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Ethical review from the inside: repertoires of evaluation in Research Ethics Committee meetings

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Abstract Evaluating the practice of ethical review by Research Ethics Committees (REC) could help protect the interests of human participants and promote scientific progress. To facilitate such evaluations, we conducted an ethnographic study of how an REC reviews research proposals during its meetings. We observed 13 meetings of a Dutch REC and studied REC documents. We coded this material inductively and categorised these codes in two repertoires of evaluation: a repertoire of rules and a repertoire of production. In the repertoire of rules the REC applies rules, weighs scientific value and burdens to the participants and makes a final judgment on a research proposal in a meeting. In the repertoire of production, REC members check documents and forms and advise researchers on how to improve their proposals and can use informal communication. Based on these findings, we think that evaluations of the practice of ethical review should take into account the fact that RECs can use a repertoire of rules and a repertoire of production to evaluate research proposals. Combining these two repertoires can be a viable option so that the REC gives researchers advice on how to improve their proposals to prevent rejection of valuable research.

Keywords: research ethics committee, research ethics, The Netherlands, ethnography, ethical review

Introduction

Research ethics committees (RECs) review proposals for medical research involving human participants in order to deal with the central tension in medical research: protecting the interests of human participants versus allowing scientific progress. However, the quality of REC review has been criticised from two sides: one believes that RECs fail to provide adequate protection for research participants and the other that RECs unnecessarily impede the research enterprise (Fost and Levine 2007, Koski 2003, Saunders 2002, Savulescu 2002, Shalala 2000, Steinbrook 2002). To deal with these criticisms, many authors and governmental organisations have called for an evaluation of REC review (Centrale Commissie Mensgebonden Onderzoek 2009, Coleman and Bouesseau 2008, Department of Health and Human Services 1998, Feldman and Rebholz 2009, Grady 2010, Taylor 2007). To date, the empirical basis for such evaluations remains small. Most previous studies have

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focused on administrative procedures and efficiency, variations in REC reviews of multicentre research, differences in assessing specific issues or implementing regulations, and on the function of REC letters (Abbott and Grady 2011, Angell *et al.* 2006, Angell and Dixon-Woods 2009, Dixon-Woods *et al.* 2007, Dixon-Woods and Angell 2009, Edwards *et al.* 2007, O'Reilly *et al.* 2009, Redshaw *et al.* 1996, Taylor 2007). However, little information is available on an important part of the review process: the evaluation of research proposals during REC meetings (Abbott and Grady 2011). So far, only Parker *et al.* (2005) and Fitzgerald *et al.* (2006) have observed how RECs evaluate proposals for medical research and Hedgecoe (2008) has observed reviews of social science research. This is especially problematic since the REC meeting is the place where the tension between protecting research participants' interests and allowing scientific progress is likely to come to the fore. So, to contribute to the empirical basis for determining how to evaluate REC review, we studied how an REC evaluates research proposals during its meetings.

Background of ethical review by the West Holland REC

To ensure confidentiality, we refer to the REC we studied as the West Holland REC and to the corresponding medical centre as the West Holland Medical Centre. In The Netherlands the Medical Research Involving Human Subjects Act (MRA), the European Directive on Good Clinical Practice, the Declaration of Helsinki and requirements issued by the Central Committee on Research Involving Human Subjects (CCMO) form the regulatory framework for RECs. Dutch RECs are formally independent governmental bodies. Twenty-two of the 27 Dutch RECs, however, including the West Holland REC, receive their funding, facilities, personnel and workload from one or a few non-profit institutions and are thus strongly linked to those institutions. The West Holland REC consists of a legal scholar, a methodologist, an ethicist, a pharmacologist, a patient representative, a pharmacist, five physicians (a paediatrician, a neurologist, a surgeon and two internists) and a nurse. The West Holland REC reviews a wide range of studies, from large multicentre phase III drug trials, investigator-initiated surgical trials and public health research to qualitative studies. This is comparable with most other Dutch RECs (De Jong *et al.* 2010). The task of a Dutch REC is to systematically evaluate a research proposal and to approve or reject it. The West Holland REC has internal regulations and procedures for managing the review process and researchers are given specific instructions on how to submit the documentation for their research proposal (the proposal itself, the informed consent form [ICF] and several forms for administrative purposes). To allow members to prepare for the meetings, they receive copies of the submitted documents one week prior to the scheduled meeting.

