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SOCIAL INCLUSIVITY VS ANALYTICAL ACUITY? A QUALITATIVE STUDY OF UK RESEARCHERS REGARDING THE INCLUSION OF MINORITY ETHNIC GROUPS IN BIOBANKS

ANDREW SMART

Bath Spa University

RICHARD TUTTON

Lancaster University

RICHARD ASHCROFT

Queen Mary, University of London

PAUL MARTIN, ANDREW BALMER, RICHARD ELLIOT

University of Nottingham

GEORGE T.H. ELLISON

St George's, University of London

ABSTRACT

This paper examines how the drive to include minority ethnic groups in biomedical research raises challenging questions for the governance of some biobanks. Using findings from a qualitative study with researchers working at 10 UK biobanks that have been designed to explore common complex diseases, our study highlights the potential discordance between the twin imperatives of 'social inclusivity' and 'analytical acuity'. While the researchers interviewed were keen to include minority ethnic groups in their research, they were also concerned that this could have deleterious effects on the precision of their analyses. In our discussion of these findings we show that there remains considerable debate as to the impact of including participants from minority ethnic groups on analytical acuity. Nevertheless, a principle of justice requires that potential participants from all ethnic groups should be given the opportunity to participate in and benefit from biomedical research, and UK law requires public bodies (including research councils) to demonstrate that there is no unintentional or unjustifiable 'racial' discrimination in their activities. Researchers' concerns about analytical acuity could result in calls for study designs that examine every 'different' ethnic group, which would have consequences for the governance of some biobank studies and for efforts to challenge the discredited yet resilient idea that differences between ethnic groups are innate, essential and immutable.

A INTRODUCTION

The importance of including minority ethnic groups in biomedical research on ethico-legal grounds is well recognised. As a principle of justice, participants from minority ethnic groups should not be denied the opportunity to participate in, and benefit from, biomedical research. Indeed, this principle is enshrined in the Race Relations Act 1976 (as amended by the Race Relations (Amendment) Act 2000) (RRA), which prohibits discrimination by public bodies or public servants providing healthcare, education or other social services on the grounds of 'racial' or ethnic or national origin. Moreover, there are potential health benefits in exploring differences between ethnic groups, not least in respect to differences in disease prevalence and therapeutic outcomes. However, the inclusion of minority ethnic groups in biomedical research raises challenging questions for the governance of biobanks. These include how to: avoid discrimination; promote inclusivity; provide 'best value' for the populations they are designed to represent; and maximise public value by allowing the extraction of useful information for healthcare and further research. Furthermore, important concerns have been raised about the potential for contemporary genetic and biomedical research that explores differences between putative 'racial' or ethnic groups to reinvigorate discredited ideas about 'racial science'.

In this paper, we explore these issues using data from a qualitative study of researchers from a range of UK biobanks studying the aetiology of common complex diseases. To set the context, we chart the development of an 'inclusion and difference paradigm' in the US (following Epstein 2004a, 2007), and explore the extent to which this paradigm is evident within the UK. We then present selected data from research which explored how geneticists and biomedical scientists working in these contexts use classifications of 'race' and/or ethnicity, and the implications for scientific and healthcare practice (Martin, *et al.* 2007). We use these data to identify a perception among our interviewees that there are two potentially conflicting imperatives facing the inclusion of participants from minority ethnic groups in UK biobanks—a drive for 'social inclusivity' and a desire for 'analytical acuity'. After critically evaluating the viewpoints of the researchers we interviewed, we discuss the significance of their perspective for the governance of biobanks, and societal perceptions of ethnic groups.

However, before proceeding, we feel it is important to offer a word of caution about some of the terms used in this paper. 'Minority ethnic group' is commonplace 'short-hand' for a complex set of social relationships, and the processes that create, sustain and modify these. We share the current and widely-held sociological

position that ethnicity is one of a range of concepts used to consider social identities that are related, in one way or another, with notions of 'decent' or 'ancestry' (e.g. Cornell and Hartmann, 1998; Fenton, 1999, 2003). As such, 'ethnic groups' are fluid cultural or political groupings of people who classify themselves (or are classified by others) into socially constructed groups (Jenkins, 1997). These groupings can be labelled in a variety of different ways, although it is recognised that some of the characteristics used to classify ethnicity and label ethnic groups (such as geographical origins) are common to the related social constructs of 'race' and 'nationality' (Jenkins, 1997; Cornell and Hartmann, 1998; Fenton, 1997, 2003). We therefore use the term 'minority ethnic groups' and the phrase 'participants from minority ethnic groups' without implying that the notion of ethnicity, or the way in which 'minority' and 'majority' groups are produced and recognised, is necessarily straightforward. Instead, we take the notion of an ethnic group, and which groups constitute a 'minority' or 'majority', as fluid, context-specific and dependent on how ethnicity is conceptualised and produced. We would thus encourage readers to avoid seeing our use of these terms as meaning that ethnic groups are 'natural' or immutable entities, or assuming that 'majority' and 'minority' status necessarily corresponds to specific ethnic groups rather than others.

