# Reassessing the ‘gift relationship’: the meaning and ethics of blood donation for genetic research in the UK

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Thesis submitted to the University of Nottingham

For the degree of Doctor of Philosophy, November 2004

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## Abstract

This thesis is based on a critical re-appraisal of Richard Titmuss' classic formulation of gift relationships, which has long been a point of reference for thinking about blood donation in Britain. It argues that Titmuss' interest in the intersections of social systems and health care, together with his concern with mutuality, has been lost in the characterisation of blood donation as a uniquely altruistic activity. This argument is applied to some key assumptions about blood donation in Britain in the thesis, which considers their historical and political contours, and interrogates them in the light of the development of large biobanks which require blood samples for genetic research.

In examining the revival of this 'mobilising metaphor' for genetic biobanks, interview data from UK National Blood Service donors and with others donating blood for a genetic research project is generated and analysed. This reveals that the notion of gifted blood has considerable acuity in summoning up social allegiances based on a sense of community. It is suggested however that mutuality (not one-dimensional altruism) is the model implied by these participants' stance to blood donation or participation in research. This resonates with the re-evaluation of Titmuss' work, in which debates about practical mutual provision and social insurance are more prominent than is generally acknowledged.

Biobanks, as with blood banks of a traditional kind, are bound up with an assertion of common interests. The tacit use of notions of gifted blood and solidarity in the context of contemporary policies on biobanks are revealed as problematic. The thesis concludes by underlining the importance of having an explicit political debate about the UK Biobank, and of developing mechanisms to negotiate and protect the collective interests to which it refers.

## Acknowledgements

My thanks go first of all to my supervisors, Robert Dingwall and Paul Martin, for being unfailingly interested in the ideas discussed in the following pages and for all their help in converting these into the thesis.

Thanks also to the Institute for the Study of Genetics, Biorisks and Society (IGBiS) and to the School of Sociology and Social Policy, both at the University of Nottingham, for providing a stimulating academic home for this work. Discussions with Pru Hobson-West, Sujatha Raman and Richard Tutton, amongst many others at IGBiS, helped me tease out the implications of the research as it progressed. Gill Farmer, Alison Haigh, Patricia Hulme and Alice Phillips all provided invaluable knowledge of university procedures as well as administrative support. Alison Taylor transcribed many of the interviews.

The Wellcome Trust Biomedical Ethics programme provided generous funding for my doctoral training and research costs. The programme also provided me with many useful contacts with other researchers at postgraduate and postdoctoral level. Another invaluable source of enthusiasm and expertise was the Postgraduate Forum for Genetics and Society, amongst whose members is Klaus Hoeyer from the University of Copenhagen, whose work on biobanks is referred to in the thesis.

My heartfelt thanks to Mike Sandys, who helped in at least a hundred ways, on both the academic and the domestic front. And finally to Joni Sandys, who arrived in early 2003 to put it all into perspective.

# Chapter One: introduction

## I Blood donation and population genetic research

The announcement of plans for national genetic biobanks in a number of countries marked a new stage in a long history of collecting human tissue for medical research.[1] The UK Biobank, which aims to be the largest of its kind in the world, follows several similar developments elsewhere, some of which have been highly controversial (Kaye and Martin, 2000; Palsson and Haroardottir, 2003; Rose, 2003). It will collect blood and other human tissue samples, together with personal medical information, and make data from these available for a wide and unspecified range of research projects (Barbour, 2003; Martin, 2001). Whilst the availability of patient records from the National Health Service (NHS) is seen to be an invaluable resource for this initiative, there is another resource that will be crucial to its success or otherwise. This is the voluntary involvement of hundreds of thousands of citizens through donating their blood and other tissues, and agreeing for these to be used (together with their personal and medical information) for genetic research by public or commercial researchers.

Given public uncertainty about developments in genetic technologies and their applications, particularly in commercial contexts, enthusiastic participation in such a project can by no means be guaranteed. There is on the one hand a high level of support for medical research conducted in universities and the NHS. On the other hand, there is considerable concern about the use of genetic information in diverse contexts.[2] It is not surprising then that we have seen a plethora of policy initiatives

[1] A recent census conducted by the Department of Health (2000) revealed the extent of this kind of 'archiving' of body tissues (donated or retained) in England.

[2] See Human Genetics Commission (2001), and Gaskell et al (2003), on both these points.

addressing the use of human tissue and genetic information for research, and, more specifically, for genetic databases (HL, 2001; Human Genetics Commission, 2002; Wellcome Trust and Medical Research Council, 2000).

The idea of donated blood as gifted, a notion that is deeply embedded in the historical fabric of British society, features in many of these. This has, I shall suggest, been a key 'mobilising metaphor' for the UK's biobank project.[3] Whilst it relates to a bioethical ideal of altruism, it has some distinctive meanings in a British context. These can be traced to the origins of the blood service during the war and post war years: the image of the National Blood Service (NBS), as it is now called, was forged in these years. Whereas the language of donated blood as a gift appears to bridge old and new, I shall argue that it serves to elide the differences between very different contexts for donation, and to avoid confronting the implications of an emergence of markets in genetic information.

Another feature of these policy discussions to date has been the allocation of a key role to bioethicists in defining acceptable directions for the applications of new scientific developments. The crucial role played by bioethicists in the debate about biotechnologies and their applications has been scrutinised by a number of sociologists, though mainly in the context of US public policy (Evans, 2002; Kelly, 2003). With the growth of policy dilemmas entailed by new genetic technologies, bioethicists have become increasingly involved in declaring the principles and

[3] I draw on Shore and Wright's thinking about the power of particular words or clusters of words in a policy context here: 'Mobilising metaphors become the centre of a cluster of keywords whose meanings extend and shift…Their mobilising effect lies in their power to connect with, and appropriate, the positive meanings and legitimacy derived from other key symbols of government' (Shore and Wright, 1997:20).

defining the parameters within which such technologies might be considered to be socially acceptable (Crigger, 1998; Evans, 2002; Kelly, 2003).

Accordingly, new international guidelines and formulations for these new applications were developed.[4] Prominent amongst the recommendations for operating large genetic databases in a socially acceptable manner has been an emphasis on the informed consent of the individuals involved. This derives from the conventions of informed consent in medical research, and these in turn from the prominent place of the 'default principle' of autonomy in bioethics (Wolpe, 1998). There is, however, an ongoing debate about whether the deployment of such conventions is a sufficient basis for the governance of population genetic collections - research collections of biological samples, or genetic data derived from them, together with related medical records. Data of this kind is considered to be of considerable commercial value for pharmaceutical research, as well as of interest for new work in genetic epidemiology (Kaye and Martin, 1999; Lewis, 2004). As these biobanks aim to hold data and tissue for cohorts of people selected on demographic criteria, many of their participants will not have a prior interest in any particular genetic disease. Whereas clinical research participants are traditionally viewed as patients, these biobanks seek to involve people on the basis of their membership of a population, community, or nation.

Turning to the sociological view of these developments, a great deal of the empirical work conducted on the new genetics has focused on the experience of those with genetic diseases, and those identified as being at risk of such disease. Here, by exploring the ways that predictive knowledge is used, sociologists have made an important contribution to the debate about these developments (Katz-Rothman, 1988; Lippman, 1991; Spallone et al, 2000). In addition, these developments have been

[4] See, for example, Human Genome Organisation [HUGO] Ethics Committee, 2000, 2003.

scrutinised in relation to sociological theories of identity, reflexivity, and knowledge.[5] However, as these strands of work coalesce, we find that sociological accounts tend to stress the transformative power of genetic knowledge. It is unclear how relevant this will be to thinking about the experience of those who participate in the new genetic biobanks, whose rationale is the study of whole populations.

## II Rationale and scope of the study

My interest in this area of research developed in the course of sitting on a NHS Local Research Ethics committee that processed high numbers of proposals from researchers in both public and commercial sectors. In the course of this it became evident that 'extra' blood samples were often sought in conventional clinical trials for genetic research, with the consent of the research participants.[6] At the time, there was little discussion of this practice or of the implications of aggregating the genetic data derived from these opportunistically collected samples.[7] It was usually felt to be the case that as long as individuals' consent was properly sought, no particular concerns were raised by this practice.[8] My judgement that it would be important to look at this from a social perspective formed the kernel of the research application that eventually led to this study, a process that is described more fully in chapter five.

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[5] This literature is reviewed in chapter four.

[6] Some NHS ethics committees had a policy that the taking of a single 5ml venous sample, with consent, did not require any oversight (Kerrison, 2004).

[7] The extent of tissue banking by pharmaceutical companies, and the commercial value placed on such tissues has since been documented by a number of authors, notably by Lewis (2004).

[8] Blood donated in this way was often described in the information and consent forms as a 'gift' to the researchers. As will become evident as the thesis unfolds, this terminology turns out to be embedded in some important assumptions.

My study begins from the perspective that the meanings and ethics associated with blood donation for research cannot be assumed to be universal, and will be particular to different domains. The thesis revisits some key assumptions about blood donation in Britain, and considers their historical and political contours. It then draws on an analysis of the accounts of blood donors to embed this exploration of the social contexts for donating blood in particular settings. It will be important to note at this point therefore that I have not conducted a study of the general meanings of blood donation for genetic research, which I believe to be domain-specific and very wide-ranging. The scope and limits of this empirical study are delineated in chapter five, as is the case for drawing some more general conclusions for this field of policy from these particular cases. The main point to note here is that my interest is primarily in blood donation for genetic research for population collections, rather than for research in clinical contexts involving people with genetic disease and their families. As will be evident below and throughout the thesis, I have also revisited some of the assumptions about traditional blood donation, and find that these in turn have a bearing on the questions surrounding contemporary developments in population genetics.

## III Structure of the thesis

It was the debate about newly emerging commercial possibilities for genetic research that formed the backdrop to the re-emergence of the idea of donated blood as a 'gift' in a number of professional and bioethics guidelines (Tutton, 2004). In chapter two I shall attend to this revival of the idea of gifted blood in current policy debates, and relate it to a wider tendency for policy on this contemporary phenomenon to be cast in strikingly traditional terms. Here too I shall outline the wider policy landscapes

surrounding the regulation of genetic research in the UK. For reasons that go beyond the immediate challenge posed by the post-genomic sequencing research agenda, the governance of medical research in the UK is in a state of transition. There have been important changes in the governance and regulation of medical research and the use of human tissue. However, it is not evident that these have come to terms with the relationships between public and industry research initiatives, ties that are at their most dense in the field of genetic research (Krimsky, 1991). I shall show that the uncertainties here extend to the regulation of the use of human tissue.

The intersection of social, political and medical systems for managing donated blood was the subject of Titmuss' famous book 'The Gift Relationship' (Titmuss,1970). However, as the arguments put forward by Titmuss ossified over time, they were often characterised in terms of the altruism of individual donors. In chapter three, I shall explore Titmuss' work on blood donation and the way that it has been taken up. I question whether we can rely on the prevailing reading of Titmuss *even* in relation to 'ordinary' blood donation, that is blood donation for the NBS. Instead, my reading emphasises another aspect of Titmuss' work, his interest in mutuality and in the network of institutions that emerged from nineteenth century working class traditions (Titmuss, 2001 [1965]). Along with trades unions and savings clubs, systems of mutual insurance for sickness and disablement famously influenced Beveridge's plans for the NHS (Beveridge, 1948, cited in Yeo, 2001). Titmuss' interest in mutuality has been somewhat lost in the characterisation of blood donation as a uniquely altruistic activity.

In chapter four I shall review some of the tenacious assumptions embedded in the bioethics model, and the challenges that have been made to these on a number of fronts. Here I shall also draw on literature from sociology and anthropology. At the

outset of my study (in 2000), there was very little literature about the new genetic biobanks - a number of empirical studies have since emerged about the dynamics of participation in such biobanks, which provide important points of reference for my discussion. However, an established body of sociological work on the involvement of lay people in clinical research documents the profound influence of the norms of the clinic on peoples experience of such involvement (Fox, 1996; Williams and Calnan, 1996; Corrigan, 2003). The hopes and expectations associated with biomedicine are evident well beyond these immediate clinical contexts (Rose, 2000; Conrad, 2001). I shall suggest that these continue to be relevant to thinking about new kinds of population genetic research, notwithstanding the fact that such research will primarily involve subjects who are well at the time they are recruited.

The rationale and the methodological approach taken to the study are discussed in chapter five. Taking an ethnographic stance, I was able to take account of the particular dynamics and conditions that prevailed at the time that I undertook my preliminary fieldwork. This work, which took place at a time when the issue of donated tissue was a highly sensitive one amongst the research community, involved interviews with a range of people concerned with blood and tissue donation in different contexts. It included informal discussions with staff at the NBS whose perspectives were likely to be relevant for my understanding of the background to policies about biobanking. It was evident from these discussions that the way that the NBS itself operated had changed beyond recognition since the 1960s when Titmuss had described it (Oakley and Ashton, 1997; Martlew, 1997). Accordingly I set out to see whether I could interview NBS blood donors about their perspectives, both on 'ordinary' blood donation, and on the emerging possibilities around donated blood being used for genetic research. I wondered what kinds of accounts blood donors would give today about their commitment to this practice. What were their thoughts

about how the blood would be used? And what kinds of moral reasoning underlay this? My account of the interviews I undertook with National Blood Service donors in one donor centre, and my analysis of these donors' perspectives, are given in chapter six.

In chapter seven I describe my second set of interviews, with people who had donated blood for a genetic research project. Importantly, the 'arthritis genetic research project' offered no treatment or intervention, nor did it offer any feedback on the findings of individuals' tests or genetic analysis. In these senses it resembled the arrangements that will be made for participants in many of the large genetic databases or biobanks. My aim here was to explore the basis on which people without any particular interest in genetic disease might take part in these biobanks.[9] In addition, I wanted to consider whether donating blood for population genetic research raised special or particular issues for these research participants.[10]

It should be evident then that my two interview settings were selected with a view to exploring some of the contrasts between different kinds of blood donation - as one involves blood donation in a more traditional setting, the other blood donation for a genetic research project. However, as will be seen below, I found that there was some

[9] Psoriatic arthritis is not considered to be a monogenic 'genetic disease'. In this sense, those involved in the arthritis research project did not necessarily have any particular interest in genetic disease.

[10] For the collection of large scale biobanks, blood is the most commonly requested biological sample. DNA is then extracted and preserved by freezing it (Hirztlin et al, 2003). However, other tissues may also be collected. UK Biobank presently proposes to collect blood and urine samples, although there has been some discussion of collecting other samples, such as hair. (UK Biobank sample handling and storage subgroup, 2004).

important common ground in terms of the basis on which blood was entrusted in these contexts.

## IV How I shall (not) use Titmuss

Building on the long-standing influence of Titmuss in the world of social policy, there has been a substantial revival of interest in his work in recent years. Much of this work meshes with an ongoing re-appraisal of the history and success of the welfare state at a time when both welfare policy and the academic field of social policy are in some flux (Miller, 2003). These are important debates, including questions about the socialist vision of the welfare state and whether it can be directed towards the redistribution of wealth; a challenge to whether altruism can be considered to have been a motive for the welfare state (Page, 1996) and, related to this, a questioning of the reality of a post-war consensus on welfare (Baldwin, 1990). I shall not, by and large, address these debates on social welfare policy, with the exception of considering how blood donation fits within images and myths about post-war Britain.

Titmuss' work is invoked in contemporary policy contexts in ways that are remarkably nostalgic. A similar problem occurs with his own and others' reference to the earlier anthropological literature on gift relationships. I shall question the casting of the debate about genetic research in traditional terms of shared endeavour and national heritage. Yet there is a case for re-embedding research about participation in biobanks within a recognition of relationships between citizens and the state. Hoeyer's work on the regional biobank in Northern Sweden is a case in point here. For Hoeyer, people's responses to an invitation to participate in the biobank is considered in the context of a 'narrative of progress' and also of particular configurations of relationships between citizen and the Swedish state (Hoeyer,

2004:106). Hoeyer draws on more contemporary anthropological literature on exchange relationships to draw attention to the function of biobanks as mediators between the ethical stance that blood is not a commodity, and the commercial imperative to trade in blood-based information (Hoeyer, 2002).

In my analysis of blood donors' perspectives in two different settings in one English city, the blood is seen to be entrusted to institutions - the NBS, the NHS, and the University - that are known and recognised amongst these donors. I shall explore the implications of this kind of *informed trust*, as I shall call it, for the dynamics of participation in population genetic research. I find that the imagined community symbolised by the NHS is central to these relationships - notwithstanding the complex and multi-layered connections that now exist between research, commerce and the state. These ways of imagining the uses of the blood and the community that will benefit from it are seen as central to thinking about what meanings will be associated with blood donation for a national biobank in the UK.

In the concluding chapter I shall review the findings of the research as a whole and draw on these to unpack their relevance for current policy debates. One implication of the trust that many donors placed in University researchers, the NHS and the NBS is seen to be the importance of effective systems of governance that recognise collective and shared interests. This will provide a counterbalance to relying so heavily on individual participants' scrutiny of particular projects, something we know does not necessarily occur when they give their 'informed consent'.[11] A model of

[11] The extensive literature on the application of the principle of informed consent in the diverse contexts of medical research is beyond the scope of this thesis to review this literature in detail. See Doyal (1998) for a review of some of the perspectives expressed. See Corrigan for a consideration of the contradictions and problems involved in applying these coventions to the

reasoning that envisages donors as 'altruists' is seen as deflecting from the important task of developing policies for genetic research that may be identified with shared or mutual interests. A recognition of participants' sense of belonging to a community with interests in research will have implications for the boundaries that should be drawn around the use of their donated tissue. Rather than managing these issues through the bioethical codes that have traditionally governed such research, this will in turn require debate and resolution at a political level.

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newer field of pharmacogenetics (Corrigan, 2004). Kaye (2004) reviews the particular issues arising from participation in population collections, and argues for additional safeguards here that take account of the collective interests involved, including those of future generations. Kaye's work is discussed in chapter two. The mounting of a philosophical critique to reliance on mechanisms of informed consent, and the contribution of social scientists to this, is considered in chapter four.

## Chapter Two: the emergence of new contexts for the use of donated blood

### I Introduction

In this chapter I shall describe the emergence of new kinds of genetic research, with a focus on their implications for the 'banking' of blood and data. Although such biobanks are a recent development, there is a long tradition of archiving and using human tissue in medical contexts. In addition, the uses to which donated blood can be put have diversified throughout the second half of the twentieth century. Technical developments now allow for genetic analyses using small blood samples to be undertaken on a large scale. The involvement of new commercial actors, notably pharmaceutical companies, in these activities completes the shift of the economy within which blood is used from a 'corporeal' to an 'informational' one (Tutton, 2002:537). At the same time, donated blood is still used in the treatment of patients following blood loss in serious accidents and acute illnesses.

As I shall describe in chapter five, my research was driven in part by an interest in the ways in which blood donation for genetic research was being described. In particular, it was not unusual for donated blood to be described as 'gifted' in guidelines and documents about the use of human tissue for genetic research. This discourse, I noted at the outset, was evident at a local level. I had observed for example that individual consent forms for medical research often requested an additional sample of blood, that was to be understood as a 'gift', and that was to be used for genetic analysis. It is likely

that those drawing up these forms had reference to the concepts of gift and altruism that appeared in the Nuffield Council and Medical Research Council's guidelines on the use of human tissue in research (Nuffield Council, 1995; MRC, 2001). Tutton's analysis of these guidelines places them squarely in the context of commercial interests and involvement in biomedical research and the uncertainty surrounding the acceptability of such involvement to the public (Tutton, 2004). Such uncertainty was heightened by the scandals at Alder Hey[1], and the subsequent uncovering of widespread practices of organ and tissue retention that were no longer seen as acceptable (DH, 2000). Added to this was the state of flux surrounding the governance of medical research more generally (Martin, 2001; Kerrison et al, 2003).

Concepts of gift and altruism recur in the House of Lords report on 'Human Genetic Databases: Challenges and Opportunities' (HL, 2001). They re-emerge as 'genetic solidarity and altruism' in the Human Genetic Commission's report on the use of human genetic data, and are reiterated in the Government's 'Genetics White Paper' (HGC, 2002; DH, 2003:78). In the context of developments in genetic research, the concept of donated blood as 'gifted' seemed to evoke values associated with blood donation in an earlier era.[2] Indeed, the revival of a more traditional language is evident in other aspects of policy discussions about this most contemporary of developments.[3] The tension between

[1] See 'The Royal Liverpool Children's Inquiry Report by Redfern et al (2001).

[2] An alternative explanation for these references to donated blood as gift would be to anchor the transaction in a property model. Laurie argues that the term 'presumes the surrender of all residual interests in donated samples' (Laurie, 2002:317). However, as I shall discuss in some detail in the following chapter, the use of the term has considerable historical and political resonance in the UK.

[3] For example, the Genetics White Paper - which primarily addresses the implications of

notions of patient and donor altruism that are deeply embedded in traditional formations of the NHS and the dynamics and structures of contemporary genetic research are, I shall argue, fundamental to thinking about the meaning of donating blood for genetic research in Britain today.

I shall begin by tracing the development of collections of human tissue from informal collections to the large population collections or biobanks that are now emerging, and reviewing the debate that has greeted these developments. In part III, I shall focus on the Icelandic case that pioneered the first national biobank and, in so doing, shaped that debate substantially. I then move to discuss the emergence of the UK's new Biobank in more detail (in part IV). To presage an extended series of discussions about the Biobank protocol, some of which I shall allude to below, it was eventually decided that UK Biobank participants would be asked to donate blood and urine samples (UK Biobank sample handling and storage subgroup, 2004). In addition, they would consent to the use of their medical records held by the NHS, and the data from some further questions that they would be asked about their health and lifestyle. They would be asked to give 'broad consent' for the use of these data - that is they could consent or refuse to participate in the Biobank in its entirety, but could not be informed in advance of, nor specify the kinds of

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developments in genetic research for the NHS - looks backwards to the founding ideals of the NHS. The Paper, entitled '*Our inheritance our future'* stresses the concept of the social solidarity represented by the NHS; people can take genetic tests without fear because 'everyone, regardless of risk, is "insured" by the NHS' (Department of Health, 2003: 8). This kind of emphasis on pooling and sharing risks is unusual in today's policy climate in the UK, which tends rather towards a stress on the limits of the responsibilities of the state towards its citizens. Indeed, it echoes the rationale of the Beveridge report of 1942.

research for which these samples and data would be used (UK Biobank, 2004; Newton, 2004). After describing these developments in more detail, I move to place them in the context of the policies that characterise governance of biomedical research and of human genetics in the UK (in V and VI). In the concluding part of the chapter I shall begin to confront the implications of new interrelationships between biobanks, commerce and the state for how we think about the meaning of blood donation for genetic research.

The focus on population genetic research and biobanks, rather than other dimensions of genetic research projects will be evident from this introduction. One reason for this focus is that the development of genetic biobanks appears to crystalise contemporary developments in genetic research using human tissue and involving the inter-penetration of state with commercial interests. Whether biobanks will be 'the future' of genetic research, or whether the future will consist rather of smaller scale projects and a return to more local arrangements for the banking of tissue is an open question. However biobanks presently constitute a central plank through which policies and strategies in this field are mobilised, and through which blood donations for genetic research will be sought on a large scale. It is likely too that the debates surrounding these higher profile developments will be formative for policies that impact on the use of blood across the canvass of genetic research in the UK.

## II Genetic biobanks and the use of human samples in research

### The precursors of biobanks: informal collections of human tissue

Genetic biobanks are a recent development in a long tradition of archiving and using human tissue in medical contexts. Historically, human organs and smaller 'tissues' were collected in UK hospitals, often without consent, to be used in medical training and research according to the policies of those hospitals (DH, 2000, 2001). More recently, it became expected that consent would be sought for the retention and use of human tissues: in practice however, the ways in which consent was sought varied. As with other areas of medical research, such practices were governed mainly by professional guidelines and conventions. In the wake of the events at Alder Hey it became evident that a gap had emerged between the assumptions of pathologists and those of patients' relatives about routine practices at autopsy (Redfern et al, 2001).

Following this, and a series of related inquiries, the regulation of the donation of body tissue for research became the subject of intense scrutiny in the UK. Whilst body tissue was once widely discussed in terms of surplus and waste, once routine practices of exploiting body tissue have become emotive and controversial issues.[4] It is important in

[4] One of the confusing aspects of this debate - and one about which there has been much complaint from researchers - is the lack of recognition of the diverse circumstances in which human tissues may be retained and used (Furness and Sullivan, 2004). For example the retention of organs at post-mortem, the obtaining of a 5mls blood sample for a research project, and the storing of tissue or 'cell-blocks' after surgery are all blurred in the term 'human tissue' (Retained Organs Commission, 2001).

thinking about the issues surrounding the use of human samples for genetic research to acknowledge that in recent years researchers using conventional techniques for research have also been confronted by these shifts in expectations (Kmietowicz, 2001; Ward et al, 2004). The shift in attitudes around the use of human tissue in medical research over a short time is evident when we consider that just ten years ago leading bioethicists advocated the position that tissues taken in the course of medical treatment be considered for these purposes as 'abandoned' (Nuffield Council, 1995). This is in contrast to the current position, in which consent is posited as central to such activity (Hansard, 2004).

Collections of human biological samples for DNA analysis have been routine in variety of non-commercial settings for some time (Hirtzlin et al, 2003:476). Firstly, collections in hospitals, primarily for the purpose of diagnosis and treatment but used also for research and training.[5] Secondly, collections of DNA held by police or judicial authorities. Thirdly, there have been small-scale collections of population data relating to particular communities held in universities and research institutes.[6]

The current trend towards the build up of larger scale collections of tissue and information for genetic research is associated with a number of technical developments. These include the invention of molecular automated techniques and bioinformatic techniques which lend themselves to mass screening and databases (Hirtzlin et al,

[5] Registers of those with rare genetic diseases have existed for several decades in the UK, usually having overlapping functions of research and provision of services such as counselling (Chadwick and Berg, 2001).

[6] Hirztlin et al summarise these precursors of the biobanks in their description of biobanking in six EU countries (Hirztlin et al, 2003).

2003:476). For the collection of large-scale biobanks, blood is the most commonly requested biological sample. DNA is then extracted and easily preserved by freezing it (Hirztlin et al, 2003). However, other samples may also be collected, depending on the goal of the research. There is considerable interest in the pharmaceutical industry in the potential of such developments for use in industry, particularly in the field of pharmacogenetics (Martin and Kaye, 1999:14; Lewis, 2004). It is worth noting at the outset that there are extensive academic-industry links in this field (Martin and Kaye, 1999:3; Lewis, 2004). At the same time, these developments are of interest to scientists in the public sector who are interested in taking forward large studies with a view to exploring the interaction between environmental and genetic factors in causing common disease (Berger, 2001). Ultimately, it is envisaged that there may be a wide range of uses for large-scale collections of genetic data. In some cases the collection of tissue samples and data for this kind of research has proceeded incrementally, through the expansion of existing epidemiological studies and cohorts, as appears to have been the case with 'Cohort Norway'.[7] In other cases however we have seen the setting up of high profile large biobanks to facilitate this new research agenda.

Genetic biobanks can be distinguished from other large research projects by their role in providing human tissue or genetic data together with personal and medical data to a range of research projects. Hirztlin et al's survey of practices in biobanking in six European countries delineates six main types of human biobanks: small public collections, large public collections, databases only, private collections, private not-for-profit collections and specialised collections - for instance forensic institutes, blood banks and sperm banks

[7] See www.medisin.ntu.no/ism/forskning/population-based-research (accessed on 1/10/04).

(Hirtzlin et al, 2003:484).[8] They found that outside pharmaceutical groups and biotech companies, biobanking was organised on an informal basis, and often undertaken on the fringes of an organisation's other activities, of research, treatment, and so on. Therefore biobanking of this kind often had no dedicated budget, being subsidised by research contracts (482). Policies and practices in biobanking in these contexts were diverse. For example, questions about who owned the samples 'lead to an unexpected variety of answers' (482). Usually the host institution was considered to own the sample, but in other cases ownership was said to belong to individual researchers, or to those who had provided the samples. Similarly, the practices around obtaining informed consent, have only become a contentious issue more recently: written consent on an informed consent form was not always obtained for the secondary uses of the tissue. In summary Hirztlin et al underscored the limited regulation around biobanking (485).[9]

Commercial companies have for some time held and traded large banks of genetic data (Lewis, 2004). Lewis divides access by pharmaceutical companies to genetic tissue and databases into the following four categories: 'in house' collections of tissue held by pharmaceutical companies themselves, often collected in the course of their own clinical trials; collections held by genomics companies acting as intermediaries between these companies and patients; collaborations with university or public sector collections (such as those held by pathology laboratories); and finally the newly built 'public' biobanks (Lewis, 2004:181). Lewis cites the words of Novartis' head of pharmacogenetics to

[8] The survey did not cover national large scale population databases as the few of these in existence had only very recently been established.

[9] Note however that the recent EU Directive 2004/23/EC on tissue banking is likely to lead to the standardising of practices and protocols in this field, including genetic biobanking.

illustrate the extent and importance of tissue banking in the private sector and particularly amongst pharmaceutical companies:

> *We now systematically collect DNA from every patient in every clinical trial, analyse that for variations and then at the end of the trial do association studies between genetic variation, efficacy and adverse effects.* (Melton 2003:923, cited in Lewis, 2004:188).

Estimates from several sources point to the tissue collections being held 'in-house' by pharmaceutical companies being extensive.[10,11] The role of companies which act as intermediaries between the public and the pharma companies is notable here too: one such company, First Genetic Trust, is said to be based partly on the belief that companies will not keep genetic data safe. The promise to maintain patient privacy through maintaining its own secure database is at the heart of its activities (Lewis, 2004:189). Thus the business model explicitly addresses the problem of public distrust in this field. Interestingly, in the light of discussions about the problems around the issue of 'broad consent' to participate in biobanks, the company offers the possibility of updating or re-contacting donors when necessary (Lewis, 2004). Finally here, commercial companies have accessed patient tissues and data from the public sector to a significant extent: traditionally in the UK and elsewhere these have been from tissue 'surplus to the

[10] It is difficult to establish the extent of tissue collections in the private sector, however these are extensive as Lewis has documented (Lewis, 2004:182).

[11] Note that biobanks are only one of a range of collections of human tissue. Other kinds of tissue collection in different contexts include, for example, those of embryos from IVF treatment, of blood stored for surgery, and other clinical products (Lewis, 2004).

requirements of patient care' in hospitals.[12] Amongst these collaborations, one that is generally overlooked is the potential use of NBS tissue banks by research organisations.[13]

## Population collections

The concept of 'population collections' for genetic research emerged more recently to describe the growing number of proposals for establishing genetic databases:

> *Population collections, unlike other medical research databases, will contain the information and DNA samples from individuals of a whole population. This population can include a whole country, such as Estonia, Iceland and Singapore, or a regional group such as the Vasterbotten region of Sweden and Newfoundland in Canada… Information within the population collection can be kept for many years and used for multiple, secondary research purposes, by different researchers simultaneously.*
>
> (Kaye, 2004:117)

Thus biobanks provide a repository of donated tissue (usually blood samples) and medical

[12] These arrangements have not to date been well documented. An exception is the case of Peterborough district hospital, which established a tissue bank in 1996 that now supplies more than 30 commercial biomedical organisations, and has been explicit about this collaboration (Womack and Gray, 2000).

[13] A National Blood Service paper on tissue banks sets out a long term strategy that involves expanding involvement in tissue banking and the exploiting of such resources for engineering of (tissue) products and services (NBS, 2002:3).

information. I shall use the terms 'population collection' and 'biobank' inter-changeably. As with other collections of this kind, the new UK Biobank for example is described by its management as a 'resource' for researchers, rather than a research project in itself (Newton, 2004). It follows from these definitions that the consent required for biobanks will be different from that required from specific research projects or programmes. In general, biobanks propose to obtain 'generalised consent for an unspecified set of common diseases and for an undefined period of study ' (Austin et al, 2003:451).[14]

It is this last requirement has provoked the most commentary in the literature. Whilst it was the presumption of consent for the use of information from Iceland's Health Sector Database that catapulted the controversy around these initiatives, a range of issues have since been discussed that pertain to the social, ethical and logistical difficulties of obtaining appropriate consent for genetic databases. Some of these are discussed below in relation to developments in Iceland and the UK. Questions about informed consent have been the most prominent in the debate about biobanks, at least in its early stages. More recently it has been suggested that such an emphasis militates against a fuller

[14] Austin et al identify eight biobank projects/proposals that meet these and other definitional criteria, in Iceland, UK, Estonia, Latvia, Sweden, Singapore, Quebec, and the Kingdom of Tonga. Each of these involves support from both government and involvement of commercial organisations. Other projects in the US are referred to by Austin et al (those in Minnesota and Wisconsin, proposed by non-profit medical clinics), and the Framingham Heart Study is a well known large scale study that incorporates genetic research. However, the absence of a national health service and of an analogous system of medical records renders the situation in the US markedly different from that of the countries that I focus on here. In addition, it should be noted no definitive list can be made, as new biobanks will emerge and some are likely to fail.

consideration of the dynamics of participation in biobanks (Hoeyer and Lynoe, 2004). Hoeyer, whose work is discussed in chapter four, argues that the exclusive emphasis on individual consent tends to devolve responsibility for decisions about genetic research to individual donors (Hoeyer, 2003:237).

There has been a muted debate about the relevance and rigour of the science which underlies the new biobanks. Research on the relationships between the gene and various environmental factors will draw on traditions and techniques of epidemiology, a discipline which is distinctive amongst established medical disciplines for its emphasis on population level phenomenon. However, the marrying of genetics and epidemiology is as yet a relatively new and unproven enterprise (Beaty and Khouri, 2000; Kaprio, 2000). Reservations were expressed, in private at least, by experienced geneticists and other scientists and practitioners (Jones, 2001). Taking a broader sweep, an editorial in the Lancet summed up the case for scepticism:

> *The major risk factors for human illness are not likely to be affected by the range of applications that knowledge of the human genome will bring forward. Malnutrition, poor water and sanitation systems, unsafe sex, tobacco, and alcohol make up the top five risk factors for human disability*'
>
> (Lancet 2001:357)

## The emergence of national biobanks

The emergence of national biobanks is a recent development in the field. There are national biobank projects or proposals in Iceland, Estonia, Latvia and the UK, as well as

related developments in Sweden, Norway, Newfoundland, Singapore and elsewhere. I shall focus on the developments in Europe and Scandinavia, which I believe to have been more influential in the discussions about the UK initiative. Each national biobank has markedly different aims, operational arrangements and regulatory regimes. Importantly too, whilst governments have a significant role in sponsoring many of these initiatives, they differ substantially in how the relationships between public and private sectors are envisaged or defined. It is of interest then that discussions about the possibility of forming a national biobank in the UK were underway during the formative years of these various projects (see section IV, below). In terms of size, the aim is to achieve cohorts from in the order of 200,000 in Norway, up to a million in the case of Estonia. In the Icelandic case, the participation of the whole population of around 290,000 is sought.

The Icelandic biobank is the pioneer of the national genomic databases, having been established after the passing of new legislation in the Icelandic parliament in 1998. Partly for this reason, and partly because of the nature of the exclusive arrangement with the commercial company seeking to exploit this resource, the Icelandic databank has proved highly controversial. The controversy was fuelled by the deployment of an 'opt-out' model for consent rather than a mechanism for opting in: the consent of the entire population was assumed unless they took active steps to remove themselves from the project. (I shall discuss the debates surrounding the Icelandic initiative in more detail in the next section). In contrast, a Norwegian initiative builds on existing population studies to create a national collaborative project, 'Cohort Norway' across which blood samples will be collected for DNA analysis together with other health data. In Estonia a national Genome Project (EGP) was established 2001, following the passing of the Human Genes Research Act (Estonian Genome Project, 2002). It conforms more closely to the

Icelandic model in that the research to be carried out using the biobank is funded and carried out by a commercial company, which has exclusive rights to the data.[15] However markedly different arrangements have been put in place for seeking the consent of participants and indeed in other aspects of the protocol of the Estonian biobank: signed consent forms are required from participating donors, each of whom has the right to access genetic data about themselves. The project provides for genetic counselling to be made available to those who learn of a predisposition to disease through their involvement (EGP, 2002).

Each biobank will require access to medical and lifestyle data, and to donated blood samples for analysis using genetic techniques. All seek generalised consent from participants for research. Therefore biobanks will depend directly on public support more directly than most scientific projects in that they require the active support and enrolment of large numbers of the population.[16] Yet they appear to have considerable potential for controversy (Rose, 2003). Arrangements surrounding consent and commerce in relation to these projects have been pivotal to how acceptable they are seen to be by their publics. The Icelandic biobank, for which the legislative framework was established five years ago now, has been through several stages of implementation and response to criticism. In the next section I describe the unfolding of these developments over time.

[15] See www.geenivaramu.ee

[16] It should be noted that these national biobanks are at an early stage of development and it is as yet unclear which of these will be fully realised: some may never go ahead.

## III The Icelandic biobank and the debate about informed consent

In December 1998, the Icelandic parliament passed a bill authorising the construction of a National Health Sector Database. The new legislation allowed for the medical records of the entire population to be collated and input into a database. In addition, the medical records of now deceased Icelandic citizens were to be included. To this health information database would be added a database of genealogical records and, in time, a database of genetic information. The legislation which established the database was to underpin the development of the larger biogenetic project (Palsson and Haroardottir, 2002:275). Special permission would be required from newly established commissions on ethics and data protection to link the information on the three databases. The license to run the database would be granted to one company which would then have exclusive access to the data for a period of twelve years, or longer if the license was renewed.

Although it had the support of the two main political parties, the database project was debated extensively in the Icelandic parliament especially between April 1998 when the bill was first introduced, and December of the same year when it was ratified, resulting in some significant changes in the project. Beyond this, it was debated at a series of town meetings, discussed in hundreds of newspaper articles and extensively covered by the world press. It is generally agreed then that a substantial debate took place during this time and has continued - about issues around 'the ownership of and access to genetic information and medical records' (Palsson and Haroardottir, 2002:279). In the course of the debate, proponents tended to stress the opportunities the project would create in terms of medical advances, and also in the wider sense of entrepreneurship and private initiative. Critics cited ethical concerns, including those around privacy and ownership

(Palsson and Haroardottir, 2002:280). A civil association, Mannvernd, was created to voice these and other concerns about the database initiative.[17] Although the infringement of the accepted standard for informed consent in medical research attracted a good deal of international attention, concerns went beyond the traditional domain of bioethics. Opposition was vocal on a number of different fronts, including: physicians' concerned about the implications of these developments for their own status and for their relationship with patients; broader arguments about the arrangements entailed in the biobank; and the objection in principle that a national biobank with a commercial tie-in constituted 'the commodification of an entire population' (Lewontin, 1999; Rose, 2001).

When the Ministry of Health granted the license to run the database to the company deCODE Genetics, these concerns escalated. Although based in Iceland, the company was funded by a venture capital company in the US.[18] The debate then came to encompass the dynamics of multinational companies and their relationship with the biobank. Many dimensions of the Health Sector Database (HSD) initiative and of the debate surrounding it are distinctive to the Icelandic context. Much of the media coverage and some of the early academic coverage focused on the significance of a relatively homogenous gene pool of an island population - notwithstanding the significance of migration to the island and the debate about the extent of genetic diversity - and this is widely seen as underpinning the attractiveness of the data to commercial companies. As is well-known, Iceland has exceptional genealogical records. The

[17] See www.mannvernd.is

[18] Other work at deCODE involved 'gene hunting' which was pursued via contracts with physicians to collect data and tissue with consent from patients in particular disease categories (276). In turn deCODE set up a contract with pharma giant Hoffman La Roche for access to the material (275).

national census of 1703, for example is ‘arguably the first of its kind in the world’ (276).

However, an initiative like the HSD is as dependent on medical records as it is on genetic and genealogical data: Iceland has kept medical records on a national basis since early in the twentieth century, with a systematic collection of such data being available for the whole population since the Second World War. An exclusive license was given to deCODE genetics to set up and run a database of this information for twelve years, and to exploit that unique dataset. It was the nature of this commercial dimension, meshed with the controversy over arrangements for informed consent, which proved so potent a controversy in Iceland.

## Iceland and the debate about informed consent

Initially, it was proposed that individuals’ medical records would be included in the Health Sector Database and linked to Icelandic genealogies and DNA samples, without opportunity for opt-out. Following domestic and international pressure, this was changed to a system allowing Icelanders to ‘opt out’ of the database (Arnason, 2004:33). deCODE Genetics, which was to run the database, subsequently agreed to develop methods that allowed for the deletion of information about those who decided to opt out at a subsequent stage. The picture in Iceland is complicated by the intersection of three different databases, each having different arrangements for consent: the HSD presumes blanket consent with the possibility of individuals opting out. For the genealogical database there is no consent obtained. For the genetic database being built up by deCODE, explicit written consent is envisaged. This however may change in view of recent legislation and current debates (Arnason, 2004:33).

High levels of public support and the fact that only seven percent of Icelanders have opted out is sometimes cited in vindication of the assumption of consent for the national biobank. However others argue that, notwithstanding this apparent substantial support from the Icelandic population, 'quantitative facts about extensive debate and overwhelming majority opinion must not be confused with the qualitative notion of consent to participation in research, which implies an understanding of the issues consented to' (Arnason, 2004:38). It is clear that the 'opt out' policy remains a contentious aspect of the Icelandic biobank. In addition it seems that some improvements could be made at the level of implementation to ensure the 'opt-out' option is available in practice to those who may wish to take it (Merz et al, 2004).

The position of the Icelandic government has been to place the database in the context of the case for collecting medical data for public health purposes via a computerised system, and storing that data on a centralised database. The commercial involvement is held to be a way of ensuring that these activities are fully funded. It is indeed widely held that the collection of data for such purposes is legitimate and can legally be exempted from the rules of individual informed consent.[19] [20] Ethicists describe the case of government collection of medical data as morally different from that collected for commercial purposes.[21] However a detailed analysis of the operation of the HSD database and the

[19] This point of view is widely, but not unanimously held, and is codified in the EC Directive on data protection (Directive 95/46/EC).

[20] This is also so in the UK where a system of presumed consent operates in effect for much collection of health data - indeed there are no arrangements for NHS patients to withdraw from disease registers or other forms of public health monitoring.

[21] This consensus is reflected in the legal frameworks governing data protection in Europe, in which

exclusive commercial access to it points to the 'primacy of commercial purpose' according to Merz et al (2004:1202). They argue that 'the database may serve the interests of deCODE genetics more than it serves the public, undermining the claim that presumed consent for this data collection and its proprietary use is ethical' (Merz et al, 2004:1201).

The debate, which continues, addresses both principles about informed consent for the new biobanks and issues about the feasibility of operating a system of informed consent for projects involving such large numbers of people. The stance taken by most of the biobanks to date is to define themselves as a resource for researchers, without specifying the boundaries of the kind of research which may be undertaken using the resource. Arnason, writing about the ongoing debate regarding the best position to take in the Icelandic case, notes that if broad consent is then sought for research which is not specified the concept of informed consent is arguably misleading. 'It is, however another and an open question whether it is wise to require informed consent for all secondary research purposes' (Arnason, 2004:42). In place of the traditional informed consent, Arnason puts forward the case for 'an explicit written authorisation for participation in database research based on general knowledge about the database and the research purposes and practices' (Arnason, 2004:44).

Arnason is not alone in not finding arguments for presuming consent to use of medical records in HSD convincing, yet not seeing the traditional requirements of informed consent as suited for purpose of this kind of database: there is a strong sense here of

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exemptions to the usual protections for individuals apply if data is held in the public interest, with public health monitoring being accepted as one such case: EC Directive 95/46 and related guidelines.

neither side of the argument being quite convincing. Thus the development of policies which would maintain a balance of individuals' rights and consent with the potential benefits from population research is very much on the agenda (Chadwick, 1999; Chadwick and Berg, 2001). For many though, the model used in Iceland is seen as a counterexample to the kind of model which is sought. In Iceland, the controversies over consent have cast a shadow over the biobank, and its legitimacy is still widely questioned some five years after its inception.

## Informed consent and the (commercial) dynamics of population genetic research

Beyond Iceland, a wider debate about the principles and logistics of consent for population collections was triggered. A number of objections have been raised to the feasibility in practice of relying on individual informed consent (IC) for the protection of research subjects involved in larger scale genetic research and related information databases.[22] These include the importance of including a whole or representative population group for research of this kind to be valid; the practical difficulties of effectively informing large numbers of research subjects; the question of the extent to which people can understand the technicalities of the new research agenda, and of whether a lengthy process of obtaining IC in these circumstances is burdensome. In addition there is the broader uncertainty of whether anyone can predict the social consequences of genetic research. In the face of potentially major social consequences, there has been some discussion about how mechanisms of collective consent are important as an additional layer of protection against social consequences of research that

[22] These arguments have been reviewed in some detail recently by Arnason (2004) - who is concerned with current policy issues in Iceland in relation to the biobank - and by Kaye (2004), who reviews them in relation to the governance structures of the UK Biobank.

go beyond harm to individual participants (Kaye, 2004; Weldon, 2004; Weijer, 1999).

To these debates we can add a challenge to the centrality of the notion of informed consent and a critique of its philosophical underpinnings, to which I shall return in my review of the literature in chapter four. The sociological literature points to the importance of viewing the dynamics of research participation in the context of relationships with biomedicine and both the values and the institutions that are associated with it. (See chapter four for further discussion of these issues.)

Kaye's recent review of the debates on consent puts forward the following points: it is argued that, if the principles of individual informed consent were strictly applied, this would make a population collection 'unworkable' because of the need to continually re-contact participants and also inconvenience participants. In Europe, under directive 95/46/EC, information collected with consent is allowed to be further processed under certain conditions. Whilst Kaye finds some justification for applying this exemption to population collections, she argues that such exemptions may compromise individual rights and should be used sparingly, for:

> *Implicit within this exemption is the notion of the many checks and balances that are part of the culture of a medical research practice, which are a basis for the public trust essential to the functioning of medical research. [However, ] the values that are implicit in a medical research culture located within a national health system do not have primacy in the context of a population collection.*
>
> *(Kaye, 2004:125, my brackets)*

The solution proposed by Kaye is that individuals be asked for broad consent, informed about the organisation in charge of data collection, the kind of research envisaged, and the type of data that would be collected. They would then be kept informed on a prospective basis about the future uses of their data. In addition to having the right to withdraw all the information concerning themselves from the database, each individual would have to re-consent to the use of their data every five years. In addition, Kaye proposes that a structure be established to protect the wider collective interests of the participants in the database, such as a trust which would hold the legal title to the information and be run by trustees. This kind of formal arrangement would be particularly important if the company running a database were to fold, leading to the possibility that biobank information would be sold as part of a company's assets. As will be seen below, the current arrangements for the UK's biobank do not encompass arrangements for representing the collective interests of those involved.

## IV The development of UK Biobank

In the UK, there have for some time been a number of known collections of tissue and genetic information, most of which are disease specific, and enroll participants through clinicians who are in contact with patients with the specified disorder. More recently, several regional collections of genetic data have been established. These include the Avon longitudinal study of pregnancy and childhood, which has been following some 14,000 families based in the area; the study includes detailed questionnaire based lifestyle data as well as health data and genetic data based on donated blood samples. The North Cumbria Community Genetics Project (NCCGP) collects specimens of blood from

mothers and newborn babies, along with medical and lifestyle information and data on birth. Both studies have high levels of enrollment (Chase et al, 1998; Williamson et al, 2004).

The idea for a national UK biobank began formally in 1998 when the MRC was given additional funds to set up a DNA collection (Barbour, 2003). Following a workshop in 1999, and additional support from the Wellcome Trust and the Department of Health (DH), an expert panel was established to develop a research proposal. It was evident from an early stage that there was enthusiasm in the commercial sector for a large-scale collection of health and genetic data. In particular there was an interest in accessing NHS information:

> *The NHS is probably the largest single source of medical information and well-characterised biological samples in Europe and encompasses substantial sub-populations of important ethnic groups…NHS records provide a large longitudinal population database that is of great value…*
>
> (Fears & Poste, 1999:267)

The expert panel published its report on a DNA collection in March 2000, recommending the creation of two prospective cohort studies, one of middle aged people, and the other a birth cohort. It is the idea of studying a cohort of middle aged people (aged 45-69) that has been taken forward, in anticipation of this cohort providing useful data sooner as they develop disease in later years. There is at present no detailed independent account of the developments surrounding the biobank.[23] Whilst official accounts stress the development

[23] There is however a useful short account by Barbour that gives an overview of the development of

of scientific protocols and the background of developments in genetic epidemiology, we might expect that a fuller history would also include a consideration of the commercial interests in this kind of initiative. At governmental level, the biobank is nested into a series of policy initiatives concerned with innovation and the UK's place in the global knowledge economy. As we shall see in the following sections, the new agenda for a 'third way for clinical research' (Fears & Poste, 1999:268), one that necessitates extensive public-private collaborations, has emerged into a more traditional landscape of governance and regulation.

