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Beyond regulatory approaches to ethics: making space for ethical preparedness in healthcare research

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ABSTRACT

Centralised, compliance-focused approaches to research ethics have been normalised in practice. In this paper, we argue that the dominance of such systems has been driven by neoliberal approaches to governance, where the focus on controlling and individualising risk has led to an overemphasis of decontextualised ethical principles and the conflation of ethical requirements with the documentation of 'informed consent'. Using a UK-based case study, involving a point-of-care-genetic test as an illustration, we argue that rather than ensuring ethical practice such compliance-focused approaches may obstruct valuable research. We call for an approach that encourages researchers and research communities—including regulators, ethics committees, funders and publishers of academic research—to acquire skills to make morally appropriate decisions, and not base decision-making solely on compliance with prescriptive regulations. We call this 'ethical preparedness' and outline how a research ethics system might make space for this approach.

INTRODUCTION

Frustrations with centralised, compliance-focused approaches to research ethics are well documented,[1–6] yet such systems have become normalised in many countries. As a UK research group examining ethical issues in healthcare, we frequently hear researchers talking about having 'done ethics' or asking 'have you got ethics?' Statements such as these position ethics as something tangible that exists outside the research process, to be 'obtained' through application to external bodies. Here, we argue that the dominance of such conceptualisations has been driven by neoliberal approaches to governance, where the focus on controlling risk has led to over-reliance on procedures such as documenting consent as a way of managing (all) the ethical risks associated with healthcare research.

Using a UK-based case study, taken from a recent 'roundtable discussion' in this journal,[7] we examine the ways in which an (over)emphasis on procedural and regulatory aspects of research ethics undermines and undervalues researchers' opportunities to prepare for and navigate ethical issues as they arise in practice, and can obstruct valuable research. We draw on the concept of 'ethical preparedness' to describe a research workforce that is empowered to work in morally appropriate ways, and suggest how research communities—including regulators, ethics committees, funders and publishers of academic research, as well as researchers themselves—might foster an environment that encourages, empowers and supports researchers in being prepared to do this ethical work.

The case study

In 2019, a clinical research group proposed a trial to evaluate the use of rapid genetic testing in antibiotic prescription.[8] The 'Pharmacogenetics to Avoid Loss of Hearing' (PALOH) trial used a point-of-care test (POCT) to predict in which children aminoglycoside antibiotic use might induce hearing loss. Aminoglycosides are broad-spectrum antibiotics frequently prescribed for children admitted to neonatal intensive care units (NICU), as recommended by the National Institute for Health and Care Excellence.[9] They have a well-established side effect of irreversible hearing loss that has been linked to the genetic variant m.1555A>G, present in roughly 1 in 500 of the UK population.[8] Consequently, genetic testing is recommended in children requiring antibiotics, so that an alternative antibiotic regimen can be implemented to prevent aminoglycoside-induced deafness.[10]

Genetic testing is currently offered through National Health Service (NHS) laboratory services, with results usually taking three to four days, which has made testing for the variant unviable within acute clinical settings where antibiotic treatment must be initiated swiftly when indicated. Approximately 90 000 babies are admitted to NICU each year in the UK,[8] many of whom require urgent antibiotic treatment, therefore, rapid testing is likely to be helpful. Detection of the m.1555A>G variant before an aminoglycoside treatment is started would potentially prevent approximately 180 cases of profound irreversible deafness annually in the UK. Indeed, aminoglycosides are recommended as a first-line treatment not because they are more effective than alternatives, but because they have a narrower spectrum of activity and therefore do not as readily contribute towards the development of antibiotic resistant pathogens.[9]

The research team worked with an industry partner to develop a POCT capable of providing results for the m.1555A>G variant within 25 min, which was approved for use by the Medicine and Healthcare products Regulatory Authority. As technologies are notoriously difficult to integrate into practice, it is important to assess their implementation to understand if and how they might become part of a clinical setting.[11] This is particularly important for POCTs, which create new geographies of responsibility[12] by moving practices previously confined to the laboratory into clinical settings.[11] Accordingly, the PALOH trial was designed to assess the implementation of the device within two NICU settings. This would be the first trial of a genetic test as a POCT.[8]

