
Article:
Reddy, B.P., Walters, S.J. orcid.org/0000-0001-9000-8126, Duenas, A. et al. (2 more authors) (2019) A role for MCDA to navigate the trade-offs in the National Institute for Health and Care Excellence's public health recommendations. Operations Research for Health Care, 23. 100179. ISSN 2211-6923

https://doi.org/10.1016/j.orhc.2019.02.001

Abstract

Recommendations made by the UK's National Institute for Health and Care Excellence (NICE) consider a range of relevant factors. Most famously, this includes interventions' incremental cost-effectiveness ratios (ICER). Given the ICER's primacy in such decision-making, it is sometimes assumed as almost analogous to an optimisation problem, maximising the number of Quality Adjusted Life Years generated by the health system subject to costs. However, structured OR techniques could still prove beneficial in informing the broader decision-making problem. Decisions are currently arrived at by advisory committees through a combination of structured processes and relatively unstructured deliberations. In principle, decision makers are expected to consider dozens of relevant factors after the completion of the economic modelling stage. No model is currently used to combine these, and MCDA may be suitable to better structure and aid these discussions and to highlight the opportunity costs associated with them. This paper outlines some of the factors currently considered in public health settings, proposes a number of approaches as to how MCDA-inspired techniques could be grafted onto current NICE processes incrementally, and considers the appropriateness of their use in this setting given NICE's role in the health system. The paper focuses on the work of NICE's former Centre for Public Health Excellence (CPH) as public health has a specific focus on equity and the determinants of health, and is therefore has the most obvious need to balance ICERs and other factors.

Keywords: MCDA; evidence-based policy; evidence-based decision-making; public health; health economics; decision analytics.

1. Introduction

Economic appraisals in public health are complex. Equity issues require careful consideration, evidence is more limited than elsewhere [2] by both pragmatic and ethical necessity, and an intervention's outcomes may have effects on external issues such as crime, violence, economic growth, social cohesion and well-being [3]. In public health settings, prioritising and trading off between such issues is clearly politically complicated.

There has been increasing academic interest in attempting to use multiple criteria decision analysis (MCDA) approaches to help guide the decision-making processes used in health care prioritisation for some years [5-8] . Public health decision-making is potentially a very suitable area to investigate the application of MCDA approaches, both due its supposed 'weaknesses' – MCDA can offers new ways to both generate evidence [9] and quantify value judgements [9] – but also because of its strengths – public health interventions' consistent cost-effectiveness [4] could make it a low risk setting to investigate and pilot potential approaches in the National Institute for Health and Care Excellence (NICE). Successful approaches could if desired thereafter be employed across NICE appraisals, leading to more rational – or at least more transparent – processes for public health appraisals in future.

The aim of this paper is therefore to show that multiple criteria are already used in NICE committees, and to describe a series of MCDA approaches that might be used to strengthen

the existing evidence-based decision-making processes as part of the development of NICE's public health recommendations.

Figure 1 about here

Evidence-based approaches to healthcare have become mainstream in recent years in the UK, particularly since the foundation of NICE in 1999. Applications of the methodology to public health settings are still evolving, given its complexity [2]. NICE's Centre for Public Health Excellence (CPH) use to use a multi-stage decision-making process from prioritising which topics to investigate to their ultimate implementation (and potentially future revision of the guidance area); this is shown in Figure 1.

This paper focusses in particular on the where decisions were made through deliberation by experts on on what were called Public Health Advisory Committees (PHACs). Most topics under consideration follow the same process: an effectiveness and/or cost-effectiveness review is carried out to investigate where similar approaches have been tested before; economic modelling is conducted using the parameters discovered in the prior review to estimate the cost-effectiveness of approaches where gaps exist in this literature; and experts are invited to give testimony where findings remain inconclusive and to gauge whether or not potential approaches would be effective or implementable 'on the ground'. Deliberations are required throughout – for example in questioning the experts or in ensuring the economic models are fit for purpose – and continue afterwards in settling on the guidance's final wording.

There are a range of economic evaluation techniques that can be used during economic modelling. Prior to 2014, cost-utility analysis (CUA), cost-benefit analysis (CBA) and cost-consequence analysis (CCA) were all permitted for public health appraisals. All three methods can be used in any NICE appraisal that considers both health and non-health outcomes or that has a social care focus [10], though CUA is generally carried out in all cases.

NICE's policy in practice is CUA-led. Where the incremental cost effectiveness ratio (ICER) is low enough (i.e. below £20,000), interventions should be recommended almost automatically, regardless of other issues (except in the case of certain cancer treatments). Above this figure, committees should also take into account other factors (especially once a £30,000 ceiling has been breached), namely [10]:

- the degree of certainty around the ICER;
- the presence of strong reasons suggesting that the change in quality of life has not been adequately captured; and
- innovation.

Public health appraisals are also required to take into account equity: "the need to distribute health resources in the fairest way within society as a whole" [15]. NICE neither defines, limits nor prioritises the varying potential classifications of equity as part of such decisions, but the impact upon inequity is a recurring theme in what is considered important in its decision-making processes. Aside from the ICER, NICE documentation has regularly specified criteria that should be considered by committees as part of the decision-making process, a selection of which is shown in Table 1. Some relate specifically to equity concerns, others relate to

health issues not captured from the quasi-utilitarian CUA framework (which therefore carried some moral imperative). For many such criteria therefore, it can be difficult to separate these into health/non-health or equity/non-equity boxes. This paper will therefore simply refer to them as 'other factors'.

Table 1 about here.

