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Ethical review: Standardizing procedures and local shaping of ethical review practices

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ABSTRACT

Since ethical review practice has developed in relation to specific regulatory regimes and local contexts, it cannot be understood without paying attention to the institutional context of ethical review practices. We believe the tendency towards strong central governance and standardization in ethical review implies a lack of understanding of how specific local institutional contexts actually affect ethical review practices. Our question is: "How do local institutional contexts relate to the way REC's shape their formal mandate, and what are the implications for research governance?" To get in-depth insights in how REC's shape their formal mandates in every-day practice, we did a qualitative ethnographic-sociological study of three Dutch REC's in different contexts: an academic context, a care context and a commercial context. In analyzing these three REC's we paid attention to the procedures operative in REC practices, the cultures and everyday experiences of REC members, the scientific, social and financial resources that are available to REC's, and the evaluative perspective REC's employ. We conclude that specific local, institutional contexts offer valuable resources for ethical review. To track this, insight into the institutional configuration as a whole is necessary. Variations in the ways REC's shape their formal mandate should not be regarded problematic, but rather as fruitful opportunities for public learning.

Introduction

Practices of ethical review have brought along discussions on the mandate of Research Ethics Committees (REC's). Should ethical review committees discuss not only ethics but also scientific quality of studies? (Angell, Bryman, Ashcroft, & Dixon-Woods, 2008) Should social science research be treated differently than medical research? (Haggerty, 2004) Should low- and high-risk research be treated differently? (Millum & Menikoff, 2010) And how should bureaucratic control and scientific freedom and progress be balanced? (Olivier, 2002). These discussions about ethical review reflect broader discussions on governance of science.

In studies of governance of science, and the professions, sociologists and historians have sketched trends of rationalization and standardization. These trends display that scientific and professional practices, to publicly account for the quality of their work, have become focused on quantitative standards for quality, while trust in professionals and experts as persons has diminished (Porter, 1995; Weingart, 1997, 1999). While standards might help to coordinate the work of professionals and to control the quality of their work, these rules also entail that variety in scientific and professionals practices is decreasing. In medicine and public health the quest for Evidence Based interventions and the extensive growth of guidelines for clinical practice is indicative of this tendency. Although many authors have pointed to the benefits of this trend for enhancing public control on professionals, it has become clear that it also creates tensions between centralized professional standards and local practices. Processes of standardization and tensions between standardization and localization not only have become evident in medicine and health care (e.g. Berg, 1997; Berg, Horstman, Plass, & van Heusden, 2000; Bowker & Star, 1999; Horstman, 2013; Wehrens & Bal, 2012), but also in ethical review practices (Hedgecoe, 2012).

In western countries, ethical review has become an obligatory passage point for all research with human beings. Since ethical rules about balancing risk and benefits, as formulated in international ethical codes, have played a major role in ethical review from the start, it might be argued that standardization is intrinsic to ethical review. However, since then, ethical notions have been developed into international and national regulations regarding ethical review. Several countries have installed a central, national

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ethical review board, and the European Clinical Trial Directive is a further centralization of ethical review. As Hedgecoe has demonstrated, these processes of standardization in ethical review have resulted in considerable tensions for local ethical review boards (Hedgecoe, 2012). Ethical review is thus an interesting case to study tensions between standardization of ethical review and local practices. In this article we will do so for the Netherlands.

In different European countries national ethical review bodies have different functions. In European countries the central board may function as an appeal body (Sweden), as a central distributor of clinical trial protocols (Portugal), or as an ethical assessor in parallel with local committees (Hungary) (Hedgecoe, Carvalho, Lobmayer, & Raka, 2006). The Dutch Central Committee on Research involving Human Subjects (CCMO) has multiple roles and acts as an appeal body, an assessor of specific protocols, and as coordinating body supervising the work of (local) Research Ethics Committees (REC's). The CCMO's mandate is based on the Dutch Act on Medical Research Involving Human Subjects (WMO), a law that covers both ethical and scientific review. The rationale behind the so-called 'dual ethical review system', of both local committees and a central committee, is to ensure the quality of ethical review while leaving room for local aspects. Over the years, there have been numerous debates on the definition of these 'local aspects', which resulted in the CCMO establishing a guideline defining local aspects as only assessing local feasibility. That implies assessing the informed consent form, whether the required expertise for the research is available, whether insurance coverage is adequate and whether the study is in line with local logistics and resources (CCMO, 2011).