A compliance-focused approach to ethics

The research group applied to the Health Research Authority (HRA) for ethical approval to run the study, which was reviewed by a research ethics committee (REC) who paid particular attention to the proposed methods of seeking consent. While a clear benefit of the POCT was a much shorter timeframe for the delivery of results, this reduced the window in which consent could be sought from participants or their proxies. Consent for genetic testing is often a detailed and lengthy process whereby patients are afforded the opportunity to consider the advantages and disadvantages of a particular test and given time to come to a decision. These practices stem from a time when there was no acute clinical decision to be made as a result of such testing, and where some would choose not to know their inheritance because of the lack of available interventions. When a baby is admitted to NICU, treatment decisions often need to be made within minutes, and parents are usually asked to give consent to a range of investigations and treatments.

To navigate this, the researchers proposed a two-stage consent process, whereby consent would be sought for the clinical use of the test (as part of the range of investigations and treatments) and participation in the research study separately. That is, parents would be told that part of the care of the child would involve a test that would help them decide on the best course of antibiotics, as some can cause deafness in genetically predisposed babies. Later, parents would be asked for consent for their child's data to be included in the clinical trial. At this point, if parents did not want to participate in the trial, their data would be excluded. After detailed consideration, the REC was satisfied with this approach, which they thought would allow babies to receive the best clinical care, and give parents the opportunity to consent or refuse to enter that data into the trial. However, before approval is granted REC decisions are reviewed by the parent body, the HRA, who raised concerns that the trial might be in breach of the Human Tissue Act.

The 2004 Human Tissue Act governs healthcare research and aims to ensure 'appropriate use' of human tissue. The Act sets out provisions regarding DNA analysis, and states that it is an offence to be in possession of 'bodily material intending that any human DNA in the material be analysed without qualifying consent' [13](p.28). The HRA's concern was that qualifying consent was not in place at the point of collecting bodily material (the sample collected for the POCT) and advice from the Human Tissue Authority (HTA) and legal experts was sought. Eventually an understanding was reached whereby the trial design was approved on the basis that administering the test represented a clinical decision, rather than a research question. The approach was then deemed permissible under Schedule 4 Part 2 of the Human Tissue Act which outlines that 'the medical diagnosis or treatment of the person whose body manufactured the DNA is an excepted purpose for DNA analysis' and therefore does not require formal consent [13](p.50).

The difficulties in gaining approval resulted in significant delays to the project and, for a while, threatened the entire concept of acute genetic testing. This case offers a good example of how the construction and understanding of the ethical issues involved can be misplaced within a system oriented towards compliance. The HRA focused on what is permissible within the remit of the regulations, rather than what is ethical within the context of the specific setting. In doing so, discussions centred on consent processes and their documentation, which overshadowed all other considerations, including the details of the clinical context in which testing for genetic risk of antibiotic induced deafness is a well-established practice. For example, children with a diagnosis of cystic fibrosis are often tested for the variant in non-acute settings. What is novel was not the genetic test itself, but the speed in which results are delivered. Arguably, it is unethical not to trial the intervention in practice, given that it could provide clinicians with information that would improve care. In the following section, we contextualise this case, arguing that the focus on compliance has been shaped by the dominance of neoliberal approaches to governance.

Reliance on regulation as research ethics

The question of whether proposed activities can be reconciled with the wording of the specific directives given in the Human Tissue Act is an interesting approach to deciding the ethical aspects of a study. This logic follows what Allen[3] terms a 'Weberian Orthodoxy' approach, whereby practice is regulated through centrally formulated policies that are intended to direct practice in an absolute way. This compliance-approach to research ethics is rooted in neoliberal approaches to governance.

