
Ethics as ritual: smoothing over moments of dislocation in biomedicine

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Abstract Applications of biomedical R&D currently imply substantial societal concerns. This paper explores, based on semi-structured interviews with scientists in Norway, how biomedical researchers experience and tackle such concerns in their daily work. It shows how ritualised routine responses to dislocatory moments help maintain order in the daily work of the interviewed scientists; they do not address directly but instead smooth over concerns by a ritualised way of using ethics. This may foreclose substantive reflection and function as a stabiliser for ‘business as usual’. Overall, the current way of responding to concerns as described by the interviewees may contribute to a depoliticisation of important issues. The paper contributes to sociological work on ethics by linking it to recent discussions on Responsible Research and Innovation (RRI) and by the empirical research presented. The insights can also help improve science policies such as RRI.

Keywords: biomedicine, ethics/bioethics, Science and technology studies, governance, professional self-regulation

Introduction

Biomedicine constitutes a range of fields connecting R&D in genetic technology, health and society. Proponents stress its potential for disease prevention, better patient treatment and more personalised health care systems. Critics mention potential disadvantages, such as genetic discrimination, privacy violations and the possible disruption of how people conceive themselves and society when human body set-up becomes predictable and modifiable. What does it mean to be ‘healthy’ when genome sequencing shows that a research participant with no apparent health issues may become ill in the future? What effect does such news have on people? How do they evaluate probability? And what if the information is wrong? These are examples of societal concerns that arise from current clinical applications of biomedical R&D.

This article explores how scientists and clinical researchers in biomedicine currently respond to societal concerns. That is, who raises concerns, which concerns emerge and how do researchers account for and address these? For example, researchers in clinical genetics need to constantly reassess links between mutations and disease because ‘many genetic mutations have been misclassified as harmful’ (Nature 2016). Changes in the perceptions of which genetic mutations are pathogenic or not have major consequences for carriers of such mutations. In Norway, it became public in 2017 that twenty-one women had their ovaries and/or breasts removed after genetic counselling wrongly stated that they carried a variant of a gene

that leads to breast cancer.¹ Although the gene variant in question was at the time of the incidents classified as class 3—'uncertain evidence for classification'—women were told it had a role in breast cancer. Several of the women concerned reported to the media the severe side effects and consequences from surgically removing the affected gland or organ.² An investigative report queried whether the scientists making the assessment were up to date with international research and whether internal control mechanisms failed.³ Since the women were informed months after the clinic discovered the mistake, at least one woman had her breasts removed after the discovery and before notification of the error.⁴ This paper does not explore this dramatic case because it remains under public investigation. However, the case shows the importance that scientists deal with concerns regarding ethical, legal and social aspects (ELSA) of their research.

The key concern of the paper is scientists' self-governance regarding science–society-related concerns. The findings presented here are also important for new science policies that highlight reflexive and participatory governance under the rubric of Responsible Research and Innovation (RRI). This policy idea has replaced previous policies focusing on ELSA of technosciences (Hilgartner *et al.* 2017, Zwart *et al.* 2014). RRI aims to enhance research and innovation actors' ability to identify concerns (e.g. concerns regarding social desirability and positive impacts, but also concerns about negative impacts) and to integrate reflexive governance in research and innovation work. RRI encourages scientists to identify and anticipate (Owen *et al.* 2013) concerns and to respond to such *anticipated* concerns. However, before policies demand that scientists and innovation actors adapt to *potential future* concerns, we need more knowledge about their ability to respond to *present* concerns (response-ability) and about their practices of responding (responsiveness).

In addressing this knowledge gap, this paper contributes to the sociological work on ethics that explores how social agents do and live ethics in their daily work (Brosnan *et al.* 2013, Haimes 2002, Hoeyer 2006). In contrast to more principle-oriented, normative-ethics approaches, the focus of such work is not to assess scientists' compliance with guidelines and principles. Instead, sociological work on ethics explores empirically how scientists manage ethical, societal and legal issues in their daily practices. In particular, I build on scholarship that explores how scientists account for and deal with societal concerns related to their research practices (Heeney 2016, Hoeyer *et al.* 2017, Metzler 2010, Parker 2007, Pickersgill 2012, Wainwright *et al.* 2006).

Dealing with societal concerns in research practice

There is a paucity of theoretically informed empirical research on the kinds of concerns raised in research practices and the responses that follow, despite the significance of the responsiveness concept in RRI perspectives. 'Responsiveness' in RRI refers to adapting research in response to societal concerns (Hoven *et al.* 2013: 58). RRI proposes that scientists collaborate with other societal stakeholders in order to anticipate and take care of social and ethical concerns and to respond to democratic challenges by actively aligning research with societal values. RRI can be seen as an attempt at fostering reflexive governance by including a range of social actors so that R&D responds to their needs. This requires response-ability. With this term, I mean having the ability to implement responsiveness. What forms do scientists' concerns take and how do they respond?

Previous research on these questions tends to focus either on how scientists view concerns relating to their work or on how they encounter concerns in research practices. Wainwright *et al.* (2006) conducted an ethnographic study of stem cell laboratories to investigate what

scientists viewed as societal and ethical concerns. They found that scientists voiced concerns about ‘sources and perceptions of embryos,’ topics that at the time also featured prominently in media coverage and policy debates on stem cell research in the UK (pp. 736–741). Parker (2007) studied how scientists enacted ethical concerns in clinical genetics practices. He found that encouraging scientists to explicate their issues to their peers in a ‘genetics club’, which he cofounded, generated more ethical issues than initially presented (Parker 2007: 2256). By gathering scientists in a space devoted to ethical reflection, Parker thus shifted from observing ethics to facilitating ethics. From such a perspective, which we can also find in socio-technical integration research (STIR) (Fisher and Mahajan 2006), social sciences and humanities (SSH) scholars actively facilitate the encounter of concerns in research practice. STIR tries to enhance reflection on concerns in research practice by being present in the laboratory and by repeatedly querying natural scientists on their choices. Such interventionist studies presume that natural scientists would not encounter or reflect on concerns without prompting by an SSH scholar. But is that correct? In fact, how scientists view and encounter concerns related to their work seems to be understudied.