These criteria have been identified from a variety of standalone NICE documents, and it is likely that some of these will have much in common and could be further amalgamated. However, there clearly exist many criteria that are expected to inform decision making. All in all, this implies a particularly complex decision-making process, all carried out without a formal model after that of the modelling stage. This may allow some criteria to be ignored, the impact of certain outcomes to be misjudged and other predictable biases to creep in [19-21]. The economic modelling stage does not currently consider equity issues, meaning the full opportunity costs of decisions cannot be investigated numerically.

Final decisions relating to the guidance have to be made by people, regardless of the frameworks used to structure them. These judgements are "informed by science but nevertheless judgements" [16]. There are circumstances where not all data is available, or where political realities need to be considered before making binding judgements. Politics is ultimately inseparable from health policy [22] and public health in particular has an inherently political role [23] and decisions must be considered in this context.

Since 2014, public health responsibilities in England and Wales have moved from the NHS to local governments, and hence NICE public health guidance is now located in an arena where unlike the NHS there was not a tradition of applying the principles of evidence based medicine. Decision-makers will now in principle be more accountable to democratic processes and to their constituents, though there remains a 'reasonable expectation' that local authorities will comply with any guidance published [24]. NICE has tried to address this by committing to working with local authorities and other organisations to help coordinate how best to implement findings in their local context [17]. But guideline development committees must therefore consider this reality in drawing up pragmatic recommendations, and the potential challenges it poses to their implementation.

Within NICE, guideline committees remain something of a 'black box'. Consensus eventually emerges within the group about guidance, but this is difficult to observe or measure and thus remains something of an enigma. Committees do not publish a list of criteria that have been considered (aside from economic modelling reports), and neither are the implicit weightings to compare the importance of criteria. The "accountability for reasonableness" framework [28] requires that decision-makers' reasoning and assumptions are made explicit for a decision-making process to be considered as fair.

The deliberative process currently used in NICE therefore has its downsides, being neither fully explicit nor transparent, limiting its openness to public scrutiny. However, some deliberation will always be required given factors relevant to the specific topic under consideration and to ensure decision-makers are held accountable. An overly prescriptive box

ticking exercise that incorporated multiple criteria – however well designed and intentioned – would eliminate important democratic aspects of debate [29]. The question therefore is not whether deliberation can be replaced, but whether it can be improved. OR principles of informing decision-making through better structuring processes [30, 31] potentially fit in well in this context, and MCDA in particular has much to offer given its potential for managing conflicting aims as part of this process [32].

2. Incorporating an MCDA framework

Given that the ICER is not the sole criterion of note in all decisions and other factors will vary in importance from appraisal to appraisal, nuance and careful consideration (and hence some form of deliberation) are likely always to be required. Four options of increasing complexity are outlined in this section that aim to ensure criteria are considered appropriately as part of this, shown in Table 2.

Table 2 about here.

2.1 Listing which criteria have been used as part of deliberations

Given that some non-health factors are required to be included at some stage in the decision process, there may be merit in allowing techniques that explicitly acknowledge these to be used in order to ensure decisions can be justified rationally. No such technique could be realistically expected to capture all potentially relevant factors in all potential circumstances (and the choice of criteria to use is itself potentially a normative one). Some deliberative process will still be required to counter such deficiencies, and to avoid the risk of overly prescriptive decisions that lack face validity.

The establishment of an explicit checklist of factors that were considered as part of each guidance process would at least ensure that the public can be confident that the most common or important 'other factors' have been taken into account in deliberations each time (even if no such list can be comprehensive). The criteria listed in Table 1 could serve as a starting point for such a list (though it should be refined in future as was not intended to be systematic). Committees could acknowledge whether or not they feel they engaged meaningfully on each of the issues, and the presence of the list may encourage them to consider such issues if they had not already. This process might also allow for increased confidence in the process, and would explicitly acknowledge the role for non-QALY factors in such decisions. It may subsequently be possible to analyse previous decisions (whether by researches inside or external to NICE) to estimate the apparent the presence of such criteria on decisions and the threshold, in a similar manner to Schmitz et al. [42].

This approach might allow for a more realistic appraisal of topic areas at the margin of what constitutes health by allowing such analysis to consider non-health factors in an explicit way – thereby better highlighting the opportunity costs associated with such decisions than current processes are characterised with at present. However, this approach could plausibly

inadvertently pressure committees into claiming that they have considered every issue on the checklist (regardless of reality). Therefore, the more formal approach below may be more appropriate.

2.2 Arranging these criteria into a performance matrix or CCA

Compared to a CUA-led approach, cost-consequence analysis may offer a suitable approach for highlighting the opportunity costs of providing 'more equitable, less cost-effective' interventions, as suggested by Weatherly et al. [44]. It may also better describe the challenges presented by inter-sectoral effects, which are particularly relevant in local government settings. CCA may allow short-term, medium-term and long-term effects could then be presented simultaneously, so that the decision-makers can prioritise – or discount costs and benefits – as it sees fit.

Table 3 about here.

CCA-derived techniques that eschew weighting are effectively equivalent to performance matrices, which could be useful in ensuring that decision-makers are fully informed on the range of consequences likely to occur for each decision. A simple example is shown in Table 3, with criteria representing the benefits arising from two hypothetical interventions. Criteria could be chosen on a case by case basis, with due consideration of the criteria on the checklist outlined in the previous section but also incorporating other relevant criteria. One challenge in this process is in ensuring that the CCA is kept to a manageable size, and this will require judgement. Benefits could be considered in aggregate and compared against the cost of each intervention. For certain decisions, this could highlight dominated options, ensuring that common sense decisions are chosen. In others, even without explicit weighting, it may be clear to decision-makers that one intervention performs much better on all key criteria and hence indicating a clear preferred choice, without formal dominance.

