Biobanks and bioethics: the politics of legitimation

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Introduction

On 24 September 2003, a joint press release was issued by the funders of the UK Biobank: the Wellcome Trust, the Medical Research Council (MRC) and the Department of Health. It announced the publication for comment of an 'Ethics and Governance Framework' to govern the operation of Biobank UK, funded with £43 million the previous year. The political significance of the Framework was summed up by the Biobank's chief executive, Professor John Newton, who commented: 'The project is in the interest of public health and we will be relying on the public's goodwill to make it a success. We will not begin recruiting until we have the right ethical and scientific frameworks in place'. (Wellcome Trust, 2003: 2) Although the notion of an explicit dependency between a new scientific endeavour and the ethical self-regulation necessary to maintain public trust in that endeavour is not new, the form of its realisation in the case of Biobank UK highlights the problem of legitimation faced by genetics in general and biobanks in particular.

Legitimacy can be defined as 'the capacity of the system to engender and maintain the belief that the existing political institutions are the most appropriate ones for the society' (Lipset, 1959, 77). If this belief is not present, or if it exists in only tenuous form, a government's ability to formulate and implement policy will be inhibited by its citizens' lack of trust in its institutional processes and outcomes (Dogan, 1992). Citizens may decide not to cooperate, to cooperate partially, or actively to oppose a particular policy initiative. The maintenance of the legitimacy of the relevant institutions is therefore a *sine qua non* of any new policy development and has an acute significance in initiatives such as the population based genetic database of Biobank UK which are dependent on the active cooperation of citizens. Public trust in biobanks which combine genetic and health information would not be problematic if the only foreseeable consequence was the opportunity to improve public health by understanding the interaction between genetics and environment in common disease processes without offending cultural norms. Since this is not the case, and since the regulation of genetic technologies has consistently demonstrated the sensitivity of the social context in the translation from research to application, the politics of legitimation form a natural part of policy implementation.

Civil society opposition to the creation of such databases is often couched in concerns about the allegedly unique nature of genetic information and the resulting implications for privacy, surveillance, discrimination, and commercialisation. The extent to which a governance framework can effectively protect such powerful information from abuses directly impacts on public trust in this regulatory field. At the same time one should not forget that whatever form of regulation is adopted also has to be seen as legitimate by science and industry. To take one recent and dramatic example, the collapse of the Swedish biobank company UmanGenomics despite its much vaunted ethical foundations was due to a failure to work through both the requirements of the scientists involved and the intellectual property requirements (IPR) of a successful market venture in this field (Rose, 2003). Where industry is content with a regulatory framework that facilitates its economic interests, civil society may feel that certain citizenship rights have been compromised in the interests of commercialisation. Alternatively, civil society stakeholders may be content with ethical arrangements that industry may regard as a constraint on its activities. Thus, and as Biobank

UK has clearly recognised, scientific advance in genetics is dependent on the construction of novel forms of regulatory legitimacies.

When an issue is politicised in an atmosphere of policy and knowledge uncertainty, a policy community may feel that the construction of such novel forms is more appropriately achieved through an adaptation of the familiar than through the development of quite new institutional arrangements (Hellström 2000). One such option in the regulatory sphere is the use of a fresh source of expertise which, if sufficiently established, may take the form of an 'epistemic community': 'a network of professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge' within that domain (Adler and Haas 1992, Haas 1992; Verdun 1999). An epistemic community can be heterogeneous, even composed of a variety of disciplines, but it must share beliefs about its knowledge base, the interests of the community, the causes of problems, and the principles under which it operates (Haas 1992). It is functional to the extent that its expertise offers interpretations of political reality which provide policy makers with a means for defining and codifying their interests, providing orientation and dealing with conflict.

The conventional technocratic approach to regulatory has relied on science-based epistemic communities to provide a 'rational' basis for policy decisions. However, the experience of genetic technologies, particularly GM foods and agriculture, has demonstrated the limited utility of the technocratic approach as a response to politicisation. Its difficulty is that 'the political implications of decisions are denied, the conflict over ends neglected, and technocracy proceeds as if problems were challenging….yet ultimately computational' (Radaelli, 1999: 764). In such a situation it can be anticipated that the state will turn to a familiar legitimation device – the use of an epistemic community – but redefine the nature of the expertise required. In the case of biotechnology, there is increasing evidence that ethical expertise is being employed as the means for dealing with public concerns (Wynne 2001).

Taking Biobank UK as our centrepiece, in this paper we analyse the politics of legitimation accompanying the emergence of population based genetic databases and the contribution of bioethics to the power play therein. The analysis has three parts. Firstly, it explores the nature of the legitimation problem experienced by biotechnology and considers the extent to which bioethics can be regarded as an epistemic community capable of responding to that problem through a regulatory contribution. Secondly, drawing on a range of documentary and internet sources, it examines the ethical content of the policy discourse of biobank regulation in four countries in terms of the balance of power expressed therein between the rights of citizens, science, industry and the state to the control of genetic information. To what extent do the bioethical discourses of different nation states seek to legitimise different conceptions of citizenship rights? Thirdly, the analysis deals with the contribution of the international discourse and networks of bioethics to the policy debate of biobank regulation. Is there an international epistemic community of bioethics acting as a source of ideas, values and expertise for national ethical discussion?

