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ORIGINAL ARTICLE

Accountability, Governance and Biobanks: The Ethics and Governance Committee as Guardian or as Toothless Tiger?

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Abstract The huge potential of biobanks/genetic databases for the research community has been recognised across jurisdictions in both publicly funded and commercial sectors. But although there is tremendous potential there are likewise potential difficulties. The long-term storage of personal health information and samples poses major challenges. This is an area is fraught with ethical and legal uncertainties. Biobanks raise many questions of the control of rights, of consent, of privacy and confidentiality and of property in human material. It is thus unsurprising then that there has been a lively debate as to how biobanks should operate, the boundaries of participation and what governance structure, if any they should adopt, a debate which has been engaged in across the academic community and by funders and researchers alike. This paper asks despite the good intentions can ad hoc ethics and ethics and governance committees long term provide an effective solution to the legal and regulatory challenges arising from biobanks.

Keywords Biobanks · Governance · Ethics · Ethics committees

Introduction

Over the last two decade the use of large population genetic databases- more commonly known now as "biobanks" has rapidly increased both nationally and internationally. From UK Biobank and the Avon Longitudinal Study of Parents

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and Children (Children of the 1990s project)[1] to Iceland's Decode database and beyond they are regarded as an important research activity by the scientific community. They have been established by public funded projects and also in the private sector [9]. What is a genetic database? The House of Lords Science and Technology Committee in 2001 defined these as being "collections of genetic sequence information or of human tissue from which such information might be derived that are or could be linked to named individuals" [20]. Gibbons [14] has suggested that

> "It is simultaneously too broad and vague to serve as a statutory definition and too narrow. In referring only to "genetic sequence information" it omits collections of personal, medical or genealogical data". ([14], p. 324)

She also notes that another restriction is the reference to named individuals. She suggests that

> "Examples of other factors that a more sophisticated definition might address include the purposes for which collections are created or maintained; their potential uses; design aspects including the degree of technical sophistication, accessibility, structural organisation, arrangement and search ability, intended duration, location, ownership, management structure and size". ([14], p. 324)

It should also be noted that the lines are still further blurred in that others refer to these as tissue banks for example the UK Children's Cancer Tumour Bank. Here our focus is upon the large genetic databases usually referred to as biobanks or as population biobanks. These typically provide a resource which enables epidemiological research in relation to a wide range of conditions [15].

The huge potential of such biobanks/genetic databases for the research community has been recognised across jurisdictions in both publicly funded and commercial sectors [26]. There are notable advantages for researchers to be able to undertake long-term epidemiological studies with specific cohorts. But although there is tremendous potential there are likewise potential difficulties. The long-term storage of personal health information and samples poses major challenges. This is an area is fraught with ethical and legal uncertainties. Biobanks raise many questions of the control of rights, of consent, of privacy and confidentiality and of property in human material. It is thus unsurprising then that there has been a lively debate as to how biobanks should operate, the boundaries of participation and what governance structure, if any they should adopt, a debate which has been engaged in across the academic community and by funders and researchers alike [5, 8, 14, 39]. This paper asks despite the good intentions can ad hoc ethics and ethics and governance committees long term provide an effective solution to the legal and regulatory challenges arising from biobanks.

The paper begins by considering the rise and rise in the use of ethics committees in general. It examines the different types of ethics committees in general and the nature and role of biobank ethics/ethics and governance committees in particular. Secondly, it considers the extent to which biobank ethics/ethics governance

[1] http://www.alspac.bristol.ac.uk.

committees need "teeth" i.e. powers of enforcement to provide effective accountability. It considers the arguments for and against enforcement. The final section of the paper suggests that while such "teeth" may indeed be need for effective regulation of biobanks in general what is needed may be a different type of "tiger". While specific enforcement powers may be a necessary part of an effective regulatory structure this can and indeed should be seen as only one part of a much broader debate regarding the regulation of research.

