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# **Trust, regulatory processes and NICE decision-making: Appraising cost-effectiveness models through appraising people and systems**

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## **Abstract**

This article presents an ethnographic study of regulatory decision-making regarding the cost-effectiveness of expensive medicines at the National Institute for Health and Care Excellence (NICE) in England. We explored trust as one important mechanism by which problems of complexity and uncertainty were resolved. Existing studies note the salience of trust for regulatory decisions, by which the appraisal of people becomes a proxy for appraising technologies themselves. Although such (dis)trust in manufacturers was one important influence, we describe a more intricate web of (dis)trust relations also involving various expert advisors, fellow committee members and committee Chairs. Within these complex chains of relations we found examples of both more blind-acquiescent and more critical-investigative forms of trust as well as, at times, pronounced distrust. Difficulties in overcoming uncertainty through other means obliged trust in some contexts, though not in others. (Dis)trust was constructed through inferences involving abstract systems alongside

actors' oral and written presentations-of-self. Systemic features and 'forced options' to trust indicate potential insidious processes of regulatory capture.

### **Keywords**

health technology assessment, NICE, pharmaceuticals, regulation, trust, uncertainty

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### **Introduction: Developing understandings of trust in regulatory decision-making**

Trust is often described as integral to the social processes of scientific research (Shapin, 1995; Collins, 2001), as it is for decision-making within the regulation of technologies (Bodewitz et al., 1987; Downer, 2010). Hedgecoe (2012: 663) has recently harnessed ethnographic methods in opening up the 'black box' of regulatory decision-making, emphasizing the importance of local situational-relational knowledge, presentation-of-self and the interpreting of such 'facework' (Giddens, 1990: 85) when analyzing how decision-making processes and outcomes 'happen' 'on the ground' (Light and Hughes, 2001: 559). In this article we seek to build on this and other recent work (e.g. Abraham, 2008; Downer, 2010; Stark, 2013), to explore how regulatory decisions are embedded within relations of trust and distrust. To earlier work we add empirical and theoretical refinements via an ethnographic study into the regulation of the cost-effectiveness of new and expensive medicines, as carried out in England by the National Institute for Health and Care Excellence (NICE).

Earlier studies have afforded valuable insights into the difficulties of regulatory decision-making, given uncertainties arising from experimental data as well as the complexity of reconciling 'heterogeneous data' across several systems of expertise, within a decision structure contorted by power dynamics involving multiple stakeholders (Bodewitz et al., 1987; Black, 2008). More recent insights, drawing upon documentary and/or interview data, highlight trust as indispensable in guiding 'negotiated' (Abraham, 2008: 415) and 'tacit' judgements (Downer, 2010) that become fundamental where regulation is as much 'art' as 'science' (Bodewitz et al., 1987: 247). Hedgecoe's (2012) study of local research ethics committees in England, collecting observational and interview data, provides insights into how relations with applicants give decision-makers a 'feel' (p.671) for the proposals they are scrutinizing. Hedgecoe (2012:676), alongside Stark (2013), accordingly emphasizes the symbolic nature of such trust and the weight of interpreted interactions (Collins and Evans, 2007) in shaping regulatory decisions towards different outcomes.

These recent studies focus on trust in the 'regulatees', such as the manufacturers of aviation (Downer, 2010) or pharmaceutical (Abraham, 2008) technologies and various professional-experts who are more or less closely bound to them or, in Hedgecoe's (2012) and Stark's (2013) cases, researchers applying for ethical clearance for clinical studies. There is much less emphasis upon trust in fellow decision-makers and decision-support within the regulatory organization. Given that the data scrutinized and analyses considered are increasingly technical and produced across multiple disciplines and abstract systems (e.g. Downer, 2010), many regulatory committees are themselves becoming more multidisciplinary, with no one individual being expert, or even fully proficient, in all the pertinent considerations which inform decisions. Accordingly, trust in other experts (Abraham, 2008) and regulator-

colleagues – as well as the interface of these collegial relations with trust in manufacturers and the data they provide about their technologies – may become increasingly salient and requires detailed investigation.

One tension within the emerging literature on trust within regulatory decisions pertains to the analytical connection between trust in individuals and considerations of abstract systems. Hedgecoe (2012) draws on his own data and other empirical studies of regulation (e.g. Collins, 2001) in stressing the importance of interpersonal relationships, developing a corresponding critique of Luhmann's (1988) and Giddens's (1990) emphases on the expanding role of abstract systems. Yet this tale of two contrasting narratives belies more recent sociological approaches to trust (e.g. Möllering, 2005; Brown and Calnan, 2012), that emphasize interwoven systems *and* interpersonal encounters as bases for trust. Indeed, this understanding is present within Giddens's (1990: 83) consideration of face-to-face interactions and commitments at 'access-points' as informing and informed by views of abstract systems, with one feeding back upon the other.

From these latter perspectives, interpersonal trust is reliant upon more or less implicit understandings of the normative frameworks that bind actors (Möllering, 2005), whereby understandings are developed through the application of 'ideal-typical knowledge' (roughly construed generalized understandings) of the prevailing normative structures within particular organizations and settings (Brown and Calnan, 2012). These latter theorizations indicate the need for a more complex understanding of trust that considers system-perceptions *and* interactions. Such an approach is implicit within Hedgecoe's (2012: 672) analysis, in the gradual systemization of ethics committees' understandings of particular

research teams as these develop over time (see also Bodewitz et al., 1987: 258), but would benefit from more explicit and detailed analysis – especially where this pertains to regulation involving larger, less familiar and more distant organizations. The transnational context of pharmaceutical manufacturing and testing is one salient example (Petryna, 2009).

Abraham's (e.g. 1995; Davis and Abraham, 2013) expansive research into pharmaceutical regulatory practices has focused on the influence of these large transnational manufacturers, raising concerns about changes in the regulation of medicines safety, particularly the increasing 'capture' of regulatory procedures by industry. Trust is denoted as one route by which such capture may be enacted (Bodewitz et al., 1987; Downer, 2010), with regulators seemingly shifting from a more 'investigative'/sceptical towards a more 'acquiescent'/docile format of trust (Abraham, 2008) – especially as their resources (not least of which is time) are squeezed by new policies advocating quicker patient access to new products (and quicker manufacturer access to the market).

Abraham's two modes of trust echo distinctions between more critical-conditional and more blind-accepting trust approaches presented elsewhere (Walls et al., 2004; Calnan and Rowe, 2008). However, there is friction between descriptions of increasingly acquiescent tendencies over time (Abraham, 2008) and broader narratives of trust in experts (Giddens, 1990), healthcare organizations (Calnan and Rowe, 2008) and regulators (Wall et al., 2004); all of the latter suggest the increasing salience of a more critical trust in understanding the perspectives of various stakeholders. These two positions are not irreconcilable: none of the latter narratives relate to perspectives of the regulatory bodies themselves, which are the focus of Abraham's study. However, the friction nevertheless indicates the possibility of an

approach that considers combinations of Abraham's (2008) starkly contrasted 'investigative' or 'acquiescent' modes.