Biotechnology regulation and bioethics

In its 2002 report outlining a strategy for the life sciences and biotechnology in Europe, the European Commission recognises a fundamental tension at the heart of its policy. On the one hand, Europe has the scientific and industrial potential to be a global leader in new biotechnologies, including human genetic technologies. On the other, it acknowledges that

'public support is essential, and ethical and societal implications and concerns must be addressed' if Europe is to benefit from these technologies' (European Commission, 2002). Traditionally, public support for new technologies has been assured through governmental regulatory arrangements that have relied heavily for their legitimacy on the authority of scientific advice concerning the risks associated with a technology. Characterised as the technocratic approach, these arrangements have usually taken the form of expert advisory committees closely integrated with the bureaucratic apparatus of regulatory policy making and implementation. However, as the European Commission implies, this approach has shown itself to be singularly ill-equipped to deal with the political pressures generated by the experience of GM foods and crops ('green' biotechnology) and there is no reason to assume that the health applications of genetic science ('red' biotechnology) will, in regulatory terms, be any less demanding (Salter and Jones, 2002). In the case of biotechnology, surveys of European citizens have shown them to be at least as concerned about its implications for their cultural values as for their health and safety (Commission of the European Communities, 2003).

Certainly, the UK government is aware that the political sensitivity of biotechnology requires changes in the form of its regulation. Its 1999 Review of the advisory and regulatory framework for biotechnology found that current arrangements 'are too fragmented, are difficult for the outsider to understand, lack transparency, do not clearly take on board the views of all potential stakeholders and broader ethical and environmental considerations, and are insufficiently flexible to respond to the fast-moving nature of biotechnology developments' (Cabinet Office and OST, 1999: para 37). Following the Review, three new strategic commissions were created (the Human Genetics Commission (HGC), the Agriculture and Environment Biotechnology Commission (AEBC), and the Food Standards Agency (FSA)) with a commitment made to more open government in terms of enhanced public consultation, transparency of practice and broadened definitions of the expertise required for committee membership. The political ambition of these reforms is to use the principle of openness as a source of quasi-democratic authority to shore up the legitimacy of the advice and decisions of the regulatory committees.

However, open government is, at best, a vague and ill-defined response to the political problem of regulatory legitimacy, difficult to operationalise with any consistency and regarded with suspicion and hostility by the established culture of the UK's scientific and advisory system (Flinders, 1999; Frewer and Salter, 2002). Questions such as what type of public consultation should be used over what issues; how the results of consultations should be introduced into policy making (if at all); what transparency means in practice (e.g. availability of minutes, open meetings); and how the criteria for committee membership should be determined, have themselves become the object of political wrangling. Add to this the fact that more open government can readily politicise previously uninvolved constituencies and its practical attractions to the beleaguered civil servant with the responsibility for managing biotechnology regulation rapidly diminishes. Rather more attractive is the option of a fresh authoritative source of expert advice, clearly different from that of science but one which can be integrated with the regulatory process using the same organisational form of expert consultation.

From this perspective it is perhaps unsurprising that one of the most notable political consequences of the uncertainties surrounding the new genetic technologies has been the adaptation of regulatory forms to include expert committees dealing with, and pronouncing on, the ethical implications of these technologies. Their purpose is to routinise the

discussion of the ethical differences embedded in opposing cultural traditions and provide an authoritative means for resolving regulatory disputes. Accompanying this new legitimating function has been a new epistemic descriptor for the committees, that of bioethics. Over the last decade, numerous national bioethics committees have been established with state support: for example, the President's Council on Bioethics (United States), the Austrian Commission on Bioethics, the Comité consultatif de Bioéthique de la Belgique, the National Bioethics Commission (Greece), the Nordic Committee on Bioethics (Norway) and the Comitato Nazionale per la Bioetica (Italy). At the European Union (EU) level, the European Group on Ethics and New Technologies (EGE) has played an important role in the development of new regulatory mechanisms with Framework Programmes 5 and 6, particularly in relation to human embryo research (Salter and Jones, 2002b). With a keen awareness of its political function it describes its ethical Opinions on genetic technologies as 'a necessary stage in the debate about the relationship between new scientific breakthroughs and the evolution in attitudes that this progress brings'. With suitable self-confidence, it continues: 'This stage must enable European society and political decision makers to make the necessary trade-offs with greater understanding and the necessary perspective' (EGE, 2001: 12).

To what extent is the prominence of bioethics committees in national and international regulatory decision making indicative of a new and coherent epistemic community of bioethics with the characteristics outlined earlier of shared knowledge base, beliefs and principles? Bioethics emerged as a term with social currency in the early 1970s when academics from, predominantly, medical ethics, philosophy and law became engaged in the study of what a standard text on the field describes as 'the moral dimensions – including moral vision, decisions, conduct and policies – of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting' (Reich, 1995; see also Martensen, 2001). Interpretations of the development of the new field of bioethics differ markedly in terms of such basic questions as what it is and where it is going (see e.g. Carson, 1997; Charlesworth, 1993; Elliot, 1996; Dell'Oro and Viafora, 1996). Pellegrino posits an orderly process of evolution through three phases of 'proto-bioethics' (the articulation of human values), the enunciation of philosophically defined principles to guide bioethical debate and, finally, 'global bioethics' where the perspectives of social science, the humanities, and medical ethics are combined to produce a more flexible understanding of issues (Pellegrino, 1999). Others perceive disorder. Thus internally there has been energetic debate over the need for bioethics, on the one hand, to adopt coherent principles and rules and, on the other, to incorporate an appropriate recognition of cultural diversity (Callahan, 1999). Meanwhile, some external critiques have viewed its origins as more political than ethical, driven by the utilitarian service of interests rather than the search for truth (Maclean, 1993; Rothman 1991). To that extent bioethics may be portrayed as performing the classic function of an ideology as much as that of a moral philosophy (Nelson, 2000: 15). As Haimes notes in her review of the social research into bioethics, part of the difficulty of gauging the precise nature of its identity (or identities) is the absence of empirical work on its institutions, ideologies, knowledges, and notions of 'ethical expertise' (Haimes, 2002: 110).

