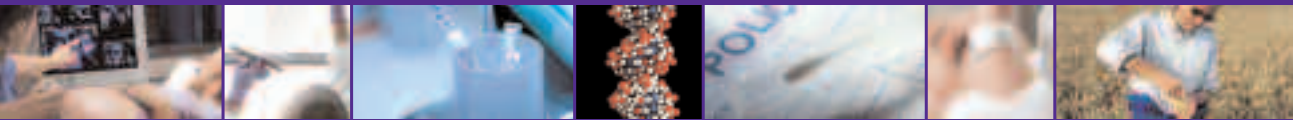


Genomics and society

ESRC Science in Society Programme

biology chromosomes organs genetics





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Preface

The science-society relationship is recognised as no longer being one in which the needs of the public are dictated by those in authority. But what is it to become? How can those in government, science and the private sector facilitate the science-society relationship more effectively? How can the public in all its diversity become more engaged in the production of science and its role in society?

The goal of the ESRC's Science in Society Programme is to explore and help develop the rapidly changing relations between science (including engineering and technology) and the wider society. These brochures are intended not only to bring together the findings of research projects in the Programme, but also to draw on wider insights into the relationship of science and society.

To that end, although these brochures provide an overview of academic research, they hope to prompt questions that go beyond the academic to the role of science and technology in daily life and experience, in all its diversity.

“New and rapidly expanding capabilities in the biosciences raise a host of important questions for the science-society relationship”



Foreword

New and rapidly expanding capabilities in the biosciences raise a host of important questions for the science-society relationship. The ESRC has established a new national research capability in the social and economic context of genomics¹. The Science in Society Programme funded additional work relevant to genomics and society including privacy and confidentiality of genetic information: fairness of access. Who owns and controls genetic information? Who should? How is consent for use understood, given, refused or undermined? Will there be major worldwide inequities?

Much of the research discussed here investigates the impacts of scientific and technological advances on the settings in which they will be used. One project explored the technology that allows medicines to be customised for individual patients and asked how this might work in practice. What considerations need to be agreed before it is introduced? How will clinicians deal with the technology in their clinics and how would its benefits be conveyed to its users? Who will get to use it and how will we decide?

In a somewhat different vein, the use of therapeutic biological sciences for terrorist purposes has become reality. In response, the governments in the UK and the US have passed legislation governing how toxins, pathogens, and various bioscience techniques could be used in research laboratories and how their export to other countries should be limited. Researchers looked at how this has affected the way we view technologies that can be used for social and economic benefit, but may also be turned into weapons of war or terror. Should some kinds of research no longer take place and do we think that this is that bad a thing? How has the scientific establishment been forced to change by the political limitations placed on science that can be used to threaten society?

These are the kinds of questions that are asked by the researchers whose work is discussed in these pages. I hope that you will find them thought-provoking and that they will demonstrate the richness and diversity of the social science research that has been commissioned through the ESRC's Science in Society Programme.

Steve Rayner
Director

¹ <http://www.genomicsforum.ac.uk/>



Executive Summary

Genomics is one of the 'life sciences', that is, one of the branches of natural science dealing with the structure and behaviour of living organisms. Building on genetics, the study of single genes, it aims to provide a description not only of the entire DNA sequence in an organism, but also of how this sequence interacts with its environment. This includes not only the elements that comprise the organism, but also the external influences on that organism. From industry, to manufacturing, to medicine, to crime detection, advances in genomics will inevitably have a profound effect on many parts of people's lives.

We would expect such an important realm of innovation to stir up plenty of controversy and debate. Current public discussions about genomics tend to take two forms.

The first type, often found in the media, revolves around a number of assumptions, usually focussed on the seemingly limitless potential of genomics either to solve current problems or to wreak devastating havoc. For example, many people still worry that because we can map an organism's genome we can automatically create new life. In fact, although it is a remarkable discovery, the map of a genome is still only a giant list. It does not reveal what each gene does, or which gene is active in which parts of an organism.

Such assumptions as these rest on technical misunderstandings, but they can also reveal more complex, social attitudes towards new technologies. For example, public discussion of assumptions about genomics can lead to debates about values and beliefs, and the nature of identity and community. It can raise questions about the allocation of responsibility and accountability for the design and use of new technologies.

The second type of public discussion about genomics is usually conducted among experts who work in related areas, for example scientists or policymakers. It often focuses on the moral and ethical concerns surrounding advances in the life sciences, drawing particular attention to the ways in which technological innovations based on genomics are a force for social change, and how they are likely to transform our daily lives.

Both types of discussion tend to cast genomics in a single role: as a science that will transform our society and shape our lives in the years ahead. And yet, neither public discussion explores the activities of experts in this field, be they scientists or policymakers, and the influences that shape their work.

If we look at genomics only in terms of its future, it becomes easy to forget that advances in genomics and related technologies are being shaped now by the values, beliefs and choices of individuals and institutions. This is the starting point for the five projects collected under this theme.

