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REVIEW ARTICLE

# On cost effectiveness analysis and fairness: Normalizing control of and resistance to NICE technology appraisals

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## Abstract

This study examines National Institute for Health and Care Excellence's (NICE) application of cost effectiveness analysis (CEA) for normalizing patients' access to newly licensed health technologies. Drawing upon evidence from the appraisal of four drugs developed for a rare form of cancer, this study demonstrates that the discourse of CEA provided a medium whereby contradicting ideologies of fairness were contested and resistance was provoked. Far from being docile, the patients whom the NICE technology appraisal sought to administer were actively challenging the legitimacy of the calculation of CEA. The patients' recalcitrance not only undermined the normalizing force but also compelled NICE to revise its application of CEA to suit their own interests. This study concludes that the discursive characteristic of calculating technologies not only constituted but was also constituted by conflicting interests and power struggles.

**KEYWORDS**

cost effectiveness analysis, fairness, NICE, resistance

## 1 | INTRODUCTION

The National Institute for Health and Care Excellence (NICE) was set up in 1999 to address the so-called "postcode lottery" in healthcare provision in the National Health Service (NHS) (House of Commons, 2002). It has developed technology appraisal programs so as to formulate technology guidance to standardize the practice of clinical professionals in terms of providing health technologies to patients with a specific illness. A new health technology has to fulfil both clinical effectiveness and cost effectiveness if it is to be made available on the NHS. The formulation of the technology guidance relies on cost effectiveness analysis (CEA), which translates those two criteria into numerical figures, namely, quality-adjusted life years gained (QALYs) and incremental cost (ICER) per QALY gained (NICE, 2004, 2013). The

application of the CEA is intended to maximize QALYs for the amount of funding available to the NHS (Dolan, Shaw, Tsuchiya, & Williams, 2005). NICE expressed the belief that its technology guidance would promote fair distribution and efficient utilization of limited public money (Brazier, Ratcliffe, Salomon, & Tsuchiya, 2007).

The formulation of technology guidance, however, was criticized for being too linear toward the relays of calculation. Some have argued that the QALY mechanism might have inherent technical defects as its application requires manipulation of available clinical trial evidence and statistical modeling (Neumann, 2005). Dolan, Edlin, and Tsuchiya (2009) also argued the linear calculation of ICER per QALY might not capture the social value of a health technology, which is believed to be equally influential for the fair distribution of health care. The ideology of fairness derived from CEA discourse might not reflect moral ethics valued by the patients and clinical professionals (Dolan & Olsen, 2002). Reality might escape the utility maximization theory that informs the QALY-based CEA and the ambitions that underpin the mechanism. Normalizing force might be undermined by unreliable technicality of clinical and cost effectiveness quantification and the contesting ideology of fairness.

The application of calculating technologies might not necessarily lead to what government programs espouse to deliver (Arnaboldi & Tommaso, 2011; Kurunmaki, Lapsley, & Miller, 2010). NICE's reliance on financial calculus had been criticized for certain undesirable impacts upon patient access to newly developed health technologies (see House of Commons, 2008, 2013). The appraisal of four clinically effective drugs developed for a rare form of kidney cancer, namely, renal cell carcinoma ("RCC"), had attracted great controversy and resistance among the affected patients and clinical professionals. Previous Foucault-informed studies deemed calculating technologies as normalizing techniques that transformed the subjects into calculable and governable objects (Edwards, 2018). Clegg (1994), however, argued that the exercise of normalizing control would inevitably lead to resistance (see also Knights & Vurdubakis, 1994). The power relationship, constructed through normalizing techniques, might suffuse with "the recalcitrance of the will and the intransigence of freedom" (Foucault, 1983, p. 221). Drawing evidence from the case of RCC, this study examines to what extent the subjects whom the technology appraisal program sought to administer might resist NICE's normalizing control. This study argues that the affected patients and clinical professionals were not docile or ignorant of the subjugated knowledge (see Ladva & Andrew, 2014). They might be actively entering the discourse of the QALY-based CEA, through exposing its technical defect and deploying contesting ideology of fairness, to challenge the legitimacy of NICE's technology appraisal. This study pays particular attention to what extent the QALY-based CEA served as a discursive medium by which resistance was provoked to contest normalizing control. It aims to draw out the implications concerning the impact of their interplay upon NICE's application of the QALY-based CEA (Armstrong, 1994; Preston, 1992).

This paper is structured as follows. First, it discusses the theoretical foundation of CEA and its role in promoting fair distribution of health care in the NHS. It pays attention to the construction of meanings of fairness through contesting discourses between CEA and moral/medical ethics. Drawing upon conceptual framework of governmentality, this section also discusses the interplay between normalizing control and resistance in a discursive field constructed through the application of calculating technology. This is followed by the research design, which explains the use of critical discourse analysis to depict the interrelation between power and resistance arising from contesting discourses of CEA amid NICE, patients, and other constituents. The next section presents evidence drawn from the case of RCC. The focus is on the resistance aroused by the affected patients and other constituents in the discursive field of the QALY-based CEA. This section also examines impact of the resistance upon NICE's application of the normalizing technique. The final section presents concluding discussion.

## 2 | NICE's CEA—FAIRNESS AND NORMALIZING CONTROL

### 2.1 | Constructing the meaning of fairness through the calculation of CEA

The lack of national clinical standards in the NHS had been problematized as an issue that had caused variation in healthcare provision and difficulty in health service planning (Department of Health [DoH], 2000). The so-called

"postcode lottery" issue was one of the major problems that the U.K. Government attempted to address when reforming the NHS (BBC News 2008a; DoH, 2004, 2010). Under that political mindset, NICE was established in 1999, and given the pivotal role in providing evidence-based guidance on the use of new and existing health technologies. "Patients should have fair access and high standards of care wherever they live" and there would be "clear guidance on the best treatments and interventions from the National Institute for Clinical Excellence (NICE)." (DoH, 2000, p. 58).