This knowledge gap becomes even more pertinent when we seek findings on how scientists respond to concerns. The relevant literature often presumes that responses to concerns must have something to do with applying ethics. For more than a decade, scholars conducted considerable work in the field of empirical bioethics. However, this literature often attempts to illustrate philosophical ethics argumentation by providing empirical examples (Ives 2008) rather than starting with exploring how scientists deal with potentially manifold concerns. Even authors outside this tradition tend to depart from the question of how research integrates ethics (Heeney 2016, Pickersgill 2012), rather than the other way around, namely starting with concerns in research practice. This further reinforces the discourse that ethics and contemporary biosciences are necessarily entangled and that only ethics offers conceivable responses to concerns.

Consequently, the dominant thesis in respective scholarship is that research practices transform in multiple ways because they become intertwined with ethics (Mayrhofer and Prainsack 2009, Pickersgill 2012, Wainwright *et al.* 2006). For example, Pickersgill (2012) showed through focus group interviews with neuroscientists that bioethics was ‘embedded within the very fabric of laboratory life’ (598) and that scientists normatively reflected in all their daily practices, from blood taking to sharing data. However, while Pickersgill showed how scientific practices transform due to ethical norms, these transformations seemed mainly limited to the recruitment of participants (e.g. by promising payment or an ‘inconvenience allowance’). Pickersgill’s interviewees did not transform broader practices of scientific conduct, such as which research questions they ask or how they relate to societal needs, as RRI’s responsiveness dimension would envisage. Thus, scientists reduce what they may experience as a concern to a menu of concerns defined by the discipline of applied ethics. One exception in this body of literature is Metzler (2010), who looked beyond the ties between bioethics and biosciences to untangle how these two relate, exploring empirically what work bioethics was doing. Her work, which partly rejected the claim that bioethics is an integral element of biosciences, shows the need to pursue the kind of research questions raised in this paper. Another notable exception is Hoeyer *et al.* (2017), who focused on cross-national genetic research and data sharing. They investigated moral decisions and social ties enacted in the everyday routines of scientific work without predefining these as ethical decisions or ethical structures. In this manner, they found the kind of divergences between moral and social work in research practices and official ethics policies and frameworks that are important to this paper.

Thus, although bioethical principles and practices certainly have become an important element in biotechnological assemblages and a rather hegemonic form of science governance

(Braun *et al.* 2010, Gottweis and Petersen 2008, Rose 2007, Salter and Salter 2007, Tallacchini 2015), Metzler (2010) and Hoeyer *et al.*'s (2017) work shows the analytical importance of sociological work on biomedicine. Hoeyer *et al.* (2017) focus conceptually on 'flows of materials' (Hoeyer *et al.* 2017), and Metzler's (2010) methodological approach was to analyse self-interpretations of scientists in an Austrian biobank project by means of grounded theory. That they did not start with ethics makes their work more interesting and supportive of the approach of this paper. Therefore, it is a valuable research endeavour to focus on the moments when scientists experience a concern and to analyse their responses to challenging situations that may require that they change their practices.

Thus, my analysis focuses on scientists' responses to moments when science–society-related concerns emerge that require broader reflection, societal debate or possible changes of research practices. Such moments can be considered 'moments of care' (Latimer and Puig de la Bellacasa 2013), 'moments of disconcertment' (Verran 1999) or 'moments of dislocation' (Howarth 2000: 111ff, Hajer 2009: 5). I lean principally on the last phrase because an important element of dislocation is the possibility of discontinuity; that is, dislocatory events are difficult to fit in the existing discursive order to the extent that they might disrupt such orders (Howarth 2000: 111). Dislocatory moments occur when we recognise that our normal ways of doing or embedded practices no longer work. Put in another way, at such junctures practitioners become aware of disharmonies or anomalies between their established practices or identity and the expressed objectives or purposes of an organisation or policy. Their established ways of doing are thus called into question, often through the perception of some kind of external threat, and consequently new alternatives or possibilities are made possible (Glynos and Howarth 2007: 110).

However, such a disruption of existing orders does not necessarily happen—it depends on how subjects articulate and construct their experiences of dislocation. Glynos and Howarth (2007) outline three possible responses to dislocatory events. First, subjects might not know how to deal with the dislocation and therefore they continue what they are doing as if their practices were natural. For example, they can complain about what they perceive as merely bureaucratic routines, such as informed consent, but they do nothing about those routines. Second, they might disregard the dislocatory experience in order to maintain things as they are, for example by slightly modifying practices, such as inviting ethicists in their projects, but otherwise continuing as before. Finally, they might contest norms, which are constitutive of practices, publicly; that is, foreground the political dimension and demand alternative practices. Only the latter would imply that subjects, such as scientists, adapt existing practices or introduce new ones. In other words, 'keeping the disconcertment is important' (Verran 1999) in order to reach the responsiveness that the RRI framework suggests. In the following, I pursue this idea to explore what scientists experience as a doable response when they encounter concerns that trigger moments of dislocation.