The Rise and Rise of Ethics Committees

The last three decades have been notable for the rise in the use of ethics committees in the UK. Ethics committees may be used for a range of purposes. One type of ethics committee is a hospital ethics committee to which controversial treatment decisions can be referred.[2] While such ethics committees are common in other jurisdictions such as the USA and Canada only limited use has been made of them in the UK. Two other types of ethics committees may impact upon the operation of biobanks. A second type of ethics committee is the research ethics committee. Since Nuremberg there has been pressure nationally and internationally to ensure that the conduct of research is ethical. This led to the establishment of committees to whom researchers would submit their research project protocols for approval. Initially such committees were established in the UK through the auspices of the Royal Medical Colleges. In the 1990s the approval process became increasingly centralised following the publication by the Department of Health of what was known as the Red Book [3, 10, 29]. All research concerning NHS patients, NHS staff or conducted on NHS premises had to be subject to research ethics review. This position is continued today under the NHS Research Governance Framework [12]. Thus, research ethics approval was seen as a necessary legitimator. While this was not initially required by statute there was a further de facto sanction which was that failure to get approval by a research ethics committee would lead to journals not accepting research for publication.

Research ethics committees became embedded into ethical review by law in 2004 through the enactment into English law of the EU Clinical Trials Directive which made research ethics committee approval in relation to clinical trials concerning medicinal products mandatory ([19], pp. 248–259; [31]).[3] Biobank projects themselves require ethical approval through the research ethics committee system, as also do research projects which seek to use material which is stored within the biobanks themselves. However, the majority of research projects are not required by law to have research ethics committee approval. Otherwise as has been noted elsewhere research ethics committees themselves lack "teeth" in the sense of

[2] See for background Slowther et al. [37].

[3] Directive 2001/20/EC on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use implemented into UK law by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031.

binding statutory power to regulate research activities and police researchers (See further [16]).

While research ethics committees have been scrutinisers of the validity of research practices one interesting development is that in recent years ethics committees have become to be seen also as "legitimators" of research practices. Statutory provisions have provided that research ethics committee approval can render certain research practices lawful as exceptions to general statutory provisions. For example, the Human Tissue Act 2004 provides that "appropriate" consent must be obtained before tissue is used for research purposes.[4] However, it also provides that use may be made of spare human material in research which has been anonymised without individual consent under the Human Tissue Act 2004 as long as approval for such use has been mandated by a research ethics committee. Similarly adults lacking mental capacity can be included in clinical research in an emergency situation under the Mental Capacity Act 2005 without further consent having been given as long as this has been subject to research ethics committee approval [32].[5]

A third type of ethics committee, and the form of committee which is the main focus of this paper, is that of the specialist ethics or ethics and governance committee attached to a particular research project. Here our focus is upon ethics and ethics and governance groups and committees established to provide oversight in relation to the operation of biobanks. While research ethics committees are concerned with approval of a range of different projects across the geographical area to which they are attached in contrast ethics and governance committees concerning biobanks in the UK are committees which are dedicated to that particular biobank. NHS research ethics committees are wholly separate and distinct from the projects which they are concerned to approve. They do not have an "official" long-term link with a specific organisation which they are concerned to scrutinise. In contrast a biobank ethics/ethics and governance committee may be established as an advisor, watchdog or both in relation to the operation of the biobank. The very growth of such committees is an interesting phenomenon. They can be seen as providing confidence, checks and balances, a perceptible wall of accountability. But to whom? While biobank ethics committees can be seen as policing decision making is there a danger that the very fact that they exist suggests that they are legitimating that very same decision-making and actions by the biobank itself. It might be suggested that such a committee is both a watchdog but also a legitimator and that this may present an uneasy position. Moreover if they are able to effectively act as a watch dog, effectively provide advice and guidance they need to have the status to achieve this. However, good the advice given this may ultimately prove futile unless coupled with enforceability.

The concept of specialist advisory ethics/ethics and governance groups/committees for biobanks date back for many years. The Human Genetics Commission

[4] Sections "The rise and rise of ethics committees" and "Ethics committees biobanks and the question of "teeth"" Human Tissue Act 2004.