Government programs lay claim to the knowledge of a problem that it seeks to address so that such problems could be analyzed and solutions for desirable outcomes could be proposed (Miller & Rose, 2008). Actualizing government programs relies on calculating technologies that render reality into a calculable form and transform events into numerical information so that the domain in question is susceptible to evaluation and intervention (Rose & Miller, 1992). NICE has developed a program of technology appraisal, which relies quite substantially on CEA to translate complex clinical and cost effectiveness data into numerical information. Such information serves as the founding basis for the formulation of technology guidance, making the issue of patient access to new health technologies susceptible to normalizing intervention. NICE would only recommend a health technology to be funded by the NHS if it is both clinically effective and cost-effective. NICE believes that the theoretical reasoning of CEA provides a sound justification for NICE to legitimize its technology guidance (Drumond and McGuire, 2002).

Clinical effectiveness of a new health technology is calculated on the basis of generating more QALYs than existing treatments in the NHS. NICE considers QALYs to be "the most appropriate generic measure of health benefit that reflects both mortality and health-related quality of life effects" (NICE, 2013, p. 35). The QALY model converts complex health benefits of a health technology into a common numerical figure of year in full health by combining life expectancy and quality of life (Pliskin, Shepard, & Weinstein, 1980). In order to quantify abstract quality of life, NICE adopts the mechanism of EQ-5D (see NICE 2013). This mechanism assigns a weighting, ranging from 0 to 1 to each health state, where a weighting of 1 corresponds to perfect health and a weighting of 0 corresponds to a health state judged equivalent to death (Gold, Siegel, Russell, & Weinstein, 1996). The duration of time spent in each health state is then multiplied by the weighting to derive the number of QALYs. NICE requires its appraisal committee[1] to take into account data from all relevant studies of the best available quality when analyzing clinical effectiveness of a new health technology. The committee must produce "an unbiased estimate of the mean clinical effectiveness of the technologies being compared" (NICE, 2013, p. 36).

The QALY mechanism is intended to generate scientific evidence-endorsed figures, which would allow "NICE to make its decisions consistently, transparently and fairly" (NICE, 2008a, p. 17). NICE considers that health distribution relying on maximizing the number of QALYs should entail distributive neutrality. The goal is to maximize QALYs for the whole society instead of giving preference to identifiable "victims" (Loomes & McKenzie, 1989). "NICE means that … the weight given to the gain of a QALY is the same, regardless of … the age or sex of the beneficiaries, their deservedness, and the extent to which the recipients are deprived in other respects than health" (Rawlins & Culyer, 2004, p. 225). In other words, fairness would only be achieved if all QALYs are treated as equal social value (Shah, 2009; Weinstein, 1988).

In addition to clinical effectiveness, a new health technology has to fulfill the criterion of cost effectiveness, which is reflected on the ratio of ICER per QALY gained. This ratio is calculated as the difference in costs between the new health technology and the existing one divided by the net increase in QALYs (Drumond, Wilson, Kanavos, Ubel, & Rovira, 2007). NICE believes that the calculation of such ratio allows meaningful and objective comparison of cost effectiveness across different specialities and diseases. NICE has requested the appraisal committee to adopt specific mathematical and statistical modeling to extrapolate the mean value of cost and benefit in order to formulate ICER per QALY gained (NICE, 2004, 2013).

A new health technology is deemed to be cost-effective if its ICER of gaining an extra QALY does not exceed the opportunity cost threshold that society can bear (Culyer et al., 2007). The opportunity cost threshold is intended to signal the maximum amount of resources which is regarded as appropriate to divert towards the production of an additional QALY (Devlin and Parkin, 2004). The health technologies accepted within the threshold are believed to produce the largest possible number of QALYs for the given level of resource (Brazier et al., 2007). NICE, however, has been

reluctant to admit that it has adopted a definite threshold as a cutoff point for rejecting or accepting a particular health technology. On one hand, NICE has stressed that there is not "a precise maximum acceptable ICER above which a technology would automatically be defined as not cost effective or below which it would" (NICE, 2013, p. 67). On the other hand, however, NICE accepted that "below a most plausible ICER of £20,000 per QALY gained, the decision to recommend the use of a technology is normally based on the cost-effectiveness estimate and the acceptability of technology as an effective use of NHS resources" (NICE, 2013, p. 68). There has been some evidence suggesting that the threshold adopted by NICE is between £20,000 and £30,000 per QALY (see National Audit Office, 2015a, 2015b). However, NICE has not provided any scientific reasoning to justify its adoption of any such threshold.

NICE's technology appraisal program specifies stringent methodologies for data collection and statistical modeling formulation to ensure that: "our advice is based on the most up-to-date evidence available" (see https://www.nice.org.uk/Media/Default/About/Who-we-are/NICE_Charter.pdf). However, the creditability of the QALY-based CEA calculation is subject to reliable estimation of future cost and benefit and potential manipulation of statistical models. NICE has admitted that the appraisal committee may have doubts about the degree of certainty in respect of the ICERs or the extent to which the change in the quality of life is adequately captured. It is also likely that health benefits of an innovative technology might be more complex to quantify and be fully incorporated into QALY calculation (NICE, 2008a). The inherent technical limitations might give rise to potential dispute about the legitimacy of technology guidance derived from the QALY-based CEA as the calculation is suffused with estimation and manipulation.

## 2.2 | Alternative ideology of fairness derived from moral ethics

Not only the technical efficacy of the QALY-based CEA is disputable but also the meaning of fairness derived from QALY maximization (Newdick, 2005). From the perspective of bioethics (or medical ethics), the QALY model has been criticized for being "a cold calculating doctrine that neglects moral issues, for example, the needs of those who are worst-off in the society (Hayry, 2002). Harris (1991) argued that health distribution based on QALY maximization may lead to discrimination against particular groups in society with lower than average capacity to benefit from treatment. Increasing empirical evidence has suggested that society is willing to give high priority to those whose health without treatment is poor even though this may sacrifice aggregate health gain for society as a whole (see Dolan & Olsen, 2002; Nord, 2001). Dolan et al. (2009) argued that social value of QALYs is not linear in terms of quality and length of life as perceived by NICE. Their empirical evidence showed that society is willing to give more weight to the QALY of people with worse lifetime health prospects. The "identifiable victim effect" reflects the "rule of rescue" defined as the powerful human proclivity to rescue endangered life of an identifiable person, no matter how much it might cost (Cookson, McCabe, & Tsuchiya, 2008).