Methodological reflections on interviewing on concerns

The issue at stake in this paper is 'responding to social and ethical concerns in practice,' namely, what scientists say they do when a concern emerges. The article draws on 15 semi-structured interviews with scientists within biomedicine, among them also clinical researchers that a colleague and I conducted between April and November 2015. Biomedicine here covers research in biobanks, research on hereditary genetic diseases and research on genome sequencing and biomarkers. The 15 interviews are part of a wider set of 37 interviews within bio- and nanotechnology research communities in Norway. The first finding of the analysis of the 37

interviews was that only scientists in biomedicine provided accounts of disruptive concerns regarding their research practices. We can only speculate on the reasons for this, but it might be related to their working with humans and living matters, and to their training through ethics courses in biomedical education.

The majority of interviewees were full professors, many of whom were principal investigators. These interviewees, due to their considerable experience with biomedical research and hands-on experience with project management, generated rich responses to the research questions. Each interview lasted approximately 1 hour, and all interviews were recorded, transcribed and anonymised. I analysed and coded the interviews manually using Atlas.ti software. Because of the difficulty of eliciting candid responses about societal concerns and about challenges of science–society relations in research practices in relatively short interviews, we approached the topic through several questions. For example, we probed scientists not only for the societal relevance of their work but also asked what they considered to be the ethical, legal and social aspects of their research, then asking them to recount an instance in their research practice when they experienced a concrete challenge related to these topics.

Responding to concerns in research practices

In the following, I analyse how the scientists within biomedicine conducted themselves when concerns emerged and whether they responded to concerns by adapting their practices. I organised the presentation of the empirical analysis within the earlier discussion of dislocation: from doing something about the dislocation that might lead to a change of practices to not doing anything.

Meeting concerns preemptively through proactive communication

As in other countries, in Norway, biotechnology has prompted substantial debate (Levold 2014) and public protest was a concern of the interviewed scientists, who were well aware of the potential for public reactions. While hopeful discourses prevail in the current public discussion (Solbu and Sørensen 2018), such discourses are open to public contestation and are particularly vulnerable to arguments that genetic testing (e.g. for BRCA variants) may cause more harm than good (Ross *et al.* 2013). Consequently, biomedical scientists feared the potential dislocation of ‘biomedical narratives of hope’ (Metzler and Just 2017). For example, interviewee 18 was worried that a forthcoming media article about her research on genetic mutations in colon cancer patients might be susceptible to a negative spin if journalists linked the technique she was using (genome sequencing) to the public debate on detecting Down syndrome in embryos.

Some respondents thus considered it necessary to respond to such concerns about possible negative public reactions by communicating their work more proactively. For example, the Nord-Trøndelag Health Study (HUNT), a longitudinal population health study in Norway involving a major biobank, followed an active communication strategy as part of its effort to enroll the entire Nord-Trøndelag County population. HUNT had a comprehensive website where it published project and article summaries. This proactive strategy was good advertising, but it also developed from concerns that were raised. Interviewee 15, a leading figure in the HUNT biobank, stated:

“I think the smartest thing we do is, first, to talk publicly about challenging or difficult issues. We don’t do it the other way around: we don’t hope that people won’t notice, so we

can go about things in peace; instead, we open up for transparency from the beginning.” (IW 15)

The quote illustrates that interviewee 15 responded to his concern that research participants might become negative towards biobanks. In a similar vein, interviewee 30, who worked with genomics and cancer research, mentioned open meetings as an important element of their proactive communication strategy:

“In this project, we believe that societal aspects are important. For example, the biotechnology council is involved. We had a few public meetings, and our websites include a lot of information for the general public. [...] We try to communicate the rationales behind our approaches and our methods, for example, which opportunities and challenges these imply for the public health system, and how we can apply them in treatments. It is not the results of our research projects that are important to communicate, but the way we work and think.” (IW 30)

The reflections of interviewee 30 were interesting because he showed considerable reflexivity about communicating matters of concern. Thus, he voiced a clear understanding of the importance of contextualizing science and society questions. In sum, scientists' responses to concerns regarding the general public were about questioning and modifying their own communication practices.

Tendencies to contest existing practices in response to concerns

Above, I introduce biomedicine scientists' concerns regarding society in general. Turning now to particular publics, a concern for scientists was whether they should inform the respective relatives if they find in one person a genetic disease that is likely to occur in other family members. Interviewee 18, who worked on mapping hereditary cancer, experienced this as extremely difficult. According to the law, she was not allowed to conduct proactive genetic counselling. But she had been in situations where family members were estranged, which was likely to result in the information on hereditary diseases not reaching everyone concerned. There was a clash between her identity as a scientist and her sense of responsibility to others. During our interview, she questioned existing practices. She then reasoned that informing people would be intrusive and involve both 'the right not to know' and issues of privacy because of 'genetic exceptionalism.' Having mentioned these established ethical terms, she ceased reflecting further on her unease, as if others had already said everything about what she had experienced.

Thus, in moments of dislocation when her identity was threatened, well-known ethics concepts helped her resolve the anomaly; however, this constituted a non-response in order to not violate existing rules. In general, she thought that informing others should be the responsibility not of the family members but of the health care system, although she did not initiate a process that could lead to such a change of practices. Indeed, the dilemma that she perceived is set up by bioethics. As Dove *et al.* (2017) point out, a dilemma between a personal 'right not to know' and family sensitivities occurs only when one buys into the notion of individualistic autonomy and an individual-centred understanding of rights and responsibilities (Dove *et al.* 2017: 154). Thinking through the issues in terms of relational autonomy (conceptualizing genetic information as belonging to both the individual patient and the family) (Dove *et al.* 2017: 156) could lead to a different framing of the problem; for example, the scientist could consider to discuss this dilemma both with the concerned patient but also with other research participants in the extended family.

