

Conceptual model for robust decisions

Modified version of paper under review at *Sociology of Health & Illness* as: *Kleinhoult-Vliek, T., de Bont, A., & Boer, B. Arguments in Networks – a conceptual model for robust health care coverage decisions*

INTRODUCTION

Long-debated and carefully made negative health care coverage decisions are sometimes followed by extensive media coverage and public discussion. Health care coverage, which deals with whether a health care technology is provided or not on a national level, is a contentious subject when the headlines, featuring sick people no longer receiving their too-expensive medicines, virtually write themselves (Abelson & Collins, 2009). Not rarely, public controversy results in the reversal of the original decision. These reversals often happen through a direct appeal to the Minister of Health or other public authority, circumventing the original decision process and the reasons given therein (Aggarwal et al., 2014; Burls et al., 2005; Clarke et al., 2001; MacKenzie et al., 2008; McIver & Ham, 2000). Negative coverage decisions may also be appealed in court (Moes et al., 2017; Moreira, 2011). Such court proceedings may likewise circumvent the original rationale, even when they do not overturn the original decision. They deal instead with whether due procedure was followed in e.g., coming to the final decision (Moreira, 2011) or in establishing the knowledge upon which the decision was made (Moes et al., 2017). The public controversy around these coverage decisions show that the reasons provided for the original decision were considered inappropriate or inadequate.

Decisions so controversial that they are circumvented do remain the exception: the majority of decisions pass relatively unnoticed by the public eye, the reasons provided remain unquestioned; they cannot be considered controversial in that sense. These decisions do, however, need resolve the perceived tension between the individual and the collective good (cf. Prainsack, 2018). This tension is inherent to all coverage decisions, embodied respectively by on the one hand, the general rules or criteria laid out for such decisions and, on the other hand, the patients present in the deliberative setting (Carlsen & Norheim, 2005; Hashem et al., 2018; Moreira, 2011, 2012; Rooshenas et al., 2015). Resolving this perceived tension is generally achieved through finding pragmatic ways to come to a rationale (Callon et al., 2009; Calnan et al., 2017; Moreira, 2011; Russell & Greenhalgh, 2014). As shown above, public controversies have proven fruitful research sites in terms of showing forms of reasoning that may otherwise be taken for granted (Moreira, 2011). Little is known about how rationality is constructed, how the inherent tension is dealt with, in taken-for-granted ways (cf. Lehoux et al., 2010).

This chapter will address the question: how are relatively robust run-of-the-mill coverage decisions made? We will draw from Science and Technology Studies (STS) literatures on controversy and robustness. We will conceptualise robust decision outcomes, including the publicly available reasons provided, as networks of elements that are able to withstand pressure 'out there', and describe how this is achieved through three steps: identification of elements, designing networks of elements, and through testing these differing networks. This will be illustrated by data gathered in previous qualitative comparative case study research in the setting of Dutch health care coverage decisions and will lead to several recommendations for policy and research.

ROBUST DECISIONS AS NETWORKS

Rip (1985, 1986, 2010) embarks upon his operationalisation of the robustness of decisions through what he terms an ‘informal technology assessment’, in essence a public litmus test for decision outcomes. Robust outcomes, Rip writes, are able to withstand “the pressures to which they will inevitably be exposed” (Moreira, 2013; Rip, 1985). These public pressures thus test robustness: the proof is in the pudding. The STS field may pride itself on a long history of studying this pudding, namely public controversies, as fruitful sites for exploration of the role of technology in society (Jasanoff, 2012; B. Martin & Richards, 1995). Scholars describe how polities have dealt with controversies as diverse as nuclear power plants, radio-active waste storage, Bovine Spongiform Encephalopathy, HIV/AIDS, Genetically Modified Organisms, nanotechnology, but also coverage decisions (Callon et al., 2009; Epstein, 2011; Moreira, 2011). These studies describe the work that is put in to uphold or defuse a controversy, highlighting the insufficiency of traditional, ‘certified’ expertise, as always making the reader sensible to the many ways in which assemblages of the elements of the controversy come to be, and in which closure was perhaps achieved (B. Martin & Richards, 1995). However, as Rip contends: “the analyst of controversies should limit himself to identify robustness and trace the processes that produce it” (Rip, 1986). This shows an important distinction: many STS scholars study the ‘public life’ of controversies, whereas Rip’s primary object is the robustness as the outcome.

Starting with Rip, then, we read that robust outcomes contain:

Arguments, evidence, social alignments, interests, and cultural values, many of them inter-related and therefore lending support to the dominant view. (Rip, 1986, p. 353)

Elsewhere, Rip speaks of “alignment of findings, arguments, perceptions, interests, and dominant values – and circumstances.” (Rip, 2010). From this, we derive a first important aspect of a robust outcome: robust outcomes are based on multifarious elements of different kinds. Rip continues,

The difference between an only fashionable and a robust view is a matter of degree, and perhaps also a matter of actual effort that actors are prepared to exert. In both cases, the views are available in the cultural repertoire, but with increasing robustness, the linkages between elements of the view and with their context increase in number and in articulation (and sometimes also in scope). (Rip, 1986, p. 353)

Two more aspects of robust outcomes according to Rip are then, first, making these networks of elements requires effort as it is achieved actively, and this effort exceeds just bringing all these elements together. Setting up robust networks of elements involves matching up, ‘clicking together’ some of these elements (Rip, 1986). Second, Rip speaks of the characteristics of the links between elements: as they are articulated they increase in number, and sometimes in scope. What follows

logically is that the making of these links is an important, powerful act in achieving robustness. Rip distinguishes two separate linking activities, namely articulation and consolidation. By articulation, he understands that elements are actively joined together that were previously unlinked, as described above, including increasing the scope of the decision. Consolidation, for Rip, is the next step in terms of robustness, where several elements are so strongly linked together that the link itself is 'black-boxed' and becomes difficult to call into question (Rip, 1986).