## Public policy and consultation

In parallel to the scientific and technical development of the biobank project there has been a plethora of related policy initiatives. During 2000/01 the House of Lords Science and Technology Committee held an inquiry into genetic databases which included a call for evidence from interested parties (HL, 2001). The House of Lords report sets out with a positive statement on human genetic databases, and strongly endorses the principle of establishing a national biobank. It is evident from the report that research organisations, the NHS and government are seen as the key actors in this terrain. Members of the public feature primarily as NHS patients who are asked to provide help for future generations; the main recommendation being that those asked to participate be reminded of the help provided by earlier patients in developing current medical treatments (HL, 2001, paragraph 1.23). The ideal of 'genetic solidarity and altruism' as one of the bases for public policy in this field was subsequently made explicit by the Human Genetics

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the protocol for the Biobank, its reception by the scientific community, and the official milestones in the development of what is now Biobank UK (Barbour, 2003).

Commission (HGC, 2002:18). Here, the HGC draws upon a quantitative study that gives evidence of strong public support for the use of genetic research to further understanding and treatment of disease (HGC, 2001). It is acknowledged though in the report that the implications of the public's reservations about commercial access to genetic data, also evidenced in the report, have not as yet been given full consideration (HGC, 2002:19). One feature of these documents and in the consultations that I shall discuss in the next section, is that altruistic participation features as the primary, often the only, role for members of the public. As seems to be the case with a number of other consultation exercises in the same field, 'the public's right to determine the scale and scope of Biobank are not even considered' (Kerr, 2003a:217).

Meanwhile, a number of other consultations and ethics workshops were organised by the sponsors of the project. In 1999, in response to the Icelandic controversy and in anticipation of the various social and ethical problems raised by biobanks, the Wellcome Trust commissioned a report and organised a national workshop on the potential difficulties the study might face (Martin and Kaye, 1999). This was followed in 2000 by a market research study and consultation exercise on *'Public Perceptions of the Collection of Human Biological Samples'* (Wellcome Trust and MRC, 2000) and a consultation exercise with primary healthcare professionals. Finally, additional consultation exercises were undertaken with people from previously under-represented groups and with primary care practitioners. Despite the considerable effort made at assessing public and professional opinion, the role of these consultation exercises in the strategic direction of Biobank UK is unclear.[24] The same sense of ambiguity about the

[24] The House of Commons Science and Technology committee report on 'The Work of the Medical Research Council' makes this point about the lack of clarity on how consultation would be used to

reasons for consultation featured in the recent consultation about the Biobank's Ethics and Governance Framework. The period for consultation was short (28 days) and the numbers involved were small, given that the framework has been put forward as a cornerstone for ensuring the legitimacy of the project, and ensuring its operations are widely acceptable.[25] More importantly perhaps, respondents were asked to comment on a draft framework document lacking many important details about the operation of the biobank, the arrangements for seeking concept from participants, and for representing their interests in other ways.[26] We are told that 'a number of respondents' commented on their satisfaction with the Ethics and Governance Council's remit and selection procedures…'. On the one hand, 'a number of respondents commented that its powers might not be sufficient in relation to the individual uses of the resource, investigation of compliance, and procedures for addressing concerns' (UK Biobank, 2004:35). It is clear from the report that respondents expressed significant reservations about the relationship between commercial organisations and the biobank, and that there were diverging views on proposals for the transfer of assets - about which minimal information is provided in

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affect the project: the MRC's representative indicated to the committee that consultation 'was about "informing the ways that we are planning" but would not result in a change of tack (HC, 2003:26).

[25] The document was made available on a website and sent to 'over 100 stakeholders', prompting comments from 29 respondents, of which 17 were explicitly representing the views of groups or organisations (UK Biobank Report on consultation on Draft Ethics and Governance Framework: UK Biobank, 2004).

[26] The methodology used, for example asking respondents to rate various aspects of the framework from 'very acceptable' through to 'very unacceptable' is unwieldy for such small numbers of respondents commenting on such complex issues. Consequently, it becomes difficult to evaluate statements made in the report on the consultation, such as 'most respondents found the EGF's proposals around consent 'very acceptable' or 'very unacceptable' (UK Biobank, 2004:15).

the framework. It is perhaps in the response of the Biobank's funders that the ambiguous status of the consultation is most pronounced: the publication of a summary of comments received was accompanied by an announcement that it will develop a second draft of the governance framework. In the meantime though this project will proceed: it is fully funded and operational, seeks to start pilot studies this year, and expects to start full recruitment next year (Newton, 2004).

Notwithstanding the efforts at consultation, there has been no major political or parliamentary debate about the development of a national biobank in the UK, an absence commented on by the House of Commons Science and Technology committee Chair (HC, 2003).[27] Instead, market research has featured prominently in the efforts of the biobank sponsors to identify the public's views on this kind of initiative. The report of one such recent study commissioned by the Wellcome Trust (WT) and the Medical Research Council (MRC) concludes that most participants are 'very supportive' of medical research and of the proposed biobank and 'likely to take part' (People Science and Policy Limited, 2002). Nevertheless, the report identifies considerable levels of confusion about the need for such an initiative. It describes how significant concerns were expressed about particular areas of the project, notably about the implications of access by commercial companies to biobank data (20-21). However, many of the report's recommendations are primarily directed to questions of presentation of the proposed biobank to participants. Where more substantive proposals were made, regarding for example further consultation on what research what be supported by participants (26), they seem to have rarely have been referred to in the subsequent debate.

[27] The Chair of the Committee called for *'an open-ended, democratic debate about how to conduct this research and how to make it safe.'* (HC debate, 3 July 2002, col 368).

The proponents of a new national biobank refer to the initiative as a 'scientific flagship', aiming to be 'the largest project of its kind' in the world (DH, 2002; Newton, 2004). Notwithstanding these ambitions, the processes leading up to the establishment of the biobank have been the subject of some criticism in the scientific community. It seems that the complexity and secrecy of the tendering process have played their part here. These are said to have been more concerned with infrastructure and resources than with science. Two of those involved in the bidding 'said it was more akin to bidding to do a bridge or motorway rather than to do a scientific project' (Barbour, 2003:1735). Importantly too, it is not clear that there is a scientific consensus in favour of the chosen protocol as the mechanism for developing population genetics in the UK. Here again, secrecy has played its part in fueling suspicions for the peer review reports on the protocol were deemed positive but were not made available outwith the protocol committee, contrary to usual practice in this field (Barbour, 2003).

It is fair to say then that the attempt to elicit public views on UK Biobank itself has been limited to small-scale consultation and larger scale market research. One has the sense that what is being researched here is the acceptability of the project in the sense of how far people will respond positively to an invitation to participate and accept the responsibilities involved. There has not, to date, been a sense that the public are invited to scrutinise and comment on the priorities and boundaries of the initiative. Professionals on the other hand have had a prominent role in the processes of scrutiny (Kerr, 2003a:217), particularly those ethicists, lawyers and physicians who are prominent players in the established committees advising government.

In the absence of a wide-ranging political debate, therefore, those who have been asked to advice on the development of the UK Biobank have a particular and somewhat ambiguous role to play. Although selected on the basis of their expertise in particular fields, it seems they are implicitly being asked to identify policies that would be acceptable to a wider public. This is not an unusual role for expert groups on bioethics, whose activities are prominent in the wider field of human genetics. There is, as I shall discuss in chapter four, very limited literature on the role played by bioethics bodies and institutions in the UK. The situation is somewhat different in the US, where these bodies play a more prominent role in public life. Kelly suggests that such 'public interest bodies are flexible but stable spaces in which scientists and other interested bodies struggle over the boundaries between science and politics…' and calls 'for greater attention to the complex relationship between ethics, science, and policy in governance' (Kelly, 2003:357). Writing more specifically on the debate about genetic engineering[28] in the US, Evans sees them as having a distinct tendency shift the debate 'towards thinness' (Evans, 2002:7).[29] It would be interesting to see further studies looking at the interplay of such bodies with science governance in the UK.

[28] By this term, Evans indicates a range of genetic technologies, including those of 'germline engineering' (altering the genes in some cells in someone's body in such a way that their descendants will also be affected), gene therapy, and cloning (Evans, 2002).

[29] Evans is concerned about the debate amongst professionals, which he argues has been eviscerated, as well as the need for a public debate on genetic engineering, which he shows has been unduly limited by particular formulations of argument, namely those that are formally rational. (This style of ethical reasoning is characterised by a focus on ends, or consequences). These particular styles of argument are prominent within bioethics, whose practitioners are seen as having an important role in translating broader debates into commensurate principles (Evans, 2002: 1-9).

The initiative to develop a national UK biobank took place during a period of unusual change in both the political landscape and the regulation and governance of medical research in the UK. In the following sections I move away from the immediate issues around populations collections, and towards these wider landscapes. My aim here is to describe the overall picture of policies and regulation in this field.

## V The regulation of medical research in the UK

Traditionally, regulation of medical research in the UK has depended very much on the guidelines and institutions of the medical profession (Martin, 2001; Kerrison et al, 2003). Both Martin and Kerrison et al note how the basic framework for research had, until very recently, gone unchanged since the 1960s. In 2001, Martin pointed to the absence of primary legislation in this field in the UK. He delineated the importance of the work of five sets of institutions in this context: the courts, professional bodies, the non-statutory advisory committees on genetics, the research ethics committees, and the Data Protection Agency. Whilst the courts depended to a considerable extent on common law in this field, there were limited precedents in relation to the exploitation of tissue for genetic research, leaving some significant uncertainties regarding the use of such tissues (Martin, 2001:175). Meanwhile the professional guidelines which would guide the court's determination of cases differed in important respects. Indeed there were (in 2001) few professional guidelines relating to the operation of large-scale genetic databases. Whilst NHS Research Ethics Committees were seen as having an important role in reviewing research protocols before they proceeded, they lacked wider powers to oversee developments or enforce decisions. The Data Protection Agency, charged with regulating

the use of personal data, requires individual's consent for data to be stored by most bodies but effectively exempts public health monitoring and research. Finally Martin noted the emergence of advisory committees to provide advice to government on new developments in this field, seeing these as constituting a new layer of governance.

Reviewing the position three years later, in 2004, several important areas of change can be identified. The law about the use of human tissue has been reviewed and revised, leading to the Human Tissue Act (HC, 2004). Secondly, some key measures have been brought forward to catch up with developments in genetic science and particularly the possibility of human reproductive cloning. Thirdly, the NHS governance framework has been overhauled and tightened up in some respects. I shall discuss these developments in turn, but focus on the discussion of the Human Tissue Act (HTA), which encapsulates some key policy developments for the current field of study.

A good deal of the consultation and the legislative drive preceding the HTA has been concerned with the principles which should underlie the donation of whole bodies and organs, and the removal of material from deceased persons. The government sought to underpin consent as the fundamental principle underpinning 'the lawful storage and use of human bodies, body parts, organs, and tissue and the removal of material from the bodies of deceased persons' (Hansard, 2003:1). The Act is in three parts: the first deals with consent for the storage and removal of bodies and human material in specified circumstances, including medical research; the second establishes a new regulatory authority, the Human Tissue Authority; and the third, in dealing with 'various supplementary issues…' makes it 'an offence, with specified exceptions, for a person to have human material with a view to analysing its DNA without consent' (Hansard, 2004:

3).

The Act represents a significant wider shift in thinking about the agency of patients and relatives in relation to hospital settings in particular. The criticisms leveled at the Human Tissue Bill by influential bodies such as the MRC and the Royal Society as it progressed through parliament can be seen in the light of their role as defenders of the interests and activities of researchers.[30] In addition, these bodies, who have successfully lobbied for significant changes in the form of amendments to the bill, are concerned with the uncertainties surrounding the implementation of the regime (Proffitt, 2004). A number of key questions (which will in turn have implications for biobanks) remain unclear. Whilst it addresses the necessity of consent for most uses of human tissue, and clarifies who is legally deemed to be appropriate to give consent in various circumstances, the dilemmas about what would constitute appropriately informed consent are not addressed at this stage. The Act does not address the question of conditional consent to the use of tissue, that is consent for some uses but not others. The details of the operation of the new Human Tissue Authority are as yet unclear. Although it is clear that it will be charged with enforcing the new legislation through a system of licensing for research using human tissues, it is unclear how it will interpret its mandate in the wider sense.[31] Finally, it is

[30] The MRC, Royal Society, and the Nuffield Council all made prominent statements about the dangers of the bill 'going too far' (Blakemore, 2004; Nuffield Council, 2004, Royal Society, 2004). These criticisms, which received substantial news coverage, are summarised in an article entitled 'Human Tissue Bill could jeopardise research, scientists warn' (Pincock, 2004).

[31] For example, it is not how the law will be applied to private DNA collections created by the pharmaceutical industry: Will it cover data and tissue collections collected within the UK, but held 'offshore'?

argued that the clauses concerning the non-consensual analysis of DNA will be difficult to put into practice. Some feel that these clauses risk criminalising legitimate research (Furness and Sullivan, 2004). Notwithstanding the uncertainties surrounding it, the Act will clearly have implications for genetic research. By announcing its intention to make the unauthorised use of DNA analysis an offence, the government has, even before the implementation of the new legislation, made a symbolic statement about a new regime in which patients' interests are to be made more explicit.

A second area of change concerns the regulation of several newly emerging scientific developments in genetic techniques. Following the development of techniques in cloning, a number of specific measures have been brought forward to regulate the use of these techniques in the UK. Notable amongst these is legislation banning reproductive cloning (Human Reproductive Cloning Act, 2001). The position taken by the UK Government seeks to enhance public confidence in the use of cloning techniques for therapeutic research by outlawing cloning for human reproduction and developing a robust framework for the regulation of these techniques in research. Here the Human Fertilisation and Embryonic Authority has been given the role of licensing those clinics which wish to undertake research using these techniques, alongside its wider role licensing infertility clinics and their use of the most controversial genetic techniques, such as pre-implantation genetic diagnosis. It is clear however that some commercial activity in the field of population genetics remains unregulated, notably the trading of genetic information from human research subjects.

The role of the Human Genetics Commission (HGC), established in 1999, has grown to include conducting consultations about and commissioning surveys on the public

perceptions of the use of human genetic information (HGC, 2000, 2002). Beyond this they also have a voice in formulating key policy issues. Their advice is referred to, for example, in the government genetics white paper (DH, 2003). Nevertheless it is evident that, notwithstanding rigorous attempts to consult on these issues, their consensus position cannot be seen as representing that of the population. In addition, the Commission is an advisory group: as with other such bodies, if its advice conflicts with commercial or political imperatives, it may not be heeded.

Moving to consider the wider structures supporting these more specific regulations, the development of a new framework of NHS governance is a significant development.[32] The new framework is concerned with research across the board, and is closely related to the new measures required by the EC Clinical Trials Directive. It has extended the responsibilities of NHS bodies in relation to all research conducted under their auspices. New regulation replaces the historic reliance on professional codes of ethics with legal statute and places legal requirements on institutions, including NHS trusts (Kerrison et al 2003). Related to this, the operation of NHS Research Ethics Committees (RECs) has in many respects been standardised. In the new framework, these shift from being part of medical profession's self-governance arrangements to become part of a centralised structure. However the impact of these reforms may not entirely address the concerns which have been voiced for many years about the role and scope of RECs. These committees can only assess individual proposals, and have not been given any mandate to oversee wider developments. Nor have their powers of enforcement have been addressed in the new regime. It can be argued that, whilst the professional control of such bodies

[32] Department of Health (2001): Department of Health Research Governance Framework for Health and Social Care.

has been loosened, the new framework does not do enough to protect their independence. They may be seen to 'risk capture by industry or governmental interests' (Kerrison et al, 2003:554).

Finally, the government's recent genetics white paper (DH, 2003) sets out the wider parameters within which it is developing genetics services and research. Authored by the Secretary of State for Health and focused on the NHS, the paper also covers related developments in genetic research and sets out plans for investment in research and development, of which the knowledge parks and the UK biobank are the more prominent. This is primarily a statement of the 'big picture' from the government's point of view: the detailed policies that will follow are as yet not evident. Although a view of the NHS as a resource for the national economy is evident in these policy statements, mechanisms for reconciling these with more traditional concepts of welfare have not as yet been addressed.

In summary, there is a picture of considerable change in the regulation of medical research in the UK, particularly in relation to the use of human tissue for such purposes. Whilst the legal frameworks have been clarified in some respects, there is a good deal of uncertainty about the new position. Not least is the question of what weight will be given to the differing interests and voices of those who have a stake in medical research in the UK, amongst them patients, publics, medical practitioners, industry and commerce, and researchers. The government explicitly locates the development of the HTA to the concern following the events at Bristol Royal Infirmary and Alder Hey (Hansard, 2003). Nevertheless, the balance which it seeks to find between divergent groups remains elusive.

## VI The governance of human genetics in the UK: policy landscapes

> *The regulatory framework, in its very construction, houses an awareness of the crisis of public faith in the state's ability to balance the interests involved in the applications of human genetics.*
>
> *(Jones & Salter, 2003:21)*

In this section I draw on some key analyses of the wider dynamics of science governance in the UK, in particular those of Jones and Salter (2003), Irwin (2001) and Kerr (2003a,b), to consider the framing of contemporary UK policies about genetics. According to these analyses, the notion of a crisis of trust in science is a key part of the policy landscape here. One response to these perceived crises has been the increased prominence of notions of public engagement and citizenship at various levels of government. In the absence of social consensus about issues such as genetic research and the cloning of embryos for research, we have seen a proliferation of the activities of expert groups in this domain. Paradoxically, many of these bodies are concerned in part with advising on lay perspectives on these developments.

### Policy responses to a 'crisis of trust'

Public confidence in the effective management and regulation of science have been the subject of policy discussions for some time. In the UK, this concern has been focused on problems in the agriculture and food sectors. Here, Irwin traces a new phase in the construction of scientific citizenship to the late 1990s (Irwin, 2001). A key marker here

was the Government's Public Consultation on the Biosciences, which was concerned with the lack of faith in the regulation and oversight of science and innovation.[33] In the course of time, public trust came to be viewed as a key measure of success or failure in this field. 'Open government' and 'transparency' were posited as responses to a crisis of trust in the management and regulation of science (Jones and Salter, 2003:32-33).

We have undoubtedly seen an increase in the number and scope of consultative processes in the field of science policy in the UK and Europe in recent years. Both government bodies and influential public bodies like the Royal Society and the Wellcome Trust have adopted practices associated with 'public engagement'. In addition there has been a marked trend towards 'transparency' of decision making, at least in the sense of availability of information about the deliberations of committees and public bodies, and about their membership. However, a number of commentators suggest that both the transparency and the democracy of science policy are deserving of closer scrutiny.

Jones and Salter suggest that, in the field of human genetics policy, transparency occurs largely at the stage of implementation, rather than at the agenda setting and formative stages (Jones and Salter, 2003:35). They refer to the HGC and other quasi-official bodies, such as the Nuffield Council here. In addition to online publication of proceedings, the HGC conforms to models of open government through including lay representatives in meetings, holding some meetings open to the public and media, and undertaking wider consultation. However, the rationale for such work is characterised in

[33] I draw on Irwin's description of this exercise (Irwin, 2001). The report on the consultation was published in 1999: Public Consultation on the Biosciences, Report of the Advisory Group to the Office of Science and Technology.

terms of the public having access to the facts and analysis that underlie regulatory decisions, and some limited opportunity to comment on these (Jones and Salter, 2003:35). Looking more closely at 'transparency', they find that what is revised is the assumption that a deficit of information suggests a deficit in lay people's ability. However, they argue, in many of the documents relating to public policy in human genetics, the assumption that, if the public had the appropriate information, they would support the new technology, has been retained: 'This is where transparency reinvents the deficit model' (Jones and Salter, 2003:34).

Many recent initiatives by government and related groups are informed by an awareness of a wider range of 'stakeholders' than featured in earlier policy modes, including members of the public. Nevertheless, the discourses of active citizenship which feature in science policy commonly mask the limited involvement which is offered to citizens via the consultations associated with this mode of governance. Underneath the 'public's right to information', we can detect a corresponding public duty to become informed and involved (Kerr, 2003a). Notwithstanding the proliferation of information and consultation events though, there are few routes to substantively influence research priorities and regulation.

The role allocated to the public's views on developments in genetic technologies in the inquiries undertaken by these bodies has tended to mirror the tendency elsewhere. Often, the public's views have been sought on the implications of such developments, rather than on questions about what research should be conducted or what new technologies should be accepted. For example, the HGC report on the use of human genetic information concentrates on issues around informed consent, and brackets questions

about commercial involvement in medical research and concern about the impact of patenting on this domain (HGC, 2002; Kerr, 2003b).

In exploring the implications of policy discourses in this field, Jones and Salter locate these in relation to several 'modes of governance' ranging from the elite science model - characterised by decision making by closed committee, with the input of scientific experts being decisive - to the democratic model-open - adversarial, incorporating widely different viewpoints.[34] Between these is a pragmatic model, 'a corporatist mix of the constituencies involved, closed, but involving non-experts-effectively an adaptation of the traditional model with an emphasis on managing efficiency'.[35] In scrutinising the relationship between the undoubtedly prominent discourses associated with democratic model and the practices of government, they note the tendency for policy makers to withdraw into insider networks when the pressure is on (Frewer & Salter, 2002, cited in Jones and Salter, 2003:34). Thus it is the relationship of the outcomes of those inquiries

[34] Jones and Salter base their analysis of different modes of genetic governance in the UK in part on a discourse analysis of key documents in this field including consultation documents produced by the state and relevant official bodies and those of selected stakeholder groups. The consultation documents produced by the Human Genetics Commission feature strongly here. Other source documents are fully listed by the authors (Jones & Salter, 2003:27).

[35] Irwin places these dynamics in the context of shifts in UK science policy during the course of the 1990s. One marker of these shifts was the influential government review of the biotechnology framework held in 1999 championing processes of open government. See note 27. Irwin points to a number of other influential reports that emphasised the need for greater openness and transparency in government in response to a 'crisis of trust' in science and its regulation. Notable amongst these is the House of Lords Select Committee on Science and Technology report: HL (2000) Science and Society 3rd report, London: HMSO.

which deploy more democratic processes to other levels of state governance which operate on more traditional elite lines which are under scrutiny. The case of stem cells is used here as an example. It was recognised in the course of a public debate that some citizens opposed the use of embryonic cells, wherever limit was place on their maturity, for research. The matter was resolved - or appeared to be resolved - by a return to a reliance on traditional scientific authority, the input of which was decisive in framing the subsequent legislation (Jones and Salter, 2003:37).

One area of policy rarely considered to be within the scope of public participation is that of the regulation of commercial involvement in research. Kerr identifies some shared assumptions about the contribution of commerce to security and justice in the genre of advice giving of the bodies I have referred to above:

> *The spirit of capitalism involves investment, innovation and scientific progress for the public good, balanced with the need to reward individuals and corporations for their inventions.*
>
> (Kerr, 2003b:149)

If the mechanics of progress in science were traditionally assumed to be linear, indeed straightforward, so too it was traditionally the case that commercial interests and public sector research could easily be distinguished from each other. Neither assumption can be maintained in a time of intense developments in genetic research in which collaboration between industry and the state is extensive (Lewis, 2004). Nowhere is this more so than in the field of population genetics, where there is considerable enthusiasm on both sides for such collaborations.

## VII Concluding remarks

We can see in the new national biobanks an intertwining of economic aspirations and scientific projects. The Estonian biobank is perhaps the most emphatic about the importance of the initiative to the national economy: its proponents exalt the commercial success of its Finnish neighbours and suggest that the biobank might become 'our Nokia', generating similar wealth (Simm, 2002; International Special Reports, 2001, cited in Fletcher, 2004). The Republic's President celebrated its anniversary with a speech underlining the development of biotechnology as one of three key factors in the Republic's progress since the restoration of independence. In Iceland too, a prominent reason given by supporters of the National Health Sector Database for the project being in the national interest is its creation of high tech jobs and stimulation of the growth of the domestic biotechnology industry.

In the UK too, concern about staying at the forefront of developments in biotechnology is pronounced in current policy debates. The early discussions about a national biobank project refer to innovation, international competitiveness and the UK's place in the global knowledge economy. Here, partnerships between the NHS and commercial organisations are seen as critical to the government's agenda (Gould, 2003). Likewise, the commercial sector requires the involvement of the public sector to be able to undertake population genetic research (Fears and Poste, 1999). The kind of collaborations which are sought are highlighted in the 2003 Genetics White Paper (DH, 2003) and in a recent official report by the Department for Trade and Industry's Biotechnology Innovation and Growth Team (BIGT), which argues the need to promote clinical research in the UK.

> *The NHS is a unique institution globally, providing a gateway to the largest single pool of patients in the world, and caring for those patients from cradle to grave…The NHS should be a leader in clinical innovation, with the infrastructure and the expertise to support cutting edge clinical research that improves patient care. Such a capability would provide a significant competitive advantage for the UK bioscience sector, which no other country would be able to match. It would act as a clear incentive for companies to establish themselves in the UK.*
>
> *(BIGT, 2003:7)*

The aim of keeping the UK 'at the forefront of modern health research and technology' (MRC, 2002) encompasses the twin goals of providing health benefits and generating wealth through the biotechnology industry. The emergence of the UK Biobank can be viewed in this light. Yet the implications of deploying the NHS patient population as a 'central resource for an emerging market in genetic information' (Martin, 2001:181) are rarely addressed in these discussions. Nor do the new regulatory and governance frameworks which have been described above fully confront the regulation of this kind of market.

It is evident from the developments described in this chapter that the uses to which donated blood can be put have changed beyond recognition. Donated blood samples have become an immensely valuable resource, both for commercial and for public health research. Commercial tissue banks, population collections, and national biobanks have been developed as resources for the new agenda of population genetic research. If the

proponents of these argue that they have enormous potential for the understanding of common diseases, it can be countered that they also have enormous potential for controversy. Historically, in Britain, donating blood was seen as being of direct benefit to others in one's community, and the management of such blood was seen as a realm entirely separate from commerce. I have described how the concepts of altruism that are associated with traditional blood donation have been deployed by public bodies in relation to the new biobanks. However the picture I have drawn in this chapter is one of extensive, complex and multi-layered interactions between public and private initiatives in the field of genetic research and biobanking.

I have sketched the development of a number of national biobanks, and of UK Biobank in particular, and reviewed some of the policy and regulatory frameworks in the field of medical research. There have been significant and important changes here in recent years, which have begun to shift the historic pattern of reliance on self-regulation by the medical profession. However, these changes do not address the question of the commercial use and exploitation of tissues donated in 'public' contexts (such as NHS hospitals or GP surgeries).

Meanwhile, new 'modes of governance' are evident in the broader field of science policy. These stress processes of active citizenship and of transparency in government in response to a 'crisis of trust' in science. However a feature of the development of UK Biobank has been a reliance on traditional scientific authority, a reluctance to open the scientific rationale and protocol for the project to wider scrutiny, and an impression given of a closed circle of decision makers. These styles of decision making, which would have been unremarkable perhaps fifteen years ago, contrast sharply with the democratic and

pragmatic modes of governance which are currently prominent in UK science policy. It is unlikely that though that the biobank can be shielded from the influence of these other debates and the expectations generated by them.[36]

In the field of genetic research, with the range of uncertainties of outcomes and consequences which are entailed, individual choice has become a mantra indispensable for policy (Kerr, 2003b). This resonates with the emphasis placed on the informed consent of individuals in the expert deliberations of bioethicists. Meanwhile key decisions have been made on research using such techniques, and indeed on the establishment of a national biobank. But unlike some scientific initiatives, which can weather opposition, population biobanks depend fundamentally on contributions from large numbers of lay people. More precisely, they depend on the donation of samples of blood, in addition to consent to use of their data for wide-ranging research. In the light of the challenge of enrolling support of this magnitude and level, it is notable that in the UK, as elsewhere, proponents of a national biobank have situated it within a narrative that invokes a distinctive national identity and capacity for innovation.[37]

[36] The establishment recently of an Ethics and Governance Council (following in the footsteps of the interim Ethics and Governance Group, whose work and position I have described above) would seem to indicate some recognition of these expectations. It is not clear though how it will interpret its mandate, nor whether it will have the power of veto over the uses of samples that is proposed in the Genetics White Paper (DH, 2003: 68). The suggestion that the *participants*-or their representatives - should have such a power does not appear to have permeated policy discussions at this level.

[37] I draw on Fletcher's analysis of the Estonian biobank, to which I referred in the previous chapter

We are left with some questions about these new developments. How will donating blood for such biobanks be viewed in the UK? Can we see blood donated for this kind of project as a 'gift', in the sense of an unconditional contribution to a national endeavour? And is reliance on informed consent a sufficient model for protecting the interests of participants in genetic biobanks? Whilst I have reiterated important questions about the legal frameworks and regulatory mechanisms for these, my thesis does not deal with these directly. Rather, it is concerned with the wider social and cultural context of donating blood for biobank in the UK.

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and shall return later in the thesis (Fletcher, 2004). See the UK Department of Trade and Industry (DTI) White Paper 'Excellence and Opportunity' (DTI, 2000) for an indication of the importance attributed to a positive public outlook on science, and the commercialisation of research undertaken in the public sector, for Britain's 'knowledge economy'. The theme of the dual benefits of genetic research for the NHS and the economy recurs in the Genetics White Paper (DH, 2003:70).

## Chapter Three: re-reading Titmuss' 'The Gift Relationship'[1]

### I Blood, Titmuss and nostalgia

Blood donation has long been a dramatic symbol of interdependence. Overlaid onto this symbolic and biological potency, the ambiguity about whether blood is a gift or a commodity has existed for some decades (Starr, 1999). The possibilities for using donated blood have expanded substantially since the 1940s when blood depots were first set up in Britain, and recently culminated in the development of large-scale research using genetic information derived from blood. Although some important technical developments underlie the emergence of such biobanks, the questions that have been raised to date about them have less to do with these technologies, and more to do with what might be called the 'regimes of value' that govern them (Appadurai, 1986:4). They concern especially the deployment in commercial contexts of genetic information derived from donated blood, and the challenge posed to public policy by this development (Knoppers et al, 1999; Martin, 2001; Kaye, 2004). The tension between seeing donated blood as belonging to the common good and as a commodity is managed differently within different national regimes.

In the previous chapter I observed that the metaphor of donated blood as a 'gift' has re-emerged in the context of formative policy discussions in the UK about the use of blood for large-scale genetic research and biobanks. I suggested the revival of

[1] Throughout this chapter references to Titmuss' work, unless otherwise stated, are to the new edition of The Gift Relationship that incorporates additional chapters on the current context of blood services and transfusion medicine (Oakley, A. and Ashton, J (Eds), 1997 *The Gift Relationship: from human blood to social policy* by Richard Titmuss. London: LSE Books).

traditional concepts is also evident in other aspects of the discussion about contemporary developments of genetic research in the UK. In this chapter I shall revisit Titmuss' work on blood donation and review the substance, context, trajectory and influence of that work. The interpretation that I shall put forward emphasises the systemic approach taken by Titmuss in 'The Gift Relationship' (1970), and challenges the way that this work is often represented as a tale about individual blood donors' generosity. Let us take a recent example, one amongst hundreds in which Titmuss' gift relationship is cited in policy and literature on blood transfusion:

> *In this country, unlike some others, the donation of blood remains a 'gift' (as Titmuss portrayed it) with no money being offered or taken. This is not the case in some other countries where blood donors are paid.*
>
> (Chief Medical Officer, 2004:29)

By invoking Titmuss in this contemporary policy document, the Chief Medical Officer evokes a sense of history and of national identity yoked to a model of blood donation in this country as altruistic. The absence in this statement of an acknowledgement that blood is imported (primarily from the US), is notable.[2] This characterisation tends to bracket the importance of the systems through which blood - and now other donated tissue - is donated, exchanged, and used.

Indeed, nostalgia about blood donation is tangible in both policy and popular discourse. This can be traced to the origins of the blood service during the Second World War. In the UK, blood depots were first set up in 1939, to meet the needs of air raid casualties, and were seen as proving their worth at the time of Dunkirk (National

[2] Due to the risk of transmission of CJD, the NBS has depended for some years on commercial sources of plasma (Watson, 2001).

Blood Authority, 1996). The image of the National Blood Transfusion Service, established in 1946, is welded to the war and post war years. As members of the Royal family donated blood alongside factory workers, donors enacted a drama of national solidarity. Those who remember the 1950s and 1960s, about which Titmuss wrote, talk of a visible, tangible community feeling in the blood donor sessions, where 'everybody knew each other'.[3]

## II Re-reading Titmuss

Over the years a particular reading of Titmuss has often been taken up in the clinical and policy literature on blood donation. In this reading, the idea of donated blood as a gift is used to denote the altruism that is attributed to individual blood donors.[4] Considerable effort has been expended in identifying what distinguishes these individuals, and what accounts for their altruism (Piliavin, 1990; Piliavin and Callero, 1991). Thus a book about the social organisation of health services with particular reference to blood became associated with the idea of individual altruism, and continues to be used as a point of reference for this. This can be explained to some extent by the circumstances of the publication of The Gift Relationship (TGR). It was the last work to have been published during Titmuss' lifetime, and so for many it stands as a culmination of his work on welfare as a whole. Certainly the passion for the moral importance of altruism is evident in this book. However, I would argue that the emphasis on this dimension by many reviewers of the book, and the blurring of its reception with the obituaries which followed a couple of years later, has obscured the

[3] Peter Howells, now archivist to the NBS, talking of donor sessions at Stockport in the 1960s, on Jonathon Miller's BBC Radio programme 'The Nation's Health', September 2002.

[4] See Piliavin (1990) for a review of the psychological research on blood donors that includes a consideration of this search for altruism.

detail of the empirical studies in which the arguments were embedded. Titmuss was very much concerned too with the practicalities of mutual provision of health services and blood services in particular, as well as the more general issues entailed in the shift from informal helping to formally organised help. An illustration of this is to be found in a paper on 'Social welfare and the art of giving', published shortly before he embarked on the research for TGR. In it, he mourns the erosion of institutions that had emerged from late nineteenth century working class traditions:

> *By means of a great network of friendly societies, medical clubs, chapel societies, brotherhoods, co-operatives, trade unions and savings clubs, schemes of mutual insurance were developed as a method of prepayment for services members could claim when they were in need- in sickness, disablement, unemployment, old age, widowhood, and death. The 'good' risks and the 'bad' risks, the young and the old, shared one another's lot.*
>
> (Titmuss 2001 [1965]:165)

The compassion expressed through this provision, the hatred of the unjust Poor Law are of course important in this account. But in this paper, which - given its date and its subject matter we can see as a precursor to TGR - the emphasis is on the practicality, the effectiveness, the mutuality of these arrangements.

The aim of this chapter is to depart from the reading of Titmuss that has predominated in much of literature on blood donation, and to set out some other interpretations of the relevance of Titmuss' work for my current interests. I seek to re-embed Titmuss' 'gift relationship' in the context of the interest in systems and policies that underlay it. I shall begin with a description of the empirical work undertaken for the book, which has tended to recede from view. In reviewing the influence of this text, I also acknowledge some of the critiques and differing interpretations of his work. Although

there is an active reappraisal of Titmuss' legacy for the field of social policy I only touch on this vast subject here. More relevant to my concerns here are the changes that have occurred in blood services since the 1970s, and I shall briefly consider the implications of these. Returning to the point about the systems I shall consider the anthropological literature about gift relationships from which Titmuss drew some inspiration, and the implications of more recent theoretical work about gift relationships. Finally, I shall return to consider the significance of the deployment of this concept in the context of what Tutton calls the new 'informational economy' surrounding donated blood for donated research (Tutton, 2002:537).

## 'The Gift Relationship' (1970)

Titmuss begins by examining the question of demand for blood and its derivatives, noting the increasing need for blood associated with developments in medicine and surgery in particular. That increased need was associated with a problem of supply, despite an increase in the proportion of blood donors in the UK population over the previous 20 years. However, as Titmuss noted, there was an imbalance between the attention being given to supply and to demand: 'Very little [was] known, medically and sociologically, about who receives blood and why' (Titmuss, 1997:197, my brackets). An important - and prescient - detailed discussion about 'wasted blood' follows, including problems of unjustified use of blood by clinicians. Titmuss goes on to marshal the available international data on blood demand and supply, with an emphasis on the UK and the US. In the case of the US, the lack of a single national or state level programme for blood is seen as causing complex problems, as for example in the case of hospitals regularly cancelling surgery because of lack of blood, yet tending to hoard supplies until they became outdated (113).

Titmuss famously saw voluntary blood donation as 'a gift'. Less well known is the typology of donors he set out in the course of grappling with the problem of defining a 'voluntary community blood donor' (140). A range of types were delineated, depending on varying forms of reward or inducement available to the donor (128-141). Not all unpaid donors have the same status for Titmuss: his typology includes a continuum from 'the captive voluntary donor' (in the armed forces or in prison) to 'the voluntary community donor'. The patchwork of provision for blood donation and supply in the USA threw up diverse arrangements for donors.[5]

For Titmuss, 'the voluntary community donor is the closest approximation in social reality to the abstract concept of a 'free human gift' (140). Without immediate reward or sanction, these donors would donate blood 'for unnamed strangers without distinction of age, sex, medical condition, income, class or ethnic group' (140). This ideal donor type, then, symbolised Titmuss' ideals of mutual social provision for medical need, regardless of social standing. For theoretical, moral and practical reasons, these donors were of great interest to him.

After noting the absence of a substantive study of characteristics of blood donors in England & Wales, Titmuss went on to set out the details of his 'pilot study'[6] of 3,800 donors, undertaken in 1967 in three hospital regions of Birmingham, Manchester and the metropolitan South-East. Questionnaires were the main form of data collection for the study. A good deal of the data collected via this method was concerned with delineating the demographic profile of blood donors, data which I shall not review in

[5] Interesting examples of these are 'the family credit donor' and the 'responsibility fee donor', who together - according to Titmuss' estimates - made up approximately 50% of blood source in the mid-1960s (150). These forms of contracted arrangements are discussed below.

[6] The full study was never undertaken.

detail.[7] Of more interest to the thesis is the data collected on motivation. The replies to a question about 'why you first decided to become a blood donor' are coded and described in the following categories: altruism (a general desire to help); gratitude for good health; reciprocity (wanted to repay blood received by self or friends or family, or in anticipation of the fact the blood may be needed by them); replacement (of another donor who could no longer give blood); awareness of need for blood; duty; war effort/defence services; rare blood group; to obtain some benefit (e.g. learning blood group, health checks); personal appeal; general appeal, and miscellaneous (293-303).[8] The frequency of replies expressed in terms of altruism, reciprocity, replacement and duty is remarked on by Titmuss: 'Practically all the donors whose answers we set down in their own words employed a moral vocabulary to explain their reasons for giving blood' (305). However, this was not seen in terms of 'pure altruism':

> *No donor type can be depicted in terms of complete, disinterested spontaneous altruism. There must be some sense of obligation, approval, interest; some feeling of 'inclusion in society; some awareness of need and the purposes of the gift. What was seen by these strangers in the here-and-now could be (they said or implied) a good for themselves-indeterminately one day. But it was not a good which they positively desired for themselves either immediately or ultimately.* (306)

[7] Titmuss concluded that the donor demographic profile was broadly similar to that of the general population, after taking into account the age limits set out by the service, and medical and social factors affecting blood donation by women of childbearing age.

[8] I do not give the numerical breakdown for these categories here: Titmuss himself acknowledges the sometimes arbitrary distinctions made by coding in this way. How to distinguish between altruism, reciprocity and duty? The donor's own vocabulary was used as the basis of coding (297).

Contrary to popular belief that all donors in the US were paid, Titmuss estimates that 'about one third of all donations were bought and sold' (150). Just over half the donations were made in the context of some kind of contract. Most of these were either 'the family credit donor' - who makes a predeposit donation of one pint of blood each year in return for which he and his family are 'insured' for their blood needs for one year or the 'responsibility fee donor' - where the recipient of blood was charged a fee, to be refunded if they subsequently donate blood or find someone to do so on their behalf (135). Most of these donors were men. Although the picture seems to have been more complex than was subsequently represented in both popular and academic quarters, there is no doubt about the existence of poor and destitute blood donors. As one blood bank director noted at the time: 'One of the most important [ethical considerations] is exploiting for its proteins a population which is least able to donate them - the poorly nourished skid row population' (Greenwalt, 1966, cited in Titmuss:170). Some blood donations were unpaid and not contracted under any of the systems described. However, there is an intriguing absence of perspectives or voices from American donors (paid or unpaid) in Titmuss' work.

Whilst it is the motives of individual donors which have captured popular and academic imagination, Titmuss' concern was very much with the blood programmes, rather than with individual donors motives and behaviours per se. He proposed that the act of paying donors at the beginning of the chain cascaded into a set of consequences for the system as a whole. The different systems for managing blood are discussed in the context of different medico-legal regimes in the US and the UK.[9]

[9] Titmuss observed for example that costs of US medical system in general included expensive malpractice insurance and defensive medical practice.

Included in the comparison is a review of available evidence on the risks for those receiving blood and its products. The risk of 'contaminated blood' (serum hepatitis infection being the main concern at that time) is reviewed in relation to donor characteristics and selection in the different systems. In tackling the problem of contamination of donated blood, donors' self-disclosure of health history was seen to be vital. Donor truthfulness is an issue which has continued to preoccupy those concerned with providing blood services, and has been addressed in terms of individual personality characteristics by numerous psychological studies. For Titmuss, appropriate disclosure would be facilitated by a system in which donors received no incentive or payment. This point was pivotal in his argument that 'a private market in blood entails much greater risks to the recipient of the disease' (214).

Titmuss was equally concerned with other elements of the blood programmes, for example with problems he identified with the commercial incentives in the preparation of blood products by commercial laboratories, as well as higher administrative costs and problems of co-ordination in the market system (271). Thus the analysis encompassed practical, social and moral considerations. Notwithstanding the detailed analysis of a mass of empirical data on blood, the enduring feature of the study is an exploration of the social meaning of blood donation. Subsequent developments left the two blood donation systems which Titmuss wished to compare hardly recognisable. It was his underlying moral arguments and his championing of the importance of mutual provision for health care and welfare which were ultimately to prove his most important contribution (Reissman, 2001; Oakley and Barker, 2004).

## The influence of 'The Gift Relationship'

'The Gift Relationship' was not without its critics, some of whom challenged its fundamental tenet that paid or voluntary donation was the crucial factor in explaining the efficiency of the different systems in the US and the UK. We can see, even in Titmuss' own text, that comparison of other national regimes in which donors were paid would have tested the assumption.[10] Nevertheless, the book is credited with playing an important role in policy. In the US, a task force was appointed, with the subsequent development of a national blood policy which aimed to move towards a voluntary donation system.[11] In the UK, speculations by economists about the advisability of paying blood donors remained in the realm of academic discussion and had no discernible influence on policy. A number of recent discussions by those involved in formulating clinical and public policies about blood donation testify to the extent to which Titmuss' work continues to be influential, both in the UK and internationally (Robinson et al, 1999; Berridge, 1997).

The book is widely held to be a classic of social policy, a foundational text. It replaced 'the traditional conceptual framework for policy analysis focusing on administrative aspects with one that seeks to understand the underlying objectives of different social policies' (Oakley and Ashton, 1997:8). At the time of its publication though, this status might not have seemed assured as the arguments made in the book

[10] Other factors have been put forward which may have explained the differences in 'contamination' of blood in the different systems, including technical factors in blood banking.

[11] The representation of commercial firms on the bodies concerned with bringing in such a system limited its efficacy; however the proportion of paid donors in the USA decreased in the course of the 1970s, and the FDA tightened up its surveillance of commercial blood banks and brought in a ruling that blood had to be labelled 'paid donor'/ 'unpaid donor' (Oakley and Ashton, 1997:6).

attracted criticisms from a whole array of disciplinary perspectives.[12] Amongst the anthropologists there was a view Titmuss made only 'token' use of anthropological theory gift on relationships (Leach, 1971). Summing up some of the criticisms with the benefit of hindsight, Oakley and Ashton point to 'a tendency to idealise giving as not only social, but somehow natural…misunderstanding the anthropological literature in casting the giving as somehow essentially virtuous' (Oakley and Ashton, 1997:8). Economists subsequently discussed Titmuss's turning upside down of economic theory at some length; his identification of the problem of adverse selection (amongst 'suppliers' or paid donors of blood, resulting in the problem of 'bad blood') feeds into a longer running conundrum of economic theory. But for economists, Titmuss' incursion into their territory is generally seen as rather suspect.[13]

Several of the critiques may be more directly relevant to this discussion. Firstly, it is suggested that Titmuss had a tendency in some parts of his work to essentialise a social and biological need to help. Critics question his 'assumptions about the altruistic potentialities of average citizens' (Pinker, 1971:211, cited in Page, 1996). Secondly, Titmuss - like Mauss (1990[1950]) - drew on theories of gift relationships in traditional societies to address their concerns about social cohesion in the face of modern forms of society. Yet the leap made by Mauss from ideas about gift relationships to systems of social insurance is questioned (Douglas, 1999).

Whilst academic debates about Titmuss have tended to be characterised by a concern with points of theory, there has also been a tendency for Titmuss' work to be

[12] A number of criticisms were also made about the methods and analysis used by Titmuss and his research team in the study. Rapport and Maggs (2002) revived an earlier discussion of these points in the course of calling for more substantive and rigorous empirical research on the motives of egg donors.

[13] See for example, LeGrand (1997).

subsumed into ideological arguments. We can attribute the mixed and prickly reaction to 'The Gift Relationship' partly to its stepping on diverse disciplinary toes, and partly to the passionately political nature of its characterisation of the blood donor system in the British welfare state. Despite - or because of - extensive discussion and criticisms levelled at it, the image or metaphor of blood donation as a 'gift to strangers' (281) with a moral dimension is evident across the different sets of literature on blood donation. Although Titmuss' ideas continue to reverberate through debates about blood donation, there is a tendency for such work to take up individual themes from his work, notably the ideal of the altruistic donor, and the risk of 'bad blood' from paid donors.

## Changes in blood services

The ways in which blood services are organised have altered substantially since 1970. Amongst these many changes, it is the implications of newly discovered infections that have received the most attention from social scientists.[14] These risks and the way they were managed are seen as posing a threat to the legitimacy of and trust in blood services, across different kinds of national systems.[15] With the advent of HIV/AIDS and the related transfusion crisis (in which infection with HIV was the consequence, for some, of receiving blood) the question of accountability of the much vaunted state system was raised. In France for example, the system floundered despite the absence of a market in blood, and state officials were incriminated of colluding in lies which

[14] Note however that the recognition of the risks entailed in transfusing infected blood has long been a part of the challenge faced by blood services: at the time that Titmuss wrote the main identified risk for blood recipients was infection with hepatitis. The possibility of donors not telling the truth about their health status famously formed a part of Titmuss' argument against the use of monetary incentives at any stage in the chain of blood supply.

[15] See for example, Waldby, 2004; Murphy 1999.

had catastrophic consequences for recipients of blood action (Casteret, 1992:229, cited in Godbout and Caille, 1998). In the US, private firms applied preventative measures with alacrity, for fear of legal action. Technical developments (HIV/AIDS tests for donors and heat treatment of blood) were to resolve the crisis, but different national regimes implemented these at different times; the US was the first to implement routine testing of donated blood for HIV.[16]

The partial resolution of the HIV crisis, insofar as management of blood products is concerned, has not put an end to questions about infection via blood products. Whilst technologies are being developed to test for newly discovered risks, these risks can only be managed by the traditional methods of screening donors via questions about their health history: this screening becomes ever more complex. Nevertheless, the risk of transmission of CJD in the blood of UK donors has for some years resulted in the dependence of the NBS on commercial sources of plasma, primarily from the US (Watson, 2001).

A less-studied aspect of change is the development of technologies that have transformed the way that blood is used. Today, most donated blood is used in the manufacture of blood products.[17] These are then regulated to manufacturing standards. Whilst attempts to manufacture 'artificial blood' have not to date been successful, we can see the emergence of hybrid products as having already changed

[16] An FDA approved test failed to find approval amongst the UK authorities, who introduced HIV testing some 6 or 7 months later with techniques developed by British and Dutch scientists (Berridge, 1997).

[17] This process of transforming blood into products had already started in the late 1960s. However, the proportion of blood collected in the UK that is processed to make products has now increased to around 95% (Martlew, 1997).

the landscape of blood supply.[18] Such manufacturing processes entail commercial arrangements. In Britain, the NBS charges the NHS for each unit of blood supplied, and maintains large tissue banks that it aims to use in collaboration with research organisations (NBS, 2002). There is an established, legal trade in blood, although within the UK payments are calculated to cover only the cost of production, transport and so on. Global commerce, disease and travel have had an impact on blood policies and services to the extent that they can no longer be regarded as bounded by national domains (Kate O'Neill, 2003).