Meetings are held twice a month, take on average three hours, are supervised by a chair and proceed according to a standard agenda: opening, incoming mail, continued review of proposals, review of new proposals, review of amendments to approved studies, advice on feasibility of multicentre studies approved by other Dutch RECs, reports on serious adverse events and reports and queries. The chair of the REC introduces proposals with a summary and then invites members to comment on the proposal itself, the ICF and other forms. Members ask other members questions to help understand the proposal or make evaluative comments on a certain aspect of the proposal and suggest a course of action. Other members can respond to this, leading to discussions. The chair then summarises the comments and the envisaged course of action. Ten to 15 new proposals are discussed per meeting, making a total of about 300 a year. It takes on average two meetings to reach a decision to approve or reject a proposal. Rejection rates are about one per cent.

Method

Between 2007 and 2009 we used ethnographic techniques to study the way in which the West Holland REC evaluated research proposals during its meetings. The first author, JP de Jong, observed 13 REC meetings and took detailed and extensive field notes of the conversations and interactions between members. After each meeting, he wrote down a preliminary interpretation: a first impression of the meeting, together with salient observations and a preliminary characterisation of the evaluation of proposals. Sound recordings were made of nine meetings to check whether the conversations were adequately described in our field notes and to extract verbatim quotes. Our field notes were supplemented with documents from the West Holland REC (its annual reports and website) that contained information about review meetings. Under Dutch law it was not mandatory to obtain ethical approval for our study from an REC. We obtained the consent of the West Holland REC to observe and record its meetings.

The qualitative analysis of our field notes was facilitated by coding the notes and retrieving segments with MAXqda2. Our analysis was guided by the inductive techniques described by Strauss and Corbin (1990) and consisted of three steps. Firstly, through inductive, open coding and comparison between REC meetings, JP de Jong identified elements pertaining to the evaluation of research proposals, using the preliminary interpretation to aid the development of these codes. Because little information exists on what kind of evaluative practice takes place during REC meetings, the second step in our analysis was to arrange our codes according to what we considered to be open and straightforward questions: In which action(s) does evaluation take place? How is evaluation carried out? What is the goal of evaluation? Where and when does evaluation take place? Who evaluates? How are the evaluators and the evaluated related? Although these questions were developed with an inductive approach, we were also inspired by the theoretical framework for analysing evaluative practices called 'situated judgment', developed by the sociologists Boltanski and Thévenot (2006). Using this framework one can analyse the 'operations persons perform when they resort to criticism [and] collaborate in the pursuit of a justified agreement' (Boltanski and Thévenot 2000: 208–9). Boltanski and Thévenot developed this framework by connecting philosophical theories of justice to empirical sociological research. The framework of situated judgment therefore permits one to describe different worlds of evaluation – consisting of abstract values and the sociological context – and this broad scope of analysis suited our purposes. Moreira (2005) used this framework to describe the evaluative practice of clinical guidelines development meetings, and from him we borrow the term 'repertoire of evaluation' to denote the types of evaluation we uncovered. So we use repertoires in a different sense from that of discourse analysis, because we have analysed our material not in terms of the social psychology of language but in terms of the practice of evaluation, consisting of values and the sociological context (Potter and Wetherell 1987). We were also drawn to the framework of situated judgment because it supported our emerging hypothesis that more than one type of evaluation was present in REC meetings. We hypothesised the existence of two types of evaluation with two images in mind: a court of law passing judgment and a factory improving its product. To identify a specific repertoire of evaluation and to distinguish between repertoires of evaluation, we performed a third analytical step: categorising codes into groups, together forming a certain repertoire. We categorised inductively by assessing the coherence and consistency of the emerging repertoires, and deductively by comparing them to Boltanski and Thévenot's (2006) worlds that resembled our repertoires: the 'civic world' and the 'industrial world'. To increase

Table 1 *Two repertoires of evaluation*

	Repertoire of rules	*Repertoire of production*
Evaluative actions	Applying rules Weighing	Checking Advising
Manner of evaluation	As a unity	Efficient
Goal of evaluation	Final judgments	Production of knowledge
Place of evaluation	REC meeting	REC meeting and informal communication
Evaluator	REC	REC and researcher
Relationship between REC and researcher	Hierarchical	Co-workers

consistency of coding and categorisation, samples of data were independently analysed by a second researcher (MCB Van Zwieten) and the emerging repertoires of evaluation were regularly discussed with the project leader (DL Willems) and fellow researchers. Finally, we gave a presentation on the repertoires of evaluation to the West Holland REC as a means for respondent validation.