Such a development would also be in keeping with the phenomenological and neo-institutional roots of sociological analyses of trust and organizational decision-making – with their emphasis on the 'taken-for-granted' (Möllering, 2006). From these perspectives, trust – and indeed any decision – is always and necessarily to some degree acquiescent or 'docile' (Simon, 1982: 202), especially when faced by manifold complexity (Luhmann 1985). Considering where trust involves the confronting of uncertainty in a more investigative-critical manner and where, within the same regulatory appraisals, trust is assumed in a more acquiescent or blind format can therefore tell us much about the nature of regulatory decisions and the subtle influences of power within these (Stark, 2013).

#### **NICE cost-effectiveness appraisals: Increasingly complex and multidisciplinary**

Trust can be conceptualized as a social process by which uncertainty and complexity are 'bridged over' on the basis of expectations regarding individuals' competence and motives, in light of broader social contexts that support these actors' abilities and constrain their intentions (Möllering, 2001; 2005). Following Khodyakov (2007), amongst others, we understand trust as a process rather than as a single decision. The development of NICE technological appraisals is of special interest in that: a) growing complexity and uncertainty (Moreira, 2011; Syrett, 2006) may be making trust more necessary; b) the imposed reformatting of NICE regulatory decision-making may be shaping the development of trust and distrust in particular directions (Abraham, 2008); and c) abstract systems and institutions, in which (dis)trust is embedded, have developed various relational dynamics

around NICE over its regulatory history (Black, 2008). The interweaving of these tendencies becomes apparent in the development of NICE as a regulatory organization, as is briefly explored below.

The decision to nationalize healthcare while leaving the manufacturing of medicines in the commercial sector has led to particular regulatory dynamics developing around the British state's oversight of 'safety, efficacy, cost-effectiveness, profits, pricing and advertising' (Abraham, 2009: 101). Each of these different aspects has attracted varying rules and depths of (self-)regulation, but for many years pricing and cost-effectiveness were balanced between two rather *ad-hoc* and pragmatic systems: the Pharmaceutical Price Regulation Scheme – where manufacturers effectively set their own prices while keeping their profits below an agreed level (see Abraham, 2009); and 'dilution', where National Health Service (NHS) spending decisions were decided locally by senior doctors in keeping with budgetary constraints (see Crinson, 2004).

Although both systems still operate over the bulk of NHS drug purchases, attention to differential patient access to some newer and expensive medicines (criticized as a 'postcode lottery') led to the pursuit of a more nationally-homogenous proceduralism under the auspices of NICE in 1999. The shift from informal, behind closed doors 'club' governance to highly formalized evidence-based decisions was designed to build a system of objective and transparent regulation (Moran, 2003), centralizing and neutralizing decisions over patient access to expensive medicines via the rationality of NICE technological appraisals. NICE was accordingly heralded as a distinctively modern Special Health Authority, epitomizing the evidence-based policy approach espoused by the Labour administration that



inaugurated it. The institute was charged with defusing sensitive rationing decisions and publishing clinical and public health guidelines through systematic appraisals of existing evidence (Crinson, 2004).

Yet the new system, despite clear criteria and rational procedures centring upon the cost per quality adjusted life year (QALY) added by a medicine, has continued to attract high levels of criticism (Littlejohns et al., 2009). From the earliest appraisals, criticisms have been levelled at NICE for not sufficiently including patient and public voices, as well as for hindering and delaying access to medicines (Crinson, 2004). Any system of access to healthcare technologies involves bioethical dimensions configured, at least in part, by dominant governing ideologies of those in power (Thompson, 2013: 19). NICE could be considered to sit somewhat awkwardly between the evidence-based 'culture of the expert' and deliberative democratic ideals of the New Labour administration. These tensions can be seen as having been exploited increasingly by the pharmaceutical industry, which has challenged NICE through legal contestations of decision-making procedures, through the influence of patient groups and media criticism, as well as by making pricing agreements with the Department of Health that have circumvented and thus undermined NICE decisions (Crinson, 2004; Abraham, 2009). The undermining of NICE may have eroded the original zealous spirit with which it was established (Abraham, 2009), though that point is difficult to establish. NICE has only categorically rejected 14 per cent of the technologies it has appraised, with the annual percentage of outright 'no' decisions increasing between 2004 and 2009 (Cerri et al., 2014: 137). The more recent position of NICE has again involved tensions between the much weaker emphasis on evidence-based decision-making of post-2010 Conservative administrations and the need to curtail NHS spending within a climate of

austerity and inexorable demand. Constrained finances arguably render NICE's pursuit of value-for-money more important than ever, yet NICE itself is beset with budgetary pressures.

Central to a NICE appraisal of a drug is the modelling of its typical benefit – usually drawing on emerging data from limited trials with less than perfect quality-of-life outcome measures – in relation to its additional cost (via incremental cost effectiveness ratios or cost per QALY). Multidimensional complexity and uncertainties are already apparent within these projections (Pinch, 1993). The gradual amendments to NICE procedures following various politicized episodes of critique have resulted in further complexity, as further uncertainties have been 'revealed' and the scope of decisions widened (Bodewitz et al., 1987; Crinson, 2004; Moreira, 2011). Procedures to take into account end-of-life impact, technological novelty and equality-of-access issues, alongside a more explicit yet flexible threshold (NICE, 2009), can each be understood as emerging more or less directly in response to various political, media and/or legal challenges to NICE decisions regarding particular drugs.

The introduction and increasing use of Single Technological Appraisals (STAs) since 2005, whereby one new drug is considered against existing standard treatments (rather than against other novel competitors), has simplified processes in some senses. However, this was a response 'to ensure that NICE appraisals can be published as soon after the licensing of new drugs as possible' (Littlejohns et al., 2009:420) and therefore compresses consideration of evidence amidst this 'fast-tracking' of regulatory decisions (Abraham, 2008). STAs thus differ importantly from Multiple Technological Appraisals (MTAs):

whereas in MTAs a number of similar medicines are modelled alongside one another in terms of their relative cost-effectiveness by an independent team, the focal point of STAs is a cost-effectiveness model of a single drug prepared by its manufacturer. This shifts the regulatory context towards the type of setting explored by Downer (2010) where, as with his case study of aviation safety in the United States, regulators come to delegate important aspects of regulatory work to manufacturers.

Further inputs into STA decision-making are multidimensional, ranging from critical remodelling of outcomes measures from clinical trials by independent experts along with considerations of different approaches for extrapolating and modelling quality-of-life, advice from expert clinicians over existing practices and the likely clinical validity of trial data, the advice of patient-experts who may have experience with the new technology, as well as written submissions from other stakeholders. This combination of quantitative analysis, technical or clinical interpretations, qualitative narratives and advice create significant problematics of 'integration' (Brown and Calnan, 2012: 62; Downer, 2010) or 'hybridity' (Moreira, 2011) across disciplines, especially when any one of the key drivers of the cost-effectiveness models may offer up 'vast fractal complexity if probed deep enough' (Downer, 2010: 85). While the NICE technological appraisal committees include a diverse array of clinicians, health economists and 'lay' members, it is very seldom the case that any one member possesses the specific clinical expertise, familiarity with illness-specific quality-of-life economic modelling *and* detailed knowledge of the pharmacology involved. Instead, such assorted decision-makers together 'must collaborate to form judgements based on compromises, best guesses and interpretations of limited evidence' (Downer, 2010:86).

