultimately rejected) in that instance included both reducing the discount rate from 3.5 to 1.5% and reducing the cost-effectiveness threshold to £15,000/QALY. Note that the proposed threshold reduction was not linked to the proposed discount rate reduction, but rather to empirical estimates of the opportunity cost of health foregone within the NHS considerably below NICE's prevailing policy threshold [21, 23]. We critiqued the proposals, noting that while the rationale for some of the recommendations was questionable, the changes were warranted

[24]. Accordingly, the government's rejection of ultimately sensible proposals is unfortunate.

The summary of submissions to the consultation on vaccine assessment guidelines may help anticipate reactions to NICE's current consultation. The key recommendations within the consultation were rejected by all pharmaceutical manufacturers and associated representative bodies and by all health charities and other related non-governmental organisations that participated [22]. The principal reason cited for opposition was a concern that the changes would make it harder for vaccines to achieve cost effectiveness. Other comments included concerns that the proposed changes would damage investment in vaccination in the UK. Accordingly, it appears opposition to reform was influenced by respondents' expectations that their interests would not be served by the proposed changes.

The vaccine appraisal methods proposals noted the need for consistency between appraisals of different intervention types, observing that reducing the threshold for vaccines but not for other interventions would disadvantage immunisation [21]. Our commentary on those proposals noted that such inconsistencies would be irrational and inefficient [24]. Indeed, this issue of inconsistency was an objection raised within the consultation responses and cited by government in their rejection of the proposals [22]. Unless the revisions to NICE guidelines currently under consideration apply equally to all interventions, those proposals will be caught in the same trap of inconsistency. Clearly the process of reforming co-dependent guidelines must be aligned; continuing with separate processes that mutually inhibit reform is a nonsensical situation. Ongoing failure to synchronise economic evaluation guideline revision to achieve simultaneous adjustment will permanently harm the quality of evidence on which policy decisions are made and by extension the health of UK citizens.

Probably the most important potential obstacle to discounting reform relates to the cost-effectiveness threshold. As mentioned above, the NICE review notes a discount rate reduction could also require a threshold reduction. The review also very explicitly notes an agreement (the 'Voluntary Scheme') between drug manufacturers represented by the Association of the British Pharmaceutical Industry (ABPI) and the Department of Health and Social Care (DHSC), in which Section 3.20 rules out revision of NICE's current threshold range for the duration of the agreement (January 2019–December 2023) [20]. That agreement also contains a commitment in Section 3.22 stating that within the duration of the agreement "... changes to NICE methods and processes would respond to the new types of innovation coming to the market, be consistent with improving the health gain achieved by spending on new innovative medicines and support faster adoption of the most clinically and cost effective medicines."

How binding Section 3.22 is remains unclear. Ostensibly the statement is a commitment to maintain appraisal methods likely to be accommodating of new interventions, which appears to prioritise the interests of manufacturers over population health. An alternative interpretation of Section 3.22 from the health economist's perspective is simply that changes to methods guidelines should continue to ensure reimbursement decisions enhance rather than diminish population health. A revision of discounting is perfectly compatible with the latter interpretation.

Regarding Section 3.20 of the Voluntary Scheme, reducing the discount rate might not necessarily require a reduction in NICE's £20,000–£30,000/QALY threshold range. NICE could simply make decisions according with the lower portion of the threshold range to tighten decision rules without breaching Section 3.20. Indeed, this certainly seems possible given empirical work suggesting that NICE's actual decision threshold range is considerably above its stated range [25].

The option of exploiting the flexibility provided by NICE's threshold range offers a pragmatic path to discounting reform. Decoupling the necessary reduction in discount rates from a reduction in the threshold, which appears warranted independent of changes in discounting rates, not only avoids conflicting with the Voluntary Scheme, but also avoids likely opposition from pharmaceutical manufacturers and patient advocacy groups. Indeed, such lobby groups might actively support a revision if the expectation of improved ICERs is explicit, but the de facto tightening of the threshold is not. A disadvantage of this option is that the required tightening of decision rules would be implemented behind closed doors. Without transparency on the tightening of the threshold in practice, the retention of the current threshold range could prompt concerns that a decision framework that is arguably already too permissive will become even weaker.

If a reduction of NICE's stated threshold is judged an essential companion to a discount rate reduction, then revising discounting becomes part of a larger and more contentious project of decision rules reform. The past 15 years has seen growing interest in estimating an empirical threshold for the NHS [14, 15, 26]. Reforming the threshold is plainly overdue, as NICE's existing threshold range is acknowledged as not being based on evidence [27]. Without such reform, the legitimacy of NICE's recommendations on healthcare resource allocation remains in question.

