Expertise in the appraisal phase

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INTRODUCTION

Whether a health care technology is made available to patients, for example through a (national) formulary, benefits package, or insurance scheme, is decided by means of health care coverage decisions. Making these decisions well is notoriously complex as it leans on a wide variety of heterogeneous considerations that are brought together in the decision-making process (Cerri et al., 2014; Dakin et al., 2015; Hughes & Doheny, 2011; Russell & Greenhalgh, 2014; Vuorenkoski et al., 2008). The most-studied part of this process is the assessment, which examines the available scientific evidence such as the (cost-) effectiveness of the technology, often employing Health Technology Assessment (HTA) methods (eg. Franken et al., 2012; Kleijnen et al., 2012; Le Polain et al., 2010; Makady et al., 2017; Salas-Vega et al., 2016). Notably, such scientific knowledge bases have been shown essential but not sufficient for making good coverage decisions (Calnan et al., 2017; Moes et al., 2016; Samenleving, 2017; Shirazi et al., 2017). Therefore, many coverage decisions feature a second part, sometimes (but not always) a distinct step in time and space: the appraisal. An appraisal entails the formulation of a (recommended) coverage decision based on a contextualisation of the given evidence (Jansen et al., 2017; Kleinhout-Vliek et al., 2020; Oliver et al., 2004; Patera & Wild, 2014; Walley, 2007). Previously, contextualisation has broadly been defined as taking into account a variety of values and considerations (Patera & Wild, 2014). Some, such as the English National Institute for Health and Care Excellence (NICE), have specified contextualisation to mean establishing "what is good for society" or, in other words, providing a societal weighing of the evidence (Culyer & Rawlins, 2004; NICE, 2008; Shah et al., 2013).

Little is known about how societal weighing works and how exactly appraisal committees may achieve this. Recent work on deliberative coverage decisions more generally does show that expertise in these decisions may comprise three distinct elements. First, the expertise is substantive; committee members are able to understand and work with different types of knowledge. These types include not only the scientific input deriving from the assessment but often also knowledge provided by patients ('experts-by-experience') as well as 'local' knowledge regarding the institutional setting where the decision-making process takes place. Second, committee members respond appropriately to these different types of input and combine them into one decision, which involves being 'rational' and being 'human'. They also deal with any tensions that may arise between knowledge types (Calnan et al., 2017; Gkeredakis et al., 2011; Hughes & Doheny, 2011; Jenkings & Barber, 2004; Moes et al., 2016; Moreira, 2011; Russell & Greenhalgh, 2014). Third, committee members are experts at adhering to not only substantive requirements which are generally in the form of formalised decision criteria but also processual requirements (Russell, 2017), often those laid out by the widely-used Accountability for Reasonableness framework (Daniels, 2000; Daniels & Sabin, 1997, 1998, 2008; Hasman & Holm, 2005). These three elements of expertise would appear, however, not specific to appraisals so the question remains: what does societal weighing expertise look like?

In this study, we will fill the gap concerning societal weighing expertise by examining the appraisal phase of Dutch health care coverage decisions, which also, like NICE's decisions described

above, explicitly aim for a "societal weighing" of the evidence base provided in the assessment (Zorginstituut Nederland, 2016, 2017). Furthermore, Dutch decision-making practice provides an excellent case because the appraisal is set up as a separate meeting, a distinct moment in time and space, making it easier to distinguish from the assessment phase (Commissie-Dunning, 1991; Stolk et al., 2002; Stolk et al., 2001). In the Netherlands, the National Health Care Institute ('the Institute', in Dutch: *Zorginstituut Nederland*), an arm's length body, is responsible for advising the Ministry of Health on the contents of the basic benefits basket. This basket outlines the bare-minimum health care insurance package that is obligatory for all Dutch citizens. The Dutch coverage decision-making process usually starts with a scoping session, in which stakeholders are invited to contribute relevant considerations. This is followed by a meeting of the Scientific Advisory Committee ('the assessment committee', in Dutch: *Wetenschappelijke Adviesraad*), in which the scientific knowledge base is established based on HTA methodology (Franken et al., 2012; Kleijnen et al., 2012; Makady et al., 2017; Salas-Vega et al., 2016). The Package Advisory Committee ('the appraisal committee', in Dutch: *Adviescommissie Pakket*), convened once-monthly at the Institute, is subsequently responsible for the societal weighing of the evidence and the formulation of coverage advice to the Minister (Couwenbergh et al., 2013; Zorginstituut Nederland, 2016, 2017). The Institute uses four formalised criteria in this advice, namely effectiveness, cost-effectiveness, feasibility (including budget impact considerations), and necessity. 'Necessity' is, as a consequence of being a formalised criterion, present in the documents providing input for the appraisal as they outline the available information per criterion. It has, however, also been considered to be established especially in appraisal (Couwenbergh et al., 2013; Kleinhout-Vliek et al., 2017; Kleinhout-Vliek et al., 2020; Mastenbroek et al., 2006; Zorginstituut Nederland, 2017). Therefore, this chapter will explore how the appraisal committee *constructs necessity* as this may aid in uncovering elements that are specific to societal weighing expertise (Hoedemaekers & Oortwijn, 2003; Poley, 2002; Stolk et al., 2002).