In a wide range of contexts, these projects all challenge the unquestioned expertise of scientists or policymakers, and the idea that relevant knowledge is concentrated among experts. The research shows us that:

- There is no simple division between public (uninformed, partisan and diverse) and expert (informed, neutral and single-minded). In contrast, there is a spectrum across society of different types of knowledge and understanding, all of which influence how people interact with science and technologies.
- The category of 'experts' is not one homogeneous group. It comprises individuals with different kinds and levels of knowledge. These factors will help shape how each person approaches their work. In addition to these professional influences, there will also be personal factors: throughout their lives, individuals shift between identities and move between different social groups. The projects gathered in this brochure explore and question how experts involved in the development and implementation of genomics research and related technologies engage with their work, what factors influence their approaches, and how.

If we are to understand the implications for society of advances in genomics and related technologies, and facilitate the development of appropriate policies, it is important to gain as full an understanding as possible of how people respond to these developments – both within the laboratory as well as outside it. These projects explore such questions as: Who is making the crucial decisions in this discipline, with what authority and on what basis? What

are the methods of the scientists and policymakers, and how are they shaped by institutional cultures? What will be the implications of these activities for society?

The projects include:

- *Farmers' Understandings of Genetically Modified Crops Within Local Communities* examined the role of farmers in the debate surrounding the implementation of GM crops. How do farmers and their families construct their understandings of the science and technology surrounding GM crops through interaction with others and how does this influence their intentions and actions?
- *Pharmacogenomics, Diagnostic Tests and Clinician Acceptance* explores the adoption of pharmacogenomics by healthcare workers. How do clinicians or researchers react to the possibilities of implementing these new technologies? How is the technology incorporated into both the drug development process and clinical practice?
- *Doing Embryo Ethics: Safety and Efficacy in Research and Practice* has investigated the ways in which professionals working in the field of assisted conception deal with the 'everyday ethics' of research and service provision within laboratories and clinics in the UK.
- *Accountability and the Governance of Expertise: Anticipating Genetic Bioweapons* assessed how individuals and organisations in the biological and medical sciences are responding to growing concern about the proliferation of weapons-related expertise, following the 9/11 terrorist attacks.

- *Dual Use Controls and Genomics Research* focused on biological weapons, examining ways of balancing the risks and benefits of research and of finding solutions to biosecurity problems by providing feedback to policymakers about the local impact of security controls.

Illuminating the complexities, ambiguities and contingencies of scientific practice and policymaking, these projects draw attention to the following conclusions for policymakers and science and technology professionals:

- Dangerous assumptions: it is easy to make assumptions about how particular social groups will respond to new technologies. For example, people rarely use technical data to decide that science and technology is risky. They tend to build on experiences, relationships and beliefs to develop ideas about what is dangerous and why.
- Diverse publics: different values, beliefs and identities influence people's responses to science and technology. Engagement with the public must be rooted in an understanding of the diversity and fluidity of that public. This not only means that there are many different social groups, but also that individuals may move between different social groups.
- Challenging scientific neutrality and assumed expertise: cultural assumptions also influence the production and dissemination of science and technology. Many diverse factors - values, beliefs, identity - influence those involved in the development, uptake and use of these technologies in various settings.

- Multiple types of expertise: it might be easy to think that there is a simple division between experts and publics. In fact, across society there are many different levels of expertise, and their involvement is crucial for successful technological innovation.

- Unintended consequences: regulations intended to promote one aspect of security (eg biosecurity) may be endangering other forms of research that use the same basic technology (eg that used to construct bioweapons).
- Clash of guidelines: professional norms of disinterested scientific practice may clash with, or influence, or be influenced by other behaviour guidelines. These may be personal to individuals, or have developed from the laboratory or clinical setting.
- The need for evolution: just as science and technology is continually developing, so must regulation. The current attitudes of scientists and policymakers may influence developments in the future. Regulation should be treated as a practical activity based on experience, and the context of research must be negotiated and practically secured.

The research covers an intimidating range of themes, raising a wide variety of crucial questions about scientific practice and policymaking. The findings are relevant not only in the challenging field of genomics and the life sciences, but also more generally across the many disciplines of science and technology.



Introduction

“We’ve now got to the point in human history where for the first time we are going to hold in our hands the set of instructions to make a human being.” John Sulston, Wellcome Trust.

The 'life sciences' include any of the branches of natural science dealing with the structure and behaviour of living organisms. Genomics, one of these branches, is more difficult to define. Most people have heard of genetics, the study of single genes – the fundamental units of heredity and their activities. Genomics is the next step. It aims to provide a description of the entire DNA sequence in an organism and its interplay, both internally between cells, tissues, organs, all the elements that comprise the organism, and externally, with the influences on that organism. It studies how all the genes work together; how they interact with their environment, and how these interactions affect our biological systems, our physiology. If we understand a gene as containing instructions for building a particular protein, then the genome of an organism can be described as the complete book of instructions for all the proteins in that organism.

Genetic engineering in the scientific sense has been pursued since the early 1900s, when European plant scientists began using Gregor Mendel's genetic theories to manipulate plant species. Modern genetic engineering began in the 1950s with the discovery of the three-dimensional double helix structure of DNA. Since then, scientists have gradually advanced scientific understanding of genetics and developed related technologies. Now and in the future, it is likely that genomics will play a part in almost every part of our society: the detection of crime and the nature of evidence in court cases; manufacturing food crops – changing our environment and helping to solve problems of food scarcity in developing countries; the demographic implications of new medical interventions; to all kinds of industrial uses.