Neoliberalism, as a social, political and economic concept dominates modern societies[14 15] and is reproduced in the material cultures of everyday life.[4] Driven by the organising principles of people as self-interested individuals, self-regulating markets and free-trade,[15] neoliberalism promotes individual rights and autonomy. Within this context there is a particular focus on the construction, measurement, and management of risk.[16] The premise is that quantifying risks and making them transparent liberates individuals to act freely, making their own judgements about the risks that are acceptable to them. The growth in neoliberalism has been accompanied by a political and economic transition towards the 'knowledge economy', which positions knowledge as a commercialisable commodity with the capacity to drive economic growth.[17] This has brought changes in the way that knowledge is governed, with a particular emphasis on making research predictable, accountable and regulated.[17]

Within this context, the contemporary conceptualisation and governance of research ethics has developed with a particular focus on managing risk by protecting the autonomy of research participants above all else. The idea that healthcare research is a 'risky' activity has been reinforced by a series of high-profile scandals (eg, the unauthorised retention of organs at UK hospitals), that have provided additional impetus for government intervention to calculate and address such risks. The approach to this has been the development of frameworks to regulate the medical and scientific use of the body, and establishment of institutions to monitor adherence to the guidelines.[18] The HRA is an example of such a regulatory body, which seeks to ensure that research is conducted ethically, and employs RECs to review applications to conduct research within the NHS.

With the protection of individual rights and autonomy central to neoliberal approaches, special attention has been focused on the concept of consent in research, which has come to be seen as an 'ethical panacea'.[19 20] So prominent is its positioning that it is often argued that research ethics has been reduced to only considering consent, and a very specific form of consent; 'informed consent'. The tautology of the term has been given ample attention; consent itself necessarily means that the person giving it is adequately informed.[21] Moreover, Sisti and Stramondo[22] argue that the standard model of 'informed consent' in medicine pays exclusive attention to procedural mechanisms, and as such is conceptualised as a sort of checklist which must be fulfilled before a rational decision is made. This approach to ethics seeks to reduce the complexity and risk associated with research activities through these rigid consent practices.

In this way, informed consent is a heuristic that 'for the past four decades… has dutifully served as a check on medico-moral paternalism'[22] (p.69). With research ethics approval systems so pivoted towards consent, and specifically this procedural notion of 'informed consent', it often becomes the frame of reference used to consider whether specific activities are deemed ethical. In some instances, consent seems to be positioned as what Callon[23] terms an obligatory passage point—the only solution to the problem of ethics. In the case of PALOH trial, it meant that ethics approval centred on how and when the study team intended to seek consent.

This compliance-approach, driven by neoliberalism, encourages a focus on decontextualised activities and how they can be reconciled with centralised regulation in a rigid and standardised way. It does not encourage attention to the nuances of specific contexts and cases, or for decisions to be tailored to specific circumstances. When ethical issues in research are treated as if they are predictable and controllable, with specific courses of action that can be recommended regardless of context, attention is diverted from the actual ethical issues at stake towards the standardised practices that have come to symbolise research ethics, such as 'informed consent'. Sisti and Stramondo[22] argue that processes of oppressive socialisation, illuminated through feminist literature, undermine the standard bioethical model of 'informed consent', which is predicated on individual autonomy. In this sense, compliance-based approaches 'do ethics' in a nominal way, that do little to ensure research is ethical.

Although the PALOH trial was eventually approved, it is interesting to note that the researchers were not required to change any aspect of the trial design. Instead, the change in decision came from a negotiation, not about the activities planned, but about the terminology used. In their original application, the researchers had described their consent process as an 'opt-out' consent model. Admittedly, this is confusing and inappropriate terminology—as pointed out in a roundtable response not only is 'opt-out consent' an oxymoron, it also does not represent the consent model that the researchers intended to employ, which was in fact a two-stage process.[24] Yet, rather than considering the specific research activities proposed, the HRA focused on these semantic issues, withholding approval until convinced that the use of the POCT could be classified as a clinical decision, and therefore permissible under the terms of the Human Tissue Act.