Aim

This chapter describes the phases of constructing necessity by examining the contents of and the proceedings at Dutch appraisal meetings through observations, transcriptions, and subsequent analysis of audio recordings of four meetings. These meetings varied greatly in terms of type of health care technology appraised. This is supplemented with interviews with appraisal committee members and Institute employees (n=13). We answer the question: how does the Dutch appraisal committee construct necessity?

METHODOLOGY

Approach

In order to explore the Dutch appraisal, we analyse four cases of specific coverage decisions. Argumentations used to construct necessity that could potentially be employed by the appraisal commit-

tee include but are not limited to, the morbidity and need experienced by the patient, availability of alternative treatments, the financial cost per individual patient, and compassion with vulnerable groups such as children or small numbers of patients generally. These necessity argumentations are part of a list of twenty argumentation types derived from a realist review of argumentations used to establish the necessity of coverage of health care technologies worldwide (Kleinhout-Vliek et al., 2017). For an overview of these twenty inductively-formulated argumentation types, see Table 1. The Netherlands is a particularly fruitful setting for studying necessity as the Dutch use two of these twenty necessity argumentations, namely individual severity of illness ('Morbidity/Severity') (Franken et al., 2015; Reckers-Droog et al., 2018, 2019) and the cost that the individual patient will incur ('Individual Cost'), as their explicit, *a priori* formulated, necessity *criterion*. As such, these ought to be present in every decision document inputting into the appraisal (Couwenbergh et al., 2013; Hoedemaekers & Oortwijn, 2003; Niëns, 2014; Stolk et al., 2001).

Necessity argumentations are of interest for two reasons. First, these argumentations are employed not only by professional decision makers but also by other parties, such as patients, who may also be present at the appraisal meeting (further information below). Second, necessity argumentations are variable in usage as their perceived validity and allotted weight differs per decision, making their patterns especially vivacious (Kleinhout-Vliek et al., 2017; Kleinhout-Vliek et al., 2020).

To study necessity argumentations in appraisal we have chosen a case approach (Creswell & Poth, 2017; Ragin, 2004) because researching a similar process in a variety of situations is considered helpful for gaining insight into commonalities across situations, especially when it concerns context-dependent social processes (Dussauge et al., 2015; Lamont, 2012). In this, we hold that the context is case-specific and thus differs per decision situation (Asdal, 2012; Asdal & Moser, 2012). The cases chosen concern four health care technologies, namely eculizumab (Soliris®), front teeth replacement, maternity care, and paracetamol-vitamin D tablets. These cases are relatively run-of-the-mill; three were discussed in the Dutch media but only sparingly (Berkhout, 2017; Unknown, 2015, 2016; Van der Aa, 2016). They share two characteristics that resulted in their selection. First, the cases vary widely, i.a. in terms of type of technology, price, and number of patients affected, with necessity argumentations playing a pivotal role in all four, as suggested in informal conversations by contacts at the Institute (front teeth replacement therapy, maternity care, and paracetamol-vitamin D tablets) or the literature review (eculizumab (Soliris®)) (Kleinhout-Vliek et al., 2017). Second, the appraisal meetings took place between 2015 and 2017, meaning that the first author could either be present at the appraisal meeting, listen to the audio files, or do both (see Table 2).

Methods

Our dataset comprises four cases and the data on these cases were gathered through observations, transcription of audio files, documents, and interviews. The Institute consented to the first author accessing the setting of appraisal committee through an explicit invitation to do so by the secretary of the committee. This invitation included the 'closed' pre-meeting for the eculizumab and the paracetamol-vitamin D cases and additional observations at the scoping session for the latter. The

Argumentation type	Description
Definition of Illness	Whether the ailment is considered an illness for which treatment is necessary
Dignity	Whether (lack of) coverage is considered to affect the dignity of the patient to such an extent that it needs to be amended
Equity/Fairness/Justice	Whether coverage would be necessary to counter injustice/inequity/lack of fairness in (access to) treatment
Human Right	Whether (lack of) coverage is considered to affect the human rights of the patient to such an extent that it needs to be amended
Individual Cost	Whether lack of coverage would stop patients from buying necessary care themselves due to prohibitive cost
Individual Responsibility	Whether the individual is considered responsible for paying for this treatment
Medical Necessity	Whether or not a treatment is considered to be "medically necessary" or a "medical necessity"
Morbidity/Severity	Whether the physical and/or psychosocial morbidity associated with a certain ailment constitutes such a need that coverage is considered necessary
Moral Hazard	Whether there is considered to be a possibility of over-usage (i.e., unnecessary increase in demand, when people use more than they need as a result of coverage)
Need	The extent to which the patient is considered to be in need for which treatment is necessary
(No) Alternative	Whether or not viable alternatives are considered to be present which would make coverage more or less necessary
Patient-Diagnosis	Whether an illness is self-reported rather than diagnosed by a doctor
Range of Normality	Whether the experience of the patient is considered normal or abnormal to such an extent that coverage is deemed necessary
Rule of Rescue	Whether the identifiability of individuals close to death is considered to heighten the necessity of coverage
Similar Treatments	Whether similar treatments are covered or not (meaning that this type of treatment is considered necessary)
Small Number of Patients	Whether the small size of the patient population is considered to heighten the necessity of coverage (due to, amongst others, the inequality in terms of research expenditure or difficulties in obtaining high-quality data)
Societal Impact	Whether coverage is considered necessary to allay the impact this disease has on people beyond the patient
Societal Functioning	Whether coverage would aid a person's necessary functioning in society
Societal Responsibility	Whether society is considered responsible for paying for this treatment
Vulnerability/Compassion	Whether a compassionate response to vulnerable groups, e.g. children, in the form of coverage is considered to be a necessity