If a threshold reduction is necessary and the Voluntary Scheme's commitments are binding, then NICE is left with limited choice over discounting revision: it could wait for expiry of the Voluntary Scheme in 2023 and revise both the discount rate and the threshold then; it could revise discount rates now and leave adjustment of the threshold until later; or it can persist with the status quo. Which choice is best in

terms of net population health is an empirical question, the evidence for which is likely incomplete at present.

Whatever path NICE chooses, it is concerning that it will have to navigate around the Voluntary Scheme to make reasonable methods reforms. The constraints the Voluntary Scheme appears to place on NICE put the interests of manufacturers over patients. This conflicts with the principles that NICE states guides its work, including ensuring the best health outcomes from within the available budget [28]. It also conflicts with a commitment within the NHS Constitution to make the most effective and fair use of resources [29].

3 Discussion

It is possibly too easy to use the contradictions between the Voluntary Scheme and NICE's principles and the NHS Constitution to launch criticism. The reality of the government's legitimate interest in the success of the UK pharmaceutical industry will always mean principles are traded-off in practice. Nevertheless, the issues raised by NICE's discounting consultation are important and illustrate broader questions regarding the balance between fair and consistent economic principles and the realpolitik of resource allocation.

We are confident that a reduction in discount rates to 1–1.5% for costs and health effects is justified, notwithstanding a number of important technical issues surrounding discounting that still require resolution. Such a revision will likely reduce the ICERs of screening and vaccination programmes, as well as the many interventions that have long-lasting beneficial health effects. We cannot anticipate by how much these ICERs will fall; therefore, we also cannot predict by how much the threshold should fall as a consequence. Despite this, a revision in the de facto threshold accommodated within NICE's current threshold range seems an expedient path to reform. While NICE might judge the reduction of discount rates without a concomitant reduction in the threshold to be preferable to the retention of the status quo, this is likely to exacerbate problems if and when a threshold reduction does occur as prices and reimbursement decisions are unlikely to be revised in response.

Discounting can often seem a highly abstract issue that is difficult to grasp. The apparently weak rationale for choosing one discount rate over another that makes an enormous difference to the cost effectiveness of some interventions can feel disconcerting. In reality, the theory and evidence for the choice of discount rate is much stronger than many appreciate. Consequently, we feel the case for revision is robust and equity considerations demand NICE should do more to appropriately balance health gains in the present and the future.

NICE's review of discounting has very usefully informed debate on discounting. Placing the issue of a discounting

alongside threshold revision firmly frames considerations within a practical context. We hope NICE will continue its clear-minded analysis in order to address the need for a discount rate revision and, if necessary, an accompanying adjustment to the threshold. Experience from the recent consultation on vaccines indicates that the current discounting consultation is very likely to elicit submissions concerning special interests. For the sake of the common good, we hope NICE adjudicate these carefully and elevate sound methodological principles above narrow competing interests.

The impact of any discount rate revision will apply directly to England and Wales, which explicitly fall within NICE's remit. It would seem likely that appraisal and reimbursement decisions in Scotland and Northern Ireland would likely have to align themselves as divergence would present obvious inconsistencies in the use of public spending within the UK. There could also be international repercussions to discount rate revision. The UK is a leading nation in terms of CEA research output [30], so a discount rate revision there may prompt health technology assessment agencies in other countries to also revisit their guidelines. It is, however, unclear how influential UK CEA methods are internationally. Indeed, NICE have specified an explicit cost-effectiveness threshold range for over a decade [31], yet this has not prompted many other nations to adopt a similarly explicit threshold. An indirect consequence of any NICE discount rate revision for CEA in other countries will be through international reference pricing mechanisms. The magnitude of such effects will vary with many factors including the nature of the intervention, the UK's weight in pricing baskets and the UK's position within product launch sequences.

4 Conclusion

NICE's review has very usefully addressed important theoretical and empirical issues regarding discounting. The rejection of favourable discount rates in special cases is welcome as is the tentative indication that reducing the discount rate is merited. Importantly, NICE's review clearly notes the potential obstacles to methods reform presented by a current agreement with pharmaceutical manufacturers not to alter the cost-effectiveness threshold. This raises some broader concerns regarding NICE's autonomy to employ evidence-based and theoretically consistent CEA methods in the face of industrial interests. These concerns have important implications for both efficiency and equity that cut to the core of NICE's mission. Despite this, the current NICE review provides an excellent foundation for a necessary revision of discounting and we urge NICE to navigate around the obstacles associated with the threshold.

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