“Growing knowledge of the role that genes potentially, yield

The human genome was first mapped in 2001, more accurately described two years later, and finally completed in May 2006, with the publication of a detailed analysis of the DNA sequence on chromosome one. This, the largest of the human chromosomes, contains 3,141 genes, more than 1,000 of which were completely new to science. These genes, many of which are involved in over 350 diseases, comprise about eight per cent of our genome. Scientists can now describe the order of the chemical building blocks or bases contained within each of our genes, which together comprise our DNA.

These advances are likely to have a profound effect on people's lives. Most obviously, greater understanding of human genetics may lead to remarkable changes in healthcare, for example, in identifying genetic predisposition to disease, and improving drug therapy through the development and use of personalised medicines (pharmacogenetics or pharmacogenomics, also known as PGx, *Pharmacogenomics, Diagnostic Tests and Clinician Acceptance*). But genetic engineering influences many other areas of life. Examples from among the projects in the Science in Society Programme include the introduction of new seed technologies into farming and food production (*Farmers' understandings of genetically modified crops within local communities*), and the use of genomics in the development of biological weapons, raising concerns about security and the remit of regulation (*Accountability and the Governance of Expertise: Anticipating Genetic Bioweapons, Dual Use Controls and Genomics Research*).

Mapping the genome is an extraordinary achievement. Growing knowledge of the role that genes play could, potentially, yield extraordinary benefits in our daily lives. However, the development and use of this knowledge is far from straightforward. At a purely functional level, we now understand that genes do not provide a simple, deterministic blueprint of a living organism. Genetic activity is complex and, in many ways, still mysterious. In particular, genetic influence is mediated by the many different factors in an individual's environment. In a similar way, when we consider the development and implementation of new technologies based on our growing knowledge of genomics, we find that this is also being shaped by our environment.

As the research in this brochure reveals, the science and technology of genomics raises unprecedented challenges, not only in terms of intellectual advancement, but also because of the complexities of society.

Most commentary on this area has tended, implicitly or explicitly, to divide society into 'experts' (those who pursue scientific advances) and 'the public' (the recipients of those scientific advances), and to concentrate on uncovering and analysing the responses of 'the public'. However, the projects grouped under this theme and described in this brochure take a different approach. They are all concerned with the interaction between genomics and society. Rather than focusing on the 'the public', they

play could, extraordinary benefits in our daily lives”

each examine aspects of the experiences of those who develop or implement the science and technology of genomics, across a wide range of disciplines, from agriculture to bioweapons, healthcare to fertility.

For example, in his project on farmers' acceptance of genetically modified crops, Professor Andy Lane and his team are exploring the factors that influence how farmers (with and without previous experience of genetically modified crops) regard genetically modified herbicide tolerant crops. Previous research in this area has, surprisingly, largely ignored this group, focusing instead on the policies and practices of national governments and international organisations, or on the acceptability of GM products with consumers. Although the project is not yet complete, its findings are already significant, revealing that farmers react to this technology much as they would any new technology, and are little influenced by the concerns of the local public community.

Similarly, in the realm of healthcare, although there is considerable interest in the potential benefits of pharmacogenomics (PGx, the relationship between genetic variation and drug response), research has focused on its future 'promise' and the social and ethical questions it raises, rather than examining its impacts on the setting in which it will actually be used. In his project on clinician acceptance of

pharmacogenomics, Dr Graham Lewis has been investigating what happens within the clinic or laboratory context regarding the implementation of PGx: how do clinicians or researchers understand and respond to the opportunities or risks of adopting these new technologies? How is the technology incorporated into both the drug development process and clinical practice? And what is the role of regulatory agencies in facilitating clinical incorporation?

This last question is the starting point of the next three projects, which are all concerned with the impacts of regulation and formal guidelines within the laboratory, each taking a different approach to this area. A particular focus of Professor Anne Kerr's project, *Doing Embryo Ethics: Safety and Efficacy in Research and Practice*, has been the development and implementation of formal ethical guidelines in the context of practice, especially the management of tensions around the role of bodies like the Human Fertilisation and Embryology Authority. Her project explores practitioners' accounts of the 'unintended consequences' of regulation, in relation to professional norms of disinterested scientific practice and their informal 'moral thinking' in particular.

“It becomes easy to forget that advances now by the values, beliefs

In *Accountability and the Governance of Expertise*, Dr Brian Rappert and Professor Malcolm Dando assessed how individuals and organisations in the biological and medical sciences were addressing the shared problem of responding to the growing societal concern with the proliferation of weapons-related expertise. They were also concerned with very practical questions about the potential development of biological weapons, for example, to what extent current and future bioscience research might advance this development, and the success of various methods being used to warn scientists and members of the public about the dangers of genetic weapons.

