Governing Health Research from Within:
Empowering the Actors Who Occupy Regulatory Spaces

26-27 January 2017: Wellcome, London

WORKSHOP REPORT

WORKSHOP DESCRIPTION

The architecture of health research has vastly expanded over the past two decades. Today, research involves and crosses between genomic data, tissue, health and lifestyle data, metadata and social media, reaching far into the private spheres and interests of patients, research participants and the wider population. This creates many new regulatory objects requiring attention, and also blurs distinctions between traditional roles such as clinician/researcher, and patient/participant. These developments often result in a burgeoning of silo-based regulatory spaces – focusing respectively data/tissue/cells/trials/databases/internet – which are being occupied with an ever-expanding population of new actors, far beyond the classic actors such as regulators and self-selecting patient groups. This workshop sought to identify the dynamics affecting this expanding range of actors and the challenges that they face in navigating and influencing health research through regulation. It also sought to examine deep questions about how these actors can be empowered, together with traditional regulators, to co-produce optimal governance and practices across the entire spectrum of human health research. In short, we aimed to begin reimagining health research regulation in terms of the human practices experiences that drive it, while developing methods to evaluate those influences and their role in determining what counts as good governance.

We did not seek to propose yet another new model, nor a one-size-fits all framework of governance across research sectors. Rather, this workshop was motivated by a desire to move away from the incremental, anachronistic and silo-based development of regulation – often driven by legal mechanisms – towards an integrated, interoperable vision of governance as co-produced practice that could reach across many of the domains of health research. To this end, we sought to learn from actors with experience of existing alternative models of governance and harness their knowledge and experience towards developing tools that would allow us to identify obstacles to good governance, as well as to develop mechanisms that move away from default, topic-specific, regulatory exceptionalism.

Objectives of the workshop

- Learn from the experiences of relevant actors across various illustrative areas of health research. Assess the relative merits of existing ethics and governance tools (consent, risk, ethics approval) according to their role in various areas of research.
- Gain a deeper understanding of the relative roles of law and other human practices in delivering good governance. Ask: who occupies the regulatory spaces in-between hard law and successful research outcomes, acting in a stewardship fashion to help researchers navigate the regulatory course.
- Explore whether and how such actors and the surrounding apparatus assist in determining good governance, and how such evaluation can be designed and conducted.
- Carve out, through in-depth discussions, the mechanisms and practices that can be taken forward towards the successful re-conceptualisation of a dynamic, and pluralistic vision of HRG, while avoiding the trap of a one-size-fits-all model.
- Build on our existing connections with patient groups, researchers and other actors who are experimenting in the field of health research governance (HRG). We expect this to be an exercise in strengthening links across sectors as well as in empowering relevant actors and stakeholders.

PARTICIPANTS

Alex Bailey, Catherine Blewett, Tom Booth, Will Bowen, Roger Brownsword, Emilie Cloatre, Edward Dove, Isabel Fletcher, Carol George, Sharon Gordon, Agomoni Ganguli Mitra, Nils Hoppe, Klaus Høyer, Graeme Laurie, Katherine Littler, Thomas May, Catriona McMillan, Jonathan Montgomery, Kieran O'Doherty, Annette Rid, Nayha Sethi, Annie Sorbie, Mark Taylor, Samuel Taylor-Alexander, David Townend.

Participating remotely: Rachel Smith

LiminalSpaces

WORKSHOP SUMMARY

Session One – Actors in Governance: participants and participation

Klaus Høyer presented Denmark as a 'research radical country', with deliberate government intention to break down regulatory silos and make the entire country serve as a research cohort. Central person register has existed since 1968 initially for tax purposes, then for care, but can and is used for research. Two regulatory trends were highlighted: (i), the Danish government worked to remove ethics approval demands and the role of informed consent for data warehouses; (ii) there is more focus on public involvement too, patient-centred care (discourse on autonomy and data security). At the same time, there is very little use of the data.

David Townend spoke of: (i) what the discourse on informed consent can learn from victimology, and (ii) whether free and informed choice is ever completely free. His comments were inspired by the rise of populism and underlying mistrust of authority. Basing his thoughts on Nils Christie's article "Conflict as Property", which argued for the usefulness of conflicts in society, David suggested that *consent* is a property of individuals (conceptually not legally), but is often 'stolen' by institutions. This further suggests the need of a new property paradigm in research, engaging communities in research approval, engaging consent at a much earlier point, even using media better: 'who is the next Brian Cox of bioethics?', he asked.

Session Two – Actors in Governance: the 'public'

Kieran O'Doherty spoke of the definition and scope of public deliberation and what role it a can play for health research. He approached the topic as a critical friend – drawing out insights as to what public deliberation can, and indeed cannot, do. Public involvement is key and the model of public deliberation can be useful (as a specific kind of conversation). Based on Gastill's (2008) definition of deliberation, Kieran and colleagues have developed a standard design for public deliberation. Deliberation helps gather knowledge about an unknown area quickly. Participants need a certain amount of technical knowledge (from experts). Deliberation is dialogue and reasoned debate (but not necessarily towards a consensus). It is, however, non-representative and requires an appropriately situated actor, funding, and evaluation as to its appropriate epistemic weight.