Table 1- Overview of the twenty argumentation types that fall under the necessity criterion and their respective descriptions (Kleinhout-Vliek et al., 2017)

secretary also provided audio-recordings s/he herself used to write minutes to be analysed for this study. The first author was present at three out of four appraisal committee meetings (for the cases eculizumab, front teeth replacement therapy, and paracetamol-vitamin D tablets), where she observed and took field notes. These notes were supplemented by audio files of the same appraisal committee meetings and one additional case (maternity care). These audio files were transcribed verbatim. Moreover, we analysed nine documents pertaining to these cases. For each case, this entailed the document that was provided to the appraisal committee (the 'discussion document')

and the final 'appraisal report' (see Table 2). For the documents, only the main body of text was analysed (i.e., excluding appendices).

For triangulation purposes, the first author interviewed seven policy advisers ('Institute employees') who worked on the cases as well as six appraisal committee members present at the meetings, some of whom were interviewed multiple times, to a total of thirteen people over twelve interviews (for a precise overview of who was interviewed when, please see Table 2). All approached interviewees consented to being interviewed, except one Institute employee, who declined due to a full

Case	Observations	Document analysis	Interview
Eculizumab (Soliris®)	file 1 (October 2016)	3.1 discussion document 3.2 appraisal report 3.3 patient contribution	-
Front teeth replacement	file 2 (February 2015)	2.1 discussion document 2.2 appraisal report	Institute employee 3 (April 2015) Institute employee 4 (May 2015)
Maternity care	file 3 (January 2015) *Audio file only*	1.1 discussion document 1.2 appraisal report	Institute employees 2 & 5 (October 2016)
Paracetamol-vitamin D tablets	file 4 (October 2016)	4.1 discussion document 4.2 appraisal report	Institute employees 1 & 7 (October 2016) Committee member 5 (October 2016)

Table 2 – Overview of data collected pertaining to the case studies

schedule. Three interviews were group interviews (type: field-formal, meaning that the questions were of a semi-structured nature and the interviewer took on a somewhat directive role) (Frey & Fontana, 1991). Institute employees 2 & 5 and 1 & 7 were interviewed in pairs at the request of the employees themselves, as they considered their answers would supplement one another (in the former case, the interviewer did not know two people would be present until the moment of the interview). The group interview with Committee members 1, 4, 5 & 6 was done out of convenience, as committee members are often only present at the Institute once a month and this presented a good opportunity. Again, the interviewees considered their answers to complement one another. Oral informed consent was given for use of interview data, written informed consent was given for publication, and a formal waiver for ethical approval was obtained [reference number to be added]. The interviews were conducted by the first author using a topic list with non-structured, open-ended questions, and the interviews were audio-recorded and subsequently transcribed verbatim. The topic list included for Institute employees: how this technology arrived at the Institute agenda, the scoping session, how they retrieved any additional information, the appraisal meeting, how they arrived at the text in the different documents, and more general topics pertaining to the Institute. This was done to gain deeper insight into the working processes at the Institute, especially concerning different forms of input for the appraisal meeting. For committee members, the topic list concerned the appraisal committee's functioning generally, how different types of information

are usually dealt with, and specific experiences they could recall. These questions were formulated in order to gain insight into the cases but also to obtain reflections on tentatively formulated phases of necessity construction. Lastly, all interviewees were probed about necessity argumentations.

This dataset was analysed as follows. The list of twenty necessity argumentations (Kleinhout-Vliek et al., 2017) was used as sensitising concepts to guide the first step of the detailed content analysis of the documents and transcribed committee meetings, in which the necessity argumentations were used as a list of codes (Table 1). The explicit mentioning, 'black on white' or 'out loud', of necessity argumentations was tracked across the documents and audio files through coding specific utterances as one or more of the argumentation types, using Microsoft Excel to put utterances that had received the same code together in the same row. The first tentative patterns were subsequently elucidated based on this tracked argumentation use. For the formulation of the phases, we chose a chronological and person-dependent (first this person spoke, then that person contributed) rather than substantive (these argumentations were used more often than those) patterning. These patterns formed the basis for the different phases, formulated and refined in further extensive discussions within the authorship team, then supplied and solidified by information retrieved from the interviews. These interviews specifically clarified the dynamics around the Institute employees' and the patient and patient representatives' contributions. Additional observations served to see whether data saturation was achieved (Table 3). A member check with the appraisal committee and several personal communications (committee meetings of December 2016 and February 2017, member check through a presentation to the committee on 14 April 2018, personal communications with committee members 5, 6 and 7) to see whether the interpretation made by the authors stayed close enough to the interpretation of those observed (Sayer, 2011) (see also Table 3). Especially the member check and the personal communications have positively impacted the reliability of the study in this regard; the personal communications followed the member check to clarify the interpretation of our data in a number of places, these are indicated in the text through reference to '(interviewee X, personal communications)'.

RESULTS

This section first describes the working procedure of the Institute and the appraisal committee, succeeded by an introduction to the case studies and descriptions of the way in which necessity is constructed per phase of the appraisal meeting.