Proposals to give more weighting to QALYs might contradict the ideology of fairness derived from the calculation of CEA. Doland and Olsen (2002), however, argued that distributive justice cannot be achieved by solely relying on utility maximization without taking into account moral aspects of choices. Daniels and Sabin (2002), drawing upon Rawls's theory of justice, argued that the distribution of health should not be solely based on economic calculation but take into account the moral ground of protecting opportunities so that individuals most in need can function normally and participate in the political, social, and economic life of the society. For Rawls (1971), social justice is not about determining how much we owe each other by measuring utility gained by individuals. "[I]n the absence of strong and lasting benevolent impulses, a rational man would not accept a basic structure merely because it maximised the algebraic sum of advantages…." (p. 13). His conception of "justice as fairness" promotes the ideology that "the rights secured by justice are not subject to political bargaining or to the calculus of social interests" (p. 25).

NICE has developed social value judgments with the intention to demonstrate its commitment to the moral aspect of health care distribution.[2] NICE's principles of social judgments could be seen as an application of the "accountability for reasonableness" framework for public resource allocation advocated by some bioethicists (see Daniels, 2000). However, the principles might be symbolic as there is no indication as to what extent they have been

systematically integrated into the QALY-based CEA calculation (Shah, Cookson, Culyer, & Littlejohns, 2013). NICE might have deliberately detached its CEA calculation from the abstract social value judgments as it has dismissed some of the ethical principles. "When there are limited resources for healthcare, applying the 'rule of rescue' may mean that other people will not be able to have the care or treatment they need. … The Institute has not therefore adopted an additional 'rule of rescue'" (NICE, 2008a, p. 21). For NICE, applying the subjective social value judgment principles might undermine its intention to maximize QALYs for the NHS as a whole. The ideology of fairness derived for moral ethics might therefore contradict that of NICE.

## 2.3 | Normalizing control and resistance

Calculating technologies entail the discursive characteristics that translate abstract political rationality and the aspiration of policy initiatives into concrete reality (Rose, 1991). Such technologies, functioning as inscription devices, covert reality into a calculable form and translate events into numerical information. Numerical information renders the establishment of societal norms (see Miller & Rose, 2008). The norms prescribe acceptable forms of behavior or standards with which individuals are expected to comply (Walters, 2012). In other words, calculating technologies serve as a source of social power that enmeshes individuals within a web of calculative practices, which make them accountable by reference to the prescribed norms (Miller & O'Leary, 1987). It is thus through the relays of inscription and calculation that authorities of all types can exercise their power to render individuals amenable to control (Rose & Miller, 1992).

Through the construction of the meaning of fairness, ICER per QALY serves as the norm to standardize health technology provision in the NHS. The QALY-based CEA transforms the provision of a new health technology into a calculable form so that NICE can exercise normalizing control over the patients and clinical professionals. "It was envisaged that NICE would provide a "single source of advice" to the health service … and clarifying what patients could and could not expect from the NHS" (House of Commons, 2008, p. 9). To that end, technology guidance is intended to serve as a source of power that entangles the patients and clinical professionals within a web of calculative practices. Complying with NICE technology guidance is statutory as the NHS is required to ensure that a treatment is made available within 3 months after NICE has published the relevant guidance (see NICE, 2018 and Parliament, 2012). Clinical professionals are expected to act in accordance with the guidance when determining the provision of health technologies to patients with the same condition. In addition, reflecting on the legitimacy of NICE technology guidance, the NHS Constitution defines what patients are entitled in the NHS (DoH, 2015). Patients would be coerced to accept NICE's creditable expertise in determining their entitlement to health technologies. In other words, the discourse of cost effectiveness is intended to serve as a normalizing technique that objectifies the patients and clinical professionals into self-governing individuals who acquiesce with NICE's ideology of fairness.

However, reliance by NICE on a theoretically sound calculating technology for normalizing control may not create conditions that make the QALY-based CEA function as intended because such programmatic technique might intertwine and tangle with conflicting interests in a chaotic manner (Lapsley, 2009). "'[R]eality' always escapes the theories that inform programmes and the ambitions that underpins them" (Miller & Rose, 1990, p. 11). As mentioned earlier, the calculation of ICER per QALY is subject to estimation of health benefits and future cost and manipulation of statistical modeling. The formulation of QALYs had been criticized for being depending on subjective assumptions of "value judgements, such that the factors included in a QALY and the weight given to them may vary" (House of Commons, 2008, p. 34). NICE admitted that "Those developing NICE's guidance are therefore inevitably required to make judgements … about interpreting the quality and significance of the evidence available …" (NICE, 2008a, p. 4). Moreover, the application of the QALY-based CEA might be suffused with struggles of ideologies of fairness among NICE, clinical professionals, and the patients (Dolan et al., 2009; Klein, 2013). The ideology of fairness derived from moral ethics apparently contradicts NICE's belief in QALY maximization. NICE's reluctance to justify its use of the ICER threshold and incorporate social value judgments might incite the patients and clinical professionals to resent and challenge NICE's belief in QALY maximization.

The conceptual framework of governmentality often perceives the subject that government program seeks to control as docile and controlled by the apparatus of domination derived from the norms prescribed by the discourse of calculating technologies (Edwards, 2018; Rose & Miller, 2008). This study argues, however, that the technique of normalization might not in fact "exert a deterministic form of power on targets" (Brivot & Gendron, 2011, p. 141), but rather that it is subject to resistance (Gilliom, 2006). "For where there is the exercise of power, there is always the potential for resistance" (Covaleski, Dirsmith, Heian, & Samual, 1998, p. 299). Individuals are not incapable of mobilizing resistance in the web of normalizing control (Haggerty & Ericson, 2000) "Individuals can resist endeavours aimed at categorizing them in certain ways and interpreting their individuality in accordance with some dictated law of truth" (Brivot & Gendron, 2011, p. 141). They are not ignorant of subjugated knowledge or unable to deform the normalizing technique (see Kinghts & Vurdubakis, 1994). Clinical professionals might deploy their professional knowledge and dominance in the NHS (see Ferlie & McGivern, 2014) in order to dispute the creditability of the calculation of the QALY-based CEA. Patients might exploit their own perspective of moral ethics to protect their right to receive the treatment in the NHS whose institutional values endorse a service for all (DoH, 2015; Klein, 2013). In other words, NICE's reliance on the QALY-based CEA, suffused with technical defects and the struggle with ideologies of fairness, might trigger revolt from those whom the calculating technology seeks to normalize. Exercising normalizing control to establish power relation might therefore induce resistance by which the patients and clinical professionals divert the formulation of technology guidance to suit their own interests (see Clegg, 1994; Covaleski et al., 1998).