Interviewee 30 experienced a similar concern: how to respond when you discover that a genetic mutation was likely the direct cause of a person's cancer. In the dislocatory experience interviewee 30 described, a teenager had died of a cancer that had first appeared when he was a child. The scientist thought the family should be informed that the cancer was due to a genetic mutation so other family members could undergo testing. The situation felt particularly difficult because the family was grieving. The way interviewee 30 responded to his concern was to tell the family's general practitioner, who should, in the interviewee's opinion, counsel the family to undergo genetic testing. However, the interviewee reasoned that the hospital should have a formal policy on such issues and that individual doctors should not be responsible for evaluating such cases. Thus, when the interviewee saw the necessity to do something about the current practices, he did what he thought he could do (informing the family physician) but did not take any further action to initiate writing public guidelines. Other countries have adopted responses on a more general level than individual research projects. Finland, for example, has established a contact protocol for possible carriers of hereditary diseases (Tupa-sela 2012).

In both cases, interviewees tended towards contesting existing practices but did not take action to trigger collective reflection on questions that could initiate a change of the current situation, despite their recognition that the normal way of doing things was flawed and should be reconsidered. In the first case, the moment of dislocation was absorbed by the existing social practice of ethics; in the second, responsibility was ascribed to others. What also becomes clear from the interviewees' accounts is that scientists did not consider that patients themselves could sort out such concerns. The scientists did not foster or facilitate participatory medicine (Prainsack 2014) or shared decision-making (Spatz *et al.* 2016). In sum, the responses to moments of dislocation remained mainly personal, internalised reflections on how public regimes should change, without prompting collective reflection.

Meeting threats of dislocation with the help of professional ethicists

All interviewees argued that Norway provides a tightly regulated environment for their research work. The Biotechnology Act regulates the use of genetic technology in medicine—it governs areas such as assisted fertilisation, embryonic diagnostics, pre-implementation genetic diagnosis and genetic examinations. In addition, there are specialised laws, like the Norwegian Biobank Act, and scientists must apply for approval of their research proposal to research ethics committees (REC) when they begin a project that includes research on human subjects or their biomaterials. However, the scientists told that there was a difference between the formal policies governing biomedicine in Norway and how they dealt with issues *in practice*:

“We kind of make our own rules, but we take care to have a dialogue with the regional ethics committees, and we seek advice from bioethics experts, so we can be sure that we've thought of everything. Yes. We don't want to do something illegal. We don't want that.”
(IW 18)

Here, the interviewed scientist was concerned about disharmonies between the regulatory system and the intricacies of research practices. Interviewees mentioned incidental findings as a topical example of this. Internationally, the decade-long debate on the return of incidental findings has intensified because clinics increasingly apply genome sequencing (Clift *et al.* 2015, Ross *et al.* 2013). Thus, the introduction of genome sequencing into daily practices potentially dislocated established orders and ways of doing things. In Norway, the Biotechnology Act distinguishes between predictive and diagnostic tests. Since some tests already in the past became predictive, with genome sequencing there will be more such incidents in the future. For

scientists, it involved both care for the patient and concerns about acting legally. For example, interviewee 37, who worked in a genetic medicine department in a hospital, was concerned about what to do if she found out that the patient she was conducting a genetic test on carried a disease other than the one she tested for.

Interviewee 37 responded to the threat of dislocation by contacting people within bioethics. She and other interviewees established close collaborations with bioethicists. This suggests that interviewees considered expertise on ELSA necessary to deal with concerns within biomedicine. Interviewee 16 told about a commission she participated in during the early years of genetic medicine:

“There were also a few philosophers on board. There have always been many philosophers, and that was very good. They have an enormous influence. This is very important. Philosophers have an enormous influence on biotechnology development.” (IW 16)

Many scientists interviewed considered it as a normal procedure to get professional ethicists on board when they began groundbreaking new research:

“We could have conducted this work as mere diagnostic work, but we chose to set it up like a research project. That means we applied to the regional ethics committee. We did so because the technology is so new and there are some ethical issues linked to it, and we also have this cooperation with [two professional ethicists] who examine the ethics of the entire project. We made quite a big thing out of it.” (IW 18)

Apart from ethics professionals, RECs were frequently mentioned as prescribed forms for ‘making a big thing out of’ responding to concerns. For example, a REC helped interviewee 18 with her concerns about incidental findings. The REC advised her to coordinate with them a list of genes that she might offer feedback on to patients. Accordingly, interviewees experienced these procedures for approval by the ethics committees not always as an administrative hurdle—as one maybe might have expected—but also as a valuable and necessary step. The view that ethics was ‘part of the game’ was widespread among the scientists interviewed:

“This means that there are a great many proposals for ethical approval and these kinds of things, but this is part of . . . I am not as frustrated about it because this is part of the game. We must justify why we do what we do.” (IW 16)

The interviews indicated that REC approval was considered a way to deal both with concerns and as a quality certificate. Interviewee 29 was particularly positive about RECs:

“For us it was very important to have such a process with approval by ethics committees and these kinds of procedures that quality-assure research. You are interested in doing research . . . and one does not always see the ethical aspects and consequences the research can have. So I’m glad to have these committees.” (IW 29)

Thus, interviewee 29 did not primarily view the REC as helping her to deal with a concern that she experienced; instead, she argued that it relieved her from worrying that she might encounter something of concern.