As this case demonstrates, when consent is invoked in this way, it can obstruct ethics in practice as well as valuable research. It becomes what Corrigan[20] refers to as 'empty ethics'. Without wishing to deny the importance of consent procedures and centralised regulations within research practice, we question whether such dependence on it to do ethical work alone is achievable. Allen[3] observes that national frameworks can encourage a mindset that considers any course of action not explicitly anticipated within the guidance as impermissible. Holding researchers accountable to decontextualised regulation acts to locate responsibility for navigating ethical issues within regulatory organisations, sending a message to researchers that ethics is not their job, or that REC approval is detached from ethical practice. Others have argued that this view of ethics is transmitted to the next generations of researchers, who are often conditioned to think about ethics in terms of this form-filling framework.[1] Moreover, bureaucratic regulations and procedures may serve to remove the everyday ethical questions most relevant to the practice of research.[25] So not only does a default to this compliance approach imply that ethics is not the job of researchers, it may also overlook the more important questions.

Facilitating a person-centred approach through ethical preparedness

We have presented a critique of neoliberal approaches to research ethics, arguing the focus on compliance and 'informed consent' to do all the work does little to ensure that research practices are ethical. Cascio and Racine[1] recommend researchers adopt a 'person-orientated research ethics' approach to account for the relational and 'everyday ethics' overlooked by regulatory approaches and propose a framework through which it might be applied. While we agree with the principles of situating relational and contextual understandings of participants at the centre of ethical considerations, the proposition of addressing the shortcomings of regulatory approaches by moderating researchers' behaviour seems to suggest that systemic failings are caused by a deficit on the part of researchers. Yet researchers are often well rehearsed in such ethical work, as demonstrated in their care for participants and the deliberate ways they design and perform research activities.[4 26 27] Rather than a framework through which to apply a relational and situated ethics approach, we argue that researchers need spaces and opportunities in which to foster a person-orientated ethics approach more readily.

We describe this as ethical preparedness, and suggest it requires action across the whole research community—including regulators, ethics committees, funders and publishers of academic research, as well as researchers themselves—to redress the pivot towards centralised regulation, and create an environment that supports the research workforce to navigate real-life ethical challenges in practice. The term 'ethics preparedness' has been used previously in research ethics, focusing often on emergency and disaster planning.[26] Here, we use ethical preparedness to describe the state of being prepared to consider ethical issues in everyday practice as they arise in particular contexts. This requires we look not only at the performance of ethics, for example through the documentation of consent, but also recognise and value the everyday ethical work that researchers undertake, as it is through these practices that ethics is negotiated. Pascoe Leahy[27] describes this as 'subtle ethics', and there lies the problem: they are subtle, unspoken, unaccounted for, and therefore, often undervalued within a neoliberal system; and may not even be recognised by researchers or the wider research community. To make space for ethical preparedness, it is vital that these subtle practices become more visible and appreciated. This means recognising that ethical work is not done as a discrete event at the outset but continues throughout and beyond a research project.

Ethical preparedness in regulation

Such continuity of ethics work is not well accommodated within current regulatory systems. Rossiter and Robertson[17] argue that neoliberal systems of research evaluation put emphasis on 'predictable, regulated and accountable knowledge, with ends that are known even before the research begins'. This approach is visible in the way that regulations, such as the Human Tissue Act, are mobilised to direct behaviour, sending the message that the researcher role is that of compliance rather than as an active partner in achieving the aims of legislation. These aims would be better realised through the facilitation of ethical preparedness, whereby researchers are given space to determine how particular contexts reconcile with the spirit of regulations. To achieve this, researchers must be seen as partners in delivering ethical practice, and regulators should provide a framework of resources, including mentoring services, and spaces to learn and share experiences with peers, to support this ongoing work.

Such an approach would have enabled the PALOH trial research team, HRA and HTA to develop a collaborative approach to navigating the ethical issues the research posed, rather than relying on a dichotomy between research and clinical practice to circumvent barriers imposed by restrictive regulations. Indeed, the distinction between research and practice is becoming increasingly blurred as technological advances bring new forms of 'experimental care',[28] and therefore, reliance on a clear demarcation of the two to resolve anything is problematic. As new frameworks are emerging, such as learning health systems,[29 30] it is increasingly important to reflect on how we can move towards ethical preparedness rather than simply new compliance-based approaches.