Finally, Dr Paul Nightingale explored the effects of global regulations on local research in his project *Dual Use Controls and Genomics Research*. The project explored how banning the technologies used to produce biological weapons also inhibits their development for socially beneficial applications. The project hoped to help find a solution by providing information to policymakers about this side-effect of their regulations.

The focus of these projects – the scientist or professional as subject – is surprisingly rare. Although much has been written on how lay people or consumers regard genomics and related technologies, clinicians, scientists and other experts in this field are seldom the focus of such research, although they play such a crucial role in its development, both influencing and being influenced by, their work in this field (Kerr 2004).

In fact, as this brochure goes on to discuss, this is part of a more general tendency to think about genomics in terms only of its future promise, as a science that will shape our lives, that will transform our society, in the years ahead (for example, Department of Health 2003). This way of presenting the discoveries of genomics makes them seem inevitable and immutable: it becomes easy to forget that advances in this arena are being shaped now by the values, beliefs and choices of individuals and institutions.

in genomics are being shaped and choices of individuals and institutions”

In contrast, these projects demonstrate how, when we consider the implications of genomics and related technologies for society, a simple division between public (uninformed) and expert (informed) will not do. For a start, as projects from across the Science in Society Programme reveal, ‘the public’ comprises many different groups, with a rich diversity of views and experiences, knowledge and understanding, all of which is dynamic, responsive and fluid. As the projects under this particular theme show, the same is true of the category of ‘experts’. The interaction of different institutional and disciplinary backgrounds with diverse personal circumstances, in particular contexts, will produce different mindsets, different approaches. People shift between identities and between categories: public, expert, patient, consumer; none of them is fixed. The projects grouped under this theme shed much needed light on the ways in which individuals, within the laboratory as well as outside it, construct their approaches to these new technologies. Together, these projects illuminate the complexities, ambiguities and contingencies of scientific practice and policy making.

This document starts by exploring some of the common assumptions that shape our thinking with regard to the issues discussed under this theme, *Genomics and Society* and presents some of the cross-cutting themes that emerge from the research grouped under this theme. The brochure ends with some of the implications that the research has raised about the relationship between society and developments in the life sciences. Rather than offering a definitive conclusion, this final section is intended to prompt further thinking and raise questions about the communication and implementation of science in society.



Challenging Common Assumptions

“Chronic fatigue is in the genes, study finds”, “Scientists find gene for bone disease”, “‘Hate gene’ breakthrough – Filipino researchers claim to find gene for homophobia”, “Gene breakthrough could revolutionise rice crop”

The genetic maps we are developing and their implications seem to promise miracles – or do they? The media is surely increasingly less guilty of ‘genetic pornography’, as Lewis Wolpert, Professor of Biology as Applied to Medicine at King’s College London and former chairman of the British Committee on Public Understanding of Science, put it in his criticisms of the contemporary mass media portrayal of current work on genetics. But, although media reports of genomic and genetic discoveries are

increasingly sophisticated, both building and responding to the public’s growing understanding of these areas, they still reveal a number of common assumptions, as the sample of headlines above suggest. Moreover, these assumptions are also often subtly reinforced by discussions of genetics and its implications for society found across scientific and policy papers.

Revolutionary Breakthrough or Cataclysmic Nightmare?

The first set of assumptions focus on the vast changes that could potentially be wrought by the new, growing understanding of the role of genomics, and the seemingly limitless potential for these discoveries either to solve current problems or to wreak devastating havoc. These assumptions remind us how easy it is, in the face of such spellbinding science, to forget or underplay not only the acknowledged complexity of genetic technologies and knowledge, but also the fact that there is still a vast amount that is still unknown.

A comprehensive blue-print

Although the idea of complete genetic determinism has been demolished, it is still a common assumption that possessing the genome map of an organism gives us the information to make designer babies, develop new organisms or crops, repair bodies or breed new species, just like that. This is far from the case: for a start, the mapping of the genome, although it is a massive achievement and an equivalent breakthrough, is still, in the end, only a giant list of information.

There is much to add to this list, including what each gene does and which gene is active in which parts of the body. And this list is only the beginning: the cellular reactions that constitute living beings are actually created by the proteins that are encoded by DNA – and just what these proteins actually do is a question that remains to be answered.

A silver bullet

Closely related to the assumption that genomics can provide a comprehensive blueprint for an organism, is the assumption that it can lead directly to the discovery of the silver bullet for a disease or emotional dysfunction (Conrad 1999). This rests on a mechanistic misunderstanding of the human body, which suggests that the study of genomics comprises a simple process of first finding out what individual genes do and then manipulating them. It assumes a wholly inaccurate certainty of outcome, hiding the complexity of both the science and its subject. Apart from single gene diseases with high penetrance, the influence of genetics/genomics is always mediated by an individual's environment (age, gender, diet, lifestyle, etc). This means that in the great majority of examples, when we discuss the role of genes, we are talking about probabilities rather than causality.

My own personal medicine

Just as the knowledge gained from genomics turns out to be far from straightforward, so the introduction into society of technologies based on this knowledge is also likely to be more complicated than it is often portrayed.