CCA is permitted for use in the economic modelling reporting stage (during phase 3 of Figure 1), but its use elsewhere in public health guideline development committees might allow for trade-offs between health and equity issues (and others) to be considered more explicitly by decision makers than is currently possible. Its use could also, if desired, allow for weighting of the performance matrix to create a de facto MCDA model.

2.3 Incorporating weighting

Given such a wide range of such criteria must be considered simultaneously by decision-makers, judgement and deliberation alone may not be sufficient to ensure the best decisions are made [7]. It may not be possible for committees to identify dominant options, potentially leading to decision paralysis. Weighting could overcome this in principle and moderate the effects of some of the systematic biases that can occur when intuitive approaches are applied

to complex problems [19]. By ensuring that such weighting is openly stated – and assuming that scoring is carried out appropriately – it is potentially a relatively trivial job technically to combine these using the weighted average (or other suitable) technique into a formal MCDA process [46]. Whether or not such approach would be appropriate in practice however is more complex, and is returned to in the discussion (below). The issues explored in this section are the what-if analyses to explore weights, a brief overview of which MCDA approach to use in given circumstances and how the approaches could be used on a case by case basis.

What-if analysis could function as an intermediate step between CCA and weighting, though as more criteria are included assumptions would be required to allow for firm conclusions. By way of example, consider a situation where the committee appraising the interventions in Table 3 had decided that health and non-health related factors were overall about the same importance, i.e. each carried an initial weight of 50% (ignoring the costs of the interventions for now), but could not decide on the importance of equity vs educational importance In this example there were orders of magnitude of difference between criteria, and weightings are easier to interpret if the matrix is normalised. As an example, the educational impact is higher for Intervention A is can be set to 100, and hence its impact for Intervention B is 100*960000/1200000= 80. Using a weighted sum approach, Intervention B would be chosen if the equity impact carried 80% or more of the non-health component (an overall weighting of 40%).If this weight does not sound credible to the decision-makers, a clear course of action has been identified. Sensitivity analyses can also be used to explore these assumptions further. Any such model, whether using what-if analyses or building a weighted model, could incorporate criteria from the checklist of relevant factors and from specific issues relating to this particular topic (as with the CCA approach described in the previous section).

Related research by Walker et al. [50], Mussen et al. [39] and Phillips et al. [51] examined how a list of criteria (like a CCA) could be converted into a hierarchy, scored and weighted – in effect performing a multiple criteria decision analysis – as part of the benefit-risk assessment for medicines for the European Medicines Agency. While these approaches generated a composite score of benefits and risks – which is potentially confusing – the principle of how they structure the approach is still instructive in how such techniques have been applied. It is conceivable that a similar approach could be employed to explain the benefits of adopting a public health intervention, with costs considered independently.

For more complex problems, taking into account the cost alongside the benefit could be carried out through deliberation or by considering the 'cost-effectiveness' of approaches according to the aggregate benefit derived, which is very similar to the STAR approach outlined by Airoldi et al [52]. This technique used MCDA approaches to facilitate local governments in deriving their own appropriate 'efficient frontier' to weigh up costs and benefits (however they define these) and given the budget they are willing to make available. This could be calculated using the criteria and/or weights specific to the decision makers and potentially the political nature of the problem at hand. Such an approach could be similarly useful for PHACs to compare costs and benefits of an appraisal's alternative approaches using such an approach. Relevant criteria and impacts could be chosen on a case by case basis to ensure flexibility, though this would make inter-appraisal comparisons difficult. The approach could nonetheless be useful as an internal decision support technique in identifying the best option(s) of those available.

It seems appropriate that, in practically any circumstances that use an MCDA model is used, the (health-only) ICER calculations are also calculated as a form of sensitivity analysis to ensure that such results are not deemed too cost-ineffective from a solely NHS perspective. Such analyses could even facilitate discussion with other government departments to allow collaboration and cost-sharing (even if in practice such agreements may prove difficult).

Even with multiple such criteria, CCA will likely not capture all possible factors either – and decision-making will still require deliberation to avoid arriving at overly prescriptive answers. It seems plausible that this extended CCA approach could be used alongside a CUA approach, and not in competition with it. This could be during the evidence gathering phase of guidance development (see Figure 1), where it could be used to formally collate results of unmodelled data quantitatively (and likely only for complex cases that merited the approach). Discussion would continue to play a major role, but this could be facilitated by the model which could highlight which factors needed further debate.

2.4 Replacement of the current process with expanded "welfare score"

One potential approach is formulating a broader MCDA framework to be used consistently in every appraisal, which would replace the QALY with some measure which attempts to incorporate all relevant concerns (not confined to health alone). This could then be used similarly to the ICER, allowing the calculation of the total cost-effectiveness of an intervention using this 'overall benefit score'. Attempting to incorporate all relevant information at all levels would establish the approach as effectively a broader-scale start-to-finish MCDA technique to guide the entire process outlined in Figure 1. While this approach may seem similar in principle to the STAR approach [52, 53], there are risks associated with using pre-defined weights and criteria which may or may not be relevant to the decision (in contrast with the approach outlined in section 2.3 which allows criteria and weightings to be decided on by the PHAC on a case-by-case basis using swing weighting).

Because the same approach would be used each time, committee members would not be involved in designing it or in deliberating on the model's assumptions and findings – thus missing out on the nuance, soft factors and "socio-technical process" of model building which STAR emphasises. The involvement of stakeholders has been shown elsewhere to increase the likelihood of public acceptance [18], improve the quality of decisions [54] and increase the likelihood of managerial 'buy-in', which may in turn increase the likelihood of successful implementation [55], even if in some circumstances political considerations may limit the opportunities for meaningful stakeholder involvement [56].