[5] Mental Capacity Act s 32(8), (9).

discussed the utility of the use of ethics committees in relation to Biobanks in their report *Inside Information* in [21]. It commented that

> "In view of the long-term nature of genetic research involving longitudinal studies, we believe that there should be continuous oversight to ensure that participants can be confident that any proposal for further research, access by external research groups and questions of wider benefit will be subjected to careful scrutiny. Such a body could also act as the custodian of the information used to encode or encrypt the samples or personal information, thereby ensuring that the various research groups are unaware of the identity of the participants. *We therefore recommend that the governance of genetic research databases and DNA collections should allow for oversight by an independent body—whether it is an ethics committee or another body—which is separate from the owners and users of the database*." (Human Genetics Commission at para. 5.45)

Here perhaps the most celebrated and certainly one of the most discussed examples of an ethics committee overseeing a biobank is that of UK Biobank. UK Biobank is a major population database involving 500,000 subjects of between 40 and 69 years of age who have been enrolled in the database over a 20 year period. The ethics and governance structures of UK Biobank were subject to extensive consultation prior to their adoption by the funders. UK Biobank operates under the auspices of an Ethics and Governance Framework. UK Biobank has an Ethics and Governance Council which is designed to operate at arms-length from the funders. It has an independent chair[6] and members appointed under Nolan principles. Its terms of reference are

"Remit

- To act as an independent guardian of the UK Biobank Ethics and Governance Framework (EGF) and advise on its revision;
- To monitor and report publicly on the conformity of the UK Biobank project ("UK Biobank") with the EGF;
- To advise more generally on the interests of research participants and the general public in relation to UK Biobank.

Functions

1. To keep the creation, maintenance and use of the resource under review in order to advise and report publicly on the conformity of UK Biobank's activities with the EGF;
2. To consider and advise on revisions to the EGF that may be required to respond to changes in the legislative or regulatory context, developments in ethics or advances in science or technology;
3. To advise on UK Biobank policies that relate to or flow from the EGF (such as those on recruitment, access, or complaints handling);

[6] Currently Professor Roger Brownsword, Emeritus Professor of Law at the University of Sheffield.

4. To keep under review applications for access to the resource with regard to the interests of research participants and in accordance with the Intellectual Property and Access Policy;
5. To approve any transfer of the resource (or substantial parts of it) to a third party, for example, in the event of a liquidation, as set out in the Memorandum and Articles of Association of UK Biobank Limited" (UK Biobank Ethics and Governance Framework [40]).

There are several perceptible advantages in the use of such ethics and governance operating alongside biobanks. The first advantage is that of objectivity. Such committees have the ability to provide unbiased advice and act as a check and balance away from the scientific imperative. Decisions may thus not solely be driven by scientific concerns but rather could weigh up impartially a broader range of issues. Secondly, such a committee can provide a far broader range of perspectives upon issues under consideration because membership of ethics committees are typically drawn from different disciplines. Thirdly, such committees may provide a flexible response to new developments and challenges as the science advances. A biobank can be seen as a living entity which will need to respond to such developments given the time period over which it will run. In the case of UK Biobank for example this is a 20 year period. The ethics committee can provide a source of counsel as new issues develop over time allowing the project to grow and develop and effective advice be given.

However, while there is potential some fundamental issues need to be considered when such committees are established. For example is an ethics/ethics and governance committee sufficiently distanced from the biobank which it is monitoring? The answer to this question may depend upon the manner in which they are constituted and how they are left to operate. The independence of a selection process for a biobank ethics/ethics governance committee is crucial. Its day to day operation is also important. If an ethics committee operates totally at arms-length from an organisation then it may be seen as more independent. The effectiveness of such committees will relate to the information which they are given in relation to the organisation which they are scrutinising.

Should the role of such committees be simply advisory or should it extend further? Is it enough to provide advice and be heard or should their advice be sought and be held to be binding. Should they have an active role in policing the biobank? Of course biobanks could be policed by the courts. Biobanks and the researchers who use the resource may be liable to research subjects for their actions. But is this sufficient? Should accountability of biobanks and researchers be simply left to the individual researchers and organisational integrity or be dependent upon whether if something goes wrong later on an aggrieved research subject decides to litigate? Litigation is long cumbersome, expensive and could ultimately destroy a biobank through the resultant adverse publicity which could lead to participants withdrawing en masse. Instead would it be a better approach for an ethics and governance committee to be able to pre-empt problems with a biobank if in its view an approach which is taken which is fundamentally inappropriate, unlawful or unethical? If it is given an active role in policing a biobank would that on its own be simply enough.