The evidence suggests, therefore, that as an epistemic community bioethics may be emergent but it is certainly not yet fully formed (see e.g. Kapstein 1992). Rather, what we have is a hybrid professional group drawn from a variety of disciplinary backgrounds with a common occupational interest in the definition, organisation and application of ethical arguments regarding new health technologies. Yet despite the self-evident inconsistencies and

confusions surrounding its internal identity, the social and political value of the bioethics label continues to increase when measured in terms of such crude quantitative indices as numbers of courses, conferences, websites and committees. As an epistemic community it may be divided and conflictual but this has in no way inhibited its expansion as a socio-political activity. It may have no entry criteria, save that of self-labelling, and no common form of certification but, as the growth in its advisory role demonstrates, it has political utility. Indeed, it is able to turn its internal divisions to good use and claim that it can represent a broad collection of informed viewpoints on a variety of socially relevant areas. Furthermore, unlike other expert epistemic communities it is able to claim both an impartial interest in the policy process and no interest in the policy outcome. It is, in that sense, a natural instrument of policy legitimation.

Population based DNA biobanks

Population based DNA biobanks such as Biobank UK are designed to collect genetic information, link it with medical and other data, and investigate the combined effects of genotype and factors such as environment and demography on disease risk. Of themselves biobanks are not new and refer simply to an inventory or archive of biological material which may be compiled for diagnostic, therapeutic or research purposes. What is new and politically sensitive is the combining of genetic and health information for whole populations. The ready scientific justification for this endeavour is that such biobanks are 'the appropriate next step in translating recent advances, such as the mapping of the human genome, into knowledge of direct clinical and public health relevance' (Wellcome Trust, Medical Research Council, Department of Health, 2002a: 8). For industry, the biobank future appears equally unproblematic and lies in the potential of the databases for identifying new forms of therapeutic interventions for common diseases, enabling rapid pharmaceutical advance and the introduction of personalised medical care (Beskow *et al*, 2001).

However, for civil society the attractions of biobanks are less obvious. Databases of personal genetic information constitute a unique form of information about private individuals, which in turn poses unique concerns about its handling compared to typical medical records. Although conventional medical records may contain similar information about an individual's health to a genetic record, and both can be accessed without their presence, the information contained in genetic records is unique because of its *certainty* in revealing two things: the genetic health vulnerabilities of the individual, and their biological relationships to others (Roche and Annas 2001; UNESCO 2003). Consequently, such records also contain socially sensitive information on matters such as paternity, and the future health vulnerabilities of biologically related individuals (who may not have been required to give consent for their relative's sample to be taken). Annas (1993) has used the metaphor "future diary" to refer to the ability of the genetic record to provide information on factors that will contribute (if not determine) the future health of the individual. Further, the social mystification of DNA suggests that knowledge of one's genetic inheritance is likely to have a greater impact than knowledge of other medical data. Because of these reasons, it has been argued that the rules regarding the storage and use of genetic data must be different from those protecting medical records (Roche and Annas 2001).

In fact, such concerns have been expressed in civil society reaction to biobanks. The Icelandic Health Sector Database, the first and most well known of the new biobanks established and run by deCode Genetics, has experienced continuing conflict over its

arrangements for informed consent and privacy (Pálsson and Harðardóttir 2002; Rose 2001). Similarly, a planned genetic database for the Kingdom of Tonga initiated by an Australian biotech company Autogen Limited was terminated in the face of entrenched resistance from church and community groups concerned about the lack of public consultation prior to the Tongan Health Ministry's agreement with Autogen, and the apparent disregard for the role of extended family in Tongan culture when constructing the informed consent process (Burton, 2002; Austin, Harding and McElroy, 2003). Even in the UK, where human genetic technologies have in the main experienced an uneventful ride, the biobank project has experienced some local difficulties. Criticism has come not only from the predictable quarter of oppositional groups such as Genewatch but also from the very organs of the state: the House of Commons Select Committee on Science and Technology and the Human Genetics Commission (HGC) (Wallace, 2002). The Select Committee expressed the fear that 'the project's long term viability could be threatened if Biobank's funders fail to adopt a more open approach and engage not only the projects' participants and stakeholders but the wider public' (House of Commons Select Committee, 2002: para 63).

Biobanks thus combine scientific and industrial promise with political danger. The nature and scale of the data collected raises novel issues regarding the rights of the citizens involved, not only in the research process but also in the subsequent applications of the research findings (Annas, 2000). As the customary means for dealing with possible public mistrust, regulation then becomes the political site where the conflicting concerns of civil society, science and industry are addressed. In the remainder of the paper we examine how bioethics is employed as an instrument of compromise between these different interests. The empirical focus is the biobanks of the UK, Iceland, Estonia and Latvia—the only genetic databases in existence at the time of writing with the ambition of representing the national population, and therefore experiencing the politics inherent in such an endeavour.[1]

Method

The research was conducted through literature and web searches. Principal routes in were Europa (the European Union website - http://europa.eu.int/index_en.htm) and its links to member state government sites; and HumGen (http://www.humgen.umontreal.ca), the Montreal-based search engine covering international policies and legislation related to an array of human genetics issues. From this survey an analysis was carried out of: (a) the major policy statements formulated in relation to the regulation of biobanks and, (b) the ideological and practical contribution of bioethics to those policies. The analysis was structured as follows.

- At the national level, we analysed material relevant to the structure and ethical frameworks of the major national databases. (Table 1 outlines the main characteristics of the four projects.)
- At the EU level, since the UK, Estonia, and Latvia are all subject to European Union integration, and since much EU policy has been produced regarding genetic databases, we examined the policies relevant to biobanks and bioethics.
- At the international level we analysed statements produced by bodies such as UNESCO, WHO, and HUGO that appeared to be broadly influential in the formulation of national and EU policies in this field. We used this information to assess the extent to which the latter may have influenced the regulatory

[1] Other countries such as Sweden, Canada, and the United States have, or are planning to have, genetic databases at the level of region or smaller.

arrangements of the four national databases, and in particular the contribution of bioethics. (Table 2 lists the primary documentary sources selected at the EU and international levels.)