B 'INCLUSION AND DIFFERENCE' IN THE USA AND UK

The sociologist Steve Epstein has recently described how the 'inclusion and difference paradigm' weaves together 'two ostensibly different areas of scientific and government concern—the status of socially subordinated groups, and the meaning of biological difference' (2004b: 8). Epstein (2007) documents how campaigners acting on behalf of 'groups' such as women and ethnic minorities (as well as children and the elderly) have lobbied for changes to the conduct and governance of biomedical research in the US. Advocates from these diverse constituencies coalesced around the claim that 'the white male' had become the normative 'standard' for biomedical research participants. They argued that the consequent exclusion of other 'populations' was predicated on the potentially false assumption that the results of studies undertaken on white men could be extrapolated to all human beings. They claimed that women, children, the elderly and individuals from different ethnic groups could differ both socially *and* biologically in ways that mattered for medical research and treatment.

Amidst debates about the veracity and legitimacy of these claims, new governance regimes were implemented in the US in an attempt

to ensure that the practices and outputs of publicly-funded science are equal and fair (Epstein, 2007). Thus, s 492B of the Public Health Service Act (added in 1993) mandates that 'members of minority groups' should be 'included as subjects' in clinical research, and that trials should be designed and carried out to explore if 'minority groups' are affected 'differently than other subjects in the trial'. Epstein argues that a consequence of these developments has been what he calls a 'categorical alignment': 'the categories of identity politics, the biological categories of biomedical research, and the social classifications of state bureaucrats [have become] one and the same system of categorization' (Epstein 2007: 91). For example, the Office of Management and Budget's (OMB) classification of 'race' and ethnicity 'provided the basis for the coding scheme used by the National Institutes of Health in determining compliance' with the legislation regarding the inclusion of 'minority groups' in NIH-funded research (Epstein, 2004a: 196). Thus, although the OMB has explicitly acknowledged that the categories used by this classification are 'social-political constructs' (Office of Management and Budget, 1997), they have nonetheless become integral to biomedical science (Friedman *et al.*, 2000; Stevens, 2003). Indeed, there is concern that genetic and biomedical research which uses 'racial' and/or ethnic group categories could revive the discredited yet resilient idea that such groups have innate, essential and immutable characteristics. This includes not only research using traditional 'racial' group categories, but also research using ethnic group categories which are sometimes classified using 'racial' criteria (such as skin colour), 'racial' categories (such as continental groupings) or 'racial' labels (such as 'Caucasian'). The fear is that such research could thereby reinvigorate 'racial science' (the study of biological differences between social groups as if these are innate and genetic in origin) and 'scientific racism' (the use of 'racial science' to explain and justify inequalities among social groups) (Brawley, 1995 cited in Epstein, 2004a; Juengst, 1998; Ellison and Jones, 2002; Duster, 2005; Kahn, 2006; Epstein, 2007).

Within the UK, some of the discourses associated with the US 'inclusion and difference paradigm' have recently become apparent. Currently, there is no UK equivalent to s 492B of the Public Health Service Act. However, under s 71 of the RRA (as amended in 2000), relevant public authorities (and private sector bodies performing functions on behalf of public authorities) have a general statutory duty to promote 'race equality'. To facilitate implementation of this requirement, the UK Commission for Racial Equality (CRE, now part of the UK Equality and Human Rights Commission) established a Code of Practice (CRE, 2002). Mirroring the RRA, this includes: (1) a general duty requiring public bodies to eliminate unlawful discrimination on the grounds of 'racial' or ethnic or national origin,

promote equality of opportunity, and engender good relations between people of different 'racial' groups; and (2) a specific duty (applied to some public bodies) to publish a 'race equality scheme' that identifies the arrangements made for meeting the general duty and the methods involved therein.

In terms of the governance and conduct of biomedical research, a number of key institutional actors now operate under the auspices of the RRA. Appendix 1 of the Code of Practice lists most of the UK's Research Councils as non-departmental public bodies (NDPBs). NDPBs are bound by the general duty (to eliminate unlawful 'racial' discrimination), but not by the specific duty (to produce a 'race equality scheme'). Despite this, several of the UK Research Councils listed in Appendix 1 have produced 'race equality' schemes, including those most closely associated with biomedical research (the Medical Research Council, the Biotechnology and Biological Sciences Research Council, and the Economic and Social Research Council). While privately funded biomedical research charities are not bound by the Code, at least some—including, for example, the Wellcome Trust—adhere to similar internal codes regarding 'race equality'.