Working procedure

The Institute's working procedure for formulating an advised decision follows the general assessment-appraisal pattern (Patera & Wild, 2014). Agenda setting varies and may happen through pharmaceuticals gaining market access or by another party, such as the Minister of Health or a professional organisation. Once it is placed on the agenda, one or two Institute employees take

Observations and audio file	Interview
December 2016	Institute employee 6
Observations only	(March 2015)
February 2017	Committee member 5
Observations only	(March 2015)
	Committee member 3
	(August 2015)
	Committee member 2
	(September 2015)
	Committee members 1, 4, 5 & 6
	(February 2017)
	Committee member 1
	(February 2017)
	Committee member 6
	(October 2017)

Table 3 – Overview of additional data collected

responsibility for this dossier; in this study, these were different people for each case. After a scoping session with interested parties, the scientific evidence reports are written by other Institute employees with expertise in therapeutic value, cost-effectiveness, and budget impact. These are bundled and combined with a short explainer by the one or two Institute employees who hold final responsibility for this dossier to benefit the assessment phase. The assessment phase takes place at the Scientific Advisory Committee (in Dutch: *Wetenschappelijke Adviesraad*, WAR), based on which an assessment report is composed by the secretary of this committee. This report provides a summative conclusion on the valuation, the size, and the probability of the effect of the medicine. This assessment report is sent to the stakeholders for consultation and consequently combined with input from the scoping session as well as a fresh explainer into a 'discussion document' by those responsible for this dossier. This is aided by the secretary of the assessment committee and approved by the secretary and chair of the appraisal committee, to benefit the appraisal phase (Committee member 5, personal communications) (Zorginstituut Nederland, 2017).

The appraisal subsequently takes place at the meeting of the Package Advisory Committee (in this text: the appraisal committee). The committee is comparatively small (Patera & Wild, 2014): eight to ten external experts (e.g. in medical ethics, pharmaco-economics, or medicine), who are not employed by the Institute, comprise the committee. Like NICE's Social Value Judgements, the Dutch appraisal explicitly aims for a societal weighing of the provided scientific evidence (Couwenbergh et al., 2013; Zorginstituut Nederland, 2016, 2017).

The committee members read the assessment report in advance of the meetings. All meetings, which are in principle open to the public, were preceded by a 'closed' meeting, in which patients and their representatives were absent but the Institute employee(s) responsible for the dossier were present, and the files are already discussed (observations February, November 2015, October, December 2016, and February 2017, see also Zorginstituut Nederland, 2016).

Cases

We studied the appraisal deliberations for four significantly varying cases.

Eculizumab (Soliris®) is an orphan drug currently licensed for Atypical Hemolytic Uremic Syndrome (aHUS) and Paroxysmal Nocturnal Hemoglobinuria (PNH). After four years of provisional coverage, a temporary coverage arrangement, the final advised decision to the Minister was to be drafted by the Institute in 2016. The discussion document (document 3.1) states that there is debate on whether the incremental cost-effectiveness ratio (ICER) for treatment of aHUS with eculizumab approximates the reference value at €80,000 per QALY for severe diseases. The calculated cost-effectiveness ratio was thus considered "highly unfavourable", but clinicians and patient organisations had initiated independent research on shortening the treatment period through improved start-stop criteria, which was expected to result in a more favourable ICER. A grant was already obtained for this research (though not for the medicine itself). After the formal presentation by the Institute employee responsible came the contributions of one patient and two patient representatives (in this case, the mother of a patient and a clinician). Especially the mother's emotional contribution was followed by an extended silence on the part of the committee, and many committee members vocalised their appreciation of these contributions. For the deliberations, the research on the new protocol was the primary focal point. The committee thought investing in this a worthy cause; the final advised decision stressed that the committee considered the initiative so commendable that it needed to remain possible to reimburse eculizumab from public funds within the research protocol (Document 3.2). Relief on the part of the patients was palpable; the chair suggested the committee take a break, and the patient (representative)s were congratulating each other, also a few committee members offered their congratulations (observations/audio file 1).

Front teeth replacement was discussed in the appraisal committee in February 2015 after the College of Dentists (in Dutch: *College van Adviserend Tandartsen*) placed it on the agenda through the contacts that Institute employees 3 and 4 had with them. The reason provided was that current legislation was perceived as a perverse stimulus with the situation being as follows. All dental care is covered by the Dutch basic benefit package until the insured's 18th birthday but not afterwards. This means that when young people lose their front teeth or were born without them, they may prefer to have them replaced before their 18th birthday (as the costs are approximately €3,500 for front teeth implants), whereas it is often better to do so later as the oral cavity is not fully grown until the age of 22. In the appraisal committee meeting where the coverage of front teeth implants was discussed, the topic was not considered of major importance or interest, even a little laughable, for its small budget impact (audio file 2 and interview with Institute employee 5). Institute employees 3 and 4 were especially aware of its political history; one regarded it a mistake that could have been prevented that current legislation did not specify the extended coverage until the age of 22. The discussions in the appraisal committee seemed relatively straightforward, with everybody largely leaning in the direction of extending coverage, until one Committee member apparently "wanted to stimulate the discussion by deliberately going against the tide" (interview Institute employee 3). This resulted in a longer discussion, with the final decision apparently taken for pragmatic reasons

(namely the time it would take to change the legislation; coming back to it in the appraisal meeting next month would mean another year's extension) (observations/audio file 2). The final advised decision, then, was that as long as the claim was made before the 18th birthday, coverage would be continued until the age of 22 (Document 2.2).