- At the level of national and transnational bioethical policy networks, we examined the composition and contribution of those networks. (Tables 3 and 4 lists the disciplinary background of members of national and suprastate ethics committees.)

Particular issues arising out of this analysis were then followed up by telephone and e-mail.

Table 1
Characteristics of existing or planned population-based genetic databases

Feature	Country (Population per UN estimates, 2000)			
	Estonia (1 367 000)	**Iceland (282 000)**	**Latvia (2 373 000)**	**United Kingdom (58 689 000)**
Objective (from regulatory framework /protocol)	"…to identify disease genes… to set up a health care database so [Estonians] can benefit from the personalized medicine of the future	"…increasing knowledge in order to improve health and health services."	"Determination of single nucleotide polymorphisms [for] genetic testing and in population based genetic studies; Development of individual treatment and individual prevention of diseases; Discovery of novel disease controlling genes and their functions."	"…to investigate the separate and combined effects of genetic and environmental factors (including lifestyle, physiological and environmental exposures) on the risk of common multifactorial diseases of adult life"
Population (approx. #)	1 000 000; pilot project, 10 000	Potentially the entire population	Potentially the entire population	Representative sample of 45-69 yr olds (500 000)
Type of data	Tissue samples; questionnaire data; interview data; physical exam	Tissues samples; health record data (all from existing records)	Tissue samples; information on health status, genealogy & lifestyle (not clear how collected)	Tissue samples; questionnaire data; interview data; physical exam
Time frame	Pilot project initiated 2002; database will be established over a five year period	Database initiated 2000, but in 2001 put on hold due to protests	Pilot project phase until 2003; population-wide database phase will commence 2007	Full implementation January 2003; anticipate 10 yr prospective work
Oversight	The Estonian Genome Project Foundation	Monitoring Committee (one rep each from health, IT, and law) appointed by the Minister of Health; to work with existing Data Protection Authority	Council of the Latvian Genome Project	Coordinating Centre (Hub) and Regional Centres (Spokes), selected by bid; plus an independent oversight body
Regulatory framework	Estonian Genome Project, 2002; Human Genes Research Act passed 2000 by Riigikogu (Estonian Parliament) Available at: http://www.geenivaramu.ee/mp3/trykisENG.pdf	Act on a Health Sector Database. Passed by Alþingi (Icelandic Parliament) at 123rd session, 1998-99. Available at: http://government.is/interpro/htr/htr.nsf/pages/gagngr-log-ensk	Law on Research on the Human Genome adopted June 2002; Latvian Genome Project. Website under construction, some information available at: http://forum.europa.eu.int/irc/rtd/cogene/info/data/pub/Latvian%20Genome%20Project.htm	Protocol for the UK Biobank, 2002. Wellcome Trust, Medical Research Council, and Department of Health. Available at: http://www.ukbiobank.ac.uk/

Table 2
Suprastate-level ethical guidance for population-based genetic databases

EU
Council of Europe (1997). Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo, 4.IV.1997. European Group on Ethics (EGE) in Science and New Technologies to the European Commission (1998). Ethical Aspects of Human Tissue Banking. Available at: http://europa.eu.int/comm/european_group_ethics/gee1_en.htm European Group on Ethics (EGE) in Science and New Technologies to the European Commission (1999). Ethical Issues of Healthcare in the Information Society. Available at: http://europa.eu.int/comm/european_group_ethics/gee1_en.htm European Parliament (2002). Legislative resolution on the proposal for a European Parliament and Council directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells (COM(2002) 319 – C5-0302/2002 – 2002/0128(COD))
International
Council for International Organizations of Medical Sciences (CIOMS) (2002). International Ethical Guidelines for Biomedical Research Involving Human Subjects. Available at: http://www.cioms.ch/frame_guidelines_nov_2002.htm Human Genome Organization (HUGO) (1996). Statement on the Principled Conduct of Genetics Research. Available at: http://www.gene.ucl.ac.uk/hugo/conduct.htm International Society of Bioethics, Scientific Committee (SIBI) (2000). Bioethics Declaration of Gijon. Available at: http://www.sibi.org/ingles/declaracion.htm Inter-Parliamentary Union (1995) Bioethics and its Implications Worldwide for Human Rights Protection. Resolution adopted by consensus by the 93rd Inter-Parliamentary Conference. Available at: http://www.ipu.org/english/strcture/confdocs/93%2D2.htm United Nations Educational, Scientific, and Cultural Organisation (UNESCO) (1997). Universal Declaration on the Human Genome and Human Rights. Available at: http://portal.unesco.org/shs/en/file_download.php/cbfc78b607fb773ab0726cefb5231fbaDeclaration+text -+english.pdf UNESCO International Bioethics Committee (IBC) (1995). Bioethics and human population genetics research (Report of the Subcommittee on Bioethics and Population Genetics). UNESCO (2003). International Declaration on Human Genetic Data. SHS/EST/02/CIB-9/3 World Health Organization (WHO) (1997). Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services. Available at: http://www.who.int/ncd/hgn/hgnethic.htm World Medical Association (WMA) (2002). Declaration on Ethical Considerations regarding Health Databases. [Note: this declaration draws on the spirit of previous WMA declarations--Helsinki, Geneva, Lisbon—to specifically address databases.] Available at: http://www.wma.net/e/policy/SMACDATABASESOCT2002.htm

Biobanks and the ethical discourse of policy

As Professor Newton recognised of the UK endeavour, genetic biobanks are now seen to require a robust ethical framework if they are to carry out their work with the active support of citizens. Thus the bioethical discourse is elevated to the status of a *sine qua non* of the biobank project. For citizens this can be construed as a discourse regarding the use of their genetic and medical information where the key question is the relationship between, on the one hand, their rights as citizens over that information and, on the other, the rights of science, industry and the state. Effectively, then, what we are looking at is a rights based discourse of power over the control of the genetic information of citizens which, depending on the juxtapositioning of the values within that discourse, will establish and legitimate a particular balance of power between the participants. To the extent that a citizen's rights over their genetic information are expanded or contracted, so also is the nature of their citizenship.