Importantly, Rip highlights the availability of different possible networks of elements, which differ in robustness. Some are on the "fashionable" end of the spectrum, while others are more robust. This theme has been expanded by Callon, Lascoumes and Barthe, who highlight the productivity of controversy. For them, controversy yields a robust solution because it "allows the *design* and *testing* of (...) [multiple] solutions that integrate a plurality of points of view, demands, and expectations" (Callon et al., 2009, p. 32, emphasis added). The idea that controversy is not just a fruitful research site but that controversies may also be productive in a broader sense has also been described by Rip, who already noted in 1986 that governments may have a specific task to encourage learning from controversy (Rip, 1986); Nowotny even conceptualises robustness as resulting specifically from such repeated testing (Nowotny, 2003). Callon et al specify how this learning-from-controversy should be encouraged: namely through what they term *hybrid forums*. In these, specialists and laypersons design and test plural solutions to the controversy, or networks of elements, together (Callon et al., 2009). In this, the designing resonates clearly with the work of Rip as described above. The testing process, aimed at "taking more into account", Callon et al. specify to entail a series of negotiations and compromises between all present (Callon et al., 2009, p. 32). Callon et al. argue in sum that controversy should be made part and parcel of the decision-making process instead of remaining 'out there': controversy is to be actively encouraged in a 'safe' space as more, and more different, people have a stake and a say.

Health care coverage offers a vibrant topic to explore the productivity of controversy in such hybrid forums (Moreira, 2013). Moreira argues that hybrid forums dealing feature 'hybrid knowledge' (cf. Nowotny, 2003), a form of understanding that exceeds the purely technical and involves the exploration of links between different arguments (Moreira, 2011). Such an exploration of links strongly resembles what Callon et al. call the design of a solution, and what is visible in Rip's work as the process of bringing a decision outcome together; what we will conceptualise as designing linked networks of elements. This designing step takes place after the identification of the elements as proposed by Rip, which is therefore the first step of our model. These elements here comprise of findings (that is, evidence that is considered 'scientific'), arguments, and values – in the knowledge that this is a reduction of the variety of elements present. These three types are generally present in health care coverage decisions: scientific findings of experts in the shape of Health Technology Assessments and the like; arguments such as concerning what is considered good care; and values such as justice, equality, and solidarity (Calnan et al., 2017; Lehoux, 2014; Lehoux et al., 2010; Makady et al., 2017; Vuorenkoski et al., 2008). Step 2 of our proposed model then, designing the networks, is specifically conceptualised as forging links between all these different elements.

These links are actively articulated, increased in scope, and sometimes even ‘black-boxed’. After the elements have been identified and the networks designed, the third step is testing the multiple solutions, that is, the decision networks – and choosing one.

In the remnant of this chapter we will draw on several years of field work on the use of argumentations in the appraisal of health care coverage technologies, to show how the decision trajectories of two specific cases illustrate this 3-step model as they link multiple, diverse elements into a network which is relatively robust.

COMPARATIVE CASE STUDY METHODOLOGY

This chapter builds on previous research at the Dutch Health Care Institute, which employed a case studies approach (Creswell & Poth, 2017; Ragin, 2004). Case study analysis is well-placed to provide insight into health care coverage decisions as it gives an in-depth take on processes that entail valuation (Dussauge et al., 2015; Lamont, 2012). We opted for two cases with high contrast (Lamont & Thévenot, 2000) in terms of decision outcome, number of patients affected, type of technology, and price: eculizumab (Soliris®) and paracetamol-vitamin D tablets (for more information, see boxes 1 and 2). Both were discussed in the Dutch media but caused little to no public controversy (Berkhout, 2017; Unknown, 2016; Van der Aa, 2016).

The data consisted of observations at appraisal committee meetings (n=3, one meeting for eculizumab and two for paracetamol-vitamin D tablets, with field notes taken), interviews with committee members (n=4 in three interviews) and with Institute employees (n=2 in one interview). The interviews were all semi-structured, and the two group interviews were of the field-formal type, both with the purposes of data triangulation (Frey & Fontana, 1991; King et al., 2018). Moreover, five documents pertaining to the two decisions were analysed, and the audio files for the appraisal committee meetings obtained to reference the field notes. The secretary of the appraisal committee granted access to the meetings and (audio) files. Data analysis and formulation of the conceptual model was enriched by other previous observations at appraisal committee meetings (n=4) and interviews with committee members (n=6) and Institute employees (n=7 in six interviews) (see Tables 1 and 2).

Case study	Documents and audio files
Eculizumab (Soliris®)	discussion document appraisal report patient contribution (part of discussion document) audio file
Paracetamol-vitamin D tablets	discussion document appraisal report audio file

Table 1 - overview of documents and audio files analysed per case

Interviews and observations date	Description
November 2015	Observations appraisal committee paracetamol-vitamin D tablets
October 2016	Committee member 5
October 2016	Institute employees 1 & 7
October 2016	Observations appraisal committee eculizumab and paracetamol-vitamin D
February 2017	Committee members 1, 4, 5 & 6
October 2017	Committee member 6

Table 2 - overview of interviews and observations analysed

DUTCH HEALTH CARE COVERAGE DECISIONS

In the Netherlands, all citizens are insured through private insurance, which covers at least the bare minimum set by the government: the basic benefits basket. The Dutch National Health Care Institute (in Dutch: *Zorginstituut Nederland*, in the rest of this chapter: ‘the Institute’) is responsible for advice to the Minister of Health as to the contents of this benefits basket. The Institute utilises four formalised criteria to come to this advice. These are: 1) effectiveness and 2) cost-effectiveness of the health care technology, 3) feasibility of coverage (including total budget impact), and 4) necessity, which rests in part on the individual severity of illness and individual affordability (Zorginstituut Nederland, 2013). These well-established criteria (Franken et al., 2012) are brought together in the final advice document, which is sent to the Minister, who makes the final decision.