In the next three sections we present our analysis of the evaluation of research proposals during REC meetings by describing two repertoires of evaluation: a repertoire of rules and a repertoire of production, and consequently show how these repertoires interact.

Primary data in the form of quotations are indicated by quotation marks. Additional information to clarify quotations is placed between brackets. JP de Jong translated the quotations from Dutch. Table 1 summarises the two repertoires of evaluation.

The repertoire of rules

In this section, we describe the first repertoire of evaluation in which research proposals are evaluated: the repertoire of rules. When a research proposal is evaluated within the repertoire of rules, one of the REC's activities is applying rules. This begins when the REC decides whether or not a research proposal falls within the scope of the MRA and whether the REC, in the words of its members, is 'competent' to 'judge' the proposal 'formally', for example, when a member says: the researchers 'don't do anything extra [compared to standard patient care], so it's not [does not fall within the scope of the] MRA', to which another member adds: 'One isn't allowed to say anything right now'. So, if the committee does not consider itself to be competent it will not review the research proposal at all. If a research proposal does fall within the scope of the MRA its further evaluation is also based on rules. Committee members can explicitly refer to laws and regulations to substantiate this evaluation, saying things like: 'These are just the rules' and 'It's not allowed by law'. The REC may also refer to more general rules as 'principles':

> The general principle should be that if it's possible [to carry out a study only] with adults [participants], you must do so. The point is that somebody else has to decide on behalf of these children because they aren't able to.

Besides the MRA and other 'external regulations' (like the Directive on Good Clinical Practice), an additional source of rules are the rules and regulations of the REC itself. These

include a regulation for REC activities, a procedure for submitting research proposals, a list of criteria for the protocol and the ICF, a list of the documents to be submitted, a procedure for lodging an appeal and objection and a complaints regulation. Finally, the REC also uses verbal agreements as rules, as illustrated by the following quote: 'We have all agreed that we would look more carefully at the exemption from insurance [when a study poses minimal risks to participants]'.

Ideally, in the repertoire of rules each member of the committee applies rules in the same manner and comes to the same conclusions, which makes the committee act as a unity. As the REC regulations state: 'The committee strives for unity in its decision making'. When committee members agree in their evaluation and envisaged course of action, this agreement is often implicit, with one member making a remark and the others agreeing tacitly by not protesting. Sometimes a member makes this agreement explicit: 'We all agree on this'. Furthermore, committee members consider themselves as belonging to a larger unity – the committee – which is demonstrated by the fact that they often use the plural 'we' when evaluating research proposals. This is illustrated by the following quotes: 'We approve of this', 'We don't agree [with this aspect of the research proposal]', and 'We should take that into consideration'. To protect its unity, the committee strives for independence and seeks to avoid conflicts of interests. The REC rules and regulations therefore stipulate that:

> if a member of the committee is involved or has an interest in a research proposal that is to be judged, s/he will not take part in the discussions and decision making about it.

This is evident in cases where the chair passes her position on to a fellow committee member during the evaluation of a proposal in which she is personally involved.

However, committee members can also interpret the rules or the facts to which the rules apply differently, leading to differences in evaluation and endangering the committee's unity. Differences are often solved swiftly by a committee member providing some additional information or by asking the researcher to do so. However, greater threats to the committee's ideal of acting in unity – and thus to judging whether a research proposal should be 'approved' or 'rejected' – can arise when members differ not so much on the interpretation of rules or facts, but on determining the value of the two key aspects of a proposal: the scientific value and the burdens to participants. This brings us to another activity typical for the repertoire of rules: weighing. The following is an example of this: 'We should weigh the importance [of this knowledge] against the burdens [to participants]'; to which another member adds: the researcher 'doesn't remove our concern about the ratio between burden and importance'. As a rule, the scientific value of the research should outweigh its burden to participants, as illustrated by the following two quotes: 'Although this study is quite burdensome, (it's) also important research' and 'Despite being vague research, it carries very little burden'. If the scientific value does not outweigh the burden to participants, the committee will reject the proposal. Although weighing is thus a crucial activity in this repertoire of evaluation, it can also lead to conflicts between members and threaten the unity of the committee. For example, one member attacks the scientific value and another member counter-attacks, based on the burden to participants, saying, 'When they finish their pilot [study], they [will] know just as much as when they started', followed by another member's response: 'But that's … not serious, [it's] not dangerous [to the participants]'. The conflict can also develop the other way around, with one member attacking the burdens to participants, and another counter-attacking on the scientific value, for example: 'I thought it quite burdensome to the control [participants]', followed by the response: 'I think the research

question justifies the burdens'. In case a conflict cannot be solved by discussion the committee's last resort to restore its unity is voting.