As an example, consider the possibilities offered by genomics for the creation of medical treatments that can be personalised to respond to the needs of the patient. This raises again some of the assumptions discussed already, about the uncertainty and complexity surrounding the role of genes and health. But it also introduces a plethora of complicated, social impacts arising from the implications of gene-based medical care. As the World Health Organisation has noted:

“Genomics is special in that gene-based approaches introduce a new language of ‘probability’ and ‘susceptibility’ to medical care, and furnish information about disorders; that often is of great interest to third parties – be they families, governments, insurance companies, law enforcement or scientific researchers.”

As this suggests, the implications of genomics – the new levels and types of benefits and risks that this new discipline may bring – will ripple out into many areas of life, with implications not just for the individual, but also for society in general. How will these advances affect our institutions and the way society operates? On the one hand, the genetic information so gained is likely to prompt the development of new medical treatments. But could this knowledge also create problems, for example, for people with genetic disorders, in terms of employment or insurance?

Moreover, although most genetic testing is used for diagnosing rare genetic disorders, a growing number of genetic tests have population-based applications, including carrier identification, predictive testing for inherited risk for common diseases, and pharmacogenetic testing for variation in drug response. These introduce questions about the regulation of such genetic tests, and underline the growing tensions between the desire to enable individual choice and the need to protect members of society from its possible implications.

“Fears that genetic engineering might get out of control and run amok reveal concerns specifically about the risks of new technologies”

Pandora's box

Going to the other extreme, another set of assumptions underlies the fears that surround genomics. The 'Pandora's box' assumption is particularly found with application to plants/crops. It concerns the fears that foreign 'genes' (genes added to a crop or animal by genetic engineering) will escape into the environment and badly affect wildlife (however construed), or that it may be harmful to health if eaten by humans. It is well summarised by the quotation below:

“Whenever a genetically engineered organism is released there is always a small chance that it too will run amok because, like exotic organisms, it is not a naturally occurring life form. It has been artificially introduced into a complex environment that has developed a web of highly synchronised relationships over millions of years. Each new synthetic introduction is tantamount to playing ecological roulette. That is, while there is only a small chance of it triggering an environmental explosion, if it does, the consequences can be thunderous and irreversible.” (Rifkin 1985)

Closely linked to this concern is the idea that if we interfere with the genetics of the human race, our activities will somehow slip out of control.

Frankenstein's future!

The image of Frankenstein is a popular one in society's debate about the future role of genomics. It does seem uniquely suited to the current time, as we develop the knowledge and expertise to create new forms of existing species, but, in fact, the image of Frankenstein has provided a useful symbol of man's relationship with technology since Mary Shelly created her monster in 1818, and may help us to understand some of the long-running themes of the ongoing cultural debate about science and technology and its impacts on society, (see Turney 1998).

As the Frankenstein image suggests, much of the ethical debate about the future applications of genomics has focused on actual or potential human applications of genetic engineering. For example, it would be easy to think that the potential for human cloning fundamentally threatens our individuality (Hausekeller 2006). But in a human being, describing genetic identity is not the same as capturing someone's unique personal identity. Once we understand that someone's genes are only part of what makes them who they are, alongside upbringing, relationships, environment, experiences, memories, then it is easier to understand that the formation of personal identity is far more than biological cellular structure. The fact is, that knowing about some of the pieces involved does not mean that we know how they fit together and function as a complex adaptive system.

Looking Beyond the Surface

Although for the most part these assumptions can be explained away with more detailed, more accurate information, this does not mean that they should simply be dismissed. The hopes and fears that they express offer insights into deeper, perhaps more complex, attitudes towards genomics, as well as other new technologies. For example, fears that genetic engineering might get out of control and run amok (Pandora's box) reveal concerns specifically about the risks of new technologies, and the need to take adequate precautions.

This echoes the findings of projects carried out for the Science in Society Programme on the nature of risk perception and technology (for example, *Gender Theories and Risk Perception: A Secondary Analysis*, see the brochure on *Science, Gender, Ethnicity and the Life Cycle* in this series). These projects show how, when people consider the risk factors of a new technology, they make this judgement not in terms of the probability of a disaster happening, but based on their own experiences and world views. As well as considering their own and others vulnerability, they become highly concerned with questions of power: Who is responsible for managing the potential for risk? Who is making sure that the benefits or disadvantages of a new technology are equitably distributed? Who will be accountable if something goes wrong?

Bearing this in mind, it is remarkable to realise how little of our public discourse about genomics and its related technologies, focuses on the nature of research, and the influences that shape it. Indeed, researchers have observed the *“lack of literature on professional practice in this area, and the tendency to black box professionals' roles, alongside the genes, knowledge and technologies with which they work. Professionals are something of an absent presence in the literature on genetics and society”* (Kerr 2004). It is this absence that forms the focus of the research projects discussed in this brochure.



Cross-Cutting Themes: Expertise Explored

The science of genomics captures both our intellect and our imagination, transforming the way we think about our world, ourselves. As with other forms of technology, there is and will continue to be, much complex interaction between society and the study of genomics as they mutually develop. However, by focusing on our hopes (and fears) for the future, and the likely impact of these technologies on society, public discussion has more or less overlooked the actors and influences involved in their current development. As the projects in this area of the Science in Society Programme demonstrate, there are many intricate, overlapping socio-cultural, ethical, commercial and professional influences shaping every aspect of the development, take-up and modes of implementation, of these new technologies.