NICE methods guidance also emphasises the importance of committees being able to exercise flexibility and pragmatism in choosing the relevant issues to be considered for a given topic [10]. Given that the current approach is already sometimes seen as being too prescriptive [57], it is very possible that an extended MCDA approach incorporating this super-QALY could be at further risk of this. In public health in particular, it is unlikely that any one-size-fits-all approach is likely to be appropriate given the range of possible issues that might need to be appraised. The range of options that have always been available to guideline committees in the reference case, dependent on specific problem, indicates the apparent need for flexibility

in how to formulate guidance. These issues are not new and have been considered since NICE's foundation [58].

The discussion process is currently the only approach available in attempting to balance the range of concerns in any given guidance topic. Because no two such topics are ever exactly the same in public health, such deliberation is vital to ensure that all perspectives are considered. Because any proposed super-QALY model could not realistically always capture all factors, deliberation would likely still be required anyway. It would also require a *de novo* estimation of the cost-effectiveness threshold (assumedly in terms of this hypothetical total welfare score), which would be a major challenge in and of itself. Given the challenges associated with implementing such an approach – and the relative acceptance of current approaches – it may be more realistic in the short term to make incremental changes (as in the previous sections) rather than attempting root and branch reform of NICE processes that this approach would require, and certainly any attempts to introduce such an approach should be piloted carefully.

3. Discussion

For MCDA approaches to be considered suitable for use in NICE the techniques must be technically feasible but also practicable in reality, taking into account contextual, institutional and other factors that may affect the likelihood of a working model's subsequent implementation. This mirrors the "accessibility" and "acceptability" barriers described by Williams and Bryan [59]. While all four approaches outlined in section 2 all should be scientifically possible, there are clearly identifiable potential barriers to their implementation subsequent to this – particularly in the final approach – and understandable reasons to be cautious in updating current NICE processes.

Without doubt, the use of CUA has increased the accountability of decision-makers and the transparency of decisions to the public and patients, and has facilitated decisions that are more consistent, impartial and capable of achieving the stated objectives of the health system [60]. This paper highlights that there may be room for further development of this, but MCDA does not necessarily have to compete with CUA to do so. For the time being it could be used only for non-economic decision problems, as previously described. It is possible that there may also be a case for eventually replacing the current strategy of 'CUA followed by deliberation' with one of 'CUA, followed by an MCDA model, followed by deliberation' for sufficiently complex problems.

3.1 Methodological issues

Many practical issues remain outside the scope of this paper as to how to transfer such techniques into real-world settings, such as which MCDA approach is best, whose weights to use, who should choose the criteria, and who should be involved to begin with. But these issues are inextricably linked with the context of the decision problem and what role the analysis is intended to play in the decision-making process. In some scenarios timeliness will be key, in others the need to incorporate a broad range of stakeholders (or the views of the

public) will be of more importance. There are several potential advantages to MCDA approaches, but not all will be relevant for all given decisions.

The design of the approach to be used should be based what is achievable given the strictures on the decision and must be carefully designed within such bounds [9]. To impose the 'best' approaches to use without knowing the exact context in which decision-makers wished to use them would be inflexible and unnecessarily dogmatic. Applying such approaches in the real world often requires compromises from gold standards. Ultimately, as Schein argued, for such problems it is the client who must own the problem and its solution [61]. But it seems strongly advisable that any new approaches pursued by NICE should incrementally add to their current decision-making process rather than attempting root and branch reform.

Nonetheless, failing to use swing weightings would pose significant methodological problems, which is why it is now the predominant approach used [46]. Swing weighting requires the consideration of outcomes only of the courses of action under consideration (from best performing action to worst, on each criterion) [47], and how much that difference matters. In a given appraisal, for example, if all potential courses of action had very similar ICERs then the importance to the decision (and hence the weighting) of ICERs should be relatively small, even if we would normally otherwise consider ICERs to of crucial importance to decisions.

If the public health guideline development committees are not given discretion to alter weightings to reflect such issues on an appraisal-by-appraisal basis (as would be the case in the approach outlined in section 2.4), then the results of the model will be flawed, and hence either be ignored by the committee (making the MCDA phase redundant) or will be taken seriously (which is worse). This super-QALY approach poses other serious methodological hurdles that would influence its likelihood of implementation. Assuming that the criteria and weights are to be chosen to reflect the public's preferences there are a couple of options available:

- A national survey, along the lines of the influential Measurement and Valuation of Health study [41] could be carried out. This could use a discrete choice experiment or other approach to ascertain the apparent weightings that members of the public place upon various factors.
- A citizens council meeting could be convened by NICE to ensure that priorities and assumptions reflect public preferences, as with their social value judgements report [62].
- Allowing Directors of Public Health (DsPH) at local government level to use their discretion in choosing criteria and their weights, and make these answerable to the democratic system.

Some DsPH may choose to alter criteria and weightings regularly, making the technique closer to the STAR approach outlined in section 2.3 rather than that of 2.4. In other cases, given that there would inevitably winners and losers compared to the status quo, it is strongly advisable that the proposed weightings be investigated prior to implementation to identify the likely impact on services and the opportunity costs of doing using such an approach. However, such analyses would be particularly difficult to carry out for every local government area of the country. Without carrying such a scoping analysis, the controversy to both the public and the medical community of what could prove to be major changes to the prioritisation patterns could well challenge its use in practice. And no matter how much prior analysis is conducted,

because swing weighting is not proposed the results would still in any case be (perhaps unjustifiably) flawed methodologically.