Important insights into the asymmetric nature of this 'collaboration' already exist from an earlier study into considerations of evidence within NICE decision-making. Milewa (2006) describes the 'boundary politics' by which the forms of data and kinds of participants are valued differently within the process. Quantitative data and those familiar with statistical analysis were perceived as having more authority, with clinical experts particularly deferred to (Milewa and Barry, 2005; see Syrett, 2006 for a similar description of decision-making elsewhere within NICE). This contrasted with the more limited value given to patient advocates, partly because their experiences were seen as anecdotal but moreover because these views were described as 'always positive' and therefore of less worth (Milewa, 2006: 3108).

The relevance of trust is implicit within such studies, although the authors (Milewa, 2006; Syrett, 2006) do not directly address the concept. Other studies of NICE STAs, or other regulatory processes involving sophisticated technologies (e.g. Downer, 2010), tend not to advance beyond documentary and interview material as far as observing the deliberations and collaborations *in situ*, partly due to the sensitivity of the data discussed (Bodewitz et al., 1987:245). NICE technological appraisal meetings partly take place in an *open* setting, where the general public, media, employees of other pharmaceutical companies and others may observe (though not record) the proceedings. It is in this part of the meeting where manufacturer representatives are invited to offer clarifications in relation to specific queries from committee members and where the experts (clinicians and patients) are also encouraged to speak and answer questions. But it is in the *closed* part of the appraisal meetings – attended only by the committee-members (decision-makers), NICE personnel and the independent health economics advisors-scrutinizers (the Evidence Review Group or

ERG) – where appraisals appeared to be ‘decided’ upon. Our non-participant observations of both open and closed parts of the STA meetings thus granted us an important opportunity to open up the ‘messy reality’ behind the ‘white-boxing’ (ostensible transparency) of STA regulatory decision-making (Wynne, 1988; Downer, 2010: 86, 90). We now move to offer a more detailed account of the design and methods of data collection upon which our analysis of the nature and influence of trust relations within NICE STAs was based.

### **Method and sample**

In order to provide a ‘backstage’ ethnographic understanding (Hedgecoe, 2012: 666) of how uncertainties are recognized, ignored, grappled with and managed within regulatory decisions, we triangulated documentary and interview data with observations of NICE meetings (both open and closed), following three medicines through the committee stages of the NICE STA process between 2011 and 2014. Based on an initial scoping study and pilot work, three products were chosen on a basis of variation in the socio-cultural resonance of the illnesses they were designed to treat and included: a less ‘prominent’ but widely prevalent illness; a more high profile type of cancer; and a rare but life-threatening condition. The study was given ethical approval by the relevant university ethics committee.

Across the three cases and in our pilot work we observed twelve decision-meetings (including three pilot observations) using two observers – one focusing on recording content, verbatim quotes and procedure, the other on thick description of the setting, interactions and broader social dynamics of the meetings; we analyzed the official documents produced by NICE at the different stages of the STA process, both those

available online to the public (Appraisal Consultation Documents and Final Appraisal Determinations) and the documents prepared for those involved in the meetings, such as the detailed review documents prepared by the independent academic advisors (the ERG) alongside the reports by the drug manufacturers; and we interviewed 41 of the stakeholders involved (see table 1 for an overview), including varied members of the relevant appraisal committee and the chair of each committee, members of the ERG, representatives of the pharmaceutical manufacturers who attended the open meetings, expert clinician advisors, and expert patients. We supplemented this appraisal-specific sample by interviewing a range of managers within NICE.

**Table 1 about here.**

Interviews were largely based on one overarching format (adjusted slightly after piloting), though questions were partly tailored to the relevant roles and experiences of particular individuals. The interviews aimed to encourage participants to move between the specifics of the case-study appraisal and more general experiences and views of NICE STAs. This was to facilitate a contextual understanding of peculiarities and specificities of our cases in relation to more general norms and patterns and *vice versa*. Interviews lasted between 40 and 90 minutes and explored more general views on the STA(s) regarding considerations of the (likely) decision-recommendation reached and its key drivers, issues of uncertainty and ways in which uncertainty was overcome, other influences on decision-making from within and beyond the committee meetings, and views on NICE and its processes more generally.

The analysis was focused on the central theme of handling uncertainty. Combining the perspectives of different researchers through co-observations and by using different

interviewers, and considering the insights afforded by the different forms of collected data (documentary, observation fieldnotes and interview transcripts) – the analysis explored different uncertainties as these were ‘revealed’ or ‘kept closed’ (Moreira, 2011) at different points of the STA process. In considering how uncertainty was handled and ‘bridged’ in order to reach a decision (Möllering, 2001), trust emerged as an important theme. The data coded as relevant to trust were considered critically in light of existing theory, while these theoretical assumptions (along with those present in the literature review above) were also interrogated in light of the data (Meyer and Lunnay, 2013). Salient themes emerging within these analytical processes are outlined below.

### **Investigative (dis)trust of manufacturers: Combining system and facework insights**

The central basis of the cost-effectiveness appraisals is trial data and the insights these are assumed to ‘project’ (Pinch, 1993) regarding the impact of the drug upon patients’ length and quality of life. As acknowledged, both regarding pharmaceuticals (Will, 2010) and other technology regulation (Downer, 2010), outcomes measures in trials themselves seldom map neatly onto the key considerations of regulatory decision-makers. The main clinical trials that informed the three appraisals had been designed many years earlier and were largely inadequate in generating appropriate data for appraising cost-effectiveness regarding quality of life, more narrowly focussed as they were on clinical effectiveness. Extrapolations from the surrogate endpoints measured in these trials to modelled cost effectiveness for the ‘average’ patient were accordingly necessary (Abraham, 2008; Will, 2010). These inferences involve many assumptions (MacKenzie, 1990: 354) but should be performed in line with

prevailing norms within health economics, as a means of developing legitimate incremental cost effectiveness ratios (ICERs) for the appraisal medicine (Philips et al., 2006).

Unlike Multiple Technological Appraisals (MTAs), the cost-effectiveness modelling within STAs is initially developed by the pharmaceutical manufacturer, before being scrutinized by independent academics (the ERG) and the committee. Such delegation to the manufacturer occurs within several forms of technology regulation (Downer, 2010) and, in our STA cases, was the basis of several concerns for committee members:

I think that multiple technology appraisals, when you've an independent assessment group, independent from the company, producing the model ... and presenting the data, you know, you would be more confident that because of their independence, that the outputs are probably more what one may expect. (Case Z-08)<sup>1</sup>

Thus the format of STAs shaped the relative confidence or system-trust (Luhmann, 1979) regarding the modelling of data. Concerns regarding the STA system were regularly related to the instrumental strategies of the pharmaceutical industry, in the form of wariness toward presented data:

Drug manufacturers are, you know, are a bit like second-hand car salesman ... they'll say, 'Oh yeah, it's a lovely runner', you know, 'One ... one careful lady owner only.' But, you know, which may or may not be true but they are basically trying to flog their product ... they're not charities. (Case Y-06)

These less-than-trusting assumptions, based on the market orientation of medicines manufacturing and related perceptions of underlying motivations, were common themes in



the interview accounts of NICE committee members. Various members described how their experiences on the committee had gradually led to perceptions of STA processes as involving two sides playing a game:

While I used to get a little bit frustrated, let's say, when there were glaring omissions or when critical points are buried within hundreds of pages of material that you need to read ... that's just part of this process and, just, it's ... it's just an understanding that ... that's their job. Their job is to try and put their best foot forward in whatever model they have produced, to make their drug look as cost effective as possible and, as long as you understand that and ... then just get on with it and have a good ERG that can critically appraise what they've done, well that's really what it's all about.