Elsewhere, the National Health Service (NHS) and certain NHS organisations (NHS Hospital Trusts, Primary Care Trusts and Strategic Health Authorities (SHA)) are bound by both of the general and the specific duties. All NHS organisations have implemented measures to identify concerns about 'race equality', and these are monitored through reporting mechanisms such as Annual Delivery Targets (Department of Health, 2006). The collection of data on the ethnicity of NHS patients has been mandatory within UK hospitals since 1995 (Gill and Johnson, 1995; Aspinall, 1995). Such data are routinely analysed to identify variation in the uptake of health services, ostensibly to assess any differences that might reflect unlawful discrimination.

Despite these recent legal changes, information on the inclusion of participants from minority ethnic groups in UK-based biomedical research can be hard to find, as many investigators do not provide data on the ethnic background of study subjects when reporting their research findings (Ellison and Rosato, 2002; Hussain-Gambles, 2003; Heiat, Gross and Krumholz, 2002). However, several recent studies have uncovered evidence that minority ethnic groups have been underrepresented (Heiat, Gross and Krumholz, 2002; Mason, *et al.* 2003; Ranganathan and Bhopal, 2006; Bartlett, *et al.*, 2005 cited in Mehta, 2006). Although the reasons for this are still being explored (e.g., Jolly, 2005), Mehta (2006: 668) has argued that:

Widening minority ethnic group access to, and representation across, UK biomedical and clinical research will... depend on a number of

interdependent factors and processes. At the least it will require the development and delivery of a clear policy framework and its guidance, coupled with increased or better targeted resources. More accessible culturally and linguistically competent recruitment programmes are also needed. Establishing greater clarity about equality and diversity issues will be key to these developments. Among the most pressing issues is a need to: consistently and usefully define the UK's different populations and subpopulations; identify the contexts in which ethno- or population-specific data [are] actually important; and ascertain the relative sample sizes necessary to draw meaningful conclusions.

Traces of the 'inclusion and difference paradigm' can be clearly discerned in Mehta's 'equality and diversity issues', which similarly span the domains of biomedical science policy and practice.

These interconnected concerns about definition, relevance and veracity have been reflected in debates surrounding the flagship British biobanking project, UK Biobank. While Ranganathan and Bhopal (2006) underline the importance of UK Biobank recruiting volunteers from diverse ethnic backgrounds, Mehta and Saggart (2005: 207) warn that the project 'may have limited value for minority [ethnic] groups'. Mehta and Saggart (2005) echo the recommendations of population geneticists Tate and Goldstein, who suggested that UK Biobank should intentionally over-sample participants from minority ethnic groups 'to allow identification of gene-environment interactions specific to the minority groups' (2004: S42). UK Biobank thus faced a difficult political and scientific choice. Its options included: over-sampling from all minority ethnic groups; collecting equal samples of two or more ethnic groups; using a strictly 'representative' sample of participants from all ethnic groups in numbers proportionate to their numbers in the wider UK population; or excluding participants from all but one ethnic group. Eventually, UK Biobank decided to generate modestly boosted samples from a small number of selected minority ethnic groups as well as a larger core sample from the UK's 'majority' ethnic population (Tutton, 2008). This compromise not only excluded some minority ethnic groups, but the samples it included from selected minority ethnic populations were still numerically smaller than that from the 'majority' ethnic population.

The remainder of this paper will show that such debates about the inclusion of minority ethnic groups in UK biobanks reflect a disjuncture in the 'inclusion and difference paradigm' which has important ethico-legal implications. Drawing on data collected in a wider project exploring the use of 'race' and/or ethnicity in contemporary UK-based genetics and biomedical research (Martin *et al.*, 2007), the analysis presented here explores the views and experiences of researchers working at UK Biobanks that have been

designed to explore the aetiology of common complex diseases. In particular, it focuses on evidence of the discordance between the twin imperatives of social inclusivity and analytical acuity that influence the perceived relevance of ethnicity as a sampling, descriptive and/or analytical variable.

C METHODS

While there are many different types of biobank (Gibbons *et al.*, 2007), we chose to focus on those which aim to study common complex diseases such as diabetes and hypertension, for three specific reasons. First, these studies often analyse differences within populations by classifying research participants into sociodemographic subgroups. Second, all such biobanks collect data for analysing gene-gene and gene-environment interactions in which ethnicity might be perceived to act as a potential confounding variable (either as a marker of ‘collective genetic affinity’ or of ‘collective environmental exposure’; Ellison and Jones, 2002). Thirdly, it has been suggested that such studies will be important for future healthcare policy and practice (Bell, 1998; Khoury, Burke and Thomson, 2000), so that any findings linking ethnicity, genetics and health could have a significant impact within the public arena.