A third instance set-up to help deal with concerns was locally established committees. One interviewed department head was concerned about scientists who were not sufficiently cautious when delivering to patients the results of their genetic testing. Her department responded to

this concern by establishing a local ethics board led by one of their professional ethics collaborators and including scientists in genetic medicine. Thus, clinicians would no longer deliver feedback directly to patients. Rather, the local ethics board reviewed the results and evaluated them in the context of the research study participants' signed informed consent forms. Finally, the board provided the relevant feedback to participants. This shows that internal management (in which professional ethics people interacted with clinicians and scientists) could close moments of dislocation. In the concrete case, they narrowed the concern by relating it to informed consent. That is, the concern was 'not doing anything wrong'; the focus was on formalistic processes instead of aiming at good decisions with and for the patients or research participants.

Covering up concerns through completing formalities

Above I show that, when scientists experienced concerns, they often sought help and advice from professional ethics experts. However, professional ethics experts were not always consulted because most concerns were handled in a ritualised, formalistic manner by informed consent. Informed consent is 'one of the central articulations between the biomedical system and society' (Felt *et al.* 2009), not just in Scandinavia (Ursin *et al.* 2008) but internationally. The content and effect of the principle of informed consent in biomedicine have been widely debated since 1972 (see, i.e. Beauchamp 2011, Corrigan 2003, Hoeyer 2006, Manson and O'Neill 2007). However, in this paper I pursue a different set of questions and solely focus on the function of informed consent as a tool of responsiveness as it emerged in interviewee accounts.

To begin with, in our interviews, informed consent forms were the cornerstone of responding to moments of dislocation in which the normal way of doing things was threatened. Actually, interviewees presented informed consent as the one-size-fits-all response to most of the ethical concerns they mentioned. For example, interviewee 37 reflected extensively on her concern with incidental findings and the speed of technology development: What if scientists told a patient that his genetic material was free of disease markers, but 3 years later, when the technology had improved, he was informed that he had a hereditary disease after all? Her solution was as follows:

"It's a difficult situation when we suddenly have new knowledge to add to our patient's records. This is a typical example where I could see the need to include this in the consent form: 'would you like us to contact you in case our evaluation would change because technology development is so rapid?'" (IW 37)

Interviewee 37 was concerned about a complicated problem, but the response, namely informed consent, to her seemed quite straightforward. Here, she advocated a generic instead of a patient-centred approach to consent. Only the latter would lead to high-value, shared informed decision-making (Spatz *et al.* 2016: 2064). Research has shown that models of consent should reflect preferences of research participants and be context specific (Kelly *et al.* 2015) and that patients who engaged in shared decision-making and received a decision aid were clearer about what they wanted and could expect from treatments (Stacey *et al.* 2014). In our interviews, generic approaches were more widespread. Our respondents told us that the more complicated a problem was, the more complicated informed consent forms became. Interviewee 27 recalled that, a decade ago, informed consent and REC approval were all that were needed. But now—due to vast electronic systems and systematic data collections—his experience was that formal demands had increased:

“The first informed consent form was one page. Now we really follow many rules and standards, and the form can be four pages. There has been a change. Generally, there is much more focus on it, and we are very careful.” (IW 27)

In general, no interviewee raised concerns about the necessity of genetic testing, the quality of genetic information or about questions of patients’ self-identity and society changes due to biomedical developments. What they talked about was debates about broad consent and re-consent (see, i.e. Lunshof *et al.* 2008, Steinsbekk *et al.* 2013). An interviewee reported that, some years ago, the previously mentioned HUNT study conducted a large research project that involved a broad mapping of genetic markers of all participants. However, the interviewee told us that a concern emerged because the participants had not consented to such genome sequencing. As a response to this concern, the REC decided that the participants should be informed about the research plans and be granted the opportunity to withdraw. As a result, the interviewee described that they sent a two-page letter to 95 000 participants, with 25 participants ultimately opting out of the new research. Although this was a resource-demanding solution, interviewees agreed with and considered these informed consent practices necessary. For example, interviewee 30 worried that it would be more difficult to enroll research subjects if broad consent became the standard.

In sum, all the scientists used informed consent, which they considered an important strategy to deal with concerns. However, this does not imply that they all thought that informed consent functioned as intended:

“The biggest problem with informed consent forms is that the patient is supposed to be informed, and that is relatively complicated. You can imagine that if you have to deliver one of those difficult diagnoses, it’s kind of an illusion how much information the patient actually manages to absorb in such a situation. Thus, I think they generally grant consent on the wrong grounds. Informed consent is only a sign of trust, period.” (IW 30)

Here, the interviewee experienced what research also showed, namely that preferences regarding informed consent are deeply relational in the sense that research participants trust a particular scientist at an institution (Kelly *et al.* 2015: 9). In the quotation, the interviewee argues that what was considered a good response to concerns—namely, obtaining consent from patients involved in research—was not something patients were concerned about when confronted with an actual, serious diagnosis. While acknowledging the need for informed consent, IW 30 criticised informed consent procedures for being remote from patients’ concerns. The interviewee experienced the ambiguities of such a procedural response to concerns, which informed consent represented, as problematic in emotional, delicate situations. However, he did not consider changing practices in response to this concern. For example, informed consent obtained minutes before a procedure or right after a diagnosis does not represent a reasonably good standard (Spatz *et al.* 2016). Employed in this way, informed consent is only a pragmatic routine. Even worse, informed consent may countervail concerns instead of solving them because scientists may use it like a ‘decree absolute, effectively divorcing (and excluding) them [patients] from further input in the research process’ (Heeney 2016: 15). For instance, asked whether there exists a research that should never be carried out, one of the scientists Pickersgill interviewed, answered, ‘a good experiment is a good experiment as long as you’ve got full informed consent, actually!’ (Pickersgill 2012: 588).