The ethics agenda of biobank regulation is politically significant because it is composed of those issues regarded as culturally sensitive by the policy discourse. To the extent that the issues are formally embodied in policy, they then become the criteria of regulation. The policy discourses of regulation of the UK, Iceland, Estonia and Latvia biobanks share a common bioethics agenda, derived from the principles of medical ethics articulated for centuries and still informing bioethics teaching in modern medical schools. These can be expressed as a set of citizenship rights regarding the use of personal genetic data:

- Right to informed consent:
    - consent to participate and supply data
    - consent on the use to which personal data will be put.
- Right to confidentiality and anonymity of data.
- Right to withdraw data.
- Right of access to:
    - own personal data
    - aggregate data (general public right).
- Right of ownership of data (citizen, state, industry, charity).

However, while the agenda is agreed there exists considerable disagreement over the precise ethical content of each item. Furthermore, as the political pressures on the regulatory arena change, there is a natural tendency for that content to be reformulated in response. Ethical movement thus becomes an indicator of political tension.

Informed consent

The Iceland case illustrates that consent to participate in genetic biobanks is not an automatic citizenship right (Pálsson and Harðardóttir, 2002). For here the perceived economic potential of the Icelandic Health Sector Database (IHSD), when linked to a genetic biobank through an exclusive agreement with deCode Genetics, inspired Iceland's Prime Minister to express his willingness to 'sweep away ethical constraints' that might slow up the project (Rose, 2001: 15). In keeping with this ambition and the maximisation of the industrial interest, the initial principle of citizen involvement was 'presumed consent' (i.e. non-informed consent) but following political protests this was amended to a type of informed consent where citizens who did not wish to have their data included in the database could actively opt out by a given deadline. Effectively this was therefore a time limited right which expired with the deadline.

In contrast, the policies of the other three biobanks state that citizen participation is voluntary. The Estonian Genome Project (EGP) framework devotes some energy to detailing what is required for informed consent to participate and will not use existing banked samples for the purposes of the database without first informing the subject and giving them the opportunity to withdraw and have their tissue sample destroyed (Estonian Genome Project, 2003). In neighbouring Latvia there has been some considerable policy learning and ethical adjustment. The first draft of the Law on the Research on the Human Genome ignored informed consent entirely but was subsequently amended to include a chapter on informed consent, understanding of risks, rights of the 'donor' of data to withdraw from the project and other ethical considerations (Putnina, 2002). Meanwhile, Biobank UK is currently consulting on its Ethics and Governance Framework on the basis of a comprehensive consent 'to participate in UK Biobank' (Wellcome Trust, Medical Research Council, Department of Health, 2003). In the Protocol which established the Biobank this consent from citizens included 'follow-up through NHS registers, their general practice and other medical records, for permission to use their data and blood samples for various analyses and specified and unspecified biochemical and genetic tests and for permission to contact them again at a later date' (Wellcome Trust, Medical Research Council, Department of Health, 2002a:31).

The UK Biobank's approach to consent signals an ethical dimension with which the other biobanks have yet to deal explicitly: the application of that consent to a variety of uses of personal data which cannot be known at the point when the consent is given. To what extent can such consent about the unknown future be accurately described as *informed* consent (Annas, 2000; Chadwick and Berg, 2001)? It is both a difficult ethical and technical problem. Reflecting on the relationship between informed consent and the demands of genetic data, Baroness O'Neill observes that 'human capacities to consent and dissent [on the use of their genetic data] are….being stretched, strained and perhaps overwhelmed by developments that arise not only from the combined revolutions in genetics and informatics, but by other developments within medicine which bring together hugely complex arrays of information and intricate regulatory systems' (O'Neill, 2001: 695). In political terms, population based genetic biobanks stand at the research frontier where the engagement between regulatory needs and ethical capacities are at their most acute, and where solutions are only just beginning to emerge. At present this problem is addressed largely in a negative sense by the citizen's option of withdrawal from a biobank (see below). Given the large unknowns in the use of genetic data once submitted, this may not be a sufficient right when measured against the reassurance it may or may not offer in the context of future research scenarios.

Right to confidentiality and anonymity

The congruence of this citizen right with the interests of science and industry coupled with the familiarity and technical accessibility of its delivery renders it the least controversial, least ethically demanding and most uniformly addressed. All of the biobanks offer at minimum the protection of subject data through coding and the encryption of identity markers. The remit of the EGP's Ethics Committee includes the protection of 'identity, security of person, [and] privacy' and a security system designed specifically for the database (Ethics Committee of the Estonian Genome Project Foundation, 2003). (There is also allowance for protection against discrimination, though this would presumably only arise should confidentiality mechanisms fail). Although less information is available regarding this aspect of the Latvian project, a parliamentary speech issued assurances on the protection of donors' rights and government controls over the security of the computerised

databank (Putnina, 2002). In Iceland the database is in part governed by the Data Protection Authority which established clear guidelines on the storage and processing of personal data and the citizen's right to protection. Similarly in the UK, the methodology for the Biobank's data storage and collection is governed by the 1998 Data Protection Act and will be monitored for effectiveness throughout the project.