“Farmers see this new technology as fitting in well with their increasingly pro-environment activities”

Adoption and Incorporation

The first two projects in this theme explore how particular social/professional groups have taken up genomic technologies – one related to agricultural impacts, the other to healthcare. The first project, *Farmers’ Understandings of Genetically Modified Crops Within Local Communities*, examines the role of farmers in the debate surrounding the implementation of GM crops. The second project, *Pharmacogenomics, Diagnostic Tests and Clinician Acceptance* looks at the factors influencing the uptake of PGx in clinical practice.

Project: Farmers’ Understandings of Genetically Modified Crops Within Local Communities

Although extensive consultations and discussions about GM crops had been held with the public, the biotech industry, pressure groups and policymakers, such as GM Nation, (<http://www.gmnation.org.uk/>) and the work of the Agriculture and Environment Biotechnology Committee (http://www.aebc.gov.uk/aebc/reports/public_attitudes_advice.shtml), when this project started, little account had been taken of what farmers themselves thought about this new technology. As we go to press, this project is entering phase two, so it must be stressed that these are only preliminary findings.

However, even these are instructive, showing how important it is for policymakers to recognise the diversity that exists within ‘the general public’ and engage with different social groups in appropriate ways, as well as consulting the more obvious expertise of scientific experts, or pressure groups, to acknowledge and involve the relevant knowledge of different social groups, especially those who will be using these technologies.

Farmers cannot be easily classified as experts or lay-participants in this debate; but nor are they to be classed as one homogeneous group. This project has carried out in-depth interviews with farmers, some of whom have and some of whom have not been involved in the government-backed Farm Scale Evaluations (FSEs) for GM crops, including herbicide-tolerant oilseed rape, sugar beet and forage maize. (These country-wide trials, the biggest such investigation ever undertaken in the UK, were run to test whether such GM crops would be better or worse for wildlife than conventional crops, and inform government decisions about whether or not to license them for commercial use).

Initial findings from the project suggest that all the farmers questioned have responded to Genetically Modified Herbicide Tolerant (GMHT) crops much as they would to any new technology, that is, by trialing and assessing how the advice of the companies and trade associations, as to how to manage the crops, was borne out in practice in their local circumstances.

The farmers interviewed who had been involved in the FSEs, expressed the belief that GMHT crops offer them benefits that are both economic (in terms of better margins through lower costs provided by less, and more flexible, spraying) and environmental (since being more flexible and using less herbicide allowed the farmers to spray later than for a non-GMHT crop).

Furthermore, these tacit evaluations are seen as more realistic to the farming community, than the narrower focus of the scientific evaluations of the trials. Indeed, farmers are often critical about the way in which they were not consulted on the design of the trials and how the outcomes were reported, especially the environmental benefits they perceived arising from fewer and more flexible applications of herbicide.

Indeed, the FSE farmers see this new technology as fitting in well with their increasingly pro-environment activities, even though the official FSE results were more equivocal about these benefits. Non-FSE farmers seem to be equally optimistic about the benefits of GMHT crops as a new technology, and between the two groups there is a very consistent and positive response, which contrasts strongly with the public view of these crops. The recommended management practices from the biotech industry and farmer groups have proved acceptable to all FSE farmers.

“Genomics companies are vigorously developing disease-based diagnostics”

The project has identified a range of formal and informal influences on the farmers' views and actions. It turns out that the local public community is, perhaps surprisingly, of very little influence to farmers' decision-making and thinking about new technologies. More significant influences emanate from within the agricultural community, especially those they work with most closely, including family, employees and consultant agronomists. There has been discontent with the way the Government and the Department for Environment, Food and Rural Affairs have dealt with the farmers as a group, particularly that the farmers' own expertise and knowledge has not been taken into account when policies were implemented. They feel that there is a gap between what the government implements and their own daily experiences.

A significant finding of the project so far, is that, while farmers have acknowledged the wider contested debate around GM crops, their situated experience and knowledge around such technologies (a novel crop variety) has led to a widespread view amongst this group, that this is not a major problem.

As mentioned, these are only the initial findings of the project, but it is hoped that the final results of these analyses will be used to inform understanding of the most appropriate ways to manage a new farming technology, where the likely impacts are unclear or contested by different groups. The project will help innovators to identify the most important relationships to foster in the process of introducing a new technology.

Farmers' Understandings of Genetically Modified Crops Within Local Communities

Professor Andy Lane, Dr Sue Oreszczyn and Dr Susan Carr at the Open University

How do farmers and their families construct their understandings of the science and technology surrounding GM crops through interaction with others and what influence does this have on their intentions and actions?