The maternity care case was addressed by the appraisal committee in January 2015 in response to an appeal to the general public by the Minister of Health to send in suggestions for parts of the basic benefit package that could be removed. The primary argumentation for suggesting that maternity care could be removed from the package was that pregnancy is a choice and foreseeable (that is, unnecessary to be insured for, as the birth is something you know will happen). In line with this, mere days before this appraisal committee meeting took place, a newspaper had commented on how strange it was that "beschuit met muisjes smeren" (the preparation of a traditional Dutch treat for friends and family paying maternity visits) was often done by maternity care workers and therefore part of the basic benefit package. The Institute employees, however, concurrently received "signals" from the Ministry that it should not be removed from the benefits basket (Institute employees 2 and 5, interview). Several versions of the advice document had to be discussed at the appraisal committee, which led to much frustration at coffee machine afterwards. The final document, however, was the first where the criteria were used "really well" (interviews with Institute employees 6 and 5). The deliberations in the appraisal meeting focused on two elements. First, "the domain question" (audio file 3): to what extent is maternity care a type of curative care? The second element concerned the idea of whether the need for maternity care is "foreseeable", meaning that if you know you are going to need something someday, you should not be *insured* for it (as you can save up, you know it is coming). The final decision was indeed to continue maternity care coverage (Document 1.2).

The paracetamol-vitamin D tablets file came onto the agenda of the Institute due to some national policy changes, by which a fairly large number of tablets was left behind on a list of covered medications (in Dutch: *Geneesmiddelenvergoedingssysteem*). In a letter to the Institute, the Minister of Health explicitly stressed the need to pay attention to the necessity of coverage of these tablets, which included 1000 mg paracetamol, vitamin D, and calcium tablets. The Institute employees responsible acknowledged that they, at first, called it an "outflow advice" but were "not allowed" to call it that (interview with Institute employees 1 and 7). It was discussed at the appraisal committee in October and November 2016. A number of pharmacists had inputted, as patient representatives, to the scoping session; the secretary of the committee, brought in the argumentations supplied by them. As a consequence, much of the deliberations focused on what constitutes individual affordability for specific vulnerable groups. The second element that was primary in the discussions was the comparator medicines; if we compare it to other medicines available at the drug store without a prescription, it should not be reimbursed. As a corollary, the question was whether these medicines constituted "self-care" medicines or not. The final advised decision was to not cover paracetamol-vitamin D tablets except for certain medical indications. The rationale was that reimbursing would actually be more expensive than not, because of the prescription rule. This rule is an extra charge

levied when a reimbursed medicine is bought at the pharmacy on prescription, which was circumvented by the negative advised decision (Document 4.2).

General setting

> The meetings of the appraisal committee take place in a sizeable meeting room that is relatively light, even though the blinds are drawn. There are two entrances: you can enter the room from 'within' the building (behind the security gates) but also from the 'outside', provided your name is on the list, which is checked at the reception. Ten people are seated around tables set up in a large square. There are thermoses with coffee and tea and plates of biscuits. An 'audience' of eight more people, me included, sit on the rows of chairs set up on one side of the room, where we can see the committee and the presentation screen well. I seem unable to shake the feeling we are watching a staged performance. It is clearly one of these occasions where you feel careful about making noise: I open my water bottle as quietly as possible. Given this fairly formal setting, I am struck every time by how warmly the committee members greet one another when they come in, how at-home they seem (one even brought her dog!), and even more by the apparent light-heartedness of it all, the sheer good humour that characterises the proceedings. (Condensed field notes 2, 3, 4)

In this setting, the deliberations on the four cases followed approximately the same order. We have separated this order out into four phases, namely 1) the contribution of the Institute employee(s); 2) the contributions of the patient(s) and/or their representative(s); 3) the actual deliberations of the committee; and 4) the formulation of the decision. This separation into four phases allows us to show how necessity is constructed in each phase.

Phase 1: Institute employee(s)

The contribution of the Institute employee(s) is the first of four phases we distinguish in the Dutch appraisal meeting, and we will show the impact of these contributions on the committee deliberations that followed.

The first phase of the 'open' meeting that followed, after the meeting was formally opened by the chair, comprised the contributions by the Institute employee(s). The individual severity of illness (code: Morbidity/Severity) and costs per the individual patient (code: Individual Cost) are formulated as official, explicit elements of the formalised necessity criterion. These were contributed by the Institute employee in the form of necessity argumentations, often by means of a formal presentation (observations 1, 2 and 4; audio files 1-4). Generally speaking, the appraisal committee took the individual severity of illness and costs per individual patient as 'given' in their deliberation; they did not explicitly mention them in their deliberations (observations 1, 2, 4/audio files 1-4). This pattern was broken only in the paracetamol-vitamin D case, in which the low severity of illness was indeed actively questioned by a committee member but not discussed any further.

The applicability of the individual cost argumentation was also questioned explicitly on behalf of the patient representatives by a Committee member, which did prompt a response that served to re-establish its applicability in general. Neither argumentations were 'weighed' compared to other argumentations.