Right to withdraw data

The right of citizens to withdraw their personal data conflicts with the interest of science and industry to maintain the statistical integrity of the population based genetic databases, particularly given the ambition to use those databases as the vehicle for longitudinal studies. Although all the biobanks incorporate this right, its interpretation varies indicating the forces of local politics at work. Indeed, in Iceland the withdrawal right was not part of the original Act on a Health Sector Database but was included in a subsequent amendment and supplemented by the 2001 Regulations on the keeping and utilisation of biological samples in biobanks (Icelandic Ministry of Health and Social Security, 1998). Interestingly, the Regulations stipulate that on withdrawal samples will *not* be destroyed but a coded list of persons who opt out will be provided to biobank centres so that these individuals' data is not used in further studies – a somewhat diluted version of withdrawal (Icelandic Ministry of Health and Social Security, 2001). In its consultation on its proposed Ethics and Governance Framework, UK Biobank offers a set of graded options for withdrawal (complete withdrawal, discontinued participation, and no further contact requested) which attempt to balance the interest of the citizen in the removal of the data with the interest of the scientist in some form of continued access to that data. The right to withdrawal thus becomes an ethical site where negotiations may be conducted and compromises sought. In Estonia there appears little room for negotiation with donors having the right to have their data deleted from the database on request with any violation of this right, including coercion to participate, being punishable as a criminal offence.

Right of access to data

An individual's right of access to their genetic data is linked to control over their own identity. This varies across the four biobanks, as do the ethical justifications for the differences. In Estonia, personal genetic data is available to participating citizens on request or they may decide that the information should be withheld from them. Likewise in Iceland the deCode Genetics database is subject to the prior requirements of the 1997 Act on the Rights of Patients which stipulates that patients are entitled to information about their health (condition, prognosis, risks and benefits of treatment, etc.) upon request. The UK Biobank takes a different and less open approach. Although the Biobank Protocol acknowledges that 'individuals will have the legal right to access their personal data, if required', it also makes clear that 'they will not receive routinely any individual information relating to their blood samples (including biochemistry and genetic findings)' (Wellcome Trust, Medical Research Council, Department of Health, 2002: 32). Behind this prohibition lies the assumption that participants should only be provided with health information about themselves in the clinical situation where a trained professional can provide appropriate interpretation and guidance. The Ethical and Governance Framework comments: 'it would not be constructive and might even be harmful to provide [health] information but not interpretation, counselling and support [and] UK Biobank will not be able to provide such counselling and support' because it is purely a research activity (Wellcome Trust, Medical Research Council, Department of Health, 2003: 11). Participants are to be protected from the consequences of self-knowledge - in their own interest.

While UK Biobank may be reticent about citizens' access to their own genetic data, it takes a quite different position on the right of citizens' access to aggregate data. Both the UK and Estonian Biobanks are clear that continuing public engagement and the feedback of findings is a necessary condition of an acceptable public profile. (The funders of UK Biobank conducted public consultations in the lead up to its creation (Wellcome Trust, Medical Research Council, Department of Health, 2002b). Indeed, one feature of the EGP framework is its public 'teaching' role and the raising of awareness in biotechnology. While Iceland is vague on public dissemination Latvia is suitably sensitive about the need to gain public support through a public education campaign and in the drafting of its biobank protocol noted that the project should be 'protected against the rapid changes in public opinion or political situation' (Putnina, 2002). This wording suggests that the purpose of a public information campaign would be to give the appearance of gaining public support for the project without necessarily ensuring that it exists.

Right of ownership of data

The right of ownership of the biobank data determines who is able to gain intellectual or financial profit as a result of the investment in its collection and analysis. None of the four biobanks ascribe rights of ownership to the citizens who donate the genetic data. Instead, in three of the countries – the UK, Estonia and Latvia - the ownership issue is circumscribed by the ethic of what Titmuss described in his discussion of the donation of blood to the NHS as the 'gift relationship' where citizens unselfishly make a personal gift in the interest of the common welfare (Titmuss, 1970). Thus the UK Biobank promises to use the knowledge produced to identify and resolve health problems at the population level and the Estonian and Latvian Genome Projects pledge to provide personalised health information to individuals and their physicians to supplement individualised care. To deliver these promises, the three projects are establishing disinterested intermediary organisations which are deemed to act in the interest of both the biobank participants and the citizenry at large. In Estonia and Latvia the intermediary is an agency appointed by the state and, in the UK, a charitable company limited under guarantee.

In contrast, the guiding ethic of ownership of deCode's Icelandic project is determinedly commercial. Here the Icelandic Parliament (Alþingi) granted exclusive rights to the national medical and genetic data to deCode Genetics (with the caveat that the Icelandic Ministry of Health and Social Security and the Director General of Public Health must be guaranteed access to statistical data at all times). However, although the formal ethical discourse shows a clear division between the UK, Estonia and Latvia, on the one hand, and Iceland, on the other, other factors suggest that in reality the political balance between citizen and industrial interests is likely to be less clear cut. Commercial interests have been involved in the creation of both the Estonian and Latvian databases. The EGP Foundation created and operates EGeen Incorporated to commercialise and market the project to international pharmaceutical companies and private investors and the Latvian project has established Genome Database (GenDB) to perform the genotyping required (EGeen, 2003; Abbott, 2001). In the UK case, although commercial interests are not involved in the physical creation of the database, the Biobank Protocol emphasises that 'involvement of the pharmaceutical and biotechnology industry in the project is ….essential to maximise delivery of potential health benefits' (Wellcome Trust, Medical Research Council, Department of Health, 2002: para 5.4.2). Equally, the Ethics and Governance Framework accepts that 'commercial companies and other research endeavours that stand to make a profit will therefore be allowed access to UK Biobank if their proposal falls within the UK

Biobank purpose and passes the usual scientific and ethical review' (Wellcome Trust, Medical Research Council, Department of Health, 2003: 27).

Unlike the NHS bloodbank where the gift relationship alone secures the health benefits for citizens, biobanks are dependent on industrial involvement and the profit motive for that benefit to be accrued. As a consequence the intrinsic political significance of the right of ownership is inevitably diminished as it becomes a contingent right. Instead the ethical focus shifts to the means that will be used for monitoring that involvement and for ensuring that the citizen interest is not subverted by the demands of the market.