## 3 | RESEARCH DESIGN

Miller and Rose (1990) reasoned that analyzing the discursive field requires an attention to language as the relation between politics and language is mutually constitutive. Language functioning as an intellectual technology transforms phenomena into numerical information through calculating techniques so that the pertinent features of the domain, such as health care provision, can be normalized and administered. Information is not the result of neutral calculation but is suffused with power struggles that inscribe the reality in "such a way as to make the domain in question susceptible to evaluation, calculation and intervention" (Miller & Rose, 1990, p. 7). Given the crucial role of language in discourse, this study adopts critical discourse analysis (see Fairclough, 1995 and Wodak & Meyer, 2006) to examine to what extent the discourse of the QALY-based CEA constituted and was constituted by power struggles derived from conflicting intentions among the NICE, the patients, and other constituents, such as clinical professionals. It argues that the appraisal of new health technology was not always programmable and amenable through linear calculation of CEA. It pays attention to power struggles through examining exchanges of discourses about the CEA calculation as it contains texts that "show traces of differing discourses and ideologies contending and struggling for dominance" (Wodak, 2006, p. 11). Theoretical framework of governmentality has paid insufficient attention to the impact of consequences of normalizing control upon the formulation of calculating technologies and norms. This study is primarily concerned with the reaction of the patients and other relevant constituents toward NICE's normalizing control. It concentrates on the extent to which recalcitrance mobilized by the patients and other constituents would constitute the formulation of the QALY-based CEA calculation. In other words, this study is interested in the extent to which power struggles in the discursive field of calculating technologies would induce changes therein (Armstrong, 1994; Preston, 1992).

Qualitative secondary data were drawn from documents in relation to the appraisal of drugs developed for RCC, which were published by NICE between 2008 and 2009. This was one of the most controversial and significant cases as disputes in respect of the formulation of technology guidance for the drugs forced NICE to change its application of the QALY-based CEA. When appraising the four drugs, NICE's appraisal committee was required to issue its preliminary recommendations by taking into account clinical effectiveness and cost effectiveness figures provided by Peninsula Technology Assessment Group (PENTAG). Public consultation on the preliminary recommendations was then conducted before the final appraisal determination could be published (see NICE, 2014). In total, 15

**TABLE 1** Results of cost effectiveness analysis

| Health technologies | ICER per QALY (PENTAG figure) | ICER per QALY (manufacturer figure) |
|---|---|---|
| Bevacizumab plus interferon | £171,301 | £74,978 |
| Sunitinib | £71,462 | £28,546 |
| Sorafenib | £102,498 | £90,630 |
| Temsirolimus | £94,385 | £55,814 |

Abbreviations: ICER, incremental cost; PENTAG, Peninsula Technology Assessment Group; QALY, quality-adjusted life years gained.
Source: NICE (2008b).

institutions and clinical experts were consulted and two institutions were invited to comment on the preliminary recommendations.[3] They included clinical and medical professionals representing cancer charities as well as the Royal College of Physicians and the Oncology Federation, representatives of pharmaceutical companies, and one healthcare commissioner. The public and patients were also given the opportunity to comment. NICE received a total of 307 responses from the public and patients.[4]

In total, 119 documents were examined, which included the assessment group's analysis of the clinical and cost effectiveness of the drugs in question, the draft guidance published by the appraisal committee, as well as response letters from the consultees and commentators. This study adopts an analytical level of discourse (see Fairclough, 2006) in order to analyze the extent to which consultees and commentators deployed their clinical expertise and experience to dispute the creditability, and challenge the legitimacy, of the preliminary guidance. The analysis focused on the extent to which patients and other relevant constituents conveyed their own meaning of fairness to contest that derived from CEA calculation. Moreover, as the discourse also occurred in the media, this study drew evidence from press reports with regard to the reaction of and response from the patients and clinical professionals. The discourse between NICE and its constituents was also examined as this study analyzed the extent to which challenges from constituents were addressed by NICE. This aim was to tease out the impact of the resistance upon NICE's application of the QALY-based CEA.

## 4 | DISCOURSE OF CEA: THE CASE OF RCC

RCC is a rare and highly vascular type of kidney cancer. RCC is often asymptomatic until it reaches a late stage, that is, metastatic. The prognosis following diagnosis of metastatic disease is poor. Approximately only 10% of people diagnosed with Stage IV RCC live for 5 years or longer after diagnosis. In 2007, four new licensed drugs were referred to NICE for technology appraisals. According to the initial QALY analysis conducted by PENTAG,[5] all four drugs were clinically effective when compared to existing NHS treatments as the number of years of progression free survival increased in each case. However, PENTAG also suggested that none of them met the criterion of cost effectiveness. As Table 1 shows, the figures of ICER per QALY gained estimated by PENTAG were much higher than those provided by the drugs manufacturers. In order to justify the creditability of its numerical information, PENTAG explained that the variances were due to the reason that it adopted a more robust and conservative approach when estimating doses usage, relevant costs, and length of survival for its economic models. The difference nevertheless reflected that the formulation of the allegedly scientifically verifiable ICERs was subject to interpretation and manipulation of empirical evidence derived from the same clinical trials.