As a committee member explained, the reason for this lack of use of the severity of illness and costs for the individual by the committee is that it is not their mandate to weigh these explicitly (Committee member 4, personal communication). This does not mean the Institute employee's input is ineffective. One committee member commented on the introduction by Institute employees, that:

> CM5 [T]he discussion, at some point, heads into a different direction.
> CM6 Yes, that's right. (Group interview with Committee members 1, 4, 5 and 6)

They acknowledged the impact on the deliberation: the Institute employee's argumentations deriving from formalised criteria are considered authoritative and steering the direction the committee's discussion takes.

In some cases, it could be argued that the appraisal committee did give a different formulation to these two explicit necessity criteria, that is, operationalising them differently (resulting in a different argumentation type code). This would involve not calling the individual severity of illness as between "0.71 and 1.00" (code: Morbidity/Severity, document 3.1) but instead, highlighting the daily consequences for the patient (code: Societal Functioning, observations/audio file 1). A similar reframing was observed in the front teeth case:

> [Just consider] what that means for someone, right, missing front teeth, in daily communication. (Observations/audio file 2, code: Societal Functioning)

This clearly shows how the committee may sometimes employ a different operationalisation, resulting in a different argumentation type code, of the criteria brought in by the Institute employee.

In sum, necessity is thus constructed in this first phase not by weighing formalised criteria explicitly but by rephrasing them and/or allowing them to steer the appraisal process implicitly, which committee members consider to positively impact the deliberations.

Phase 2: patient (representative)(s)

For the second phase of the appraisal, which consists of the contribution(s) of the patient (representative)(s), we will also describe how they affect the deliberations of the committee.

In the second phase, patients and/or patient representatives such as medical doctors, gave a short statement (observations/audio file 1). These people differ per case and are not always present. The observations/audio file data show that necessity argumentations that a patient (representative)

contributed were hardly ever mentioned by the appraisal committee. In the eculizumab case, the patient representative mentioned that the decision was:

> [A] story (…) that concerns (…) justice. (Document 3.3 and observations/audio file 1, code: Equity/Fairness/Justice)

> Not only is [coverage] the best option for the doctors and us; it is also for society as a whole. (Document 3.3 and observations/audio file 1, code: Societal Impact)

Neither of these argumentation types were mentioned as such by the appraisal committee (observations/audio file 1). The patient representative also brought in two argumentation types that were repeated once but not discussed further. First:

> As of [29 October 2014], the life of our little daughter Rosa, just 1 year old, forever lost its ease and was never again taken for granted. (Document 3.3 and observations/audio file 1, code: Vulnerability/Compassion)

This clear call for compassion was repeated by Committee member 7 (observations/audio file 1) but not discussed by the committee. The same goes for the functioning of the family generally, which the patient representative described as a "roller coaster" due to the high uncertainty of coverage. This element of uncertainty was mentioned in turn by the same committee member but also not discussed further (observations/audio file 1).

Though patients were only physically present in this dataset in the eculizumab case, their contributions were a primary topic of discussion during the interviews. Several committee members commented on what they experience when faced with patients and their representatives during the appraisal, and 'Distance' was the most important aspect identified:

> We need to keep the distance [from the patients]. [With emphasis:] Someone needs to keep the distance. And it should be us. (…) It's like a war, the generals have to decide where the bombs will fall, and they should not see the mess it creates. (Committee member 2, interview)

> [A good decision] requires a kind of distance from that specific [patient perspective]. (Committee member 3, interview)

To function well, the committee members feel they require metaphorical distance from the patients, which explains the lack of explicit discussion of argumentations contributed by patients or their representatives. Another committee member reflected:

> The patients challenge the committee to keep their position. (…) You need to stay detached. [But the patients' input] gives handles for substantiating [your position]: you must explain it well. It challenges you as a group and as a person. (Committee member 7, personal communication)

This committee member suggested that the patients' input increases the quality of the final (advised) decision as the process is "challenged" by the contributions.

Summarising, necessity is constructed by the committee during the deliberations by not weighing the patient (representative) contributions explicitly but by allowing them to challenge the decision-making process implicitly, which committee members consider heightens the quality of the justification or rationale for the decision.

Phase 3: deliberation

The next phase we describe is the deliberative discussion by the committee, where many different argumentations are contributed by the committee.

The discussion was usually initiated by the chair, with ample opportunity to speak and to respond to one another for the other committee members. The professed goal of the discussion is to ascertain whether there may be reasons to deviate from the reference value for cost-effectiveness (Committee member 5, personal communications), which range in three classes from 10 to 80,000 euro per Quality-adjusted Life Year (QALY). If the cost-effectiveness falls within a certain reference value range given a certain individual severity of illness, it is classed as favourable; if it does not, it is classed as unfavourable (Zorginstituut Nederland, 2017, 2018). The discussions both started and ended with a 'round' around the meeting table, where committee members were invited to speak in turn. In the deliberative phase of the meeting, members may make statements and respond to one another before the final decision (observations 1, 2, 4/audio files 1-4). The deliberations were subsequently summarised by the chair of the committee, based on which the secretary wrote the appraisal report, a summative report of the appraisal committee argumentations. The final advised decision was taken based on this combined document by the Institute's Board of Directors and sent to the Minister of Health who took the final decision (Couwenbergh et al., 2013; Zorginstituut Nederland, 2016, 2017).