The process of coming to this advice comprises several steps, relatively common in its set-up (Patera & Wild, 2014; Walley, 2007). Generally, it starts with a scoping session in which stakeholders are invited to submit initial comments on the health care technology under consideration. This is followed by the assessment phase, wherein the scientific evidence, which includes information on the effectiveness, cost-effectiveness, budget impact, severity of illness, and affordability, prepared by Institute employees, is rigorously examined by the assessment committee (in Dutch: *Wetenschappelijke Adviesraad*). The outcomes of this examination are subsequently contextualised in the meeting of the appraisal committee (in Dutch: *Adviescommissie Pakket*). In this meeting, which specifically aims to ‘bring in’ wider societal values pertaining to the technology under consideration, the scientific evidence is first presented by an Institute employee, followed by input from patients (representative)s and/or other stakeholders. Subsequently, the appraisal committee, which comprises eight to ten external experts from fields such as pharmaco-economics and health care ethics, commences their deliberations. At the end of these deliberations, in which every member is expressly given an opportunity to speak and respond, the final advice is formulated. This advice is then summarised, approved by the Institute’s Board of Directors, and forwarded to the Minister (Zorginstituut Nederland, 2016, 2017).

THREE-STEP MODEL FOR ROBUST DECISIONS

Our conceptual model comprises three steps towards robust decisions, which we conceptualise as networks of diverse elements. The first step is identification of many different elements (findings, arguments, values). Second, networks are designed from these elements through linking elements, broadening the scope of the network, and black-boxing links. For the third and final step, the networks that have thus been designed are tested for robustness, including the moment where one network is chosen over alternative networks.

Step 1: Identifying elements

The first step in coming to a robust decision is to identify different elements that may make up the network. We are not suggesting ‘all’ elements can be identified; rather, efforts in this area are rewarded with many different elements, and many different types of elements. One way to obtain many elements is through inviting experts-by-experience and laypeople, such as patients or other members of the public, into the deliberative setting of the decision. In the Dutch appraisal committee, deliberations do indeed start with contributions from Institute employee(s) and, sometimes, patient (representative)s. The appraisal actively invites these contributions, treating them as valuable, especially as structuring the deliberations in terms of coming to an advised decision (Cerri et al., 2014).

These contributions contain the three types of elements of networks: findings, arguments, and values. These three element types are clearly visible in the dataset on eculizumab (see Box 1) and paracetamol-vitamin D tablets (see Box 2). *Findings* included the individual severity of illness, contributed by the Institute employee and by patient representatives, and the extent to which the societal functioning of the patient is hindered by the disease, described by the patient representative in the case of eculizumab. *Arguments* include the small number of patients, making necessity of coverage greater because of the difficulty in obtaining trustworthy cost-effectiveness data, mentioned by the Institute employee in the case of eculizumab, and the absence of viable alternatives, remarked upon by both the Institute employee and a patient representative for eculizumab. For paracetamol-vitamin D tablets, arguments contributed by pharmacists included the fact they considered substitution to heavier medicines likely. *Values*, then, include the justice of coverage and a clear call for compassion, also contributed by a patient representative for eculizumab. In the case

Eculizumab (Soliris®) is an orphan drug licensed for Atypical Hemolytic Uremic Syndrome (aHUS) and Paroxysmal Nocturnal Hemoglobinuria (PNH). The cost-effectiveness ratio of the medicine was considered “highly unfavourable”, usually a decisive criterion (as visible in many coverage decisions for cancer drugs, as well as the PNH decision, which was negative). Patients and clinicians had, however, taken the initiative to research methods to shorten the treatment period, expected to result in a more favourable cost-effectiveness ratio. The deliberations in the appraisal committee hinged on this independent research; they considered the burden of disease combined with the risk taken by the patients so commendable that it yielded positive advice, provided the work on the research protocol and indication criteria would continue (unpublished results).

Box 1 – eculizumab

The Institute was set to make an advised decision on a list of tablets, collectively named 'paracetamol-vitamin D', after it had been set on the agenda by the Minister of Health. This in response to changes on a list of covered medicines (*Geneesmiddelenvergoedingssysteem* in Dutch), on which these tablets were 'left behind'. The Minister of Health explicitly asked the Institute whether these were in fact "necessary to be insured". The final advised decision was to no longer cover these tablets, except for certain medical indications. The reason given was that covering these relatively inexpensive tablets would turn out to be more expensive, because of the 'prescription rule'. This rule is an additional charge levied by the pharmacist when a covered medicine is bought at the pharmacy on prescription (unpublished results).

Box 2 – paracetamol vitamin D

of paracetamol-vitamin D tablets, values mentioned by a committee member, speaking on behalf of patients, included solidarity with vulnerable groups (audio files #1 and #2/field notes #161014).

This overview showcases that the provenance of elements may be somewhat counter-intuitive. Findings, for example, are not only brought in by certified experts. Rather, individuals speak as a

Collection of voices (...) sometimes speaking as a patient, as a doctor, as a member of the public, from the voice of medicine, the voice of the life world, speaking as both a panel 'insider' and 'outsider', sometimes even within the same utterance. (Russell, 2017, p. 219).