The biobanks considered for inclusion in our study were identified from a range of sources, including the Medical Research Council, the House of Lords Science and Technology Committee, the National Research Register, and the campaign group GeneWatch. Our sample was purposively selected to ensure heterogeneity (Ritchie, Lewis and Elam, 2003) using criteria relating to cohort size, study design, research focus and geographical location. Our final sample comprised 10 biobanks, from which we interviewed 17 researchers including epidemiologists, clinicians, geneticists and other research staff. The interviews were conducted in accordance with the British Sociological Association’s ethical guidelines (BSA, 2002). As the scope of confidentiality in our study was potentially limited by the possibility of identifying a biobank from our description of its research focus, we agreed with our respondents that quotes from individual researchers would be labelled anonymously (PGD 01-PGD 17) as a precautionary measure.

In the interviews, we asked respondents whether ‘race’ and/or ethnicity were felt to be relevant to their research and, if so, how these were conceptualised, operationalised and measured, and whether there were any associated practical, scientific or socio-ethical concerns. The research team (AS, PM, RT, RA and GTHE) read anonymised interview transcripts and devised, discussed and agreed

upon a list of key themes emerging from the data. A coding frame based on these themes was then applied to all the transcripts using Atlas-ti (a qualitative data analysis software package), to identify commonalities and differences within and between the different interview transcripts (Mason, 1996; Spencer, Ritchie and O'Connor, 2003). The focus of this paper emerged through discussion within the team about the relationship between two issues raised by some of the interviewees in their responses to our questioning: (1) the inclusion of participants from minority ethnic groups in research samples; and (2) the impact that variations in ethnicity may have on the precision of their analyses. To explore this relationship further, we extracted and analysed a number of descriptive codes that had been applied to the data, including 'representativeness', 'inclusion' and 'statistical power'. We selected the extracts used in the analyses that follow to represent the range of views expressed by the 12 respondents in our sample of 17 interviewees who had discussed these issues.

D FINDINGS

We have discussed elsewhere (Ellison *et al.*, 2007; Martin *et al.*, 2007; Smart *et al.*, 2008) how most of the researchers working in the biobanks we examined used the term ethnicity (rather than 'race') when classifying their study participants, how they conceptualised ethnicity as having both socio-cultural and genetic components and how they tended to adopt the categories developed for the UK censuses (or something very similar) for the purpose of classification. Nevertheless, as we mentioned earlier, some of the categories and labels used to identify ethnicity can overlap with those used in more traditional 'racial' classifications. This is notable because, despite the researchers' ostensible rejection of 'race', some of the terminology used in the UK censuses categories which they adopted is based on just such geographical and phenotypic characteristics (e.g., 'Asian' and 'Black'). As such, the researchers' preference for using 'ethnicity' does not necessarily mean that their work was devoid of any 'racial' connotations. Indeed, there is some evidence to suggest that biomedical researchers have adopted ethnicity and ethnic classifications as sanitised versions of 'race' (Outram and Ellison, 2006). In our study, one of the researchers' key justifications for adopting the categories used in UK censuses was that they enabled them to check the extent to which their study cohorts were 'representative' of the wider UK population—ie, the extent to which their study contained similar proportions of participants from different ethnic groups to those recorded in the general population. However, as we will see, the issue of having study cohorts that were 'representative' involved a

complex interplay between the twin imperatives of social inclusivity and analytical acuity.

1. The imperative of social inclusivity

When asked to discuss the inclusion of participants from minority ethnic groups in their studies, the researchers we interviewed responded in three different ways. Inclusion was discussed as: a fundamental ethical obligation; an aspect of research governance; and a practical challenge. The following three extracts, from researchers involved in the same study of gene-environment interactions in common complex diseases, all reflect their opinion that there might be a fundamental right to participation on equal grounds within biomedical research, and how ignoring this right might ‘disenfranchise’ the group(s) concerned:

[It is] totally unacceptable from an ethical point of view, to exclude a substantial proportion of the population from this national study. (PGD 15)

[We’re] having other languages represented so that we don’t, that no one is disenfranchised as such from participation. (PGD 04)

... as a principle we mustn’t exclude any part of the community that is the UK population from research. [We aim to] create the resource in a way that that part of the UK population can basically be served... given that by definition they are going to be a minority component of [the study]. (PGD 10)

The final comment illustrates how, for this respondent, the desire for inclusivity was grounded in the idea of producing a ‘resource’ to ‘serve’ the whole of the UK population. However, a respondent working in a biobank that focused on exploring the aetiology of coronary heart disease noted that the ideal of equality of participation in research could create challenges in terms of recruitment policies and practices:

... we’ve just sought to deal with people as being equally eligible and equally, you know, then if anything trying to over-compensate to encourage ethnic minorities by, when we’ve had families who are from that, you know, using them to represent to other families, go on the radio to their own community (PGD 08)

In this project, the desire to promote equality became a practical matter that required allocating extra resources to recruitment.