Inevitably pharmaceutical companies had an incentive to provide lower ICERs in order to further their commercial interests. The appraisal committee, however, was in a position to dismiss the reliability of their ICER/QALY figures. It supported the figures of PENTAG and concluded that none of the treatments was cost-effective in its preliminary

recommendations. For example, in the case of sunitinib versus interferon-$\alpha$, the appraisal committee indicated that "the probability that sunitinib would be considered cost effective at a willingness to pay threshold of £30,000 per QALY is zero" (NICE, 2008b, p. 7).

## 4.1 | Contesting the credibility of the QALY-based CEA calculation

After the draft guidance was published in August 2008, key constituents and the public were invited to comment on the preliminary recommendations. Sixteen out of 17 consultees and commentators[6] and 300 out of 307 of the public disagreed with the preliminary recommendations. Most of them were concerned with the reliability of PENTAG's QALY analysis, the suitability of NICE appraisal methodology, and the impact on equality in relation to patients' access to the four clinically effective drugs.

With regard to the reliability of the QALY analysis, some consultees drew upon their expertise to dispute ICER per QALY figures provided by PENTAG. The clinical expert representing the National Cancer Research Institute believed that PENTAG's QALY analysis was "flawed" as he believed that not only had the assessment group interpreted the empirical data incorrectly but also that it had failed to include more up to date publicly available empirical data (see https://www.nice.org.uk/guidance/ta169/documents/royal-college-of-physicians2). A similar view was expressed by British Uro-oncology, as it commented that "We do not consider that the assessment took all relevant data into account, specifically the recently announced overall survival data in the sunitinib vs. interferon trial which was 26 vs. 22 months" (see https://www.nice.org.uk/guidance/ta169/documents/british-urooncology-group-bug2). Furthermore, its clinical expert pointed out that the cost of sunitinib was not properly projected as it argued that PENTAG's estimation of dose intensity had not incorporated evidence from the latest clinical trial and had failed to consider Pfizer's agreement with the Department of Health to offer the first cycle of treatment free. The drawback of data analysis had led Pfizer to infer that "This unfortunately has the effect of perpetuating inconsistencies in the approach to the sunitinib clinical data and also the drug's relative cost effectiveness" (see https://www.nice.org.uk/guidance/ta169/documents/pfizer2).

It was not just the reliability of empirical data interpretation that was questioned. Several consultees, such as Macmillan Cancer Support, argued that "This appraisal highlights methodologically flaws in the technology appraisal process" (see https://www.nice.org.uk/guidance/ta169/documents/macmillan-and-rarer-cancers-forum4). In particular, they did not believe that the QALY was a suitable measure for capturing all aspects of clinical benefits delivered by the four drugs. Kidney Cancer UK commented that "In our view the central measure of a QALY is a woefully inadequate measure of patient benefit, calibrated as it is on the basis of a number of truly heroic assumptions" (see https://www.nice.org.uk/guidance/ta169/documents/kidney-cancer-ukjames-whale-fund-for-kidney-cancer2). The British Uro-oncology Group expressed a similar view and argued that NICE's calculation of clinical effectiveness was "inherently flawed and which will inevitably under-estimate the benefit that patients will receive from these drugs" (see https://www.nice.org.uk/guidance/ta169/documents/british-urooncology-group-bug2). Clinical professionals' skepticism about QALY-based CEA could be summarized by the comment made by Dr. Anderson from the Old Age Faculty of the Royal college of Psychiatrists when giving evidence to a parliamentary inquiry.

> *When clinicians hear about health economic analyses many of them see it as made-up stuff. You just take some data and create an equation that is based on assumption after assumption…. You fiddle about with an equation and come out with a number. If you want you can fiddle about with it some more and come out with a different number (House of Commons, 2008, p. 35).*

Some consultees did not approve the principle of "a QALY is a QALY is QALY" adopted by NICE. The National Kidney Federation supported the Citizen Council's criticism of the EQ-5D model and advised NICE "to consider the severity of the condition, clinical need and other factors that contribute to social value judgment should be weighed alongside cost effectiveness" (see https://www.nice.org.uk/guidance/ta169/documents/national-kidney-federation2). Some

patient experts urged the appraisal committee to "take into account the orphan status of these treatments and thus the fewer beneficiaries" and QALYs derived from the drugs with this nature should be given more weighting (see https://www.nice.org.uk/guidance/ta169/documents/patient-expert2). Bayer, for example, reiterated its Sorafenib as a life extending drug (i.e., an orphan drug) and stated that "We do not believe that using the QALY for advanced RCC patients is a suitable and sound basis for making recommendations to the NHS in this patient group" (see https://www.nice.org.uk/guidance/ta169/documents/bayer4).

Building upon the defects of PENTAG's analysis and methodological flaws of the QALY model, several consultees further argued that the preliminary recommendations were detached from clinical reality. Cancer Research UK stressed that "Although we understand that NICE often has to make difficult decisions, in this case there is a clear separation between what NICE finds to be a valuable treatment and clinical opinion" (see https://www.nice.org.uk/guidance/ta169/documents/cancer-research-uk2). Clinical experts expressed the view that their extensive expertise and experience in dealing with the clinical effectiveness of the four drugs had not been taken into account by NICE during the decision-making process. The British Uro-oncology Group protested that the appraisal committee seemed to assume that:

> *Clinicians had no ability to select the appropriate treatment for individual patients. … NICE can continue using a methodology that is ill-equipped to reflect the clinical utility of these drugs. … Alternatively, NICE could approve a technology that reflects what clinical experts, patients and licensing authorities have accepted" (see https://www.nice.org.uk/guidance/ta169/documents/british-urooncology-group-bug2).*

Some other interested groups had given examples countering NICE's assessment of the clinical effectiveness of the four drugs. The Welsh Assembly Government, quoting an oncologist, pointed out that "[T]hose of us who have used these new treatments have patients who are alive with an excellent quality of life more than 3 years after started treatment. These patients would not be alive now if they had only had access to interferon" (see https://www.nice.org.uk/guidance/ta169/documents/welsh-assembly-government2). Kidney Cancer UK indicated bluntly that "If adopted, the provisional recommendations would result in large numbers of premature deaths" (see https://www.nice.org.uk/guidance/ta169/documents/kidney-cancer-ukjames-whale-fund-for-kidney-cancer2).