Yes it may provide advice which would avoid bad practice, promote good practice and also incidentally avert future litigation surrounding the use of such material. But in relation to the ethics committees developed in the UK to date which guide and advise biobanks there appears to be something missing-enforcement powers. But is this type of body sufficient to effectively perform its role or does it ultimately need "teeth"? We explore this issue in the next section.

Ethics Committees Biobanks and the Question of "Teeth"

At present it appears that those ethics committees which have been established in the UK in relation to biobanks do not have such "teeth" enabling them to "formally bite" and hold a biobank to account. So for example in relation to the high profile example of UK Biobank as Gibbons has noted that while UK Biobanks Ethics and Governance Council can operate as the independent guardian of the Ethics and Governance Framework it does not have any formal legal status [14]. Moreover as she comments it is UK Biobank itself rather than the Council which has the ability to amend the framework at will. She stresses that the Ethics and Governance Council remains simply advisory. However, that does not mean that the issue of accountability has not been addressed. So for example, in relation to UK Biobank the Ethics and Governance Framework provides that

> "Normally the Council will communicate its reflections and criticism informally. If the Council is not satisfied with UK Biobank's response, it could make a formal statement of concern (e.g. to the Board or funders) or, if necessary, make a public statement that certain actions should or should not be taken. In the extreme, members of the Council could resign in protest and announce this publicly." (UK Biobank Ethics and Governance Framework [40], Para III. A.2)

But are such assurances sufficient? Is it enough that ethics committees can rely on the word of the biobank funders that they will behave? As Gibbons states

> "At most the EGC could threaten to report any ethical concerns to UK Biobanks funders, go public with its criticisms or its members could public resign in protest". ([14], p. 341)

She queries the effectiveness of such an approach and she comments that

> "Since resignation en masse by EG members would leave UK Biobank without any oversight body this seems an especially unattractive prospect". ([14], p. 341)

She goes onto say that

> "Accordingly UK Biobanks current self-governance structure may not set the most desirable precedent." ([14], p. 341)

This approach, as Gibbons has noted, is in sharp contrast to that of the Icelandic Biobank which is subject to statutory oversight. There is statutory regulation in the

form of the Regulation on Scientific Research in the Health Sector under which the National Bioethics Committee is established along with hospital ethics committees.[7] Such committees have a statutory duty both to monitor research and to revoke permits to undertake research. Criminal penalties are attached in relation to violation of this legislation. Is this then the way forward in the UK? As Gibbons notes oversight, regulation and enforcement is something which may vary.

> "What is deemed appropriate or necessary for some biobank types—bigger or more complex ones for example- may well be prohibively expensive, unachievable, disproportionate or simply overkill for others. Some biobanks may require mandatory, intensive ongoing scrutiny with "teeth". For others a lighter touch or even optional approach may do." [17]

Is an effective ethics committee then only one which has the power to call an organisation to account? What is interesting about the Icelandic approach is that this is not simply an issue which is about the regulation of biobanks in general or the accountability of biobanks in particular—the issue is rather framed in terms of the rights of patients and the regulation of research.

But would giving any biobank ethics committee within the UK at present really solve the problem? One of the major difficulties for any ethics committee in England and Wales calling a biobank to account is the basis on which it gives its advice. One fundamental problem which still faces biobanks, researchers and ethics committees alike is that of the fluidity and uncertainty of many of the legal and regulatory frameworks applicable to their operation. Does this mean then that ultimately we are considering this issue from the wrong starting point? Has the ad hoc development of regulatory responses in this area obscured what is the fundamental question? Before we consider whether to give biobanks ethics and governance committees "teeth" it is suggested that we need to consider just why they will be "biting" and on what basis. Are their decisions legitimate or rather than leaving many of these questions to individual ethics and governance committees should we instead reflect upon the fundamental ethics and governance issues which underpin the area itself? As will be seen in the next section biobanks ethics and ethics and governance committees operate against complex and uncertain legal and ethical parameters.

Legal and Ethical Regulatory Parameters: A Matter of Fundamental Uncertainty?