Inclusion was also discussed in terms of being an external pressure—a requirement of research sponsors and ethical agencies. One researcher examining gene-environment interactions in common complex diseases reflected critically on funders' requests to include participants from minority ethnic groups in the research project on which they were working:

... you get the feeling they just throw these things in just hoping that someone is going to pick out certain bits of it. You do really wonder what the [funder] had in mind when they put out these proposals to be honest. (PGD 14)

Other interviewees revealed the potential influence of ethics committees on the design and conduct of research. The following extracts are from a respondent who undertook studies of health and development, and from a researcher exploring renal disease, respectively:

... the pressure comes more from ethics than some funding groups... (PGD 03)

... where we come a-cropper are the bloody ethics committees. Absolutely a pain in the butt (PGD 12).

In both instances, the respondents were discussing the requirements placed on them by ethics committees to ensure that research documentation and processes were accessible to those whose did not speak English.

From these examples, we can suggest that the rationale for promoting the inclusion of participants from minority ethnic groups, and judgments about its feasibility, were subject to different pressures: researchers' normative judgments about 'fairness'; the processes of research governance; and practical concerns about the conduct of research. However, as shown below, such notions of inclusivity were accompanied by concerns about the perceived impact of 'heterogeneous' study samples.

2. The imperative of analytical acuity

When asked to discuss whether 'race' or ethnicity were relevant to the sampling, analysis and/or interpretation of their research, six interviewees voiced concerns about analytical acuity (i.e., the precision and clarity) of their study findings. A common concern among these respondents centered on the potential limitations of 'representative' samples, given that these generate relatively small

sub-samples of participants from minority ethnic groups that might limit the ‘statistical power’ required for robust comparative subgroup analyses. This viewpoint is illustrated in the extracts below which are, first, from a scientist undertaking studies of childhood health and development and, then, from two researchers examining gene-environment interactions in common complex diseases:

So we’ve got about 5% of our children who are actively taking part who are from non-white background and they, by the time you split them by what background they are, you’ve got very small groups. And I think it’s very unlikely that we’re ever going to split them for analysis at all. (PGD02)

... it’s no good just having a small number, a small percentage. What’s the South Asians, is it 7% of the population, or something like that? So if you only have that sort of equivalent amount of people in your sample there wouldn’t be any point really. (PGD 14)

[The study] was powered to look at gene exposure characteristics... It is impossible to envisage that that same power calculation could be transferred down to fractional populations... in answer to people who complain that maybe this isn’t going to be a gene exposure study in people of ethnic minority groups, it’s because we’ve done the sums and they don’t add up, you know, we can’t make the cohorts large enough to do a meaningful [comparative] study [of ethnic ‘subpopulations’]. (PGD 04)

While ‘representative’ study samples may be one way of promoting inclusivity, none of the interviewees felt that this was a scientifically sound approach, and none felt that adopting ‘representative’ study samples would help them to ensure that their studies’ findings were applicable to the whole population. In fact, it was argued that ‘representative’ study samples inevitably provide less reliable evidence for any minority ethnic group contained in the sample compared to that provided for the ‘majority’ group, simply on the basis of the differences in statistical power provided by the smaller and larger samples of subgroups generated by ‘representative’ sampling. For this reason, it was argued that the drive for inclusivity would only be scientifically credible if it was suitably ‘powered’. The scientists who reported this concern suggested two possible responses: increasing the recruitment of participants from all minority ethnic groups (by over-sampling or ‘boosting’ the sampling of these groups); or restricting studies to equally-powered comparisons of predefined sets of ethnic groups (i.e., selectively sampling a limited number of specific ethnic groups).

A related concern was that including participants from different ethnic groups in study samples could (and would) introduce ‘unhelpful variation’ into analyses. As this scientist, studying hypertension, argued:

... in a sense you wanted to get as homogenous a group as possible and because of knowing that frequencies of variations in genes vary between the different ethnic groups in a sense that could be a confounder for when you’re going testing in case-control association type studies. (PGD 05)

One response to the perceived problem of confounding, due to that component of genetic variation ‘known’ to be associated with ethnicity, was to restrict studies to ‘single populations’. As this respondent suggested:

If you want to do a study on Afro-Caribbeans then you use a different sampling frame really, and similarly for the Indians or Bangladeshis or whoever. (PGD02)

To this end, two of the biobanks in our sample restricted participation to the ‘majority’ ethnic group within the UK population, variously labelled as ‘white’, ‘Caucasian’, ‘British’ or ‘European’.

In summary, some of the scientists interviewed aimed to create study designs that would produce sufficiently large samples of one or more ethnic groups to generate robust findings for subsequent comparisons. This suggests that their decisions about the feasibility and value of exploring health differences across and between ethnic groups were (at least in part) judged according to the logic of inferential statistics. In particular, decisions about including participants from minority ethnic groups were made by calculating the minimum sample size required for analysis using ‘power calculations’. As such, inclusivity was conceptualised in terms of how differences between ethnic groups (particularly perceptions about ‘known’ genetic differences, rather than about social differences or social determinants of phenotypic differences) might compromise analytical acuity.