The data on how necessity is constructed during the deliberations can be best characterised as *bringing new argumentations together*. This is visualised for the front teeth case, where the appraisal committee wrestled with the tension between not covering cosmetic (that is, as falling within the Range of Normality and thus unnecessary) surgery and making sure young people are able to do things like eating an apple (audio file 2, code: Societal Functioning).

This tension was resolved by one committee member, who humorously brought the following new necessity argumentations together:

> I had a strange association with the contraception debate, where we said, "You should pay for that yourself", but up to a certain age, we think that it needs to be reimbursed because of the situation that, just for example, a 14, 15-year-old with parents who think otherwise would not be able to – that it could result in unwanted pregnancies, and we would like 18-year-old girls to enter adulthood without an unwanted pregnancy. [Laughter] They must both have good teeth and not have an unwanted pregnancy! [Laughter]. (Committee member 9, observations/audio file 2, codes: Similar Treatments and Vulnerability/Compassion)

Bringing in new necessity argumentations and combining them was also visible in the maternity care case. The public regarded the preparation of *beschuit met muisjes* or *beschuitjes* (a traditional Dutch treat for friends and family paying maternity visits) by maternity care workers as unnecessary. The appraisal committee, however, did not consider this a decisive reason for denying coverage. These different viewpoints were expertly brought in and combined in the following way:

> If you look at that article in Trouw [Dutch newspaper] of this week, following the draft advice that was released, you'll see that maternity care is associated straightaway with prepping beschuitjes. [Laughter] And if at that point someone would say, "Wait a minute, er, should I pay for that?" I would have some sympathy with that. (...) [But] I think it's important to indicate something like: "Yes, but wait a minute, maternity care is about other matters, er, breastfeeding, detecting risky situations, etc., etc., for which it is completely just to be calling for solidarity". (Committee member 8, audio file 3, codes: Societal Responsibility and Vulnerability/Compassion)

Committee members and Institute employees describe the appraisal as an "open, moral" place "with permeable borders" where many "things" interact "organically" to form an advised decision (Committee members 2, 6, 4, Institute employee 4, (group) interviews). Specifically, the appraisal committee "brings in" new necessity argumentations "from the outside" to be "woven together" (Committee member 1, interview). In fact, this bringing in from the outside is part of their official task (art. 14, Zorginstituut Nederland, 2016).

In sum, necessity is constructed in this phase by bringing in new argumentations derived from the outside, from society, with sources including newspapers and previously-taken decisions, and weaving these considerations together.

Phase 4: decision

In the final phase of the appraisal, the committee formulates its positive or negative coverage decision advice.

The committee regularly gave additional recommendations, generally phrasing advice as: "yes, provided that…" or "no, unless…" (observations 1, 2, 4/audio files 1-4). For the eculizumab case and maternity care case, the advised decision was positive, provided that the work on the indication

protocols would continue (documents 1.2 and 3.2). Similarly, the paracetamol-vitamin D tablets are not covered except for certain medical indications; one of the committee members even summarised their deliberations as if directly giving the Minister advice. The primary rationale was that reimbursing these medicines would actually make them more expensive, due to the prescription rule:

> You may make many more [medicines] available outside the pharmacy. Given the situation, this is our answer: if it has to be bought at the pharmacy, it has to be reimbursed. But we advise you to think carefully about the prescription rule, because that creates a completely unequal ratio between those cheap medicines that are and those that are not available on prescription. (Committee member 6, audio file 4, code: Similar Treatments)

The committee thus gives recommendations to a broad set of actors including the manufacturer, the professional organisations involved in indication protocols, and the Minister of Health. We analyse this dynamic as a way of completing the construction of necessity: with these recommendations, the decision is placed back into society as it is linked directly not just to patients and the Minister of Health but to other stakeholders who will impact what care entails in practice.

DISCUSSION

In order to describe how necessity is constructed in Dutch health care coverage decisions, we followed the use of necessity argumentations across documents and the meetings of the appraisal committee at the Dutch Health Care Institute. Necessity is constructed by first, allowing explicit criteria contributed by the Institute employee to steer the process. Second, by allowing patient (representative) contributions to challenge the process: the decision should be sensitive to but not captured by particular interests. Notably, both the knowledge that is contributed by the Institute employee and the patients and/or their representatives implicitly shape the deliberations that follow. The third element we identify is bringing in new argumentations from the outside and weaving them together carefully. Fourthly and finally, necessity is constructed through formulating recommendations, making the decision more societally embedded than a tersely formulated 'yes' or 'no'.

In the introduction, we outlined our interest in societal weighing expertise and concluded that expertise in health care coverage decisions generally comprises 1) understanding different types of knowledge and 2) combining them into one decision, whilst 3) adhering not only to substantive requirements but also processual ones (Calnan et al., 2017; Gkeredakis et al., 2011; Hughes & Doheny, 2011; Jenkings & Barber, 2004; Russell, 2017; Russell & Greenhalgh, 2014). In terms of expertise pertaining to societal weighing specifically, we see that all three elements are confirmed by our dataset on constructing necessity to a certain extent. The committee indeed deals expertly with different types of knowledge. In this dataset these contain on the one hand argumentations

representing scientific knowledge contributed by the Institute employee (individual cost and severity of illness) but on the other hand also the patient (representative)'s experiential knowledge. We show that although these considerations are often not mentioned explicitly by the committee, they sometimes get rephrased, and they always steer the discussions implicitly, and are therefore considered crucial to the final decision. The committee also combines many argumentations and does so expertly. The overlap with coverage decision expertise, we argue, indicates that these parts of constructing necessity may indeed be classified as elements of societal weighing expertise and highlight the precise way that processual requirements, such as the presence of stakeholders, may impact appraisal deliberations. This relationship between necessity construction and expertise in societal weighing specifically is even stronger for the latter two phases of constructing necessity, as they show how argumentations are brought in from society (in our dataset, sources included newspapers and stakeholders), and the (advised) decision is embedded in society in turn. These two elements give a distinct flavour to societal weighing expertise that other studies of health care coverage decision-making expertise appear not to have hit upon.