Themes & Questions

-Pervasive linkage of data breaks down the regulatory silos in Denmark.

-Danish GP data controversy reminiscent of England's care.data fiasco

-Does breaking down silos risk eroding participant protection? Should we worry about exporting trust to the private sector?

- Consent and justifying data use: is the 'me' society misinterpreting liberalism?

-Consent managed as property: responsibility for participant? Why not a person paradigm versus a property paradigm?

- Friction/Conflicts useful for society but in disagreement, can we be democratic?

- Can the collective nature of data strengthen a proprietary model because the individual must concede to group, or will the individual trump the collective? People feel robbed when decisional power is taken away.

-Centralisation of data management also means trust, security, and property at mercy of central authority.

Mark Taylor presented on the role of the CAG (Confidentiality Advisory Group) in protecting the public interest in confidential patient information.. While the consent or anonymise paradigm predominates, CAG has a statutory role in advising on setting aside the common law duty of confidentiality to facilitate patient data use for medical purposes that would not otherwise have a lawful basis. This is consistent with safeguards established by Parliament. Mark outlined some of the decisions that have been taken by CAG in relation to its approach. For example, express dissent would not be overridden except for in unusual circumstances. CAG also advocates a transparent approach, including that everything reasonable should be done to tell people what you are doing with their data.

Session Three – Actors in Governance: researchers

Sharon Gordon presented lessons from the Grampian Data Safe Haven (DaSH). There are various permission pathways, which can cause confusion, research waste and delay: via ethics, Caldicott Guardians, the Public Benefit and Privacy Panel (PBPP), ethics committees, data custodians, publics, NHS R&D, sponsors, research co-ordinators, research & innovation, safe havens, and researchers themselves. For each of these pathways, different forms need to be completed (similar questions, but asked slightly differently) and amendments are not always communicated across the pathways. In order to empower the actors, we might require a clearer permissions pathway: who, what, when, why, i.e. a single point of contact to submit approvals applications to and receive applications from; one application form for all applications; training and proportionate governance. The role of a research coordinator to help navigate these regulatory landscapes was very important.

Tom Booth outlined his various roles as a researcher, as a doctor taking consent, as a reviewer, and as a participant (pointing to the different identities and demands of these roles). He discussed the handling of incidental findings (and lack of guidance on how to handle them) as a researcher and doctor, providing an illustration of the different models of practice and lack of clarity in governance. Using results from a survey conducted by his team, he suggested that better science will provide better answers in terms of governing incidental findings: the more we understand the nature and relevant of the findings, the better the normative steer towards reporting those findings.

Themes & Questions

-Worries about trust are sometimes the result of being asked about trust in particular area of medical research.

- Use of deliberation requires evaluation reg. epistemic weight. Currently has no (proper) fit in regulatory regimes: how about conflicts between the two?

- How valuable are appeals to public interest? Are they sufficient to capture overlapping consensus? Disagreement as to proper interpretation?

-Public deliberation and public interest emerging as regulatory tools/concepts?

-Various permission pathways in approval create obstacles and frustration.

-Clearer pathways for application are required, including single point of contact, single form stewardship, training and proportionate governance.

-Biggest delay in approval is still probably faulty research design. There is a need for a whole system approach that makes it clear that regulation and good governance is a shared community responsibility and concern.

Session Four – Governing the new and the unknown

Thomas May, continuing the theme of incidental findings, suggested that emerging technologies will require new frameworks for understanding incidental findings. The American College of Medical Genetics and Genomics (ACMG) recognised a potential controversy between primary, secondary and incidental findings, leading them to change recommendations on this matter. How we define a 'finding' will have repercussions on how we regulate reporting them. The ACMG's tripartite categorisation of findings caused confusion amongst the workshop participants. This was a good example of an attempt to impose clarity and certain through definition and rules that had precisely the opposite effect.

Emilie Cloatre presented the area of governing complementary and alternative medicine (CAM) as a problem for law and regulation. Law finds the distinction between proven/unproven crucial and struggles with the issue of CAMs. CAMs present new modes of knowledge and actors. Law is not responsive, and does not provide enough engagement points for stakeholders, and it makes assumptions about knowledge and who gets a say: in particular, what constitutes 'legitimate' medical knowledge.

Session Five – Current Governance: experiences, gaps and good practice

Alex Bailey spoke of the limits and lacunae in the Medical Research Council (MRC) UK-wide application process. The MRC application is comprehensive, though long, with a one-size-fits-all model. As research (e.g. increased use of data) and social landscape (e.g. revisiting the 14-day rule for embryo research) change, ethics review perhaps needs to move from a front-loaded process to more of a flexible, on-going process.