(Case Z-08)

This interview excerpt captures a rather typical position of the committee members towards manufacturers and their submissions. There was a basic assumption that the manufacturer would seek to illuminate or obscure data in order to cast their technology in as positive light as possible. These perceptions of the pharmaceutical industry system with its particular norms, values and practices (Möllering, 2005) shaped a general default position of scepticism when reading submissions:

I think the committee starts from the position that they don't trust the manufacturer  
.... (Case X-05)

Such a tendency was corroborated in our own observations as well as the views of others. One clinical expert described committee members trusting the manufacturers 'as far as they can throw them' (Case X-fieldnotes). Not all committee member participants referred to a distinct distrust, however, with a small number referring to remaining 'open-minded'. But if

committee members generally saw manufacturers as playing a game – ‘a game of cat-and-mouse’ as one put it – a number of them nevertheless considered this game to be underpinned by some basic assumptions and parameters:

Yes, there is trust ... that they are not deliberately trying to deceive us. (Case Y-05)

I don't know of anything they deliberately hide. They might emphasize the tone of things but I don't think they hide, as far as I'm aware of. (Case Z-05)

Starting from these basic system-understandings, committees quickly developed views regarding specific submissions and the manufacturers behind these in light of the perceived quality and transparency of submitted written documents (Hedgecoe, 2012). As noted already, these submissions could be very long and at times it was suggested that the length of a submission was a deliberate ploy to ‘bury’ weaknesses amidst complexity. Conversely, clear and transparent submissions were appreciated and elicited positive esteem of the case being made and of the manufacturer:

It's to do with whether or not it looks as though it's hiding stuff and, you know...whether you can follow a sort of audit trail of how the numbers that make up the final calculation have been derived. And sometimes that's straightforward and often it isn't. (Case Z-01)

Committee members referred to the quality and legibility of individual reports as very important (Stark, 2013). Ongoing direct experiences with submissions from certain manufacturers over a number of different appraisals could shape more generalized perceptions of specific manufacturers (Giddens, 1990), which nuanced the default position of a lack of ‘system-trust’ (Luhmann, 1979) in drug manufacturers more generally:

I think some of the companies produce much better open and transparent models than others. (Case Z-08)

These could lead to perceptions of specific companies, especially of some larger manufacturers, as being more likely to manipulate data in particular ways:

I guess just informally as well, I sort of...just, certain companies get a reputation.

(Case Z-12)

From our interview data it was difficult to evaluate the extent to which these reputations shaped the ways in which individual submissions were read, but general views regarding certain manufacturers were aired by a number of committee members.

Following scrutiny of the initial submission, a dialogue would usually emerge between the ERG and the manufacturer (with communication taking place via NICE) and, later on, between the committee and the manufacturer, whereby the manufacturer would be asked for further clarification or evidence regarding particular aspects of the cost-effectiveness modelling. The response of the manufacturer at this point could be interpreted positively, as a result of its perceived willingness to substantiate the credibility of its product, or more negatively, when the lack of a direct, constructive reply was seen as damaging the credibility of the manufacturer and submission (Hedgecoe, 2012; Stark, 2013).

In all three of our cases, manufacturers' omitting or including certain details in their written submissions and written responses, as well as in their oral 'presentation-of-self' in the appraisal meetings, appeared to damage the view of the committee towards their submission at different moments. These lapses were noted by many committee members as well as by others involved, such as this expert clinician:

You know, I had a [good] reason to give trust to them [but] I have to say I was irritated with [manufacturer] though .... Because I ... I wanted them to step up to the plate a bit more because I wanted the drug to be available .... And I thought they could have done a better job. (Case Y-08)

Indeed, in our fieldnotes of the same case, a poor performance of the manufacturer in the meeting, as well as in the written submission, appeared to do much to undermine credibility:

The manufacturers seemed to lose their credibility as the meeting developed, due to their increasing inability to answer questions of clarification. These included questions that related to the obscurity of the techniques used in the statistical analysis, the reason for the lack of up-to-date references and failures to respond to earlier queries from NICE. (Case Y fieldnotes<sup>2</sup> – open meeting)

Similarly, in Case X, the credibility of the broader submission was damaged by interpretations of specific aspects of the manufacturer's written and oral presentation-of-self. In the words of one committee member:

I'm a clinician, looking at another clinical trialist ... and going on the fourth of these trials, with [a large number of patients<sup>3</sup> as] incorrect enrolments, I ... I have immediately serious questions about the quality of these studies. (Case X-01)

Alongside the use of problematic trials as evidence in the written submission, those representing the manufacturer in the meeting were unable to clarify various concerns of the committee:

And that was somewhat frustrating and you could see that from the committee members, that they were quite frustrated with the manufacturer for not providing the information that they requested. (Case X-08)

Committees' default lack of trust could be overcome through effective and compelling communication, but – as with the two cases described above – could also shift towards disdain due to misjudged and/or ill-informed communication. This latter tendency was usefully explained by another committee member who worked for a manufacturer:

[I]t is almost sort of a bit adversarial, 'the enemy', kind of thing and I understand ... some of the reasons for that ... some of that is the fault of the manufacturers and who they send. Sometimes it's not the appropriate people .... A little bit too marketing rather than clinical or health economics ... I think that gets the ... the Chair's back up a little bit. All the members of the committee get a little bit riled if they hear some sort of marketing speak when asking a question to the manufacturer. (Case Z-12)

'Marketing speak' – in evasive or simplistically positive accounts of medicines given by non-experts – not only reinforced negative perceptions of the underlying motives of the manufacturer, but the lack of expertise and ability to bring clarity to a complex process was seen by some as manufacturers 'playing a game of confusion', as one chair suggested during a closed session. The boundary between marketing and knowledge production within pharmaceutical development is blurry (Sismondo, 2008) and, as we have seen, committee members expected and tolerated certain levels of favourable presentation of trial data, to the extent that the drivers and assumptions within such modelling were articulated in a clear and expert way. Where expertise and/or clarity were understood to be lacking, however, this

was likely to heighten distrust.