If a super-QALY approach were to be used in any case, a weighted sum approach would probably be most suited, as it is easiest to understand technically – and could hence be more easily amended. Overly complex mathematical-looking models run the risk of disfranchising decision-makers rather than informing them [63], undermining the chances of taking relevant factors not included in the model into consideration during subsequent deliberations.

Mathematical complexity may be more justifiable for the approach outlined in section 2.3, where criteria and weights can be selected on a case-by case basis. If decision makers proved to be uncomfortable trading off cost-effectiveness vs. equity directly, swing weighting (and other weighted sum approaches) would not be possible. In such circumstances, it may be better to consider using approaches that satisfice [64] – i.e. recommend alternatives 'good enough' in key criteria, rather than maximising some overall objective function. The most obvious key criterion would likely remain the ICER – it is difficult to imagine situations where an extremely cost-ineffective intervention should be adopted regardless of its performance on other criteria. Outranking approaches – which punish poor performances on key criteria – therefore appear to merit further investigations in this regard. The fact that such approaches rely upon the principle of dominance may allow them to build naturally upon the approach in section 2.2.

3.2 Acceptability to decision makers

Methodological feasibility is only one part of the puzzle; Hoffman [65] argued that acceptability is even more important to whether an evaluation is implemented than accessibility and communication issues. While academic interest in applying MCDA approaches to health technology assessment settings has been growing, it is perhaps telling that no formal MCDA approach has yet been embraced by NICE.

However, MCDA approaches have been nominally used in HTA processes both overseas [66, 67] and on a limited scale in the UK in AGNNS [5]. Whether any of these approaches considered the opportunity cost is unclear and (given the relative lack of discussion of it in the referenced literature) seems unlikely. This seems obviously problematic from a health economic perspective and risks undermining the roles for which MCDA could prove useful in such settings. The Institute for Clinical and Economic Review's 2017-19 value assessment framework rejected MCDA techniques for being too complicated for reliable use [68]. In NICE, MCDA approach may instead be used to fill in gaps in some sub-stages of the guidance decision process [37]. The first three approaches outlined in the last section were designed in such a way as they could be introduced incrementally (and possibly sequentially), without necessitating root and branch reform of NICE methods. Given the emphasis on flexibility in the literature of both MCDA and public health, this seemed crucial to their feasibility.

Nonetheless, they are not intended to be the *only* possible avenues by which changes could be introduced that incorporate multiple factors and special circumstances. The recently published NICE methods guidance on Highly Specialised Technologies [69], for example, rejects the appropriateness of utilitarian methods in such settings and proposes using an

unorthodox health economic methodology to ensure that subsequent decisions would be acceptable to the broader public. The approach specifies the relevant criteria to be used, while ensuring that decision making is informed by parallel economic modelling. The framework therefore has similarities to that outlined in section 2.1. In some ways however it is much more radical. Aside from specifying the criteria, a nominal ICER threshold of £100,000 is implied and the approach uses a form of equity weighting to reflect the magnitude of individual QALY impacts on patients.

Because the MCDA approach to be used is dependent on the context [46, 70], and this context will often be unique in public health settings, approaches used are not necessarily wholly replicable and neither can they can be wholly value-free [71]. MCDA approaches have a number of subtle advantages over harder OR approaches, such as the management and incorporation of soft issues [72, 73], providing structure to messy problems [30, 70], facilitating participants to explore differing views [70], in allowing difficult conversations to take place [74, 75] and in ensuring buy-in to increase the likelihood of implementation [55, 76]. Given that policy-making requires the building up of consensus [74] (and the need to "muddle through elegantly" [77]), rather relying on evidence alone, it is vital that such issues are considered to ensure a recommendation's acceptability, and hence implementation. Fully engaging with such issues may be even more important when considering local government level reactions to guidance, where contextual factors are particularly pronounced [78].

MCDA approaches, similarly to action research, remain "somewhat enigmatic, as there are comparatively few guidelines for would-be researchers to follow" [71]. But as these approaches are increasingly employed, more general rules will be possible. ISPOR's MCDA taskforce has produced two excellent and accessible reports that help to address the gaps that exist [79, 80]. But there is still some way to go before they no longer need to "require as much art to be exercised as science" [46].

The strongest case against implementing major changes is probably that NICE is already well-respected and practically all relevant stakeholders take its guidance seriously. This argument is a strong one, particularly for an approach with such massive ramifications across the health service, and thus people's lives. Given that the ICER-led approach is described by the former Chair of NICE as overly reductionist [57], to add another prescriptive layer of red tape to the process could lead to further criticism. While MCDA is flexible enough to have a range of potential approaches that could help inform the decision-makers in several ways, we must be careful not to describe MCDA as a panacea that will cure all the challenges faced by NICE.

3.3 Deliberation of model's results

Deliberation is almost certain to remain an fundamental part of NICE's decision processes subsequent to the completion of any such model, allowing decision-makers to be held to account in a way that simple box-ticking or the generation of seemingly scientific scores cannot. Even with terabytes of data accompanying pharmaceutical applications, no medicines agency in the world uses a quantitative approach to approving or denying access to drugs without ultimately using deliberation to settle on the final decision [51]. With less data available, deliberation in public health becomes even more important. But deliberation is potentially subject to the biases discussed earlier [19], and the framing of evidence in a more accessible

and structured way could help to reduce these; this is the ultimate case for further incorporating MCDA approaches.