So, in the repertoire of rules, REC activities consist of applying rules, weighing the scientific value and burdens to participants and judging whether to approve or reject a research proposal. Besides unity, the committee strives in these activities for 'finality'. It works towards a final conclusion or decision. As one member puts it: 'We can only approve or reject; we cannot give provisional approval'. However, the committee can also choose to suspend its decision on a proposal when it wants changes to be made to the proposal or more information. Then, after getting a response from the researcher, the committee will discuss the proposal again in a later meeting under the agenda item 'pending projects'. However, the committee considers this course of events less desirable: 'We want to look at this [proposal] again, although I don't like that conclusion'. The end-point of the REC's evaluation is its final judgment – an approval or rejection – after which the researcher can proceed as planned. As the REC rules and regulations state: 'If the circumstances remain the same, the judgment passed by the committee remains valid'. If researchers want to make changes to a study, they have to submit an 'amendment' which will be judged by the committee.

In the repertoire of rules, evaluation takes place during REC meetings and when REC members prepare for meetings. As the REC regulations put it:

> The researcher who will be directly responsible for the study on human participants is obliged to have the Research Ethics Committee review the intended study prior to … the actual initiation of the study … The committee will discuss the research proposal … during one of its meetings … [and] inform the researcher of its substantiated … judgment in writing … Lawful decisions can only be made during a meeting.

The preceding description of the repertoire of rules makes it clear who evaluates and who is evaluated: the REC evaluates the researcher. In this repertoire, evaluation takes place within a hierarchical relationship: REC members comment on proposals by saying that the researchers 'must' clarify, motivate or change certain aspects of the research protocol or of informed consent procedures. Also, a researcher literally has to 'submit' a proposal. Other wordings directed at researchers such as 'allow', 'accept', 'permit', 'may', 'reject', 'grant exemption', 'reject' and 'approve' also place the researchers in a hierarchical relationship with the REC. The REC also has a hierarchical relationship with the CCMO. The hierarchical relationship between the REC and the CCMO – the REC in this case having the lower rank – is illustrated by the fact that the REC's internal regulations state that 'the person who submits [a research proposal for review] … can lodge an appeal against a judgment issued by the … [REC with the CCMO]'. Furthermore, during meetings REC members sometimes explicitly refer to the CCMO as a source of authority, as is illustrated by the following two quotes: 'Would the CCMO approve of this?' and 'Can this be directly deduced from the MRA? Not from the text of the act, but [it can be deduced] from other CCMO documents'.

The repertoire of production

We now turn to the second repertoire of evaluation in which research proposals are evaluated: the repertoire of production. When a research proposal is evaluated in the repertoire of production, one of the REC's activities is checking. This is illustrated by the abundant use of forms. The REC's website provides researchers with detailed information on what documents to submit, including forms such as the general review and registration form

(GRRF), the West Holland Medical Centre appendix (containing institute specific questions), and the ICF. As specified in the CCMO directives, the REC has to 'check the completeness and accuracy of the GRRF form'. According to the CCMO, the purpose of this form is:

> to support the reviewing committee in quickly listing a number of important points … [and] to function as a checklist for the person submitting the research file … The GRRF form remains an aid.

Upon the submission or a research proposal, a secretary checks whether all the required documents are present and notifies the researcher promptly in case the submission is incomplete. During the meeting itself, the REC members check whether forms have been filled out correctly, making comments like: 'The GRRF form lacks information on the principal researcher and the amount of blood [that will be taken from the participant]' and 'Several answers [to questions on the GRRF form] are incorrect: … funding, phase of research'. The REC also checks whether other documents contain the required elements, as illustrated by the following two quotes: '[In the ICF] the section on privacy is missing' and '[In the protocol] information on the safety of drug … [X] is missing'.