The international discourse and networks of bioethics

The rights based discourse of the biobanks forms part of an international bioethical domain of policy statements, legitimations and political ambition which impact to produce common agendas, if not common solutions, at the national level. Bioethics may not be a united epistemic community but it is undoubtedly an influential transnational policy network capable of working easily across the political spaces of multi-level governance to help shape the national politics of biobank legitimation (Salter and Jones, 2002b; see also Coleman and Perl, 1999; Nunan, 1999; Reinicke, 2000).

The international political impetus for bioethics was established on 11 November 1997 when the General Conference of UNESCO adopted the *Universal declaration on the human genome and human rights* which, in its own words, forms part of 'a framework of thinking, known as bioethics, which relates to the principles that must guide human action in the face of the challenges raised by biology and genetics' (UNESCO, 1997). Propelled by the continuing activities and reports of UNESCO's International Bioethics Committee (IBC), the Declaration has acted as the template and rationale for a series of bioethical initiatives by other organisations such as the Council for International Organisations of Medical Sciences (CIOMS), the Human Genome Organisation (HUGO), the International Society of Bioethics, the World Health Organisation (WHO) and the World Medical Association (WMA) (see Table 2). In Europe, and drawing extensively on the Declaration, the Council of Europe's *Convention on human rights and biomedicine* (popularly known as the 'Bioethics Convention) provided bioethics with formal legitimacy in the European political culture. Other activities, and notably those of the European Group on Ethics (EGE) mentioned earlier, have then reinforced that legitimacy and given it succinct expression through their contribution to the resolution of practical decision making problems in the EU's dealings with human genetics. At critical points in the life of Framework Programmes 5 and 6, the EGE has been summoned to act as a respected political broker over difficult issues relating to human embryo research (Salter and Jones, 2002b: 812-3).

One measure of the influence of the international bioethics networks at the national level is the fact that the ethical agendas of the biobanks studied here faithfully reflect those addressed by international guidelines. As we have seen, there are national variations in terms of the way in which the agenda items are dealt with but the framework for the debate is taken as given. In this respect it will be interesting to see the extent to which UNESCO's recently adopted *International declaration on human genetic data* (2003 – Table 2) is able to move that agenda forward. The Declaration not only provides broad ethical guidelines for the collection, processing, use, and storage of genetic data, and the promotion and implementation of databases but also encourages states to 'involve society at large in the decision-making process' and promote the establishment of 'independent, multidisciplinary

and pluralist ethics committees' to govern such databases (UNESCO, 2003: 5). The latter edict of broader public involvement in the process of domestic biobanks governance may resonate uneasily with the elite assumptions of existing models.

A second measure of influence is the possible formal acknowledgement of supra-state bioethics sources by the projects themselves, and here the data is somewhat opaque. Estonia is the most explicit in this respect. Its Genome Project states that its regulatory framework as incorporated in the Human Genes Research Act was 'prepared by an international working group and guidance was obtained from all available international documents dealing with genetic research'. In addition, the EGP's Ethics Committee 'abides by generally acknowledged ethics documents, primarily the Human Genes Research Act, the Helsinki Declaration of the World Medical Association, and the Universal Declaration on the Human Genome and Human Rights of UNESCO' (Koik, 2003). The other countries are more reticent. Latvia's Scientist's Code of Ethics, currently the main instrument guiding its Genome Project's ethical regulation, provides comprehensive advice but does not refer to specific international guidance (Senate of the Latvian Academy of Sciences, 1997). Article 6 (Rules on Science Ethics) of the Icelandic Act on the Health Sector Database states that the 'collection, transfer and processing of data in the Health Sector Database shall at all times be conducted in full compliance with recognised international rules on science ethics and rules established on their basis and current in Iceland at any time' but does not say what these rules are (Icelandic Ministry of Health and Social Security, 1998). Finally, the UK Biobank Protocol under Ethical Considerations lists the influence of the Council of Europe's Recommendation on the Protection of Medical Data, but other than that purely national codes and policies such as those of the Medical Research Council. (It is of course perfectly possible that this national guidance already corresponds to international bioethical codes.)

If the national acknowledgement of supra-state bioethics guidance is less than complete, there are also national and international differences on who is to be regarded as a legitimate bioethics expert for biobank regulation. We noted earlier the debates within bioethics regarding its epistemic identity and this diversity is reflected in the disciplinary composition of both the national bioethics committees with responsibility for the biobanks (Tables 3 and 4) and the international committees which have helped shape the ethical agenda.

Table 3
National ethics committees: discipline of membership*

Discipline	UK Biobank Ethics and Governance Interim Advisory Group	Ethics Committee of the Estonian Genome Project	Latvian Central Medical Ethics Committee	Icelandic National Bioethics Committee
Law	2	1	1	2
Theology	0	1	1	1
Medical Science	1	2	9	4
Medical Ethics /Philosophy	2	0	0	0
Nursing	0	0	1	2
Interest group	2	0	2	0
Social science	1	0	0	0
Policymaker/ Politician	1	0	1	1
Other	0	3	0	1
TOTAL	**9**	**7**	**15**	**11**

*discipline as self-identified on website.

Table 4
Suprastate ethics committees: discipline of membership*

Discipline	UNESCO International Bioethics Committee	European Group on Ethics
Law	11	4
Theology	0	1
Medical Science	15	3
Medical ethics/ Philosophy	3	2
Nursing	0	0
Interest group	0	0
Social science	1	1
Policymaker/ Politician	4	0
Other	0	1
TOTAL	**34**	**12**

*discipline as self-identified on website.

The national committees perform the important legitimating function of monitoring and measuring the performance of the biobanks against the rights based criteria discussed earlier. In the cases of the UK and Estonia, the ethical committees cited are those explicitly created to govern their respective biobanks. Latvia's biobanks falls within the remit of its Medical Ethics Committee and Iceland's comes under its National Bioethics Committee (although in the case of the latter the intention is to establish an Interdisciplinary Ethics Committee for the biobank) (Coles, 2003; Thorsteinsdottir, 2003).