This project aims to:

- investigate the attitudes, intentions and practices of early adopters and non-adopters of GMHT (Genetically Modified Herbicide Tolerant) crops in relation to their social setting, that is through their interactions with, in particular, family members, neighbouring farmers, seed companies, farming advisors and the local community
- ascertain the acceptability to farmers (both those with experience of GMHT crops and those without) of recommended management practices for GMHT crops used in the Farm Scale Evaluations (FSEs)
- develop models of social learning systems appropriate to support individual farmers within informal social settings who decide to adopt such contentious new technologies.

<http://www.sci-soc.net/SciSoc/Projects/Genomics/Farmers+understandings+of+genetically+modified+crops.htm>



Project: Pharmacogenomics, Diagnostic Tests and Clinician Acceptance

Moving from agriculture to healthcare takes us to the second example in this section. This project by Dr Graham Lewis at the University of York, is exploring the adoption of pharmacogenomics (PGx, that is, the relationship between genetic variation and drug response) by healthcare workers. Although there is considerable interest in the potential benefits of incorporating PGx into clinical practice and there are also a number of products being developed, there is a lack of robust evidence that can help structure how, when and where such technology should be introduced. Most social science research specifically related to pharmacogenomics (PGx) or –genetics (the two words are often used interchangeably, although there is some debate about their meanings) has tended to concentrate on providing an overview of the ‘promise’ of PGx and the social and ethical questions it raises. But what about events within the clinic or laboratory context? How do clinicians or researchers react to the possibilities (opportunities or risks) of implementing these new technologies? How is the technology incorporated into both the drug development process and clinical practice?

Using documentary research and semi-structured interviews with key stakeholders in relevant clinical fields, the pharmaceutical genomics and diagnostics industries, regulatory agencies and policymakers and healthcare delivery managers in the UK, US, and European

Union, Dr Graham Lewis and his team are exploring the factors influencing PGx uptake by clinicians and healthcare systems, using the areas of oncology, cardiovascular disease, asthma and psychiatry, and general practice, as examples. This project explores the relationship between the scientific-medical development of PGx and clinician acceptance, including:

- the relationship between drug and diagnostic in the context of PGx introduction
- the role of regulatory agencies in facilitating clinical incorporation
- the role of commercial incentives.

The relationship between drug and diagnostic

Medicines incorporating PGx data will comprise a therapeutic agent and diagnostic (Dx) test, ie, the product will take the form of a kit. The patient will first undergo a test to determine their genotypic profile, and the clinician will then use this information to determine if there is a suitable (PGx-based) drug for the condition presented. The latter stage may be automated to some degree, to minimise the knowledge required for appropriate prescribing behaviour. This is the general model for PGx, whether treatment takes place in the doctor's surgery or a specialist clinic.

Several PGx tests are already on the market. As well as pharmacogenetics-based diagnostics, genomics companies are vigorously developing disease-based diagnostics, such as in the area of oncology. Given the lack of definitive

information on why doctors presently fail to incorporate existing tests into their practice, this is an area that will benefit from additional research. Development of appropriate diagnostics is also crucial to clinical use, and the PGx diagnostics industry will be the cornerstone of PGx development and subsequent clinical acceptance. With the imminent arrival of many more such interventions, policymakers need to understand how and why clinicians do or do not use such technology currently, what influences their decisions now, and what is likely to do so in the future.

The role of regulatory agencies in facilitating clinical incorporation

The approach that regulatory authorities adopt towards PGx products, including diagnostic components, is another key question facing industry and clinicians as such products will require co-approval by regulatory authorities around the world. Will PGx-based data be considered just like other clinical data or will regulators impose new demands? More specifically, what stance will regulators adopt towards clinical acceptance issues?

Regulators are conventionally pictured as intervening at the end of the drug development process to ensure the safety and efficacy of medicinal products. The development of pharmacogenetics-based treatments has the potential to alter this linear approach to regulation as the development process becomes orientated towards groups of patients identified on the basis of their genetic make-up.

Agencies in the US, EU, and global forums such as the International Conference on Harmonisation have only recently started to examine the implications of PGx. However, in the US, the Food and Drug Administration has intimated that clinician acceptance will be a crucial component in assessment, and indications are that regulators will want assurance that practitioners will use a PGx test/treatment if it is approved.

The project will track the factors influencing the uptake of new diagnostics-based therapies based on pharmacogenomics; determine the approach of regulators to the issue of clinical acceptance in terms of regulatory assessment in the US, Europe and Japan, paying particular attention to areas of inter-regional agreement and dispute; and analyse trends and developments in the diagnostics industry relating to PGx development and incorporation into clinical practice.

Commercial factors

Finally, another important issue is the role of the market and commercial incentives. When response to a drug is dependent in part on genetic variation, even when that drug is well-tried, it may be that there is little commercial incentive for the pharmaceutical industry to engage in developing either the evidence base or PGx tests to support its use, and a form of 'market failure' may occur. Changing this situation may require direct support, or incentives to encourage public-private partnerships for example.

Pharmacogenomics, Diagnostic Tests and Clinician Acceptance

Dr Graham Lewis at the University of York

How is pharmacogenetics (or –genomics) incorporated into both the drug development process and clinical practice?