To what extent, then, Titmuss' work on blood systems be seen as standing the test of time? Clearly, the argument about blood contamination has been complicated by the developments described above, highlighting the point that the importance of technical factors in blood banking were perhaps underestimated by Titmuss. But the assertion that for both practical and moral reasons, policies should not allow for a payment of blood donors has continued to influence policy both in the UK and in the USA (Oakley and Ashton, 1997). In Europe, debates about the moral and practical importance of unpaid blood donation continue, and here Titmuss' study is also invoked, albeit with diverse interpretations.[19]

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[18] Thanks to Julie Kent for this point. The EU Directive on Tissues and Cells for Transplantation, which concerns the procurement and management of cells and tissues used for human applications, such as transplantation, extends to such manufactured products.

[19] When an amendment to an EU directive stipulated that members' blood services should ensure that all donations of blood and blood components are voluntary and unpaid, Titmuss' argument that unpaid donations were safer than paid ones was invoked by some MEPs. However it was recognised that the UK had a particular problem with such a policy due to its requirement to import plasma from the USA (Watson, 2001). As is evident from this example, the equating of unpaid donors with safe blood is no longer sustainable as other factors, particularly technical ones are recognised as being central to the safety of blood products. The

One of the difficulties in evaluating the ongoing relevance of Titmuss' work to blood donation is to be found in the lack of substantial empirical work on the impact of the changes in the UK's National Blood Service. These changes include the implementation of increasingly selective criteria for donors, who we can then no longer think of as 'universal donors'; the organisational changes in the course of engineering a national service from a collection of local arrangements; the formalising of the application of manufacturing standards to blood products; and the introduction of charges - per unit of blood supplied - to the NHS (Martlew, 1997). Neither have consequent changes in the ethos for those employed in the service been explored in any depth in the academic literature.[20] In general, the institutional arrangements which govern blood donation have not in recent years been the matter of academic research by social scientists in the UK. An exception is work by Healy, who takes up Titmuss' emphasis on looking at the different systems of blood donation by comparing several blood collection regimes in Europe, and explores the ways in which 'collection regimes … shape the kind of activity that blood donation is' (Healy, 2000:1654).

For Waldby, the continuing significance of Titmuss' work is to be found in its recognition of 'a constitutive relationship between the distribution of biological tissues and formation of social relationships more generally' (Waldby, 2002:309). The

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importance placed on blood banking systems 'based on solidarity' (and unpaid donations) has recently been raised in relation to concerns about umbilical cord banking for autologous uses (European Group on Ethics in Science and New Technologies, to the European Commission, 2004:18).

[20] See chapter 6 for some observations on the staffing of today's NBS donor sessions. Whereas such sessions were previously staffed by medical and nursing personnel, the majority of NBS 'donor carers' are not qualified health professionals. Lay donor carers are trained in venepuncture.

exchange of donated blood or other bodily substance, continues Waldby, is 'simultaneously a technical/material and a social act. Bodies that are materially implicated in each other through tissue donation and transplantation are also socially implicated, and medical systems that exchange and circulate tissues are also social systems.' (Waldby, 2002:309). Waldby is particularly interested in the implications of new kinds of bodily donations, those of embyros, sperm, and other cells and organs, for the social and political economy. However we can also take from her analysis a reminder that the emergence of new kinds of systems for exchanging donated blood merit further consideration, whether they involve 'ordinary' blood donation or the donation for genetic research.

## Anthropological literature on exchange relationships

Despite TGR's adoption by those concerned with blood donation, and in the world of social policy, these professional communities rarely reflect the subtleties of the analyses from the anthropological literature from which the book derives its name. Meanwhile, anthropologists have been critical about the unidimensional deployment of a revered concept, and have not generally been engaged with the debates about donations in this context. In this section I shall briefly review the antecedents of Titmuss' 'gift relationship', and some of the lines of development of this anthropological literature from which I draw out three themes which I suggest can enhance our understanding of the issues currently at stake in blood banking/biobanking. Firstly, the anthropological literature about gift relationships, from its earliest inception, stressed the analysis of gift giving in the context of processes over time and of social structures. Secondly, the recent literature (that is, the literature subsequent to that referred to by Titmuss) challenges the more romantic ideas and discourses about human relationships. Thirdly, more contemporary work

directs us to the possibility of exploitation - or 'symbolic violence', to use Bourdieu's term, under the illusion of giving gifts.

Ideas and schemes about gift relationships loomed large in the anthropology of the early part of the century, prompted initially by observation of ritual exchanges of gifts which accompanied trading or life events in diverse societies. Malinowski's famous Argonauts of the Western Pacific devoted hundreds of pages to descriptions of the kula, 'an overseas network of exchange relationships that link Trobrianders with people living on other islands of the Massim region [in Papua New Guinea]' (Weiner, 1988:9, my brackets). As Douglas notes, Malinowski 'took with him the idea that commerce and gift are two separate kinds of activity, the first based on exact recompense and the second spontaneous, pure of ulterior motive' (Douglas, 1999:vii). The social and symbolic meanings of those exchanges of armshells and shell necklaces in this context were obscured by the overlayering of functionalist theories which are no longer current in anthropological theory today (Weiner, 1992:8). Nevertheless the study continues to be enormously influential in pioneering a detailed study of exchange relationships.

Drawing on Malinowski's and diverse other ethnographic material, Mauss developed a theory of gift relationships which was intended to be generally applicable to 'archaic' societies. In 'The Gift', the emphasis is very much on the reciprocity of giving. One contribution of the study was to 'have introduced a realistic idea of individuals in the pre-market social systems' by incorporating the (modern) idea of self interest, in the context of Durkheimian project. (Douglas, 1990:xiii). The interest in reciprocity in pre-capitalist societies is then deployed in relation to Mauss' concerns about the social transitions faced at home (Mauss, 1950/1990:71-78).

Taking for the moment a simple genealogy of the gift relationship concept which would include Malinowski, Mauss, and Levi-Strauss, we can trace some of the

influence of their ideas on subsequent anthropology (Douglas, 1990). Much of this subsequent work has taken place in the context of thinking about relationships of exchange in both the broader and the narrower sense. The influence of Mauss and Levi-Strauss on economic anthropology has been substantial, but much of this will be outside the scope of the current review. Thinking of anthropology more widely, Douglas points to the way the recording of 'all dues, gifts, fines, inheritances and successions, tributes, fees and payments' quickly became a standard part of fieldwork accounts, with Evans Pritchard's work on the Nuer a notable example (Douglas, 1990:vii ).

The idea that the gift is part of a system is perhaps the most important feature of the anthropological literature as a whole. Most of the literature emphasises the idea of being able to, and indeed obliged to, return a gift. Mauss moved away from idealistic interpretations of the gift to argue that 'gift cycles engage persons in permanent commitments that articulate the dominant institutions' (Douglas, 1990:ix). The idea/l of reciprocity has been an overarching norm in anthropology and in political economics (Weiner, 1992). The more empirical and particular turn of ethnography in recent years though, undermines the fixing of gift giving into one set of meanings. Instead, we have a body of literature with diverse interpretations of diverse practices of gift and exchange relationships.

Much later, work by Bourdieu underlined the differences between the subjective experience of a gift relationship and the view of it 'from the outside'. Bourdieu examined the pattern of gift exchanges over time (Bourdieu, 1977). A gift, as he famously pointed out, cannot be immediately returned without offending the honour of the participants. Thus at the moment that a gift is given, it is not a reversible action. Bourdieu emphasised the way in which (in pre-capitalist societies) gift giving constructed social bonds and obligations as burdensome as those of economic debt.

Ultimately, the ideology of apparently disinterested gift giving is seen as being no more and no less than an imposition of, and complicity with, a symbolic meaning. Bourdieu makes this point forcefully, pointing to the 'symbolic violence' which notions of giving may do to real 'relations of domination' (Bourdieu, 1977:196).

Weiner conducted fieldwork exploring contemporary and historical aspects of the kula in the Trobriand islands, where Malinowski had conducted his fieldwork 50 years previously. In her thinking, the search for fame, success, and immortality, via exchanges with an economic dimension, are motivations which drive the system. Again the theme of illusions is underlined:

> *At the centre of kula are the illusions that exist. A basic premise that underlies kula exchanges is the notion of equality, that is, the exchange of an armshell for a necklace equal to it in value. Yet in practice, partners reach towards the opposite, to gain ever-larger shells that consequently create hierarchy and profit.*
>
> *(Weiner,1988:154)*

In Weiner's ethnography, there is an emphasis on the idea that whilst some possessions are given away as part of a kula cycle, there are others which are 'inalienable: 'Some things, like most commodities, are easy to give. But there are other possessions that are imbued with the intrinsic and ineffable identities of their owners which are not easy to give away…The loss of such inalienable possessions diminishes the self and by extension, the group to which the person belongs' (Weiner 1992:7).

It is not a simple matter to extrapolate from the legacy of anthropological work points of 'relevance' for the present study. One of the strengths of ethnographic

work is its refusal to reduce human experience to points. Sometimes though such work hints at directions which may be worth exploring in a new context. One thing though is clear about this body of literature: it is not about saying certain objects 'are gifts' and others are not, it is about the dynamics of relationships between people. As Frow (a critical theorist) writes 'Gifts are precisely not objects at all, but transactions and social relations (Frow, 1997:124). This perspective highlights the moral and political choices to be made about blood: these choices are about where the limits on commerce are to be placed, and whether blood is to be exchanged within or outside the commercial realm.[21] In addition, I take the analytic implications of the anthropological work I have described to include the need to analyse patterns of 'giving' over time and place (the act or moment of donation should not be the only focus); and the importance of power in rhetoric about giving. Before moving to some conclusions about the implications of the use of notions of gift in relation to contemporary blood donation for genetic research, I shall touch on the wider context of Titmuss' work on health and the welfare state.

## Titmuss on health and the welfare state

It is evident that the experience of the post war years was formative for Titmuss' work about the British welfare state. In his estimation, the experience of the British population during the Second World War sowed conditions which would both allow for and necessitate universal solutions to problems of health and welfare (Deacon, 2002:71). Titmuss believed that a unity of experience and purpose was part of the national post-war experience, and saw in this a partial explanation for the success of blood services. A 'deep nationalism' suffuses this and other aspects of Titmuss' work

[21] On this point at least, Titmuss reading of the theory was clear, for he presents us with (and advocates a position within) that choice.

(Rose, 1981:488). The assumption of the existence of a 'post-war consensus' is itself a subject of discussion amongst historians and political scientists (Webster, 1990). Recent re-appraisals of British post-war history tend to question the universality of experience, and point rather to the importance of compromise and pragmatism in the settlement from which the welfare state emerged (Baldwin, 1990). If the avowedly common experiences of war and sacrifice played an important part in his thinking, the earlier years of economic depression and unemployment had also stoked Titmuss' commitment to a universal welfare system (Reissman, 2001:2). The establishment of the NHS was seen as a linchpin of this:

> *The most unsordid act of British social policy in the twentieth century has allowed and encouraged the sentiments of altruism, reciprocity and social duty to express themselves…In part this is attributable to the fact that, structurally and functionally, the Health Service is not socially divisive…*
>
> (Titmuss, 1997:292)

Titmuss' exposition of a vision of a state in which welfare would be universally available, without means testing or judgement, in contradistinction to the legacy of the poor law and the public assistance system which succeeded it, has continued to be enormously influential (Reissman, 2001; Deacon, 2002). He is credited with influencing subsequent thinking to the extent that we may think of a 'Titmuss paradigm' in social policy.[22] The Titmuss paradigm no longer holds the line in the

[22] Deacon refers to a 'quasi Titmuss paradigm' as being more accurate, for Titmuss' many followers generally 'found his arguments for unconditional welfare more convincing than his belief in altruism…'; interpretation hardened the paradigm to one which came to emphasise material causes of need almost exclusively, leaving out the sense of human agency and engagement which had preoccupied Titmuss (Deacon, 2002:30).

way it once did. Contemporary scholars do question how relevant the stress on universality and comprehensiveness is for British social policy today. But few have questioned the importance and reach of Titmuss' ideas in this field.[23]

## III A challenge to the revival of 'gifted blood' as a framework for policy

It will be evident from this short review that the changes in blood services have significant implications for how we think about donated blood. Important amongst these is the move away from a self-sufficient national blood supply. The implications of this and of technical developments include the inter-penetration of blood systems with trade and commerce at various points in the supply chain. At the same time we have seen the re-emergence of the image of blood donation as a 'gift' with a moral dimension in relation to new ways of organising genetic research.[24] One effect of the revival of this discourse is to shape the debate about population genetic research and the UK Biobank in such a way as to emphasise shared endeavour in the context of universal interests and national heritage. In this debate, members of the British public have tended to be cast as altruists within a particular reading of Titmuss. The idealised characterisation of donors as inherently, and purely, 'altruistic' extends to other areas of policy.[25] A more informed reading of the literature on the gift

[23] With the exception of TGR, Titmuss work on the NHS receded from view and was less well-known than his work on social policy. Only very recently have we seen a re-appraisal of his contribution to the sociology of health and illness (Illsley, 2004) and to a social model of health (Oakley and Barker, 2004).

[24] Some further examples of the use of the term 'gift' and the concept of altruism in these policy contexts are given in chapter 2.

[25]Taking for a moment an example from outside my field of empirical study, it is interesting for example that the Human Fertilisation and Embryology Authority (HFEA) has been

relationship points to an number of other dynamics that need to be taken into account. Later in the thesis, I shall emphasise the idea of mutual or shared interest amongst these.

The idea of a 'gift without calculation', whether in fully industrialised capitalist or in other kinds of societies, has been roundly criticised by anthropologists. Whereas bioethicists seek to draw an absolute distinction between gift and commodity, an approach that draws on the anthropological literature will recognise that blood is both.[26] This then leads to a recognition of the role of institutions such as biobanks in mediating between these two ways of seeing donated blood (Hoeyer, 2002). The challenge for policy goes beyond defining blood as a 'gift' (when it is clearly also a commodity), to negotiating a socially acceptable framework within which information derived from blood can be exploited.

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committed to 'a culture of altruism' (Deech, 1998) in relation to egg donation. Whilst this has provided some protection from such donations being commodified, it also appears to have blinded these policy makers to the interests and practical considerations underlying women's decisions to make such donations. Acceptable donors will be of childbearing age, and likely to be motivated by their own experience of having a family. The HFEA however prohibits the payment of realistic expenses to the women who choose to undergo the medical procedures that are involved in donating eggs. It is now having to reconsider the guidelines which prevent the payment of realistic expenses (for example for child-care) to donors (HFEA, 2004).

[26] There can be no doubt that blood, or rather the genetic information derived from it, has become valuable in the commercial domain (Lewis, 2004).

# Chapter Four: literature review

## I Introduction

Whilst the question of which literature to select for a review is always a strategic one, this is particularly so in the case of the subject that I have chosen for this research. The collection of tissue for large-scale population biobanks is a new practice, and sociological analyses of the implications of these are only just beginning to emerge.[1] There are a number of ways to approach this emergent field. Theoretical concepts of donated blood as a 'gift' has been woven into many of the discussions about the ethics of tissue donation for genetic research, particularly in Britain, a theme whose implications I have begun to discuss in chapters two and three.

The main aim of this chapter is to consider some of the other points of departure that have shaped the academic debate. In parts two and three, I shall review several of the analytical frameworks that have been prevalent in much of the discussion about the new biobanks. I begin with the discourse of bioethics which has been very being influential here. I then move on to delineate some points about the shape of social research on developments in genetics. I discuss the shape of the wider field of social research on 'the new genetics' through several theoretical lenses that are prominent in the sociological literature. Often this literature has a primarily theoretical orientation,

[1] The literature on biobanks dates from the late 1990s, at which time debates about Health Sector Database were underway in Iceland, and a commercial company UmanGenomics gained rights to exploit the material held by a public research biobank in Northern Sweden (Abbott, 1999). Although the Swedish regional biobank attracted some interest in the scientific press, it was not accompanied by same the level of interest as the biobank initiative in Iceland. The literature on the latter is discussed in chapter 2.

and only a limited engagement with empirical work looking at the diverse experiences that surround and shape the implementation of such developments. Following developments in clinical genetics, a focus of research in this field has been the exploration of the implications of genetic screening and testing for those identified as being 'at risk' of serious genetic disease.

I shall then review some of the 'older' literature related to the donation and collection of human tissue in the context of medical research, and the sociological literature on involvement in research more generally. Finally, I shall consider the implications of some recent studies on participation in biobanks for my own work.

## II Bioethics

Discussion about peoples' involvement in medical research has conventionally seen as 'belonging to' the disciplines of medical ethics or bioethics.[2,3] Recently, the social issues arising from developments in human genetics have similarly been defined as ethical issues, and many of the inquiries and deliberations by diverse national and

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[2] Medical ethics is generally seen as an older discipline concerned with ethical issues arising from the practice of medicine, whereas bioethics is seen as a wider body of work concerned with responding to a plethora of new developments in the biological sciences since the early 1970s (Reich, 1994). These include, for example, ethical issues arising from experiments and trials involving human subjects, from dilemmas about intervention at the end of life, and about technologies for assisting reproduction.

[3] Following Weisz (1996), bioethics can be defined in a number of ways relating to key institutions, to discourses, or to issues peturbing public opinion.

international bodies have drawn on the established rubrics of bioethics. To a considerable extent, both academic and policy discussions about biobanks have been influenced in their early years by the bioethics discourse. As I observed in chapter two, the emphasis on discussing mechanisms and principles of informed consent in these discussions bears the mark of the traditional bioethics discourse. My aim here is to review the shape of that discourse, and its implications for these developments.

## The principles of bioethics

The recent history of professional bioethics in the US is well-studied by sociologists and by ethicists themselves. Most commentators agree on the significance of one particular text in distilling for key audiences some of the key principles of bioethics. In an often referred to text book, professional ethicists Beauchamp and Childress (1989) focus on four key principles that have since become associated with the biomedical ethics discourse, those of non maleficence, beneficence, autonomy and justice. The status of this particular text is generally attributed to the authors' achievement in eliciting a manageable number of key principles from a wide body of ethics literature. The first two of these principles - which address the consequences of actions: not harming anybody and, more positively, achieving positive good - are seen as principles by which an intervention can be assessed. Alongside these are those principles associated with deontological approaches, those of autonomy and justice (Dingwall, 2002:161).

These principles have diverse origins, being historically informed, philosophical or legal concepts (Moreno, 1995). Their application to research involving human subjects is conventionally traced to the Nuremberg code. However historically informed perspectives point to more complex trajectories through which such

principles came to be applied in research settings (Hazlegrove, 2002; Nicholson, 2000; Dingwall, 2002). Nevertheless, the Nuremberg code is perhaps the most oft reiterated reference point for bioethics, deriving as it does from an attempt to defend post-war science from association with the abuses of medical practices under the Nazi regime (Hazlegrove, 2002). Reference to these key principles continues through the World Medical Association's Declaration of Helsinki (World Medical Association, 1964) and subsequently in revisions to that declaration, and in key policy documents from both professional and industry groups.

## Principlism and bioethics

The transformation of bioethics from a 'rambling narrative' to a discipline characterised by predictable and accountable decision making frameworks has been traced by Evans (2000:32). In Evans' analysis, the shift in the context of bioethicists' work is given some weight: increasingly bioethicists moved from being involved in particular cases to a position in which they were expected to advise and adjudicate on matters of policy. Whilst I recognise the existence of other approaches to ethics, such as feminist and communitarian approaches, I shall focus on the implications of the more dominant principlist approach. As will be seen below, this approach has been particularly influential in policy.

As the profession grew in numbers and scope, the principles described by Beauchamp and Childress became a point of reference and of accountability for advice given in diverse fields. Notwithstanding the richer approach of the original text itself, those principles became in effect a matrix for decision making. For Evans, their hold can be related to the wider phenomenon of 'formally rational' decision making in modern life (Evans, 2000:32). Making decisions that are visibly proportionate and legitimate

is enormously assisted by the availability of a scale on which such decisions can be assessed. However this simplicity is gained by discarding information or questions deemed to be not relevant to the assessment. This shift to a predictable calculus or moral decision making is analogous to the innovations of double entry book keeping in the world of trade (Evans, 2000). The style of reasoning associated with the new discipline of bioethics, has, he argues, had particular implications for the debate on human genetic engineering in the USA.[4]

The disadvantages of what has come to be called principlism have not gone unnoticed by its many critics within bioethics. Nevertheless, they are often referred to where moral dilemmas are faced by decision-makers in clinical, research, and policy contexts. Arguably this has become something of a ritual:

> *Throughout the land, arising from the throngs of converts to bioethics awareness, there can be heard a mantra…'beneficence…autonomy…justice…'. It is this ritual incantation in the face of biomedical dilemmas that beckons our inquiry.*
>
> *(Clouser and Gert, 1990:219, cited in Evans, 2000)*

Nevertheless, the principles have continued to hold sway, in part because of their

[4] Evans makes the point that debates about policies on controversial genetic technologies, such as those involved in 'gene therapy' and in human cloning have been somewhat taken over by bioethicists in the US. As a consequence, some particular styles of reasoning have dominated, and others (e.g. those of theologians) have been in effect disallowed in the public debate. Evans analysis refers particularly to the deliberations of the President's Commissions that have been charged with making recommendations about the regulation of such technologies (Evans, 2004).

apparent simplicity and clarity.[5] For Evans, this kind of principlism is closely related to the functions of state intervention in ethics, and to the requirements that those interventions be legitimated (Evans, 2000:35).

## Autonomy and informed consent

Within the framework described above, autonomy became 'the default principle of applied principlism, the principle to be appealed to when principles conflict' (Wolpe, 1998:43). For some, this is explained by reference to the political traditions and values that nurtured the development of bioethics (Fox and Swazey, 1984). I shall return to this point below. Others relate the dominance of autonomy to the ease with which this particular principle can be seen to be operationalised. In applied ethics, the obtaining of informed consent from individuals has by and large been seen to be an effective way of operationalising the principle of autonomy. The importance of informed consent in protecting individual autonomy is widely assumed and accepted within the routine work of bioethics in clinical and research contexts. There is, in the relevant journals, a staple diet of papers that focus on boundary cases where, for reasons of vulnerability or incapacity people cannot provide informed consent (O. O'Neill, 2003:4).[6] Similarly, the literature recognises situations where peoples' ability to refuse is compromised by the circumstances or institutions they find themselves in. Within this genre too, there is a discussion about the problems posed by the ideal of individual consent in relation to the case of those public health measures which require uniformity across populations. We can also point to the

[5] Other approaches to ethics, such as feminist or communitarian ethics, have not to date been influential in the debates that I am concerned with here.

[6] The following examples of 'hard cases' are derived from O'Neill's review (Onora O'Neill, 2003).

collection of public health and epidemiological data as activities that are recognised exceptions to the assumption that individual consent is given primacy.

More recently there has been a good deal of work exploring appropriate levels and mechanisms of information. Some of the empirical work here points to a recognition that the balance to be struck between general and more detailed information is not one that is realisable through general guidelines (O'Neill, 2003). In addition to the importance of different contexts, individuals will have very different requirements and expectations (Bekker et al, 1999). Some of the literature discusses the intellectual and practical tensions experienced by those charged with applying general guidelines on these matters to particular clinical contexts. It is not unusual for an elaboration of these difficulties to end in a heartfelt plea for a return to a more traditional paternalistic form of medicine (Corrigan, 2003:787). This oscillation between the ideals of fully informed individual consent, and the messiness of practice also occurs in recent discussions about tissue donation for research.

I shall return to this theme later in this chapter when I discuss the initial debate and discussion about the Icelandic biobank. These debates echoed the influence of the 'default principle' of autonomy and its accompanying concern with informed consent, sometimes to the exclusion of other social issues. Here, as elsewhere in medical research, there are few established mechanisms to recognise, articulate, or protect collective interests. As we saw in chapter three, the absence of attention to such mechanisms is reflected, in turn, in their absence in the systems of governance and regulation that have so far evolved to oversee biomedical research.

## Critiques of the bioethics rubric

The principle of autonomy has been the subject of extensive discussion by, amongst others, sociologists and anthropologists, lawyers, and indeed bioethicists (Frank, 2000). Fox and Swazey's critique of the paradigm of values and beliefs associated with American bioethics was a milestone in the sociological critique. In their analysis, the principles governing bioethics are seen as:

> *an impoverished and skewed expression of our society's cultural tradition. In a highly intellectualised, but essentially fundamentalist way, it [bioethics] thins out the fullness of that tradition and bends it away from some of its deepest sources of meaning and vitality.*
>
> (Fox and Swazey, 1984:34)

Since that time, the criticism of the emphasis 'on the individual and his rights, as opposed to the web of human relationships that engender mutual obligations and interdependence' (Weisz, 1990:3) has been further fleshed out. A number of authors have taken up the analysis of bioethics institutions in a historical context (Guillemin, 1998). However there are few studies of the ways in which other countries have taken up or modified frameworks of bioethics. With the exception of Hazlegrove's study (2002) about the post-war years, the ways in which bioethics has been appropriated in the UK are not well-studied.

An important point to acknowledge is that bioethics is itself a shifting terrain. Frank's review of some recent publications by bioethicists and others underlines these changes, and argues that sociologists have not taken sufficient account of them. One example that emerges from a detailed examination of bioethics in relation to

contemporary medical care is that autonomy is arguably in decline (Frank, 2000; Wolpe, 1998). For, taking account of developments in managed care in the US, it is arguable that very little individual autonomy is available to either patient or physician in new bureaucratic systems of care (Frank, 2000:385). Nevertheless, autonomy remains the dominant principle in the bioethics discourse.

One way to take account of these apparent contradictions is to recognise the different domains within which bioethicists operate. Callahan (1999) distinguishes between the domains of clinical, regulatory and health policy on the one hand, and those which he terms foundational and cultural on the other. The last two are seen as being the territory of the elite professionals whose role includes debating and elaborating the details of a system of knowledge. Callahan likens these to the roles taken by bishops and senior church officials, in contrast to the day to day work of local clergy. Amongst these elite members of the profession then, we find a greater degree of debate and discussion about principles. In contrast, principlism reigns more uniformly in the areas of clinical, regulatory, and health politics. Here, where the processes of bioethics abut official state decision making, accountability is seen to be particularly important. The function of the bioethics principles here is related to the need to legitimate decisions when explaining them to citizens (Evans, 2000).

This sociological analysis of the functioning of principlism illuminates an apparent contradiction between the more sociologically informed bioethics of some academic discourse, and that of quasi regulatory institutions, such as the UK's NHS ethics committees (RECs). These committees, which have undertaken a quasi-regulatory role, are constituted with reference to the more established principles described above. For example the REC members' training materials refer substantially to Beauchamp and Childress' principles. The role of these bioethics on official state

bodies or government studies is better studied in the US, where indeed bioethics has a higher profile role in this context. Kelly's recent study of such bodies in the US suggests that bioethics plays a number of key roles, including managing 'boundary conflicts' and defining legitimate participants in bioethical discussions (Kelly, 2003:340).[7] Although bioethics as a profession does not have the same profile in the UK as in the US, there are nevertheless a number of influential bodies whose deliberations and reports are influential in this field. These include the Nuffield Council and the Human Genetics Commission, whose influence on policy frameworks in relation to the use of human tissue for research are discussed in chapter two. It is notable that these bodies are prominent amongst those drawing on discourses of gift and altruism in this context. The distinctive ways in which the principles and discourses of bioethics have influenced a network of institutions in the UK have not to date attracted empirical study.[8] It seems though that there is a substantial interpenetration of bioethics, policy, and sociology discourses in this particular field.

[7] Kelly explores these arguments through using evidence from the operation of the US Human Embryo Research Panel, a public bioethics committee established by the NIH which played 'an important role in facilitating the political problem of dealing with interested publics on this issue whilst negotiating and reaffirming boundaries between science and public life, and between public and expert judgements in controversial areas of science.' (Kelly:343). The central role of consensus reports by US public bioethics bodies is underlined by Kelly, citing Moreno's work in this context. For Moreno, the influence of such bodies is related to their effectiveness at framing value issues in terms of a wider societal consensus about perplexing questions raised by biomedicine' (Moreno, 1995).

[8] Although there is no shortage of published complaints about the procedures of NHS ethics bodies, from social and medical researchers alike (for example Tully et al, 1999; Lux et al, 2000) few researchers set out to study these institutions as a primary focus.

## Social science and ethics

As social scientists have increasingly engaged with work on new technologies, including genetic technologies, they have made important contributions to the discussion about moral issues which are traditionally considered to be the domain of bioethics. Traditionally, the contribution of sociologists to bioethics been assumed to be one of providing empirical facts to inform the ethicists arguments. This relegation is increasingly being challenged, together with the assumptions underpinning this kind of hierachy of knowledge (Hoffmaster, 2001; Haimes, 2002). Genetic screening in pregnancy and assisted reproduction are two areas where sociologists have made sustained theoretical contribution to the debates, often in the course of writing about empirical work they have undertaken. Sociological work in this field has included work an examination of diverse actual and often unintended social consequences of such interventions, with rather different findings from those found in bioethical discussions (Spallone et al, 2000).

The association of ethics with the normative, and sociology with empirical 'facts' has some accuracy in terms of broad brush strokes. However, an examination of work in these disciplines points to a more complex relationship between these modes. For example, an analysis by Jennings (1990) of the writing about neo-natal intensive care units by ethnographers and by ethicists critiques the belief that their work in this field can be characterised by their respective concerns with normative and empirical aspects. Jennings analyses the different stances between the two approaches along three axes: the degree of agency given to the individual, on the one hand, and the context of agency on the other; the ways of studying and describing moral phenomenon; and finally, the notions of social change held by each.[9]

[9] 'For ethics, the individual is always the primary unit of analysis and the agent, rather than the

I shall briefly review some areas of tension that are evident in the dialogue between the two disciplines. Firstly, bioethicists and sociologists have differing roles in relation to governments. It is notable that whereas the voice of sociology is rarely heard in the public domain or indeed in the networks and committees of policy makers the pronouncements of bioethicists are often to be heard (Spallone et al, 2000). It is striking too that the voices of bioethicists are prominent amongst the expert committees that advise governments on a plethora of new developments. At times their power to define the parameters of debate recalls a style of intellectual engagement that Bauman calls 'legislative' (Bauman, 1992). For Bauman, writing primarily about an earlier era of modern intellectuals, this kind of authority 'involved the right to command the rules the social world was to obey…was legitimised in terms of a better judgement, [and] a superior knowledge guaranteed by the proper method of its production' (Bauman, 1992:11). The universality associated with this mode of intellectual generates an aura of confidence, and, importantly, tends to obscure the particular assumptions of their theoretical frameworks. Continuing the reference to Bauman's model, we can characterise sociologists as 'interpretive intellectuals' par excellence: they have enjoyed a distance from the modern state, conducted their affairs more autonomously, and tended to define their role and expertise more in terms of interpretative strategies.

Secondly, there are the substantial differences in the philosophical underpinnings of the two disciplines. For the modernist philosophers whose work informs the discipline of bioethics, universality and foundationalism are central to the ways they

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context of agency, is the focus. By contrast, ethnography tends to look at the action and agent shaping power of the world. It highlights the context of agency, whether that context is conceptualised primarily in symbolic-cultural or institutional-systemic terms (Jennings, 1990: 268).

have engaged with moral issues (Haimes, 2002:96, and Bauman, 1993:4). In contrast, the irreducibility of human experience to universals is a key tenet of (late) modern sociology. There is, to differing degrees - and notably in ethnography - an emphasis on the particulars of time and place in the study of peoples lives. Sociologists (especially ethnographers, who have been prominent in this debate) claim that this concern with the particular will help 'to connect bioethics more closely to peoples' lives and the situations in which moral dilemmas arise' (Hoffmaster, 2001:7). Many of the tensions between sociology and bioethics follow from these differences in perspective. The consideration of moral questions without reference to their social context, the enormous emphasis placed on individual choice, and the corresponding modelling of social actions in terms of individuals' decisions are subject to criticism from a sociological perspective. For Kleinman, a consequence of modelling ethics as being about a person's individual choices, is that 'it simply does not account for the social processes of moral life' (Kleinman, 1999:72).

A third area of tension has been the different methodological conventions that follow from these philosophical differences. Traditionally, bioethicists have conducted their enquiries with references to particular styles and conventions of moral reasoning, whilst sociologists contributions were relegated to ascertaining and describing facts (Nelson, 2000; Haimes, 2002).

## Autonomy and trust

It is at the frontiers of bioethics that we find some of the most thoughtful critiques of the principle of autonomy, and of its social and political resonances.[10] In reviewing

[10] I am indebted to Frank for this observation: 'Thus if sociological ethnographies of medical practice offer bioethics a compelling reflection of its practices…bioethics - at the frontiers…-

some of these, Frank observes that 'the dilemma of bioethics after autonomy is the dilemma of contemporary social life' (Frank, 2000:394). The obtaining of individual consent to medical procedures and research provides some important protection for patients and research subjects against coercion and harm and, for doctors, against accusations of abuses of various kinds. But it does not seem to increase trust. O'Neill, a philosopher, observes that the quest for trustworthiness has been energetically pursued through 'additional legislation, regulation, and institution building aimed at the discipline and control of medicine, science and biotechnology, and specifically at ensuring that ethical standards are met (O. O' Neill, 2002:126). Alongside this are the new systems associated with the audit agenda, the development of an audit culture that 'actually creates the very distrust it is meant to address' (Power, 1994:13, cited in O. O'Neill, 2002:133).

Some detect a 'new bioethics' that is more adventurous, open, empirically informed and influenced by the sociological critique.[11,12] Yet the tenacious hold of the four principles on the practice of bioethics in official committees and advisory bodies is remarkable. As I have discussed in chapter two, one implication of the dominance of bioethics as a lens through which to consider developments in biobanking has been a tendency to focus on informed consent as *the* linchpin of socially acceptable practice in this context. Autonomy, with its operational analogue informed consent, is

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may be offering an ethical critique of sociology that deserves to be taken equally seriously' (Frank, 2000:393).

[11] See for example Kleinman (1999). However Kleinman acknowledges that 'this is not (at least not yet) the dominant stream of bioethics' (Kleinman, 1999:70).

[12] See also Hedgecoe's call for a 'critical bioethics' which acknowledges the social science critique with a view to developing a more empirically informed and reflexive bioethics (Hedgecoe, 2004).

predominant in many of the policy and academic discussions about biobanks. These points have sometimes seemed to overshadow other issues about the social regulation, organisation, and operational details of the biobanks. In addition they have precluded a consideration of the collective interests that arise from such initiatives, and of mechanisms that may be developed to support those interests (Kaye, 2004).

Fox and Swazey's (1984) seminal analysis of the historical and political formation of bioethics drew attention to the specific ways of modelling moral reasoning and decision making that characterised the discourse. These were then linked to prevailing ideologies and values in American political culture. The assumption of a rational cognitive style of decision making was linked to the quasi-economic idea that costs and benefits of particular interventions or research projects could be calculated. Attention was drawn to the reliance on a model of contractual relations in this most moral area of human activity. Subsequent contributions, particularly those by Evans (2000) and Wolpe (1998) have further developed the sociological analysis of the political roots of bioethics. It is hard to imagine how bioethics might look if shaped by different political traditions. Yet some of the recent literature on biobanks from bioethicists do prompt speculation about this.[13] There is, too a greater degree of cross-fertilisation between different disciplines in these current debates than has traditionally been the case. Nevertheless, where bioethics is directly involved in policy debates and advice, it tends to prescribe formulae which echo the famous four principles. In the next section, I turn to the sociological literature to begin to explore

[13] Chadwick and Berg's suggestion that 'solidarity' be central to the debate about biobanks is seemingly reminiscent of more European political traditions (Chadwick and Berg, 2001). However, in the absence of conventions for applying such principles, this suggestion has remained at the level of academic discussion, rather than being taken forward into the arrangements for governing the new biobanks.

what alternative approaches are available to framing the social and moral issues around biobanks.

## III The shape of social research on the new genetics

My aim in this section is to discuss the shape of the broader field of sociological work on the new genetics, indicating the prevailing theoretical frameworks within which these new developments are viewed. As I have already indicated, the literature on biobanks themselves is quite limited. In general terms, social research in this field has tended to follow the clinical trajectory of developments in genetics. To a considerable extent then sociological work has been focused on those affected by rare genetic diseases and those being screened for these in genetic clinics. Beyond this clinical context, there is less qualitative work about the differing perspectives taken to genetics. At a theoretical level I consider the influence of the governmentality perspective and of the Risk Society thesis. I shall suggest that these distinctive theoretical approaches as applied to work on the new genetics have a common emphasis on the individual subjective management of risk.

### Genetic governance and the management of risk

A number of exponents of a governmentality perspective apply this to their analysis of a range of practices of genetic discourses and practices. These practices include those of genetic testing, screening, and surveillance (Nelkin and Andrews, 1999; Petersen and Bunton, 2002; Novas and Rose, 2000; Polzer et al, 2002). Central to this agenda is an interest in the way that the self becomes defined in terms of genetic make-up. Here, there is a focus on the way that the re-categorising of illness and pathology in terms of genetic susceptibilities creates new categories of 'at risk'

individuals (Novas and Rose, 2000:485). These individuals are then seen as facing new forms of obligations in relation to others, particularly family members (Novas and Rose 2000; Hallowell, 1999, Polzer et al, 2002). For Polzer et al, for example, the practice of clinical genetic testing for malignant melanoma risk invokes three interrelated duties or responsibilities: the duty to acquire genetic risk information to facilitate the early detection of disease, the duty to engage in more precise risk management on the basis of one's knowledge of genetic susceptibility to disease, and the duty to communicate ones genetic risk to family members (Polzer et al, 2003:162). Through the fulfillment of these duties, individuals construct themselves as healthy and responsible citizens. Relational aspects of genetic risk have been explored in some depth in clinical contexts, notably by Hallowell, whose work on 'genetic risk and responsibility' is based on those attending genetic counselling for hereditary breast cancer. As Hallowell's work underlines, whilst such the offer of such tests constructs new choices, there are considerable difficulties inherent in resisting such testing (Hallowell, 1999).

The transformation of peoples' subjectivity and identity through their involvement in the practices of genetic screening and clinical testing have been the focus of interest for many of those working within this theoretical framework. Petersen and Bunton, influential exponents of this approach, define their agenda as a consideration of 'the broad impacts of genetic ideas and technologies on conceptions of self and society' (Petersen and Bunton, 2002:3). A key theme in the genetic governance literature is the process of self-governance, notably through the contemporary ideology of active citizenship (Novas and Rose, 2000). Novas and Rose emphasise the need to explore how genetic practices and discourses operate in conjunction with other social norms, notably the duty to be well - and other discursive constructions of the healthy citizen. The responsibility to prevent and manage genetic diseases is analysed in relation to a

broader neo-liberal ethos of 'enterprising responsible personhood' (Novas and Rose, 2000:488). Their analysis underlines the processes of seeking out of knowledge which 'comes to be regarded as residing in multiple sites, which are to be actively sought and assimilated for purposes of the care of the self and the care of others' (Novas and Rose, 2000:506).

Notwithstanding its aspirations to explore how people are responding to 'the governing discourses surrounding the new genetics' (Petersen and Bunton, 2002) more broadly, work deploying this approach has tended to cluster around clinical genetics. Or more accurately around the implications for those identified as being at risk of a serious genetic disease.[14] There has often been an assumption in this approach that the implications of genetic risk will be transformative across all domains. Whether these notions of transformation will be relevant as genetic technologies become more a part of routine diagnosis, treatment and research across a wide spectrum of illnesses is unclear.

## The 'Risk Society' thesis

Here I aim to consider some of the ways in which the work of Beck and Giddens has been translated into current social research in the field of the new genetics, rather than to give a full overview of their extensive work in relation to risk and trust. In doing so, I draw upon a number of outlines and critiques of the implications of the risk society thesis, written by those involved in empirical and theoretical sociology,

[14] Although they do take their work beyond the genetics clinics, Novas and Rose remain focused on 'those at risk' of a serious genetic disease, and indeed of the more proactive patient groups (Novas and Rose, 2000). Novas and Rose draw on data from webforums and chatrooms for those at risk of Huntingdon's Disease in this paper.

primarily those of Dingwall (1999); Kerr and Cunningham-Burley (2000), Lupton (1999), Lupton and Tulloch (2002).

'Risk Society' begins with an outline of what is seen as the core problem of 'advanced modernity': that 'the social distribution of wealth is systematically accompanied by the social production of risks' (Beck, 1992:19). The hazards which inevitably accompany modernity include those effects of new technologies which are difficult to see, predict or control. A key tenet of the Risk Society thesis is that these hazards produced by complex modern societies are perceived as risks, rather than dangers. Risk, it is said, 'assumes human responsibility and that "something can be done" to prevent misfortune' (Lupton, 1999:3). There is a slipperiness about the extent to which these risks are seen as increased in an objective sense in contemporary societies, or amplified in a subjective sense. The idea of risk has been appropriated in many different ways (Wilkinson, 2002:462), but the assumption that a heightened sense of risk is part of the make-up of today's citizens is widely made.

In addition to the observation that hazards and dangers are conceptualised as risks, rather than as givens, there are a number of interlocking assumptions underlying the risk society thesis (Dingwall, 1999). For the purposes of the present discussion the following themes are important elements of the thesis: the contemporary era of 'late modernity' is seen as fundamentally different from a previous era of 'early modernity'; and the impact of social and technological change in this era is such that there is a loosening of bonds to traditional social roles, norms and certainties for individuals. Several consequences are seen to flow from this: the turbulence associated with 'disembedding' from traditional social forms throws doubt on expert systems of knowledge; and individuals freed from the certainties of authority and tradition are under greater pressure to produce their own accounts of meaning and

biographies of self. Risk is now considered to have taken over from material need as a primary concern. Finally, the emergence of a new kind of politics is postulated in which new alliances are formed in these new political and ethical spaces.

The analytical focus on risk is mirrored in an interest in dynamics of trust in these new contexts, especially in relation to systems of expert knowledge. The dynamics of trust and relationships with expert systems are explored in some depth in Giddens' work.[15] Doubt about the validity of technical expertise is seen as characteristic of this phase of modernity: 'The fact that experts disagree becomes familiar terrain for almost everyone' (Giddens, 1994:186). For both Beck and Giddens, a different quality of individual responsibility characterises the late modern era. This approach is influential across the field of the new genetics, although this field also includes studies by those who are more critically engaged with the Risk paradigm and the assumptions surrounding it. Kerr and Cunningham-Burley have eloquently set out the case for human genetics as a 'case study' in Risk (Kerr and Cunningham-Burley, 2000:294). These authors aim to revisit key features said to characterise the Risk Society - notably individuation, choice, reflexivity, and new political alliances - in the context of a range of interlocking developments around the new genetics. They stress the extent to which in the UK, individual choices about reproduction, health, and lifestyle take place within the context of increasing state and market surveillance on the one hand and a declining sense of collective responsibility for welfare on the other. Here they draw on Bauman's work on the ways in which doubts and fears becomes privatised - as do the projected escape routes from these troubles (Bauman, 1992:xviii). They doubt that new forms of politics are emerging from lay peoples involvement in this domain at present, suggesting that the effect of lay ambivalence

[15] Although Beck is seen as the primary architect of the risk society thesis, Giddens' work is widely seen as part of the framework.

about human genetics is ‘more sedative than revolutionary, remaining largely privatised and inert’ (Kerr and Cunningham-Burley, 2000:294). An important feature of peoples’ experience to which they draw attention to here is that lay people - although they may express a sense of alienation from the representatives of modern institutions - are also reliant on them in many ways (293).

## Lay knowledge and biomedicine

This dynamic of ambivalence on the part of lay people in relationship to medical experts is already a familiar terrain for medical sociologists, in their confronting of the ways in which people choose to depend on modern medicine, as their ‘best hope’ (Williams and Calnan, 1996). The wide-ranging theoretical debate about the politics of knowledge and expertise is embedded in sociological work throughout this field. Both the sociologies of health and illness and of science and technology have been deeply concerned with the problems of differential expertise in relation to technical domains (Williams and Popay, 1994; Wynne, 1992; Irwin and Wynne, 1996). Numerous studies have explored the contests of knowledge that emerge in particular contexts as - increasingly - scientific pronouncements come under scrutiny. When applied to biomedicine, however, these debates are constrained by a recognition of that reliance, or dependence, on the personnel and institutions of this dominant system of medicine.

Nevertheless, the concepts of lay knowledge or expertise, variously defined, have been central to the reworking of medical sociology from a more traditional analytical framework. They are evident too in the literature on lay people’s knowledge in relation to genetics. An example in the field of genetics is Kerr et al’s study of the different kinds of expertise that are held by lay people in respect of the new genetics

and health (Kerr et al, 1998).[16] The extent and sophistication of this knowledge is contrasted with the assumptions inherent in the 'deficit model' of public understanding. These findings are used in support of a call for greater level of lay people on committees and advisory groups, and for 'the calling of lay experts to act as special advisors' (Kerr et al, 1998:58). More recently however, there have been important critiques of the way that the lay/ expert divide has tended to lead to an unhelpful dichotomy. Further, it is argued, experts are expert, whatever their training and provenance. In a sense then the term 'lay expert' is an oxymoron (Collins and Evans, 2002). Nevertheless, these concepts remain prominent in the sociological literature about the relationships of patients with medical personnel and institutions. At a theoretical level, they go hand in hand with the challenge to the notion of passive patients. Linked to this is the political aim of enhancing the power, or at least the voice, of patients and lay people in relation to health care and policy. There are also some methodological implications that follow from the focus on lay expertise, a point to which I shall return in the following chapter. The point that I wish to underline here is that in the context of this work it becomes difficult to address the *limits* of lay expertise, or indeed of lay interest, without seeming to invoke the traditional 'deficit model'.

By way of conclusion to the first two parts of this review, I suggest that the coalescence of several strands of theory that I have discussed in these two sections

[16] Their careful analysis of focus group discussions makes useful distinctions between technical, methodological, institutional and cultural types of knowledge in this context (Kerr, Cunningham-Burley and Amos, 1998:41). It is not my intention here to challenge the relevance of these findings or the implications that the authors draw from them. My point is rather one about the lack of work addressing the limits of (lay) expertise, a point whose implications I shall return to later in the thesis.

has had some unexpected effects. The proponents of a Risk Society thesis have generally emphasised the centrality of a process of complex, reflexive weighing up of personal risks by individual actors in making decisions. In this framework, scientific expertise is widely seen to be dispersed, fractured, or contested; there is seen to be a crisis of trust amongst lay actors in relation to scientific experts. Meanwhile, deployment of a governmentality perspective in this context has also been associated with an emphasis on the individual subjective awareness and management of genetic risks, despite its wider ranging ambitions. To some extent each of the theoretical lenses I have discussed above, those of bioethics, of the focus on lay knowledge, of risk society, and governmentality, are associated with an emphasis on individuals' incorporation of concepts of risk into knowledge, subjectivity and life strategies. I shall return to this in the concluding section of this review. Meanwhile in the next section I turn from broad contemporary theoretical frameworks to a more specific consideration of the sociological work on the donation and collection of tissues for research.

## IV The collection and donation of tissue for medical research [17]

### Genealogy of work on tissues and organs

Until recently the phrase 'tissue donation' tended to be used to refer to the donation of organs and other tissues for use in for medical treatment: here the literature is

[17] The collection of tissue specifically for the purpose of epidemiological genetic research was rare until very recently when the development of new techniques made larger scale work more feasible. (See discussion in chapter 2). However, genetic registers of those with rare genetic diseases have existed for several decades, usually having overlapping functions of research and provision of services such as counseling (Chadwick and Berg, 2001).

primarily concerned with the donation of whole organs. Many of the donated organs were 'cadaveric donations', giving rise to particular ethical dilemmas which are not relevant to my present concerns with the donation of a replenishable tissue such as blood by the well population. An underlying theme with organ donation is scarcity: thus much of the literature is concerned with the procurement and supply of organs, with their distribution and fairness in allocating these to those in need. These considerations have not held the same significance in relation to blood donation for medical treatment or research. I refer to the literature on organ donation as a preamble to this section because the sociological discussion about medical ethics, its discourse and its regulatory role, has historically been anchored in this literature.

Fox and Swazey's work is the most sustained sociological study of organ donation. For them, the experimental nature of much of transplant medicine was central feature of this terrain, as were the suffering and the hopes of those receiving these organs their relatives (Fox and Swazey, 1992). The failure to protect patients and relatives from the suffering entailed in unsuccessful experimental treatments was analysed in the relation to the nexus of agents charged with overseeing ethical practice in medicine. The emphasis on heroics of medicine and the rhetoric surrounding it was seen as drawing strength from the denial or avoidance of death which is a feature of modern American society. Lock has subsequently continued this line of thought, placing particular emphasis on the rhetorical use of the term 'gift of life' (Lock, 1996). In Lock's view, the moment of the 'gift of life' is privileged over the life of the donor and indeed over the longer-term outcomes for the recipient. The relevance of this account for other kinds of tissue donation is to be found in its underlining of the rhetorical use of the idea of 'gift'. This remains a widely used metaphor in clinical contexts as diverse as organ donation and blood donation, and one which has been criticised by a number of sociologists.