All but one of the consultees and commentators were concerned with the impact of the preliminary recommendations on equality. An ideology of fairness derived from moral ethics was deployed to challenge the legitimacy of the preliminary recommendations. Cancer Research UK stressed that "This appraisal also clearly raises some broader questions relating to whether patients in the UK are getting fair and equal access to new medicines on the NHS" (see https://www.nice.org.uk/guidance/ta169/documents/cancer-research-uk2). The National Kidney Federation stated that "To deprive this small group of patient of access to these new drugs … is to totally deprive them of any hope for the future. … We don't feel that this minority should be penalized for the sake of the majority" (see https://www.nice.org.uk/guidance/ta169/documents/national-kidney-federation2). One clinical expert expressed that "It is the role of NICE to look at equality for all patients including those disadvantaged with a terminal illness. This decision punishes them for this very reason (see https://www.nice.org.uk/guidance/ta169/documents/patient-expert2). Dr. Chao, a prominent oncology consultant, reiterated that "The NHS … was created to make healthcare available to all, the most fundamental of equalities. We all recognize the need for cost effectiveness in the NHS, but this 'one size fits all' is the ultimate inequality" (see https://www.nice.org.uk/guidance/ta169/documents/dr-david-chao2).

The perceived methodological flaws of the QALY analysis and its negative impact on patient equality had led most consultees to show little faith in the preliminary recommendations. Cancer Research UK stressed that it did not believe that the evidence derived from the QALY analysis "is a basis from which reasonable interpretations of cost effectiveness can be drawn" (see https://www.nice.org.uk/guidance/ta169/documents/cancer-research-uk2).

Several consultees and commenters requested NICE to redo the appraisal by using appropriate comparative data and with expert oncology input. Pfizer, for example, urged a reappraisal of sunitinib by taking into account the additional empirical evidence and its proposal to offer the first cycle treatment free, which would reduce the cost to the

NHS of sunitinib by 18.5%. The request to redo the QALY analysis was also endorsed by other consultees, such as the National Cancer Research Institute, Cancer Research UK, the Welsh Assembly, National Kidney Federation, and Macmillan Cancer Support.

In responding to the comments, NICE accepted the shortcoming of PENTAG's initial QALY analysis and agreed to commission the assessment group to conduct another analysis. Moreover, NICE accepted that its appraisal methodology adopted at the time was not able to capture additional benefits valued by the patients with rare forms of disease. NICE indicated that it had developed a supplementary guidance for appraising life extending drugs and asked the appraisal committee to take the guidance into account when deliberating upon the final assessment decision (see discussion below).

## 4.2 | Contesting the ideology of fairness: The voice of the public and patients

During the process of consultation, 304 out of 307 (99%) respondents from the public disagreed with the preliminary recommendations. Many respondents argued that the drugs were clinically effective as 49.5% of them believed the drugs would extend survival and 35.5% of them indicated the drugs would improve quality of life. A respondent expressed that "These new technologies offer the only real hope of clinical stability, improved quality of life, and an extension of life." With regard to cost effectiveness consideration, 53 respondents indicated that the drugs should be provided to patients regardless of cost. One respondent stated that "You [NICE] say it is apparently not 'cost 'effective' to prolong RCC patients' lives. Yet they are given interferon—which is recognized not to be clinically effective in this type of cancer …. A complete waste of money but also total madness." There was also dispute about the use of QALY for measuring the clinical effectiveness of the drugs. One respondent argued that "The recent statement made by NICE … that these drugs only extend life by a few weeks is a blatant lie! I know of patients who are now in their third year on the drug." There were also a significant number of respondents deemed rejecting the four drugs on the basis of cost effectiveness as immoral and unfair. One respondent expressed that "It is morally wrong to withhold treatments that can make a difference on the grounds of cost alone." Another respondent stated that "It would appear that by denying effective therapies to NHS patients that are available to citizens of other countries, the British government places less value on the lives of its citizens than other governments do on theirs."[7]

Although the comments made by the public had little bearing on health economics and clinical expertise, most of the respondents referred to their personal experience or belief in moral ethics to defy the creditability of the preliminary recommendations. Two petitions were launched by the public to show their support and sympathy toward the patients of RCC. One of the petitions, namely, the Fight for Life Campaign, obtained more than 4,000 signatures from the public demanding that NICE makes the drugs available for patients. Its organizer stated that "[T]he general public are so angry, annoyed and outraged at the way you play God with people's lives…. You have made a terrible mistake … as it goes against the Hippocratic Oath and the right for each person to have the right to live" (see note 7). In responding to those comments, NICE did not express any dismissive counterargument. It merely reiterated its response to the consultees and commenters by pointing out that it was in the process of developing a supplementary guidance for appraising life extending drugs, which the appraisal committee would be required to taken into account when deliberating upon the final appraisal determination.

The case of RCC had also attracted extensive coverage in the media as there was discourse about the morality of the QALY calculation. Moral ethics were deployed by affected patients to challenge the legitimacy of the preliminary recommendations. In fighting for their right to receive the medicines, a group of RCC patients attempted to occupy NICE headquarters to demand face-to-face discourse with NICE senior management. One of the demonstrators expressed his anger directly toward the chief executive and pointed out that "I'm dying and he's taking any hope away from me" (BBC News, 2008b). Another demonstrator conveyed his aversion toward NICE's reliance on financial calculation. He argued that decision about whether he should receive the drugs "needs to be decided by consultants and not by the accountants at NICE" (The Guardian, 2008).

The preliminary recommendations had also attracted criticisms from clinical and medical professionals. Within a letter sent to a national newspaper, 26 leading cancer consultants remarked that NICE's assessment methodology was not equipped for assessing cancer drugs. They argued that

> *NICE has shown how poorly it assesses new cancer treatments. Its economic formulae are simply not suitable for addressing cost-effectiveness in this area of medicine. … It just can't be that everybody else around the world is wrong about access to innovative cancer care and the NHS right in rationing it so severely (see BBC News 2008c).*

For NICE, ICER per QALY represented the opportunity cost of consuming limited public funding, which should be constrained if fair distribution were to be achieved for the whole society. For patients with RCC, however, ICER per QALY represented the price tag that NICE placed on the value of their life. It was the price tag preventing them from receiving "expensive" but clinically effective treatments. In their view, CEA was a calculating mechanism that rationed healthcare instead of promoting fair access, which was perceived to be contradictory to the founding principle and core value of NHS (see Klein, 2013 and DoH, 2015).