If done properly, one of the real advantages of MCDA approaches is to allow the deliberation that will take place to focus on areas that will actually make a difference to the decision and to remove the need for unnecessary argument in areas of little consequence, making decision-making better, quicker and less fraught. Key issues can be teased out during both the building of the model and in examining its results. Sensitivity analysis can feed back results to participants about disputed values in the weighting or scoring stage to see if it changes the final rankings. The increased transparency offered by the approach will require decision-makers to address why decisions that deviate from its findings were chosen, further increasing the process's accountability. Designed carefully, the incorporation of such an approach into the process should empower the decision-makers, rather than undermine the final deliberative decision process as "it is precisely (this) process that is the point" [81].

4. Conclusions

There are several simple approaches which could be used to incorporate equity or other factors more directly into any decision-making stages concerned with cost-effectiveness, such as:

- publishing a checklist of considerations considered in deliberation;
- increased use of CCA to aid the deliberative process;
- the incorporation of what-if analyses to quantitatively analyse the CCAs; or
- weighted CCAs – which would function as effectively equivalent to case-by-case MCDA approaches. An extended, total benefit function could also be used consistently between decisions and irrelevant of context.

Each of these approaches has their merits, though the final one could be problematic as both current NICE methods and MCDA literature emphasise context-dependent flexibility. Given that no model can capture every factor, it could lead to politically (and institutionally) unfeasible decisions that are perceived to lack common sense.

MCDA offers new options to decision-makers; however, it should not be considered a panacea and any approach used will have to be carefully tailored to fit with NICE's aims and objectives in the future. We do not believe that multi-criteria exercise seems appropriate for replacing deliberation in such complex decision problems, as ultimately nuances in the data would inevitably be overlooked. However, a well-designed MCDA could be used instead to better structure any such debate, making the decision process more effective and potentially quicker. As with current economic models, MCDA techniques can only inform decision-making, and individuals will still require further judgement to interpret results in a broader context.

NICE already has successful protocols in place for decision-making, so there is certainly a risk to changing these. Given that its health economic approaches can be thought of as a method of structuring decisions problems under given constraints – and MCDA is designed for use in structuring more complex problems – there is no reason why current approaches cannot continue to be used where they have previously been successful, supplemented by MCDA techniques where necessary. These approaches need not necessarily be in conflict. This

paper highlights that there is no single ‘correct’ MCDA approach that NICE and other decision-makers should use in all circumstances; it hopes to inform and provide nuance to debates about where it might allow decision-makers to be better informed as to approaches’ advantages and disadvantages, and to suggest plausible MCDA frameworks that could be incorporated into current processes. MCDA techniques, where used, should be chosen based upon the context of the decision problem. Where formal approaches are required, outranking approaches have many advantages (particularly for those with limited experience of using MCDA techniques previously) with regards to technical issues such as double counting, criterion independence and the risks of conflating costs and benefits. But value measurement approaches (such as weighted sum techniques) could also be used where rankings of alternatives are necessary, and are potentially easier to understand. Seeking to use MCDA to solve all perceived problems with the current NICE processes is neither reasonable nor realistic, but by targeting its use to suitable settings it could well be beneficial.

1. Marmot, M., *The status syndrome: how your social standing affects your health and life expectancy.* Bloomsbury, London, 2004.
2. Kelly, M., et al., *Evidence based public health: a review of the experience of the National Institute of Health and Clinical Excellence (NICE) of developing public health guidance in England.* Social science & medicine, 2010. **71**(6): p. 1056-1062.
3. Kawachi, I. and B.P. Kennedy, *Socioeconomic determinants of health: Health and social cohesion: why care about income inequality?* Bmj, 1997. **314**(7086): p. 1037.
4. Owen, L., et al., *The cost-effectiveness of public health interventions.* Journal of Public Health, 2012. **34**(1): p. 37-45.
5. Devlin, N. and J. Sussex, *Incorporating multiple criteria in HTA: methods and processes.* London: Office of health economics, 2011.
6. Thokala, P. and A. Duenas, *Multiple criteria decision analysis for health technology assessment.* Value in Health, 2012. **15**(8): p. 1172-1181.
7. Baltussen, R. and L. Niessen, *Priority setting of health interventions: the need for multi-criteria decision analysis.* Cost Effectiveness and Resource Allocation, 2006. **4**(1): p. 14.
8. Diaby, V., K. Campbell, and R. Goeree, *Multi-criteria decision analysis (MCDA) in health care: a bibliometric analysis.* Operations Research for Health Care, 2013. **2**(1): p. 20-24.
9. Reddy, B., et al., *Using MCDA to generate and interpret evidence to inform local government investment in public health.* EURO Journal on Decision Processes, 2016: p. 1-21.
10. NICE, *Developing NICE guidelines: the manual.* 2014, National Institute for Health and Care Excellence: London.
11. NICE, *Methods for the development of NICE public health guidance*, in *NICE: London*. 2006, National Institute for Health and Care Excellence: London.
12. NICE, *Methods for the development of NICE public health guidance*. 2006, National Institute for Health and Care Excellence: London.
13. NICE, *Methods for the development of NICE public health guidance*. 2009, National Institute for Health and Care Excellence.: London.
14. NICE, *Methods for the development of NICE public health guidance*. 2012, National Institute for Health and Care Excellence.: London.
15. NICE, *Social Value Judgements: Principles for the development of NICE guidance*. 2008, National Institute for Health and Care Excellence: London.
16. Rawlins, M., D. Barnett, and A. Stevens, *Pharmacoeconomics: NICE's approach to decision‐making.* British journal of clinical pharmacology, 2010. **70**(3): p. 346-349.
17. Morgan A, E.S., Field J, Owen L, Jones D, Minchin M, McArthur C, Doohan E, Hodgson G, Pickard L. . 2011, NICE.*, *Supporting investment in public health: Review of methods for assessing cost effectiveness, cost impact and return on investment*. 2011, NICE: London.
18. Golan, O., et al., *Health technology prioritization: which criteria for prioritizing new technologies and what are their relative weights?* Health policy, 2011. **102**(2): p. 126-135.
19. Tversky, A. and D. Kahneman, *Judgment under uncertainty: Heuristics and biases.* science, 1974. **185**(4157): p. 1124-1131.
20. Kahneman, D. and A. Tversky, *Prospect theory: An analysis of decision under risk.* Econometrica: Journal of the Econometric Society, 1979: p. 263-291.
21. Slovic, P., *Perception of risk.* Science, 1987. **236**(4799): p. 280-285.
22. Broom, D., C. Banwell, and D. Gardner, *Antecedents of Culture-in-Health Research.* When Culture Impacts Health: Global Lessons for Effective Health Research, 2013: p. 15.
23. Turnock, B., *Essentials of public health*. 2011: Jones & Bartlett Publishers.
24. NHS Commissioning Board, *Commissioning policy: implementation and funding of NICE guidance*. 2013.