This is also visualised by a committee member in the eculizumab case, who stated that:

You want this [initiative] to be rewarded! The cost-effectiveness improves highly significantly. (...) Postponing [the decision] would be bad for the patient and the [health insurance] premium payer. (...) Economically speaking, the logic is zero. (Committee member 11, audio file #1)

This committee member moves deftly and quite naturally from his or her personal response, to the criterion of cost-effectiveness, to potential effects on patients and members of the public, to an economic line of reasoning. Such dynamics raise questions on the identity and distinctiveness of expertise and its role in policy making – not for nothing has this been a long-standing debate in STS and adjoining fields (Callon, 1999; Collins et al., 2010; Fischer, 2011; Jasanoff, 2003; Nowotny et al., 2013; Rip, 1985, 2003). In terms of both these aspects, we would follow Callon et al. (2009) and Moreira (2011, 2013) in not focusing on teasing out the differences between contributions but holding that contributions of more types of people yields more types of elements. Naturally, these elements may clash with one another; some will argue in favour of, and others against coverage of this particular health care technology (Kleinhout-Vliek et al., 2017). This is not problematic, however, as they may simply become part of different networks (see step 2 below).

Step 2: Designing networks

In arriving at a robust decision, the second step is designing the networks of elements (Callon et al., 2009), where three activities may be separated out: articulating links between elements, broadening the scope of the network, and black-boxing links (Rip, 1986).

Articulating links is the primary method for connecting elements into decisions (D. Martin et al., 2001; Singer et al., 2000). The document with reasons provided for a decision always contains a variety of both formalised criteria and case-specific argumentations (Kleinhout-Vliek et al., 2020). Links are made all the time in deliberations, and we are specifically interested in links made between different types of elements. This is visible in the paracetamol-vitamin D case, where it was argued that:

People who take these medicines often have more costs due to comorbidity and/or cannot afford them because of a low average income coupled to a lower socio-economic status. (Discussion document #2).

This is a clear linking of the value of equity with the finding of severity of illness and the argument of personal responsibility. For the eculizumab case, a strong linked network was already available, because a negative coverage decision had been made on the same medicine for a different indication, PNH (see Box 1). The new links articulated included the value placed on the courage of the patients in terms of shouldering the uncertainty of relapse, and the fact that they should not “be duped by the manufacturer’s criminal acts [in terms of repeatedly failing to provide high-quality data]” (Committee member 10, audio file #1/field notes #161014).

Some of these elements, such as the negligence of the manufacturer in terms of providing evidence of sufficient standard had been noted before, though it had not impacted the PNH decision in the same way. This shows that though some elements had been contributed before, they may become part of *different* networks (cf. Callon et al., 2009). It thus benefits the deliberations that the elements and the subsequent links are made *in situ*: it highlights the expertise brought to bear in articulating these links between different elements.

Broadening the scope of the network appears to be not common in the published literature, where decisions hinge on explicated reasons and are rarely described to concern other areas of health care (cf. Rip, 1986). However, the coverage decisions studied contain recommendations, and we pose this falls squarely in this category. In the case of the paracetamol-vitamin D case study, one of the appraisal committee members broadened the scope of the coverage decision, formulating it as if directly giving the Minister of Health advice on the prescription rule (see Box 2). This is not part of the remit of the basic benefits basket, or indeed, of the appraisal committee. However, recommendations like these provide an essential strengthening element of a network: the scope of the decision is broadened by going beyond the coverage decision. Specifically, the direction in which the network is broadened through such recommendations remains at the committee’s discretion. Sometimes they formulate advice to the Minister, sometimes to other stakeholders, such as committee member 13, who calls for the expertise centre to communicate to other countries the desire to pressurise the manufacturer (audio file #1/field notes #161014). In this way, the committee does not only specify what a good basic benefits basket is but actively broadens its remit to specifying what good *care* entails.

Black-boxing links is the final and most robust aspect of designing networks. The example provided by Rip concerns the black-boxed link between smoking and cancer (Rip, 1986, p. 354). This, even more than broadening the scope of the network, may be considered uncharted territory. Coming from a strong history of providing elaborate reasonings, with as many (predetermined) elements and links between elements visualised as possible (eg., Bærøe & Baltussen, 2014; Guindo et al., 2012), we argue the idea of black-boxing may seem counter-intuitive. However, cost-effectiveness in and of itself could be seen as black-boxed, linking many separate elements such as quality-adjusted life years, costs per treatment, and effectiveness, into a widespread coverage criterion (Franken et al., 2012). In this sense, the committee's deliberations (almost) always employ a link that has been black-boxed for a long time. Black-boxing is also visible to some extent in the appraisal committee's work we have studied, for example in the advice on eculizumab. The potential network of a negative decision, where the costs per QALY are insufficient given the severity of illness, is common, even so common that it has been described as "simply stamping the file" (Committee member 6, personal communications). The black-boxing here has happened through past decisions, in which that stamp was formed, allowing it to be "simply" used in later decisions. Other black-boxed links include another negative decision linking the finding of affordability (with the rule of thumb of cheaper than €100) and the argument of it being cheaper *not* to provide through the collective health insurance as this will keep prices up. Black-boxing links thus happens (but is naturally not explicated), with some links so black-boxed they will be difficult to prise open.