### 4.3 | Struggling for the ideology of fairness: The U-turn

As evidence shown from the process of consultation, NICE's reliance on the QALY calculation for normalizing the provision of the four drugs developed for RCC had induced resistance from the patients and clinical professionals. Not only the technical defect of the QALY analysis but also moral ethics was exploited by the patients, the public, and clinical professionals to challenge the legitimacy of the preliminary recommendations. They argued that the reliance on a technically and methodologically flawed calculating technology would not foster a fair distribution of limited NHS funding but lead to discrimination against vulnerable patients.

In order to address the alleged methodological flaws in QALY-based CEA, NICE asked its Citizen Council to evaluate whether the severity of a disease should be taken into account (see NICE, 2008c). The view was supported by some health economists as they urged that NICE's technology appraisal should "depart from the 'a QALY is a QALY is a QALY' rule (see Weinstein, 1988) in order to adopt a system that gives greater weight to health improvements occurring higher up the severity scale" (Shah, 2009, p. 83). In responding to the Citizen Council's recommendation, NICE issued a supplementary guidance specifically for appraising end of life treatments, which may be life extending for patients with short life expectancy, and which are licensed for indications affecting small numbers of patients with incurable illnesses (NICE, 2009a). To that end, NICE appraisal committee was permitted to give greater weight to QALYs for patients receiving end of life treatments.

The development of the supplementary guidance, to some extent, showed NICE had given in to the criticism that its QALY-based appraisal methodology might not adequately capture the health benefits produced by life extending drugs. The guidance, however, did not specify how the extra weighting should be systematically applied. NICE's appraisal committee would have to reach its own judgment about the extra weighting. The possibility of subjective interpretation, whether a form of manipulation or not, might reflect the argument that fairness, as a social construct, cannot be merely realized through linear calculation but is subject to negotiation in the discursive field constituted by struggles for interests and ideologies.

By taking into account additional empirical data and agreement between the drugs manufacturers and the Department of Health, PENTAG had reassessed the clinical and cost effectiveness of the four drugs. PENTAG's analysis was then provided to the appraisal committee, which was then further analyzed and verified by its own decision support unit. There was still some discrepancy among the manufacturers, PENTAG, and the decision support unit. For example, for sunitinib, the figure of the manufacturer was £29,440, that of PENTAG was £65,464 and that of the decision support unit was £49,304. Although PENTAG and the decision support unit both reiterated that the discrepancy was primarily caused by differences in assumptions made and economic models adopted, they did not justify why their own figures still showed a significant variance. PENTAG's and the decision support unit's additional analyses were put

forward for another round of consultation. Although there was less resistance this time, some clinical experts, such as those representing Kidney Cancer UK, still expressed reservations about the QALY analysis and the discrepancy in ICER figures. Several consultees and commentators echoed that the drugs fulfilled the criteria for life-extending end-of-life treatments and should be approved for the NHS. Dr. Chao stated that "NICE has a critical role in promoting equality through the elimination of the 'post code lottery.' I would urge the Chairman and Committee … to approve the kidney cancer drugs as soon as possible" (see https://www.nice.org.uk/guidance/ta169/documents/dr-david-chao4).

When deliberating the final decision, the appraisal committee did not solely rely on the figures derived from the QALY calculation. It reiterated that its members had considered not only all empirical analysis but also comments with regard to fairness made during the consultation and appeals, and the supplementary guidance for life extending drugs. According to the final appraisal determination, only sunitinib had been recommended for the first-line treatment of advanced and/or metastatic RCC. The appraisal committee had not referred to any of the figures of ICER per QALY provided by PENTAG or its own decision support unit when making the final decision. It did, however, stated that "the Committee was persuaded that the ICER for sunitinib 'no post-study treatment group' could be less than £50,000 per QALY gained" (see note 9). In order to justify the appraisal outcome, NICE appraisal committee stated that "[T]he Committee was satisfied that sunitinib currently meets the criteria for being a life-extending end-of-life treatment. … The Committee concluded that sunitinib as a first-line treatment for advanced and/or metastatic RCC could be recommended as a cost-effective use of NHS resources" (see also NICE, 2009b and 2009c).[8] NICE's chief executive at the time, Andrew Dillon, supported the decision by adding that

> *Many people have made the point very strongly that they regard the ability of the NHS to extend life as being of special importance…. We wanted to make sure that they (the appraisal committee) had enough flexibility in all circumstances to make a recommendation where drugs have the ability to give people some additional life (BBC News, 2009).*

After a decision-making process of over a year, NICE issued technology guidance for sunitinib (No. 69) in 2009 (NICE, 2009b). Its approval was not entirely in line with the opportunity cost threshold that NICE referred to as the norm. Nevertheless, the decision was welcome by most consultees and commentators. Dr. Chao stated that "I congratulate the committee on being the first adopter of the new end-of-life drugs criteria" to approve sunitinib for the NHS (see https://www.nice.org.uk/guidance/ta169/documents/david-chao2). To some extent, giving more weighting to QALYs produced by sunitinib might have compromised NICE's ideology of fairness. The QALY-based CEA, employed to formulate technology guidance, was not merely a linear calculating technology but was constituted by the interplay between normalizing control and the resistance of those whom health technology appraisals sought to administer in the discursive field of CEA calculation.