In addition to checking documents, the REC employs another activity in the repertoire of production: giving advice. Advice is a non-obligatory recommendation and can concern practically any aspect of the research proposal. As an example of advice concerning study methodology: 'I propose that they either use a … [placebo] treatment or put more emphasis on the hard outcome measures', to which another member adds: 'We'll indicate that it would benefit the quality of the study if they use a … [placebo] treatment'. The REC can also advise on how to decrease burdens to patients or to increase the benefits to patients. As an example of decreasing burdens, a member remarks: 'What they do with a CT [computed tomography] scan, they could do with an MRI [magnetic resonance imaging, a scan that poses no radiation risks] as well, we should advise that'. As an example of increasing benefits:

> It would be better to do a crossover study, because in that case the patients from this one group can get the other treatment after the [initial] treatment [as well], because neither treatment has a hundred per cent chance of success.

Furthermore, the REC can advise on how to improve the wording on the ICF and so goes beyond judging it as inadequate: 'On the ICF it says ''race'', [that]'s an offensive word and biologically incorrect, [it's] better [to say] ''ethnicity'''. Our final examples of giving advice concern efficiency and speed. We will elaborate on these aspects of the repertoire of production in the following paragraphs. Advice in terms of efficiency is illustrated by the following quote: 'We'll advise against using placebos, because in my experience they're terribly expensive'. And the following is advice in terms of speeding up the research process: 'It would be better if they did a randomised study and skipped this step'.

In the repertoire of production, the goals of evaluation are cast in terms of production such as speed and volume. To start with the former, the REC considers the speed of the review process to be an important goal, as is evidenced by an example from its annual report: the 'advantage of this method of working is that the review process is not prolonged unnecessarily', and as a member says in a meeting: 'That was fast, going through such a big stack'. Also in its annual report, the REC stresses its speed by saying that 'the submitters usually receive the committee's written response one week after the committee meeting', and by presenting a diagram showing the time span from submission until final decision for each

proposal. Furthermore, under the heading 'Looking forward', the REC presents modifications to accelerate the review process. As early as in the second sentence of its annual report, the REC proudly announces that it produces the highest volume of reviews: 'The REC of the … [West Holland Medical Centre] is still the committee that reviews the highest number of scientific protocols per year [in The Netherlands]'. To complete this image of the production of evaluations by the REC, we note that its annual report consists for a large part of figures on which categories of research it reviews, in what numbers, what the 'throughput' time is, and how much meeting time the REC spends on reviewing. All of this is expressed in numbers, percentages, averages and graphs. Furthermore, to increase the speed of review and decrease the researchers' workload, the REC takes several measures to help researchers submit proposals correctly. These measures include providing detailed information on what to submit, when to submit it, how to submit it, what regulations apply, examples of protocols, notifying the researcher promptly in case of an incomplete submission and allowing digital submission of protocols. Also, according to the annual report:

> If the committee has no important questions concerning the content, but does have a number of 'technical' remarks, the application will be dealt with by the committee's secretary, which can save a considerable amount of time for both the applicant and the committee.

An aspect of evaluation related to production is efficiency: evaluations should be produced efficiently. So REC members are not only concerned with the outcome of their work – the evaluations – but also with how this relates to the input they deliver themselves. REC members invest valuable resources (time and effort) and want to do so efficiently, as the following quote illustrates: '[The forms] have been filled out correctly. That's because somebody's working on that professionally. [It's] smart to hire such a person, [it] saves us a lot of time'. The concern for efficiency also extends to the work done by researchers: the REC advises researchers on how to organise their work efficiently. For example, when the REC discusses two related research proposals submitted by the same researcher – study X and study Y – a member remarks:

> I think [the researcher] should first carry out study [X because] if … [the result] isn't reproducible, they don't have to carry out … study [Y].

The REC also makes its concern for efficient investment of resources explicit in the quote discussed in the paragraph on giving advice: 'We'll advise against using placebos, because in my experience they're terribly expensive'. On the other hand, the REC can also deliberately refrain from improving, for reasons of efficiency. This is often the case with ICFs, for example, when the layout of the ICF could be improved and a member says: 'We shouldn't overdo it'.