Ethical preparedness within research ethics systems

Research ethics systems are often pivoted towards anticipating and addressing ethical issues a priori, without recognising that ethical matters 'shift and change as we move through an inquiry',[31] and actions to deal with one ethical challenge may well kindle others.[32] Positioning the role of ethical review at the beginning of a research project not only sends the message that ethical issues have been dealt with, but gives researchers neither the responsibility nor space for ongoing ethical work in practice. We consider that research ethics systems must adopt a more advisory and supportive role, and here ethical preparedness means providing researchers with opportunities to discuss their projects in a collaborative, constructive and continuing way throughout the research process.

In this model, ethics committees would be focused on supporting the agency of researchers in navigating ethical issues in practice, as much as protecting the agency of participants. The role for bureaucratic devices, such as consent forms and auditable procedures, would be a way of documenting the ethical work that researchers have undertaken, rather than delivering the ethical work itself. For the PALOH trial, such a model would have meant that the HRA would have adopted an ongoing advisory and supportive role, collaborating with the team to work through ethical issues as they arose.

Ethically prepared researchers

Researchers too should accept responsibility for navigating ethical issues in practice. Drawing on a feminist ethics of care, Edwards and Weller[32] advocate for a situated ethics approach, whereby rather than decontextualised rules and regulations, researchers are encouraged to take a caring approach to work out the best course of action in any situation. Therefore, there is a role for peer support in sharing and learning form experiences, and supporting each other to navigate these tricky terrains.

These habits of care around ethical issues, must be encouraged throughout research careers. Ongoing ethical work should be valued and made visible within research teams, groups and support networks. Spaces to share challenges may range from informal peer support groups, to organised professional assemblies such as GenethicsUK, a national forum that brings together health professionals and other interested parties to discuss and explore difficult ethical issues encountered in genetic medicine.[33]

The role of funders and publishers in normalising ethical preparedness

To embed ethical preparedness within research practice, we need to be more explicit about expectations of researchers as active participants in a continuous process of ethics work; moving away from the talk of having 'got ethics' that opened this paper, to talk instead about 'being ethical'. Funders and publishers of academic research have a role to play in normalising these expectations by being clear about this ongoing role, and ensuring that the researchers they fund have access to the support and resources necessary to fulfil these expectations. Similarly, published research must reveal more of the ethics work required in practice, so that rather than an ethics section that details little more than which ethics committee approved the study, academic papers discuss the situated ethical approaches the research required.

As we have outlined, developing a research environment that is orientated towards ethical preparedness requires participation across the research community to make space for and support researchers' abilities to navigate ethics throughout research projects. Sustaining supportive environments to explore and navigate ethical issues, accessible throughout the research process, not only provides the support needed to do ethical work, but also reinforces the message that researchers have an active role in determining what constitutes ethical research practices. The role for centralised regulation and guidance must be to support this situated approach, not come at its cost, to facilitate an ethically prepared research community. This paper has focused on UK-based regulatory frameworks for research ethics but we consider it may be relevant in other countries with analogous research ethics systems.

Correction notice This article has been corrected since it was first published. The open access licence has been updated to CC BY. 17th May 2023.

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REFERENCES

1 Cascio MA, Racine E. Person-oriented research ethics: integrating relational and everyday ethics in research. *Account Res* 2018;25(3):170–97.
2 Pickersgill M. *Edinburgh research explorer experiences of ethics, governance and scientific practice in neuroscience research in neuroscience research*, 2021.
3 Allen G. *Getting beyond form filling: the role of institutional governance in human research ethics*, 2008.
4 Edwards R, Holland J. Reviewing challenges and the future for qualitative interviewing. *Int J Soc Res Methodol* 2020;23(5):581–92.
5 Lee RR, McDonagh JE, Farre A, *et al*. Data protection, information governance and the potential erosion of ethnographic methods in health care? *Sociol Health Illn* 2022;44(1):1–7.
6 Haggerty KD. Ethics creep: governing social science research in the name of ethics. *Qual Sociol* 2004;27(4):391–414.
7 McDermott JH. Genetic testing in the acute setting: a round table discussion. *J Med Ethics* 2020;46(8):531–2.
8 McDermott JH, Mahood R, Stoddard D, *et al*. Pharmacogenetics to avoid loss of hearing (PALOH) trial: a protocol for a prospective observational implementation trial. *BMJ Open* 2021;11(6):e044457.