A major challenge for those operating biobanks in England and Wales and for their ethics and governance committees is that at present they operate within what is a very complex legal regulatory spectrum [16]. The law which is applicable in the area has developed piecemeal and over time. It is in many respects parasitical upon existing common law principles which in turn were often developed to deal with issues wholly unrelated to health care law in general and the regulation of clinical

[7] No 552/1999, issued under the Act on the Rights of Patients, No 74/1997.

research in particular. Furthermore this is accompanied by an overlay of a myriad of statutory provisions which relate to specific areas.

So for example, particularly pertinent to biobanks is the law concerning human material currently contained in the Human Tissue Act 2004 [27, 35]. This legislation was passed following huge controversy concerning the unauthorised retention of human material leading to major inquiries in the form of the Royal Liverpool Children's Hospital inquiry (Alder Hey) (Alder Hey Report [2]) and that of the Bristol Royal Infirmary Interim Inquiry (Bristol Inquiry Interim Report [4]). The current law provides an overarching regulatory framework governing a range of issues from transplantation to research. It is rooted in the concept of "appropriate consent". One of the major problems of this area is that despite the years of discussion which followed Redfern's Inquiry into the organ retention scandals at Alder Hey and Professor Sir Ian Kennedy's interim Bristol Royal Infirmary Inquiry into organ retention issues at that hospital the resultant Human Tissue Act 2004 simply left too many questions open.

The Human Tissue Act is rooted in the notion of "appropriate consent". What, however, constitutes such consent is not, however, defined by the legislation and it is the case that uncertainty surrounds the nature of consent in relation to material used in Biobanks—particularly around questions as to whether consent should be generic or specific. While the Act 2004 is silent as to whether consent should be specific or generic consent during the debates on the Bill in the House of Lords Lord Warner commenting for the government:

> Let me state clearly that the Bill does not require consent to be specific to each research project for which tissue might be used. Consent can be broad. Consent to research can be generic and enduring.[8]

The Human Tissue Authority Code of Practice, Code 1, Consent states that: 'Consent may differ in its scope as it may be generic or specific' (Human Tissue Authority [22], para. 35). It then provides:

> Generic consent typically only applies to research. If conducting research on samples of tissue it is good practice to request generic consent because this avoids the need to obtain further consent in the future. It is still important, however, that the consent is valid. (Human Tissue Authority [22], para. 36.)

The Human Tissue Authority Code of Practice on Research also provides that

> To facilitate the use of valuable human tissue in research, the HTA advises in line with the MRC and NRES that consent should be generic because this avoids the need to obtain further consents. It is still important, however, that consent is valid. If the intention is to store the tissue for an as yet unknown research purpose or as part of a tissue bank for research then this should be explained, setting out the types of research that may be involved, any wider implications and the circumstances under which the tissue will be disposed of. (Human Tissue Authority [23], para. 47)

[8] HL Deb vol 664 col 370 22 July 2004. See also Dr Ladyman, HC Standing Committee G col 51 27 Jan 2004.

It is uncertain to what extent a blanket generic consent policy could prove subject to subsequent Human Rights Act challenges. For example, litigants may attempt to use Article 8 of the European Convention of Human Rights to challenge this provision in the future. Article 8 safeguards the right to privacy of home and family life. It includes both respect for informational privacy and also for decision-making autonomy.[9] There is the possibility that an individual may claim that they have been given insufficient information to determine how their human material should be used when they consented and that this has consequently undermined their privacy rights. This may be particularly the case were the proposed uses of the material intended to be controversial or have a particular religious or cultural dimension.

Consent in the context of long term retention and use of material and information by Biobanks can prove problematic [24, 30]. Biggs questions the value of informed consent [3]. She quotes another commentator Hofmann in 2009 who has compared broad consent to obtaining consent to withdraw £900 from a person's bank account and then claiming that it is legitimate to take £9,000. She suggests that

> "Clearly simply giving a broad consent does not authorise any and all subsequent actions. When combined with the concerns expressed earlier about paying inadequate attention to whether participants fully understand the implications of their involvement in research broad consent seems a dangerous practice that is detrimental to autonomy. It is one thing to avoid ascertaining whether a potential participant understands the risks and implications of engaging in a project but quite another to deliberately disregard their rights whilst claiming that they have broadly consented." ([3], p. 91)

Other writers have suggested that consent by itself may obscure broader considerations to facilitate individual privacy [24]. Broader issues such as community participation need to be addressed enabling the participation of research participants in setting the research agenda.