### **Trusting in expert others: The limits of investigative trust**

Rather than routinely displaying acquiescent trust, therefore, committee members often took a highly investigative and at times aggressively contemptuous approach towards manufacturers. One expert-patient noted:

I was glad I wasn't one of the manufacturers because I felt they were mauled ... really ... I was open-mouthed with the ... the aggressive tone that the committee came at them with. (Case X-02)

Yet alongside investigative and non-trusting approaches certain levels of acquiescence were also apparent. For example from one of our pilot observations:

... a newish member of the committee raises significant concerns about basis of the whole model and the width of the confidence intervals which seemed to render a meaningful decision/estimation very problematic. The Chair says (s)he 'hears' him and indeed the committee member 'is preaching to the converted', but that this model from the manufacturer is 'much much better' than the usual standard within this specialism, therefore this is not the case on which to make a stand.<sup>4</sup> (Fieldnotes-pilot closed meeting)

Thus even where submitted models were deemed to raise large concerns regarding residual uncertainties, these could nevertheless be 'bridged over' in light of understandings of what was 'normal' and thus expected within submissions.

Trust certainly appeared to shape decision-making but a lack of trust or even distrust in a submitted model and the manufacturers behind it was, on its own, an insufficient basis for a 'no' decision. In part, this was because 'distrust of manufacturer' would be an inappropriate argument within the framework of rational reasoning and documentation that NICE committees are required to produce, especially given the normalization of a limited trust in manufacturers. In addition, a lack of trust in authors of submissions was, on its own, insufficient for overcoming the myriad complexities and uncertainties surrounding the model (Hedgecoe, 2014: 69). (Dis)trust in manufacturers was thus only one element of a broader web of trust relations and other modes of handling uncertainty.

As noted above, the extrapolation from trial data to quality-of-life for the average patient was central to a submission. Views of the credibility of this modelling were strongly influenced by the clinical experts invited to attend the open part of some of the meetings. Indeed, the accounts given by these experts, often representing a relevant Royal College, could amidst certain conditions appear to be decisive (c.f. Milewa and Barry, 2005). As one committee member described:

[T]he evidence wasn't great ... but the evidence they did have did show improvement and what swayed it actually for me, and for a lot of people, was the expert ... the [specialist] who said that this really was a change of treatment paradigm. Because it was such an expensive drug it ... it got through actually, but it was on the verge of not getting through. (Case X-06)

Yet invited experts could also be seen to have an agenda (see quote from participant Y-08 in the preceding section). These agendas were sometimes described as concrete conflicts of

interest in terms of working (or having worked) with the manufacturer or the patient group, or in terms of more subtle concerns that these clinicians wanted the drug for patients in their specialism. The committee member (Case X-06) quoted directly above described this same decisive expert as 'an advocate, obviously, of the drug'. Thus there seemed to be tensions between the lauded expertise of these clinicians and the motives that rendered them less trustworthy. Committee members described different ways of overcoming this aspect of uncertainty, and some distinguished between 'good' experts and others who were less credible:

Because they were ... they were ... they actually did answer good questions, they were good .... And they gave a good analysis, you know. They're not always .... Those two were good. (Case Y-07)

How 'good' experts were to be distinguished from others was not easy to elucidate. For example, whereas our fieldnotes for one of the meetings for case Z recorded:

The expert clinician appeared to have a bit of an agenda; more so than other appraisals we have observed. He seemed keen to keep emphasizing the importance of [the key feature of the submission], almost whatever the topic ... which could well be valid but fitted nicely with the case of the manufacturer. There were quite a lot of discussions between this expert and manufacturers before the meeting. (Fieldnotes case Z – open meeting)

Later in the closed meeting a committee member said:

I was quite impressed about how clear [name of expert clinician] was, and he was quite objective ... he seemed quite convinced ... [about the extrapolation as a] predictor of survival.



The chair agreed, saying:

he was objective and he was sensible ... [the case] is contorted but there is something in it .... (Fieldnotes Case Z – closed meeting)

Other committee members referred to trying ‘keep in their minds’ that the individual who carried such great expertise could also have a biased agenda:

You know, if a treatment really isn’t particularly effective, I try and keep that at the front of my mind, despite when the [expert] doctors are saying, ‘Oh we need this treatment’, or the patients are saying, you know, ‘We ... we would really like to have this treatment’; because sometimes I think they do miss the fact that this is not a new wonder drug. (Case Y-10)

As this last excerpt touches on, committee members also had to consider the views of patient-experts. The role of patient-experts has increased since NICE appraisals were inaugurated, in an attempt to enhance legitimacy by extending societal input into decision-making (Moreira, 2011). The accounts of patient-experts were described by some as useful in understanding the impact of the technology on ‘real’ patients (outside of clinical trials) and in bringing a human face into the deliberations:

I think we have a lot of compassion .... And when they tell us about the ... you know, sometimes how they have to live, there is a lot of compassion there and I think we do trust that they are telling us how it feels. (Case X-07)

Yet this willingness to listen and to understand the patient perspective sat rather uncomfortably alongside a broader recognition that patients were keen to access the

medication and that in many cases had links to the relevant patient organizations:

There's no patient expert that'll ever come along and kind of ... attempt to talk you out of it ... I think they're usually very carefully selected. My experience is that they tend to be heavily involved in self-help groups or patient support groups and that's a kind of a self-selecting. (Case Z-09)

Despite concerns regarding self-selection and other biases, alongside the difficulty of integrating individual qualitative narratives within quantitative econometric models, these expert-patient accounts did influence decisions. In Case Z, for example, the committee remembered the compelling account given by the expert-patient and referred to it in subsequent meetings. This was influential later in the decision-making when the committee Chair gave 'the benefit of the doubt' to the submitting manufacturer's 'less conservative' basis of modelling quality of life in order to acknowledge the impact of the medicine on patients' lived experiences. The accounts of the patient-expert and clinical-expert were referred to in reasoning this endorsement.

Giving the benefit of the doubt to this component of the model also implicitly gave the benefit of the doubt to the clinical and patient-experts. Despite close links with the patient organization, as seemed to be common, these accounts could not simply be discounted through distrust. Indeed, such views, especially those of the clinicians, were vital for the committee to cut through the manifold clinical uncertainties referred to elsewhere. The need to come to a decision and the reliance of the committee on these experts rendered some level of trust in experts' accounts a 'forced option' (Barbalet, 2009). With manufacturers'

modelling and experts, we saw a nuanced relationship between investigative and acquiescent trust, with the two held together in tension becoming an indispensable basis of regulatory decision-making.

### **Trust in committee colleagues and the ERG: Bridging expert-systems and uncertainties**

Thus far we have drawn attention to the multiple relationships that were fundamental in shaping the decision-making within our three NICE STA cases, as well as the different forms of (dis)trust that characterized those relationships. As was noted by one committee member quoted in the second data section, 'having a good ERG' was seen as the solution to the limited trust in the manufacturers' submission. The format of the STA means that these independent experts bear a great weight of the uncertainty involving the content and construction of the cost-effectiveness modelling, yet as one ERG expert noted this depended somewhat on the nature of the decision problem:

If ... the decision relies very heavily on the economic model, I would think the committee relies very heavily on the ERG. (Case Z-07)

Whereas more clinically oriented uncertainties were dealt with by listening to clinical experts and the clinician members of the committee, health economic considerations were deferred to the ERG to a large degree. But each committee also included at least one health economist and the views of these committee members regarding the ERG's assessments could be important in shaping how accepting or critical members were toward these assessment. One committee had only one health economist and accordingly the view of this committee member was referred to as being quite influential. In another committee, where there were a few health economists, a more discursive approach could emerge in debates

about the relative merits of the ERG's analysis, the possibilities for modelling added value and the assumptions implicit in each of these.