We see that the use of informed consent as response to concerns can smooth over the dislocatory moment that the concern triggered. However, in distancing scientists from the threat of dislocation, practices of informed consent enabled ‘business as usual’. These problems with a

formalistic use of informed consent schemes that the scientists reported underscore the need for the debate on which standards should guide informed consent (Spatz *et al.* 2016; Dove *et al.* 2017).

Concluding discussion: Ritualised responses to concerns

Scientists within biomedicine managed in different ways to relate their work to societal concerns and to respond when they encountered potentially disruptive concerns. A first finding is that interviewees' various techniques to tackle dislocatory moments constantly referred to and enrolled other actors, such as professional ethicists, ethic boards and other regulatory institutions. Most of the time, scientists within biomedicine signalled both reflexivity and preparedness in discussing concerns and dealing with them in a substantive way. Nevertheless, they seldom felt able to respond themselves by changing their practices, but instead sought help from outside their own field such as ethic experts or regulatory frameworks and placed on them the responsibility for responding to concerns. Accordingly, they were concerned when ethical guidelines were not clear (e.g. in the case of genetic counselling). In such cases, they tried to clarify these. A second finding related to the first is that individual scientists did not feel themselves competent to deal with ELSA concerns on their own. Response-ability seemed to require knowledge and competencies that scientists sought from professional ethicists. A third finding is that informed consent provided scientists with response-ability. However, responsiveness was limited to adapting the consent form to include additional or broader concerns. All findings have in common that ethics was part of the response to concerns.

The empirical analysis shows the significant discursive power of ethical procedures. Despite my attempt to approach concerns in a conceptually open way, ethics talk prevailed in the interviews. This aspect was undeniable. In the interviewed scientists' accounts, it was striking to observe how much 'the language of ethics appeared as a technology of scientific governance' (Braun *et al.* 2010). Respondents were fluent in the language of ethics, including technical terms such as 'genetic exceptionalism' and 'right not to know', and they spoke eloquently in this language register. Apparent in the interviews was Petersen's (2011) argument that bioethics offers a range of techniques for identifying concerns (e.g. incidental findings or family members that withhold important information from each other) and, importantly, a range of techniques (informed consent and ethic committees) to manage these.

However, the concern menu of bioethics that the interviewed scientists drew upon was rather narrow—there was little reflection on broader concerns, such as the effects of the existing research system or the larger impact on society. The bioethical discourse seemed to limit the spectrum of societal concerns discussed (see also Gottweis and Petersen 2008); it structured the possible fields of actions so that scientists did not address some concerns. This becomes clear in the dramatic example in the introduction of the paper: questions of how sound the interpretation of genetic information is, humility towards the production of scientific knowledge, maintaining high-quality international scholarship or shared decision-making with patients are all concerns that are out of reach of the quality assurances that ethic committees can offer. The scientists do not necessarily ask important questions about the negative consequences for research participants and society in general. For example, genetic medicine effects how society thinks about disease, and it is prone to move boundaries of what people consider of 'being sick'.

The observed dominance of ethical governance carries the danger of creating a bureaucratic management of concerns. The most important example of this in the interviews was how interviewees tended to vest response-ability in a consent form. Thus, they restricted responsiveness

to adapting the form. The problem with this is that one looks too much at formalities in the process than at caring for good decisions and best outcomes together with research participants. At the same time, this paper shows how focusing on formalities may improve scientists' perceived response-ability since they have available both an ethics tool (the consent form) and professional ethics expertise. That is, asking ethics experts for advice or extending informed consent forms gave scientists response-ability. Normally, one would expect ethics to stimulate reflection, but surprisingly the opposite was true: ethics helped interviewees smooth over moments of dislocation. In the accounts of IW 18 and 30 in the second empirical section, I show an emergence of profound reflections and attempts to build social relations through care for patients, but in the end, the availability of ethics discourses in combination with demanding responsiveness on a more general (not individual) level de facto shut down such reflections. In sum, changes in research practices did not flourish and the formalised use of ethics tools (e.g. informed consent) did not help in this regard.

My argument, developed through this research, is that dislocatory experiences are responded to in a formalistic fashion; using ethics in a ritualistic way has the consequence that scientists keep the political dimensions of practices in the background. Rituals are repetitious forms or codes of performance that operate within easily recognisable frames that are meaningful and do not need to be explained to the communities in question. This includes informed consent forms but also the delegation of responsibility related to care for patients as well as ethics expertise. Thus, as I have shown, such routine responses to dislocatory moments help to maintain order in the daily work of the interviewed scientists and to reduce their discomfort. This is achieved because, according to the interviewees, they experience an improved ability to act on the perceived—primarily ethical—challenges. However, the routines structure the way the responses are performed in a way that makes it difficult to ascertain whether the described kinds of action addressed the roots of the problems (i.e. the medicalisation of society but as well entrenched ideas of individualistic autonomy) or merely were performances of governance. Moreover, routinised responses to concerns cloud the issues to an outside public. The findings of the paper contradict the dominant thesis that research practices transform because of ethics, rather I confirm that ethics has a tendency to perpetuate the status quo. These findings might not be specific to Norway because they were also pointed to in other contexts (Latimer and Puig de la Bellacasa 2013, Petersen 2011). In sum, the current way of performing responses to concerns as described by the interviewees may contribute to a depoliticisation of important issues.