A number of other important questions have also been raised in the course of sociological and anthropological work on organ donation. These include questions about how and why bodily integrity is regarded as a human right, or more precisely, 'what conception of human essence is presupposed in the value of bodily integrity ?' (Csordas, 2000:213). The revelations of retention of organs without consent by hospitals in the UK have recently generated a considerable amount of discussion and debate about the values underlying bodily integrity and the discordance between those values and very recent practices in medical autopsy (Furness, 2001; Retained Organs Commission, 2001). It is clear from this that there is a plurality of views on the exploitation of body tissues for research. Although some profess a sense of detachment from discarded or donated body parts, for others these remain related to the identity of the person who gave them or had them taken from them.[18]

It is now possible for a wide range of donated tissues to be used in therapeutic contexts. These range from blood, the earliest tissue to be effectively donated, and whole organs, to sperm, ova and embryos and, more recently, stem cells. In addition to the varied circumstances in which such tissues are donated, it would seem that donor's and recipient's relationship with these different body tissues will vary. For example, Waldby et al's recent empirical research suggests that donated blood is not generally seen to have the same intensely personal charge that is reported for some organ donations (Waldby et al, 2004). Blood donated for genetic research may carry a different meaning however, as the analysis of personal DNA may be seen as inherently more personal. Although this is sometimes assumed or inferred, there is little qualitative work addressing whether blood donated for genetic research is

[18] Waldby et al (2004) refer to this sense of attachment to donated or discarded parts of the physical self as 'bioidentity'.

special for donors.

As I have discussed earlier, there is a growing body of work about the experience of being tested for a genetic illness. However, epidemiological projects and biobanks collect blood samples and health information from large samples of the population, usually selected on demographic criteria. These participants, then, would not (necessarily) have any particular interest in a genetic disease, nor can we assume that the findings about a sense of 'genetic responsibility' will be relevant to them. Both the status of participants in biobanks and the processes of participation will be significantly different from those involved in their precursor genetic registers. Whether the same or related themes of risk and responsibility will occur outside the context of clinical research is as yet uncertain.

## The status of human genetic material and information

Given developments in the commercial exploitation and patenting of human genetic material, a widely debated feature of genetic research using donated tissue is the property status of such tissue. Much of the literature here emanates from the fields of law and ethics. A number of key papers in these fields have set the scene for much of the subsequent discussion by social scientists. De Witte and Ten Have reviewed a range of models of the body as property, and their implications for positions on ownership of human tissue in this context. Drawing on some of these positions, a 'line of reasoning can be constructed from ownership of human body to its parts, including genetic material and next to ownership of genetic information' (De Witte and Ten Have, 1997:59*)*.

Notwithstanding the requirements to protect the integrity of human bodies and their

parts, there are many opponents to the notion of doing so via a property framework, that is to the designation of body parts as property. Some however do advocate the relevance of the category of property as a means of dealing with some of the new dilemmas about genetic material (Grubb, 1998; Laurie, 2002). Prominent amongst these is Grubb, for whom property *is* relational, and more subtle than is sometimes claimed for, 'the categories of property are never closed or static, and shift with societal norms' (Grubb, 1998:312).

Although social scientists have joined in the discussion about the status which should be ascribed to individual's genetic material in property terms, their distinctive contribution lies rather in widening the analysis of the implications of the use of human biological material. As Sharp argues, an emphasis on property can lead to preemptive closure of the debate:

> *Once issues of property ownership and autonomy take centre stage, they displace competing cultural constructions of the body, other possible reactions to the dilemmas of biotechnologies, and, finally, the shaping of alternative ethical responses.*
>
> (*Sharp, 2000: 299)*

Social scientists have sought, rather, to discuss the ways in which the emphasis on property models is revealing of particular social and cultural values. In particular Strathern (1999) has argued that the emphasis in Western societies on conceptualising relations in property terms is revealing of the ways in which the culture is dominated by such ideas. Others have considered the consequences of framing the debate in this way. For example, Everett explores this in relation to the debate on genetic privacy and gene patenting in Oregon: here the use of the property metaphor by both sides of

the debate is seen as reinforcing 'deterministic assumptions and [avoiding] fundamental questions about the integrity of the body and self identity '(Everett, 2003:53).

The broader implications of the way patents are being applied in the context of genetic research have been a focus of attention for those concerned with the expansion of capitalism into 'hitherto uncommodified areas' (Jameson,1991:36, cited in Rabinow, 1996:130). Many papers analyse the significance of the John Moore case in the American courts, seeing in it an encapsulation of some key elements in the contemporary debates about the implications of research exploiting human genetic material.[19] For Rabinow, the issues at the heart of the case as judges struggled to 'locate' the wrong that was done, are not novel issues. They illustrate the longstanding tension between a Christian view of the body as a sacred vessel, and 'the tenets of the market culture's "rational actor' view of the human person as contractual negotiator' (Rabinow 1996:130).

The relationship between new kinds of comodification and the history of the use of human tissue is the subject of Lock's work, which is prefaced with a recognition of a historical perspective on the exploitation of corpses and body parts in Europe. Whilst recognising that the contest over the exploitation of body has a long history, Lock is

[19] In the case concerned, a physician developed and patented a cell line from his patient's cells, without his permission. (Moore v. Regents of the University of California, 249, Cal Rptr 494). The patient - John Moore - did give consent to surgery, including the removal of his spleen, from which cells were taken. When Moore discovered that his tissue had been used to develop and patent a cell line, he alleged breach of fiduciary duty by his physician, and a conversion interest in the uses made of his tissue. At the heart of the case was a dispute about the claimant's concept of his excised body tissue as his own property (Rabinow, 1996:138-144).

concerned with the more recent incorporation of biological materials into a global market (Lock, 2001). The trade in organs is seen as driving a redefinition of parts of self. Drawing on Taussig's analysis, Lock finds in the current regime of organs trade, a 'commodity fetishism' characterised by an alienation between persons and things.[20]

A number of authors have explored the implications of developments in biological sciences and genetics for the relationship between academic research and commerce. With the redrafting of patenting law, 'the line between theoretical and practical science [is] increasingly hard to draw [and] the stakes are increasingly measured in terms of real capital in addition to the symbolic capital and authority the old system was based on' (Rabinow, 1991:130-131). Krimsky's seminal book reported empirical research on the relationships between academic researchers and commercial companies in the context of the rise of industrial genetics (Krimsky, 1991). For many, the increasingly close ties betweeen the university sector and biotech companies threaten the values of openness and freedom of inquiry which are associated with the former. Others though point to the competitiveness, secrecy and self-interest which characterised scientific projects in the university sector even before developments in industrial genetics (Chadwick and Hedgecoe, 2002). Nevertheless, new conflicts of interest have arisen from researchers' involvement in both sectors (Knoppers et al, 1999; La Montagne, 2001).

[20] Anthropologists have been concerned with the commodification of bodies or parts of bodies in a number of contexts, notably the organs trade, surrogate motherhood, medical experiments and trials, and now with the manipulating and exploiting of cells by new biotechnologies. See Sharp (2002) for a review of this literature, and Appadurai (1988) for an anthropological perspective on the processes through which things and people become commodified.

## V The sociological literature on participation in research

Notwithstanding a plethora of papers surveying the ethical and regulatory implications of the developments of biobanks in recent years, we know little about the experiences and views of those involved in them. (Important exceptions by Haimes and Whong-Barr, Hoeyer, and Williamson et al are discussed below). However it will be useful to note some of what is known about peoples involvement in medical research and more specifically in genetic research prior to embarking on this new exploration.

Sociological studies have identified a range of ways in which the norms of the clinic will influence participation in medical research. Beginning with Fox (1996) there has been an ongoing discussion about the relationship between medical research and clinical practice, about which there is now a significant body of literature. More recently the literature has extended in scope to encompass the dynamics of research participants' decision making and choices in this context (Mueller, 1997; Weitz, 1991). Whilst medical research has become more differentiated from clinical practice since Fox's pioneering work, the overlap of clinical and research domains remains relevant. Corrigan cites the influence of clinical norms in people's decisions on participation in research, emphasising the investment of trust which research participants make in medical systems and personnel (Corrigan, 2003:780). Clinical research studies may still serve as an entrée to medical care - as Weitz showed in the case of people with AIDS (Weitz, cited in Mueller, 1997) - and have traditionally been seen by patients as a route into more effective treatment than they would otherwise receive.

Thus participation in research is seen as being intrinsically bound up with the expectations that are invested in biomedicine. In one of the few studies that explores

these themes in relation to research on genetic diseases, Stockdale showed how the hopes and expectations of people with Cystic Fibrosis, fuelled by the marketing of and misunderstanding about gene therapies, drove their involvement in such research (Stockdale, 1999). Gene therapy in particular seems to have developed 'the aura of a miracle technology: there has been a tendency to overstate the association of research in this field with the likelihood of successful therapy (Stockdale, 1999:83). Even beyond the particularly intense situations of those suffering from serious genetic disease, it seems there is a great deal of hope about the potential of these technologies, a phenomenon described by Conrad as 'genetic optimism' (Conrad, 2001). Some point to the role of the media and the representation of the O-GOD (one gene, one disease) model of causation in generating or stoking this optimism (Conrad, 1999). Others place their analysis more in the context of the ambivalence that has historically characterised our relationships with biomedicine (Beck-Gernsheim, 2000). For Hoeyer, 'biobanks are sites for genetic research that amplify *an ambivalence that has always surrounded biomedicine*: it has the power to enact life and death decisions' (Hoeyer, 2004:111, my emphasis).

A more specific form of the expectations that may attach to medical research is the interest that participants may have in the clinical or diagnostic information that researchers may be able to make available. This point takes on a particular emphasis in the case of genetic research. Such research may offer access to genetic information which will be important to people and may help them to predict their own or their relatives' susceptibility to certain diseases. Whilst genetic information is widely held to be of value in predicting disease however, not all genetic information will have this property. In many cases researchers will be unable to offer individuals information about susceptibility and risk. Both the desire for and confusion about such information is a characteristic of the terrain of much genetic research and one that is

likely to generate further debate as different policies are developed to deal with this issue.[21]

One recent study underlines this point. In the UK Anglian Breast Cancer Study, participants were given the option of stating at the outset if they would like individual feedback of findings which may be of clinical or predictive relevance to themselves or their families. The great majority of participants chose to receive such feedback, and Richards et al (2003) discuss the technical and ethical complexities entailed in giving this feedback. It is likely that for the participants in the breast cancer study, genetic information would be seen as particularly important and salient. However a number of studies also suggest that 'well volunteers' see access to genetic information as an important feature of genetic research (Gustafsson Stolt et al, 2004, People, Science and Policy, 2002).

A point that is established in the wider sociological literature is the way in which the clinical domain shapes the way in which people view a request from the researchers. The 'field of choice' which subjects, who are usually patients, have is seen as being very much framed by the context of their particular situation, including their knowledge of and access to treatments other than the trial treatment (Corrigan, 2003:783). The extent to which these points will be salient to those volunteers participating in biobanks, selected on the basis of demographic rather than clinical criteria, is unknown. Certainly, we can see the 'field of choice' of a healthy biobank volunteer being a wider one than that of an unwell cancer patient in a drug trial. However, some of these points are likely to be relevant to the experience of

[21] In relation to the national biobanks, UK Biobank seems set not to feed back information to participants. A contrasting position has been taken by the Estonian biobank, in which the offer of information on genetics and disease susceptibility is seen as central to policy.

participants in the biobanks. In the case of UK Biobank for instance, many volunteers will be healthy at the outset of their involvement. However it is the anticipation that they will develop disease that is the rationale for the longitudinal collection of data from these volunteers. Many instances of serious disease will occur over the following decade, leading to a change of status for these patients, some of whom may have been recruited through their GP. Despite the participants' initial status as well volunteers, the question of how the norms of the clinic will shape their choices and interactions remains a relevant one.

In summary, the weight of expectations (and fears) associated with biomedicine will influence the dynamics of involvement in research, in addition to more specific expectations such as the desire for information which have emerged as a salient point in relation to genetic research. How these expectations will play out in epidemiological genetic research, and in the biobanks that aim to facilitate such research, is unclear. If many of the participants in this kind of research are well, it will be as much the futures of others that are at apparently at stake as those of the participants themselves.

## VI Biobanks

### Biobanks and the bioethics rubric

The 'first wave' of the literature focused on the Biogenetic project in Iceland which, as we saw earlier, has been associated with a high level of debate and controversy. It is evident that larger scale genetic research and related information databases have posed something of a conundrum about how to put into operation widely accepted principles of informed consent. The debates around informed consent to biobanks are discussed at some length in chapter two, especially in sections two and three. In

summary, objections raised to the feasibility of implementing conventional protocols of individual informed consent include the practical difficulties of effectively informing large numbers of research subjects, and the question of the extent to which people can understand the technicalities of the new research agenda.

Many of these discussions fall into the genre of discussing 'hard cases' that I discussed earlier - that is, the discussion of the application and boundaries of an accepted rule. However, some additional points have been raised about the broader uncertainties about the social consequences of genetic research. Related to these is an important feature of all the biobanks, that is the scope of consent that is sought from participants. Whereas in most clinical research, consent is sought from participants for a particular research project or agenda, biobanks seek a general consent from donors for the use of their tissue and information derived from it (Austin et al, 2003:452).[22] Following another principle of bioethics, that of non-maleficence, another approach to the debate has been to 'weigh up' the potential harm from research to individuals against the potential benefits. This approach has in the past mainly been applied to clinical trials in which individuals may gain access to treatments and interventions. Such interventions, whilst associated with the possibility of benefit, also carry the possibility of physical harm for their participants, and it is this possibility that has held a central place in the weighing up of their acceptability. In the case of non-clinical genetic research however, it is the potentially harmful use of genetic information that has been the main concern, especially in the absence of stringent regulation against genetic discrimination. In many cases, the feedback of genetic information to individuals is not envisaged.[23]

[22] See discussion of these the scope of consent in chapter 2.

[23] However it is of note that whilst UK guidelines tend to prohibit the feedback of genetic information in such studies, and this is the line to be followed by the UK Biobank, elsewhere

Rather, it is proposed that there may be benefits to others in the future if knowledge, about the causes of common diseases for example, can be ascertained and applied to medical treatments.

Chadwick and Berg suggest that 'it could be argued that one has a duty to facilitate research progress and to provide knowledge that could be crucial to the health of others' (Chadwick and Berg, 2001:320). They propose that this 'principle of solidarity' be considered as a basis for 'a fresh ethical perspective' on [all] the new genetic databases. Such a perspective offers a refreshing contrast to the exclusive emphasis on individuals' informed consent. However it is reminiscent too of the universalist principles that have played such a central part in the way bioethics has operated. I am reminded here of Kleinman's discussion of the cultural assumptions underlying the communities that are assumed to underlie an ideal social contract:

> *Beneficent social contracts make good philosophical theory, but they deny empirical experience in local social worlds…Little is gained by installing utopian virtues; in fact, much is lost, since illusion and exaggeration distort the practical realities among which most people on earth live*.
>
> (Kleinman, 1995:48)

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there is considerable variation on this matter. For example, the Estonian biobank will feed back data on genetic susceptibility to participants. It is a matter of policy, rather than an inherent quality of this kind of research, whether or not feedback is provided.

## Biobanks and the sociological literature [24]

Clearly there are pressing policy issues to be addressed with regard to these developments, and these have perhaps reinforced the tendency of the bioethicists to operate in a legislative mode, notwithstanding the wider discussions within the discipline that have been discussed above.[25] Thus, much of the literature advocates a general or universal approach to be taken to biobanks, for example to see such databases as 'global public goods' (Knoppers and Fecteau, 2003) or to advocate an approach based on 'solidarity and equity' (Chadwick and Berg, 2001). We might expect that a sociological approach to considering participation in biobanks would give a greater emphasis to the particular contexts that shape the choices and agency of participants. It would explore the kinds of interactions that take place under the rubric of achieving informed consent for biobanks, the dimensions of privacy, and the ways in which this varies in relation to the context. Related to this, it would explore the question of the ways in which genetic data are constructed as special - or not special - in particular contexts. Given the recognition of the importance of the clinical domain in the sociological literature about participation in medical research, it would explore how these shape involvement in the various biobanks.

A very recent development is the emergence of studies that have begun to explore the

[24] I note that there is a body of data based on quantitative studies that suggests high levels of support for medical applications of genetic information (Gaskell et al, 2003:3). That same data also indicates that there is a significant minority who have concerns about such uses. In addition, there is a widely held view that access to such data by some other government agencies and commercial companies is unacceptable (Gaskell et al, 2003:4).

[25] The term 'legislative' here refers to Bauman's distinction between 'legislative' and 'interpretive' intellectuals (Bauman, 1992).

particular domains within which blood is donated, stored, managed, and exploited.[26] Work by anthropologists deploys an approach in which such donations are seen in terms of exchanges. Prominent amongst these is Hoeyer's analysis of the setting in which donations were given to the Swedish biobank (Hoeyer, 2003, 2004). In this case blood samples and data were collected in the context of a medical examination that formed part of a programme targeted at reducing cardiovascular disease. The collection of these samples, observes Hoeyer, began some years prior to the emergence of such collections as a valuable resource for commercial companies. Relationships with the public health care system are seen as crucial in shaping interactions with the research biobank: donors anticipated that they would benefit from the clinical examination, and they trusted the doctors and nurses in the 'moral domain' of the clinic. As we saw earlier, Hoeyer is critical of the importance attributed to information by *both* proponents and opponents of biobanks. Instead, he locates his discussion of participation within an analysis of the particular configurations of responsibility and trust associated with the welfare traditions of Northern Sweden (Hoeyer, 2003, 2004).

A recent study of participants and non-participants in the 'North Cumbria Community Genetic Project', effectively a regional population biobank which makes samples available to researchers outside the region, is also based primarily on interview data (Haimes and Whong-Barr, 2004). In this project, blood samples are sought from new-born babies, recruited via women attending ante-natal clinics, who consent on their behalf. In addition, health and lifestyle data, and a sample of maternal blood is collected from the mothers who agree to participate.[27] The location of the project in an ante-natal clinic is seen to frame the dynamics of participation in particular ways,

[26] Some of these have been brought together in a book edited by Tutton and Corrigan (2004).

[27] See the report on the NCCGP by Chase et al (2000).

by, for example, reinforcing the imperative to help. The kind of analysis that would contrast 'altruistic' participants with non-participants who are assumed not to be altruistic is challenged. Both these studies (those of Hoeyer and of Haimes and Whong-Barr) begin to explore a sense in which undertaking social research with those involved in such initiatives is, in effect, asking them to account for themselves as moral beings. For Haimes and Whong-Barr, one danger of the common assumption that research participants are altruistic is that non-participants are conversely assumed to be non-altruistic. A 'deficit model …of moral behavior' may emerge from such assumptions (Haimes and Whong-Barr, 2004:74).

The uncertain and untested legal position regarding the use of genetic information derived from the placenta is one instance of the ambiguities surrounding the involvement of babies and young children in genetic research of this kind. In a qualitative study undertaken with the child participants of the Avon Longitudinal Study of Parents and Children (ALSPAC), Williamson et al find that children's concerns with regard to such participation are different in significant respects to those of their parents (Williamson et al 2004).[28] This is seen to underline questions about the convention of adults giving 'proxy consent' to research on behalf of their children, a convention that has prevailed in the larger European project of which ALSPAC forms a part.[29] Another example of an epidemiological study that involves very young children and their families in genetic research is ABIS.[30] This project recruits

[28] An example is the different kinds of information that children identified as being private or sensitive.

[29] This convention of proxy consent also applies to the NCCGP project that was discussed above (Haimes and Whong-Barr, 2004:73), and in Iceland where children are included in the HSD.

[30] ABIS stands for 'All Babies in Southeast Sweden'.

children during their mothers' contact with maternity services in one region of Southern Sweden. It focuses on particular diseases, including diabetes, and differs from ALSPAC in offering feedback if children are identified as being at higher risk, and preventative measures if possible (Gustaffson Stolt et al, 2002:1334). A recent interview study with participant mothers suggests that whilst they were apparently positive about their involvement in the study in general terms, they did express some concerns about the possibility of misuse of their data and the need for its use to be restricted.[31] Proxy decision making was seen as appropriate by these parents (although we do not know of the children's views). Gustaffson Stolt et al find this encouraging in view of the concerns about whether there will be public support for this kind of project, and argue for 'a more differentiated discussion' regarding projects of this kind (Gustaffson Stolt et al, 2004:1343).

If there has been little of this kind of detailed qualitative work on the contexts of involvement in population genetic research to date (largely by virtue of these being very recent developments), the prevailing bioethics rubric has also tended to bracket discussion of the political arrangements that shape the involvement of states with biobanks. Whilst a commercial dimension in medical research is certainly not unusual, the nature of the particular ties between state health systems and commercial

[31] Gustaffson Stolt et al also document the differences between the information that the women recall receiving, and the information that has been made to them according to official protocols. For example, none recalled seeing a special video that was intended to be shown by all mothers-to be. Yet all said they had received sufficiently thorough information (Gustaffson Stolt et al, 2002:1342). This paradox of information is echoed in other studies, including my own. As I shall show in chapter 7, I found that in my interviews with participants in the genetic arthritis project that some apparent anomalies around information were revealing of some more complex dynamics of knowledge and participation.

bodies are. Prominent government involvement in and in some cases sponsorship of the biobanks has gone hand in hand with commercial investment or plans for the commercial sector to exploit the data. The balance of commerce and public control is different in each case. Nevertheless, if relationships between commerce and state are central to these initiatives, an analysis of the nature of these ties will be central to an analysis of their import. In the Icelandic case, Merz et al argue that an analysis of the detailed operational arrangements of the HSD as they have unfolded over time in reveal an initiative whose purpose is primarily commercial, although it does in addition support public health aims (Merz et al, 2004:1207). Fletcher's analysis of the Estonian Gene Project (EGP) places it in the context of Estonia's economic transition 'from a Soviet style command economy to a liberal and progressive democratic state' (Fletcher, 2004:4). Drawing on the idea of a brand state, Fletcher's analysis notes that advocates of the EGP link features of Estonian national identity with the drive to use biotechnology to establish a competitive economic position (Fletcher, 2004:10). In the words of one of the advocates for the EGP, 'it is important for us to start implementing modern technologies if we are not to fall hopelessly behind'.[32]

I observed earlier that the economic interests related to the establishment of a national biobank are rarely made explicit in the policy discussions in Britain. Yet the aim of positioning the nation at the forefront of developments in biotechnology is central to policy developments in this field. For Martin, a key point here is the 'emerging market for personal and population based genetic information'. Because 'access to these on a large scale [are] possible only via the NHS', health services are becoming implicated in that market (Martin, 2001:181). As discussed in chapter two, Martin's

[32] Dr Toomas Veidebaum, cited in Frank, L (1999) Storm brews over gene bank of Estonian population, Science, 286:5443.

analysis of the transition in the systems of governance in this context takes stock of the historic reliance of regulation of basic biomedical research in the UK on professional norms and guidelines. In this analysis, the system of research governance is seen to have been destabilised by developments in genetic research.[33] More recently, Kerrison has questioned whether the new systems of NHS governance can deal adequately with conflicts of interest of the kind emerging from the biotech industry (Kerrison, 2004).

## VII Conclusions

I have described how in the absence of a substantial body of empirical work, several broad theoretical frameworks have been influential in the literature about the interface between new developments in genetic research and the lay public. Prominent amongst these are the bioethics discourse and the governmentality and risk society paradigms. Unexpectedly, these diverging frameworks turn out to have some implications in common including a tendency to model participants' decisions on reflexive calculation, and a stress on the weighing up of personal risks by individuals. These perspectives tend to lead to an emphasis on the importance of information or knowledge in thinking about blood donation for genetic research. For ethicists, the obtaining of informed consent has been seen as central to the morality of the transaction between lay participants and medical researchers; for sociologists, there has been an interest in the expertise deployed by lay people in relation to scientific controversies and the possibilities of contesting expert knowledge. Finally, and perhaps most importantly, these theoretical approaches are universalist or global in

[33] From the perspective of bioethics too, the principles traditionally shaping ethical discussion of research are in flux according to Chadwick, who suggests that we may need 'new sagas for new times' (Chadwick, 1999:441).

their aspirations. They deal less with the dynamics of local interactions through which global developments - such as those in genetic research and genetic biobanking - will be shaped. It may be that empirical studies about the social shaping of and participation in biobanks will test the tenets of these theories which have been so influential in the field of the new genetics.

Moving to the more empirical work, the approach I have taken is to explore the literature on research and commercial exploitation of genetic tissue and information more widely. Several features of this literature were identified. Firstly, I delineated a preoccupation with the property status of donated genetic tissue, and suggested that this emphasis may tend to preempt wider debates about donating tissue for genetic research. A second theme identified was a tendency to underline the risky aspects of genetics. The consequences of defining genetic practices as ethically problematic or sociologically risky per se are highlighted if we think of the contrast between the approaches to the case of 'ordinary' blood donation and that of blood donation for biobanks in the literature. The former tends to be seen as unproblematic in stark contrast to the latter which is approached with a concern about exceptional issues.[34] It

[34] A number of factors clearly contribute to the acceptability of blood donation: it is visibly useful in emergencies, the donors' own blood is replenished in a short time, the technologies for donation and transfusion etc, are long established, and blood donation is often characterised as being in some sense universal (although in fact donor criteria are highly exclusionary). But it also seems relevant to ask here why blood donation has been seen as so unproblematic, now that blood products are manufactured (from donated blood) and there is an established market in blood. Might this too not be seen as a step towards commodification of the body? There is only very limited literature on the implications of a market in blood: exceptions include some of the discussions in the medical press about changes in the organisation of the NBS, including the introduction of charges to the NHS for blood. (See, for example, Oakley, 1996; Bowell, 1996).

is not my intention to imply that there are not particular issues to address in relation to the exploitation of donated genetic tissue for research, nor to adjudicate on whether these issues are 'exceptional' to the case of genetic techniques. (This question has been addressed at some length in the literature).[35] However I do point out that social research in this field has tended to follow the trajectory of clinical genetic research, and so to focus on the experience of people with rare and serious genetic diseases. The issues relating to people who are well donating tissue for population genetic research have yet to be explored.

In the final section I began to draw the contours of discussion about donation for blood banking and biobanking in contemporary contexts. The literature about the new biobanks shows the influence of the bioethics rubric, with the mechanics and logistics of obtaining informed consent being a prominent concern. However, there is now a move towards a wider formulation of social and ethical issues that also takes account of the particular contexts of these projects. In this review I have sought to begin to integrate some of the issues arising from new large scale biobanks into some of the older literature about involvement in medical research, including sociological work on the dynamics of participating in such research. Of the few publications drawing on empirical studies about participation in biobanks, several point to the importance of analysing that participation in the context of particular social and moral domains. To this we can add the importance of social history in shaping those domains.

[35] See for example Richards, 2002 and Ross, 2001.

## Chapter Five: rationale, methodology and methods

### I Introduction

Many of the exponents of powerful conceptual frameworks that have been influential in the literature about developments in genetics have either tended to abjure the need for empirical work, or to focus their work on situations where novelty and risk are pre-eminent. My own research is located within an emerging body of work in which engagement with empirical study is seen as essential to an understanding of these developments.[1] I was driven too by a theoretical interest in the ways in which blood donation for these purposes was being described. It seemed that reference to donated blood as 'gifted' in guidelines and policy discussion about genetic research evoked values associated with blood donation in an earlier era. But there were few sociological studies of 'ordinary' blood donation in Britain in recent years, so it was unclear what the relationship was between these representations of blood donation in Britain and the current experience of NBS donors.

After extensive preliminary fieldwork and exploration - discussed below - the project was designed to include interviews with two distinct sets of donors: NBS blood donors and those donating blood for a particular genetic research project. By including interviews with NBS donors it was hoped to embed the discusion about 'genetic donors' in some wider considerations about 'traditional' blood donation.

Before embarking on a description of the work undertaken, I shall briefly consider the rationale for undertaking an empirical study. It would certainly be possible to make a contribution by, for example developing and elaborating a theoretical agenda for

[1] See Spallone et al (2000) for a discussion of this new body of work.

sociological work on blood donation, a practice which has been intensively studied by psychologists but little by sociologists in recent years. This could be based on the secondary literature. However, in the sub-discipline of medical sociology in which I locate my work, empirical work has long been seen as having a central place in honing and developing a theoretical understanding. So for example the theoretical notion of the 'sick role'- arguably a foundational concept in medical sociology - was progressively developed, then refined, and contested through a series of empirical studies of the experience of patients (Parsons, 1951; Turner, 1986). Concepts of social class that have been influential in this field have been questioned and refined most effectively through successive empirical studies about people's life experiences and 'health chances' (Blaxter, 2000). Increasingly over the last several decades, the undertaking of in-depth interviews with lay people has been a central feature in the work of sociologists of health and illness (Bury, 1982; Blaxter, 1983; Williams, 1984; Williams, 2000). This empirical focus went hand in hand with theoretical perspectives on the importance of lay knowledge as a theoretical concept. However as I discuss in the final section of this chapter, it also solidified into a set of methods surrounding the canonical one hour interview.

If empirical work is to be undertaken, why do interviews with donors? As I have discussed in earlier chapters, there is a sense in which blood donation in Britain has been and continues to be discussed in a profoundly ideological way. Elements of that ideology include a view that donated blood is given unconditionally, should not be seen as a commodity, and will not be sold. Within this sits the assumption that donors are selflessly altruistic. I envisaged interviews as one way of exploring whether these ideologies are represented in the everyday practices and contexts of blood donation.

The rationale for undertaking interviews with donors was to interrogate some of the analytical frameworks and policy assumptions about blood donors. Overall, the study

was designed to explore questions rather than to provide definitive answers on matters of policy. Nevertheless, the relationship with policy issues is a close one, and this will be something of an experiment in doing research which seeks to be relevant to policy without being driven by the policy agenda.

## II On methodologies

I approach this chapter with an awareness of the extensive debates about methodology in both anthropology and sociology. As a researcher schooled in anthropology applied to health and with some years experience working in qualitative sociological (health) research, I am aware too of the extent to which craft knowledge continues to guide work in the field. There seems to be, as Atkinson et al describe it, 'a disjuncture between methodological ferment and the everyday practice of social research' (Atkinson et al, 1999:469). Referring to Denzin's account of the implications of the crises in ethnography, they suggest that it would be reasonable to give greater emphasis to the 'remarkable continuity and continuity of anthropological scholarship' over these troubled years' (Atkinson et al, 1999:469).[2] Whilst issues of legitimation and representation have influenced methodological conventions and innovations, many of the building blocks of social inquiry remain the same.

It will be evident that I take some of my inspiration from anthropology. A note is therefore in order about my decision to carry out a study based on interview data. In anthropology, observation remains at the heart of fieldwork, it being unusual to find an anthropological study relying exclusively on interviews. In contrast, the undertaking of interview based studies is not unusual within sociology, and especially in the field of health, although some critique the assumptions underlying many of

[2] Atkinson et al refer to anthropology here, but I apply their comments to sociology too.

these studies. In part because of the sensitivity of the topic - researching tissue donation in the immediate aftermath of the Alder Hey Inquiry [3]- it would have taken a good deal of time for me to attempt to negotiate access to observe research settings in which people donated blood for genetic research. I was not confident that these negotiations would be successful. Together with increasingly effective official gate-keeping to NHS settings, and the now well-recognised constraints entailed in undertaking a doctoral programme in three (funded) years, these considerations dissuaded me from attempting to negotiate an observation-based study at this stage. Nevertheless, the ways I took forward other elements of the study, in particular the selection of settings for interviews, the use of observation in one of my interview settings, and the analytical strategy, do reflect an ethnographic stance.

In the concluding section of this chapter I shall refer to some of the standards which can be applied to the kind of qualitative sociological research that I have undertaken. Here I shall also drawn on some recent discussions about the tensions in reporting and reading ethnographic work. Whilst ethnographers assert that writing about fieldwork is necessarily a creative activity, 'more is involved than ethnographic impressionism' (Sanjek, 1990:385). However ethnographic writing in general, and field-notes in particular, are 'surrounded by legend and often a certain secrecy' (Clifford, 1990:52). One of the changes associated with the debate on validity in ethnography is a greater attention in research accounts to the creation of texts of diverse kinds in fieldwork: interviews, field-notes, and research monographs can all be considered in this way. Sanjek discusses how the characteristically more elliptical fieldwork accounts of anthropologists can take account of these shifts in scholarship which underlie these discussions: an explicitness about the processes involved in making and selecting from fieldwork notes is proposed here (Sanjek, 1990:395-401). I have endeavoured to bear

[3] See Redfern et al (2001).

these debates in mind in my own account. I shall describe in some detail the processes of recording, storing and coding data, giving particular attention to this in part III where the large numbers of interviews with NBS donors necessarily means that the process of abstracting from interviews to final text is a more intensive one.

## III Preliminary fieldwork

My original research proposal to the funding body (April 2000) had envisaged undertaking interviews with research scientists and donors. A NHS LREC was positioned as the main gatekeeper to informants (research scientists and subjects) for this research. Some LREC members were also to be interviewed, with a view to providing a 'nested study' of different perspectives on blood donation for the same genetic research project. However, in the light of policies subsequently brought in as part of a framework for NHS research governance, I was advised that it would be inappropriate to contact researchers in this way. Therefore, my preliminary interviews became important in thinking about redesigning the project. They might also be helpful in negotiating access to interviews with donors that had previously been planned along other lines. I hoped that those I met could inform me about their perspectives on current developments and also that they might act as gatekeepers for me.

In the spring of 2001 I undertook a number of informal interviews with a view to mapping the nature and range of activities involving tissue donation for genetic research in the city in which I hoped to conduct my fieldwork. It was likely that these activities would be considerable, as the area I had selected had a high level of research activity, being a known regional centre for genetics. At this stage I was concerned with identifying key contacts amongst scientists involved in the research; and exploring some of the current issues in the field from the point of view of practitioners

and others working in the field. For this preliminary work I approached several leading researchers who I had identified as doing work in which the use of human tissue was critical, two clinical geneticists in the teaching hospital trust, and the R&D leads and managers for the two largest NHS hospital trusts. In addition I contacted Professor Margot Brazier, who was about to take up the position as Chair of the Retained Organs Commission. I received responses from Professor Brazier and the researchers and clinicians I had contacted. I then set up meetings along the lines of an 'informal interview'. One of these senior researchers, the director of a large research unit, was ultimately to facilitate access for me to interview donors in a particular genetic research project (described below). At NHS (acute hospital trust) management level the response was less forthcoming.[4] Finally, I took up an informal contact in the National Blood Service. Although originally conceived as a background discussion, I found this to be worth pursuing further, and subsequently made contact formally with the NBS's Director of Donor Services to discuss the possibility of interviewing NBS blood donors.

These preliminary interviews were conducted unrecorded with a view to facilitating the discussion about a subject about which there was a good deal of controversy at the time. They took place in the immediate aftermath of the Alder Hey Inquiry. The interviews sensitised me to the level of concern amongst professionals in the field about the controversy surrounding the use of tissues for any research - the level of unease was such that it seemed negotiating access to research participants might be very difficult. Importantly, these interviews enabled me to build up a picture of the kinds of research involving donated tissue going on in the area. There was, and still

[4] I only contacted two NHS managers, for the purpose of trying to map the extent and nature of activity in this field in the geographical area. One of the NHS R&D leads contacted me to say no research of this kind involving tissue donation was going on, another never replied to my letter or returned my call

is, no overall register of research involving donated tissue, nor specifically of genetic research on donated tissue. Therefore mapping activity at a local level was important with a view to thinking about selection of a case study, a process I describe in the next section. One conclusion from this preliminary work was that a good deal of the research activity involved those with a rare genetic disease, and their families.

## Selection of cases and sites

Within the UK researchers may collect blood for genetic research at diverse sites. Although there are various documents that would be useful in evaluating or mapping these activities, some of these are not widely available.[5] There has to date been no requirement for researchers to register this activity with any authority. It would be difficult to list accurately the many sites of blood collection/donation. A simple classification of sites representative of this activity is therefore not possible. A more theoretically informed strategy would be required to construct a study of blood donation in this context.

It is more usual than not for qualitative research to undertake sampling on theoretical criteria, and so there is no shortage or texts discussing the basis for purposive sampling strategies.[6] One approach to thinking about the theoretical rationale for designing a study is to be found in Marcus' substantive paper about ethnographic methods in contemporary contexts. Here, Marcus delineates some ways of approaching an ethnography whose object of study cannot be accounted for by

[5] I am thinking here particularly of the NHS ethics committee records, which were considered to be confidential, although their registers of research activity could be important documents in this context.

[6] These are reviewed by Hammersley & Atkinson in their text on ethnography (Hammersley and Atkinson, 1995:36-53)

undertaking a traditional intensive investigation on a single site.[7] Amongst several other modes of construction for such studies, Marcus outlines two techniques for tracing the phenomenon of a complex cultural phenomenon which I found particularly relevant to my thinking at this stage: 'following the thing'- that is tracing the circulation of commodities, gifts, and so on, and 'following the metaphor'- 'trying to trace the social correlates and groundings of associations that are most clearly alive in language use' (Marcus, 1995:109). The first of these would certainly be a relevant technique to adopt for the study of donated blood for research. But it is the second technique - that of 'following the metaphor'- which was influential in my thinking about the design of this particular study.

Ideally, I had wanted to interview people who did not have a prior concern with a particular genetic disease to enable me to explore the views of 'ordinary' donors. I use the term to recall Titmuss' interest in the voluntary community donors who gave blood for use by strangers.

Before going on to discuss the selection of different situations in which people donate blood, I shall pause to consider why I decided not to interview non-donors. There are a number of practical reasons why access to such a group would be have been difficult for myself as a doctoral researcher. In particular, there is a convention within NHS related research that those who do not consent to one research project are not contacted about this by other researchers unless there is a clear and overriding reason for doing so. Given these conventions and the expansion of NHS REC activity to include social research involving NHS patients, it was likely that it would be difficult

[7] Marcus' list begins with the more traditional or conventional technique of 'following the people' - for which Malinowski's Argonauts of the Western Pacific is the archetypal account - and includes following the thing, metaphor, plot, biography, or conflict as modes of construction for an ethnographic study (Marcus, 1995:105-110).

for me to achieve access to non-participants in genetic research. There was also a theoretical rationale for my deciding to focus on donors: I actively sought to avoid a project design which posited the perspectives of donors against those of non-donors. In my view such a project design would run the risk of focusing excessively on the apparent differences between donors and non-donors, rather than exploring involvement in more depth.[8]

Based on my preliminary fieldwork, I considered several options at this stage:

1. Interviewing donors of tissue for linkage studies at the regional genetics service.

One line of enquiry here, given the family involvement in these studies, would be to explore the relationship between consenting for oneself and for one's children in relation to these kinds of studies. A disadvantage of this approach though would be the limited relevance of the experience of those taking part in these classical studies to larger studies involving participants without a prior interest in a particular genetic disease. Specific controls surround arrangements for ongoing or future contact with these individuals and families. In practical terms, many of the tissue samples are already stored, with permission having been sought for ongoing research. New donors are limited in the main to those referred for clinical investigations and some volunteers related to the department, who provide tissue for controls. Therefore it was likely to be difficult to get access to a sufficient number of donors on a prospective basis.

[8] Subsequently Haimes and Whong-Barr drew on an analysis of participants/non-participants in a genetic study to challenge the oversimplified dichotomy between the two groups, and the assumptions that are associated with it (Haimes and Whong-Barr, 2004: 67).

2. Interviewing participants in an epidemiological or population study to be conducted the following autumn.

I was surprised to find that very few studies of this kind were underway in the region. A few such studies were at planning stage but their start dates were not established. A new unit was planned to facilitate such research separately from NHS facilities. Here again though, it looked unlikely that I could tap into this development as it was not yet operational.

Contrary to my, original, perhaps naïve, ideal of seeking 'ordinary donors' for genetic research, I could not plausibly design a strategy for recruiting and interviewing donors who would be 'typical', or 'disinterested'. At an operational level this was as a result of the limited large scale epidemiological or population research underway in the particular region at the time. (Elsewhere in the country, there were a few large scale national and regional studies developing this kind of work: some of these already had social researchers involved.) At an analytical level though it had begun to be clear to me that each such developments - including population level projects - should be considered within the particular social contexts and parameters within which they take place. This relates to a point discussed in chapter four: it is evident from the more recent literature in this field that such projects are shaped not only by the arrangements for their regulation and governance, but also by the wider social history that influences the way such projects are received.

The study which came closest to my criteria of seeking 'ordinary donors', whilst also being accessible to myself as a doctoral researcher, was a project about possible genetic causes of Psoriatic Arthritis. (This condition has no clear hereditary pattern and has not widely been considered a 'genetic disease'.) Interviews with people who

had volunteered to take part in, and donate blood for, this genetic research project became the second part of my study.

3. Interviewing National Blood Service blood donors as an additional group

Information gathered during my preliminary visit to NBS indicated that this now complex organisation had put considerable distance between itself and its forerunner local blood services. Interviewing blood donors could help to flesh out the relationship between the traditional ideals of blood donation in the UK and the experience in contemporary settings. This would then inform the study of blood donation for genetic research. I took the view that revisiting this 'traditional' kind of blood donation in a contemporary setting would enhance my theoretical re-reading of the gift relationship model. Interviewing blood donors in this setting therefore became one part of my empirical study.

In the main part of this chapter I discuss the development of interviews in the two distinct settings; the approach to these data would be to see them as providing complementary, rather than comparative, perspectives. In both settings I sought to maintain the openness and flexibility of research design that are an important characteristic of ethnographic work.[9]

I begin with the NBS study, which was undertaken first, between December of 2001 and April of 2002, after prolonged access negotiations earlier in 2001.

[9] Following Strauss & Corbin (1990) I use 'flexibility' here to denote a sense of maintaining an ability to adapt and pursue avenues of investigation that might not have been foreseen or planned, yet that appear relevant to my theoretical interests.

## IV Interviews with National Blood Service donors

The UK's National Blood Service was set up in 1993 to take over from the services previously run by regional health authorities. It is now a special health authority charged with the collection, screening and supplying of blood and blood products to the NHS, and with research and development in this field and for other purposes. As in its earlier years, the blood service still runs donor sessions at community centres and churches throughout the country. In addition, each region has one or more permanent site, where donors can drop in on any weekday and give blood without an appointment. My interviews with blood donors were to be undertaken on one such site.

### Access negotiations

Access to blood donors was negotiated through senior managers in the NBS, following informal discussions with a contact in the organisation. Whilst access was successfully achieved, the negotiations for this were lengthy and protracted as is, of course, not unusual for this kind of project. An initial letter to the Head of Donor Services at the NBS in May 2001 was followed by a meeting with two NBS consultant haematologists within the region, at which agreement in principle was reached on access to NBS sites. A number of modifications were made to the proposed procedures at this meeting, the main one being to accede to NBS' wish that donors not be offered the option of being interviewed at home.

At this stage I began the paperwork to submit an application to a NHS Local Research Ethics Committee (LREC) for approval of this project. One of the complications of negotiating this stage was that, whilst my funders required me to apply for LREC 'approval', it gradually became clear that my sponsors in NBS did not see the

necessity for this requirement. In this respect, they saw the NBS as a body standing apart from the NHS. Nevertheless, I pursued the LREC application in order to demonstrate that the study was legitimate. I gave this procedure added commitment when it emerged that my funding body would withhold the substantive part of my grant if I did not provide evidence of such clearance.

The LREC gave this part of the study approval, subject to several suggestions and conditions which were made. (After I had dealt with the suggestions the study would be given the final go-ahead by the committee Chair. The interviews with donors to the genetic research project were approved by a different committee, as described in the next section.) The committee asked me to look into the possibility of notifying donors ahead of their visit to the blood centre of my project, in order that they might be more fully informed about the project if they consented to it. In discussion with NBS it emerged that this would be difficult, as the majority of donors at this centre give blood without having an appointment to do so. Secondly, I was asked to interview only established donors, not first time donors, which I agreed to. Thirdly, and following usual LREC procedure, I was asked to submit my information sheet to the committee for approval before going ahead with the study.

Extensive email correspondence followed to organise NBS input to NHS LREC forms. My attendance at several team meetings was planned but last minute unavoidable alterations or cancellations of such meetings at NBS made this unfeasible. Instead, the final negotiations were held over the phone with the regional manager for donor services, who was able to identify a site where I would not be too much in the way. At this stage access looked promising, but a few days before I was due to begin I encountered an unexpected setback: the LREC requirement for the patient information sheet (about my research interviews) to be on NBS headed paper generated some last minute problems. Printing on NBS headed note paper necessitated involvement from

the corporate communications department at NBS, who in turn scrutinised the project outline and brief topic guide. The mention of questions about genetic research lead to a sharp intake of breath (literally) by those involved, who were fearful that this research might adversely impact on the organisation's public profile. Whilst the regional manager and team manager for the proposed site remained open minded about my research, they nevertheless said that I should not proceed until I had the 'OK' from corporate communications. When no such resolution seemed forthcoming I finally issued a polite ultimatum to the senior haematologists who had acted as gatekeeper to the organisation for me. I explained that continued delays would be difficult to contain within my schedule for the PhD and that I may reluctantly have to withdraw from the work with NBS if I couldn't start pilot interviews before Christmas (i.e. six months after initial formal contact). These consultants were able to arrange a compromise, in which my own information for research participants was on a blank sheet, with a covering invitation to consider taking part in the research on NBS notepaper. The regional manager agreed that I may go ahead but that I may still receive a call to the opposite effect from 'Communications.[10] This threat was dealt with by not answering the phone until I had actually started the interviews and established a rapport and etiquette for carrying out the interviews in mid-December 2001.

In this chapter I shall distinguish between the organisational requirements and procedures of obtaining LREC agreement and the ethical issues which I identified through working in the field.

[10] In the event, I never received a call from ' Communications'.

## The donor centre as a research setting

The donor centre at which I undertook my interviews is in a busy part of town, a place of work for many, and also popular with shoppers. Selected donors were given information about my project when checking in. Those who chose to be interviewed would then talk to me after giving blood, in the rest area where hot drinks and biscuits are provided. This was sometimes a busy environment: other donors, staff, and occasionally friends or family of donors were present at tables near to the one where I would sit with my interviewees. I often moved around from one place to another to make room for others, and once or twice, more dramatically, to make room for staff to attend to a donor who had fainted. Although donors were generous in giving their time to talk to me, many were aware of needing to return to work or other commitments afterwards.

The working day of the centre (beginning at 9.30 and ending at 5.30, with a lunch break between 11.30 and 12.30) is divided into three sessions. At the end of each session the blood is collected in bags and boxed up to be taken to the local blood centre for processing and banking. A lay team does much of the day to day work of the session, supervised by a team manager who is a qualified nurse. I spent three and a half months in the city centre blood centre interviewing several sessions each week.

A good deal of my time was spent waiting near the reception area for donors who chose to participate to approach me, and then waiting for them to emerge from their task of giving blood. During this time I talked to staff and observed their working and the comings and goings of the life of the centre.

## Recruitment and selection of interviewees

As I had undertaken to give out information about the study before people gave blood, and wait for them to approach me during their time in the centre, recruiting was inevitably a process over which I did not have full control. On some days I would sit for hours and wait for someone to talk to me, and on others I would conduct several interviews during an hour. Much of my activity here was responsive, then. However, there were ways in which I was able to influence recruitment.

In selecting potential interviewees my main concern was to recruit interviewees across a range of age groups, and of blood donor experience - from those who had given blood just a few times to those who had donated many times over years. Interviewing those who had more recently started donating blood might offer an insight into different experiences - as procedures for new donors have been altered over recent years - and perhaps a more emergent account. In addition I was interested in talking to donors of different ages. Age is likely to have a significant influence on peoples experiences of modern medicine and its related institutions: younger and older people will have had different experiences of illness and health care, and there may be ideological differences between the generations (Williams and Calnan, 1996). In the event, the question of donor career was subsumed under the age category as it emerged that long-term donors are generally older donors (NBS, 2000). Finally, I wanted to include the experience of both men and women, although I did not see it as necessary that I recruit equal numbers of men and of women.[11]

[11] Women are more likely than men to register as blood donors, but also more likely to be excluded for medical reasons. The national figures suggest that amongst established donors the numbers of men and women are close to equal (NBS, 2000).

Each day I briefed the NBS clerk accordingly on the age and gender which I was seeking - for example 'women aged 50 and over' - and she would give out information sheets to registered donors[12] falling within this group. Donors who were happy to speak to me would then approach me where I sat nearby.