Will Bowen presented the Health Regulation Authority (HRA)'s vision to streamline the regulation of research that also makes the UK attractive for research (especially post-Brexit). The HRA approval offers a single application and review for all medical research (the complication is that we have four countries in UK). In his role, Will speaks to and advises a variety of stakeholders within this process (setting up research end-to-end).

Themes & Questions

-The example of incidental findings might illustrate the need for easier, clearer governance.
- To what extent can better science provide answers regarding governance of incidental findings?
-Arising theme questions the nature of recommendations relative to scientific facts or "truths".
-Over-regulation can occur where there is an attempt to impose certainty where it does not exist.
- CAMs problematises the certainty of law and the medical model of knowledge.
- Relevant to the concept of 'actors': some stakeholders are heard more, while others have to negotiate.
-Different kinds of research might require moving away from the front-loaded process of ethics evaluation to more on-going models.
- What might be required of a genuine assessment of proportionality (cutting out REC in some cases?)
-What exactly are the gaps produced in the approval process by new studies?

Rachel Smith *(via conference call)* spoke of the perspective from the MRC (predominantly work conducted outside the NHS-including bench and animal studies-linking lab-clinic-life). Research governance is a maze for researchers and the MRC's Regulatory Support Centre unit helps guide them through it (a one-stop-shop for advice and guidance). The biggest hurdle comes from moving across research worlds (academia to NHS or commercial) and working across countries.

Session Six – Concepts and Models of Governance

Annette Rid discussed the concept of proportionality in regulation. Traditional research ethics has been institutionalised in a way that results in both too much and too little oversight. Proposing the analogy of proportionality in retributive justice, Annette suggested that research needs to be anchored in different levels of scrutiny.

Roger Brownsword spoke of his experience as chair of the UK Biobank Ethics Governance Council. Many experiences (e.g. changing landscape around access) of the EGC could be characterised as examples of liminal spaces; Roger considered to what extent there is normative mileage to be taken from liminality – how does it help us in reconstructing the regulatory environment of research? Roger demonstrated the various ways in which the EGC has effectively acted as a critical friend to UK Biobank, but the management of the on-going relationship remains a challenge.

Graeme Laurie, picking up from some of the questions laid out by the participants about liminality, spoke of the limitation (and undesirability) of law to anticipate and create regulatory objects, e.g. regulated categories such as 'personal data', 'human tissue', 'embryos' etc. He considered the implication for law of 'living with uncertainty' (such as for example using regulatory stewardship to guide actors through complex regulatory landscapes), how law might act as a 'trickster' (simply because something is lawful does not mean that it enjoys social licence, e.g. care.data), and emphasised the need to empower researchers and governance professionals so that they are in a position to plan for the future and make the right kind of decisions themselves rather than in a reactive manner.

Themes & Questions

-How does streamlining regulation fit with complexity described by others?
-If there is a more holistic view of ethics, approval and governance, where does HRA fit?
-Can HRA both regulate and promote research effectively? How will we know?
-HRA and MRC perspectives: two version of stewardship in governance? Biggest hurdles: cross-sector research and interpretation of law.
-Visibility of such stewardship is an issue (MRC RSC unit unknown to DaSH).
-Is this stewardship ethics or operational help?
-Can we create a research ecology (with anticipatory governance tools), promoting proportionality?
-To what extent do experiences of liminality help us construct the regularity landscape ahead?
-Law creates and bounds regulatory objects. What results for governance?

EMERGING THEMES AND QUESTIONS

- Are we naively assuming that we are able to measure points or elements of 'success' in good governance models? Should we focus on metrics at all?
- How do we deal with uncertainty, both in terms of science (e.g. incidental findings) and in terms of law (e.g. unbounded objects, foresighting, non-traditional models of medicine)?
- Are substantive norms of ethics fixed? If so, what does that mean for changing models of governance? If not, how can we capture this within existing or emerging regulatory regimes?
- How do we achieve both streamlining, clarity and simplicity in governance, while embracing complexity, the need for flexibility, and customization and proportionality? Should both be seen as equally valuable aims, or should they be balanced or reconciled through various ways and means?
- What is regulation for? Where does it fit? Where should it kick in? What is the relationship between regulation and good governance? Where is the role for law in all of this?
- How do models of stewardship relate to our understanding of operational impediments, institutional ethics and norms in ethics?
- How can research coordinator and stewardship roles be better defined and given more prominence within the regulatory landscape?
- How can proportionality be captured and assessed within different aspects of research regulation, and across all domains?
- How does the breaking down of silos (e.g. all study models linked by data, or all data linked across sectors and areas) affect our understanding of governance and the role of regulation?
- How are actors and stakeholders empowered? When do they feel empowered?
- How do we create a dynamic research ecology, and anticipate new eventualities and projects, without waiting for the first one to come along?