3. Discordance between social inclusivity and analytical acuity

Our analysis has revealed the existence of discordance between the two potentially competing imperatives of social inclusivity and analytical acuity in the views and experiences of the biobank researchers we interviewed. The three examples below all relate to a biobank examining gene-environment interactions in common

complex diseases. These all focus on perceived external influences on decisions taken by the project, and how these might relate to and impact on the scientific research the project would then be able to do:

[The study] is being funded by [a public funding council] and they want to include everybody in it.... to make it fair, as opposed to any genetic kind of justification... There may be some scientific benefit as well... but we don't know that for certain and there may not be. (PGD 09)

... what is driving many of the actions are the pressures on them. And it's what is acceptable in society, and what would be deemed acceptable. And what comes out look like perverse decisions. (PGD 11)

[Critics said] what you should really be doing is over-sampling [ie, 'boosted' sampling] and that's when they're getting ridiculous... it would be impossible to do and would then starting adding other power implications to the rest of the study. (PGD 15)

These extracts all reflect disquiet about how external, 'societal' pressures for inclusiveness were introduced into decision-making about sampling for the project. Responses to the perceived benefits and threats posed to scientific validity range from uncertainty about the unclear *scientific* benefits of 'inclusive' sampling, through concerns about the 'perverse' irrationality of decision-making, to fears about potential damage to the project's feasibility (in terms of recruitment) and quality (in terms of 'statistical power').

At least one other interviewee shared these concerns about the motives of external drivers for inclusivity, and their impact on the logic of study design. The following scientist, who was mapping the genetic structure of populations to create a resource for future medical research, made a similar point but in a more disparaging tone:

[The funders] said: 'well we think, you know, you'd better put in something about these ethnic people, otherwise it won't be politically correct'; so we did and then the scientific evaluation said exactly what we'd said initially: 'that's no good you can't get adequate information'. (PGD 16)

While we recognise that these remarks are potentially offensive, it is also important to note that the interviewee was exhibiting palpable irritation at perceived infringement of their control over scientific decision-making by those whose concerns were primarily social or political. As the researcher viewed it, they felt under pressure to 'put

something in' to their study about ethnicity that was not scientifically justifiable.

There was, however, one researcher who adopted a more reflexive approach to the perceived discordance between social inclusivity and analytical acuity. This interviewee, who undertook studies of health and development, recognised that a study's scientific aims, and the social context in which it takes place, are not easily disentangled:

... there is a problem about saying we've got to study everyone because they happen to be here, rather than because it's actually going to address the scientific question that we want to address. But then there is another whole overlay on top of the scientific question about you know, not making people feel outcast or not welcome or not wanted and that's, that's the difficulty.... I do think we have an obligation to be inclusive but I do think we need to do it appropriately... we need to be clear about where ethnicity is important and where it perhaps doesn't matter so much. (PGD 03)

This position appears far more sympathetic to what was described as an 'obligation to be inclusive' than that of the previous extract. However, the proposed solution of identifying 'where ethnicity is important' offers no clear solution to the conflict between social inclusivity and analytical acuity, because such decisions can be made on both scientific and socio-political grounds. Indeed, this respondent went on to reveal how the practice of being 'inclusive' has the potential to create fresh ethical dilemmas:

... this idea of being inclusive [must be] balanced against the waste of public money and resources, in terms of putting the effort to make them inclusive and then end up excluding them [minority ethnic groups] from the analysis. (PGD 03)

The final point made in this extract indicates that there is not only an ethical imperative *for* inclusiveness, but there may also be an ethical imperative *against* it, not least when resources (including participants' time and goodwill) are unnecessarily squandered collecting data on participants from minority ethnic groups that cannot be, and are not, used in subsequent analyses.

This final set of extracts has revealed how the researchers we interviewed felt that it was necessary to protect the analytical acuity of their research. In this context, inclusivity was conceptualised in a range of ways: as a challenge to scientific rationales; as an example of unnecessary/unhelpful socio-political interference in their work; and as a site of fresh ethical quandaries. However, it is notable that the drive for inclusion of minority ethnic groups in research was always presented as a socio-political rather than a scientific imperative; only

one of the interviewees (PGD09) made any allusion to its potential scientific benefits and even then this was done with a degree of scepticism.