### What kind of interviews?

I was primarily concerned with getting a sense of and insight into the perspectives of these donors. I therefore had an interest in not asking questions which were unduly precise, as they might foreclose areas of discussion which I had not thought of. Yet I also faced the expectation that I would have pre-formed questions: this expectation was manifested at various stages, from university and LREC project review, to discussions with the host organisation. My interviewees themselves expected me to have more clear cut questions than I actually did. It emerged that these expectations were shaped in part by the conventions of the market researchers whose activities were prominent in the neighbouring streets.

Instead of the fixed questions which were often expected, I used a topic guide, a well established approach in qualitative interviewing, to guide my interviews. The topic guide was altered several times in the course of the interviews as I refined areas of interest, ways of asking, and worked through some of the dilemmas which I discuss below. My early interviews were very much conceived of as a way in to understanding what kinds of questions I might be able to ask in this context, and in what kinds of ways. Thus in early interviews I often simply asked people to tell me about their decision to give blood and their experience of blood donation.

[12] That is, not first time donors.

As my confidence in interviewing in the often busy and noisy context of the donor sessions developed, interviews continued to open (usually) with a question about how and when the person had first became a blood donor, and about why they had continued doing so. More developed topic guides all covered the following themes: what is done with the blood; views on payment for blood donation; information; concerns or worries about giving blood especially at the outset.[13] Where possible I then asked about donors' views on research and genetic research, beginning with a question about whether they would see giving blood for research differently from giving blood to help people directly. This question was often difficult to address, as I shall discuss below. At the end of the interview, I often asked people who had been donating blood over some years about how the experience had changed over time. With this I aimed to move back towards their own experience and a more fluent discussion about that.

## Asking donors about the uses of blood: unanticipated ethical issues

There are a number of features of these interviews which I felt were either difficult, or unusual. Firstly, there was the fact that I had to fit into a busy environment and, related to this, that people often did not have time to talk to me for very long. Then there was the problem of my asking questions about an activity which is widely considered to be a worthwhile but straightforward one. Perhaps this was compounded by the fact that the ethos of the environment was to 'do something amazing' (as NBS advertising slogan has it) and practical. Talking to a researcher pales somewhat in

[13] Some questions which I had originally included about other kinds of bodily donations generated often rather distressing or marathon discussion about for example, procedures for organ donation or the politics of IVF. Because this would then leave me out of time or unable to move on to ask about the use of blood for research, I made a decision to exclude these kinds of questions (although not excluding spontaneously occurring discussions about these issues).

comparison. Beyond this, there were some particular ethical issues which I shall also discuss here.

I had significant difficulties in establishing the kind of narrative account which I had, to some extent, come to expect in qualitative interviewing. One of the challenges to the conventions of this kind of interviewing was posed by time constraints: respondents would already have spent some time queuing and donating blood before I spoke to them, and many would need to return to work. Some of my interviews lasted only five to ten minutes, despite the indication on the information sheet that they might be expected to take about half an hour. Sometimes these shorter interviews were negotiated with me by donors who wanted to help, but didn't have time to spend half an hour. I was reluctant to turn these down, particularly if I had visibly being doing nothing all morning. In other instances the interviewee apparently did have time, but somehow our discussion never seemed to flow or to settle into a longer account. A related issue was the lack of assured privacy - our discussions might be entirely private but might not, depending on the flow of people through the various parts of the open plan centre during the interview. (This lack of privacy also affected the donors screening interviews to some extent: symbolic privacy was achieved by the use of screens, but sometimes these interviews could be overhead.) Whether for these reasons or others, sensitive topics such as the impact of the HIV/AIDS crisis on the experience of being a donor were rarely raised in the course of these discussions. For example if I asked long-term donors how their experience of donating had changed over the years, they would tend to talk about the different ways in which the blood was stored, from glass bottles in the 70s, to plastic packs today, and about changes in the regimes of care - different types of bandages, for instance, or different advice about recovery. As will be seen from the interviews I cite in the data chapter, these interviews rarely dwelt on the personal or symbolic meanings of giving blood: they were in general quite pragmatic accounts.

Some unanticipated ethical issues arose from interviewing in this setting. These relate partly to the ideals associated with the blood service, and the images that people often have of blood donation: asking questions about the use of blood might seem to question these ideals or the basis of peoples trust. My knowledge of NBS policies was fairly limited, garnered from the available literature and public documents. In respect of the technical aspects of the blood service's work I was probably insufficiently informed. Nevertheless, I had endeavoured to familiarise myself with the available literature about the organisation, which was quite limited, and had held discussions with several senior staff members in the organisation. This gave me a different perspective on the activities of the organisation than it seemed was held by the donors. In particular, I became aware that a market system operates between the NBS and the NHS, with the former charging the latter a fixed fee per unit of blood supplied. Manufacturing standards are applied to these blood products. Where UK donors' blood is unlikely to result in the meeting of those standards, blood is sourced from elsewhere (Martlew, 1997; Robinson, 1996). When donors talked about blood donation as a sphere of life uniquely free from commerce, I did feel quite uncomfortable with my own knowledge of these policies. For example at one point in an early interview, when I asked a donor about the circumstances in her coming along to give blood, she referred me to these ideals, and to the way these were embedded in the current advertising campaign:

*R* *I just think its doing some good for someone, doesn't cost anything, no one can buy it, and it's a bit like the ad on the telly.*

*I* *The one that's on at the moment? Actually I've only heard the one on the radio.*

*R* *No there was one on a bit ago, and it was just promoting that you're doing some good for nothing, just to help people. The idea that nobody can make any money out of …it just makes you feel good.* *(NBS 32)*

I gradually became aware of a tension between my interest in the detail of how blood might be used and the popular image of blood donation in which blood is rushed to someone in need at the site of an accident. I came to see this as an ethical issue in my work. I took the view that asking questions which might directly influence how a donor saw this sphere of activity - about the arrangements by which the NHS pays the NBS, for example, about the exporting and importing of blood, or about the use of blood for research - could have serious implications. It might curtail their commitment to blood donation or undermine their trust in the organisations that manage it. Consequently I modified the way that I asked these questions, and in some - about a quarter of the interviews - I did not ask about genetic research, as I felt that it would be inappropriate. I shall return to this point in a more substantive discussion in chapter six. Certainly though, this tension would limit the questions I asked about the use of blood for research. Given these limitations, I regarded it as particularly fortuitous that my day to day waiting gave me the opportunity to ask the staff questions and to observe the work of the centre.

## The role of observation

The activities I observed in the course of my time at the blood centre were not ones which would directly shed light on the details given by donors in their accounts. They would not, for instance, enable me to comment on why people came in to give blood and what motivated them to continue. They would not then provide 'triangulation' in the sense of enabling me to check the inferences that I have drawn from the interview

data (Hammersley and Atkinson, 1995:230). Rather, my observations fleshed out my interview-based work in a number of unexpected ways, as I shall describe here.

Much of the activity I observed was concerned with donors being cared for in a variety of tacit and explicit ways. It was also evident though that the process also involved a number of risks to physical comfort and well-being - I observed some serious faints, which look like fits, whilst interviewing. Whilst both donors and staff minimised these discomforts and risks in their discussions with me, I came to see their management of these as part of their shared work in the centre. In my notes, I used the term 'cloak of competence'[14] to denote the achievement of making blood donation seem so straightforward. It also became evident from observation that the trust between the donors and their carers was similar in some respects to the trust placed in clinicians - notwithstanding the lay status of most of the carers.

This process of using observation to inform my interviews was a subtle one and a difficult one to represent. One example is the way in which my mulling over the commitment of blood donors - evident in a number of ways in the donor centre - challenged my initial thoughts about the apparent passivity of donors who didn't share my interest in the information and detail about the use of blood. This led me towards an analysis of this apparent 'passivity' in terms of a decision to hand over trust to an organisation. Another example is discussed in chapter six, where I refer to my early

[14] The term 'cloak of competence' had come to my attention by the title of the book 'Becoming doctors: the adoption of a cloak of competence' (Haas and Shaffir, 1987). Previously though it had been used by Edgerton in a classic ethnographic study of people with learning difficulties that observed their achievements in cloaking their disabilities. Edgerton's book entitled 'The Cloak of Competence' is reviewed by Richardson (1995). In relation to my own observations, it struck me that donors made blood donation look easy, whereas in my view it was sometimes quite arduous.

field notes about how the centre called to mind ‘a small factory’. The perspectives gained from these observations led me to think about the tension between how the blood service sees its role, in terms of blood products, and the way in which it is viewed by donors and those outside the organisation.

I also drew on my observations in more straightforward ways to inform my analysis of the interview data in relation to information and consent. I observed that despite stringent efforts to protect donors’ privacy, there were occasions when there were very public discussions of what we would usually consider as private matters:

> *Usually reception is so routine that the possible threats to privacy that might arise are not foremost in people’s minds. However a young woman comes in today whose experience draws attention to the potential for problems here. Apparently a notice comes up on the screen saying the donor has been asked not to give blood again, ‘permanently’. The clerk calls for the doctor who happens to be on duty to come to the screen, and he asks her about when she last came: she says she had had pneumonia and was told not to come back for 6-12 months. (Pneumonia can be an AIDS related infection flashes through my mind and no doubt the doctors.) He brusquely says she has been asked ‘not to give blood again, ever’, and she insists she should be eligible to give. I am overlooking this conversation, as are her mother and sister, hovering round the reception desk. He asks if he may phone the blood centre, she agrees and he does so. Apparently there is no contraindication, if there had been though, this would have been difficult to keep private…*
>
> *(Fieldnotes, January 2002)*

After checking in at reception, donors are usually called into a cubicle where a member of staff will run through the safety questions with them. I shall describe the screening process as it took place at the time. (Some alterations to the declaration form procedure have since been made to this by NBS.) The declaration form includes twenty-seven questions, twenty-four of these being specific questions on medical history and exposure to blood products. Staff refer to each of these by number rather than reading them aloud: the donors' task then is to say yes or no to these screening questions. Answers to these questions are ticked yes or no by the NBS staff, and the donor then signs a declaration. The declaration includes a statement that blood can be tested and feedback given to the donor if relevant, that they understand the risks involved, and that they 'entrust [their] donation to the UK Blood Service to be used for the good of patients'. Based on observation this process generally takes only a few minutes for existing donors, perhaps five or ten minutes for new donors. Donors generally answer the questions swiftly and succinctly and with a keenness to get onto the main business of giving blood. As the centre can be extremely busy on particular days, or times of day, the pressure of knowing how many people are waiting may play its part here. But even at quiet times, there is a sense in which these procedures are concerned with making manageable a complex set of information and a series of potentially very sensitive screening questions. An awareness of this gave me valuable contextual data when I came to analyse interviewee responses to my questions about the use of blood for research.

## Recording and storing data

At the beginning of my fieldwork I took field notes on the environment itself, initially guided by Spradley's suggestions for categories for observation and fieldnotes: space, actors, activities, objects, acts events, time/sequencing, goal, feeling (Spradley, 1980:78, cited in Hammersley and Atkinson, 1995:78). I usually wrote a condensed

version onsite and then a brief write up of this afterwards on the same day. The broad sweep of this observation and note-taking was useful in directing my attention to unexpected aspects of this setting, and was to be helpful in fleshing out my understanding of the environment in which my research interviews took place. I have inevitably had to be highly selective in referring to field notes. A good deal of the material though, whilst interesting, was not of direct relevance to the theoretical framework which I developed: for example I had some detailed fieldnotes about the division of labour in this setting, in which lay staff took on work which is traditionally the remit of those who are medically trained. This would be a fascinating study of changing roles and skills in a quasi-clinical setting, and could make an interesting contribution to the literature in the field. However, as with other parts of this rich set of data, a strategic decision had to be made about where to focus the analysis. In the next section I shall describe some of the ways in which I made decisions about the selection of this material in this following section on analysis. As time went on I focused more on specific themes and less on the more general descriptions of place and activities which I had written at the beginning.

For the interviews themselves I made brief written summaries, in addition to tape recording the interview. At the end of the week I entered these into a standard form which I developed. I also kept more messy notes to help me think about the process and focus of the interviews and to progressively refine the topic guides. All these records (tapes, messy notes and summaries) were used when it came to coding interviews for the interview summary matrix which was produced after fieldwork was complete. In the meantime I wrote monthly (approximately) summaries of progress, emergent ideas and analytic themes for discussion with my supervisors.

For the twenty-six interviews lasting longer than twenty minutes, a transcript was made to facilitate thematic analysis. Although my discussion is informed by the data

as a whole, it is these interviews which are cited and analysed in more depth in chapter six.

## Analysis of findings

In this section I aim to give an indication of the strategies adopted at key points in the research and of the techniques used to further the analysis.

As will have become clear from my earlier discussions of my research aims, I began with some questions about blood donation derived from my analysis of the literature. However I also wanted to adopt an open approach to the perspectives and questions that might be generated by my involvement in early fieldwork. In adopting this kind of approach I was strongly influenced by ethnographic traditions. To operationalise these I draw on some techniques suggested by Strauss and Corbin, here discussing the rationale for opening up the research questions at the beginning of fieldwork and analysis. (These are conceptualised as taking place hand in hand):

> *'underlying this approach to qualitative research is the assumption that all of the concepts pertaining to a given phenomenon have not yet been identified, at least not in this population or place; or if so, then the relationships between the concepts are poorly understood or conceptually underdeveloped…Whilst the initial question starts out broadly, it becomes progressively narrowed and more focused during the research process, as concepts and their relationships are discovered to be relevant or irrelevant.'*
>
> (Strauss and Corbin, 1990:37-38)

Techniques from grounded theory were particularly useful in undertaking a detailed analysis of the interviews at an early stage.[15] For example, the technique of 'identifying the story' enabled me to focus my interest in the phenomenon of apparently passive, trusting donors (Strauss and Corbin, 1990:119-120). This led me to think about the dimensions of this phenomenon, to challenge my initial interpretation of it as 'blind faith', and to consider how best I could characterise it in relation to the literature on trust and on informed consent. The technique of 'axial coding' is designed as a way of taking data apart, and putting it back together 'utilising a coding paradigm involving conditions, context, action/interactional strategies and consequences' (Strauss and Corbin, 1990:96). The extract which follows is from the notes made in the course of reviewing my first 25 interviews.

**Extract from field notes/ preliminary analysis, January 2002**

**Conditions**

NBS donors-being well

Blood donation is something you can do

'Do something amazing', to help others, doesn't involve money, blood is provided in case its needed-by anyone: *Blood bank*

**Context**

Not knowing that much about it- *limits of expertise*

[15] I do not conceptualise the study as a Grounded Theory study in the sense put forward by Glaser and Strauss (1967). However I have adopted some of the methods specified within this kind of work for an analysis at an early stage of my research

**Action**

Donate blood: what is important here is the physical/embodied act of donating blood, other involvement not required, not encouraged. You are looked after whilst you are doing this.

Minimise and manage risks (of bruising, fainting) *Cloak of competence*

Each of the phrases in italics- '*blood bank'*, '*limits of expertise'*, and '*cloak of competence'* - condensed my thinking about certain key phenomenon in this environment. The first two were used to give a direction for further work, and are described below. These sensitising concepts would then shape how I took forward the work in a number of ways. Taking the first concept - 'blood bank' - as an example, I was able to shift my interview questions from detailed probing about information and consent, to broader ones about the rationale for donating blood. This did indeed generate some interesting data on the social transactions entailed in blood donation - which I shall discuss in chapter six. Subsequently I went on to code each interview in relation to whether it featured this concept, and to summarise this for the data as a whole.

## Coding and summarising the data[16]

After the completion of the interviews, a data matrix was used to summarise key features of all 100 interviews, including characteristics of each interviewed donor, the circumstances in which they first gave blood and the reasons they gave for continuing to do so. In doing this I drew on others' accounts of summarising qualitative data

[16] '*The most important form of writing is a skeletal one, an outline written from, for, and sometimes inscribed directly on fieldnotes. This is indexing and it involves major decisions that will structure later prose ethnography'* (Sanjek, 1990:386).

using a manual matrix (for example, Ritchie and Spencer, 1994), but essentially I improvised a form that would enable me to get an overview of some basic characteristics of this large group. This facilitated my description of them in terms of their age, gender, and donor history, for example. Beyond this I used the matrix as a way of indexing some other features of the data for which I had coded. I could then review, for example, how blood was thought to be used (emergencies, other medical uses, research uses, and so on). This was to be useful in checking how many of these interviewees mentioned research as one way in which the blood might be used. Next to this was a section to indicate whether the idea of a blood bank was used in the interview: this was a simple way of representing my coding of this aspect of the interviews which would then enable me to check my hunches about how widely this notion was used. Finally, there was a column to record whether or not the interview contained a discussion about genetic research, and a column to indicate the approximate length of the interview. After the coding and data matrix was complete, information about basic characteristics of the donors (age, gender, occupation, years as donor and length of interview) was also stored on a spreadsheet.[17] The main aim here was to facilitate selective retrieval of the data: for example the spreadsheet would enable me to call up a list of donors who were 40 and over if I wanted to look at this group in particular. The function of the database was simply to aid with record keeping for a large group.[18]

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[17] See Appendix 1 for a list of the age, gender, and occupation of the NBS donors I interviewed. I have also given the length of interview, and the interviewees' estimate of how many years they have been giving blood.

[18] This approach was chosen in preference to the use of a computer assisted qualitative data analysis package for this particular project. The rationale given for the use of such packages varies, but includes the demonstration of a systematic consideration of the data, uniform indexing and cross sectional analysis of the data, and/or the analysis of variables within data. However it is recognised that the investment of time in coding via a particular CAQDAS

A number of the analytic themes from the early analysis of interviews with NBS donors were taken forward as 'sensitising themes' for interviews with participants in genetic research. Firstly, the notions of reciprocity entailed in the idea of a *blood bank*: would these feature in the very different case of donating blood for genetic research? Secondly, the sense that asking donors about the uses of blood often brought them up against *the limits of their expertise*. Rather than scrutinising the uses to which blood would be put, I concluded that these donors had *entrusted* an organisation, the NBS, with decisions about its use. Would these dynamics be different in a situation where donors had been given detailed information about a study in which they were actively involved? Finally, it seemed that these donors did not see research using genetic material or techniques as special in itself, summarised in my coding as '*DNA not special*?' I expressed this tentatively because there were great practical and ethical difficulties in my asking about genetic research in the context of a blood donor centre. I hoped though that my second case study would enable me to explore this issue in more detail, as there would be fewer such difficulties.

## V Interviews with participants in 'the arthritis genetics project'

For this part of the study described in this chapter, I aimed to interview donors who did not have a prior concern with particular genetic disease, but who were volunteers

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package can detract from the more flexible and fluid processes of analysis which is often critical to the kinds of fresh insights which qualitative work can bring. Inputting full data from the large number of interviews would have been a substantial investment of time which was not seen as fully justified in this case.

for a genetic research project. Their involvement included giving a blood sample to the project.

## Access negotiations

The project from which I recruited my informants is based in a university hospital in a large city in the North of England. It emerged in the course of preliminary research interviews though that the predominant research activities in the area remained the study of rarer diseases, in which there was often a substantial overlap of clinician/researcher roles.[19] The unit undertook this kind of research, but was also a leading site for the development of epidemiological genetic research in its field. Following an initial discussion, the director of the unit suggested a study which most closely fitted my criteria and was considered practicable for me to recruit interviewees from. This was a study of psoriatic arthritis, a disease affecting both skin and joints, for which the aetiology is uncertain: the unit's research was concerned with identifying the extent to which there may be a genetic component. Thus the selection of a study site was driven by the theoretical criteria combined with an opportunistic one.

My gatekeeper, the director of the research unit, was able to clarify with the relevant Research Ethics Committee that my interviews fell within the scope of the committee's agreement to ('approval for') the larger research project, and therefore did not require an independent approach to the committee.

[19] The starting point for much clinical genetic research to date has been the study of families or small groups where there is a high incidence of a particular condition (Martin and Kaye, 1999).

## Recruiting interviewees

The unit recruited volunteers for this project nationally by several means, including advertisement in local newspapers and referral by hospital consultants. Inclusion criteria for the study were a diagnosis of arthritis and of psoriasis, or of psoriatic arthritis. Following confirmation of this diagnosis, volunteers are visited by a research nurse from the unit, who undertakes a clinical examination, may take a photograph of the psoriasis; and administers questionnaires on health status, pain, and disability. Data on family history of both skin and joint problems is taken, and agreement is sought for access to NHS records for this study if required. Finally a blood sample is taken: the consent form states that the blood is 'gifted to the Unit' for research purposes, also that it may be used by other research laboratories working (only) on arthritis/psoriasis. The form states that no genetic data will be fed back to participants.

It was agreed that volunteers in the geographical area in which I was reasonably able to travel to would be given an information sheet about my interview study, and asked if they would also like to participate in the research interviews. Those who wished to opt in filled in a simple form with contact details and date of birth, which was then forwarded to me by the research nurse. No further information was available to me about these volunteers. My selection was made on the basis of age and gender, with a view to interviewing roughly equal numbers of men and women, across the age ranges. To succinctly distinguish the unit's study from my own in the discussion below, I shall refer to the unit's study as 'the arthritis genetics study' (AGP).

## What kind of interviews?

My interviews with these donors were undertaken in peoples' own homes, and were longer, fitting more closely to the conventions of qualitative health research, but

without the benefit of observing the interactions in an organisational setting. Using a topic guide, twenty-seven interviews were undertaken.

In these interviews, I aimed to explore the ways in which people had become involved in the arthritis study. When asked 'why had they said yes?' I wanted to learn more about how they think about their interest in the blood which is donated, and I was interested in what (if anything) was special about (giving blood for) genetic research. I was generally interested in how people talked about this blood donation for genetic research. I asked them about the condition itself and the ways in which it affected their lives. Coming to the genetic study itself, I asked people to tell me about the information they received, and about whether they had any worries or concerns about the study.

As the interviews developed the topic guide was adjusted and in retrospect several important shifts in emphasis or approach emerged in the course of this development. Firstly, an approach to establishing rapport in the early interviews had been to invite a detailed description of their condition. This approach had the advantage of facilitating a narrative and of demonstrating the interviewees expertise in managing aspects of the condition and of the health system. However, taking this approach in these interviews perhaps over-emphasised their role or identity in terms of patient-hood. As time went on I sought to ask more open, general questions. Secondly, my early questions asking people to tell me about the information they had received about the unit's study were generally not successful: they tended to be answered by a comment about the time which had lapsed since they had read that information. I wasn't looking to find out about recall of detail, and in time began I asking them if they could briefly explain the study to me 'as though I were a friend or someone who didn't know anything about the study'. Similarly and more importantly in view of my research interests, I modified the way I asked about DNA: in early interviews I asked about concerns or

worries about the analysis of their DNA by the unit's researchers, and was generally reassured quite actively that this was not a problem. I continued to ask this, but probed more extensively and repeatedly. I had also become aware that some people thought identification of a genetic cause would be straightforwardly followed by a genetic therapy. I moved towards asking much more specifically about peoples' hopes and expectations for benefits from the study. In general I framed some more specific questions and probes, partly in response to the issues which had emerged in more open-ended interviews, and partly simply to clarify earlier versions of questions.

## Boundaries of interviews

The question of how much to shape the interviews, and how much to follow biographical narratives as opposed to asking specific questions, emerged early on in these interviews. Both my previous experience and much of the sociology of health and illness literature emphasise the autobiographical narrative approach to interviews. More recently though I had experimented with shorter interviews, with NBS blood donors, and with the ways in which I could focus on particular issues. I did not want to focus exclusively on these peoples' roles as patients or ill people, nor did I want to gratuitously seek personal accounts and intimate confidences. In general as I undertook more of these interviews I tried to actively move away from illness accounts and towards asking people their views as citizens. Nevertheless, their experience of the physical and social suffering often entailed in having psoriasis and arthritis had to be considered an important part of the context in which they were participating in the research.

An example of my difficulties with boundaries is to be found in my first interview of this group, with Mrs Taylor[20] (AGP 1) who had first been diagnosed with Rheumatoid Arthritis at eighteen. Now in her forties, she is quite disabled by joint pain, and cannot go out of the house for long distances. More recently her condition has been diagnosed as psoriatic arthritis, by a specialist with a particular interest in this condition, but she expressed some doubts as to whether this is the right diagnosis. Much of the talk in the interview was about how she manages and how she managed to look after her husband, who died two years ago from Multiple Sclerosis, and the difficulties presented by limited and inflexible support. She lives in a council house and a friend who is a neighbour was present during the interview.

When the tape ran out (requiring turning over) after forty-five minutes Mrs Taylor was talking to me about her husband's death and the childrens' response to it in great depth and detail; she talked about how he had looked when he died, and then later in the chapel of rest, which of the children had seen him after he died and so on. I didn't want to tape record this: it was very intimate and whilst I may well have left the tape recorder on if it had been running it didn't seem right to actively switch it on. I had covered much of the ground I hoped to cover in the interview - although as this was a first it was in a sense a trawl of how to listen and what might come up spontaneously in these kinds of interviews.

[20] 'Mrs Taylor' is a pseudonym, as are the names I use to refer to interviewees elsewhere in the thesis.

## Asking about participation in research

The following section from the transcript with Mrs Taylor begins to illustrate something of my difficulties in interviewing people about a research project, their understanding of it, and the basis of their participation in it:

*I* *One of the things that I'm interested in is in this kind of research you know you gave a small blood sample –I think you've done that already?*

*R* *Yes*

*I* *And you know that they look at the genetic material, the DNA, as part of the research. That's quite a new kind of research relatively, and I'm just interested in what you think about that.*

*R* *I think anything that in the future might improve…people that get arthritis has got to be good, really.*

*I* *Yes, OK.*

*R* *I mean like I say it might not make no difference to me now I've got damage in my joints that they cant repair. But, like I say if my kids got arthritis and as soon as you're diagnosed there's something you can take..it's the same with a lot of illnesses, the same with MS, if there's something they can use to stop it then alright you'll have arthritis, you'll have a bit but you its not going to, you know you're not going to- You know if I go long distances I have to use a wheelchair. If its, if the research found something that would treat it properly then you know if they found something in your genes or something then, well if we can eliminate this gene, they wont get arthritis, its got to be a good thing really.*

*I* *Yes, OK...So it wasn't special or different or more worrying that it was genetic research or research looking at the DNA?*

*R* *No it's*

*Friend* *We just thought its no skin off our nose where its sent if it helps some people.*

*I* *Yes, yes. I mean the reason I'm asking is that some people feel that you know that some people think it's a different kind of research and they're worried about it from the point of view of things like, your privacy: its your DNA and the DNA is very personal.*

*(Both laugh)*

*R* *No I don't… no.*

*I* *No, you're both cracking up, that's just not where you're at.*

*R* *At the end of the day, if its something to do with the genes, they need to look at it…I mean I dare say in the past things have happened with your blood when you give blood that you just don't know about, but its just that now they've got to tell you. (yes) I don't see the difference. I mean if they said would your mum and dad give blood, so we could look at their genes, they'd just say yes because they don't see there's anything…*

*I* *Yes, OK, yes….Can you just talk me through, just because I'm quite new to this particular study as well, what happened and the sort of information you got..*

*R* *When I was diagnosed?*

*I* *No. When you got involved in the arthritis study. Just really, because I'm so new to it, just run me through…*

*R* *It was, Dr H (rheumatologist at city hospital) took over my care and she said they were running this study, that they hoped would be helpful, would I mind doing it, I wouldn't have to go to the hospital…and I said yeah. And then when MB (research nurse) came-the one that Dr H had [sent] he said that you were also doing this one, he said do you mind you don't have to...I said well its OK it doesn't make a difference to me.*

*I* *Because obviously as you've gathered, my take on this is different, he's taking the blood samples and the information back to the university where they're going to do the analysis of the blood …whereas my study*

*R* *It doesn't bother me because most of these studies-if you put anything on paper, you don't say this is this woman, she lives here, she's got that, its all blind isn't it. (Yes.) So I mean I'm not bothered, you can talk to me to your heart's content, it makes no difference to me, you can talk about me to your heart's content (laughs).*

It was hard to know from this interview itself the extent to which Mrs Taylor had been informed about the use of her DNA in the arthritis study. To some extent this is as a result of my own technique and approach to the interviews at this stage: being reluctant to make the interview sound like a test, I supplied information about the study and then asked for her views on this. In later interviews I found ways to avoid supplying such information until after I had sought some more indication of their understanding of the study. My questions about DNA being 'special' here evoke something of a smile and laughter: these issues are really not where her priorities and those of her friend's lie. In general terms she is satisfied with the arrangements for the research, and a little puzzled with the direction of my questions.

## Analysis

The analysis undertaken here followed similar principles as those described for the previous set of interviews: it began with detailed consideration, reflection and discussion about the early interviews. These preliminary analyses of early interviews informed the topic guides and the approach taken to subsequent interviews - see discussion above about the shape and boundaries of interviews, about the muddle

entailed in researching about consent to another research project, and about notions of DNA.

After they were completed, these interviews were transcribed and coded according to both sensitising and emergent themes. By this stage in the research I had a number of sensitising themes from my earlier work to add to my original questions about blood donation in contemporary settings. One of these was an interest in the practical notions of reciprocity summarised earlier under the heading of 'blood bank'. I was also questioning my assumptions about the centrality of information in donors' decisions about donation. In the case of NBS blood donors it had seemed that, faced with the limits of their expertise they made decisions based on more on trust in the organisation. As far as I had been able to ascertain, those donors did not see the use of research involving genetics itself as special: considering whether such research would be an acceptable use of blood was based, rather on other considerations. These findings might be particular to the case of donating blood to NBS, or might apply to other cases too.

## Recording and storing data

All the interviews with arthritis project donors were transcribed on my behalf by a professional transcriber. After re-reading the transcripts, I then devised a matrix to summarise some basic characteristics of these interviews. Originally I had envisaged using the same kind of matrix as I had used for the NBS interviews, but I found there were some differences in the data I needed to record. In addition, the functions of the overview matrices were somewhat different. The NBS matrix was to help me keep track of an unusually large data set. These interviews, being fewer, were easier to recall, and in addition I was able to have all of them transcribed, rather than selecting interviews for transcribing as was the case with my NBS interviews.

For this group, the matrices summarising data included basic descriptive data about interviewees - their age, gender, and occupation - and an indication of their 'way in' to the study and reasons they gave for their involvement. I added columns to summarise data which I had coded as relevant to my interest in 'Hopes and Benefits' from the research; Trust, and Consent. Here I would summarise the data very briefly and give a transcript page reference for it. In relation to consent I also coded for whether or not it was clear they were aware that their blood sample would be used for genetic research. Another column summarised data on 'DNA' (or use of genetic material), with transcript references. A final column allowed me to add summarised notes on the context of the interview or the experience of the interviewee in more general terms.

These summaries enabled me to get an overview of selected data, and facilitated my return to the data to undertake more in depth qualitative research. As I shall discuss in chapter seven, for example, my initial coding about informed consent - 'yes' or 'no' according to whether it was clear that their participation in the project was informed by an understanding of the use of genetic techniques - gave way to a more qualitative analysis of the dynamics of involvement.

From my review of the matrices, together with my notes taken at the time of the interview, I was able to see how new dimensions of the earlier themes were emerging. In particular, a good deal of the hopes for the research hinged on the participants' relationships with the NHS and their expectations of university sector researchers. My summary of their responses to my questions about how they would approach involvement in a similar research project hosted by a commercial company was a useful counterpoint to this. These points then informed my development of further qualitative analysis about they ways in which relationships with the NHS shaped their participation in the arthritis study.

## VI Discussion

I shall conclude my description of the methods used for this study with a discussion in which I begin to evaluate its strengths and weaknesses: I begin with a consideration of the kinds of standards that can be brought to bear on this kind of research. I then review the design of my own study, and consider its strengths and weaknesses. Here too I discuss my experience of undertaking brief interviews in difficult circumstances. Finally I delineate the scope of the study and the ways in which it can contribute to an existing body of knowledge.

### Evaluating the study

Views about the ways of ensuring validity of interview based qualitative research vary enormously, depending on the stance taken to knowledge claims, and the traditions with which the writer is located. In health related research in particular, whose publication in the medical journals prompts direct comparison with the quantitative studies which are predominant in the field, there has been a good deal of attention to this question. Notwithstanding the attempts at standardising the quality of qualitative research, it can be argued these standards are necessary but not sufficient: influential qualitative research tends to be imaginatively crafted in ways that elude checklists and methodological prescriptions.[21]

[21] It would be difficult to do justice to this debate here. Mays and Pope's paper in the BMJ set out an agenda, indeed a checklist, for evaluating qualitative (health) research, but many have been critical of the checklist approach to this agenda, amongst them Dingwall et al (Mays and Pope, 1995; Dingwall et al 1998).

Whilst ethnographers aspire to write texts that are 'full, nuanced and non-reductive' (Taylor, 2002:2), the evaluation of qualitative research also has reference to principles of reliability and validity. It is widely - though not universally - agreed that conventional considerations of reliability need some reframing to be relevant to most qualitative research. The notion of providing sufficient information for a study to be repeated and its findings tested have a limited relevance here, for subsequent researchers will face a different set of social interactions even if they do revisit the same setting with similar questions. The extent to which we can rely on (have trust in) a study can be looked at in some other ways. One of these is a consideration of the reliability of the analysis. Sanjek points to three canons of validity: theoretical candour about the choices made in fieldwork, the provision of a level of detailed description about 'the ethnographer's path'- that is of the social networks through which they gain access to 'the field'- and thirdly the importance of field-note evidence (Sanjek, 1990:395). I have endeavoured to bear these principles in mind in my own account. The previous sections describe my 'path' through the rather prosaic but important terrain of negotiating access, reiterate some of the decisions made in relation to my fieldwork, and describe in some detail the processes of recording, coding and analysing data.

To judge the extent to which that analysis is valid - shown to follow proper process of argument and reasoning - it is considered important to have a clear description of the decisions involved at the outset of the design of a study. Sampling receives a good deal of attention here, and it is often said that the sampling of cases or settings for the research may be a more critical step than the sampling of individuals. 'Purposive sampling' covers a diverse range of strategies concerned with identifying group(s) of people whose circumstances are relevant to the phenomenon being studied. However the identification of these groups does not always exactly map onto the real life opportunities available to researchers. It is widely acknowledged that researchers

have often been guided too by opportunities available to study in particular settings (Hammersley and Atkinson, 1995:36).

## Sampling cases and the relationship between the two sets of data

I shall briefly consider the question of the 'representativeness' of each of my groups of donors before moving on to consider the sampling of settings. In the case of blood donors, it is possible to relate my own group to the wider figures on blood donors and their demographic profile. Fortuitously, my selection of donors across age ranges and with approximately equal numbers of men and women is roughly comparable to the demographic profile of blood donors nationally (NBS, 2000).

For the arthritis project donors such a comparison cannot be made: as the population of donors for genetic research comprises those involved in diverse individual projects that are not registered at any central point, is not known or defined. This was to a large extent an opportunistic sample, and apart from being able to select within it on the basis of age, I have had to work within the confines of this group. Currently it seems that many 'genetic donors' are involved in specific projects about a named disease or group of diseases, as with the project from which I drew my interviewees. Some however are involved the larger scale projects and biobanks that are likely to be more prominent in the future of population genetic research. The latter group would usually be described as well, as they are recruited only on demographic criteria, and the former as unwell. Yet, as I emphasised in chapter two, some of the donors for the large biobanks will inevitably become unwell - this being part of the reason they are recruited – and my own group included those who, despite a diagnosis of PA, considered themselves pretty well.

When selecting donors to interview for the study, it was primarily the situations in which the donors were in that I wish to compare (rather than the donors as individuals). The two settings selected were chosen partly on the grounds of the considerable differences between them. In the first of these settings the donors were committed to giving blood to a national blood service whose purpose is widely accepted and approved of. They could easily envisage the way in which the blood might help someone in need. In the other setting, people were giving blood for a new kind of research using research techniques including genetic analysis, an approach entailing some uncertainty and perhaps some potential for controversy. The ways in which their contribution would help others were harder to imagine in specific terms. We can see their situation in terms of the (increasing) participation of lay people in processes of medical innovation through their involvement in a range of trials and similar procedures (Webster, 2002:448).

To recap on the question of the relationship between the two sets of interviews, I envisage this as follows: for the interviews with NBS donors, themes from the literature were one starting point for my enquiries.[22] Beyond codified description of blood donors, there was limited research on the particular contexts and dynamics of blood donation. These interviews involved a high degree of immersion in the setting, due in large part to my time spent 'waiting' in the blood centre and observing its daily comings and goings. The second set of interviews was then informed by the sensitising concepts that emerged from this work in the blood centre. Some of those concepts were then confirmed by my analysis of interviews with 'genetic donors'. In particular, it seemed that in both settings donors indicated that their donated blood was entrusted to an organisation which was then expected to make informed decisions

[22] I have set out in chapter 3 how in my view the ideas - and ideals - associated with Titmuss' influential account in 'The Gift Relationship' had become codified.

about its use. Differences do of course arise between the cases, notably from the different kinds of consent process and different levels of information, and these are discussed. But it is the unexpected commonalities that are stressed.

## Undertaking brief interviews in difficult conditions

I have described how elements of the situation in which I undertook interviews with NBS donors conspired to make these interviews shorter than the qualitative interviews usually undertaken by sociologists. I was obliged to interview donors on-site, usually after they had given blood[23], in a setting which was fairly public - notwithstanding my efforts at creating privacy. My position as a researcher but also a guest of NBS was an ambiguous one. For example if I asked people about their views on payments for blood in other countries it was sometimes taken as an indication of the direction of thinking in the organisation, an impression I then felt obliged to counter. Clearly, there were some disadvantages to interviewing in this way.

It was interesting, however, to be obliged to set aside the assumption that a longer interview would necessarily be a more valid one. As I indicated in my introduction to this chapter, the prevailing methodological conventions in sociology of health and illness stress the importance of undertaking long open-ended interviews shaped by (auto)biographical knowledge. This approach emerged in part from a sophisticated epistemological challenge to the ways that 'lay beliefs' had been represented in medical contexts (Bury, 1982; Blaxter, 1983; Williams, 1984). However and notwithstanding the theoretical sophistication of much of this work, a rule of thumb emerged, that a long interview was a good one. The implicit assumption that longer

[23] Only a handful took up the option of returning for an interview at the donor centre on a future occasion instead of there and then.

interviews would enable interviewers to be more empathetic is rarely stated explicitly. However, accounts of methods of studies in this field often describe interviews as lasting between fifty and ninety minutes - and contrast the style of interview with those of the shorter structured interview of quantitative projects. Some seem to assume a greater degree of authenticity results from longer interviews.[24]

Another convention that I have been obliged to set aside is the representing of interviews as always purposeful events with clearly devised questions eliciting clearly bounded responses. My approach was to ask opening questions that I hoped would lead to an account of blood donation based in the context of the interviewees' social worlds. Some of this resulted in confusion because the purpose of blood donation is quite reasonably seen as self-evident, and some time was spend hedging around questions that were not amenable to discussion in this physical and social location. On the other hand, questions about people's 'way in' to donating blood were surprisingly effective in giving me a sense of the context in which they viewed their involvement - even in very short interviews. Part of my difficulty with these interviews was that I was trying to elicit about a practice whose worth is taken for granted. The difficulty entailed in asking about something so morally unassailable would presumably have remained a feature of interviewing in this environment even if I had been able to undertake longer interviews in more comfortable locations.

The limitations of the interviews are more evident where I asked NBS donors questions about the uses of blood, including its use for research. Here, unfortunately, I was trying to ask people about research, including genetic research about which they often had very little knowledge, as was pointed out to me by a number of my

[24] The assumption of authenticity in interviews has been challenged by Dingwall (1997), amongst others.

respondents. As I shall describe in chapter six, asking NBS donors about genetic research was the perhaps the least successful part of this work: I inadvertently raised concerns about controversial aspects of genetic research, and in many cases it did not seem (ethically) appropriate to pursue these discussions. It may be that for this group, asking these particular kinds of questions in a one to one interview was not the best approach: it has been argued that focus groups have the potential to be a more effective and acceptable method for this kind of situation (Barns et al, 2000, Kerr et al, 1998). However my tentative findings from this part of the research were then taken forward in the second set of interviews with genetic donors: here I could probe more fully the issues of peoples views on genetics, whether or not genetic research was 'special', and consider what relevance these findings had for this group.

### How could the study be strengthened?

The interviews that I have described comprise an extensive set of data, and I have only been able to make use of selective parts of that data. For example my qualitative analysis of the blood donors is based largely on the transcribed interviews with just over a quarter of these interviews, although I argue that my description of the overall dimensions of all the interviews adds to the analysis. Although I have endeavoured to make judicious and strategic use made of these data, and importantly to describe how I have selected some and bracketed others, it is clear that more work could be done using them. For instance one of the themes that may be of interest to those involved in managing blood donation is the sense of different kinds of narrative in the different age groups.[25] To explore this would be quite a substantive piece of work in itself. However, the way that I have summarised the data would enable me to return and

[25] Most established blood donors are aged 35 and over, and there is in some quarters a concern about the lack of younger donors.

further develop an understanding of the relationship between different accounts. Recent accounts of re-visiting or re-analysing qualitative data suggest that doing so after a period of time may yield different insights (Mauthner and Doucet, 2003).[26]

A second limitation to acknowledge is that this is primarily a study about what people say about blood donation. It is informed by reference to analyses and descriptions of what happens to donated blood in the blood service and in tissue banks. However, it runs the risks inherent in any interview based study, and would be greatly strengthened by a detailed empirical investigation of what happens to the donated blood. What are the contradictions or tensions between what donors believed happens to their donated blood and how it is used, circulated, exploited for knowledge and eventually, perhaps, destroyed? In the absence of such a study (for undertaking it would be a major enterprise) I have endeavoured to bring some information from the secondary literature to bear on this question.

Thirdly, the study may, perhaps, be criticised for my decision to exclude non-donors, a decision made for a mixture of methodological and operational reasons. It is difficult to undertake a study of non-donors, not only because they are harder to access, but also because of the pitfalls that await those wishing to make comparisons. Haimes and Whong-Barr - whose interview based study encompasses some women who, having been asked, decided not to donate blood to the NCCGP - challenge the assumption that donors are 'more altruistic' than those who decide not to donate (Haimes and Whong-Barr, 2004:71). Their work draws attention to the range of 'styles of participation' that underlies the assumed dichotomy of consent/refusal. As with other medical research projects, consent and refusal to the use of blood for

[26] It seems no coincidence that some of those proposing this note the constraints of time and imagination that may be entailed in being a doctoral student!

genetic research covers varying levels of awareness, trust, compliance, and involvement.[27] It is interesting to think of 'ordinary' blood donation here, as non-donors are sometimes portrayed as being selfish, self-centred, or not sufficiently altruistic. Yet it seems that practical considerations, of time, opportunity, and health status may be at least as important in peoples decisions to donate blood as moral ones.

Fourthly, there are limitations that come with choosing a particular setting for research. I have suggested that relationships with trusted organisations - the NBS, the NHS, and the University - are crucial to people entrusting their blood. I have taken at face value the comment made by many that they would not donate blood to commercial organisations. However it would be important and interesting to complement my study of these settings with a similar one of donors to a commercial (research) tissue bank. What kinds of trust and expectations feature here? If donors to public sector banks make reference to the idea of the common good, might donors to commercial banks also do so or will they talk in different terms?

## Scope of the study: what it does (and doesn't) do

I began my study with an observation that blood donated for genetic research was being described as 'gifted blood', evoking the values traditionally associated with blood donation. I then observed that there were few sociological studies of blood donation in contemporary settings in the UK. I aimed to test some of the assumptions that had brought to bear on thinking about blood donation in these contexts. My method was to entail an empirical study of the perspectives of donors in two different

[27] These dynamics are also discussed by Hoeyer (2003, 2004). Hoeyer's work and that of Haimes and Whong Barr are discussed in the final part of the literature review, chapter 4.

cases. My interpretation of these would then be contrasted with some of the assumptions embedded in the discourses of policy and of bioethics alike.

I have not sought to establish a determinative understanding or overview of the issues entailed in all blood donation for all genetic research. Indeed I argue that the role for this kind of study is rather to explore some of the particular points of view of people with an involvement in such developments. Here I draw on Kleinman's reflections on the quandary of the tension between moral experience and ethical reflection, for of course the tension between the particulars of lived experience and the universals of ethical reflection is an enduring and deep-seated one (Kleinman, 1999). An account of this kind of approach (that is of research based on a recognition of the importance of local moral processes), can form the basis for a dialogue with those who have a stake in an issue (Kleinman, 1999:91). In the case of genetic research and biobanks, those others will include researchers, policy makers, industrial players, and other donors.

In the previous chapters I have suggested that bioethical reflection has played a pre-eminent role in policy discussions about blood donation for genetic research. Related to this, principles of autonomy and of altruism have been influential. Attending to the mechanisms of informed consent and the status of donated blood is sometimes seen to be sufficient to ensure oversight of these complex developments. Often, social or moral questions that do not fall within this rubric have been overlooked.

In the chapters that follow I begin to open up questions about blood donation. I draw on interview accounts that provide a counterpoint to the nostalgia of the policy discourses surrounding blood donation for genetic research in the UK. Together with existing and emerging literature on genetic donation that I have discussed in the previous chapter, this can, I hope, begin to challenge the terms of the debate.

# Chapter Six: donating blood in a National Blood Service donor centre: Interview data

## I Introduction

In this and the following chapter I outline the empirical work which I have undertaken to inform my thinking about blood donation in contemporary contexts. This is based on my analysis of data from interviews with people donating blood to a National Blood Service (NBS) donor centre. Earlier I drew attention to the almost mythical status of blood donation within the British welfare tradition. I also questioned the traditional narrative about 'gifted blood' in this context, opening up a process of exploring about how we might think of this practice, which I shall pursue further in the interviews that I describe in this chapter. Although I shall confine my analysis to blood donation in the particular domain that I describe, the concepts that emerge will later be seen as one way of beginning to open up the debate about blood donation for population genetic research and biobanks.

I began this exploratory study with some general questions about the social context of this blood donation. What are the circumstances in which people begin to give blood? What kinds of reasons do they give for continuing to give blood over time? I was also interested in some of the detail of the arrangement between the donors and the NBS: what kinds of information were donors given; what were their impressions about why the blood is needed, and how it is used? And do they place boundaries on where they would expect it to be used? In addition, I aimed to find out something about how NBS blood donors would view the possibility of donated blood being used for research in general and

genetic research in particular.

Having its origins in the vicissitudes of the Second World War, the history of blood donation in Britain symbolises and dramatises a narrative of national solidarity. Yet there have been many changes in the blood service in the UK and the way it is organised.[1] These changes include the introduction of commercial involvement in blood processing, payments for blood and blood products, and quasi-commercial management structures and incentives (Oakley and Ashton, 1997:11). In addition, wider developments associated with globalisation have had a significant impact on national blood policies (K. O'Neill, 2003). Notwithstanding these changes, there is a case to be made for the continuing relevance of Titmuss' work in this field, a case I began to make in chapter three. Here I referred to Waldby's analysis of the enduring significance of Titmuss' work in terms of his recognition of 'a constitutive relationship' between biological donation and social relationships' (Waldby, 2002:309). The case for re-examining these relationships, I suggested, applies equally to the systems through which 'traditional' blood donation is managed as to those concerned with new kinds of donations and new ways of using donated blood. The apparent continuity of blood donation over the years has tended to obscure the importance of the new technologies and markets that have permeated the traditional domain of blood services.

There has been - since Titmuss - a tendency to consider questions about donors and their motives separately from the social and institutional arrangements underlying blood services.[2] Indeed the latter have received little attention, with the important exception of

[1] These changes are discussed further and referenced in chapter 3.

[2] Healy's study of the organisation of blood collection in the EU is a notable exception (Healy,

the extensive literature about the politics and risks of infected blood.[3] In the more empirical literature about blood donation, questions about the social basis for contemporary blood donation have been somewhat overlooked in favour of the search for the source of individual donors "altruistic identity" (Healy, 2000, citing Piliavin and Callero's study published in 1991).[4]

Meanwhile, Titmuss' 'The Gift Relationship' (1977[1970]) has retained its status as the core work addressing policy issues surrounding blood donation. It is rare to find a policy document about blood or tissue donation in the UK that does not cite it. However, Titmuss' perspectives are seen as being very much rooted in a post-war ethos. Yet the figures on donation belie a simple narrative that would associate contemporary mores and society with a declining willingness to donate blood.[5,6] I was interested in exploring the

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2000).

[3] See for example Starr (1999), Feldman and Bayer (1999).

[4] I discuss some important exceptions to this in chapter 3, including Healy's work on the way that collection regimes within Europe differentially shape their donor profiles. Healy is particularly critical of the search for 'the elusive altruist' in the psychological literature (Healy, 2000).