Step 3: Testing networks

The third and final step is to test these different designed decision networks. That different networks may exist and one needs to be chosen has previously been described for a decision for a highly expensive treatment, which gained a positive coverage status because one set of clustered argumentations together weighed more heavily than another set (D. Martin et al., 2001; Singer et al., 2000). Callon et al. describe this process as a series of negotiations and compromises in the hybrid forum setting, which "unleashes" the learning process to be harnessed as part of the decision (Callon et al., 2009, p. 32; Moreira, 2011). The confrontation between laypersons and those holding expertise is vital for enabling this learning process. This is illustrated by the eculizumab case, where, as stated above, one relatively strong network was already available. As committee member 2 summarised:

Over the past few months, we have said no regularly, for other '-mabs' [a class of expensive drugs]. Not because we would begrudge patients their medicines but because we think prices should be reasonable. (Committee member 2, field notes #161014)

The network of this well-established negative decision was tested by this comment – all subsequent commenters contributed not to strengthening this network but to constructing the alternative. The first consideration that came up regularly was the courage of the patients and the uncertainty they had had to live with because no final coverage decision had been taken for four years. The

second was the high valuation of the proposed research protocol, especially as it was conducted independently from the manufacturer, which was considered likely to also positively affect the price (field notes #161014). We analyse the repetition as a testing of the alternative network: it becomes clear, as one committee member after the other contributes, that this is where all want to go. As committee member 6 stated, summarising:

The rules should be stretched – we want to make something possible here. (Committee member 6, audio file #1/field notes #161014)

This example shows how committee members work together in testing the networks. In other cases, it may be done by one committee member. As visible in the paracetamol-vitamin D case excerpt below, the individual responsibility for the ‘bottom’ (cheaper end) of the benefits basket is noted, informally, to apply to any medicine cheaper than €100 per year. However, this particular decision required an opening up of what is usually black-boxed, because of the strong alternative network of vulnerable groups. The committee member does so through making *more* links to this network, and then, dismissing this network through noting it as another’s responsibility.

Through the argument of not being able to afford [the tablets] it seems as if (...) there is some sort of poverty boundary where people through the calcium tablets will suddenly end up on the wrong side. But in those cases, (...) there is probably already more going on, with those people, already the government, all kinds of related measures, rent subsidies, benefits, are happening. And it won’t [mean] those benefits agencies will give extra benefits because of this tablet, but there is a whole host of expenses, gas, light, and oh yes, the costs of this medicine, so there’s much more to it. I think it is almost, how should I say it, almost a self-centred idea that we or [the collective health] insurance were going to make the difference between poverty and no poverty. So I would argue to leave the poverty and the not being able to afford [things] to agencies that deal with these things, [because] it will not be influenced by that one-and-a-half calcium tablet (...). You can talk about those 100 euros but it is always, low cost – just put it aside. (Committee member 4, audio file #2).

First, this is a notable remark as it narrows the committee’s responsibility, counter to broadening it (see above). Second, this network was quickly considered decisive; the committee responded primarily through noting that this problem indeed should not be solved through health insurance (Committee member 6, audio file #2) and the fact that “the whole system is inefficient” (Committee member 4, audio file #2). It was, however, source of little discussion. This shows that sometimes, testing a network is done by one committee member who then changes the direction of the whole discussion (as for the paracetamol-vitamin D case), but sometimes, it is a collaborative effort, which is initiated tentatively and resonates around the room (as in the eculizumab case). As committee member 6 said, reflecting on the paracetamol-vitamin D case:

We just cut the Gordian knot on very pragmatic grounds. (Committee member 6, interview)

Later, in personal communications, the same committee member said that s/he considered the eculizumab advised decision to be one of the most beautiful ones s/he had contributed to. We would analyse this committee member to be alluding to quality of the decision-making process, the testing of different networks and choosing one in particular, which can be done with little discussion (as for the paracetamol-vitamin D case) but also with many committee members contributing (as for the eculizumab case), and stating a preference for the latter form.

DISCUSSION

Resolving the tension underlying health care coverage decisions is difficult by all standards, as visualised by the publicly controversial decisions that are overturned by a direct appeal to the Minister of Health or other public authority. Studying less publicly controversial decisions has been helpful as it illustrates how this identified tension may be resolved in a manner that yields a relatively robust decision. However, it is important to acknowledge that public controversy is ‘made’ just as much as robustness is (Abelson & Collins, 2009). A lack of public controversy is by no means only dependent on the reasons given for the decision. Many other factors may play a role, a. o. the activities of interest groups, what else occupies the public agenda, how ‘publicity-friendly’ the case is (McIver & Ham, 2000). Controversy does not just happen; it requires actors to act for controversy to spring into being. Moreover, all decisions are inherently controversial. This, we suggest, is because first, they all manage the perceived tension between the individual and the collective good; between the patient who would like (continued) access to the health care technology and the crowd who would prefer their monthly insurance fee as low as possible (McIver & Ham, 2000; Prainsack, 2018). The second reason all decisions are inherently controversial is that many different elements, many different links, and consequently many different networks are always possible. As a corollary, the model this chapter proposes cannot serve as a prescription for achieving robust, publicly uncontroversial decisions. What it does aim to do, is take a theoretical angle to describe how robustness may be achieved, and as such, it does have potential consequences for possible steps towards more robust decisions. These may include more careful preparatory work both in terms of contents (identification of potential elements from a wide variety of sources) and in terms of the set-up of the hybrid forum setting, enabling everyone to contribute in a way that is sensible to the power differences that are inherent to such decision-making processes. An important resulting recommendation is for further research efforts concerning the relationship, or absence thereof, of network strength and public controversy.

This model is built on previous work on public controversies in STS (Callon et al., 2009; Moreira, 2011; Rip, 1985, 1986) stemming from the premise that in public controversies arguments are explicated that otherwise would remain implicit. This model shows the productivity of tracing

robustness in situations of this inherent perceived controversy, rather than public controversy, and highlights that explicating arguments does indeed also happen in such situations. Though we are by no means the first to focus on the day-to-day, it is a relatively under-explored area in STS' controversy studies (see for an exception, Bal, 1999). We also note the productivity of careful tracing of different elements, and different types of elements, as a way of studying contextualisation processes. This aligns with a recent call to explore decisions of value in health care and how their "inner and outer context" is taken along in these decisions (Williams et al., 2018). However, as the word 'tracing' has been purposely chosen to indicate, it is important to avoid the trap of using context as 'non-explanatory resources' (Asdal, 2012; Asdal & Moser, 2012). By this, Asdal and Moser mean that often, context is said but not *shown* to have affected decisions, and she urges research to precisely indicate how context might have influenced the final decision outcome. In this chapter this has been done through focusing on verbalised, that is, explicated, elements that are added to the decision network. The elements that are (largely) decision-specific, as most of them are, we consider context-derived.