In either case, existing relations (either direct or more abstract) between health economist committee members and their ERG colleagues seemingly influenced the way the ERG's report was considered:

I mean there's a lot of mutual respect going on there as well and [health technology assessment] is a small field and we know each others' publications long before we ever met so .... I think that also, for instance, among health economists, simply the scientific publications are an important factor in who do you trust but – of course when it comes to the doctors you don't know what kind of research they do, I have no idea about their quality as a researcher .... (Case Z-02)

This view of one ERG expert suggested that their reports and the key arguments therein were evaluated not only on the merit of their content but in relation to the ERG personnel. Also a member of an appraisal committee, this participant referred to this relatively rich basis on which to consider the views of other health economists, in contrast to a weaker, less system-related knowledge of clinicians.

These concerns highlight the difficulty faced by 'experts' working on problems that span across multiple systems of knowledge (Moreira, 2011). In such contexts, where no one committee member was an expert in all aspects of the discussion, committee members described how they came to rely upon the views of particular expert colleagues on the committee. These trusted colleagues included especially the Chair and Vice-Chair:

I do start from the position of trust for my colleagues .... So, you know, [the Vice-Chair] is there, [the Chair] is obviously very good ... you know, you can't, you can't pull the wool over their eyes .... (Case X-06)

However, the expertise on the committees was described as extending well beyond the chairs to include various other pivotal members or 'super brains':

I've thought about this quite a bit over the years and I suppose what in my own mind was kind of a two ... a two-tier model of what goes on round the committee and there's the committee at large and then there's ... within the committee there are ... it's not a hierarchy – what is it? I'd probably term them 'super brains' ..., Yeah, ... I could follow eighty per cent, I would say, of the discussion and then there are times when I have to look to the super brains to clarify the issues; to, you know, explain them to me. (Case Y-06)

This participant framed deference to some colleagues in light of their strong abilities, but also as necessitated by personal limits in understanding. These limitations were a common theme, especially concerning the more 'lay' members of the committee:

[NICE] aims to give [committee members] enough, if you like, generalist, technical training ... to be able to understand the principles of which the modelling is carried out. And there is a one-day meeting to do that. Having said that, I still feel that a lot of the discussion is of a highly technical nature ... [it] is difficult, I think, for the generalist members to fully understand those nuances and I think [they] must therefore rely on the expert members of the committee to paraphrase and to explain. (Case Z-10)

Although in various ways a forced dependence, relying on experts was nevertheless referred to as embedded within a trust and esteem for these expert committee colleagues:

There's the existing committee members whose views are ... or whose ways of expressing themselves – if that's a way of putting it – I've learnt to respect. And I know they have particular expertise but when they open their mouths you think 'I'll listen to you' and I'll pay very close attention. So yes, trust and that builds up over time and I'm also more aware of it with new committee members where I listen to them in a different kind of way. It's not that I don't trust them but I haven't learned yet what to make of them. (Case Y-11)

The above statement captures a recurring theme regarding how trust in fellow committee members built up overtime. This trust was not purely based on expertise but also on a history of views expressed and presentations-of-self (Calnan and Rowe, 2008; Hedgecoe, 2012).

The status of certain key experts within the committees was also apparent within our observations, especially in the closed meetings. Not only did some committee members present a particularly confident and articulate self, but the way the views of these individuals were heeded and thus shaped discussions suggested a particular level of esteem and trust across the committee. In case Z, for example, much of the closed part of one meeting was shaped by the concerns and opinions expressed by one committee member, who was a consultant-specialist in the domain in which the medicine would be used. This clinician's opinion on certain matters was further requested at various points by the chair, for example in resolving queries aired by another committee member. This other member

went on to affirm: 'I am satisfied by the answer of my learned colleague' (Case Z – closed meeting, fieldnotes).

Trust in key experts or 'super-brains' could therefore play a significant role in directing the discussion and atmosphere of the closed sessions wherein decisions were reached:

We've got Chairs, Vice-Chairs, there's eminent clinicians and professors so, you know, that's the whole makeup of the committee. I think what you would find is if certain individuals aren't in the room for [the meeting] one month there will be a very ... there will be a different atmosphere of debate than there would be if they were in. (Case-Y-04)

Nevertheless, in pointing to this influence, it is key to acknowledge that expert committee members did not wholly define or direct the decision-making. Various committee members suggested that while they respected and listened to particular experts, their concerns and uncertainties were not necessarily resolved:

And, you know, so I really had to go along with my more learned colleagues on ... on those aspects of it but I still think, even now, I'm not one hundred per cent sure of whether we reached the right decision. (Case-X-07)

But although uncertainty continued to linger, 'going along' with a particular decision on the basis of trust was an important and not uncommon mode of reaching a decision, as explored in the final data section below.

**Acquiescing to the Chair as a 'forced option': Trust as one tool amongst many**

As identified at various points above, trust was certainly not the only mechanism by which complexity and uncertainty were handled within STAs. Procedures – by referring to explicit rules or more implicit norms – were amongst several common approaches invoked to ‘absorb’ complexity and uncertainty (Habermas, 1976). In the fieldnotes below, we describe how two considerations within one STA decision – whether to adjust the cost-effectiveness assessment in light of the drug’s impact on patients with less than two years to live, or because the drug was especially innovative – were ‘resolved’:

One of the main patient groups has made a case within its submission that the committee should be more flexible than usual with the cost-effectiveness threshold, due to the short life-expectancy of the patient population (STA ‘end-of-life’ rule). Data were provided as a means of verifying that the patient group met the necessary criteria for such a consideration. The chair talks through a PowerPoint presentation that includes a slide making apparent that the patient group did not, after all, fit all the necessary criteria, as previously confirmed by the clinical expert.

The discussion moved on to consider the extent of innovation. The chair felt the drug was not innovative in terms of the official criteria, although referred to the need to mention that one of the charities saw it as ground breaking, as another committee member did not want to be accused of not taking the patient-experts seriously. One committee member argued for its innovativeness and that, while it was not a new drug, it might be used in a different way. Others were not convinced it worked at all. One further committee member then commented on struggling to understand some



of the statistical analyses...The meeting was fairly abruptly drawn to a close. (Case-Y fieldnotes – closed meeting)

These two forms of consideration – impact on ‘end-of-life’ for those with limited life expectancy; innovativeness – have been introduced more recently within NICE technological appraisals, in response to external pressure, and have added further layers of complexity in reaching decisions. Nevertheless these concerns were overcome relatively straightforwardly in this case, by referring collated data (on the relevant patients and on the drug respectively) to the stipulations within the NICE ‘methods guide’. This rulebook, partly a codification of the tacit norms that have gradually emerged across appraisal committees over the years, expressed specific and clear criteria that assisted decision-making.