E DISCUSSION

The researchers we interviewed were involved in studies exploring the aetiology of diseases which affect all sectors of the population, and they all felt that potential biological differences relating to the ancestry of their study participants could be relevant to the collection, analysis and interpretation of data for their research. While they were therefore concerned about how best to include some measure of ethnicity in their study designs, they perceived themselves as caught between the twin imperatives of social inclusivity and analytical acuity. Indeed, some felt compelled to meet related demands on the inclusion of minority ethnic groups imposed by research funders or regulators. These were demands that some thought could involve methodological directives with questionable scientific value, so that if they complied, they might find themselves generating evidence from studies which included sampling choices over which they would have less than total control, and which they themselves might not consider valid, reliable or generalisable. Before discussing the implications of these findings, and without wishing to discount the opinions expressed by the researchers we interviewed, there are (at least) three challenges to their viewpoint which require consideration.

First it should be noted that there is no consensus on the potential impact of sampling strategies that include participants from different ethnic groups (i.e., 'ethnically diverse study samples') on the analytical acuity of biomedical research. This is not least because the nature, extent and biomedical relevance of genetic and phenotypic differences between ethnic groups are a matter of intense, ongoing debate (for example, see Smart, *et al.* (2006) for an analysis of the divergences in perspective evident in the 2004 *Nature Genetics* Special Issue 'Genetics for the Human Race'). Despite a substantial body of published research describing a range of genotypic and phenotypic differences amongst ethnic groups from studies conducted throughout the world (e.g., Cruikshank and Beevers, 1989; Macbeth and Shetty, 2001), the internal and external validity of this research is undermined by the fluid nature of ethnicity and the crude ethnic categories used to operationalise this (see Ellison and Jones, 2002). This said, genetic and phenotypic differences have been observed in studies examining the least fluid ethnic groups, and those using the most 'robust' ethnic categories available. However, these observed differences are predominantly differences in the *frequency* of a small

number of genetic traits and phenotypic conditions (i.e., traits and conditions that occur in *all* ethnic groups but to differing degrees) and include a number that are likely to be biomedically 'neutral' (i.e., have no known or likely positive or negative impact on mechanisms that determine health or disease; Graves, 2006). At the same time, it is known that many of the social processes involved in the formation of ethnic groups (such as colonisation and migration) and in the production of socio-economic inequalities amongst ethnic groups (such as racism and ethnocentrism) can create profound phenotypic differences between ethnic groups (some of which are likely to be biomedically important; Karlsen and Nazroo, 2002). Under these circumstances, it will be difficult to know whether any of the differences that actually exist between ethnic groups will mean that studies that include participants from different ethnic groups will ordinarily involve a reduction in analytical acuity.

Second, the researchers we interviewed conceptualised ethnicity as having both socio-cultural and genetic components, but their concerns about analytical acuity primarily revolved around the potential genetic differences between ethnic groups. For example, none of our respondents emphasised the potential impact of socio-cultural or socio-economic differences between ethnic groups (or their phenotypic consequences) on the acuity of their research, despite the fact that many were involved in studies focusing on diseases in which such differences are believed to play an important (if not a predominant) role in generating ethnicised inequalities in health (Hayward *et al.* 2000). This pre-occupation with genetic differences may indicate a conceptual bias that could, itself, have substantial implications on the conduct and interpretation of biomedical research. On the one hand the underestimation of the potential role of socio-cultural and socio-economic factors (and their phenotypic consequences) in ethnicised health inequalities could, itself, compromise analytical acuity. On the other hand, focusing on (presumed) genetic differences between ethnic groups only adds fuel to concerns about the revival of discredited ideologies which propose that different human groupings have distinct biological (and even socio-cultural) characteristics that are innate, essential and immutable.

Third, the ethnic group categories that researchers adopted are unlikely to be wholly accurate markers of the variations associated with ethnicity that may be of relevance in biomedical science (including genotypic, phenotypic, socio-cultural and socio-economic characteristics). Certainly, many people, including the researchers we interviewed, recognise that there are difficulties with operationalising and measuring ethnicity in a reliable and valid manner (e.g. Aspinall, 1997, 2001; Bradby, 2003). In light of these uncertainties there are growing calls for biomedical researchers to declare the reasoning

behind the ethnic categories they use in their research, and to carefully consider the impact of the limited reliability and validity of such categories when interpreting the results of their analyses (Ellison *et al.* 2007; Smart *et al.* 2008). With this in mind, the concerns about analytical acuity expressed by many of the researchers we interviewed are far from being substantiated and doing so would require careful consideration of the specifics of the studies, the ethnic groups involved and the quality of the measures used for capturing any variations in characteristics that might be potentially relevant to the analysis.