Awareness of such insights is important for implementing RRI and similar policies. It suggests caution in how science policy institutions try to enact programs intended to ensure that social concerns are catered to. RRI and similar policies should prevent the possibility of ritualised responses, such as box ticking. Rather, they should encourage productive, creative and innovative ways both to raise concerns and then to respond to them. In particular, how RRI relates to biomedicine should not be reduced to a menu of concerns defined by the discipline of bioethics but needs to remain an empirical research question (Delgado and Åm 2018). At the same time, science policy makers should take seriously the biomedical scientists' search for competence to deal with societal concerns. Social sciences and humanities' (SSH) training could help set on the agenda reflections on concerns regarding individual autonomy, shared decision-making, and the coproduction of science and society. Interdisciplinary cooperation across SSH and natural sciences should be an integral element of implementing RRI and similar initiatives; however, without allowing for the outsourcing of RRI to SSH scholars because this again could become a routine response that leaves research practices unchanged.

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Notes

- 1 Karlsten, M. L. (18.02.2017) 21 kvinner feiloperert. Dagbladet
- 2 Olsen, K. G. (30.09.2017) Godt å bli trodd. Klassekampen
- 3 Storvik, A. G. (23.11.2017) OUS får krass kritikk i granskingsrapport. Dagens Medisin; Olsen, K. G. (06.12.2017) Nå vokser kreftgen-skandalen. Klassekampen
- 4 Olsen, K. G. (04.07.2017) Ble ikke varslet tidsnok. Klassekampen.

References

- Beauchamp, T.L. (2011) Informed consent: its history, meaning, and present challenges, *Cambridge Quarterly of Healthcare Ethics*, 20, 4, 515–23.
- Braun, K., Herrmann, S.L., Konninger, S. and Moore, A. (2010) Ethical reflection must always be measured, *Science, Technology & Human Values*, 35, 6, 839–64.
- Brosnan, C., Cribb, A., Wainwright, S.P. and Williams, C. (2013) Neuroscientists' everyday experiences of ethics: the interplay of regulatory, professional, personal and tangible ethical spheres, *Sociology of Health and Illness*, 35, 8, 1133–48.
- Clift, K., Halverson, C., Fiskdal, A.S., Kumbamu, A., *et al.* (2015) Patients' views on incidental findings from clinical exome sequencing, *Applied & Translational Genomics*, 4, 38–43.
- Corrigan, O. (2003) Empty ethics, the problem with informed consent, *Sociology of Health and Illness*, 25, 7, 768–92.
- Delgado, A. and Åm, H. (2018) Experiments in interdisciplinarity: responsible research and innovation and the public good, *PLoS Biology*, 16, 3, e2003921.
- Dove, E.S., Kelly, S.E., Lucivero, F., Machirori, M., *et al.* (2017) Beyond individualism: is there a place for relational autonomy in clinical practice and research?, *Clinical Ethics*, 12, 3, 150–65.
- Felt, U., Fochler, M., Muller, A. and Strassnig, M. (2009) Unruly ethics, On the difficulties of a bottom-up approach to ethics in the field of genomics, *Public Understanding of Science*, 18, 3, 354–71.
- Fisher, E. and Mahajan, R.L. (2006) Midstream modulation of nanotechnology research in an academic laboratory, *Proceedings of IMECE2006 ASME International Mechanical Engineering Congress and Exposition*. <https://doi.org/10.1115/IMECE2006-14790>.
- Glynn, J. and Howarth, D. (2007) *Logics of Critical Explanation in Social and Political Theory*. London and New York: Routledge.
- Gottweis, H. and Petersen, A.R. (eds) (2008) *Biobanks. Governance in Comparative Perspective*. Abingdon, Oxon, and New York. NY: Routledge.
- Haimes, E. (2002) What can the social sciences contribute to the study of ethics?, *Theoretical, Empirical and Substantive Considerations, Bioethics*, 16, 2, 89–113.