Further challenges relate to the law concerning the confidentiality and privacy of personal information. One problem surrounds the interface with regulation of genetic information [42].[10] This is regulated by the law concerning personal information. This is regulated partly through case law through the equitable remedy of breach of confidence overlaid today by the Human Rights Act 1998 and Article 8 the right to privacy also by the Data Protection Act 1998.[11] Biobanks also have to grapple with the common law position concerning property in human material. In essence who actually "owns" the materials and samples being utilised for research purposes. This is an issue which sits outside and alongside the Human Tissue Act 2004. Although English law has long recognised that there is no property in a dead body [28] the law does recognise that there is property in human material itself. So for example, certain bodily products/parts have been held to be capable of theft for

[9] See, e.g., the discussion in *Pretty v UK* (2002) FLR 45.

[10] Widows and Mullen provide an instructive discussion of what constitutes genetic information.

[11] *X* v. *Y* (1988) 2 All ER 648; *W* v *Egdell* (1990) 1 All ER 835; GMC, *Confidentiality* (GMC, 2009)*Z v Finland* (1998) 25 EHRR 371; *MS v Sweden* (1999) 28 EHRR 313; *Campbell v Mirror Group Newspapers* (2004) 2 All ER 995.

example, blood,[12] and urine[13,14] and hair.[15] In 1997 an artist Anthony-Noel Kelly, was successfully prosecuted for theft of body parts[16] from the Royal College of Surgeons. The issue of who precisely has such property though remains complex if work has been undertaken on tissue for the purposes of preservation.[17] If human material is the property of the research participant- at what point does it become the property of a biobank? Indeed has such material been gifted or merely passed over subject to come conditional use such a that of a bailment?[18] [36, 38]. Further consideration of this question goes beyond the scope of this article but the absence of legal clarity on such issues is problematic in a situation in which ethics committees attached to biobanks are expected/invited to provide advice and guidance on such issues [18]. This is particularly the case given that it is possible that research subjects unhappy as to how their samples/materials have been used may in the future bring actions in the courts in relation to e.g. property law. It is also the case that individuals may claim that control in relation to their human material is an issue for their own human rights. These issues are in many respects the tip of the iceberg. Fundamental challenges also relate to issues of intellectual property and who can and should be able to benefit from the I.P. rights arising from biobank research (UK Biobank Ethics and Governance Council [41]).[19]

Options for Reform: New Teeth or A New Tiger?

There appear then to be several major questions which underpin the operation of biobanks in England and Wales. First, is it appropriate for individual biobanks to develop their own ethics and governance structures independently or is a more centralised regulatory approach required? It is suggested that that the time has passed when reliance on ad hoc approaches in this manner alone can be seen as appropriate. While different structures may provide flexibility the absence of an overall framework and the current legal position can only provide uncertainty and may lead to fundamental problems and challenges in the future if this is not resolved. The fundamental uncertainties in relation to broad questions of principle and regulation from consent to informational privacy through to day to day regulatory challenges and issues of enforcement need further consideration. One option is that of the development of a broader regulatory framework for biobanks in general. This could be coupled with the creation of a specific oversight body for ethics committee in effect "guard" over the "guards". Gibbons has suggested that one approach would be that of the establishment of a National Bioethics Council

[12] *R v Rothery* (1976) RTR 550.

[13] *R v Welsh* (1974) RTR 478.

[14] (1974) RTR 478.

[15] *Rv Luff*, *The Times*, 13 December, 160, *R v Herbert, The Times*, 22 December 1960.

[16] (1999) QB 621.

[17] *Doodeward v Spence* (1908) 6 CLR 406. *Dobson v North Tyneside HA* (1997) 1 WLR 596 (CA),

[18] See *Yearworth v North Bristol NHS Trust* (2009) EWCA Civ 37, Quigley [36], Tutton [38].