Relationships between international regulations, a national central body and local committees and their stakeholders in the Netherlands form the background for this study. Hedgecoe has shown that on a local level not only local knowledge and practical feasibility play a role in evaluating research protocols, but that local trust relations are of great importance as well (Hedgecoe, 2012). Situated knowledge about REC applicants enables REC members to judge applicant's trustworthiness, which implies that differences may occur in ethical review depending on the local context. This informal part of ethical review, it's back office, has largely been underexplored. While there is an ongoing tendency towards standardization and centralization, the work that REC's perform in shaping their formal mandate in practice is largely ignored. Following Hedgecoe, in our study of Dutch ethical review we will give full attention to informal procedures of ethical review by asking: "How do local institutional contexts relate to the way REC's shape their formal mandate, and what are the implications for research governance?"

We provide an in-depth analysis of ethical review in specific local institutional contexts in the Netherlands. Since different REC's have their own way of working in daily practice, and their routines not only encompass certain procedures in place but also informal criteria with respect to the ethical review process, we have studied three REC's in different institutional environments, an academic- , a care- and a commercial context. As we aim to do justice to the particular characteristics of the different REC's-in-context, we will provide an analysis of each REC separately. We pay attention to: a) local procedures, b) everyday culture, c) local (social, scientific and financial) resources, and d) evaluative perspectives. In the Netherlands, the CCMO has established multiple and strong regulations on ethical review procedures. Not only on membership, but also on REC's Standard Operating Procedures, and on dealing with specific types of protocols, for instance on multi-center trails (e.g. CCMO, 2003, 2007, 2011). Therefore we will describe the local procedures for each committee concerning the selection of new candidate-members, taking minutes, meeting routines and the role of the full committee and the executive board, respectively (a). Everyday culture is an aspect of ethical review that is hard to influence/standardize for a central body like the CCMO. REC's learn from past experiences in the interaction with stakeholders. Each REC we observed had its own unique environment and experiences within their institutional context (b). We also take into account local resources REC's have access to. On a central level, the CCMO has strict regulations with respect to (financial) independency for members, but less on REC's financial resources. The CCMO has delocalized the review of protocols within specific research areas, such as studies on gene therapy and heroin addiction. Besides this central delocalization, researchers have the liberty to choose the REC they think is the most suited to their research. This means that the REC chosen by a researcher might be outside of his regular institutional context. Thus 'situated knowledge' may be relevant from both sides in ethical review (c). Finally, we will go into the evaluative perspective REC's use in ethical review practice. The CCMO has shaped the REC's evaluative framework by substantive and administrative regulations. The 'informal' evaluative perspective of REC's encompasses the way members and the committee as a whole felt about different kinds of research (d).

Methodology

Selection of REC's

To get in-depth insights in how the institutional context of REC's affects their daily work we choose a qualitative ethnographic approach (e.g. O'Reilly, 2005; Taylor, 2002). In the Netherlands REC's are quite diverse: REC's are non-affiliated, or affiliated to one or more health care institutions. We chose three REC's, which represent these affiliation categories, and from different institutional contexts: an academic context, a care context and a commercial context. The academic REC (A) is affiliated to a Medical University Centre and deals with a broad disciplinary range of protocols, from different hospital departments and university research groups that conduct health-related research with human beings. The studies vary from Randomized Clinical Trials (RCTs) to qualitative research. Protocols not only concerned investigator driven but also sponsor driven research, and research populations concerned patients and healthy volunteers. REC B operates in a care context, and is affiliated to a network of health care institutions. Each affiliated organization paid regular dues and had a deputy (member) in the REC. Non-members occasionally used their review services. The committee mainly reviews protocols from a single discipline, often utilizing research approaches that are somewhat idiosyncratic in the medical context, such as social research. Most of their protocols concerned research with vulnerable patients, which was primarily investigator-driven. Protocols were usually submitted by members of affiliated institutions, and sometimes it was initiated by professionals in training. REC C is working in a commercial context: it is not affiliated to one or more specific institutions but mainly reviews protocols of several different pharmaceutical companies. The research often took place in clinical research organizations and primary care organizations, rather than regular hospitals, and the protocols primarily concerned sponsor-driven research in the general population. This committee did not have a specific disciplinary orientation. Apart from differences in context, the REC's were geographically spread over the country. After selecting the REC's, we approached the official secretaries by e-mail. REC B was immediately willing to participate, whereas REC A and C were more reluctant to participate due to earlier criticism of stakeholders in their field. After a clarifying dialogue with the research team they were willing to participate.