Evaluation in the repertoire of production does not take place only during meetings but is more dispersed in place and time. Because REC members are (albeit sometimes distant) colleagues of a researcher, they can use alternative ways to act and communicate, outside the routes dictated by regulations. For example, when a member asks how to contact a researcher: 'Is it possible to ask this without writing a letter?' a member replies: 'I'll call the researcher'. As an example of choosing an alternative course of action, a member says: 'I think the physician should provide this information and not the trial nurse. But that doesn't belong here, I'll tell them myself'. Furthermore, in the repertoire of production, the REC uses letters to give researchers advice on how to improve their study. This can result in a reply

from a researcher explaining how s/he followed the advice, but researchers can in their turn also evaluate the REC's advice by envisaging how it would affect their study and respond to the REC with a letter proposing an alternative course of action. This can lead to a discussion between the REC and a researcher and an exchange of multiple letters. This makes the researcher and the discussion via letters part of the evaluation, and the evaluation itself a co-production of the REC and a researcher. In fact it is very rare for the REC to send only one letter during the review process, expressing its final judgment. Moreover, in the repertoire of production, neither the REC's evaluation nor the exchange of letters is the decisive step in the evaluation of a study. The REC acknowledges that it can only do so much to improve research proposals and that studies face the ultimate test during their execution; as for example when a member remarks: 'Despite the fact that it's a vague study, it's not very burdensome. That's not our problem, it's the researcher's problem, it will surely result in something'.

As described in the previous paragraph, in the repertoire of production not just the REC but researchers contribute to the evaluation of research proposals as well. Together with the fact that the REC evaluates by giving advice to researchers on how to improve their research proposals, this makes the relationship between the REC and researchers one of co-workers helping each other, as is illustrated by this quote: 'We phrase this as advice, we help them on their way'.

Interaction between the two repertoires of evaluation

There are several ways for the repertoires of rules and production to relate to each other during REC meetings. The simplest way is peaceful coexistence: both repertoires are present but do not interact. This can mean that the discussion of a particular research proposal takes place entirely within one repertoire or that the discussion of a proposal alternates between two repertoires. When the repertoires of rules and production do interact this can result in either conflict or in collaboration. Conflict can arise when evaluation according to the two repertoires leads to incompatible courses of action. Examples of such conflicts are situations in which members think that formally reviewing a study according to the repertoire of rules is a waste of their and the researcher's time, according to the repertoire of production. To illustrate this, we quote a member:

> [For this study] patients have to say 'aah' three times. Unfortunately, [this study] falls under the MRA from a legal point of view. We can't say it doesn't fall under the MRA. It would be nice if they hadn't submitted it, no one would have known a thing.

The committee consequently decides to formally review the proposal. The outcome of this and most other conflicts between the two repertoires is that the repertoire of rules prevails and proposals are formally reviewed.

In this study we came across only one type of conflict where the repertoire of production triumphs over the repertoire of rules. This is when REC members think that although a research proposal has been judged too harshly, according to the repertoire of rules, a reversal of the judgment is a waste of energy, according to the repertoire of production. To illustrate this:

> According to the law this isn't drug research … But if they're going to change this, they'll have to go to the CCMO, that's a lot of work. We could also pretend we didn't notice it. They've done more than necessary, there's no harm in that.

However, this type of conflict can also be interpreted as a collaboration between the two repertoires of evaluation: judging a research proposal in a certain way contributes to efficiency. Another example of such a collaboration is the following quote: 'Does this fall under the MRA? It's only a questionnaire', to which another member replies: 'Let's judge … [this proposal, because] we've already done the work [preparing for the meeting] anyway'. Although this type of collaboration occurs, the converse relationship between the repertoire of rules and production is far more common: improving a research proposal to be able to judge it in a certain way. An example of this type of collaborative relationship is when an REC member responds to a member that asks how strict the REC is in rejecting a proposal if the ICF is not in order: 'We've never done that [rejecting a proposal because of an unacceptable informed consent form … the form] always turns out all right eventually'. Furthermore, although we have not performed a quantitative analysis, we have the impression that the REC spends roughly the same time evaluating according to either repertoire. Because the REC spends so much time and energy on giving researchers advice on how to improve proposals according to the repertoire of production, this helps to make proposals more approvable, according to the repertoire of rules. Consequently, while it is very rare that a proposal gets approved in the form the researcher initially submitted it, rejection of a proposal is also very rare.