As for the designing and testing of networks, the "plural solutions" to the controversy are tested, according to Callon, by specialists and laypersons together in these hybrid forums, to create 'hybrid knowledge' (Moreira, 2011) or even 'socially robust knowledge' (Nowotny, 2003; Rip, 2010). From these two cases, it becomes clear that the process, for the moment, may not conform to this image completely. What remains to be established empirically, is how much do these practices resemble the hybrid forum ideal already, and how could we make it more so? One important aspect that has been the subject of extensive discussion is opening the decision setting up further to laypersons in addition to the patients already present at (some) appraisal committee meetings (e.g., Abrishami et al., 2017; Baltussen et al., 2016). This is, however, not without its problems. An oft-heard objection to such an appraisal is that it would imply a "tendency to lead to a 'levelling of the epistemological playing field' and to a collapse of the concept of expertise" (Collins et al., 2010; Epstein, 2011; Fischer, 2011). A second objection is the fact that the engagement of the public may be no more than a legitimisation exercise (Munk et al., 2016). The third danger, on the other end of the spectrum, is that of deliberations being hijacked by personal interests (Calnan et al., 2017). In response, we would follow Rip and Callon et al. in considering personal interests un-extractable and even constructive to the decision process (Callon et al., 2009; Rip, 1986). The risk of expertise collapsing is somewhat less prominent here because in both decisions examined, 'science proper' was represented by the Institute employee, who had a distinct role in the proceedings, demarcating their expertise also in non-verbal ways. Our data also highlight the appraisal committee's expertise (Calnan et al., 2017; Hughes & Light, 2002; Rooshenas et al., 2015) as being crucial in linking elements; a form of expertise that is not directly based on their respective areas of training and employment. Precisely then because of the distinct role these two types of expert play, the risk of public engagement turning into a legitimisation exercise is less easily dispelled than the other two identified problems. In our data, however, a true establishing of networks did indeed happen – it was not just 'for show' in the sense that the decision was already made beforehand. This underlines the potential of encouraging

engagement for the right reasons and in the right ways. One form this may take is through further steps to institutionalise and facilitate appeals procedures, a controversy-sensible step which may also help to counteract these risks.

From publicly controversial decisions that are overturned by a direct appeal to the Minister of Health or other public authority it is clear we need a complex, nuanced picture of how robust coverage decisions are constructed. The picture we have painted of everyday, publicly uncontroversial but inherently controversial decisions values the knowledge that certified experts may bring in the selection and linkage of elements of the decision. It also highlights that other networks, that is, other potentially robust decisions, are available for every decision made. Though no guarantee for publicly uncontroversial decisions, this model shows how coverage decisions may use the productivity of inherent controversy through encouraging the contribution of alternative elements and networks in their decision outcomes. It provides a strong rationale for careful organisation of the deliberative setting and appeals procedure in ways that are easily accessible. It highlights how future research could fruitfully explore the relationship between decision network strength and public controversy.