25. Gigerenzer, G., et al., *Helping doctors and patients make sense of health statistics.* Psychological science in the public interest, 2007. **8**(2): p. 53-96.
26. NICE, *Alcohol-use disorders: preventing harmful drinking*, in *PH24*. 2010, National Institute for Health and Care Excellence: London.
27. Ross, T., *David Cameron's plan for minimum alcohol price is scrapped*, in *The Telegraph*. 2013: London.
28. Daniels, N., *Accountability for reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles.* BMJ: British Medical Journal, 2000. **321**(7272): p. 1300.
29. Sen, A., *Development as freedom*. 1999: Oxford University Press.
30. Mingers, J. and S. Taylor, *The use of soft systems methodology in practice.* Journal of the Operational Research Society, 1992: p. 321-332.
31. Checkland, P., *Soft systems methodology: a thirty year retrospective.* Systems research and behavioral science, 2000. **17**(S1): p. S11.
32. International MCDM Society. *Introduction*. 2013 [cited 2014 12 September 2014]; Available from: http://www.mcdmsociety.org/intro.html.
33. NICE, *Technical Guidance for Manufacturers and Sponsor on Making a Submission to a Technology Appraisal*. 2001, National Institute for Clinical Excellence: London.
34. Lindblom, C.E., *The science of" muddling through".* Public administration review, 1959: p. 79-88.
35. Gigerenzer, G. and P.M. Todd, *Simple heuristics that make us smart*. 1999: Oxford University Press.
36. Kahneman, D., *Thinking, fast and slow*. 2011: Macmillan.
37. Reddy, B., et al., *Prioritising public health guidance topics in the National Institute for Health and Care Excellence using the Analytic Hierarchy Process.* Public health, 2014. **128**(10): p. 896-903.
38. Saaty, T.L., *The analytic hierarchy process: planning, priority setting, resources allocation.* New York: McGraw, 1980.
39. Mussen, F., S. Salek, and S. Walker, *Benefit-Risk Appraisal of Medicines: A Systematic Approach to Decision-Making (2009 ed.)*. 2009: John Wiley & Sons, Chichester, West Sussex, United Kingdom.
40. Claxton, K., et al., *Methods for the estimation of the NICE cost effectiveness threshold.* York: University of York, 2013.
41. Dolan, P., et al., *The measurement and valuation of health: first report on the main survey.* York: University of York, 1994.
42. Schmitz, S., et al., *Identifying and Revealing the Importance of Decision-Making Criteria for Health Technology Assessment: A Retrospective Analysis of Reimbursement Recommendations in Ireland.* PharmacoEconomics, 2016: p. 1-13.
43. Sen, A., *Utilitarianism and welfarism.* The Journal of Philosophy, 1979: p. 463-489.
44. Weatherly, H., et al., *Methods for assessing the cost-effectiveness of public health interventions: Key challenges and recommendations.* Health policy, 2009. **93**(2): p. 85-92.
45. Sanders, G.D., et al., *Recommendations for conduct, methodological practices, and reporting of cost-effectiveness analyses: second panel on cost-effectiveness in health and medicine.* Jama, 2016. **316**(10): p. 1093-1103.
46. Dodgson, J., et al., *Multi-criteria analysis: a manual*. 2009: Department for Communities and Local Government: London.
47. Ram, C., G. Montibeller, and A. Morton, *Extending the use of scenario planning and MCDA for the evaluation of strategic options.* Journal of the Operational Research Society, 2011. **62**(5): p. 817-829.
48. Claxton, K., *Three questions to ask when examining MCDA.* Value & Outcomes Spotlight, 2015. **1**: p. 18-20.
49. Reddy, B., P. Thokala, and A. Duenas, *MCDA for Resource Allocation at a Local Level: An Application in the UK*, in *Multi-Criteria Decision Analysis to Support Healthcare Decisions*. 2017, Springer. p. 175-198.