9 NICE. *Neonatal infection (early onset): antibiotics for prevention and treatment | guidance*, .
10 Bitner-Glindzicz M, Rahman S. Ototoxicity caused by aminoglycosides. *BMJ* 2007;335(7624):784–5.
11 Lyle K. Interventional STS: a framework for developing workable technologies. *Sociological Research Online* 2020.
12 Akrich M. *The de-scription of technical objects*. Shaping technology/building society, 1992: 205–24.
13 Human tissue act 2004, 2004. Available: https://www.legislation.gov.uk/ukpga/2004/30/contents [Accessed 5 May 2022].
14 Guta A, Nixon SA, Wilson MG. Resisting the seduction of "ethics creep": using Foucault to surface complexity and contradiction in research ethics review. *Soc Sci Med* 2013;98:301–10.
15 Zoron S. *Prometheus critical studies in innovation research and data-sharing policy in Sweden-neoliberal courses forces and discourses* Zoran Slavnic*, 2018.
16 Shaw SE. Driving out alternative ways of seeing: the significance of neo-liberal policy mechanisms for UK primary care research. *Soc Theory Health* 2007;5(4):316–37.
17 Rossiter K, Robertson A. Methods of resistance: a new typology for health research within the neoliberal knowledge economy. *Soc Theory Health* 2014;12(2):197–217.
18 Reubi D. Re-moralising medicine: the bioethical thought collective and the regulation of the body in British medical research. *Soc Theory Health* 2013;11(2):215–35.
19 Burr J, Gibson B. Informed consent in research ethics: an analysis from the perspective of Luhmann's social systems theory. *Soc Theory Health* 2018;16(3):241–55.
20 Corrigan O. Empty ethics: the problem with informed consent. *Sociol Health Illn* 2003;25(7):768–92.
21 Sheila M, Angus M. Consent in Medical Practice. In: McLean S, ed. *Legal issues in medicine*. Gower, Southampton, 1980.
22 Sisti D, Stramondo J. Competence, voluntariness, and oppressive socialization: a feminist critique of the threshold elements of informed consent. *IJFAB* 2015;8(1):67–85.
23 Callon M. Some elements of a sociology of translation: domestication of the scallops and the fishermen of St Brieuc Bay power, action and belief: a new sociology of knowledge 1986;32:196–233.
24 Coulson-Smith P, Lucassen A. Using biomarkers in acute medicine to prevent hearing loss: should this require specific consent? *J Med Ethics* 2020;46(8):536–7.
25 Bosk CL. The new Bureaucracies of virtue or when form fails to follow function. *PoLAR* 2007;30(2):192–209.
26 Saxena A, Horby P, Amuasi J, *et al*. Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel. *BMC Med Ethics* 2019;20(1):29.
27 Pascoe Leahy C. The afterlife of interviews: explicit ethics and subtle ethics in sensitive or distressing qualitative research. *Qualitative Research* 2021.
28 Cambrosio A, Keating P, Vignola-Gagné E, *et al*. Extending experimentation: oncology's fading boundary between research and care. *New Genet Soc* 2018;37(3):207–26.
29 Dheensa S, Samuel G, Lucassen AM, *et al*. Towards a national genomics medicine service: the challenges facing clinical-research hybrid practices and the case of the 100 000 genomes project. *J Med Ethics* 2018;44(6):397–403.
30 Faden RR, Kass NE, Goodman SN, *et al*. An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics. *Hastings Cent Rep* 2013;Spec No:S16–27.
31 Connelly S, Anderson C. Studying water: reflections on the problems and possibilities of interdisciplinary working. *Interdisciplinary Science Reviews* 2007;32(3):213–20.
32 Edwards R, Weller S. The death of a participant: moral obligation, consent and care in qualitative longitudinal research. In: te Reile K, Brooks R, eds. *Negotiating ethical challenges in youth research*. Abingdon: Routledge, 2013.
33 Lucassen A, Parker M. The UK Genethics Club: clinical ethics support for genetic services. *Clin Ethics* 2006;1(4):219–23.