REFERENCES

- Abelson, J., & Collins, P. A. (2009). Media Hying and the “Herceptin Access Story”: An Analysis of Canadian and Uk Newspaper Coverage. *Healthcare policy*, 4(3), e113.
- Abrishami, P., Boer, A., & Horstman, K. (2017). 4 Value in Co-Creation: Subjecting Innovative in-Hospital Technologies to Multi-Stakeholder Appraisal. *Public Value of Medical Innovations*, 1, 97.
- Aggarwal, A., Ginsburg, O., & Fojo, T. (2014). Cancer Economics, Policy and Politics: What Informs the Debate? Perspectives from the Eu, Canada and Us. *Journal of Cancer Policy*, 2(1), 1-11. doi: <https://doi.org/10.1016/j.jcpo.2014.02.002>
- Asdal, K. (2012). Contexts in Action—and the Future of the Past in Sts. *Science, Technology, & Human Values*, 37(4), 379-403.
- Asdal, K., & Moser, I. (2012). Experiments in Context and Contexting. *Science, Technology, & Human Values*, 37(4), 291-306.
- Bæroe, K., & Baltussen, R. (2014). Legitimate Healthcare Limit Setting in a Real-World Setting: Integrating Accountability for Reasonableness and Multi-Criteria Decision Analysis. *Public Health Ethics*, 7(2), 98-111. doi: 10.1093/phe/phu006
- Bal, R. A. (1999). Grenzenwerk; over Het Organiseren Van Normstelling Voor De Arbeidsplek.
- Baltussen, R., Jansen, M. P., Mikkelsen, E., Tromp, N., Hontelez, J., Bijlmakers, L., & Van Der Wilt, G. J. (2016). Priority Setting for Universal Health Coverage: We Need Evidence-Informed Deliberative Processes, Not Just More Evidence on Cost-Effectiveness. *International Journal of Health Policy and Management*, 5(11), 615-618. doi: 10.15171/ijhpm.2016.83
- Berkhout, K. (2017). Slikken of Stikken? Het Kan Ook Anders, *NRC Handelsblad*.
- Burls, A., Austin, D., & Moore, D. (2005). Commissioning for Rare Diseases: View from the Frontline. *Bmj*, 331(7523), 1019-1021. doi: 10.1136/bmj.331.7523.1019
- Callon, M. (1999). The Role of Lay People in the Production and Dissemination of Scientific Knowledge. *Science, Technology and Society*, 4(1), 81-94.
- Callon, M., Lascoumes, P., & Barthe, Y. (2009). Acting in an Uncertain World: An Essay on Technical Democracy (G. Burchell, Trans.): Cambridge, MA: MIT Press.
- Calnan, M., Hashem, F., & Brown, P. (2017). Still Elegantly Muddling Through? Nice and Uncertainty in Decision Making About the Rationing of Expensive Medicines in England. *International Journal of Health Services*, 47(3), 571-594.
- Carlsen, B., & Norheim, O. F. (2005). “Saying No Is No Easy Matter” a Qualitative Study of Competing Concerns in Rationing Decisions in General Practice. *BMC health services research*, 5(1), 70. doi: 10.1186/1472-6963-5-70
- Cerri, K. H., Knapp, M., & Fernandez, J.-L. (2014). Public Funding of Pharmaceuticals in the Netherlands: Investigating the Effect of Evidence, Process and Context on Cvz Decision-Making. *The European Journal of Health Economics*, 15(7), 681-695.
- Clarke, J. T., Amato, D., & Deber, R. B. (2001). Managing Public Payment for High-Cost, High-Benefit Treatment: Enzyme Replacement Therapy for Gaucher’s Disease in Ontario. *Cmaj*, 165(5), 595-596.
- Collins, H., Weinel, M., & Evans, R. (2010). The Politics and Policy of the Third Wave: New Technologies and Society. *Critical policy studies*, 4(2), 185-201.
- Creswell, J. W., & Poth, C. N. (2017). *Qualitative Inquiry and Research Design: Choosing among Five Approaches*. USA: Sage publications.
- Dussauge, I., Helgesson, C.-F., & Lee, F. (2015). *Value Practices in the Life Sciences and Medicine*: Oxford University Press, USA.
- Epstein, S. (2011). Misguided Boundary Work in Studies of Expertise: Time to Return to the Evidence. *Critical policy studies*, 5(3), 323-328.
- Fischer, F. (2011). The ‘Policy Turn’ in the Third Wave: Return to the Fact-Value Dichotomy? *Critical policy studies*, 5(3), 311-316.
- Franken, M., Le Polain, M., Cleemput, I., & Koopmanschap, M. (2012). Similarities and Differences between Five European Drug Reimbursement Systems. *International Journal of Technology*

- Assessment in Health Care*, 28(4), 349-357. doi: 10.1017/S0266462312000530
- Frey, J. H., & Fontana, A. (1991). The Group Interview in Social Research. *The Social Science Journal*, 28(2), 175-187.
- Guindo, L. A., Wagner, M., Baltussen, R., Rindress, D., Van Til, J., Kind, P., & Goetghebeur, M. M. (2012). From Efficacy to Equity: Literature Review of Decision Criteria for Resource Allocation and Healthcare Decisionmaking. *Cost effectiveness and resource allocation*, 10(1), 9. doi: 10.1186/1478-7547-10-9
- Hashem, F., Calnan, M. W., & Brown, P. R. (2018). Decision Making in Nice Single Technological Appraisals: How Does Nice Incorporate Patient Perspectives? *Health Expectations*, 21(1), 128-137. doi: doi:10.1111/hex.12594
- Hughes, D., & Light, D. (2002). *Rationing: Constructed Realities and Professional Practices*. Oxford, UK: Wiley-Blackwell.
- Jasanoff, S. (2003). Breaking the Waves in Science Studies: Comment on Hm Collins and Robert Evans, the Third Wave of Science Studies. *Social Studies of Science*, 33(3), 389-400.
- Jasanoff, S. (2012). Genealogies of Sts. *Social Studies of Science*, 42(3), 435-441.
- King, N., Horrocks, C., & Brooks, J. (2018). *Interviews in Qualitative Research*. UK: SAGE Publications Limited.
- Kleinhou-Vliet, T., De Bont, A., & Boer, B. (2017). The Bare Necessities? A Realist Review of Necessity Argumentations Used in Health Care Coverage Decisions. *Health Policy*, 121(7), 731-744. doi: <https://doi.org/10.1016/j.healthpol.2017.04.011>
- Kleinhou-Vliet, T., de Bont, A., Boysen, M., Perleth, M., van der Veen, R., Zwaap, J., Boer, B. (2020). Around the Tables – Contextual Factors in Healthcare Coverage Decisions Across Western Europe. *International Journal of Health Policy and Management*, 9(9), 390-402. doi: 10.15171/ijhpm.2019.145
- Lamont, M. (2012). Toward a Comparative Sociology of Valuation and Evaluation. *Annual Review of Sociology*, 38(1), 201-221. doi: 10.1146/annurev-soc-070308-120022
- Lehoux, P. (2014). *The Problem of Health Technology*. USA: Routledge.
- Lehoux, P., Denis, J. L., Rock, M., Hivon, M., & Tailliez, S. (2010). How Medical Specialists Appraise Three Controversial Health Innovations: Scientific, Clinical and Social Arguments. *Sociology of health & illness*, 32(1), 123-139.
- Mackenzie, R., Chapman, S., Salkeld, G., & Holding, S. (2008). Media Influence on Herceptin Subsidization in Australia: Application of the Rule of Rescue? *Journal of the royal society of medicine*, 101(6), 305-312.
- Makady, A., Ten Ham, R., De Boer, A., Hillege, H., Klungel, O., & Goettsch, W. (2017). Policies for Use of Real-World Data in Health Technology Assessment (Hta): A Comparative Study of Six Hta Agencies. *Value in Health*, 20(4), 520-532.
- Martin, B., & Richards, E. (1995). Scientific Knowledge, Controversy, and Public Decision-Making. *Handbook of science and technology studies*, 506, 26.
- Martin, D., Pater, J., & Singer, P. (2001). Priority-Setting Decisions for New Cancer Drugs: A Qualitative Case Study. *The Lancet*, 358(9294), 1676-1681. doi: [https://doi.org/10.1016/S0140-6736\(01\)06714-9](https://doi.org/10.1016/S0140-6736(01)06714-9)
- Mciver, S., & Ham, C. (2000). Five Cases, Four Actors and a Moral: Lessons from Studies of Contested Treatment Decisions. *Health Expectations*, 3(2), 114-124. doi: 10.1046/j.1369-6513.2000.00089.x
- Moes, F., Houwaart, E., Delnoij, D., & Horstman, K. (2017). Contested Evidence: A Dutch Reimbursement Decision Taken to Court. *Health Economics, Policy and Law*, 12(3), 325-344.
- Moreira, T. (2011). Health Care Rationing in an Age of Uncertainty: A Conceptual Model. *Social Science & Medicine*, 72(8), 1333-1341.
- Moreira, T. (2012). Health Care Standards and the Politics of Singularities: Shifting in and out of Context. *Science, Technology, & Human Values*, 37(4), 307-331. doi: 10.1177/0162243911414921
- Moreira, T. (2013). *The Transformation of Contemporary Health Care: The Market, the Laboratory, and the Forum*. USA: Routledge.
- Munk, A. K., Meunier, A., & Venturini, T. (2016). *Data Sprints: A Collaborative Format in Digital Con-*