[5] The proportion of blood donors in the population of England and Wales today is roughly comparable to that estimated by Titmuss for 1968: figures from the NBS indicate that 'at any one time about 6% of the adult population are active blood donors; however, a much larger proportion of the population, perhaps as much as half, will become blood donors, or at least register an interest in becoming a blood donor at some point in their lives' (NBS, 2000). Titmuss estimated blood donors as a proportion of the population in 1968 to be approximately 6% (Titmuss, 1997:91).

[6] Technical and management regimes appear to have an important influence on the supply of blood: following the introduction of more stringent screening tests in 1999 the number of blood donors declined from 2.1 million (in 1999) to 1.64 million in 2004 (CMO, 2004).

kinds of social and moral notions that had currency in the context of contemporary blood donation, before moving on to questions about blood donation for genetic research

After briefly reviewing the kind of interviews that I have undertaken, I shall explore the rationale given by these donors for their involvement in blood donation. As I shall show, they drew on diverse vocabularies to explain this to me: some talked about duty or obligation, others about satisfaction, others simply about the opportunity to give blood presenting itself. In my analysis of their accounts of how the blood is to be used, I begin to draw out the terms of blood donation as a social transaction. At the end of the chapter I shall discuss the emergence of analytical themes in this context, and show how several of these - notably those of reciprocity and of informed trust - became useful sensitising themes for the next stage of the research.

## II The research interviews

I undertook interviews with blood donors in one donor centre in one large city in the North West of England. These took place over the course of some four months in the late winter of 2001-2002 and early spring of 2002. Many donors came in to this city centre site from places of work nearby. Others took the opportunity of being in town on a shopping trip to drop in to give blood. (Only a few actually lived in the city centre). They had in common a relationship with the city through work, leisure, or sometimes family. Many had previously donated in local NBS sessions at church halls and community centres, but now found the city centre site more convenient.[7] At times this

[7] Local donor sessions at church halls and community centres typically take place once every few months. I visited several of these as part of my background fieldwork, but the peripatetic nature of

centre site was extremely busy. As I have described in the previous chapter, interviewing in the middle of these of flows of activity posed some challenges to the conventions of qualitative interviewing.

I shall recap on my approach to these interviews only briefly here[8]: I undertook 100 interviews with NBS donors, 52 of these being with men and 48 with women. These interviewees ranged in age from their late teens to late sixties, with most being in their thirties, forties and fifties. Some interviews however, were very brief, and I make a distinction between these brief interviews and those where a longer discussion took place. In this chapter I draw primarily on my analysis of those twenty-six interviews which lasted for twenty minutes and longer. It is these longer interviews that I cite at any length. However I have also described the shape of the responses across the interviews as a whole, based on a systematic analysis of selected key themes across that group. As I have described, this process included a simple quantitative check of my hunches about the shape of these data: several tables are included in the text of this chapter to illustrate that process. In undertaking the interviews I used a topic guide, and usually covered the following themes: how and why they first became a blood donor and why they had continued giving blood; what is done with the blood, views on payment for blood

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this part of NBS' work made it difficult for them to accommodate me at many of these sessions. Although the city centre was not embedded in a community in the same way that local donors sessions are, nevertheless, most of those I interviewed had begun and continued their donor careers within the region. Their commitment to blood donation was often described with reference to the history of their lives in or around the city, and to the places where they had lived and worked.

[8] See chapter 5 for a discussion of the ways I conducted interviews, stored and managed the data, and conducted my analysis. I have also discussed the ethical issues that I encountered in chapter 5.

donation, information, concerns or worries about giving blood. Where possible, I also asked donors about their views on the use of blood for research.

During the time that I waited for donors to approach me to be interviewed, I talked to staff and observed their working and the comings and goings of the life of the centre. This enabled me to fill in some detail about the processes surrounding blood donation. For example, I was able to see the detail of the information made available to donors,[9] I became aware of the relative lack of privacy for anyone in the centre,[10] and I observed some of the adverse physical effects sometimes involved in donating blood, such as bruising and fainting. In this context I became aware of the way in which both donors and 'donor carers' actively managed risks to the donors well-being.

My observations also challenged my earlier perspectives on blood donation in more substantial ways: looking at the day to day processes in the centre, I came to see blood services in a different light. At the end of each session the blood was despatched for checking, auditing, testing, and then finally to be used either directly or in the manufacture of blood products. Finally, the donated blood would finally be transformed

[9] Information in written form usually available in the waiting area includes blood safety leaflets - on do's and don't's of giving blood), 'The Donor Magazine - featuring real life stories of the medical uses of blood, and sundry other leaflets. Although research is specified as a possible use for the blood in the main information leaflet, none of these stories featured the use of blood for research. Special displays on notice boards featured similar information.

[10] I do not mean to imply that NBS staff did not take care to give the donors some privacy. However as I have described earlier, in chapter 5, this was unavoidably limited by the conditions of the donor centre.

into a medicinal product - blood products are regulated as such.[11] In this sense, the blood centre is more like a factory than, for example, a health centre. The tension between seeing donated blood as a product and managing donation as a moral transaction would be an important one in thinking beyond the immediate fieldwork, to the issues around blood and biobanking. As Hoeyer has observed, "Blood can be imagined in different ways - as both as an intimate part of the person and as a 'mere thing' and this impreciseness is central to an understanding of informed consent procedures in biobank research" (Hoeyer, 2004:99).

Observing blood donation also underlined for me the importance of something else I might otherwise have taken for granted: that blood donation is a physical practice, in which donors rely on being looked after by professional carers. NBS donor carers - who are often assumed to be qualified nurses[12] - are accorded the trust given to health professionals who are seen as having a fiduciary role in this regard. When I began to ask donors about the ways in which they expected their blood to be used, it became clear that this kind of tacit trust was central not only to the physical task of donating blood, but also to the way that people conceive of the relationship with the blood service.

[11] In the 1970s, the great majority of donated blood was transfused as whole blood. Now more than 95% of blood donated to the UK's NBS is processed to make blood products (Martlew, 1997:43).

[12] Historically the blood service teams were staffed by medical and nursing personnel; now only the team leader need be a qualified nurse, and medical staff are not routinely available at donor sessions. Lay donor carers are trained in venepuncture. Many of the staff I spoke to questioned whether venepuncture was something the blood service could legitimately expect them to do, and would have preferred nursing staff to undertake these duties.

In the early interviews my questions about what kind of information people looked at, and what they thought about the uses which were made of blood frequently elicited fairly brisk, even dismissive replies: *'I give my blood and now its gone and I have no views'* said one man (NBS 17). Another captured the spirit of these discussions when she said that she had *'no idea'* what the blood would be used for (NBS 25). Many commented that they trusted the blood service and the relevant authorities to make the best use of their blood, and didn't feel the detail to be their concern. I described in chapter five how one response to these comments was to change the way I asked questions, indeed to ask fewer questions. At a more analytical level, I felt that these recurring comments, often couched in terms of 'trust' directed me towards something important: my assumption that I could analyse peoples' decisions in relation to the information they had access to about blood donation and blood services seemed to have been misplaced. From these donors' perspectives, information was not the basis of their consent for their blood to be used. The dynamics of trust which were entailed in handing over blood were to emerge as an important theme in my research. I shall return to a further discussion of this theme below. (See especially section headed 'The uses of blood: formal consent or informed trust?) In the following section I begin to explore the overall rationale given for donating blood.

## III Accounts of donating blood

Many people, donors and non-donors alike, perceive blood donation as worthwhile or altruistic (NBS, 2000). In asking people about how and why they had first come to donate blood I did not expect to establish what made them different from those who had not done so. (There is an extensive body of psychological literature about blood donors,

much of it devoted to the question of what differentiates donors from non-donors).[13] However I thought that it would be a way of eliciting a more concrete account of donors' experience than a more general opening question.

Those I interviewed often described their initial donation in relation to an immediate opportunity, through the presence of an NBS mobile unit in their workplace or local church hall for example. Often too the decision to become a blood donor was attributed to others, a partner or spouse (usually female), or a work mate or colleague. Although a few exceptional souls described how this had been something they had always wanted to do, most attributed their initial involvement in blood donation to such opportunities, to the influence of others, and sometimes to a sense of obligation in this context. It was when I asked more about their continuing to donate blood that donors' responses became in a sense more their own stories, with a range of reasons for doing so being expressed. For some this sense of responsibility began with awareness of someone in their own family who had been ill, so that the blood donation was imagined as being *'to help somebody like my mum'*.[14] But it had then extended to *'future patients'*. Reasons for donating blood are intertwined and not easily separated, as the following two accounts show:

'Catherine Jones'[15] (NBS 81) a long-term blood donor, in her fifties, retired early from a

[13] This literature is reviewed by Piliavin, who finds that it has not resulted in any clear or credible conclusions (Piliavin, 1990:446-447).

[14] NBS 6

[15] All names are pseudonyms. As there was an informal atmosphere in the centre, people usually introduced themselves to me by their first names.

career in the civil service. When I asked her about her reasons for carrying on over a long time, she looked back to a time when she was told about the immediate uses of her donation[16]:

*R* *It was something that I was quite proud the first time I gave if you know what I mean. You think, well yes you might be helping somebody and sometimes I have been you know they did say it was for a special, you know an operation, a haemophiliac operation. So that was quite nice to think it was going to be used for an operation, you know rather than just go wherever it goes.*

*I* *So, that doesn't tend to happen so much now. Are you a rare blood group or*

*R* *Not particularly, I'm A rhesus positive so it's next to O isn't it, it's not the negative one.*

*I* *Right okay and what about did people in your family or people in your circle, ever need a blood transfusion?*

*R* *Well my mother did funnily enough in the, well she died three years ago but before that she had to have a few. So that was, it sort of felt well at least I'm giving back what she's taking sort of thing (laughs). Yes my Auntie has recently had one after an operation.*

*I* *Yes so you do know people...*

*R* *Yes you know so*

*I* *Okay and anything else at all that might have had a bearing on your keeping with it over obviously quite a long time?*

[16] Here and in the extracts that follow, 'I' refers to the interviewer (myself) and 'R' to the respondent.

*R* *Yeah I mean to be honest it's a bit of a double edged thing, I'm being a bit selfish as well because to my mind it keeps a little mini check on me as well, it means my blood pressure is. I mean I found out through here that my blood pressure was up.. When I came one time it was really high so they sent me straight to the doctor, you know they said "Go to your doctor straight away." Now I wouldn't have realised that had I not come here because I wasn't under any check-ups at the doctors.. And I always think well your blood is getting screened. So for me, I find it like a little tiny health check type of thing which, you know so I feel as though I'm doing something but also helping myself at the same time. So that's really what's kept me going. Also I think it's something that is easy and I think it's a shame more people don't do it because it doesn't hurt. So I just like to come if I can because it makes me feel better really (laughs).*

A male donor in his sixties, like many others in this group, had first attended blood donor sessions with work mates:

*I* *So tell me about yourself and how and why you came to be a blood donor?*

*R* *It started off at, I'd be about what twenty, twenty-one, twenty-two, something like that*

*I* *Right.*

*R* *At my place of work, someone decided*

*I* *What is your work, what was your work?*

*R* *It's office work. But someone decided that it might be a good idea if we all got together, some of us anyway, and came up to the blood donor centre.*

*And that's oh thirty years ago.*

*I* *Right.*

*R* *And since then I've never had any problems giving blood, I haven't been as regular as I might have been but I'm certainly well into double figures now in the number of times I've given. And I think it's a good thing, I think it's something that we can all do to help humanity in general if you like, it's just a little thing.*

*I* *Yes so what keeps you going with it all that time?*

*R* *What keeps me going?*

*I* *With doing this.*

*R* *A sense of wanting to, a sense of being part of this system which keeps the blood available because it might be me one day who needs it or someone in my family and if it ain't there then that's going to be a problem. So it's just something I think we should all do really.*

(NBS 10)

The satisfaction which could be gained from giving blood was often mentioned: one woman (NBS 32), who first gave blood because her teacher at college suggested that she and other students do so, pointed out *that 'there's not much else you can do that gives you that kind of buzz'*. An important element of that experience she continued - and part of what makes it special - is *'the idea that nobody can make any money out of …it just makes you feel good'*. Another talked about blood donation as a sociable experience which she looked forward to (NBS 41). She said that she *enjoyed 'being part of something'* as she lay down quietly on her own but with others similarly engaged nearby. Being <u>able</u> to help was a source of satisfaction for many: one male donor talked about

feeling *'as though I'm giving something back to somebody, I'm not, I'm doing very in little else so it helps me in that way, I feel good about it you know. Never had no problems wherever I've been, its been good'* (NBS 84).

Others couched their involvement in blood donation more in terms of duty or obligation. One donor, when asked about what had kept her going over twenty years as a blood donor, said:

*R* *Yes I think it's a sense of duty.*

*I* *Can you say a bit more about that.*

*R* *Well I feel, I feel that I should do it, it's sort of, I haven't got any children and I feel sometimes I've not made contribution to society. I know it sounds silly and I've worked all my life, I've never not worked but I feel it's something that we should all do, and I feel I should do it, in fact I'd like to do more to be honest. I did some time ago mention bone marrow but they told me I was too old so I was quite upset then.*

*(NBS 37)*

This sense of obligation did extend at times to obliging others to follow suit: this donor was one of several who admitted to cajoling others to volunteer. Other donors described how they had been put on a list by an enthusiast at work to be visited by the NBS mobile team. One or two donors had been expected - though not compelled - to donate whilst volunteering for the Territorial Army or other army service. To my surprise, this kind of cajoling or volunteering of others was not objected to by these donors. (I presumed that some would object but that they were not represented within my interview group). This

seemed to underline the extent to which this commitment was considered to be an obligation by many of these donors.

## IV Themes from the interviews

### Blood donation and Interdependence

Perhaps the most consistent thing about all these accounts is that they are relational. Blood donation (of course) is something which is done with others in mind. However it was not seen as a sacrifice: many pointed out to me that giving blood didn't cost them much. All of the donors I have cited above, and many others, talked about the way they were taken care of at donor sessions as being important. (Conversely, it is likely that some people stop giving blood because they do not feel appropriate care is taken during screening procedures or venepuncture). For some, the relationship to others was invoked through a dramatic, usually traumatic reason for giving blood: a family member being ill in hospital, a friend being diagnosed with cancer. One young woman who had a friend with leukaemia was most eloquent about this. Certainly there were a number of people in this situation. For many though the awareness of blood being needed was expressed in terms of a growing awareness of the vulnerability of others when they encounter accidents, serious illness, unexpected operations - and an awareness that these unexpected disasters could happen to themselves and to those close to them. 'Simon Entwistle' (NBS 58) was explicit about not thinking about these disasters when younger, but becoming more aware of them. For another donor, who I call 'Mike Barnes' (NBS 83) it was a question of thinking what would happen if you (and others) didn't donate blood. Thus the interdependence symbolised by the possibility of needing donated blood at a time of

catastrophic illness or accident featured in virtually all of these accounts.

Over the course of time, blood donation eventually becomes routine, making it perhaps even more difficult to interrogate the reasons for it. For very long-term donors, the certificates given at particular points in a donor career (twenty-five, fifty, and seventy-five donations) became important to achieve as indicators of their commitment. For one long-term donor:

> *My wife, girlfriend as she was then started me off when it would have been, I can't think… I think I started at 18 at the first one was in the docks. [Edit…] I don't know partly you get your 25 you know you go for your 25th and then you know obviously you realise at the back of your mind you realise you know it's a necessary thing and someone has to do it and you know you see the adverts now and you do, you know you do need, the Health Service does need blood so, and that's one of the reasons to keep going. But once. ..you get your fiftieth, you know its just something that's built in, its just something that's built in, it's a routine.* (NBS 71)

All of the respondents talked about how they came to give blood and why they continued doing so. Reviewing the data as a whole around these themes, I found that the most common occasion for coming in to make a first blood donation was related to peoples work, in that they had either attended a session with a work group or colleague or (amongst the older donors) at NBS mobile sessions at their place of work. For example Mike Barnes had worked as an electrician all his life, and talked about first giving blood when he was 18 because someone at work said he should. At that time, he was working

for a large engineering works, but later he had worked in many different plants in the region. If there was ever a session in the factory where he was working, he told me, he'd always given blood, wherever it was. After retiring, he had given blood at sessions in a church hall near the suburb where he now lives, and then only very recently started to come in to this particular centre which had the advantage of being open every weekday. This donor was one of several men around sixty years of age whose accounts of a career of blood donation evoked for me a strong sense of place and the way the city had changed over the decades. He had first donated blood in 1962, making him one of a few donors in my study who could recall donating blood at the time about which Titmuss wrote. He talked of a plant where thousands of workers were based, and of a blood service mobile unit visiting the site for a whole week. Other men amongst those I interviewed had worked in the docks, in large factories, in big Royal Mail sorting offices in the city centre, or for other companies since disappeared or privatised, like BT. (There are fewer women blood donors of this age, and those I interviewed had not worked in the same industries). Usually the way these men talked about blood donation was meshed into a sense that it was one way that working people could take care of each other. This particular donor told me that he felt donor sessions in church halls and community centres were 'very middle class'. This way of talking about blood donation was less evident among the younger donors, whose occupations reflected the changing face of the city's economy: many worked in offices or shops, or were employed in various capacities for the city council.

Across the interviews as a whole, thirty-seven cited work as their initial way in to blood donation. In addition, some had initially attended at student sessions run in a similar way by the NBS. For twenty-one, the route to making initial donation was through attending

with a member of their family or a friend, or their attendance was specifically influenced (or volunteered) by a family member or friend. Others, particularly younger donors, cited an appeal or NBS advertisement as the occasion for their initial attendance. These 'ways in' to blood donation are summarised in the following table.

**Table 1: 'Ways in' to blood donation (main categories)**

| | |
|---|---|
| Number asked about initial 'way' in to blood donation | 100 |
| Work sessions or attending with colleagues | 37 |
| Student sessions | 12 |
| Family or friend | 21 |
| NBS appeal or radio/tv advert | 12 |
| Other | 18 |

Continuing my review of the data as a whole, I explored the rationale or motivation given for continuing to donate blood. The data used here were the responses to a question like 'so what keeps you going with it?' or 'so what's kept you going with it over this time? There was a sense in which these responses sometimes reflected a surprise at my even asking about this: they were 'just doing their bit' or 'giving something back'. Though somewhat abbreviated, these responses do carry with them the kernel of an idea that I shall suggest is important in this context: in implying that they give blood because they have received something, or that they owe something. These discussions, then, provided

at least a way in to talking about the social basis of the practice of blood donation.

Many referred to a general perception of blood being needed, to an awareness of need in the present or past by a particular person, usually a family member, and some to a response to an NBS appeal in this context.[17] Some talked in more general terms about blood donation being worthwhile or a good thing to do for others, and others talked in terms of duty. Often some reference was made to the idea of a (blood) bank specifically as a reason for giving blood: this was explicitly linked to the possibility that they might need blood one day.

## Boundaries to the uses of blood

All the donors' accounts reflected the ethos that blood should be universally available. However, whilst no-one seriously suggested that certain categories of people shouldn't receive blood, ambivalence about those who don't give was sometimes expressed. Comments about those who shouldn't receive blood were always expressed laughingly, jokingly:

> *I hope that people who won't give blood don't get it (laughs). It sounds awful that but I think God you know I give blood, and if I want it its there…*
>
> *(NBS 8)*

[17] Of the (100) interviewees, 33 referred to a general perception of blood being needed, 27 to awareness of need in the present or past by a particular person, usually a family member, and 11 to a response to an NBS appeal in this context. 28 talked in more general terms about blood donation being worthwhile or a good thing to do for others, and 15 talked in terms of duty.

Within this system, it was felt that you couldn't reasonably specify exactly who should have the blood, despite the fact that there might be some people who you wished couldn't have it. Likewise, most felt that you couldn't specify what the donated blood could be used for. This was not a case of having no views on priorities for medical treatment and research. It was rather that the nature of the transaction was one of entrusting the blood to the bank to make the best use of:

*R* *Well I trust you've been doing the most you can with whatever I give.*

*I* *Yes, yes.*

*R* *Really you're not going to bin it and things whatever it is, if it's no good for donors you'll use it for research or a bit of both or*

*I* *Yes okay right so would you see that in the same light I mean would you see giving blood and then it being used for research say on common diseases would you see that in the same light as giving blood for more immediate medical use, yes?*

*R* *Because to me the Blood Transfusion Service they just provide a bank of blood for the NHS or whatever to decide how they want to use it.*

*I* *Okay you're not reading my questions upside down are you?*

*R* *No.*

*I* *But you are actually prompting because that was the next thing I wanted to say.*

*R* *Because it's a Health Service, not only one aspect. The Blood Transfusion People provide, you know if they lose half the blood to research to benefit somebody then that's their decision. It's like having a pot of money and*

*deciding where you've got to spend it.*

('Mike Barnes', NBS 83)

Sometimes exceptions to the ideal of universal entitlement were mentioned. There was for example the issue of patients in private hospitals: for some this posed a challenge to the ethos of the universal system, and it was felt that perhaps they should pay for the blood. Similarly, it was often said that blood should be used in this country. Although I sometimes pursued these discussions further, it is not my intention here to present a detailed breakdown of these conditions on the use of blood. In any case the case for these candidates (private patients, foreigners) to be excluded from receiving blood tended to evaporate if it was thought that surplus blood might go unused. However blood services were understood to be part of the National Health Service - as indeed they are at a statutory level, with NBS being a special health authority of the NHS. Donors felt that their voluntary donation was an intrinsic part of that system. Occasionally a scandal was referred to in which blood or organs had been traded in this country or abroad. But at no time did those I interviewed refer to established systems by which money is exchanged for blood - both within and outside the UK.[18] Similarly, the supplementing of the national blood supply with safer plasma products from other countries, notably the USA, was not discussed.

[18] Albeit with the proviso that in the UK such payment is calculated to cover the cost of production and supply of blood products (Robinson, 1996:428).

## 'The more you have in the bank the better' [19]: the notion of a national blood bank

I have begun to discuss how donors see their own interests here as interwoven with those of others: the provision of blood is seen as a social arrangement for providing blood for themselves and others. Some specifically used the phrase 'blood bank', but others I felt referred to the idea of there being a bank of blood available without actually using the term:

> *It's really a case of why not…I know people who have done it and I have a friend who has leukaemia, or who had leukaemia shall we say and you know your hear about other people who are blood donors because their lives have been saved as a result of being recipients of blood..(Yes, that's right, yes). All right I may be doing it the other way round, I hope that I never have to be the recipient but I'm willing to give because if I don't need it others will.*
>
> ('Mike Barnes', NBS 83)

Here the arrangement of donating blood is envisaged as being equally of use to oneself and to others. It is envisaged as an arrangement in which the risk that we may need blood is shared with others who may likewise become vulnerable.

To confirm my hunch about the idea of blood donation as a practical mutual arrangement for providing blood - or blood bank - I coded all of the interviews for this, which enabled me to review the data as a whole. A brief comment is in order here about this coding: the

[19] NBS 57

dimensions of this concept arguably make it difficult to code for consistently. If someone says ‘the more there is in the bank the better’, this can clearly be coded ‘bank’; if they say ‘you never know when you might need it’, thus demonstrating the common interests of donors and potential recipients, I would also include them. It is the notion of reciprocity (as opposed to selflessness) which is important in my thinking here rather than the specific use of the term ‘blood bank’. The coding and counting here is not intended as an absolute device but rather as an analytical tool to review the shape of the data as a whole.

I found that about half (47) made some reference to the idea of NBS as a blood bank at some point in the interview. The mutuality of such an arrangement is enhanced by the thought that the health screening for blood donation can function as a health check. One expressed this as follows:

*R* *And I mean I know for a fact that when you come to give a blood test if there's anything wrong they'll find it.*

*I* *They'll let you know yes.*

*R* *So really basically as long as I'm reasonably fit that I know when I left here, when my blood goes to whoever it goes to for testing they can do all the, if they find anything wrong they will let me know. It's better than going to the doctors.[Edit] I know that I'm firing on four cylinders.*

*I* *Sure and in a way it's a nicer way of knowing that than going and asking the doctor.*

*R* *That's it, that's how I look at it.*

(NBS 100)

Often donors said it was recognising the possibility that they might need blood themselves which enabled them to accept repeated, detailed and to my mind intrusive screening questions before they gave blood. Donors consistently pointed out to me that the fact of their being asked these detailed questions would be a source of reassurance that the blood was as safe as possible if they themselves needed blood in the future. Linked to this was the widely expressed view that blood donation should not be rewarded with payment, for moral and practical reasons. In many of the interviews I asked people about their thoughts on the arrangements for paying blood donors in some other European and Scandinavian countries, several of which offer token payments to blood donors. However, they often replied by making a comparison with the US, illustrating the extent to which Titmuss' arguments are embedded in a wider set of social beliefs about blood donation systems. For example one woman in her sixties said:

> *I think you know if you want to give the gift of life it should be freely given and it wouldn't necessarily be freely given if money was concerned. You know the people who are very, very desperate for money might come in and sell a few pints or something and that all makes it very wrong.*
>
> (NBS 92)

A few took a more pragmatic view of the issue, saying that the paramount issue was obtaining sufficient blood, and that payment could be one means of ensuring this. But even these pragmatists insisted that they would not themselves accept any payment for donating blood.

Some replied to my question about the practice of payment (in other countries) with a detailed discussion of the kind of problems this would lead to. Sometimes my questions were taken to indicate that there was a possibility that the NBS was considering paying donors. My need to contradict this impression had a tendency to curtail these discussions. But when I was able to persevere with the discussion, the pride in a system of voluntary, unpaid blood donation was often evident.

### The place of the NHS

The extent to which the blood service is embedded in the NHS was implied in many of the ways that people talked about blood donation. Often this point was made implicitly in talking about instances in which blood might be required for accidents or serious conditions. It is not that there would be an extended discussion of the roles of the NHS and the private sectors, but it was taken as read that emergencies were dealt with by the former. *'Operations, transfusions, babies'*[20] were the examples usually given of points of crisis when blood might be needed. None of the examples given by any of the interviewed donors made reference to people being treated in the private sector.

At times there was what might be called a 'thicker description' of the ways that blood donation is embedded in the NHS and the wider welfare state. Comparisons were made with other countries in which emergency treatments were paid for by the patient, whereas here *'at least one thing at least if you're seriously ill you get to, you don't have to worry about the bill at the end because you know it's there. I mean if you're really seriously ill, a road accident, you're seen to straight away and when you work it out there's blood*

[20] NBS 37

*there'* (NBS 100). As the interview went on this man insisted that people should donate blood *'willingly and for self satisfaction'*. In these more discursive accounts the importance of the relationship with the NHS was made explicit, as was the ethos underlying voluntary blood donation. So here in my discussion with a female donor in her thirties:

*I* *Can you just, I think I understand what you're saying but can you just spell it out for me, in a way what's special or particular about blood donation that money shouldn't come into it?*

*R* *I think it comes down to that word donation in my head, its like something you feel like, you feel good about it because its a thing you do sort of in a voluntary sort of process and you enjoy doing because its something you give the National Health isn't it?*

*(NBS 41)*

Usually though these discussions were less self-consciously idealistic or ideological: it was in the detail about the way blood is used or the contrast with other countries that the importance of the NHS emerged. Often the NHS was used as a framework to delimit the boundaries within which the blood should be used. In a few interviews I tried to probe what was important about unpaid blood donation. It was, one respondent replied, a problem of where to draw the line - the consequences of paying for blood at point of donation would cascade through the system altering it substantially[21]:

[21] In an intriguing parallel with Titmuss' arguments, it was not uncommon for donors to contrast the British system with that of the USA if I pressed them about their allegiance to the blood service. Some of the donors may have known about Richard Titmuss work from the substantial newspaper

*People would say oh we've got to pay for this blood, why not pay for organs. And basically you're coming into a private health system or paid for private health system rather than a national health system and unfortunately, I'm being, by social inclination I'd prefer to have a national health service and a national blood transfusion service that's funded by the people without paying..*

('Andrew', NBS 57)

When these donors entrusted the NBS with their blood, they did not expect to be involved in making decisions or drawing boundaries about the use of the blood: it was for the organisation to make appropriate decisions about the use of blood. However, they made it clear that they did not expect it to be used in other contexts:

*I* *Okay, can you tell me from what you know about the kinds of ways that the blood is used?*

*R* *I just, the only thing I don't know about is do they sell the blood to other countries, that's the bit that annoys me.*

*I* *Yes, I hope not, I mean I'm not from NBS.*

*R* *When you read about it and you think do they sell it abroad and you don't, you're not giving it to do that are you?*

*I* *No.*

*R* *Do you know what I mean? Not for them to make a profit about it in some way. I know I know it probably gets ploughed back into the NHS and they*

---

coverage of it in the early 1970s, although none mentioned this.

*need it but you don't give it for that do you?*

(NBS 8)

It seems clear from these accounts that donors' understanding of the place of the blood service in the NHS was sustaining their commitment in several ways: through it they could imagine others' need for blood, they could trust the organisation to whom it was given, and they could expect that the use of blood would be delimited by national boundaries. In addition the association with the NHS meant that the donated blood would be used within ethical boundaries. It was not that donors stated categorically that non-nationals should not receive their blood. However, the idea of blood donation as embedded in the nation is often made, in various ways, in these accounts.[22] Nor - as I shall discuss in the next section - did they often feel sufficiently informed or expert to be certain of the moral boundaries around new developments such as genetic research. However, where discussions arose about the use of blood by commercial companies - for whatever purpose - this kind of use was not seen to be within the terms of a national blood service. Importantly then, the association of the blood service with the NHS played an important part in defining and delimiting the imagined uses of blood.

## The uses of blood: formal consent or informed trust?

When I asked about the uses to which the blood is put, donors were sometimes puzzled or alternatively embarrassed at their lack of detailed knowledge, as in the following

[22] Another example, where this point is made more explicitly, is given in the quote by 'Peter Williams' (NBS 100) in the section below. Often these points were made more implicitly, and usually they were tied into a more general discussion about how the blood should be used.

example:

*I* *What can you tell me from what you know about the kinds of ways the blood is used once its collected?*

*R* *I think the main way is probably, just for acute care I would think, operations for people who would need regular blood transfusions. I would think that my blood would probably last about five minutes you know when its been cleared because just for certain operations that's really my basic understanding of it. Just for surgeons to carry out operations. I wouldn't know what else it could be used for. I'm unaware of any other uses for it.*

(NBS 57)

NBS policies allow for the possibility that donated blood may be used for research purposes. In recent times this has been indicated on the donor consent/declaration form. However only a handful of donors mentioned research when asked about the uses to which the blood was put. The data on donors' views on how the blood would be used is summarised in the following table:

**Table 2: Stated uses of donated blood (categories not exclusive)**

| | |
|---|---|
| Number asked about uses of blood: | 100 |
| 'Emergencies' | 67 |
| Operations/transfusions | 45 |
| Other (routine) medical use | 36 |
| Research use | 7 |

It seemed that there was a gap between donors' formal consent, as indicated on the signed declaration, and the uses for the blood which were prominent in their explanations to me - such as use in operations and other such emergencies. 'Catherine Jones' who I cited earlier, put it as follows:

*R* *No I'm very lazy, I mean I know it can be used obviously for donation, for transfusions [yes] or I think they can split it all up and use the different components [yes, yes] for different, either again transfusions or research or whatever. I mean I have read at one time what they did, I mean I will admit, you just sort of, I know it's used and I don't care what it's used for.*

*I* *You take it in but you don't necessarily…*

*R* *Yeah as long as somebody, somebody somewhere is getting some benefit I mean I'm quite happy sort of thing, they can do what they want with it.*

*I* *Yeah, yeah so what you're saying is they don't necessarily need, you do cast your eye over some of the information to see?*

*R* *Oh yes, yes I mean I have read them.*

*I* *But you don't necessarily need to know all the ins and outs to be happy, to be going ahead with it?*

*R* *No because I just, I just have faith in them that they'll use it to the best choice really you know I don't mind you know [okay]. As long as it's not just thrown away, I mean as it's used for something you think well the effort was worth it.*

*I* *Yes okay, I mean you mentioned research there, would you see giving blood for research differently from giving blood for more immediate medical use like the transfusions you described?*

*R* *No I don't think so really. If it was doing some good you know if it was*

*I* *Thinking of research?*

*R* *I mean they do take the extra phial here that I think, I don't know what they do with those.*

(NBS, 81)

This sense of 'having faith in them', or placing implicit trust in the organisation, was one of the most consistent findings from my interviews with NBS donors. Later, I shall suggest that it is this kind of informed trust (entrusting something to an organisation, based on its reputation and status within the community), that characterises the relationships between donors and blood service. Compared to this, the detailed and specific information that was provided seemed to play a small part. Before I began interviewing NBS donors I was aware that each time blood was given the donor signed a written consent form. The consent form apparently indicated their agreement for their blood to be tested, and then used for suitable purposes by the NBS, with research

approved by an ethics committee being one of the uses set out in the donor information. Nevertheless, when I spoke with donors about how the blood was used, very few mentioned the possibility that it might be used for research. Most of the donors I interviewed spoke about emergencies and operations as the main uses of donated blood.[23]

For most donors, the details of what happens to blood after it is donated are not of pressing concern. Peter Williams, a long-term blood donor who had worked for many years for the Royal Mail, explained his difficulty with my questions to me in this way:

> *The problem is once I've given it what they the NBS do is it's up them. I mean once I walk through the door I forget about the NBS.*
>
> (NBS 100)

Often my line of questioning was uncomfortable, because it pressed people to think in terms of details when they were in fact concerned more with handing over their blood to the blood service - and leaving it at that. In one early interview for example I was talking with a donor who hadn't been aware that her donated blood could be used for research. She realised that this was so through my questions.[24] When I asked about the consent form she had presumably signed, she agreed that she had signed it but this it seemed had been *'difficult to take in'*. When we talked a little more about this it seemed to be part of

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[23] As noted earlier, most donors referred to emergencies and operations as the expected uses of donated blood. Only seven mentioned the possibility of donated blood being used for research purposes. (See table 1, above.)

[24] See chapter 5, for a discussion of the ethical issues that arose from these kinds of situations.

a more general process. She talked of how she had gradually realised some years ago that her blood would be tested for HIV, but how she hadn't been fully aware of this at the beginning - although here again she agreed that she had given written consent. She had realised that screening questions were concerned with risk of infection, but she hadn't for some years realised that each blood sample would be tested for HIV. This was perhaps the clearest testimony to how little the written information provided permeates the relationship with the blood service - at least for some donors.

After this I tried to avoid confronting people with issues they might rather not think about by asking quite open, hypothetical questions, such as 'Would you see giving blood for research differently from giving blood for medical use?' Often my questions were apt to generate questions in reply: who would the researchers be, what would they do if they found out more about the causes of a disease, could the blood get into the wrong hands? Given the openness of my questions about genetic research, it is understandable that respondents sought to pin down more what I meant. It is evident that there were some significant difficulties in my using these brief interviews in these difficult conditions to ask these kinds of questions.[25] Once I had recognised some ethical problems with asking blood donors about research, I avoided pursuing even hypothetical questions if I felt that they were an unwelcome intrusion. As a result only about two thirds (67) of these interviews resulted in any indication of views on genetic research. However, the twenty-six interviews to which I mainly refer in this chapter all featured some discussion of views on research, including genetic research.[26] Often respondents felt they did not know

[25] See chapter 5 for my discussion of these and an evaluation of the value and limitations of these data.

[26] I should note here that the consent form for my own research stated that my research was

enough about research to even begin to address my questions. Nevertheless, some important themes did emerge from my attempts to ask these questions.

Many donors drew my attention to what they felt were the limits of their expertise. In this context, the reputation of key institutions, such as the blood service (though rarely referred to by its official title) and the NHS shaped their responses both to my own questions and to the substantive issue of how donated blood should be used. A common response to my questions was to indicate that donors couldn't be expected to know about or understand research: in asking them I was 'going beyond' their expertise.

One response was to reaffirm principles that had already been stated. So Peter Williams, who I cited above, continued in the same vein:

*R* *So therefore if blood and research and different things then like I said I've come to the session, give my blood right, I've had my cup of tea and my biscuit and like I say when I go through the door what the Blood Service do with that it's up to them.*

*I* *You leave it behind mm.*

*R* *I mean if they say to me "Your pint of blood is going to research."*

*I* *They won't, I mean that's not*

*R* *But I'm saying, if they said to me "Well you've give a pint of blood today, it's going for research," it would probably say some lives, not save one life it might save three lives all well and good providing it's used for people in this*

---

concerned with 'exploring the meaning and ethics of blood donation for genetic research'. Some donors raised the subject in response to this.

*country and nobody else. I don't like this idea that my blood is going to some, any Tom, Dick and Harry outside the UK that's what I'm saying.*

*I* *So it's very important to you that it's a national blood system ?*

*R* *It is a national thing and I think, and I feel very strongly. If they said to me "Oh well we're going to start sending the blood all over the place" I wouldn't have it. It's the same as paying, if you want to do that no.*

(NBS 100)

The blood service - or the NHS - was to use the blood for the best purpose, which might include research. A few donors did point out to me that you gave blood expecting it to be used in more direct ways. For most though it was up to experts in the blood service and the NHS to decide. As with the more general discussions on blood use, usefulness was usually the criteria here: if it was research that would help with treatment of serious disease and 'do some good' then many donors felt that was fine. Conversely, some kinds of research were viewed as relatively unimportant or even frivolous: examples were given, including research for the cosmetic industry and infertility treatment and research, which were mentioned by several donors as being expensive but less important than research into serious disease. Research involving business ventures was also seen as questionable as 'they might sell the blood for profit'. Thus blood donors had a variety of research uses which they would wish to exclude donated blood from being used for, each being seen in its own way as not legitimate. (It would however be impossible to derive a consensus on the uses of research from this impressively diverse set of views). In the next section I move to a discussion of views specifically on genetic research.

## 'This cloning business'[27]: concerns about genetic research

When I ventured into a discussion on their views on research, many donors did express views on the use of blood for research, including genetic research. Two themes characterised our discussions about genetics and genetic research. Firstly and most prominently, there was a worry about developments in genetics, with cloning being seen as particularly worrying. Wrapped into this were concerns about research that involved interfering with or manipulating embryos. In these brief discussions, it became clear that some established uses of genetic techniques - notably ante-natal screening for genetic diseases - were a cause of concern for some. In addition many referred to newer developments and debates about genetic screening, notably the screening of potential 'donor babies'. In contrast the other prominent theme was one about the potential of new research and genetic techniques: amongst the older donors in particular genetic research was sometimes framed in terms of a rhetoric of progress.

Two scientific controversies which were prominent in the news media at the time emerged spontaneously as a reference point in many of these discussions. As these two cases seem to have crystalised the hopes and fears associated with genetic research I describe them here briefly. The first concerned the claims of Italian embryologist Dr Severino Antinori.[28] During the course of the fieldwork, claims made by the controversial scientist that he had been involved in the use of cloning to produce human embryos which were subsequently implanted into women were widely publicised. Dr

[27] NBS 87

[28] See 'Maverick in new cloning controversy', The Observer, Sunday May 26 2002, Peter Beaumont and Philip Willan.

Antinori had some years previously achieved notoriety for helping women in their fifties and sixties become pregnant via the use of IVF. He is on record as supporting the use of human cloning techniques in the context of treatments for infertile couples, including those beyond the normal age of fertility. One particular case of the woman 'a grandmother's age' giving birth was extensively covered in the media. Much of the concern expressed in my interviews was about interfering with the course of nature in these matters. I had a sense though that there were several other issues being grappled with here. Firstly, there was the question of when in the life-course it was appropriate for women to have children. Secondly, there was the question of maverick scientists in this field and how little hope there was of controlling them. If scientists in the field of fertility treatments could avoid national ethics and laws, what hope was there that scientists in other fields (such as those concerned with genetic research on disease) would be amenable to political and regulatory control?

The second spontaneous case was Christopher Reeve's promotion of experimental treatments, including therapeutic cloning, for the development of treatments for neurological disorders and for spinal cord injury in particular. This particular campaign was largely in response to the decision of the Bush administration to restrict stem cell research amongst those in receipt of federal funding for such research. Without such restrictions, Reeve felt that 'we might be in human trials [on treating neurological disorders and injuries with stem cell based therapies] by now'. He undertook a visit to the UK in the spring of 2002 in the course of which he gave a good number of media interviews. His poignant assertion that he felt he would personally have been 'in a different situation today' with government support for such research, together with his status as former Superman, ensured a level of coverage of these issues which such

campaigners rarely achieve (Burkeman, 2002).

These were not the only examples of media coverage referred to by my NBS interviewees - this was after all a year in which considerable coverage was given to developments in genetics - but they were the ones most often reiterated. The Antorini case, containing a warning of how uncontrolled science might go wrong, sometimes occurred as a justification for caution in relation to developments in genetics. In contrast, Reeve's case was sometimes referred by those whose wanted to draw attention to the hopes for progress from new genetic therapies.

Although it was occasionally the case that the interviewees were 'pro' or 'against' genetic research, it was usually the complexity and difficulty of judging these developments which came through in the interviews. For example Richard Barnes had been giving blood for over 20 years, having begun in the course of his work as a prison officer. (In the past, NBS used to go into prisons to collect donations from volunteers amongst both staff and prisoners. Richard's donor career spanned the discovery of AIDS and the introduction of measures and screening questions designed to reduce the risk of those infected with HIV donating blood). In this interview the oscillation between the idea that 'it's fantastic what can be done' with medical research, and the worry about controlling such developments was particularly pronounced:

I *Now let me ask you, would you see giving blood for research differently from giving blood for more immediate medical use?*

*R* *It depends what the research is for. I think very simply and my idea is I've my pint of blood and that's going to go to a hospital somewhere and*

*somebody is going to get it.*

*I* *Yes.*

*R* *And that's for a long while what I thought and I didn't know about all these other things that get done to it. But it depends what the research is and stuff.*

*I* *Okay well there's a couple of things, I mean one is if they ever do need to use blood for research they only need like 5mls, you know like a teaspoonful or two*

*R* *Just a little bit, yes.*

*I* *To do research, it's not like your pint would be used. And the other thing is I'm thinking of research on common diseases like say heart problems or arthritis, that, you know that kind of thing, looking at the course or treatment of those.*

*R* *Yeah I wouldn't bother too much about that.*

*I* *But there were some things that you would?*

*R* *Well there are things medical that I agree with and I think we should go down the road of making developments in that but things like all this cloning business for instance what a waste of time that is you know I mean do we want two of me or two of anybody come to that (laughs).*

*I* *No I know.*

*R* *You know you just, I don't see the point in spending the money on it, it's wasteful. So I wouldn't, I wouldn't want my blood to be used for anything like that for instance you know wasteful. I think there's a lot of things that are wasteful that could be used, better used, treating people who are actually ill.*

*(NBS, 87)*

When I described what I meant by genetic research on common diseases, Richard replied that he thought that was sensible, but then pointed out that:

> ‘*things come out of research that we didn't know were there and then they get developed don’t they and cloned. But you know things get, I mean this cloning business for instance it's, it's out of control and to me the whole world is out of control because one country says "Well we're not going to do that because we don't think it's ethical," and then somebody else says "Oh yeah well we think it's okay so let's do it," and off they go and there's no control, the whole world has gone mad.*
>
> *(NBS 87)*

Although this interviewee was particularly eloquent about the risks of a runaway world, his words echo those of others in these interviews: no-one wanted to speak against the development of research which would be helpful to those with the kinds of disease I gave as examples (arthritis and heart disease). But few felt confident about the moral boundaries in relation to these kinds of developments, or about the control which society has over such developments. Mixed feelings were common in thinking about developments in genetic research. One donor in her mid-twenties, who had only recently begun giving blood, after her friend had blood transfusions in the course of treatment for leukaemia, expressed it in this way:

> *‘I’m in two minds. Genetics is playing with you know something that’s natural. You know you can always get someone that will take it a little bit*

*too far. But you know looking at my friend its important to find out how it's passed down through her family. She's got a daughter, will her daughter get it? I think in that sense maybe it is important.'*

(NBS 52)

If mixed feelings were characteristic of some interviews, others were shaped primarily by a rhetoric of progress: particularly amongst the older donors, developments in genetic techniques were seen as fitting with an understanding of disease as often hereditary. For these blood donors genetic research was aligned with a ' (scientific) *progress for which people had made great sacrifices in the past'* (NBS 86)*.*[29] In this context, knowledge was highly valued, both in a general sense and in the sense that 'its best to know' about any genetic susceptibility to disease:

*R* *I think everybody should be, have their DNA done really and then they'd know if anything happened to somebody straight away they'd know wouldn't they.*

*I* *What they'd know what their weak points were or whatever?*

*R* *Yes, yes. It's like in families where you get the hereditary like my husband his sugar, sugar -*

*I* *Hypoglycaemia something like that, no diabetes?*

*R* *Diabetic but he only found out last year well he's 68 but his mother was*

[29] For one donor, the importance of this kind of research was so important, that he felt that blood should be sold to companies to undertake genetic research, with 'the profit ploughed back into the NHS' (NBS 10). This favoring of commercial involvement was however most unusual in these interviews.

*diabetic and his grandad was diabetic but he didn't know this unless they found out that he was diabetic you know so I mean there's research into diabetes isn't there which is a good thing.*

*I* *Yes okay, I mean some people say you know DNA or genetics, you know because it's unique to you that it's special and therefore it's very personal and therefore they have real sort of problems about research going on and all that sort of thing?*

*R* *I think everyone should be DNA'd, everybody in the country should be DNA'd.*

*(NBS 90)*

When I pressed this donor further on the case that DNA might be seen as unique in a number of ways, this suggestion was rebutted.

The concerns that were sometimes expressed about regulation reflect those identified in others studies addressing these issues more directly (HGC, 2001). Similarly, we know that some of the existing applications of genetic techniques are controversial in the UK.[30] My own exploration of these issues in this context is only very tentative, for reasons that I have described. However, it is notable that my analysis does not point to genetic information or techniques per se as being at the centre of (these donors') concerns about

[30] See the discussions on the differing views about existing applications of human genetics in The Wellcome Trust's report 'Public Perspectives on Human Cloning' (Wellcome Trust, 1998). See also the Human Genetics Council's consultation 'Whose hands on your genes?' (HGC, 2000, 2002).

genetic research. Rather, it seemed that, whether people were enthusiasts or sceptics in relation to research, the main concern that research would be frivolous or wrongly applied, without brakes.

## V Discussion

In this concluding section I shall briefly review the empirical findings for this part of the research, and begin to elaborate on my analysis of these.

I have considered the overall rationale for giving blood from these donors' point of view. In these interviews, the circumstances in which people begin to give blood are described in relation to others: those they work with, their family, or their friends. These others often provided the impetus or the opportunity for their initial visit to a blood donor session or centre. Whilst initial donations are often made at the suggestion of others (work colleagues, family, or the celebrities featuring on the NBS television adverts), a longer-term commitment to blood donation requires a rationale to sustain it. For most if not all of the interviewees, blood donation is informed by an awareness of the vulnerability of self and others. They differed in how this was expressed, for some it was a literal description of the awfulness of being at the scene of an accident, for some it was the shock of a more 'ordinary' life event, such as childbirth, or the serious illness of a parent. Some had never experienced anything traumatic of this kind, but said they gave blood for this very reason, or that a dramatic TV advertisement for the NBS had reminded them of the need for blood. In these accounts the emphasis was more literally on the physical vulnerability to accidents or medical conditions that might give rise to conditions for blood. Others, especially amongst the older and established donors, gave eloquent

accounts of the importance of donating blood and of the interdependence it symbolised.

It is in the kinds of accounts that they gave of continuing to give blood over time that we find more nuanced accounts of why blood donation is important, and about the meaning of this practice. Donors talked about the satisfaction of being able to help, about awareness of need, as well as about duty and obligation. Some pointed out that this kind of helping was easy, for it did not involve a high degree of engagement and it took relatively little time. For this group, the practicality and morality of the practice of blood donation are inextricable. These are moral vocabularies, but they are more about mutual need and care than they are about selflessness. They are also deeply practical - in contrast to the disembodied and abstract notions of altruism which have come to dominate discussion of blood and tissue donation.

I do not suggest that these donors are 'typical' of NBS donors (nor of potential donors for genetic biobanks). Indeed the interviews contain hints of the distinctive social and political history of the city in which they took place: this is a region at the heart of what we might call 'Old, old Labour', in which mutual associations of diverse kinds were been pioneered (Yeo, 2001).[31] At the same time, these accounts underline some moral tenets which are seen as central to a national blood system: these include the importance of the blood being freely given (unpaid), entrusted to an authority which runs a national blood bank through which blood will be made freely (unconditionally and without charge). Despite the availability of detailed written information on how the blood may be used - in making blood products for therapy, in audit and research and so on - that detail was not of

[31] Yeo distinguishes between the statist political traditions of 'Old Labour' and the associationist traditions of 'Old, Old Labour'(Yeo, 2001:232-233).

particular interest to most donors. Rather it was the reputation of the NHS and the blood service that forms part of it that seemed central to this transaction.