Yet the data still required interpretation in line with these rules. Sometimes this was done explicitly, as with end-of-life criteria in case Y, when two different accounts of the typical patient’s life expectancy (in different studies in the literature) were considered and the clinical expert helped to assess which of the studies were more clinically relevant. Regarding some other concerns, as with the innovativeness of this case Y technology, the Chair skirted past considerations more quickly (meeting sessions were often closed abruptly, without a clear announcement of the decision outcome), providing the impression that the issue was straightforward. However, as apparent in our fieldnotes above, various committee members perceived a much more ‘messy’ picture.

Thus the procedural aspects of STAs, such as norms and rules, were able to absorb, shift, reconfigure and even reduce complexity, but not to resolve it (Downer, 2010; Luhmann,

1979). Much uncertainty, which Renn and colleagues (2011) conceptualize as residual (unsolved) complexity, lingered on and could ultimately be resolved only by trusted individuals – the clinical expert and the Chair, in these two examples (Bodewitz et al., 1987; Downer, 2010; Luhmann, 1979: 93).

The way the Chair skirted around various concerns voiced by committee members, as seen in the example above, was seemingly facilitated by the high level of trust in this Chair, as expressed by a number of the committee members:

You know, we have a superb Chair on our committee .... I think (s)he's incredible actually. (S)he can pick up on any disease and (s)he understands it all. (Case Y-07)

Critics of such an interpretation within our analysis could point to other explanations as to how the Chair was able to 'drive to an efficient decision' (Case Z-12), such as a resigned deference of committee members who could be seen as having been purposefully disregarded. Across our interviews, though, there was a consensus that part of the Chair's role was to reach a decision despite lingering uncertainty. In an interview regarding this Case Y appraisal, it was described that:

I think [the Chair] kind of presented to the committee that ... that, 'This is a fudge factor [an imperfect resolution of uncertainty] you're just going to have to live with. We're not going to be able to ...' you know, 'deal with this.' (Case Y-08)

The impossibility of discussing or resolving every issue was held to render a degree of acquiescence (Abraham, 2008) or docility as highly necessary (Simon, 1982). Several members across the different STA committees underlined the levels of complexity and uncertainty, accepting the guidance of the chair as indispensable:

I mean clearly it's a very uncertain decision-making process anyway and I think, you know, by ... by [the chair] not guiding these things carefully what you end up doing is ... is just layering on, you know ... convoluted levels of uncertainty and so people ultimately, you know, find it very difficult to know one way or the other. (Case X-03)

Committee members' acceptance –contented rather than begrudging – of various concerns and uncertainties being bridged over by the Chair was seemingly fostered through a general understanding that their voice could and would be heard if they had outstanding concerns:

I think the current chair is very much more facilitative and tries to get everyone to say what they think and so on. (Case Y-11)

Such views, that this Chair was generally inclusive, therefore assisted an acquiescent trust of the Chair when a more 'driving' approach was being pursued.

As already discussed, acquiescence was also based on knowledge asymmetries and the Chair's understanding and familiarity with the specifics of the appraisal. Whereas part of the Chairs' working week was paid for (or 'bought out') by NICE, in order to prepare for meetings, the other committee members had to prepare in their free time:

So I mean the impression that I get is very often very few people read the whole submission. The health economists will read the health economist part. And clinical ... the clinician will read that bit .... Very few people actually try and get the whole thing in and try and understand where it's coming from. And it does feel a bit frustrating that you put all this effort. I think [one document for a meeting] was 900 pages! (Case-X-11)

This 'impression' was largely confirmed in our other interviews across many NICE committee members. Some had far more time than others to prepare, due to varying professional and other commitments, though most admitted that the volume of documentation prohibited a full reading of all the STA materials and related empirical studies. In contrast with many members who described struggling to deal with the volume of information, and/or to follow all the analysis as voiced by one member in the appraisal meeting (noted above), the Chairs were seemingly in control and well versed in the STA:

And the Chair, I ... I was, you know, sort of full of admiration both [for Chair and Vice-Chair] ... because they knew exactly what they were talking about and they knew what pages all these things had happened on .... (Case X-02)

A picture therefore emerged wherein the authority of the Chairs to bypass uncertainties was importantly explained by trust, based on views of their expertise, controlled handling of complex material, the necessity of driving towards a decision, and Chairs' (pragmatically) inclusive agendas. This acquiescent trust was, however, also based on the investigative qualities of the Chairs - as typified by the earlier quoted assertion that 'you can't pull the wool over their eyes'.

## **Conclusion**

Bodewitz and colleagues (1987: 251) argued that trust shapes science around medicines far more than science directs trust in medicines. This article has built on more recent work in this tradition (Abraham, 2008; Downer, 2010; Hedgecoe, 2012; Stark, 2013) to describe ways in which value-for-money regulation of expensive new medicines is importantly grounded

in relations of trust and distrust. Existing research has suggested that ‘regulators contend with an intractable technical problem by turning it into a more tractable social problem, such that, despite appearances to the contrary, the [regulators] quietly assess the people who build [technologies] in lieu of assessing actual [technologies]’ (Downer, 2010: 84; see also Hedgecoe, 2012). This assessment requires at least two important qualifications, at least in respect to our case study.

First, it must be recognized that the manifold and intractable uncertainties within NICE technological appraisals may be handled through an array of different mechanisms for managing uncertainty, including many calculative-probabilistic approaches, heuristics, emotions, norms and procedures (Zinn, 2008) – alongside trust. However, we agree with Downer (2010) insofar as many of these other decision-making tools nevertheless require interpretation and judgement, whereby it is ultimately only the judgements of fellow humans who can solve these reworked uncertainties (Luhmann, 1979). Thus trust or distrust in these fellows become highly salient for, if not defining of, analyses of outcomes of regulatory decision-making.

Second, past studies have tended to focus on trust in the regulatee (researchers, manufacturers, researchers linked to manufacturers and the like), whereas our study has noted the multiple and interwoven trust relations that shape NICE STA decisions. What emerged were complex networks (Tilly, 2005; Stark, 2013) or *chains* of trust and distrust (Brown and Calnan, 2016), for example: a lack of trust in manufacturers was countered by the expert scrutiny of the ERG and expert clinicians; the ERG report and other expert insights were, in turn, trusted to a greater or lesser degree based on a range of factors that

included the estimation of these experts by a few key committee members; these latter key 'super brains' were often trusted to a high degree by fellow members, which influenced the content and 'atmosphere' of discussions; and these deliberations were directed by a Chair whose ability to drive towards a decision was also grounded in trust.

What we have seen within these complex chains of relations are examples of more blind-acquiescent trust, more critical-investigative trust and, at times, pronounced distrust. While the last of these was reserved for the manufacturer, any of the relationships listed in the preceding paragraph could be seen to include more critical *and* more taken-for-granted aspects (c.f. Abraham, 2008) – in that trust always requires some leap of faith (Möllering, 2001). Investigative trust on its own can be seen as making decisions impossible (Hedgecoe, 2014). Uncertainty was so ubiquitous within STA appraisals that decision-makers became tolerant of unknowns, using trust in key colleagues, the chair, the ERG or expert clinicians to help bypass lingering uncertainties.