The disciplinary breakdown of the national and international bioethics committees provides a revealing insight into the political contribution of bioethics to the legitimation of biobanks regulation. In contrast to science-based advice, whose claim to legitimacy is based on specific forms of expert knowledge, bioethics presents itself as both expert (on moral concerns) and as a vehicle for the representation of the citizen interest. Individual members of bioethics committees (and those who organise and construct the committees) regard it as appropriate to describe themselves by their established disciplinary backgrounds. Indeed, multi-disciplinarity is regarded as a strength and the absence of members specifically trained in bioethics is clearly not regarded as a weakness. In other words, the business of ethical regulation may require a particular expertise but it is one which, it is believed, can be acquired through the experience of committee work rather than through the formal acquisition of ethical knowledge. Hence, of the committees considered here, out of a total membership of 88 only 11 (12 per cent) describe themselves as medical ethicists, philosophers or theologians.

Interestingly, the dominating characteristics of membership background are medical science, particularly medical genetics, and law with 55 (62 per cent) members thus described (see also Galloux *et al* 2002). It would appear that expertise in science and law is regarded as an appropriate qualification for being able to make ethical judgements about the interests of citizens in the regulation of biobanks and other health technologies. As a legitimating device this is likely to have its limitations. For rather than being informed by a human values orientation that could respond to citizen concerns about biotechnology, the medical, science, and legal professions are more likely to map their orientation directly on to the regulatory process and resist the precautionary values that characterise citizen discourses oppositional to biotechnology. It is generally the case that while institutionalised ethics of this nature may include public concerns within the policy process they subordinate those concerns to the dominant political culture (Rogers-Hayden and Hindmarsh 2003; Jones and Rogers-Hayden 2004; Wynne 2001). The rationality of science resonates easily with the rationality of the policy process.

So what we have is a political elision between the old, science based form of technocratic authority and the new, science based form of ethical authority. Individuals with similar disciplinary backgrounds are present in both forms but their concern has shifted from the technical to the ethical. Philosophers drawn primarily from academia and engaged in broader approaches to bioethical interrogation as a primary occupational pursuit rather than as a means of regulatory decision making are present but in numbers unlikely to be sufficient to challenge (should they choose to do so) the assumptions of their scientific and legal colleagues. In addition, a new breed of bioethicist 'representative of the citizen interest' has been added and may come from a variety of backgrounds: interest group (e.g. patients' organisations, disabled), professions such as nursing, social science and policy.

Conclusions

As an epistemic community, bioethics is divided by the different professional backgrounds of its members and united by the common legitimating function they may be called upon to perform in the consideration of ethical issues surrounding the governance of biobanks. Despite, or some would argue because of, its internal divisions, bioethics has acquired considerable political value because it is able to incorporate the different interests of citizens, science and industry within an apparently neutral discursive domain. As ethical experts, bioethicists have been given pride of place in the regulatory apparatus of biobanks and replaced the increasingly defunct technocratic model of scientific self-regulation.

Difficult issues of citizenship rights associated with the collection and storage of genetic data in terms of informed consent, confidentiality and anonymity, withdrawal, access and ownership have been brought within the remit of international and national bioethics committees, duly discussed and policy recommendations produced and implemented. The issues fall within a common agenda promoted by the international bioethics community which is then interpreted at the national level in the light of national political cultures and concerns. Although there are differences in the interpretations of the balance of rights between citizens, science and industry, these tend to be differences of emphasis rather than of substance. The rights of data withdrawal and ownership are the issues where the clash of interests are most obvious and where countries differ most in their response to this conflict.

Yet despite the replacement of the science-based technocratic model, the composition of the national and international bioethics committees suggests that it is the disciplines of medical science and law that have dominated the process of ethical agenda setting rather than that of philosophy (see also Galloux *et al*, 2002). Their influential presence in the national and transnational networks of bioethics can be viewed as an expression of their pre-existing power base in human genetics and as constituting a natural extension of their political interest in ensuring that regulation continues to achieve its legitimating goals. Assessed in terms of the politics of regulatory legitimation, it is clear that some parts of the divided epistemic community of bioethics are more powerful than others.

Their power may well be challenged. The developing nature of the citizen interest in the acquisition and use of genetic data is likely to place increasing demands for change on the present constructions of citizen rights and citizenship in the regulatory discourse. As a consequence, as Baroness O'Neill observes, 'bioethical debate will have to become more political, and take fuller cognisance of the realities of the contemporary world, its technologies and its institutional possibilities' in order to deal with what she describes as 'the ethical fragility of individualistic conceptions of informed consent' (O'Neill, 2001: 702). As it does so, and as the discourse becomes more complex, the skills of disciplines such as philosophy may be called upon to deliver a degree of ethical sophistication and political functionality unavailable to medical science and law.

Furthermore, new forms of epistemic power have a habit of developing their own logic independently of the power structures they are supposed to serve. Biobanks have recruited bioethics as a form of regulatory legitimation on the sound principle that prevention is better than cure. But they are hampered by a lack of knowledge regarding the forms of political expression the citizen interest might take should the population based collection and storage of genetic information become politically visible and contentious. Like other aspects of the

genetic story, the future public response to biobanks is impossible to second guess. If or when such a response emerges, and should it prove negative, then the regulatory engagement with bioethics will take on a dynamic form likely to energise the divisions within the epistemic community of bioethics. As cultural differences find bioethical expression, the political test of an epistemic community's legitimating strength will be its ability to routinise the discussion of differences and so reconcile an active citizen interest with the interests of science and industry.

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Word count, including refs: 10287
Word count, excluding refs: 8989