The reluctance in terms of explicitly weighing the experiences of individual patients has previously been described for a variety of settings (Carlsen & Norheim, 2005; Hashem et al., 2018; Rooshenas et al., 2015). One potential underlying reason may be what Moreira describes as 'the politics of singularities'. Personal stories, according to Moreira, have a strong allegorical character by which they may spark the imagination through being relatable, and are thus able to destabilise other argumentations (Moreira, 2012). This fact that the committee listens to but does not explicitly mention these argumentations may be a manifestation of a refusal to be drawn into such politics. Regardless of the underlying reason, this finding is fascinating in light of recent widespread attempts to draw patients and citizens into such decision-making processes (Mitton et al., 2009; Wait & Nolte, 2006), also termed a 'multi-stakeholder appraisal' (Abrishami et al., 2017). Our data underline that this will not be easily achieved, which is in line with earlier work on the practices of dealing with different types of knowledge in health care coverage settings (Hashem et al., 2018; Moes et al., 2016).

On the recommendations specifically, the brunt of the available literature covers the process of coming to these decisions and the rationales behind them, rather than looking at what the additional recommendations might be (cf., Bukachi et al., 2014; Byskov et al., 2014; Giacomini et al., 2000; Madden et al., 2005; Martin et al., 2001; Rooshenas et al., 2015; Singer et al., 2000). Follow-up research may address questions on whether other appraisal committees also give recommendations, on the underlying dynamic these recommendations may point to, and implications for the process of health care coverage decisions generally.

Strengths and limitations

This chapter describes how a coverage appraisal is performed by expert decision makers and the dynamics of using argumentations therein. To our knowledge, this study adds to existing research on coverage decisions both methodologically, through showcasing how insight can be generated by

tracing argumentation types across documents and deliberative settings, as well as content-wise, noting what societal weighing expertise entails specifically. It makes a contribution to the literature of elegant muddling through by showing the emergent shared systematics behind it (Calnan et al., 2017; Russell, 2017). Moreover, it shows how pragmatic rationality is accomplished collectively; it is not just the committee but also the Institute employees and the patients that crucially shape the deliberations.

The methodology chosen will have impacted the data; the data set comprises a mixture of nine individual and three group interviews. Though both types of interviews were held primarily for purposes of data triangulation, the data gathered in these settings will have differed. In group interviews, the members of the group may stimulate each other (rather than the researcher being the only one to take this role) in terms of encouraging recall, opinion elaboration, and variation in response. However, group members may also correct each other, and even sway each other's opinions. Influential herein are group size, familiarity, and power dynamics (Frey & Fontana, 1991; King et al., 2018). In this data set, two of the three group interviews were with two direct Institute employee colleagues, who seemed high on familiarity and relatively low on power dynamics, positively impacting the data gathered. Interviewees did indeed often supplement each other; both double interviews were in fact suggested by the interviewees themselves for that reason. The third group interview, with four appraisal committee members, also concerned peers who were comfortable expressing their opinions together. Moreover, in this case, the quieter respondents were interviewed separately as well.

A major limitation of this study is the focus on four cases. It is relatively common to only focus on one case for characterising these types of decision making (Moes et al., 2016; Moreira, 2011). The case approach has granted us increased reliability but may necessarily lack some in-depth acquaintance with each case. Another limitation is the narrow focus on the deliberations in the appraisal committee meeting only. Other studies focus on the 'back stage', thereby uncovering more work that is done 'behind the scenes' to accomplish these types of deliberations (e.g., Escobar, 2015). Future research could attempt to visualise both, especially elucidating how the two intermingle in practice (cf. Hajer, 2005).

CONCLUSION

Using heterogeneous argumentations to make well-justified decisions is a task that many public institutions work hard to complete astutely. This chapter gives insight into the processes of tackling this task in a particularly vibrant field: health care coverage. It does so through examining the construction of necessity in the deliberative appraisal of four Dutch coverage decisions by following the necessity argumentations as mentioned by the different parties involved, supplemented by interviews with both appraisal committee members and Institute employees. Necessity is constructed differently in the four phases of the appraisal meeting, which, we show, correspond to four ele-

ments of expertise in societal weighing specifically. These elements comprise first, allowing explicit criteria to steer the process. Second, being shaped by the input of patient (representative)s; these are considered to challenge the process and heighten the quality of the justification or rationale. Third, bringing in new argumentations from society and weaving them together, and fourth, formulating recommendations to place the decision 'back' into society. These elements of societal weighing expertise explicate how the committee reaches a decision that is well-embedded in society.

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