- Hajer, M.A. (2009) *Authoritative Governance. Policy-Making in the Age of Mediatization*. Oxford: Oxford University Press.
- Heeney, C. (2016) An “ethical moment” in data sharing, *Science, Technology & Human Values*, 42, 1, 3–28.
- Hilgartner, S., Prainsack, B., and Hurlbut, B. (2017) Ethics as governance in genomics and beyond. In Ulrike, F., Rayvon, F., Miller, C.A. and Smith-Doerr, L. (eds.) *The Handbook of Science and Technology Studies*, 4th edition. Cambridge: The MIT Press.
- Hoeyer, K. (2006) The power of ethics: a case study from Sweden on the social life of moral concerns in policy processes, *Sociology of Health and Illness*, 28, 6, 785–801.
- Hoeyer, K., Tupasela, A. and Rasmussen, M.B. (2017) Ethics policies and ethics work in cross-national genetic research and data sharing: flows, nonflows, and overflows, *Science, Technology & Human Values*, 42, 3, 387–404.
- Hoven, J. van den *et al.* (2013) *Options for Strengthening Responsible Research and Innovation. Report of the Expert Group on the State of Art in Europe on Responsible Research and Innovation*. Brussels: European Commission, Directorate-General for Research. Available at https://ec.europa.eu/research/science-society/document_library/pdf_06/options-for-strengthening_en.pdf (Last accessed 16 May 2017).
- Howarth, D. (2000) *Discourse*. Berkshire: Open University Press.
- Ives, J. (2008) ‘Encounters with experience’: empirical bioethics and the future, *Health Care Analysis: Journal of Health Philosophy and Policy*, 16, 1, 1–6.
- Kelly, S., Spector, T.D., Cherkas, L.F., Prainsack, B., *et al.* (2015) Evaluating the consent preferences of UK research volunteers for genetic and clinical studies, *PLoS ONE*, <https://doi.org/10.1371/journal.pone.0118027>.
- Latimer, J. and Puig de la Bellacasa, M. (2013) Re-thinking the ethical: everyday shifts of care in biogerontology. In Priaux, Michelle, N. and Wrigley, A. (eds.) *Ethics, Law and Society*, Vol. V, pp. 153–74. Surrey: Ashgate.
- Levold, N. (2014) *Biopolitikk. Kropp, Kunnskap og Teknologi*. Bergen: Fagbokforlaget.
- Lunshof, J.E., Chadwick, R., Vorhaus, D.B. and Church, G.M. (2008) From genetic privacy to open consent, *Nature Reviews. Genetics*, 9, 5, 406–11.
- Manson, N.C. and O’Neill, O. (2007) *Rethinking Informed Consent in Bioethics*. Cambridge: Cambridge University Press.
- Mayrhofer, M.T. and Prainsack, B. (2009) Being a member of the club: The transnational (self-) governance of networks of biobanks, *International Journal of Risk Assessment and Management*, 12, 1, 64–81.
- Metzler, I. (2010) Über “Moralapostel” und “smooth operators”: Die Praxis der Bioethik im Feld eines österreichischen Biobankenprojekts. In Griessler, E. and Rohrer, H. (eds.) *Genomforschung - Politik - Gesellschaft. Perspektiven auf Ethische, Rechtliche und Soziale Aspekte der Genomforschung*. Sonderheft 10: Österreichische Zeitschrift für Soziologie, Wiesbaden: VS Verlag für Sozialwissenschaften, pp. 203–29.
- Metzler, I. and Just, P. (2017) “Think positively”: Parkinson’s disease, biomedicine, and hope in contemporary Germany, *Health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine*. DOI: 0.1177/1363459317715774.
- Nature. (2016) Editorial, *Nature*, 538, 140.
- Owen, R., Stilgoe, J., Macnaghten, P., Gorman, M., *et al.* (2013) A framework for responsible innovation. In Owen, R., Bessant, J. and Heintz, M. (eds.) *Responsible Innovation. Managing the Responsible Emergence of Science and Innovation in Society*, pp. 27–50. Chichester: Wiley.
- Parker, M. (2007) Ethnography/ethics, *Social Science & Medicine*, 65, 11, 2248–59.
- Petersen, A.R. (2011) *The Politics of Bioethics*. New York: Routledge (Routledge studies in science, technology and society, 14).
- Pickersgill, M. (2012) The co-production of science, Ethics, and Emotion, *Science, Technology & Human Values*, 37, 6, 579–603.
- Prainsack, B. (2014) The powers of participatory medicine, *PLoS Biology*, 12, 4.
- Rose, N. (2007) *Politics of Life Itself. Biomedicine, Power and Subjectivity in the Twenty-First Century*. Princeton: Princeton University Press.

- Ross, L.F., Rothstein, M.A. and Clayton, E.W. (2013) Mandatory extended searches in all genome sequencing. "Incidental findings," patient autonomy, and shared decision making, *Journal of American Medical Association*, 310, 4, 367–8.
- Salter, B. and Salter, C. (2007) Bioethics and the global moral economy: the cultural politics of human embryonic stem cell science, *Science, Technology & Human Values*, 32, 5, 554–81.
- Solbu, G. and Sørensen, K.H. (2018) Auspicious, Anxious or Ambiguous? Studying the Socialisation of Biotechnology and Nanotechnology through Norwegian News Media. In Solbu, G. *Managing Science and Managing Society in Norwegian Bio- and Nanotechnology Research*. Doctoral theses at NTNU, 2018: 154, pp. 97–121. Trondheim: NTNU.
- Spatz, E.S., Krumholz, H.M. and Moulton, B.W. (2016) The New Era of Informed Consent. Getting to a Reasonable-Patient Standard Through Decision Making, *Journal of the American Medical Association*, 315, 19, 2063–4.
- Stacey, D., Légaré, F., Lewis, K., Barry, M.J., *et al.* (2014) Decision aids for people facing health treatment or screening decisions (Review), *Cochrane Database of Systematic Reviews*, <https://doi.org/10.1002/14651858.CD001431.pub5>.
- Steinsbekk, K.S., Myskja, B. and Solberg, B. (2013) Broad consent versus dynamic consent in biobank research: is passive participation an ethical problem?, *European Journal of Human Genetics: EJHG*, 21, 9, 897–902.
- Tallacchini, M. (2015) To bind or not bind? European ethics as soft law. In Hilgartner, S., Miller, C. and Hagendijk, R.(eds.) *Science and Democracy. Making Knowledge and Making Power in the Biosciences and Beyond*. New York: Routledge.
- Tupasela, A. (2012) Governing hereditary disease in the age of autonomy: mutations, families and care. In Vermeulen, N., Tamminen, S. and Webster, A. (eds.) *Bio-Objects. Life in the 21st Century*, pp. 103–16. Farnham: Ashgate.
- Ursin, L.Ø., Hoeyer, K. and Skolbekken, J.-A. (2008) The informed consenters: governing biobanks in Scandinavia. In Gottweis, H. and Petersen, A. (eds.) *Biobanks. Governance in Comparative Perspective*. Abingdon, Oxon, and New York: Routledge.
- Verran, H. (1999) Staying true to the laughter in Nigerian classrooms, *The Sociological Review*, 47, S1, 136–55.
- Wainwright, S., Williams, C., Michael, M., Farsides, B., *et al.* (2006) Ethical boundary-work in the embryonic stem cell laboratory, *Sociology of Health and Illness*, 28, 6, 732–48.
- Zwart, H., Landeweerd, L. and van Rooij, A. (2014) Adapt or perish? Assessing the recent shift in the European research funding arena from 'ELSA' to 'RRI', *Life Sciences, Society and Policy*, 10, <https://doi.org/10.1186/s40504-014-0011-x>.