- trovery Mapping*: Princeton University Press Princeton, NJ.
- Nowotny, H. (2003). Democratising Expertise and Socially Robust Knowledge. *Science and public policy*, 30(3), 151-156.
- Nowotny, H., Scott, P. B., & Gibbons, M. T. (2013). *Re-Thinking Science: Knowledge and the Public in an Age of Uncertainty*. Cambridge, UK: John Wiley & Sons.
- Patera, N., & Wild, C. (2014). Assessment – Appraisal – Decision. Lbi-Hta Decision Support Document Nr.: 72. Wien: Ludwig Boltzmann Institut für Health Technology Assessment.
- Prainsack, B. (2018). The “We” in the “Me”: Solidarity and Health Care in the Era of Personalized Medicine. *Science, Technology, & Human Values*, 43(1), 21-44. doi: 10.1177/0162243917736139
- Ragin, C. C. (2004). Turning the Tables: How Case-Oriented Research Challenges. *Rethinking social inquiry: Diverse tools, shared standards*, 123.
- Rip, A. (1985). Experts in Public Arenas. *Regulating industrial risks: Science, hazards and public protection*, 94-110.
- Rip, A. (1986). Controversies as Informal Technology Assessment. *Knowledge*, 8(2), 349-371.
- Rip, A. (2003). Constructing Expertise: In a Third Wave of Science Studies? *Social Studies of Science*, 33(3), 419-434.
- Rip, A. (2010). Social Robustness and the Mode 2 Diagnosis. *Science, Technology & Innovation Studies*, 6(1). doi: <http://dx.doi.org/10.17877/DE290R-13458>
- Rooshenas, L., Owen-Smith, A., Hollingworth, W., Badrinath, P., Beynon, C., & Donovan, J. L. (2015). “I Won’t Call It Rationing...”: An Ethnographic Study of Healthcare Disinvestment in Theory and Practice. *Social Science & Medicine*, 128(Supplement C), 273-281. doi: <https://doi.org/10.1016/j.socscimed.2015.01.020>
- Russell, J. (2017). *The Rationality of Rationing: A Rhetorical Policy Analysis of Deliberations About Resource Allocation in the Nhs*. University of Oxford, UK.
- Russell, J., & Greenhalgh, T. (2014). Being ‘Rational’ and Being ‘Human’: How National Health Service Rationing Decisions Are Constructed as Rational by Resource Allocation Panels. *Health*, 18(5), 441-457.
- Singer, P. A., Martin, D., Giacomini Bhatia, M. V., & Purdy, L. (2000). Priority Setting for New Technologies in Medicine: Qualitative Case Study. *Bmj*, 321(7272), 1316-1318. doi: 10.1136/bmj.321.7272.1316
- Unknown. (2016). Zware Paracetamol Mogelijk Uit Basispakket: Klap Voor Honderdduizenden Patiënten, *RTL nieuws*.
- Van Der Aa, E. (2016). Zware Paracetamol En Vitaminen Wellicht Uit Pakket, *Algemeen Dagblad*.
- Vuorenkoski, L., Toiviainen, H., & Hemminki, E. (2008). Decision-Making in Priority Setting for Medicines—a Review of Empirical Studies. *Health Policy*, 86(1), 1-9.
- Walley, T. (2007). Health Technology Assessment in England: Assessment and Appraisal. *Medical Journal of Australia*, 187(5), 283.
- Williams, I., Brown, H., & Healy, P. (2018). Contextual Factors Influencing Cost and Quality Decisions in Health and Care: A Structured Evidence Review and Narrative Synthesis. *International Journal of Health Policy and Management*, 7(8), 683.
- Zorginstituut Nederland. (2013). Pakketbeheer in De Praktijk Deel 3 (pp. 1-106). Diemen.
- Zorginstituut Nederland. (2016). Reglement Adviescommissie Pakket. In Z. Nederland (Ed.). <https://www.zorginstituutnederland.nl/over-ons/publicaties/besluit/2016/12/05/reglement-adviescommissie-pakket-zorginstituut-nederland> (accessed 11 February 2020).
- Zorginstituut Nederland. (2017). Pakketadvies in De Praktijk: Wikken En Wegen Voor Een Rechvaardig Pakket. Diemen.