The need to reach a decision, within a *reasonable* timeframe and with other limited resources, could be seen to impose more acquiescent forms of trust as 'forced options' (Barbalet, 2009; see also Abraham, 2008). Whether it was deferring to experts outside or within the committee because of a lack of expertise or time to prepare, because of an underlying need to rely on the manufacturer's model to some degree, or to allow the chair to drive to a decision due to limited time and overwhelming complexity – committee members could be seen to give 'the benefit of the doubt' as a way of reaching a decision.

Above all, this decision-making pragmatism would seem influenced by acquiescence to and demand for expertise, as embedded within the broader culture and identity of NICE

committees and their evidence-based decision-making. Trust involves beliefs about a potential trustee's competency *and* motives (Calnan and Rowe, 2008), yet more competent displays by manufacturers or clinical experts were seemingly interpreted as a basis for the (partial) overlooking of their compromised motives. Where external clinical experts elicited special regard they could in some cases then be extended special influence and included within the *de facto* 'workgroup' (Hedgecoe, 2014), whereby uncertainty about their motives and those of others could be accommodated and normalized (Hedgecoe, 2014: 66).

In contrast, the less competent presentations-of-self by manufacturers led to an emphasis being placed on their alternative and suspect (marketing) agendas. Patient-experts were more commonly referred to as having potentially problematic motives than clinical experts, and the enhanced legitimacy and professional status of the latter seemingly rendered their conflicts of interests more likely to be overlooked. Yet the views of both of these types of experts were usually drawn upon to some degree, despite concerns about motives, due to the usefulness of the different forms of knowledge which they imparted in cutting through other aspects of uncertainty (Hedgecoe, 2014).

The contrasting status of clinical and patient-experts, along with the ways in which distrust of manufacturers was described, draws our attention to the salience of abstract systems for trust in specific individuals and their accounts regarding medicine efficacy. In emphasizing the salience of 'local knowledge' and interpersonal trust, Hedgecoe (2012) criticizes the tendency for recent sociological accounts to emphasize trust in abstract systems (e.g. Luhmann, 1979; Giddens, 1990). Our analyses suggest that the development of (dis)trust within NICE technology appraisals was not a case of either/or and instead an intricate

intermeshing of knowledge inferred from presentations-of-self with knowledge developed through understandings of social systems.

Understandings of systemic features of the STA format, of the nature of the pharmaceutical industry, of varying trustworthiness of different manufacturers, and so on, were each more explicitly or implicitly drawn upon when considering individual written submissions or the oral responses of manufacturers within appraisal meetings. In turn submissions and interactive 'access points' (Giddens, 1990) within appraisal meetings became important 'proxies' for developing understandings regarding the competency and motives of actors behind the medicine (Stark, 2013). Similarly, the familiarity of clinical experts with certain types of evidence-based medicine and recent research (Milewa and Barry, 2005), not to mention their connections with highly-regarded organizations such as certain Royal Colleges, were fundamental to legitimating inferences regarding their expertise, which informed and were also evaluated in light of presentations-of-self in the meetings.

The salience and visibility of systems-trust (Luhmann, 1979) is likely related to specific characteristics of NICE STAs – in dealing with fairly distant, large, often transnational manufacturers (it was not unusual for manufacturers to be represented at appraisal meetings by staff who had flown in from abroad) – in contrast to the 'local knowledge' of Hedgecoe's (2012) regional research ethics committees (c.f. Petryna, 2009). We must also emphasise that NICE STAs are a very specific type of technological appraisal and, in focusing on three individual technology case-studies, our study cannot represent the breadth of outcomes of broader studies (Cerri et al., 2013). Decision-outcomes across our three cases were less positive than the average. This makes our cases less typical but



potentially more informative, in that it has been argued that organizational studies of trust benefit by studying contexts where trust is lower and, accordingly, where less is taken-for-granted (Bijlsma-Frankema and Klein-Woolthuis, 2005).

By peering inside the regulatory box – black (Hedgecoe, 2012) or white (Downer, 2010; Wynn, 1988) – our ethnographic study has shed further light on the micro-dynamics of decisions and their structuring through trust. This gives us some detailed if not generalizable insights into possibilities of regulatory capture, a fairly consistent concern when exploring trust amidst regulation (since Bodewitz et al., 1987). Considered from a distance, NICE can be seen as a largely ‘investigative’ (rather than acquiescent) organization, yet our fine-grained approach has illuminated many aspects of acquiescent trust (Abraham, 2008). The grounding of these less conditional, more taken-for-granted, forms of trust in perspectives regarding social systems helps us understand how these systems shape decision outcomes. Abraham (2008:425) argues that the politics of the regulation of medicines does not only concern the manufacturer and regulator but also the steering role of the medical profession. That clinical-experts’ conflicts-of-interests are more often overlooked, in a way that those of manufacturers or patients are not, indicates the institutional power of the profession to shape regulatory outcomes and the potential conjunction of professional interests with those of manufacturers. Moreover, the more acquiescent aspects of trust that involve ‘options’ forced (Barbalet, 2009) by time, knowledge and resource constraints, alongside an inevitable reliance on manufacturers’ modelling work, indicate both the potential for capture as well as possibilities for policy interventions to ensure a more robust basis of regulation.

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**Table 1: Type of informants interviewed**

Committee members including chairs <sup>(a)</sup>	N = 23
Managers from NICE	N = 3
Patient organizations	N = 3
Drug manufacturers	N = 5
Experts from assessment group/clinical experts	N = 7
Overall Sample	N= 41 <sup>(b)</sup>

(a) Includes statisticians, health economists, clinicians, public health epidemiologists and lay members.

(b) Three were with NICE staff, 14 were in case study X , 12 in case study Y and 12 in case study Z. There were 15 face-to-face and 26 telephone interviews.

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## Notes

<sup>1</sup> All quoted participants are STA committee-members unless otherwise stated.

<sup>2</sup> These fieldnotes have been adjusted in order to maintain the anonymity of the appraisal and those involved. Further details have been added to reflect the documentary analysis.

<sup>3</sup> Precise numbers were given by this participant but these are omitted for anonymity reasons.

<sup>4</sup> We have obscured the sex of Chairs and some other individuals for anonymity reasons.

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## Author biographies

Patrick Brown is an assistant professor in the Department of Sociology at the University of Amsterdam. His research explores trust, risk, hope and related social processes of coping amidst uncertain healthcare contexts. His recent work includes *Trusting on the Edge* (Policy Press, with Mike Calnan) and *Making Health Policy* (Polity, with Andy Alaszewski).

Michael Calnan is Professor of Medical Sociology at the University of Kent. He has published extensively on a wide range of health-related topics. His recent books include *Trust Matters in Healthcare* (2008) and *The New Sociology of the Health Service* (2009). His current research interests include trust relations and the study of dignity.

Ferhana Hashem is a Research Fellow at the Centre for Health Services Studies, University of Kent and Director of Studies for the Centre's MSc programme. She is currently working on an NIHR funded study developing an isometric exercise programme for patients recovering from cancer, as well an evaluation study for the British Lung Foundation.