Most envisaged blood being used for transfusions, in emergencies. Only a few talked about blood products, and fewer about the possibility of some blood being used for research. The NHS was seen to provide a boundary within which this resource should be used. Although donors felt that they were donating to a national blood bank, they did not expect or want to draw absolute boundaries around the uses of blood: these were usually seen to be decisions for experts in the blood service, the NHS, and the government.[32] However, as I have shown above, it was expected that the blood would be used within boundaries, for the benefit of a community roughly delimited by the NHS. I shall return to the implications of imagined community, as I came to think of it, later in the thesis. In particular, I shall argue that this notion has implications for what would be seen as socially acceptable uses of donated blood.

Asking questions about genetic research was perhaps the least successful part of this work. My questions, at least at first, were not defined clearly enough, I inadvertently

[32] The NHS benefits from an exceptional profile in the UK, with high levels of support for its principles and place in British society, notwithstanding the many dissatisfactions that may be associated with actually being an NHS patient (Appleby and Rosette, 2003; MORI, 2004). We know less about the profile of the NBS itself; the voices of those who choose not to donate or who have opted out of blood donation are rarely heard. Those interviewed by myself are presumably amongst those who trust the NBS the most. However, Giddens' (1999) concept of 'shell institutions', whose legitimacy is widely in question does not on the face of it apply to the NHS or its constituent blood services.

raised concerns and worries about controversial kinds of genetic research. In chapter five I have discussed and considered how the validity of one strand of the data - these short discussions about the unfamiliar territory of genetic research - was limited by the methods I used. In addition I was working under difficult conditions: I had quite limited time with my interviewees and a lack of privacy; in addition, there was the ambiguity entailed in being a guest of the NBS. More substantively, donors' responses often indicated that they felt issues about genetic research were at or beyond the limits of their expertise. However, their responses to these questions did illuminate some of the dynamics of involvement in blood donation and pointed me to the importance of what I have called informed trust as a basis for their decisions. Trust in the NBS is informed by the history of its well-known predecessor local blood banks and by its relationship with the NHS, which itself has a popularity based at least as much on social history as on its current performance (Lowe, 1994).

The idea that such issues were addressed in the context of the reputation of and memory[33] of the National Health Service as a public institution was one that I would explore further in the next phase of the research. Here, donors involved in a research project would face new questions about genetic research more explicitly. It would be interesting to see the extent to which they relied on written information - or informed trust - in their decisions about taking part. Here too I hoped to explore whether the notions of reciprocity and mutuality which had emerged in interviews with NBS donors would be relevant.

[33] Misztal writes of 'Habit, reputation and memory …all [being] means of preserving the past experience in order to construct a more predictable, reliable and legible present. They are all different but complementary strategies designed to help us to acquire a general sense of trust in the social world' (Misztal, 1996:156).

Returning to the blood service itself, I have tried to describe how donors approach this as a way of making mutual provision for illness and accident, within an organisation that - although it has altered substantially - has an enviable reputation. Changes at NBS that have attracted significant criticism[34] do not appear to have altered that reputation fundamentally amongst this group of donors, who continue to place their trust with it. However, a feature of trust may be said to be that it is based not on evidence but on lack of contrary evidence (Gambetta, 1988, cited in Misztal, 1996:127). In the future, the effect of the inter-penetration of commercial and public sectors in this field[35] might well be to provide evidence that undermines the existing trust in blood banking. This should be an important consideration for the nation's blood service as the NBS moves into the area of tissue banking, and is itself tipped to become a community interest company (NBS, 2002; HSJ, 2004:4). In my analysis of these interviews, blood donation is seen to be anchored in traditions of mutual help, in shared national institutions, and in a sense of belonging to a local community. Linked to this, both ethical and national boundaries to blood banking were indicated. These boundaries in turn helped to establish the legitimacy and acceptability of blood donation. Issues about legitimacy and boundaries

[34] Following the major reorganisations which resulted in the development of a new national service in 1993/1994, prompted in part by NHS reforms, the service was widely seen as having lost some public confidence. When audited by the National Audit Office, it was found to have limited accountability, and independent scrutiny of many of its functions was found to be non-existent (HC, 2000). In the wake of the HIV crisis, it has had to respond to the current problems associated with the risk of transmitting CJD through blood transfusions.

[35] Lewis (2004) notes that the collaboration between 'public' tissue banks and commercial companies is extensive. See my discussion of this in chapter 2.

are interlinked here then, in a way that may become highly relevant for thinking about the donation of blood for biobanks.

# Chapter Seven: dynamics of involvement in the 'arthritis genetics research project': interview data

## I Reprise

In this chapter I present my analysis of data from interviews with 27 volunteer participants in a genetic research project which aimed to understand more about possible genetic factors in psoriatic arthritis. It involved no trials of treatment, no information or counselling about the condition being investigated. Neither was feedback of individual genetic information offered by the research project. What then might be the basis on which people take part in such research?

As I have described in chapter five, I intended my approach to these interviews to be exploratory and open-ended. However I brought to them several sensitising themes from my review of the literature and from my earlier interviews with blood donors. I shall begin by describing these themes and then move on to give an overview of the interviewees and the context of their involvement in the project. The description of the interview data itself is divided into four sections; the first is concerned with the basis of peoples participation in the research in more general terms, the second with knowledge and informed consent, and the third more specifically with views on the use of genetic techniques and research. Following a recognition that questions about these issues were often answered with reference to the institutions associated with the research, a fourth section considers some institutional dimensions of trust. The place of the NHS is given particular prominence in my discussions as it had a pivotal place in these respondents' considerations about involvement in (genetic) research.

In the discussion at the end of the chapter I begin to analyse these data in relation to some questions about the dynamics of involvement. What can be said about the process of entrusting blood? Does donating blood for genetic research raise some special or particular issues for these participants? If participants in the research hope that it will be beneficial, what is the scope and what are the limits of those imagined benefits? The concepts of limits of expertise, and of informed trust are used here to take the analysis forward in relation to wider debates. In my discussion at the end of the chapter, it is the social and institutional contexts shaping individuals' choices that are given prominence.

## Themes and questions from the literature review

I have drawn attention to the threading of particular discourses of gift and altruism through recent policy debates in the UK as well as in the academic literature. Whilst looking back to the ways that public opinions have changed regarding the uses of human tissues in medical contexts, new guidelines on the use of human tissue also foreshadow a new research agenda. Key to that new agenda will be commercial involvement in population genetic research, which is posited as essential for health and prosperity. It is in this context that Titmuss' language of 'gift' has become a bridge between old and new kinds of donation. I suggested though that it serves to elide the differences between the different contexts for donation.

Intriguingly, the idea of donated blood as a gift is used by ethicists, lawyers and medical professionals with opposing positions in the debate about the exploitation of human tissue in genetic research. Tutton's analysis of these points of reference in recent guidelines on the use of tissue samples in research underlines this complexity, and considers them in terms of the 'boundary work' around the commercialisation of research using human

tissue (Tutton, 2004:20, citing Gieryn, 1983). As I have noted earlier, the revival of the language of gift coincides with a more traditional discourse about the NHS in the Genetics White Paper. Here the traditional basis of the NHS is proposed as a particular suitable basis for the development of genetic technologies (DH, 2003:8). A similar note is struck by the Government's advisory group the Human Genetics Council in which the ideals of 'genetic altruism and solidarity' feature in the paper on human genetic information (HGC, 2002:37).

Whilst there has been some survey and market research about the views of the British public on the uses of human genetic information, there is little qualitative social research about their approach to emerging developments in population genetic research. In particular, we know little about how the policy discourses about this kind of research - for example those of altruism described above - relate to the responses of those invited to donate blood for these new initiatives. Social research on the new genetics has focused on the experience of those with a rare genetic disease, or those identified as being at risk of such disease. Some claim that we are seeing the emergence of new kinds of 'genetic responsibilities' in the wake of the introduction of genetic testing for rare diseases (Novas and Rose, 2000). These are generally conceived of in terms of the implications of knowledge of predictive information for oneself and for relatives.[1] A wider shift towards individual responsibility for managing health risks is generally seen as an important part of the context of shaping such developments (Beck-Gernsheim, 2000). However, the issues that will be encountered by those invited to take part in epidemiological or

[1] See for example Hallowell's (1999) discussion of her work with women with the breast cancer gene which testifies to the profound sense of responsibility towards others, and to the ways that their identity of self-in-relation to others shapes their decisions about testing.

population studies using genetics are somewhat different. Such projects, and the biobanks that mediate them, will recruit participants from the wider population, many of whom will be healthy volunteers without a particular interest in a genetic disease. In most of these population studies, participants will not be offered feedback of genetic information.[2] Unlike those involved in therapeutic clinical trials, they cannot anticipate or hope for therapeutic benefits. Nor will they be offered financial recompense for their involvement - unlike those involved in non-therapeutic drug trials, to whom a nominal payment is commonly made. We know little about the issues or concerns which will emerge for participants in population genetic research.[3]

Amongst the bioethicists who are conventionally seen as the guardians of good conduct in research, great emphasis has been placed on the importance of information for the individuals involved. In relation to the clinical trials that have been the prominent method in medical research, the provision of such information is seen as enabling participants to weigh up the possible benefits and harms of a particular project to themselves. Therefore the requirement to obtain informed consent is widely seen as providing a backstop against exploitation of research subjects. However, questions have been leveled at this modern ritual of autonomy on a number of fronts (Wolpe, 1998). There is a substantial philosophical and sociological critique of the notion of autonomy, as I have discussed in chapter four. In addition, there is an empirical challenge to the ideal envisaged in the theoretical notion of 'informed consent'. Nevertheless, the idea that informed consent forms a central plank for research participation remains a prominent one, no doubt in part because (following Evans) it dovetails with the managerial regimes and requirements of a

[2] In the UK, ethics guidelines discourage the use of such feedback.

[3] The convention of rewarding subjects financially for their involvement in non therapeutic trials

large bureaucratic system (Evans, 2000).

I have suggested too that sociologists writing about the implications of genetics have (also) had a tendency to be knowledge-centric. The interest in lay knowledge and expertise may have deflected attention from other ways of looking at these developments. Another dimension of this emphasis is that developments in genetics have been of particular interest to sociologists working within theoretical frameworks concerned with the distinctive knowledge dynamics of contemporary society. However, there is also a tradition of empirical sociological work on the shaping of participation in clinical research, which points to wider norms and influences shaping involvement in such research. Here a prominent theme has been an exploration of the ways that patients' or research subjects' choices are shaped by circumstances, including access to treatment, and wider socio-cultural contexts, notably the association of expectation and hope with biomedicine.[4]

I was interested in how my own empirical study about involvement in genetic research might test the tenets of the more abstract theories which have been so influential in the field of the new genetics. Here I aimed to explore the salience of theoretical notions about the erosion of trust and responses to risk, as well as the assumptions about altruism and consent that I have described.

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of new drugs is not applied to the case of pharmacogenetic research (Corrigan, 2004).

[4] See for example, Fox, 1996; Stockdale, 1999; Conrad, 2001; and Corrigan, 2003. This literature is discussed in chapter four.

## Sensitising themes from earlier fieldwork

In my early analysis of interviews with blood donors to the National Blood Service, a number of findings had emerged I felt could usefully be seen as sensitising themes for thinking about the practice of donating blood for genetic research. Firstly and most importantly, I have characterised their rationale for giving blood as one of reciprocity or mutuality rather than of altruism: blood is donated to a 'bank' which donors themselves, their relatives, friends or strangers can draw on if needed. These interviews testified to the influence of family friends and work mates, and were witness to a concern with making provision for the risks of catastrophic ill-health which would lead any one of us to need a blood transfusion. Although the genetic research project was a substantively different situation - for it was not seen as helping to save lives as blood donation was - I wondered whether these more pragmatic notions of reciprocity would emerge amongst the participants in the genetic research project.

Secondly, there were questions around informed consent and the practice of blood donation. When blood donors talked about this practice, I found that many were not interested in the details of how the blood might be used. This was partly because they had confidence in the ethical and national boundaries within which the blood would be used. Few mentioned research as a possible use of blood donated to the blood service, despite their apparently having signed a consent form which sanctioned this. Of those I asked, most did not mind if blood was used in this way. They did make some distinctions between research which was seen as legitimate and that which was not. In view of their limited interest and self avowed limits of expertise in these fields, many accorded experts in the blood service and the NHS the role of deciding which research would be legitimate. As I approached my interviews with genetic research participants who had explicitly

agreed to participate in research, I wondered whether considerations about the institution to whom they donated the blood might (similarly) be prominent. It might be, though, that this was a case where a considered process of weighing up the detail of a research project would feature prominently. My questions then were partly about the weight that we should give to the importance of the information provided to those invited to take part in this particular genetic research project.

## II The research interviews

The project from which I recruited my informants is based in a university hospital in a large city in the North West of England (the same city in which I undertook interviews with NBS donors, as described in the previous chapter). Here, the university and NHS bodies have well-established regional services in clinical genetics and allied research activity. 'The centre' undertook this kind of research, but was also a leading site for the development of epidemiological genetic research in its field. An important feature of this project from my point of view was that it had the potential to give me access to people being asked to participate in genetic research who did not necessarily have a prior interest or involvement in a 'genetic disease'. The particular study from which I would recruit my interviewees for this part of the research was a study of psoriatic arthritis. This is a syndrome affecting both skin and joints, for which the aetiology is uncertain. The unit's research was concerned with identifying the extent to which there may be a genetic component.

## An overview of the interviewees

Twenty seven interviews with these donors were undertaken, fourteen of these being women, thirteen men, ranging in age from twenties to sixties. The occupations of this group encompassed both manual trade and professional. Nine worked in some form of public service (such as nursing, teaching and youth work). Others were employed or retired from professions such as law and architecture, in clerical or administrative work, and two of the men had manual jobs in a warehouse and at the nearby airport. Three were self-employed, several retired, and two on long term sick leave.

All had received a diagnosis of psoriatic arthritis (PA), although for some this diagnosis had been achieved quite recently. For most, that diagnosis had been made by a rheumatology specialist, following referral by their GP. This relatively rare syndrome is associated with joint pain and inflammation and skin problems, the symptoms varying from mild to quite disabling. Some found that apart from having skin flare ups they were relatively unaffected. Even so this would often mean avoiding certain situations, such as swimming baths, where they might be thought to have a contagious disease. Most of the respondents were able to work, although it was clear that some had adapted their working lives around the condition at times. For example, Mrs Collier[5], who I cite a number of times in the following sections, works in a call centre not too far from her home, and described her colleagues and managers as supportive in adapting her shifts around her required attendance at hospital for check ups and her time off sick. At the other end of the spectrum one woman had been unable to leave the house for a number of months due to pain in her ankles, and was receiving a mobility benefit payment as a result of these

[5] As in the previous chapter, all names are pseudonyms.

difficulties.

The diagnosis of PA is made through clinical criteria and judgement, there being no definitive laboratory or clinical test. Although a range of other medications can be prescribed for the condition, they have highly variable effects, and traditionally much stress has been laid on the use of external applications to ease the skin complaint. For example the application of coal tar is still recommended. It is fair to say then that treatments for psoriasis and arthritis are relatively crude. Many of my interviewees had tried a range of medications with varying success, the commonest mentioned in these interviews being Methotrexate, which is said to have a significant effect on symptoms for some patients but whose adverse effects include the risk of liver toxicity.[6] For this reason patients taking the medication are required to have regular blood tests for the purpose of monitoring the effect of the drug on the liver. One man had had psoriasis for 32 years, followed in the course of time by the development of arthritis:

> *I have a list as long as my arm of the ointments and medications I've tried, with limited success sometimes and no success at all in other. Some worked and some didn't but they…were, some of the concoctions were evil, they really were, thick, black tar, really it was like road tar in the end it was really thick, ten, fifteen, twenty percent tar which you would daub on. It smelt ghastly, even under bandages I'm sure people could detect this road mender smell (laughs) I didn't like it. And it got through onto your other clothes. I used to wear these damn things in bed and I used to have to wear*

[6] Details of the risk of these adverse effects are given in the entry for Methotrexate in the British National Formulary (British Medical Association and Royal Pharmaceutical Society Press, 2000:526).

*old pyjamas and have old sheets on the bed because it would seep through and it would stain the bedding and the pyjamas and they were good for nothing, I'd chuck them out and start again.*

(AGP 26)

The causes of the condition are unknown. In this context trying to understand the possible causes had become for many something of a project in itself, as another interviewee explained:

*When I started getting arthritis I wanted to know more about how it happened, and why it happened and everything else. (AGP 15)*

Although I often heard from interviewees that a GP or other doctor had attributed the condition to hereditary causes, this often seemed to be by way of denoting lack of knowledge of any known cause: therefore, *'it was probably a hereditary thing that caused it' (AGP 27).* Nevertheless, the fact of hereditary causes having already been considered by most seemed to pave the way for an approach by researchers concerned with a possible genetic component.

## III Participation in the 'arthrits genetics research project' (AGP)

Most of those I interviewed had been recruited to the project via their NHS consultant, usually a rheumatologist, or the hospital department which they attended, some by letter and others in person. However a few had responded to the advert which had been placed

in the local newspaper by the centre.[7] An information leaflet about the project was sent or given to each, describing the aims of the project, and explaining that the blood sample which would be needed would be 'gifted' to the centre for the purpose of research on this condition. It stated the general aim of understanding more about genetic factors in this kind of arthritis, and noted that other researchers working on the same condition might also use the data and samples provided by volunteers. There followed a visit from a research nurse who sought to gain the following data: individual medical history; family history with a focus on joint and skin condition; clinical data based on a physical examination, sometimes recorded by photograph, and finally a blood sample for analysis. It was at the end of this visit that my own research interviews were mentioned and those who were happy to be contacted in connection with these filled in a consent form to this effect, giving their contact details.

Those whom I interviewed tended to convey to me a sense that the study did not ask a great deal of them. In particular it did not require additional time consuming visits to hospital, and it did not involve them in altering their medication regime or trialling a new medicine. Most indicated that they were happy to help contribute to research for a condition which had caused them some suffering or inconvenience, and that by doing so they hoped to contribute to knowledge about and treatment for the condition. Indeed, for many of these respondents the process of teasing out possible causes was part and parcel of managing and living with the condition. Within this, the investigating of genetic causes seemed like 'the right line' of enquiry. Although hereditary causes were sometimes suspected, the familial patterns of the disease were difficult to make sense of:

[7] With their permission the diagnosis of their condition had been confirmed with their GP at the outset.

*I think, I think there are hereditary factors, the only thing was when I developed it at 18 there was no family history at all but then my grandmother developed it in her 70s, in her scalp and her fingernails and then I think she was about 80 and she started developing it on her body. But I'd had it quite some years then before she developed it in her fingers and nothing else. But on my father's side there's a history of asthma and eczema, his brother has eczema but nothing else.* (AGP 2)

In the context of this uncertainty, knowledge about the condition was valued. In addition, the more that was known the more chance that better treatments might eventually be developed. One man said it was *'only fair that people contribute what they can and if it means me contributing by me giving people information or whatever or any way that I can do it then I'll do it, I haven't got any qualms about it'* (AGP 17).

Ideas about what might be gained from the research were usually expressed in quite general terms. Perhaps because of their own experience with medications, these interviewees rarely talked of magic bullets and treatments. Many specified that they expected any improvements in treatment to develop quite gradually, over the period of their childrens' lives for example. It often seemed they were denoting a generation, a period of time, rather than indicating that these particular children would benefit from the research. Some specified that the research might help *'future generations, even if it's not the next generation' (AGP 24).*

The imagined benefits were often talked about in terms of a wider circle than immediate family, perhaps because of the uncertainty about the causes of PA - and associated

uncertainty about who might be affected by it. Mrs Collier described her thinking about this as follows:

> *Because I've had the psoriasis and arthritis since I was about 12, and I'm 31 now and I've had a lot of suffering, a lot of pain and I've been in hospital at various times, I've had two operations. And I've seen the pain and suffering that other people go through on the arthritis side and on the psoriasis side and I've seen children and I've known, I've grown up with it, with the psoriasis and known how uncomfortable and soul-destroying it can be. And I thought well if I can do something, it's just a tiny million percent of a job to try and help somebody else in the future then it's worth it. It might not be able to affect me but there's nothing, if people don't go forward to do it then we won't get anywhere will we?* (AGP 7)

This interviewee expressed satisfaction that she knew she had been able to do something to help other people. In this sense the interview reminded me of those I had previously conducted with NBS donors. Although this woman was not a blood donor, several of these interviewees had been blood donors in the past, and likened their involvement in the research to that activity. One (AGP 4) who had himself received a blood transfusion in an emergency said: *'I like to think that I'm a bit of a Tony Hancock'* (referring to the famous 'blood donor' sketch). Those whose condition was more severe sometimes said they felt that by participating in the research some good could come of their own troubles: others might be prevented from suffering in the same way.

Amongst the group there were a few activists - who would get involved in *'anything that's going on in arthritis'* (AGP 2), and some who took a strikingly passive stance, talking

about their involvement in research in terms of having been asked and 'not minding'. Most fell somewhere between these two poles. A few indicated that sympathy for the researcher's job was a factor; several emphasised how much they liked the particular consultant who had asked them to participate, and wouldn't refuse any request from her. The prospect of a visit from a research nurse was viewed positively by many. Access to information or discussion about the implications of the diagnosis was a consideration here. Two interviewees who had only recently received a diagnosis of PA had said yes to the study with a view to getting more information about the condition - and several others felt that they didn't have enough information or support from their GP.

Some study participants were hoping to get feedback on genetic tests as part of the study. One explained how he had only realised later on in the meeting with the research nurse that this kind of feedback would not be provided, and another asked me when he might hear about the results of his blood tests. Others said at one point in the interview, perhaps in response to prompting from myself, that they understood that the research did not involve such individual feedback, but then at another point that they expected that they might hear from the researchers if they found anything useful about their tests. It became clear then that the question of 'informed consent' to the study needed some further exploration. In the following sections I explore some of the wider dynamics of knowledge in the context of the interviewees involvement in the genetic research project.

## IV Themes from the interviews

### Informed consent' and the limits of expertise

In this section I shall describe how the interviews with donors gave rise to some questions about the congruence between the ideals and mechanisms of informed consent, and the

experience and perspectives of those involved as research subjects. As I have discussed earlier, individual autonomy plays an acclaimed part in new models of trust between doctors and patients, researchers and research subjects. Here, autonomy is associated with values of 'Privacy, voluntariness, self-mastery, choosing freely, choosing one's own moral position and accepting responsibility for one's own choices' (Faden and Beauchamp, 1986 cited in O O'Neill, 2003). These values are associated with a particular set of assumptions, and embedded in particular philosophies of liberal individualism (Wolpe, 1998). Where policy orientated discussions occur, the principle of autonomy is generally translated into a set of procedures, foremost amongst these being those concerned with informed consent. In the field of genetic research, where there are many uncertainties, individual consent has often been given particular weight. However, as I indicated earlier, the relevance and effectiveness of informed consent procedures have been questioned by some.

I soon became aware that it was difficult to establish to what extent participants in the arthritis genetics project had given even a minimally informed consent specifically to the analysis of their genetic material. This was in part due to my not having the opportunity to observe the visit from the research nurse at which such consent was sought. However it seemed that there might be something more to this. One of the problems for a social researcher interested in exploring this further is that in asking questions they may change the dynamics of participation. Indeed Hoeyer has likened research interviews of genetic research participants to an extended version of the informed consent process: the participant is asked to reflect on the information they have been given, and to account for the choices that they have made in explicit terms. In this sense, the interview is seen as a 'site of production for certain types of reflections' (Hoeyer, 2004:107).

I begin with the mechanics of the information sheet and consent form which I knew to be part of the study protocol. It was evident from most of the interviews that these had been given to the participants. For example Mr Andrews, (AGP 6) who had asked me about the results of his blood tests at the end of the interview, commented that he although he had been given information on the study, he hadn't *'had a chance to read all the bumf'*. Nevertheless, he had been happy to have the blood tested: '*I agreed to do it, I signed about ten forms'*. When asked about his views on the use of the DNA for analysis he said that *'up until you'd mentioned it I hadn't given it a second thought*', but when we discussed this further he didn't see the analysis of (his) DNA as a problem. It seemed in this case that it was the uncertainty about feedback of findings from blood tests that was a cause for concern, rather than the lack of knowledge about the genetic research techniques in themselves.

Only one or two others explicitly mentioned that they hadn't had a chance to read the information given to them. One, a mother of several children who was unwell herself and off work simply said *'I'm that busy I've been given all these things and I've not read them'* (AGP 5). Most though were at pains to explain how properly the study had been introduced to them:

> *He arrived and he basically introduced himself and then he gave me some literature to read through. It was just to say what the criteria for the study was, what it enabled, so you know it wasn't going to be broadcast everywhere it was for his private study at university and that was it. All written down on paper very clearly, he gave you time to look through it, did that and then he asked me to sign just a form to say that I was okay to do*

*with the study with him.* *(AGP 7)*

It was not then primarily the mechanics of the informed consent process that were at issue. I had no reason to think that written information about the study had not been given, that the participant had not had a chance to discuss any questions with the research nurse, or that they had not signed a consent form. The consent form stated the nature of the study clearly, specified the intention to undertake analysis of the DNA, and specified the nature of the transaction in terms of a gift of blood from the donor to the research team.

Some of my respondents made it clear that they simply wanted to help and weren't really interested in the details. As one respondent put it: *'if it helps other people I'm happy to go along with it'* (AGP 10). When I followed up this with some questions about the use of genetic techniques in the study he simply said *'I never really give it a thought to be honest'*. He hoped that the study would lead to the development of new treatments in the future, but didn't feel that the detail of the study was his concern.

In my subsequent analysis of the interview data I found that only in thirteen of my interviews was it clear that the consent which had been given to the genetic study encompassed an understanding that the DNA from their blood would be analysed as part of the research. In seven cases it seemed, in my judgement, that they had not known about the use of genetic material for the research. In the remaining cases the issue of informed consent was either hard to establish from my interview, or blurred in some way. I shall use these categories as a starting point for a description of the range of ways in which people engaged in the project. I begin with an apparently straightforward example of informed consent.

Mrs Burroughs (AGP 2) works as a nurse in the NHS and it was clear that her knowledge of the health system, including previous exposure to research projects through her work, was brought to bear on this study: *'I've got enough knowledge not to be scared of anything'*. There was a clear sense that she had understood the nature of the study at the outset, in particular that she did not expect any benefit from the research, that there would be no feedback of the results of DNA analysis to herself, and the nature of research as a long term process. When I probed about the use of DNA in the study she initially responded that *'to be truthful, I hadn't even thought of it'*. When we discussed it further, she said that DNA was *'just blood'*, and again that *'there's nothing about a blood sample that would frighten me whereas it might if people didn't know anything about it'*.

On the other hand when I asked Mrs Jones (AGP 3) to describe the study to me 'as if I were a friend or somebody who doesn't know anything about it', her description of the study bore a close resemblance to my understanding of it in general terms, including its long term nature, but did not include a reference to the analysis of genetic material. She had actively researched her own condition through the internet with the aid of a friendly pharmacist. The main attraction of participating in this particular study for her (and others) was that it did not involve taking unknown drugs or any other kind of experimental treatment. This made it 'absolutely right' as a research project for her to be involved in. However when I asked her about the analysis of genetic material, she said: *'I don't think I've really thought about it'*, was it special or different in some way I wondered, *'no I really don't think that'*.

It seemed important to note that what people said to me indicated some disjuncture between the ideal of informed consent and the practice in some cases. But what was more striking and consistent was the lack of concern about the genetic element of the research:

it was simply a tool in the researchers' tool kit, for after all 'they're always talking about DNA aren't they? Only Mrs Burroughs had given me an explanation which explicitly linked their stance on the genetic research to their relationship with health systems, and in her case this was all unusually straightforward: her familiarity with the NHS and trust in the medical professionals working in it gave her great confidence that any research activity of this kind would be properly regulated and administered. However I felt that as none of these interviewees had been involved in this kind of research before, it was likely that they would draw on related experience and knowledge in relation to it. I took this to include relationships with health care professionals, with the system through which most of their relationships with those professionals will be mediated, the NHS, and with the expert knowledge system of biomedicine. The aim of this section is to begin to flesh out the contexts within which the research request was taken up.

Mrs Collier worked in a call-centre and has no technical or related expertise to draw on in relation to the research. Over time, she had achieved the status of being an expert patient, particularly in the eyes of her specialist consultant. She described to me the development of her relationship with her doctors:

*R* *I mean when it comes to trusting people I don't think I would, I mean I wouldn't take anything myself until I've known that it's, somebody has been having it for years and years and there's been no serious side effects. And I'm very, and as I say about taking these tablets I'm like well you know let me look into it, give the facts on paper, let me speak to my own doctors about it. I usually go and speak, you know if they've got something they want me to go on personally I'll go and speak to the specialist, I'll go and speak to my own GP because he's very good.*

*I* *So it sounds like you've got quite, I mean obviously it's established*

*R* *I don't just kind of*

*I* *But quite good relationships with them*

*R* *Yes*

*I* *Talking through information as well.*

*R* *If I don't like it I tell them. Especially, I mean my old arthritis specialist, well he's not old but he's still the one I've got but when I first started seeing him then he was very much, "I want you to do this, I want you to do that, you will do this." And I'm like "Well no I won't, if I don't,"*

*I* *This is for your skin?*

*R* *This is for arthritis and I'd go "No I don't want to do that," and we used to have quite a few good arguments. But now he's just like "Right what do you think, shall we go this way, shall we go that way?" you know.*

(AGP 7)

Other respondents had the advantage of drawing on related scientific or technical expertise. One, a lecturer in environmental science, assessed the genetic project in this light, taking account of details such as the sample size - which was large enough to give him confidence that the project could make a useful contribution - and his knowledge that it would have been assessed by ethics committees and other similar bodies. Although none of the respondents were medically qualified, a few like Ms Fishlock, a science teacher, were able to deploy their knowledge of and access to the scientific literature to make a judgement about the research. At the same time Ms Fishlock told me in response to my question about participating in the unit's study that she would *'always say yes'* to this kind of request. Being interested in research about the condition which had affected her over many years, she generally took an active stance towards seeking out information

on treatment and research. In contrast, there were others, like Mr Gill, a driving instructor in his forties, who characterised themselves as fairly hands off in relation to issues of medical treatment and research:

*R* *I'm not really bothered. If the doctor came along and said "Take this Smartie,"*

*I* *"Take this new one, take this drug" yes*

*R* *I would take it.* [Edit]

*I* *Okay*

*R* *Give 100% trust to your doctor*

*I* *Yes*

*R* *So I would not, you know there's side effects with everything isn't there?*

*I* *Mm right so basically you would give 100% trust over to the doctor to do that job?*

*R* *Yes, yes and if he said like you know this, this drug you know works on 98% of people fine I'll take it.* (AGP 27)

It was however unusual amongst this group to seem quite so 'hands off' about their own health. It was clear to me that these individuals drew extensively on their own resources and expertise in managing the condition. This might take the form of researching medications on the internet before taking them, even though they had been prescribed by a respected doctor. Most had tried or were trying some form of diet to manage their symptoms, many were taking supplements or over the counter alternative remedies. Some had consulted alternative practitioners, mainly acupuncturists, for their symptoms. Several talked about having drawn the line at taking certain orthodox treatments, with others there was a sense that medications had been negotiated: they had strong and mixed

feelings about the drugs they were taking. As one woman said of the Methotrexate: *'It's such a strong drug and its alien to my body'* (AGP 24).

Regardless of their particular position on this medication and on orthodox medicine in general, all were necessarily involved in self-management, and many in researching the availability and efficacy of treatments. Their involvement in the research can be seen in this light. Nevertheless, there was a sense in which their encounter with the genetic research project brought them up against the limits of their expertise.

As we have seen with the examples above, all of the interviewees expressed a willingness to hand over a small blood sample for the research. But some had not seemed aware that genetic analysis of donated blood was a part of the study, to which they had consented in writing, and others felt unclear about implications. One man, who found my questions particularly difficult, said to me after the interview that the blood was 'entrusted', and should be used as the researchers saw fit. I took this as indicating both that he had very limited expertise to judge or comment on the details of the research, and that he had chosen to trust the researchers.

## 'Everybody has got their own DNA': views on the use of genetic research techniques

Was donating blood for genetic research special, I wanted to know, did it raise special concerns for the research participants? In the previous chapter I found that when NBS donors were asked about the use of genetic techniques for research, their concerns were focused on the possibility of uncontrolled science without sufficient regulation. 'Donor babies' and 'cloning' were given as examples of the consequences of this kind of runaway

science in which maverick scientists would engage in unacceptable interventions. I suggested that it was not so much the use of genetic techniques for analysing blood that would be of concern for many of these donors, as uncontrolled research. However this second set of interviews gave me an opportunity to address questions about how the donated blood was seen more explicitly, and less tentatively, as these interviewees would already have indicated that they found use of their own blood for genetic research acceptable.

It was clear that the idea of a genetic cause for this condition was not a surprising one: it fitted with a suspicion that hereditary causes might be at work in some way. In addition, it could be and usually was accommodated within a broader multi-factorial model of the causes of illness:

*R* *I've always thought that it was something more to do with it, it's not like a viral thing is it because we can't get rid of it with antibiotics and whatever. And it's not hereditary because nobody, I mean they've said that it skips generations well you know I've looked back into our family history and nobody has ever had anything. I honestly think that it has, it is to do with this, to do with you know the bits and bobs of how you're made, there is something.*

*I* *Yes so you're were saying you always thought it's something quite fundamental in*

*R* *Yes just something inside you know, I mean they've always linked it to stress haven't they?*

*I* *Mm.*

*R* *Maybe I mean stress is how you're made up isn't it, the way you think about*

*things so I mean it could even be something psychologically inside of you that's linked to your blood. I know it sounds daft but it could be because you know people they say that stress brings on many things don't they?*

*I* *Mm*

*R* *Or the way you are whether you're a deep person, whether you're, you know if you're one of these fly-by-nights that nothing ever bothers you then you're lucky. But it seems to me that it seems to be a lot of people are quite soft that it seems to affect people, you know what I mean?*

*I* *Yes, yes.*

*R* *So it seems, I don't know I definitely seem to think that it's something to do with, so I definitely think that it's something to do with the way you're made…*

(AGP 7)

Perhaps though, genetic material might be seen as special in that it was private and personal? Participation in this research involved 'donating' ones medical history, family history, medical records, in addition to a 10ml blood sample. In addition it often involved one or more photographs being taken of affected parts of the skin. For those affected by this condition over many years, talking through the detail of a medical history could be quite time-consuming and emotionally demanding. Some mentioned that the idea of having photographs taken of skin which they usually tried to cover up was uncomfortable. In contrast, for many - used to having bloods taken regularly - the giving of a blood sample was not in itself a concern. Other elements of the research were sometimes considered to be more intrusive, for example the request to access medical records. Indeed my own insistence on asking questions about their involvement in this kind of research could be seen as quite intrusive or suspicious:

*I* *So this idea about you know doing research, getting involved, actually looking at the DNA.*

*R* *Yes well I was quite happy for that when he took a blood sample away. So I assume he's going to you know get some results from that.*

*I* *And does that affect how you thought about the research at all?*

*R* *No it's great that there's research going on and that a lot of people might end up not getting it and if that's the case it will be wonderful.*

*I* *Yes okay.*

*R* *Because it's not very nice.*

*I* *Yes I appreciate that. I mean some people say DNA is a bit of a special case because DNA is unique to you and me*

*R* *Do you mean should it worry me that they know what my DNA is?*

*I* *Mm.*

*R* *Not at all, one iota.* (AGP 13)

Similarly, most respondents insisted that the use of DNA in this context is not particularly 'special'. All but one rebutted my suggestions that the use of DNA might be seen as sensitive, personal, or difficult in some specific way. I return to my discussion with Mrs Collier:

*I* *Now with the analysis of this genetic material, the DNA you know some people have concerns about DNA because you know for example it's unique, my DNA is unique to me and yours to you…*

*R* *My body, your body.*

*I* *Yes and you know some people feel they've got worries about privacy or you know that kind of thing, do you do you have any sort of concerns on that*

*score?*

R *No because I am who I am, I've got nothing to hide, I've got nothing to show. I'm just a normal working person that's trying to get through life you know some days are good some days are bad. No because there's nothing in me that, you know it's the same as a toe nail or the same as a hand nail, the same as a bit of skin it's just me.*

I *Right.*

R *It's nothing special and if they can use it*

I *You see some people think it is some people think it's*

R *Privacy is your bank account because you know how much you're in the red (laughs)*

I *Now that's critical.*

R *Exactly, exactly, privacy is the way you run your life, not the way your life is, what you're made of isn't it really? You can't change the way you are made. You can change the way you run your life, you can change the way you are in life you can change the way you are as a person but you can't change the bits inside no matter how, I mean if it's inside me it's still me.*

*(AGP 7)*

These comparisons of kinds of information and kinds of intrusions into personal privacy recurred through the interviews. Like others, Ms Fishlock (AGP9) emphasised the extent to which *'our lives aren't really private'*. People's National Insurance Numbers, and information about their bank account she said were regularly 'bandied around' with few real constraints on access to personal information of this kind. Whereas with this kind of study, she felt, the number of people who would have access to the information would be restricted and better regulated. For her, and for many others, the overriding criteria was

the potential significance of the study:

*R* *I thought they were going to see which groups we would fall into, presumably to get full blown psoriatic arthritis, the psoriasis and arthritis. You might have had to have had several factors shown in the blood and may be for a weaker strain, just one are related or not quite related or things on the same chromosome or whatever.*

*I* *Right so from your point of view, the fact that they're going to extract DNA from the blood and do the genetic analysis. Does that affect how you thought about the study?*

*R* *Well I would be very keen to be in a study like that because as I said before I don't think that this has any particular significance other than the illness itself.* *(AGP 9)*

In this context the assertion that genetics was not special was quite striking, and indeed resonates with a line of argument that challenges the assumption that genetic information has exceptional properties (Richards, 2001).

A few interviewees did make reference to the limits of their acceptance of genetics: several laughingly made reference to cloning when I asked about their views on genetic research, making it clear that cloning was out there on the fringe with 'the mad scientists'. And one specifically mentioned that he would be worried about the ethics of research which sought genetic markers for social or behavioural characteristics. (I did not specifically ask people to engage in this kind of process of 'drawing the line', but sometimes it occurred as part of a discussion about their views on the research project and the genetic element to it). In terms of 'drawing the line' against unacceptable research

though, it was less the details of the research which were mentioned and more who would run the research: research by drugs companies was singled out as being questionable. With the exception of the last point, about the merits of public sector versus commercial research, these discussions were quite brief. Often they made reference, implicitly or explicitly, to the impossibility of their considering these kinds of issues in the light of the limits of their knowledge and expertise about genetic research:

*I* *To look at the DNA you know as part of the research and you know I'm interested in how that affects how you think about the research.*

*R* *Well ultimately I'm a very optimistic trusting person and I just feel anybody carrying out this sort of research, I mean I have absolutely no problem with anybody doing anything like that with my blood or anything they want to take from me if at some future point it will help somebody. I mean I, you know when you get to extremes of genetics and DNA I'm not totally, I'm not knowledgeable enough to make an informed decision but I'm not sure I'm into cloning and that sort of thing. But from what I understand this research has got nothing to do with that at all*

*I* *Mm*

*R* *And that's about, that's about the only thing that I'm, I wouldn't say I was pro or against cloning it's just that I don't understand it enough.*

*I* *Yes you've got reservations which*

*R* *Yes definitely but I don't understand enough to say, "No you shouldn't do it," because I don't have the knowledge. But apart from that no I've got no problem with anybody doing anything, I mean I just, I think it's going to do some good.*

(AGP 24)

In their responses to my questions on possible concerns about the use of genetic techniques, each stressed the importance of these being deployed to investigate cause (over any possible suspicions about the implications of using these techniques):

> *Well nowadays I mean you hear more and more about the genetic side of things, it's only like in the last ten years that they've started looking into you know the hereditary side of things. And I think a lot of it is linked an awful lot. And if they can find a genetic link in between, I mean like you say it could only be one tiny little chromosome, one tiny little thing that could link thousands of people together. I mean it's only when you actually look inside your body and you see what it's actually made of that it's a bit like scary. So I mean as far as I'm concerned if they can find something from that side of things then, I believe in what they're doing*
>
> *(AGP 7)*

For many, it was the genetic techniques being used in the project which had made it seem worthwhile getting involved in. In the next section I move on to explore the nature of these expectations and the benefits which participants hoped might emerge from the study.

## Genetic research and 'moving things forward'

I had the sense that, for most of these participants, genetic research was not so much troubling or novel as very much on the agenda. The project's use of such techniques could be seen as an indicator of good modern science: *'At the end of the day, if it's something to do with your genes they need to look at it now'* (AGP1). This kind of rhetoric of progress was an eloquent one and it was possible that I was being swayed by

those of my interviewees who were more eloquent about this. However I checked the impression that I had formed while conducting the interviews, by coding for specific indications in the transcripts of this view of genetic research as progress. Fifteen out of the group expressed great interest or fascination even in the possibilities from this kind of research: a few were very hopeful that now this kind of research was going on *'a lot of people might end up not getting it and if that's the case that will be wonderful'* (AGP, 13). Some mentioned ways in which their families had benefited from advances in medicine. One man's daughter had needed a kidney transplant, and in this context he felt that we (all) had a duty to help with research if it can help future generations. Another made reference to the IVF treatment which he and his wife had needed many years ago, when it was still at the experimental stage. He was perhaps the most eloquent about progressing the scientific agenda in all fields of medicine: by participating in the research he would have contributed to *'moving things forward'* (AGP 14).

The fact that my own research was often included in this sweeping forward of knowledge which would benefit people shows perhaps the haziness of the notions about exactly how it might help.

In the following extract from my interview with Mr Gill, it is evident how the keenness to be involved in a genetic study can be intertwined with a sense of hope and with the expectation of a more specific outcome than is expected by the research team:

*R* *If it helps a cure, I mean if they found something in my DNA that they could pinpoint hopefully they'd come back to me and say "We could cure you".*

*I* *I mean yes.*

*R* *Or "We could ease your pain or 95%," then fine you know I've not got a*

*problem with that.*

*I* *Yes, yes.*

*R* *Like I say it's all about making that first step and you know if they can do it. I mean it's like if we reverse the tables and if you, if you was ill, somebody came along and said "Well can we take a blood sample off you and test it and see what we can find?"*

*I* *Yes, yes.*

*R* *You're going to turn round and say yes. If you don't I think there's something missing there.*

*I* *What would you say was going on if I said "No this is my blood really, I don't want you looking at all of that?"*

*R* *Yeah I don't know, I can't see why people want to do that. If it's all about curing and you know like I say if there's a chance that they could turn and come back to me and say "Well we've checked your blood, we know what's wrong with you, if we put you on this drug you'll be 95% better or 100% better" then you know.*

*I* *I mean some people say that DNA, looking at the DNA is a bit different because it's unique, you know it's unique to, so my DNA is unique to me and yours to yourself and you know because of that it's a bit.*

*R* *Yeah it's for each individual person isn't it.*

*I* *And because of that it's a bit special and you know they've got reservations about research going on that involves looking at that.*

*R* *Yes it doesn't bother me at all.*

*I* *No?*

*R* *No just I mean like I say if they can check it and see where you know I don't know how they do it but I suppose they can go back so many years and see*

*what they can find, where it started in me, you know my arthritis*

*(AGP 27)*

Others were more sanguine about the way that developments in knowledge might develop: Andrea (AGP 24) works for a design company. She described how when her sister developed breast cancer ten years ago, she had become interested in reading up and researching the background to her sister's treatment, as well as health issues in generally. She was more cautious about what might be achieved and how long it might take:

*I mean obviously one day I'd like somebody somewhere to find a reason, if not a cure some sort of treatment that works (laughs) as well as you know can be expected. Now I don't know if that's ever going to result, be as a direct result of the study but I would hope that eventually in time to come the study can be used may be to, I don't know say for example it makes me think of breast cancer and the gene, you know they discover a gene that triggers, if you have this gene you're more likely to get breast cancer or something like that and I was thinking along the lines that maybe this study might show that something either triggers it or something, you have something, I don't know.*

*(AGP 24)*

The time-scale which she expected would be required to develop any benefits was one of the reasons she gave for strongly preferring that this kind of research should take place in universities: drugs companies would, she felt, be concerned with developments in the short term.

Research in universities was seen to be more effective, because they would work to a

longer time scale and would not driven by commercial gain. Andrea was not alone in giving some clear and cogent responses to my questions about the auspices under which the research was run. These sometimes referred to particular points of difference between research and researchers in the different sectors. At other times their emphasis was more on the social and moral questions of who would benefit from research. I move on to discuss these views in more detail in the next section.

## Placing trust in the research

Although the research was being run by the university centre, it was strongly associated with the NHS, most of the participants having been recruited directly through the NHS. Loyalty to the NHS which had cared for them, despite some notable inadequacies along the way, was pronounced. As Mrs Collier put it: *'I can never knock the NHS for what they've done for me'*. Many attributed their involvement with the research to its association with the NHS and to a lesser extent with the University. In some interviews this seemed to me to be implied, yet there was no detailed explicit discussion about it. One way to explore the importance of the research being run under NHS and university auspices was to ask my interviewees whether they would have taken part in the research if it had been run by a commercial company. All but one of those I asked said they would have been less trusting of a call for research volunteers from a commercial organisation, even if doing exactly the same research.

**Arthritis genetics project donors: views on involvement in commercial research**

| | |
|---|---|
| Number interviewed | 27 |
| Number specifically asked about commercial research | 20 |
| Number saying they would trust commercial research less | 19 |

(See text for details of discussion)

Some said in absolute terms that they would not be involved. For example one man said he thought '*I'd be very dubious if it was run by a pharmaceutical company'* (AGP 6). Others thought that they would be less likely to participate and all that they would scrutinise the request more. Here are two examples of responses to this question, all of which - despite their differences were strikingly similar in tone. The first is from Mrs Collier:

*I* *So yes, say if it was the same advert but it was a pharmaceutical company say, I mean they were still doing exactly the same research?*

*R* *Probably not.*

*I* *Okay.*

*R* *Probably not.*

*I* *Can you just spell that out a bit?*

*R* *Because I'm more sceptical because you hear all of these bad things at times you know about pharmaceutical companies and they're in it for the financial gain of it as far as I'm concerned.*

*I* *Right*

*R* *I probably wouldn't say no but I would look into it a lot deeper*

(AGP 7)

I went on to probe this view by pointing out that some voluntary organisations like the MS society were now developing partnerships with commercial companies. My interviewee however stood her ground, asserting that: '*The people that are doing the research, the people in the universities, the doctors and that, they're doing it for the good of their patients, for the good of their people that they work with'.*

Mrs Collier was not the only one who related their answer to the question to personal qualities of the researcher. The sense of direct personal involvement of someone who wanted to know was seen as important: again I was included in this, but in particular they referred to the research nurse who had spent a long time talking through their medical and family history with them. Commercial research was seen to be more distant and formulaic. You would not see the face of the researcher in the same way or not warm to them.

My second example here is from Ms Fishlock, who said she would have considered a request from a pharmaceutical company. Nevertheless, my question prompted her to put forward the reasons for her preference for involvement in the kind of public sector research which the University's 'arthritis genetics study' represented:

*I* *What if a pharmaceutical company had come along say and wanted to do exactly the same study, you know doing a physical exam and taking a blood sample and they wanted to do genetic testing. They wouldn't give you drugs*

*or anything like that but they wanted to do the same study…Would you?*

*R* *For the purpose of making a drug?*

*I* *Well let's say if they said exactly the same as the ARC study did, that they wanted to understand more about the causes, which does sometimes happen with drug companies. Would you have taken a different view?*

*R* *I might have done yes because their end point would be to make a product and so they are using people for gain and you can't really say it's for the common good after all because they produce drugs.* (AGP 9)

This notion of the research being for the common good was frequently expressed in these discussions - albeit not usually in these words. Even amongst the few who would countenance involvement in more commercial research, it was important that this particular research project was seen as being: *'for the benefit of everyone'* (AGP 13). Effectively, those who would engage in commercial research would do so on different terms - one suggested that he would expect some payment. When I asked Ms Fishlock to say more about her reservations about commercial research, she said that she didn't like *'the idea of patenting drugs or knowledge'*. I countered with my lay knowledge of pharmacogenetics: it was hoped that by doing genetic research these companies could better tailor their treatments to individual patients; *'but at the end of the day, they would still be selling it'*. I had to concede the point.