[19] This is an issue which has recently exercised UK Biobank.

with a biobanks sub committee or working group to provide "appropriate targeted and tiered supervision". She suggests that

> "In addition to filing in some of the gaps left in the current governance patchwork having a dedicated, independent statutory authority could carry other benefits. Inter alia it could reduce the risk (or perception) of regulatory capture provide an expert source of information and advice to policy makers, law makers, biobanking professionals and the public alike, scrutinise legislative proposals, commission research, undertake consultations and spearhead public engagement and educational initiatives." ([14], p. 324)

At one level this can be seen as a very attractive solution. It may assist in structuring accountability, facilitating consistency in approaches across different biobanks, enabling structured exchange of knowledge and broader debates in relation to such issues. But whether bioethics can and should be the subject of a designated council in such a way is perhaps questionable given the fundamental uncertainty regarding the nature of bioethics and the divergence in bioethical perspectives-particularly given that England and Wales has a multi-cultural population. Furthermore it is submitted that this will not be sufficient given the considerable difficulties highlighted above relating to what is such a fundamental lack of clarity of English law in this area.

A second possible option is that of some form of national oversight body for research in general with specific regulation of biobanks being an off-shoot of its role. The creation of a new Health Research Regulator is something which has been was recently proposed by the UK government as part of their "Bonfire of the Quangos" strategy. The Government are committed to a radical reduction in the number of "arms-length" bodies in the NHS [6, 13]. As part of these proposals it intends to abolish a number of existing regulatory bodies in the health sector—particularly notable being the Human Fertilisation and Embryology Authority established by the Human Fertilisation and Embryology Act 1990 in the light of the Warnock Report to regulate and licensing the provision of modern reproductive technologies and the Human Tissue Authority established under the Human Tissue Act 2004 and having a wide remit regarding regulation and licensing of the use of human material. These proposals are certainly not uncontroversial and indeed have met with considerable criticism [33]. The previous Labour administration intended to combine the bodies in a single regulator called the Regulatory Authority for Tissue and Embryology as part of an earlier initiative to reduce the number of arms-length bodies but this proposal had been subsequently dropped [11].

The regulation of research and the operation of research ethics committees have come under considerable attack over recent years. It has been suggested that research ethics approval processes particularly since the implementation of the Clinical Trials Directive into English law has led to major delays. In spring 2010 the Academy of Medical Sciences announced that it was undertaking a review of the regulation and governance of research. This review was undertaken on the request of the then Secretary of State for Health Andy Burnham.[20] Its terms of reference were.

[20] http://www.acmedsci.ac.uk/p47prid80.html.

- Review the regulatory and governance environment for medical research in the UK, with a particular focus on clinical trials.
- Identify key problems and their causes, including unnecessary process steps, delays, barriers, costs, complexity, reporting requirements and data collection.
- Make recommendations with respect to the regulatory and governance framework that will: increase the speed of decision-making; reduce complexity; and eliminate unnecessary bureaucracy and cost.

Subsequently as noted above the Department of Health Report of the Arms-Length Bodies review was published. It has noted the diversity of research regulation and it stated that

> There is a strong argument for rationalising this and creating greater strategic coherence around research by placing responsibility for different aspects of medical research regulation within one arms-length body that would perform a stand-alone technical function as a research regulator. This would streamline the process of gaining permission to undertake medical research making it more attractive to universities and health institutions. Moreover there is potential for a single research regulator to have wider cross-government reach. ([13], para. 3.21)

The Academy of Medical Sciences Report was published in 2011. The Report recognised the complexity of the current ethics review processes. It also recognised the need for "independence, transparency, accountability and consistency" ([1], p. 95). Research was seen as something which should be a core NHS function ([1], p. 97). It supported the idea of a new Health Research Agency providing oversight and also streamlining regulation ([1], p. 100) and proposed that within this there should be a NHS research governance service ([1], p. 97). It made a number of specific recommendations regarding areas highlighted as concerns by the scientific community as inhibitors to research such as the EU Clinical Trials Directive governing trials on medicinal products, the aspects of the Data Protection Act which relate to health research ([1], p. 99) and aspects of the Human Tissue Act 2004 concerning the exemptions to the definition of "relevant material" under the legislation ([1], p. 99). The UK Government intends to go ahead with the proposed new research regulatory body. It can be seen to have perceptible advantages in promoting consistency of operation and oversight regarding research ethics approval processes. This new body which is intended to take over specific regulation in areas such as tissue and embryology could also be extended to cover the regulation of biobanks themselves.