Despite these three challenges to the researchers' perception that the inclusion of participants from different ethnic groups could affect analytical acuity, their viewpoint has significant implications for the governance of some biobanks. When faced with what they viewed as conflicting imperatives, our interviewees were (perhaps unsurprisingly) more comfortable discussing genetic variation and the (apparent) certainties of how legitimate sample sizes are best determined using power calculations. Indeed, Epstein (2004a) notes a similar response in his study, in which the researchers he interviewed recognised the importance of social factors in gender classification, but primarily talked about gender in biological terms and were only comfortable generalising on the basis of biological differences. These 'leanings' towards statistical and biological 'certainties' are important because they may influence how researchers seek to resolve any conflict they perceive to exist between the competing imperatives of inclusivity and acuity. The resolution of such perceived conflicts is likely to have a significant impact about what they consider 'appropriate' research designs and practices. In this way, the logic of either imperative could differentially influence questions about: what research should be undertaken; how the research question/problem should be conceptualised; how the research should be designed; which ethnic groups should be included; how ethnicity should be operationalised; and how any differences observed between ethnic groups should be interpreted and explained. Thus, on the one hand, a belief in the pre-eminence of the imperative for social inclusivity might emphasise the importance of including all ethnic groups in such research, to ensure that its potential benefits (and risks) are shared equally by all sectors of the wider population. On the other hand, a belief in the pre-eminence of the imperative for analytical acuity might lead to calls for ethnic groups to be analysed separately with studies that are specifically designed to generate evidence of equal statistical and analytical strength for each ethnic group.

Our findings show that there is a potential for biomedical researchers to be pre-occupied with genetic rather than social factors, and to be more concerned with analytical acuity than social inclusivity.

As such, it seems likely that interaction and debate with policy-makers, lawyers, social scientists and other interested parties will be necessary to address the conflict biomedical researchers perceive to exist between the imperatives of inclusivity and acuity. This is likely to require debate over the evidence available (and the evidence required) to substantiate concerns about the impact of including participants from different ethnic groups on the analytical acuity of biomedical studies. Without assuming that it will be possible to reach a consensus on these issues, there will also be a need to explore the practical, economic, ethical and scientific circumstances under which inclusivity should drive sampling strategies; and when substantiated concerns over analytical acuity might override the moral, political and ethical benefits of inclusivity. Such discussions will also inevitably raise additional questions concerning regulation and governance, such as: whether decisions about the pre-eminence of inclusivity or acuity will need to be guided, controlled or monitored; if so, how and by whom; and how changing national demographics and socio-political imperatives might affect such decisions. At the same time, the debate is also likely to raise a number of questions specific to the conduct of certain biobanks with respect to choices about study design and the recruitment of participants, as was evident in the discussions that occurred within UK Biobank (Tutton, 2008). Finally, it is likely that this debate will have to confront challenging (and longstanding) questions about the legitimacy and broader social consequences of research that focuses on differences, rather than commonalities, between ethnic groups, in particular its potential to contribute to scientific racism (Ellison, 2006).

Clearly, there is still considerable debate as to whether it is scientifically or socially 'sound' to use ethnic categories to design, analyse or interpret the results of genetic and biomedical research. In relation to the legal and ethical governance of biobanks and biobanking research in the UK, our analyses indicate that at least some researchers feel obliged to collect data on ethnicity, and/or recruit research participants from different ethnic groups. Other researchers, however, seem likely to exclude participants from some ethnic groups (particularly minority ethnic groups), justifying this on the basis of concerns about analytical acuity. Under the RRA (as amended in 2000), publicly-funded biobanks are obliged to collect information on ethnicity to demonstrate that there is no unintentional or unjustifiable discrimination in their activities. However, there appears to be no formal imperative for UK researchers to use this information, either for designing their research or for analysing their findings. Indeed, it could be argued that there are good scientific arguments for *not* using data on ethnicity in biomedical research, although only if it

could be proven that data on ethnicity are unable to sustain reliable or valid analyses and this is likely to vary from one study to the next. Similarly, it could be argued that there are good scientific arguments for *not* obliging researchers to include participants from different ethnic groups in their studies' sampling frames although, again, only if there were well-founded reasons for suspecting that such sampling frames might compromise the validity of the research and again, this is likely to vary from one study to the next.

We have reported that some researchers working on biobanks studies of common complex disease in the UK felt that they faced a dilemma: should they conduct research that they perceive to be scientifically unsound because of the principle of justice favouring equality of opportunity and a prohibition against 'racial' discrimination? We have argued that, given the current levels of scientific uncertainty and the significant implications of this issue, this matter should urgently become a topic for debate and discussion between relevant professional and stakeholder groups. In the event that genuine differences in biomedical risk or need amongst different ethnic groups are substantiated, it seems likely that biomedical scientists would then demand to be allowed to design research capable of meaningfully examining ethnic groups separately. Such segregated research designs would have important consequences for the governance, organisation and conduct of some biobank studies. Furthermore, regardless of whether the group differences that would be used to justify such research designs are genetic or social in origin, biomedical science which segregates by ethnicity runs the risk of contributing to a popular perception of ethnic groups as socially 'real', 'biologically meaningful' entities.

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