The question of the profit which might be made by a commercial company was raised directly by some. One young woman, who had initially seemed to me to be unquestioningly accepting of the research, pointed out later in the interview that because it was associated with the NHS she was confident that it was *'being done for research purposes only purely for research its not that somebody is going to make a lot of money'*

(AGP 22). Only one interviewee, himself a university lecturer, departed from the belief that the university's involvement in the research meant that it was free from all possibility of commercial exploitation, pointing out that *'most universities are looking for lots of commercial opportunities, as many as they can get'* (AGP 18). Nevertheless, the fact that the researchers' work would have been thoroughly scrutinised by science and ethics committees at the university gave him some confidence in it.

## The place of the NHS

I found that respondents drew a circle of people who might benefit from the research to include those in the present and future with this condition. For example, one interviewee who had quite disabling joint pain, felt that *'anything in the future that might improve people that get arthritis has got to be good really…'*(AGP1). There was not generally in these interviews a direct sense of association with other sufferers: most felt that they didn't want to identify with a support or campaigning group for people with arthritis. For most of the interviewees, this was linked to an insistence that they were 'not badly affected'. At the same time though the point was made that arthritis was not widely seen as being as important as more high profile diseases, such as AIDS and cancer. The research was seen as both recognising the importance of PA, itself one of the rarer kinds of arthritis, and holding out the promise of helping those with the condition in the future.

For many, the fact that the research was conducted by the university, and also associated with the NHS through the hospital consultants who had recruited them, gave sufficient indication that it was legitimate. Mr Murphy had no qualms about the research, and was emphatic that being asked by the hospital gave him every indication that the research was legitimate:

*R* *I will never, ever give to anybody in a pub that comes round with a tin, I would never do it, only on them grounds. But if I was in City Hospital and someone came up and says "Right you're in City Hospital and we want you to make a donation" I'd be the first one to put my hand in my pocket.*

*I* *Yes so you trust the hospital really to kind of to just make some decisions for you really about what's legit like you said.*

*R* *Yes, yes because at the end of the day it's probably the best way to get blood.*

*I* *Yes.*

*R* *And if the hospital said like "Could you please fill in this questionnaire?" I'd do it, I'd do it tomorrow, I wouldn't think twice about it but I wouldn't do it on either television or newspaper or people knocking on your door or anything like that, even if a friend recommended it I wouldn't do it. But if a doctor turned round and said "Would you like to fill in this form?" I would gladly do it and I've go no problems with that. But it's just I'd prefer it to be in a professional environment, you now what I mean?* (AGP 17)

Whilst these perspectives seemed to underline a loyalty to the NHS amongst the research participants, many of the interviewees had also testified to the difficulties they had faced in accessing care and effective treatment. Some had found that getting a diagnosis had in itself been a long process, or that it had been difficult to get help and understanding from their GP for this comparatively rare condition. A number had sought private consultations to resolve the question of diagnosis before returning to NHS care. Many too had undergone a protracted process of trial and error in seeking effective treatment.

In addition some of the interviewees talked about more pressing concerns about access to

health services for both themselves and their relatives related to other medical conditions. Sometimes these seemed as though they should be very simple problems to resolve, the most distressing example being the man whose local hospital A & E department could not change the dressing on his chronic wound, but neither could it tell him who would do so. Another example was from Mrs Rolfe (AGP 1) who had been entitled to help from district nurses several years ago when she was nursing her husband with MS until his death from related complications. The district nurses, she said, *'come when they can fit you in'*, which might be during an early shift or a later one: unfortunately this wait for help with bathing might mean that her husband waited all day to get up. Beyond this she was angry about the way you could only get certain treatments for MS in particular parts of the UK, effectively a postcode lottery which the MS society had actively lobbied against. Another interviewee talked about the way patients in different parts of the country are afforded different treatments from the NHS for cancer. And one man stated with certainty that the medicine you were prescribed by the GP depended on which of two piles of files your records were in.

Not all of these research participants, then, saw the NHS as having met their medical needs or as having cared for them or their relatives fairly. Nevertheless, even those who had criticisms and distressing accounts of treatment at the hands of the NHS attributed their involvement in this research project to the view that the NHS was a suitable organisation to undertake this kind of research. We know that access to and experience of NHS services is highly divergent (Baker, 2003; MORI, 2004). Yet the view that the NHS is a critically important institution in British society is a widely held one (Park et al, 2003).[8] In the next chapter I shall further develop the suggestion that the history of the

[8] We can see the DH's recent insistence on the use of one national NHS logo as indicative of

NHS as a national institution is a highly significant one when thinking about participation in (genetic) research. This goes beyond the influence of clinical norms on research participation, to encompass the social history that participants share in relation to the state and to welfare traditions.

## V Discussion: dynamics of involvement

In the concluding part of this chapter I shall briefly review some of the findings from this part of my work, and discuss some of the directions for analysis from these. In my analysis, a recognition of people's limits of expertise and of their reciprocal interests undermines the validity of relying on the models tend to prevail in discussions about participation in such research. I find the participation in this particular genetic research project and the entrusting of blood donations to it to be informed less by information and more by the reputation of the institutions involved. Thus informed trust, rather than informed consent, seems to be a more accurate description of the dynamics of involvement here.

### Rethinking altruism

I have described the tenor of my discussions with participants in a genetic research project, beginning with an exploration of the basis on which people take part in this particular project. In this case no treatment was on offer nor was genetic testing available for the participants or their relatives. The kind of research being undertaken is

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recognition of the importance of the NHS 'brand' at a time when multiple organisations are actually charged with delivering and managing health services (HSJ, 2004:36-37).

exploratory, there being no established genetic cause for psoriatic arthritis. Furthermore the aims of epidemiological research and the use of genetic analysis in this context are not widely known nor publicised through the media or through campaigns as is sometimes the case with more high profile medical research.

In the absence of an established framework for thinking about the basis of peoples' participation in this kind of genetic research, ideas about altruism have been prominent in recent policy discussions. I have suggested though that the assumption that individual generosity and altruism is a sufficient basis for participation in research draws in turn on a narrow reading of Titmuss. Another feature of the (policy and sociological) literature that I have drawn attention to is a focus on the importance of family and kinship relationships when thinking about the basis for and implications of participation in genetic research.

Amongst participants in this particular study I find that involvement in the research was indeed mediated by relationships, but that potential benefits to kin and family relationships were extended to a wider group. (As noted earlier, PA is not considered to have a simple monogenetic cause, and there is no clear cut hereditary pattern established for the syndrome). Most of the research participants talked to me about their participation in terms of the satisfaction to be had in contributing to knowledge about a condition which is not well understood. It was expected that, in time, this would lead to improvements in treatments for others. Reference was made to the care and treatment which they had received for the condition, sometimes over many years, and mainly from the NHS. Participants, who will derive no personal benefit from it themselves, attach great importance then to the association between the project and the NHS. In summary I have characterised their involvement in terms of their common interests. Mutuality, rather than selfless altruism, is the model implied by these accounts of participation in research.

I shall return to this suggestion in the following chapter.

## Knowledge and informed consent

I have shown how many of this group are resourceful in managing a sometimes distressing condition. In the course of this many had not only negotiated a path through the health system, but had actively looked into possible causes of their own condition, researched treatments, and negotiated appropriate regimens with their doctors. Weighing up the pros and cons of particular medications was part of this process for many, as was actively seeking and using alternatives to orthodox medicine. My interviewees then were 'lay experts' in the sense denoted by sociologists working with people with chronic illness (Bury, 1982; Williams, 1984). However, their words to me indicated that their encounter with the genetic research project brought them up against the limits of their expertise. In this particular domain, they do not see themselves as experts; indeed they see themselves as reliant on expertise not so much in the personal sense of being patients but in relation to the project of progressing knowledge about a disease.

A recognition of the limits, as well as the potential, of lay expertise takes some account of recent criticisms of the 'fuzziness' of the concept, whilst still recognising the many ways in which lay people may become knowledgeable about health and indeed may reasonably question current medical knowledge or government policies.[9] It also has implications for the extent to which the practice of research recruitment relates to the ethicists' abstract ideal of 'informed consent'. Despite their enthusiasm and the provision of information on

[9] I am primarily addressing Prior's concerns about the fuzziness of the concept of lay expertise and its political implications. (Prior, 2003). Whilst I am aware of important epistemological challenges to the concept, by Collins and Evans (2002) for example, I do not address these here.

the project, most of these respondents were unfamiliar with the details of the ways in which the data they gave to the project would be used, and in particular with how the blood would be analysed. Nevertheless, they had made a decision to entrust the researchers with their donated blood samples and medical information which had been requested. At first this sounded to me like blind faith. But on further consideration it became evident that this decision was made less on the basis of written and verbal information and more on the basis of a relationship with a referring physician and with researchers. Notwithstanding the importance of the personal qualities of the physicians and the research nurse (they did not meet the rest of the research team), it was the institutional location of the research within the university and the NHS which was the basis of that trust.

## Entrusting genetic material

It is not surprising, perhaps, that amongst a group of volunteers for a genetic research project, the analysis of genetic material was not seen to present special problems. Nevertheless, it presents a counterpoint to the prevailing emphasis on those situations where genetic data is considered highly risky and problematic. In this situation at least, the use of personal genetic material is not seen as intrusive, invasive of privacy, or as having implications for the course of an individual's disease. Rather, the project serves to underline how far scientists are from being able to predict outcomes and develop treatments. In the context of the participants' confidence in the researchers, the use of genetic techniques for research was seen as being fairly routine.

My respondents were aware of the unique properties of genetic information, but tended to minimise (or manage) them by pointing to other kinds of personal information that is

routinely used without people's knowledge or permission - the example of information about individuals' finances being an example given here. The idea that DNA has special implications for a sense of self is not present in these interviews, indeed when I tried to put such an idea forward it was sometimes laughed off. These interviewees' emphasis on the potential of the information for medical research signifies a fairly utilitarian approach. To the extent that DNA is seen as special, it is special mainly in this sense.

Some respondents had compared the use of genetic data in the AGP project with other uses of such data, those that identify individuals and relationships - and considered the first use to be qualitatively different from the second. They pointed to the project's purpose of analysing the data from a group of people with a common disorder, and insisted that this was not seen as threatening. Others though saw the project in terms of researchers getting an overview of information, but had given little thought to the use and analysis of genetic data. This oversight can be seen to limit the extent to which they had given their 'informed consent'. On closer examination though it tells us as much about the limits of a model of participation which envisages individuals making a contract with a researcher on the basis of the provision of written information.

### Informed trust

As we have seen, participation in this genetic research project goes beyond an individual transaction with a researcher or research project, and is informed by the reputation of the NHS and the University as public institutions that will care for and protect common interests. Researchers in the university, in contrast to those in pharmaceutical companies, were seen as sharing their loyalty to the NHS and being motivated by an interest in caring for patients and developing treatments. Notwithstanding the participants' loyalty to the

NHS, there were some distressing accounts in these interviews of the difficulties faced in getting timely care for this or another condition: the health service which they actually described was by no means ideal. On the face of it then the approach taken to the NHS seemed to be quite paradoxical. There was an imagined (idealised) NHS to which they would prefer to entrust their blood for research to help others in the future. For me this was in contrast with their accounts of their lived experience of the NHS, which did not always live up to its reputation of being a reliable system of mutual support. Nevertheless, rather than scrutinising detailed information about the research and its risks and benefits to oneself, as might be expected in the bioethics model, these participants relied to a great deal on their assessment of this wider terrain.

Each of the themes discussed in this chapter - the stance taken to genetic material, the complexities of consenting to a project on the basis of limited expertise, and the importance of the relationship with the NHS - seem to have resonance for policy. In the following chapter, I review my conclusions from the project as a whole and begin to unpack the implications which they may have for current policies as well as for the theoretical frameworks which I set out to reconsider.

## Chapter Eight: conclusions

In the study that I have described in the preceding pages, I have sought to locate my analysis of interviews with blood donors in the context of the institutions and social mores that shape their involvement. I began with a description of the policy landscapes into which the proposals for the new biobanks emerge, and moved to discuss a key 'mobilising metaphor' (Shore and Wright, 1997:20), the notion of gifted blood, in more detail. This notion has considerable acuity in summoning up social allegiances based on a feeling of community in a general sense, and on a loyalty to the NHS in particular. However, it becomes evident that its use in relation to blood donation for a biobank that has no clear limits or boundaries is problematic. At the level of national policies, biobanks, as with blood banks of a traditional kind, are bound up with an assertion of common interests. The accounts of blood donors interviewed in both settings are seen to reflect these ideas of shared interests, but also to underline some of the limits and boundaries to these.

In this final chapter I shall retrace some of the steps that I have taken in the thesis, following the order of the preceding chapters, and flesh out some of the implications of the work as a whole. These revolve around the question of the perceived legitimacy of initiatives like the UK Biobank, and related to this, to how its governance structures provide boundaries for the kind of research it will facilitate, and for a practical recognition of the shared interests of those involved.

## I Policy landscapes

I began by tracing the development of biobanks as a new context for the use of donated blood. As a consequence of developments in genetic research, the information derived from donated blood has become an enormously valuable resource for the commercial companies in this field. For a variety of logistical and political reasons, the state is being drawn more directly into facilitating and establishing such biobanks. However, biobanks require not only government support, but also the donation of small amounts of blood by large numbers of people.

Whilst millions of people already donate blood (to the NBS) each year in the UK, they do so for immediate medical use. Questions of identity are rarely raised in relation to blood donated in these contexts, nor are the processes of transforming raw blood into blood products seen as problematic. As I have discussed in chapters two and three, blood donation in Britain is enshrined as an activity outside the commercial realm - despite the complexities of manufacturing and importing blood products that are in fact entailed in the maintaining of a national blood supply. In contrast, population genetic research is a newer and potentially controversial phenomenon; it cannot be assumed that this ethos will be extended to blood donation in this context. The uncertainties that are associated with genetic research and its consequences are amplified by an intention to seek open-ended consent from biobank participants to an uncertain research agenda. The provision by national biobanks, including the UK Biobank, of data to commercial companies has additional potential for controversy.

The need to develop policy and regulatory regimes for the new challenges posed by such initiatives is clear. In the UK the particular values that shape medical research located within NHS priorities are embedded in the current legal and policy

frameworks about epidemiological research. However, the priorities that drive research in commercial organisations are different (Kaye, 2004). The issues raised by the use of tissue donated in 'public' contexts' (such as NHS clinics and GP practices) in the UK for use in commercial population genetic research are not fully resolved by the recent Human Tissue Act.[1] At one level the task facing policy makers and their advisors is one of regulating these new initiatives. Institutional procedures that are acceptable and effective will be needed. Here, the arrangements for informed consent are pivotal, both rhetorically and practically, in terms of complying with legal and ethical requirements. At another level, the challenge is to provide an account which establishes diverse activities of commercial genetic research as legitimate, a potentially difficult task given the cultural designation of donated blood as outside the realm of commerce. Hoeyer describes this task as one of constructing 'a sensitive cultural biography…to provide trade in blood-based research with some amount of moral legitimacy' (Hoeyer, 2002:13). Here, the notion of blood donation as a gift has proved critical, having been invoked by numerous advisory and expert bodies in the field.

Following Shore and Wright (1997), I suggested that in this context, as indeed in others, the diffuse features of policy, those of language and metaphor are as important as those concerned with action and regulation. Although part of the policy agenda will be concerned with regulating a new kind of initiative - the biobank - there is another role for policy, that of setting regulations within the framework of a wider and more universal set of principles (Shore and Wright, 1997:11). We can see the

[1] This issue is not unique to the new higher profile biobanks: Lewis argues that the extent of commercial exploitation of ostensibly public resources of donated tissue has for some time rendered the distinction between public and private biobanks 'increasingly irrelevant' (Lewis, 2004:198)

extensive commentary by bioethicists and other experts in this light.

The debate on biobanks has a marked tendency to seek universalist principles to apply to a diverse range of initiatives around biobanking. One such is the much vaunted principle of autonomy, accompanied by an emphasis on informed consent as a mechanism for achieving an ethical relationship between researchers and research subjects. A second is the principle of donated blood as 'gifted', which has been ubiquitous in UK policy landscapes. However this principle is remarkably multivalent. Based on an examination of the use of the term 'gift' in current UK guidelines about the use of donated tissue in research, it seems to be mainly used in the legal sense in relation to property rights in the tissue - that, once 'gifted', no longer belongs to the donor (Tutton, 2004). On the other hand, ethicists have used the concept in support of a position denying the commodification of human tissue (Holland, 2001). Thirdly, the term evokes Richard Titmuss' work on blood donation and some distinctively British political traditions and debates. I therefore moved to an examination of Titmuss' work.

## II Reassessing Titmuss' 'The Gift Relationship'

I have argued that over the years, Titmuss' work on 'The Gift Relationship' (1997 [1970]) became reified into a simple tale of individual altruism. In contrast, my reading of the original text finds that Titmuss' empirical work on blood donors shows more complexity than is allowed for by this tale. The reasons given by donors for donating blood are shown to be diverse, and reciprocity acknowledged to be prominent amongst these. The book is more about systems than it is about individuals; there is an interest in the potential of blood programmes to facilitate socially responsive and responsible policy regimes. The achievements of the NHS as

a scheme for providing practical mutual assistance are celebrated, with an evident glow of pride in this uniquely British system.

For Titmuss, the inefficiencies of the patchwork of private and public blood banks in the USA are used to support the argument against a market in blood. However, following considerable changes in the technologies, organisation and wider context of blood donation, some of the points made in 'The Gift Relationship' have been superseded or have become redundant. I make no case in the thesis for an exegetical reliance on all the elements of the original text, or for a blanket application of its principles to the contemporary phenomenon of blood donation for biobanks. However, I propose that re-reading 'The Gift Relationship' in the context of the British welfare traditions that informed it clarifies its relationship to contemporary policy dilemmas.

The notion of 'the gift relationship' is a potent symbol of a kind of social cohesion that is highly valued in British political life. Historically, blood banks symbolised the social solidarity that is associated with the founding of the NHS. The post war settlement was, as it turned out a unique historical moment in which the British State envisaged the health and welfare of its citizens to be its primary responsibility. Already, as Titmuss looked back from the vantage point of 1971 on his work undertaken in the late sixties, he saw social and political changes which, he feared, might undermine the social cohesion and solidarity that he believed characterised the earlier era (Titmuss, 1971). Since that time, we have seen a retreat from these comprehensive aspirations. Nevertheless, the potency of the post war settlement is evident in its use as a point of reference in contemporary political and public debate.

In examining the relevance of Titmuss' work to contemporary blood donation, I find it

in the emphasis on the choice to be made about where to draw the boundary between the social and the economic (1997 [1970]:219). This work was primarily an examination of the social and political systems that shape that choice. For all Titmuss' passion for the idea of gift relationships, his was an empirical study of particular systems in a social context. As I have shown, the metaphor of blood donation as a 'gift' to strangers continues to hold sway in policy and clinical literature about blood services. Beyond this, it has been revived in the newer context of genetic research and biobanks. However, whilst the definition of blood as outside the realm of commerce is an essential ideological underpinning of a British national blood service, developments elsewhere have led to an 'informational economy' in which money is exchanged for the information deriving from donated blood (Tutton, 2002). Here the continuity of terminology - referring to blood donation as 'a gift' - tends to elide the commercial implications of donated blood being used for genetic research.

## III Consent, Risk and Ethics

I began my review of relevant literature with a consideration of the influence of bioethics in both the policy and academic literature on biobanks and genetic research. I drew on the analyses of a number of commentators who trace the ascendance of bioethics from its roots amongst American moral philosophers to its prominent place amongst the bodies advising governments on diverse policy dilemmas (Wolpe, 1998; Evans, 2000). Within the political traditions of liberal individualism that nursed the development of such principlism, the triumph of autonomy within this framework is seen as more or less inevitable (Wolpe, 1998).

Although the reliance on informed consent as a guarantor of the morality of a transaction is increasingly questioned in academic bioethics, it has nevertheless

retained its status as a rubric for policy (Evans, 2000). The implications of the dominance of bioethics as a lens through which to consider new policy dilemmas become evident when I move to consider the discussion about biobanks in Europe and Scandinavia. As I discussed in chapter two, the question of how to obtain informed consent has shaped much of the early discussion about biobanks. However, one difficulty with the models underlying this emphasis is that they do not allow for a recognition of the social processes that underlie moral reasoning (Kleinman, 1999). There is, in addition, a wider critique of the deployment of a bioethics model in this context and the ways in which it constrains a debate about these developments (Hoeyer and Lynoe, 2004).

I turned to sociological research about the new genetics to consider what alternative approaches are available to consider blood donation for genetic biobanks. Empirical social research in this field has tended to follow the clinical trajectory of developments in genetics and so to focus on the issues arising from newly identifiable genetic risks and diseases. Partly by reason of this focus, the literature to date has concentrated on the response of 'genetically risky individuals' to genetic testing and diagnosis (Novas and Rose, 2000:487). An important contribution is made too by looking at the implications of these newly identifiable risks for familial relations (Hallowell, 1999). The shape of this research is such that there has been less discussion of the other social activities and allegiances that may define peoples' 'moral horizons'.[2] The associated literature on reflexive responses to (genetic) risks then dovetails with prominent strands of theoretical work on reflexivity, particularly the 'Risk Society' paradigm (Beck, 1992). Based on these frameworks, we might expect to find the playing out of individual reflexive choices to be prominent amongst

[2] The term 'moral horizon' is from Kleinman (1999:72), who also emphasises the extent to which wider social processes shape moral reasoning.

those invited to donate blood for genetic research: central to their accounts and decisions would be a critical stance towards medical or scientific expertise. As is now established however, a difficulty with the Risk Society framework is that it has not engaged with empirical research in relation to a range of institutions or domains of expertise (Dingwall, 1999; Lupton and Tulloch, 2002; Elliott, 2002). Biomedicine itself presents particular problems for this modelling of relations between lay people and technical experts (Lane, 1995). This can be related in part to the dimension of dependence on biomedicine and its practitioners to which medical sociologists have drawn attention (Williams and Calnan, 1996).

I find that a number of different theoretical frameworks - including those of bioethics, risk society, and governmentality - converge on a tendency to model decisions on calculation of risks by individuals. Added to this are sociologists' theoretical and methodological interests in lay knowledge. These apparently diverging perspectives have tended to be associated with an emphasis on the centrality of information or knowledge for those participating in genetic research.

There are now a few studies of the social context of donating tissue for population genetic research (Haimes and Whong-Barr, 2004; Hoeyer, 2004; Williamson et al, 2004; Gustaffson-Stolt et al, 2002). In pointing to the importance of the moral domain of the clinic, they seem to continue an older thread of discussion in sociology about the dynamics of involvement in medical research.[3] Regardless of the degree of actual overlap of personnel and premises in the recruitment for the biobanks, the wider issues addressed in the sociological literature are likely to be relevant here: an

[3] Interestingly, although the studies I cite refer to donation for genetic research, they recruit through community health clinics and projects, which are less represented in the sociological literature about involvement in clinical research.

investment of trust in medical knowledge and institutions will, for many, shape choices made about participation in research. As I have discussed in chapter four, we know a good deal from sociological studies about the ways in which tacit knowledge and expectations, together with limited choices, shape involvement in clinical research studies. There is too a wider context of ambivalence towards biomedicine, its promises and its failures. Added to this in recent years are the representation of genetic 'breakthroughs' in the media and elsewhere - and the accompanying optimism about new interventions - that are likely to stoke that ambivalence (Rose, 2000; Conrad, 2001). These are the cultural parameters into which the new biobanks have emerged.

## IV Blood donors' accounts and rationales

I have grounded my exploration of the meaning and ethics of blood donation with a study of blood donors in two very different contexts, to which I now turn. Many of the NBS donors who I interviewed were eloquent that blood donation was one response that they could make to an awareness of vulnerability, of the possibility of illness, which they described. For donors to the genetic research project, it was the health problems that people might have in the future, and particularly those associated with a particular illness (psoriatic arthritis) to which they referred in their accounts. I find that donors' accounts in both settings refer not only to their own interests and those of family and friends, but also those of wider groups. Amongst donors to the genetic research project, that wider group was often taken to include future generations. Therefore I propose a move away from analytic frameworks that overemphasise either 'selfless' altruism or 'autonomous' informed consent.

## Consent and moral reasoning

Although there are consent procedures in place in relation to the use of the donated blood, these were not seen as central to the relationship between donors and the blood service. Rather, the transaction with the blood bank is informed by knowledge of the place of blood donation in the NHS.[4] Blood service personnel are trusted accordingly to take care of donors, and the blood is entrusted to be used for legitimate purposes - that is for a useful, compassionate, responsible response to suffering and illness.

These accounts may seem very old fashioned - in contrast to the crisis of trust that is often said to characterises today's relationships between lay people and medical and scientific experts.[5] The NBS is able to lean on its historical association with predecessor local blood banks. However it has faced crises - notably in the wake of the HIV crisis, which donors were clearly aware of - and is not immune from public criticism.[6] Some donors mentioned scandals of trading of blood or organs that they read about. In my analysis, they were often aware of such risks and were making an active decision to place their trust with the organisation.

Nevertheless, NBS may be seen as something of a special case, in that the

[4] In some cases these accounts of blood donation were fleshed out with an explicit reference to the place in the historic achievements of the British welfare state. In other, briefer, accounts this was not so. Nevertheless I argue that this is recognised as the context of the national blood service.

[5] See discussions in chapter two on the way that a perception of a crisis of trust in relation to science has influenced public policy in the UK, and chapter four on the view from the Risk Society paradigm.

[6] See for example the report on the NBS by the Auditor-General HC (2000).

technologies of blood donation are widely accepted and seen as uniquely worthwhile. In addition, the dynamics of the interactions between NBS staff and donors are characterised by the kind of trust that is accorded to clinicians. Beyond this there is the fact that most donors make donations on a regular basis. As was evidenced by some of their responses to my questions, donation eventually becomes a routine about which they do not think a great deal, a taken for granted commitment to be fitted in at a lunch-time or between other commitments. The habitus of trust, as we may think of it, is then reinforced by the routines associated with handing over blood.

Perhaps this kind of enactment of trust can have only limited relevance to the contemporary situation in which donations will be sought for genetic research. Here, people will be faced with a decision about donating blood for a new situation. Following prevailing sociological theories, we might expect that they would scrutinise the risks involved in the research, drawing on their knowledge of related scientific developments. Following the models of moral reasoning that are associated with bioethics, they would rely a good deal on the written information provided. The signing of a consent form would then signify the basis for the relationship between participant and researcher.

However, as I have discussed in chapter seven, there was little evidence in my own interviews with genetic donors of a detailed process of weighing up of the implications of participation. More often than not there was a degree of confusion around the detail of the project they had agreed to be part of. In terms of the mechanics of informed consent, it was clear that information had been given and consent forms signed. Sometimes though these procedures hardly seemed to have permeated the relationship with the researchers. Only about half of these interviewees explicitly recognised that the analysis of DNA from their blood was part

of the research in which they were involved. However, I also explored their seeming lack of concern about the genetic elements of the research. For many of these donors, genetics was seen to be part of good modern science, concerned with 'moving things forward' in the long term.

When pressed about 'genetic research', they did express concern about the risk of individual scientists or companies doing research they felt would be dangerous or unethical. However many of these respondents were insistent that the (ethical) issues about donating blood for this research were not particular to the domain of genetic research. Nor was there a sense in these accounts of special relationships being constructed through genetics, whether these be in terms of kinship or disease groups. It was clear from their accounts that in many ways in their dealings with the health system they were knowledgeable and resourceful. Notwithstanding this resourcefulness, however, many felt that my questions about genetic research probed issues which are at the limits of their expertise.

### Informed trust

In time, they hoped that their participation would contribute to better understanding and treatment of psoriatic arthritis in the NHS. The strength of the loyalty to the NHS became evident in contrast to the stance taken in relation to research in the commercial sector: most ruled out involvement in commercial research. Researchers in the university were seen as sharing this loyalty. These researchers were seen to be more likely to share participants' concerns with developing fundamental knowledge of the illness, and more able to pursue those interests than scientists in pharmaceutical companies. It was the institutional base of the project then, rather than the details of the research itself, that seemed to influence participants' evaluation of how legitimate

and worthwhile it was. Thus the reputation of the NHS, hospitals and universities were critical to the trust that is expressed in the particular researchers and research project. Usually, that trust was shaped by a belief that these institutions would use the donated blood within their own boundaries, and would monitor the legitimate uses of the blood and genetic information arising from it. Finally, it was expected that they would conduct research that was in the interests of NHS patients, and apply any knowledge gained directly for the benefit of such patients. As I have shown, some of the interviewees explicitly recognised a role for pharmaceutical research - and few opposed commercial research per se - but felt that this could not be guaranteed to be directed towards a broader base of understanding disease. Here, they recognised and referred to the way the pharmaceutical industry is structured by its goal of delivering products that are patentable and marketable.

We can also see this dynamic of informed trust operating amongst the NBS donor group. It was within this kind of framework that donors considered and responded to my questions about the ethics of using blood for research. Many indicated to me that my questions were pushing at the limits of their knowledge. It was they felt difficult and perhaps inappropriate for them to try to answer my questions about how blood might legitimately be used. In this kind of situation, experts in the NBS, the NHS and the government were accorded the role of deciding which research would be legitimate. It was not a question of there being no ethical limits to how they thought donated blood should be used; some kinds of research - deemed to be frivolous, dangerous, or unimportant - would not be seen as legitimate. I contrast these dynamics with an assumption that underlies recent discussions on population collections and commercial genetic research using them: these sometimes feature trust in the NHS as a given resource. If we consider that trust is socially produced, [7] it is

[7] I refer here to Mizstal's work on 'Trust in Modern Societies' (Misztal, 1996).

not only our history but also our current policies that have the potential to influence it.

## V Beyond altruism: interdependence and 'Imagined Communities'

In reviewing the ways of thinking about blood donation for genetic research, I have described how the principle of blood as a 'gift' is deployed with a view to adjudicating policy dilemmas in this context. In the midst of uncertainty and a degree of controversy about contemporary developments in genetic research, the utility of this concept in a policy context is to be found in its fluidity. It can be read variously as being about the right of researchers to own donated tissues, about the generosity of individual donors, or about the altruism that it is believed should characterise citizens' response to developments in genetic research. Beyond this it has the political connotations that I have discussed in some depth. However, the use of the term has come to obscure the choices that are to be made about the social organisation and boundaries of genetic research using donated blood. In this sense its deployment in a policy context functions in a similar way to principlism in bioethics; in relying on a model of contractual relations between individuals, it tends to narrow down the terms of debate (Evans, 2000, 2002).

Amongst the contemporary NBS donors I interviewed, the term 'gift' was only occasionally used in relation to donated blood. More often though, they talked about a blood bank. Blood was seen as being donated to a 'bank' which donors themselves, their relatives, friends or strangers can draw on if needed. This was seen as one way of making mutual provision for the risks of the kind of traumatic accident or illness that may afflict people without warning. For many of those who participated in the genetic research on psoriatic arthritis, the aim of developing knowledge about the condition was in itself a worthwhile one. This was seen to be important for other

sufferers, and especially those in future generations who would have the condition. Eventually, they hoped, such knowledge would be developed into treatments. Often, the decision to be involved in the research was explained with reference to others in the family, others with the condition, or simply other NHS patients.

For the NBS donors I interviewed, the NHS figured prominently in terms of the care that would be extended to someone who needed blood in the event of an accident or catastrophic illness. For the research project donors, the relationship with the NHS was a more complicated one. In addition to expressing gratitude for the help they had received, they sometimes described how the hardships they or others had experienced had been compounded by lack of timely NHS care. Yet these difficulties seemed to have little impact on the ideal of the NHS that was referred to by donors in both situations. Nor, it seemed, did they impact on the feeling that the NHS, together with the university, was seen as the organisation best placed to undertake or manage medical research.

Notwithstanding the particular local dimensions of this research, this trust is informed by the iconic place of the NHS in the nation's history. In this sense it involves a dynamic process of active involvement via the imagination, reminiscent of Anderson's analysis of nationhood as an 'imagined community' (Anderson, 1991). Anderson's work is concerned with the experience of national subjects, who whilst not knowing most of the fellow members of their nation, nevertheless share with them communal feelings and a related identity. The emphasis here is on the imagining of communal bonds, which is seen in terms of a creative power with which individuals locate themselves in the world (Morris 1995).[8] Importantly, these forms of thinking

[8] This distinguishes Anderson's approach from those who see nationalist feelings in terms of illusions. For the purposes of my thinking here, I take just one of the pivotal points to

command ‘profound emotional legitimacy’ (Anderson, 1991:5).

Returning to my own work, I do not suggest that nationhood is experienced in a uniform way throughout different regions and generations. It is likely that local identity, allegiances and civic traditions[9] shape the accounts of the donors I interviewed and the ways they consider their involvement. However I do propose that the NHS is an institution that has historically mediated national identity and in particular a narrative of national solidarity.[10] Yet the meanings of social solidarity

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Anderson’s thesis. Glasner and Rothman invoke the idea of ‘genetic imaginations’ to refer to the way in which the project of mapping the genome makes possible new ways of thinking about society (Glasner and Rothman, 1998:1). My emphasis in this account is more on the institutions and cultural parameters into which such technical developments emerge.

[9] There is a widespread view that the North of England does have its own distinctive identity (Musgrove, 1990). Certainly the Northern cities have a distinctive economic history (Hudson and Williams, 1995). At the political level, this part of the country played a central role in the development of the mutual associations that played a prominent part in civic life in the early part of the twentieth century, and informed early ideas about the welfare state. However, understanding the processes of identity formation in relation to place is significantly under-researched field (Taylor et al, 1996:5). I note with interest however that MORI’s ‘People’s Panel’ study on human genetic information conducted on behalf of the HGC found some regional differences in terms of peoples attitudes (HGC, 2001:25).

[10] I write of a founding story or narrative, not because I dispute the reality of the existence of a heightened experience of solidarity, but because historians point to the importance of other influences in the welfare settlement, notably the interests of the middle classes who stood to benefit from universalist welfare policies. For Baldwin, ‘An individual sentiment, altruism is generally confined to narrow circles of the like-minded. Solidarity, in those few instances where it has been realised, has been the outcome of a generalised and reciprocal self-interest. Not ethics, but politics explain it.’ (Baldwin, 1990:299).

and indeed trust are negotiated and renegotiated at local levels (Ashcroft et al, 2000:393). Hence one contribution of a study such as my own is to getting a 'thick description' of the ways in which people will approach participation in a national initiative like the new biobank. It may be that this way of thinking is particularly embedded in the history or economy of this region. Yet this would not diminish the case for these perspectives to be heard at the national level where a great deal of policy is formulated.[11]

## VI Directions for policy

Importantly for thinking about population genetic research, my own findings point to a sense of mutuality based on social relations and forms of organisation, rather than an imagining of a 'genetic solidarity'.[12] This phrase, implying as it does that solidarity between a group of people should be determined by the establishing of genetic links between them, has the disadvantage of ignoring the complexities of such interconnections. In addition, it carries with it the burden of seeking to add a new strand to a universalist discourse about the ethical issues in genetic research, which in turn tends to preclude a consideration of the social contexts within which such research occurs.

Although I have discussed the processes surrounding the development of the UK

[11] See Dingwall (1977) for a longer view of the tensions between collectivism and individualism in British social policy, and, related to this, the limited influence - albeit varying over time - of the peripheral regions on the discourses of national policy and politics.

[12] As indicated in chapter 2, concepts of gift and altruism occur in policy documents about genetic databases (HL, 2001; HGC, 2002; DH, 2003), and are consolidated into the phrase 'genetic solidarity' in the later iterations of these.

Biobank, I have not so far commented directly on the detailed structures and plans for this initiative. In that they involve questions about the shape and boundaries of medical research, the decisions that are to be made about genetic research involving large-scale blood donation are - or should be - in the realm of public policy and politics.[13] At a national level, we may expect that they would be informed by national traditions and debates about health care, welfare and interdependence (Dean, 2004). It is in this sense that I find the reference to Titmuss to be relevant, rather than as a call to return to individual altruism, which I have suggested is in any case based on a one dimensional reading of his work. However my findings do support the case for devising a policy regime for the biobank that can deal with the mutual interests to which participants may refer in making their decisions. In pointing to the importance of mutuality and of informed trust, my analysis undermines the validity of relying on theoretical notions of individual altruism and informed consent in this field of policy.

Taken together with other studies about the dynamics of trust, my work does indicate some directions for policy. I am thinking here not about 'Trust' in a generic or absolute sense, but about trust in the capacity of particular institutions to manage medical research on behalf of the public. International codes of ethics and rights in biomedical research, if implemented, provide important protection from abuses of individual rights. However, based as they are on the risks associated with conventional research, they cannot be seen to offer sufficient direction for public policies in the field of population genetic research (Kaye, 2004).[14] Amongst my

[13] The title of the recent Genetics White Paper- 'Our Inheritance, Our Future' does seem to acknowledge the political resonance of decisions about developments in genetics. In its overview of research regulation though, the paper relies on the traditional protections of good conduct in research- such as the maintaining of confidentiality, informed consent, and oversight by ethics committees (HC, 2003:69).

[14] This relates in turn to the debate about the controversial 'Human Genome Diversity Project'

interviewees, the expectation that boundaries would be placed around research conducted on blood donated to public bodies was evident. Amongst these respondents too, commercial involvement in public research was generally viewed with considerable scepticism.[15]

In my analysis, the imagined community of the NHS provides a framework underlying a shared political identity for many of these respondents. From this, I extrapolate, it is important to debate and protect collective interests in this field. Although I have not addressed the question of the mechanisms through which this should happen, a number of proposals have come forward with regard to this in relation to the UK Biobank.[16] Amongst these, Williams and Schroeder (2004) have called for the Biobank to incorporate arrangements for prioritising public research priorities in its work, and to be open to public debate regarding the research that it should facilitate. With regard to pharmaceutical research, they suggest that a formal system for monitoring and reporting of actual benefits from such research using Biobank is established. Following the publication of the first draft of the Ethics and Governance Framework for the Biobank, Tutton et al (2004) draw attention to a degree of ambiguity about the status and power of the Ethics and Governance Council, and called for greater powers and independence for this new body. Given the possibility of data accumulating over time, and of the sale of such data to commercial companies, Kaye argues for a structure to protect the interests of Biobank donors, and of the

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(Lock, 1994; Weijer, 1999).

[15] It seemed that awareness of the extent of interconnections between public and private research was not high, a situation that we cannot assume will continue over time.

[16] I have restricted these references to some of the recent papers containing specific policy proposals, following the publication of a draft governance framework for the biobank in 2004 (UK Biobank, 2004). The policy background to these issues is discussed in chapter 2.

population as a whole, 'which can span generations and exist in perpetuity' (Kaye, 2004:133). If the UK's biobank is not to be accused of being an artefact linking an elitist scientific project to a wider public - as one commentator has suggested is the case for the Estonian biobank (Fletcher, 2004:11) - it would seem important that such proposals are given full consideration. Whilst it is important to acknowledge that there are problems in defining and protecting collective interests, it is evident that they cannot be addressed solely through the mechanisms relating to individual research participants.[17]

I have focused much of my discussion about policy on the new UK Biobank because of its branding as a national project, and the expectations that a project of this scope gives rise to. It is likely too that the approach taken to the national biobank will be important in shaping the regulation of other genetic research using donated blood. Importantly though, the points that I make also apply more widely to the use of donated blood in public collections that are less high profile, including regional collections, and the tissue collections held by the NBS. A nostalgic reading of Titmuss' 'gift relationship' cannot be an effective basis for governing the use of donated blood today. However, a recognition of mutuality as one basis for sustainable policy, which underlay Titmusss' work on the NHS, is crucial to the ongoing debate about the use of blood donated for genetic research. Rather than thinking of the data accumulated from such donations as 'global public goods'[18], a better starting point for this new field of policy would be to explore and recognise both the interests of the donors and the boundaries of the communities to which they donate blood. If the interests that are at play can be specified more clearly, and the

[17] See also Weldon (2004), who argues for the relevance of a proactive model of 'scientific citizenship', one that goes beyond public consent, in this context.

[18] As declared in HUGO's 'Statement on Human Genomic Databases' (2003).

boundaries of the uses of donated blood protected through statutory measures, the work of negotiating the legitimacy of the Biobank can begin.

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**Appendix 1: table of those interviewed from the National Blood Service (NBS)**

| IDNO | SEX | AGE | OCCUPATION | YEARS AS DONOR | LENGTH OF INTERVIEW (MINUTES) |
|---|---|---|---|---|---|
| NBS1 | Male | 54 | Environmental Health Officer | 23 | 15 |
| NBS2 | Male | 54 | Engineer | 30 | 15 |
| NBS3 | Male | 35 | Education | <1 | 10 |
| NBS4 | Male | 67 | Retired | 30 | 15 |
| NBS5 | Female | 67 | Voluntary Worker | 25 | 15 |
| NBS6 | Female | 47 | Carer | 15 | 20 |
| NBS7 | Male | 29 | Army | 13 | 10 |
| NBS8 | Female | 29 | Shop Manager | 10 | 25 |
| NBS9 | Male | 50 | Printing | 20 | 10 |
| NBS10 | Male | 60 | Officer | 30 | 20 |
| NBS11 | Male | 19 | Finance | 1 | 8 |
| NBS12 | Female | 37 | Care Assistant | 5 | 15 |
| NBS13 | Female | 32 | Psychiatric Nurse | 4 | 13 |
| NBS14 | Male | 29 | Housing Officer | 5 | 10 |
| NBS15 | Female | 23 | Accountant | 2 | 12 |
| NBS16 | Male | 55 | Engineer | 4 | 13 |
| NBS17 | Male | 57 | Voluntary Worker | 15 | 15 |
| NBS18 | Female | 29 | Administration | 8 | 15 |
| NBS19 | Male | 40 | Warehouse supervisor | 10 | 15 |
| NBS20 | Male | 44 | Warehouse | 20 | 10 |
| NBS21 | Female | 21 | Student | 1 | 5 |
| NBS22 | Female | 48 | Civil Service | 12 | 10 |
| NBS23 | Female | 29 | Graphic Designer | 2 | 15 |
| NBS24 | Female | 37 | Civil Servant | 3 | 13 |
| NBS25 | Female | 30 | Insurance | 10 | 12 |

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|---|---|---|---|---|---|
| NBS26 | Male | 34 | Accounts Clerk | 16 | 12 |
| NBS27 | Female | 28 | Health Care Assistant | 7 | 12 |
| NBS28 | Male | 23 | Student | 2 | 20 |
| NBS29 | Male | 46 | Electrician | 30 | 15 |
| NBS30 | Female | 46 | Finance | 28 | 15 |
| NBS31 | Male | 26 | Student Nurse | 8 | 16 |
| NBS32 | Female | 36 | Legal Executive | 15 | 23 |
| NBS33 | Male | 45 | IT | >20 | 18 |
| NBS34 | Male | 58 | Royal Mail Manager | 15 | 15 |
| NBS35 | Female | 19 | Student | 2 | 14 |
| NBS36 | Male | 40 | Catering | 6 | 11 |
| NBS37 | Female | 44 | Civil Servant | >20 | 25 |
| NBS38 | Female | 38 | Catering | 10 | 12 |
| NBS39 | Male | 40 | Architect | <1 | 10 |
| NBS40 | Female | 41 | Care Assistant | <1 | 8 |
| NBS41 | Female | 36 | Design Lecturer | 15 | 20 |
| NBS42 | Female | 43 | Grants Manager | 25 | 30 |
| NBS43 | Male | 41 | Engineer | 20 | 15 |
| NBS44 | Male | 54 | Estate Agents Assistant | 4 | 12 |
| NBS45 | Female | 55 | Packer | 30 | 15 |
| NBS46 | Female | 17 | School worker | <1 | 8 |
| NBS47 | Female | 50 | Administrator in University | 30 | 10 |
| NBS48 | Male | 50 | Utilities Manager | 12 | 12 |
| NBS49 | Female | 27 | Administrator in Council | 2 | 12 |
| NBS50 | Male | 29 | Student | 2 | 20 |
| NBS51 | Male | 38 | Designer | 12 | 10 |
| NBS52 | Female | 25 | Legal Secretary | <1 | 20 |
| NBS53 | Male | 46 | Insurance | >20 | 13 |
| NBS54 | Female | 24 | Secretary | 6 | 19 |

| | | | | | |
|---|---|---|---|---|---|
| NBS55 | Female | 27 | Medical Allied | 8 | 15 |
| NBS56 | Male | 59 | Carer | >20 | 15 |
| NBS57 | Male | 60 | Retired | >20 | 22 |
| NBS58 | Male | 36 | Driver | 4 | 29 |
| NBS59 | Female | 39 | Insurance | 20 | 11 |
| NBS60 | Male | 32 | Environmental Consultant | 4 | 15 |
| NBS61 | Male | 33 | Surveyor | 5 | 18 |
| NBS62 | Female | 31 | Civil Servant | 10 | 12 |
| NBS63 | Female | 35 | Student | 196 | 15 |
| NBS64 | Male | 47 | Electrician | 20 | 15 |
| NBS65 | Female | 21 | Student | 1 | 16 |
| NBS66 | Female | 23 | Student | 3 | 20 |
| NBS67 | Female | 28 | Bakery | 6 | 14 |
| NBS68 | Female | 47 | Teacher | >20 | 25 |
| NBS69 | Male | 57 | Retired | >20 | 12 |
| NBS70 | Male | 66 | Welder | >25 | 10 |
| NBS71 | Male | 62 | Retired | >30 | 22 |
| NBS72 | Male | 66 | Ostler | >30 | 14 |
| NBS73 | Female | 67 | Retired | 30 | 17 |
| NBS74 | Male | 56 | Administrator | 30 | 18 |
| NBS75 | Male | 44 | Decorator | >20 | 12 |
| NBS76 | Male | 50 | Graphics Company | 25 | 13 |
| NBS77 | Male | 47 | Security | 20 | 20 |
| NBS78 | Male | 60 | Accountant | >25 | 20 |
| NBS79 | Female | 44 | University | 1 | 14 |
| NBS80 | Female | 49 | Council | 5 | 15 |
| NBS81 | Female | 51 | Civil Servant | >25 | 16 |
| NBS82 | Female | 49 | Civil Servant | 20 | 16 |
| NBS83 | Male | 61 | Electrician | 30 | 30 |

| | | | | | |
|---|---|---|---|---|---|
| NBS84 | Male | 60 | Factory Work | 30 | 25 |
| NBS85 | Female | 55 | School Meals | >25 | |
| NBS86 | Male | 50 | Teacher/Union Official | 30 | 18 |
| NBS87 | Male | 49 | Prison Officer | 18 | 20 |
| NBS88 | Male | 50 | Gardener | 14 | 11 |
| NBS89 | Male | 41 | Sales/Insurance | 15 | 20 |
| NBS90 | Female | 66 | Retired | 30 | 20 |
| NBS91 | Female | 31 | Unemployed | 7 | 21 |
| NBS92 | Female | 67 | Retired | 10 | 20 |
| NBS93 | Female | 67 | Retired | 20 | 20 |
| NBS94 | Female | 52 | Home help | 6 | 18 |
| NBS95 | Male | 47 | Gas Engineer | 25 | 19 |
| NBS96 | Male | 50 | BT Engineer | 25 | 15 |
| NBS97 | Female | 53 | Secretary | 20 | 15 |
| NBS98 | Female | 52 | Personnel | 10 | 16 |
| NBS99 | Male | 43 | BT Engineer | 20 | 14 |
| NBS100 | Male | 67 | Retired | >25 | 20 |

**Appendix 2: table of those interviewed from the Arthritis Genetics Project (AGP).**

| IDNO | AGE | SEX | OCCUPATION |
|---|---|---|---|
| AGP1 | 42 | Female | Carer |
| AGP2 | 42 | Female | Nurse |
| AGP3 | 52 | Female | Self Employed |
| AGP4 | 61 | Male | Journalist |
| AGP5 | 34 | Female | Nursing |
| AGP6 | 49 | Male | Actor |
| AGP7 | 32 | Female | Call Centre |
| AGP8 | 40 | Female | Solicitor |
| AGP9 | 50 | Female | Teacher |
| AGP10 | 56 | Male | Plumber |
| AGP11 | 63 | Male | Drinks Trade |
| AGP12 | 60 | Male | Architect |
| AGP13 | 55 | Male | Financial Services |
| AGP14 | 47 | Male | Fireman |
| AGP15 | 43 | Female | Cleaner |
| AGP16 | 34 | Female | Administration |
| AGP17 | 40 | Male | Warehouse |
| AGP18 | 32 | Male | University Lecturer |
| AGP19 | 25 | Female | Clerical |
| AGP20 | 28 | Female | Psychologist |
| AGP21 | 38 | Male | Lecturer |
| AGP22 | 34 | Female | Medical Secretary |
| AGP23 | 50 | Female | Teaching |
| AGP24 | 46 | Female | Administration/Design |
| AGP25 | 49 | Male | Airport (Baggage) |
| AGP26 | 60 | Male | Scientist (Retired) |

| | | | |
|---|---|---|---|
| AGP27 | 44 | Male | Driving Instructor |