The QALY-based CEA analyzed and translated complex clinical effectiveness and cost effectiveness into numerical information to create an appearance of legitimacy so as to underpin the rationality of NICE's technology appraisal. Numerical information was intended not only to normalize patients' access to new health technologies but also to inscribe the patients and clinical professionals acting in accordance to the norms. The case of RCC, however, showed that the norm constructed by the QALY-based CEA did not turn patients and clinical professionals into docile individuals but, on the contrary, incited a degree of resistance. The discursive nature of the QALY-based CEA provided a platform where contradicting ideologies were contested and struggles for self-interests were provoked. The patients and clinical professionals exploited the discursive nature of calculating technology to exert their influence to compel changes in the application of the QALY-based CEA. The patients, in particular, were not merely calculated subjects but actively entered into the discourse to pursue their own interests. In order to alleviate such resistance and re-establish the creditability of its technology appraisal, NICE was persuaded to integrate the interest of the "identifiable" patients into the calculation of the QALY-based CEA. Changes made by NICE were not merely a reaction to rectify the dysfunctional aspect of the QALY-based CEA but were attributed to its discursive forces. It was the reciprocal influences derived from the discursive field that aggravated such changes (Miller, 1990). The formulation of NICE technology

guidance was not merely dependent on linear calculation of CEA but was also constituted by the interplay between normalizing force and resistance among NICE, the patients, and clinical professionals. The discourse of CEA served as a medium where struggles for interests and power were enmeshed and settled (Covaleski et al., 1998).

## 5 | CONCLUDING DISCUSSION

This study examined the interplay between normalizing control and resistance in the discursive field of the QALY-based CEA calculation and its impact on the application of such calculating technology. By drawing evidence from NICE's appraisal of the drugs developed for a rare form of cancer, this study found that power relation constructed by the normalizing technique was not directional but reciprocal (Miller, 1990). It demonstrated that calculating technologies created a discursive field in which not only normalizing control was purported but also resistance was made possible (Brivot & Gendron, 2011). Exercise of normalizing force and resistance was mutually constitutive in such a way that contesting ideologies were enmeshed and changes in the application of the QALY-based CEA were induced,

The QALY-based CEA was intended to fabricate and disseminate the notion of fairness so that the relation among NICE, the patients, and clinical professionals could be defined and normalizing force could be exercised. It is evidently problematic, however, for NICE to adopt a rational calculating technology to convene and transform the subjective meaning of fairness into reality. The theoretical underpinning of the QALY-based CEA did not warrant NICE adopting a definite opportunity cost threshold as the norm for accepting or rejecting a health technology. When such calculating technology was applied to the drugs developed for RCC, numerical figures induced resistance rather than conformity from the patients and clinical professionals concerned. The patients and clinical professionals did not accept ICER per QALY that was subjected to manipulation and interpretation as the norm. Neither did they see themselves and their choices to be subjugated by such normalizing technique. They actively engaged in the discourse of QALY-based CEA calculation to influence the formulation of the norms through exploitation of its technical defect and deployment of their own notions of fairness. The discourse of CEA, to a great extent, provided a medium to which contesting ideologies of fairness were exchanged and resistance was provoked so as to deform its calculation for the pursuit of one's own interest. Resistance enacted by the patients and clinical professionals, although not deliberately orchestrated to coincide with each other (see Foucault, 1986), was effective in persuading NICE to incorporate their interests into the calculation of QALY-based CEA. The incorporation of social values to approve sunitinib not only compromised the theoretical underpinning of the QALY-based CEA but also hindered its normalizing force.

The operation of government program significantly relies on calculating technologies to prescribe norms so that individuals can be turned into governable subjects (Edwards, 2018; Rose & Miller, 2008). This study further argued that calculating technologies were not merely confined to the actualization of government program but also created a discursive field, which induced recalcitrance and defiance toward imposed governing force (Foucault, 1983). The formulation of the norms derived from the QALY-based CEA was not only constituted by NICE's will to administer fair access to health technology but was also "transformed by those who bend, divert, and subvert it to service their own purposes and becomes a form of their own power/knowledge …." (Covaleski et al., 1998, p. 324). The discourse of the QALY-based CEA allowed resistance to transcend the normalizing control that such calculating technology purported to enforce. Although the discourse of CEA might be suffused with struggles for contesting ideologies and interest, its discursive nature enabled the patients to strive for their interests and NICE to re-establish its authority and legitimacy. It is the discursive characteristic of calculating technologies to which the seemingly conflicting interests were interwoven and settled (Miller & Power, 2013). Calculating technology in the government field might not produce deterministic power of control (Brivot & Gendron, 2011) but is subject to reciprocal influences (Miller, 1990). In other words, its formulation not only constituted but also was constituted by the interplay between normalizing control and resistance.

## DATA AVAILABILITY

The data that support the findings of this study are openly available from NICE at https://www.nice.org.uk/guidance/ta169/history

## CONFLICT OF INTEREST

I confirm that this paper is based on a self-funded research. There is no conflict of interest with any member of the editorial board of Financial Accountability & Management.

## ENDNOTES

[1] For the technology appraisal, NICE commissions an independent appraisal committee, consisting experts in relevant field, to assess the clinical and cost effectiveness of treatments for use within the NHS.

[2] The social value judgments include four principles, namely, respect for autonomy, nonmaleficence, beneficence, and distributive justice (see NICE, 2008a).

[3] Consultees have the right to appeal if they are not satisfied with decision made by NICE appraisal committee.

[4] As the original comments were not released by NICE, this study relied on a summary of their comments prepared by NICE's Patient and Public Involvement Programme and Equality handling team.

[5] The assessment group, commissioned by NICE, consisted of health economists and medical statisticians. None of the assessment group members was a qualified clinical or medical professional.

[6] Only NHS Cambridgeshire, a health care commissioner, was agreeable with the preliminary recommendations.

[7] Quotes made in this paragraph are available from https://www.nice.org.uk/guidance/ta169/documents/report-to-the-appraisal-committee-summarising-comments-received-by-letter-and-email-on-the-appraisal-consultation-document-prepared-by-the-patient-and-public-involvement-programme-ppip-and-enquiry-ha2.

[8] The other three drugs were rejected by the appraisal committee. Although four consultees appealed against the decision, their appeals were eventually dismissed by an independent appeal panel (see https://www.nice.org.uk/guidance/ta169/documents/renal-cell-carcinoma-appeal-decision2).

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