Discussion

We have described how the West Holland REC evaluates research proposals according to two repertoires of evaluation: a repertoire of rules and a repertoire of production. In the repertoire of rules the REC applies rules, weighs the scientific value and burden to participants and comes to a final judgment on the research proposals during its meetings. It does so in unity and in a hierarchical relationship with researchers. In the repertoire of production, REC members check documents and forms and give the researchers – their co-workers – advice on how to improve their proposal. They do so swiftly and efficiently, and can communicate with them outside formal meetings and letters. When the repertoires conflict, the repertoire of rules usually prevails. However, repertoires can also collaborate: resorting to the repertoire of rules sometimes helps to do the work efficiently, but more often, resorting to the repertoire of production helps to get a proposal approved.

We have tried to secure the validity of our study by using different datasets, by having multiple researchers carry out the analysis and by respondent validation, all of which did not show large discrepancies. A limitation of our study is that, although we had no explicit theoretical concepts in mind, our analysis was possibly influenced from the start by a prior knowledge of Boltanski and Thévenot's (2006) theory of situated judgment and the worlds they describe. Apart from studying the meetings and documents that contained explicit information on meetings, we did not gather additional information on the review process such as interviews with committee members or REC letters, for two reasons. Firstly, we focused our research efforts on the meetings themselves because they seemed to be the most understudied part of the review process. Secondly, we judged that an analysis of interviews or letters would not have altered our description of what committee members *do* when they evaluate research proposals during meetings, because we followed Boltanski and Thévenot (2006) in taking these evaluative practices at face value and not with a critical sociological or psychological stance. However, it would be worthwhile to study how evaluative practices during REC meetings relate to those in REC letters. Comparing our findings to previous studies on REC letters suggests that in letters predominantly a repertoire of rules is used (Dixon-Woods *et al.* 2007, O'Reilly *et al.* 2009).

A second limitation of our study is that we have not thoroughly investigated whether additional repertoires of evaluation were present in our material. A cursory exploration did hint at a third type of evaluation. This type seemed to revolve around personal relationships, in which committee members acted as friends imagining how it would feel to have a relative participate in the proposed research. Although this type of evaluation did not play as decisive a role in the evaluation of proposals as the other two repertoires, it would be worthwhile to further uncover this repertoire.

We believe that our analysis of the West Holland REC applies to other Dutch RECs because they have a similar constitution and work under the same regulations and because most of them are linked to a medical centre in the same way (Centrale Commissie Mensgebonden Onderzoek 2010). Our finding that a REC employs two repertoires of evaluation might also apply to RECs outside The Netherlands, since ethical review seems very similar in REC meetings around the world (Fitzgerald *et al*. 2006).

Three previous studies have observed the evaluation of research proposals during regular REC meetings. In contrast to our finding of two specific repertoires of evaluation, Parker *et al*. (2005) concluded that an Australian REC was permeated by a single common logic of evaluation, called 'the practical logic of reasonableness' of lay persons. Although this reasonableness was explicitly referred to, it was also taken for granted: it needed no further justification. Using our framework of repertoires of evaluation, this finding might be explained as a solution for the possible conflict between underlying repertoires of evaluation: forestalling the conflict by using a sufficiently general concept for evaluation with which everybody can agree.

In the second study, Fitzgerald *et al*. (2006) have described the review process in five countries, based on interviews, observations and documents. Their narrative approach focused on the abstract linguistic structure of comments of individual reviewers. This makes their approach complementary to ours, since we did not focus on the linguistic structure of evaluative comments but on the practice of evaluations, consisting of values and the sociological context. Unfortunately, Fitzgerald *et al*. do not provide enough primary data to allow an analysis in terms of our repertoires of evaluation. However, we recognise many of the narratives described by Fitzgerald *et al*. in our material, which supports these authors' conclusion that reviews seem very similar in REC meetings around the world.

In the third study, Hedgecoe (2008) observed how three UK RECs made decisions on social science research. He found that part of the role of the REC was to be supportive and facilitating, offering advice on how to improve research proposals, thereby allowing science to progress. This role seems very similar to our repertoire of production. However, Hedgecoe does not report explicitly on the other role(s) of the RECs, so we cannot ascertain whether they are similar to our repertoire of rules.