On its face this provides an attractive solution. A defined independent research regulator could regulate both biobanks and ethics committees. Biobank ethics committees could be situated as part of a broader research review structure. Less would be devolved to individual biobanks ethics committees. This could facilitate clarity and consistency and perhaps in turn gain greater public confidence. But before such a body could operate effectively there still remains much work to be done in relation to the regulation of research. First, such a body would need to have sufficient resources to undertake its task. It should not be introduced as a

cost-cutting measure. Secondly, as noted above this is an area where there is considerable legal and ethical uncertainty. The establishment of a new Health Research Regulator even if it develops a defined "arm" with "teeth" to regulate biobanks is simply not enough. Instead before ethics committees can be given effective "teeth" they need to be given further guidance as to when and how they should "bite". Moreover as this author has argued elsewhere it is suggested that neither the Academy of Medical Sciences Report nor the Government's response to date goes far enough. Its specific recommendations are tailored to addressing a number of important issues such as use of data but the remit of the committee needed to be much broader. The whole area of regulation of research requires independent re-evaluation. What is needed is rather a considered review of the legal and regulatory framework of research by a wholly independent body following the model of the Warnock Committee report [34]. The legal and regulatory framework in relation to biobanks as in other areas concerning research involving human subjects has largely developed piecemeal. It is submitted that such a pragmatic compromise can and should no longer be seen as satisfactory. We need to need to engage effectively with the discourse of human rights and position of the research participant and to re-evaluate research regulation.

Conclusions

The growth of the ethics and ethics and governance committee in relation to biobanks in the UK is its face a praiseworthy initiative. Such committees can provide good counsel, oversight, checks and balances in relation to the research process. However, it is submitted to simply establish ethics and ethics and governance bodies on an ad hoc basis for the future is not now enough. There is a danger of false reassurance. As we have seen over the last decade in relation to the Human Tissue Act and the Mental Capacity Act ethics committee approval may be used as a tool to legitimate participation in the research process without consent. There is a danger that this consequently can be seen as dilution of the participation by the individual research participant. What is needed is for us to re-evaluate not simply the role of ethics committees and the regulation of biobanks but instead to see this as only one part of the research process in general in England and Wales. Perhaps the extensive dialogue over biobanks, however, well intentioned obscures the fact that this is simply research, albeit research over a longer period and in so doing we need to be clear as to the ethical and legal parameters within which we are operating. We can be effectively informed in so doing by comparative approaches and international and EU initiatives but equally comparative analysis only takes us so far—we need to structure law and policy which provides appropriate regulatory responses for the jurisdiction under consideration [25].[21] One of the great strengths of the regulation of modern reproductive technology in the UK at least at the on-set was the fact that this was developed through a careful arms-length determination of the relevant issues in the deliberations of the Warnock Committee report. This is

[21] See Kaye in relation to the question of biobanks across Europe.

what needs to happen in relation to research in general. We are past the stage where ad hoc resolution can be seen as satisfactory. There needs it is submitted to be clear coherent regulation of genetic databases under the auspices of the new Health Research Regulator in the UK. But this by itself is not enough- the current regulatory gaps need to be addressed—the nature of property in human material—the interface between the regulation of human material and of genetic information. We need to re-evaluate whether individual ethics and governance committees necessarily provide the best solution. As noted above there are advantages in terms of flexibility and accountability of retaining such structures. But if we do then they need to have greater status than at present. In order to garner true respect they need to be able to execute effective sanctions. It is not sufficient simply to set up ad hoc advisory committees in relation to specific biobanks and to rely upon options of resignation or press publicity. Realistically reliance on such a nuclear option would only be utilised in extreme situations and could effectively destroy the biobank itself meaning that years of future valuable research could be lost. But before we go any further we need to step back and to wholly re-evaluate the area—to set research regulation on a clear statutory framework, to have a major public debate over the whole area and to provide greater clarity. We need to do this before we are forced to by another crisis or scandal such as Alder Hey. The current situation is surely not sustainable if we wish to promote effective accountability in relation to the operation of genetic databases in the future.

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