50. Walker, S., L. Phillips, and M. Cone, *Benefit-risk assessment model for medicines: Developing a structured approach to decision making*. Surrey: CMR International, 2006.
51. Phillips, L.D., et al., *Is quantitative benefit–risk modelling of drugs desirable or possible?* Drug discovery today: technologies, 2011. **8**(1): p. e3-e10.
52. Airoldi, M., et al., *STAR—People-Powered Prioritization A 21st-Century Solution to Allocation Headaches.* Medical Decision Making, 2014. **34**(8): p. 965-975.
53. Airoldi, M., et al., *Healthcare prioritisation at the local level: a socio-technical approach.* Priority-setting for Population Health Working Paper Series, Working Paper, 2011(7).
54. Beierle, T.C., *The quality of stakeholder‐based decisions.* Risk analysis, 2002. **22**(4): p. 739-749.
55. Phillips, L.D., *A theory of requisite decision models.* Acta psychologica, 1984. **56**(1): p. 29-48.
56. Bana E Costa, C.A., *The use of multi‐criteria decision analysis to support the search for less conflicting policy options in a multi‐actor context: case study.* Journal of Multi‐Criteria Decision Analysis, 2001. **10**(2): p. 111-125.
57. Whitehead, S.J. and S. Ali, *Health outcomes in economic evaluation: the QALY and utilities.* British medical bulletin, 2010. **96**(1): p. 5-21.
58. Towse A, P.C., *Does NICE have a threshold? An external view.* , in *Cost-effectiveness thresholds: economic and ethical issues.*, P.C. Towse A, Devlin N, Editor. 2002, King's Fund: London.
59. Williams, I. and S. Bryan, *Understanding the limited impact of economic evaluation in health care resource allocation: a conceptual framework.* Health Policy, 2007. **80**(1): p. 135-143.
60. Devlin, N., *An introduction to the use of cost-effectiveness threshold in decision-making: what are the issues?*, in *From Cost-effectiveness thresholds: Economic and ethical issues*. 2002, King's Fund and Office of Health Economics. : London.
61. Schein, E.H., *Process consultation revisited: Building the helping relationship*. 1999: Addison-Wesley Reading, MA.
62. NICE, *What are the societal values that need to be considered when making decisions about trade-offs between equity and efficiency? Citizens Council Meeting report: 8-9 May 2014.* . 2014, National Institute for Health and Care Excellence: London.
63. Wilson, E.C., S.J. Peacock, and D. Ruta, *Priority setting in practice: what is the best way to compare costs and benefits?* Health economics, 2009. **18**(4): p. 467-478.
64. Simon, H.A., *A behavioral model of rational choice.* The quarterly journal of economics, 1955: p. 99-118.
65. Hoffmann, C. and J.-M.G. von der Schulenburg, *The influence of economic evaluation studies on decision making.: A European survey.* Health policy, 2000. **52**(3): p. 179-192.
66. Endrei, D., B. Molics, and I. Ágoston, *Multicriteria decision analysis in the reimbursement of new medical technologies: real-world experiences from Hungary.* Value in Health, 2014. **4**(17): p. 487-489.
67. Fedyaeva, V., et al., *Mcda Approach To Ranking Rare Diseases In Russia: Preliminary Results.* Value in Health, 2014. **17**(7): p. A539.
68. Institute for Clinical Economic Research, *Overview of the ICER value assessment framework and update for 2017–2019.* 2017.
69. (NICE), N.I.f.H.C.E., *Interim Process and Methods of the Highly Specialised Technologies Programme Updated to reflect 2017 changes-Process for the evaluation of highly specialised technologies*. 2017: London.
70. Mingers, J., *Variety is the spice of life: combining soft and hard OR/MS methods.* International Transactions in Operational Research, 2000. **7**(6): p. 673-691.
71. McKay, J. and P. Marshall, *The dual imperatives of action research.* Information Technology & People, 2001. **14**(1): p. 46-59.

72. Phillips, L.D. and C.A. Bana e Costa, *Transparent prioritisation, budgeting and resource allocation with multi-criteria decision analysis and decision conferencing.* Annals of Operations Research, 2007. **154**(1): p. 51-68.
73. Sharpe, P. and T. Keelin, *How SmithKline Beecham makes better resource-allocation decisions.* Harvard Business Review, 1997. **76**(2): p. 45-6, 48, 50 passim.
74. Koch, T. and M. Rowell, *The dream of consensus: finding common ground in a bioethical context.* Theoretical medicine and bioethics, 1999. **20**(3): p. 261-273.
75. Phillips, L., *Decision conferencing*, in *Advances in decision analysis: from foundations to applications*, W. Edwards, R.F. Miles Jr, and D. Von Winterfeldt, Editors. 2007, Cambridge University Press.
76. Haas, M., et al., *Using programme budgeting and marginal analysis to assist population based strategic planning for coronary heart disease.* Health Policy, 2001. **55**(3): p. 173-186.
77. Klein, R., et al., *Managing scarcity: priority setting and rationing in the National Health Service*. 1996: Open university press Buckingham.
78. Duthie, T., et al., *Research into the use of health economics in decision making in the United Kingdom—Phase II: Is health economics 'for good or evil'?* Health Policy, 1999. **46**(2): p. 143-157.
79. Thokala, P., et al., *Multiple Criteria Decision Analysis for Health Care Decision Making—An Introduction: Report 1 of the ISPOR MCDA Emerging Good Practices Task Force.* Value in Health, 2016.
80. Marsh K; IJzerman M; Thokala P; Baltussen R; Boysen, M.K., Z; Lönngren, T; Mussen, F; Peacock, S; Watkins, J; Devlin N, *MCDA for Health Care Decisions - Emerging Good Practices: Report 2 of the ISPOR MCDA Task Force* Value in Health, 2016. **19**: p. 125-137.
81. Gruskin, S. and N. Daniels, *Process is the point: justice and human rights: priority setting and fair deliberative process.* American Journal of Public Health, 2008. **98**(9): p. 1573.

Figure 1 - Stages to CPH guidance development process