Finally, we compare our results to the work of Boltanski and Thévenot (2006) that inspired our analytical approach. Although they proceeded deductively from classic works of political philosophy to empirical material consisting of handbooks for people working in types of business, and although their material is very different form our observations of REC meetings, Boltanski and Thévenot's 'civic' and 'industrial world' correspond very well to our repertoire of rules and repertoire of production, respectively. The civic world, which Boltanski and Thévenot trace back to Rousseau, centres, like our repertoire of rules, around the unity of people and is rule-governed. This world consists of moral principles, (patients') rights and people who strive for autonomy and are to be protected. This is the moral world in which most contemporary bioethical debates, including debates on research ethics, seem to take place. The industrial world, which Boltanski and Thévenot trace back to Saint-Simon, centres, like our repertoire of production, around progress and is concerned with efficient

production. This world consists of hardworking people, working together to improve (health care) and striving for effective and efficient processes. We think this moral world is undeservedly overlooked by most bioethicists. Our finding that the West Holland REC is involved in two repertoires of evaluation can be explained by the fact that, in the words of the Declaration of Helsinki, it is 'an independent committee … in conformity with the laws and regulations' and is also part of a larger research institution (18th World Medical Association General Assembly 1964). So, on the one hand the REC is an independent committee in the civic world, the place where people use a repertoire of rules. On the other hand, the REC is part of a research industry in the industrial world, the place where people use the repertoire of production. A good example of the mixed character of RECs is that the research industry's wish for quick review has in many countries been incorporated in guidelines for REC review by requiring a decision within 60 days. Based on the above comparison with the literature, we conclude that our finding of REC review according to a repertoire of rules and of production possibly applies to other RECs around the world. However, future studies that directly observe RECs should confirm this.

We hope to have made it clear that it would be wrong to conflate the two repertoires of evaluation to the tension between the interests of human participants and the progress of science: both these values partake in both repertoires. We conclude our article by envisaging how the repertoires of evaluation affect both the interests of participants in research and science.

The repertoire of rules and research participants

In this repertoire the REC strives to apply rules in a uniform manner, and evaluates whether the scientific value outweighs the burdens to individual human participants. This helps to protect participants from the extremes of medical research. However, because rules are rigid and general, they can be inadequate for special situations or for special groups of participants. Furthermore, the question whether a research proposal is considered ethically permissible is delegated to the REC, which can make researchers feel less responsible.

The repertoire of rules and science

This repertoire has the obvious drawback of slowing down scientific progress due to the efforts involved in meeting all regulatory requirements or by banning types of research. However, when RECs succeed in applying rules in a uniform manner this also has an advantage for researchers: they can carry out research in a predictable environment. Together with the fact that REC decisions are final, this helps researchers to do research with the necessary degree of independence.

The repertoire of production and science

In this repertoire the REC gives advice to researchers that can help them to improve their research proposal. The fact that the REC and researchers are co-workers makes this advice practical and tailor-made and allows for additional forms of communication outside formal meetings and letters. Furthermore, the REC tries to do its work efficiently, which helps the progress of research. However, by interfering too much with the research methodology, the REC can endanger the independence of researchers to pursue their research as they see fit.

The repertoire of production and research participants

This repertoire has the obvious drawback of being so focused on efficiency and speed that it treats research participants as mere numbers in a calculation and threatens their interests as individuals. However, the REC's advice to researchers is not only directed at the research

methodology, it also serves the interests of the research participants, for example, by helping researchers to minimise the burdens participants may experience.

Our findings also show that how the interests of research participants and science are interrelated is different in both repertoires. In the repertoire of rules the interests of the participants should always prevail over the progress of science, whereas in the repertoire of production they are values that can be optimised more or less independently. In the light of our finding that the repertoire of rules usually prevails over the repertoire of production, this means that, in our study at least, the protection of the research participants is the dominant value in an REC review.

Thus, both repertoires of evaluation have advantages and drawbacks for the interests of human participants and scientific progress. This brings us back to the question of how to evaluate REC review and, more specifically, how to evaluate an REC that uses a repertoire of rules and a repertoire of production. First of all, we think that anyone who is concerned about the quality of REC review and wants to evaluate the review process should at least take into account the fact that an REC might be involved in more than one repertoire of evaluation. However, whether RECs should use none, one or both of the repertoires of evaluation we described is up for discussion. Our results suggest that a combination of repertoires can be a viable option: using the repertoire of production to give researchers advice on how to improve their research proposals in order to prevent rejections of much valuable research when only the repertoire of rules is used.

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