This project aims to:

- explore innovation and the introduction of new technologies into health care systems in general
- in particular, analyse the approach that regulators are adopting towards such products, the extent to which appropriate molecular diagnostics are being developed and the basis upon which clinicians and other health professionals are likely to incorporate PGx into medical practice in the coming years
- answer how regulators in the US, Europe and Japan assess PGx products, and what stance they adopt towards clinical acceptance? How will they resolve inter-regional agreements and disputes?

<http://www.sci-soc.net/SciSoc/Projects/Genomics/Pharmacogenomics+diagnostic+tests+and+clinician+acceptance.htm>

Looking at two different kinds of genomic innovation, and two different user-groups within the innovation process, these two projects provide an overview of the ways in which differing clinical, social and cultural practices influence pathways to adoption of genomics-related technologies.

These two projects link to a considerable existing body of work in the sociology of science and technology, which emphasises the need to view scientific and technological innovation not in terms of a simple linear path from the laboratory to the clinic, but as a complex system. The process of innovation involves many different social groups – and sub-groups – each of which may have a different world view, and/or be affected by different institutional and cultural processes. We cannot assume a simple uniformity of values, beliefs and behaviour across society, even among 'observers', 'lay-users' or 'experts'.

“There is considerable scepticism about the aspects of regulation,

benefits of some and their counter productive nature”

Implementation and Regulation

The last project included regulation as one of the factors influencing the development of new technologies and their incorporation into medical practice. For the next three projects the role of regulation has been the main focus. In theory, it might be thought that a simple set of regulations would, if anything, reduce any uncertainties about implementation, diminish ethical concerns by setting down a code of behaviour and help to impose safeguards. However, as the research of the next three projects demonstrates, the development and imposition of regulations is not so simple, for a variety of reasons.

- Any formal ethical codification and protocols that are adopted by official bodies concerned with regulation are also likely to interact with:
 - the unintended consequences of ethical scrutiny and oversight, such as...
 - unwritten rules of objective scientific practice and good laboratory practice
 - public expectations as expressed in popular media
 - personal, informal moral thinking, including everyday notions of trust, compassion and goodness
- the influence of social and professional relationships and attitudes (both within a particular clinic and within the larger social or professional context).

- The creation of codes of practice may be far from straightforward. There is a wide range of views, within the scientific community and among governments, about the necessity and utility of different kinds of research. There are disagreements about the nature of expertise, and how responsibility for the use of scientific discoveries should be allocated. For research related to genomics – which could result in very dangerous discoveries – this raises a multitude of questions about approaches to future policy.
- Policy controls on scientists may have unintended consequences. For example, government policies in one area of research may affect the practice of science in another.

The next three projects raise and examine some of these themes in more detail: *Doing Embryo Ethics: Safety and Efficacy in Research and Practice* by Professor Anne Kerr and Professor Henry Leese, has investigated the ways in which professionals working in the field of assisted conception deal with the 'everyday ethics' of research and service provision within laboratories and clinics in the UK. *Accountability and the Governance of Expertise: Anticipating Genetic Bioweapons* by Dr Brian Rappert and Professor Malcolm Dando, assessed how individuals and organisations in the biological

and medical sciences were addressing the shared problem of responding to the growing societal concern with the proliferation of weapons-related expertise, following the terrorist attacks on the World Trade Centre in New York in 2001. Finally, *Dual Use Controls and Genomics Research* by Dr Paul Nightingale, focused on biological weapons, examining ways of balancing the risks and benefits of research and of finding solutions to biosecurity problems by providing feedback to policymakers about the local impact of security controls.

Project: Doing Embryo Ethics: Safety and Efficacy in Research and Practice

A particular focus of Professor Anne Kerr's project has been the development and implementation of formal ethical guidelines in the context of practice, especially the management of tensions around the role of bodies like the Human Fertilisation and Embryology Authority (HFEA). It explores practitioners' accounts of the 'unintended consequences' of regulation, in relation to professional norms of disinterested scientific practice and their informal 'moral thinking' in particular.

It is clear from the initial findings that a range of audit mechanisms profoundly shape practice in assisted conception, but the extent to which this ensures that certain underlying ethical principles, such as individual choice, or equity of access, are met is a complex matter. There is considerable scepticism about the benefits of some aspects of regulation, and their counter productive nature, for example the production of so-called clinical 'league tables' by the HFEA. The intention here is to provide choice to prospective clients. Transparency and improving practice are other underlying aims. Yet the information is partial and open to misinterpretation. This can mean that reputation of clinics with apparently 'lower' results can suffer, and public funding for their service may be compromised, even although they are providing a vital service to some of the most difficult patient groups, often from low

“Professionals are strongly reflexive about these bureaucratic and

income groups. Others have expressed concerns that certain patients are not offered the full range of available treatments when this could adversely affect the statistics for the clinic. However, when we go beyond what one participant called ‘HFEA-bashing’, it is clear that bureaucracy can also be experienced by professionals as beneficial. Regulations can be variously interpreted and employed by practitioners to solve pressing ethical dilemmas that they face in the course of their practice. This is particularly apparent when the team are faced with patients who they feel ambivalent about treating. Bureaucratic measures such as the welfare of the child investigation can compliment professionals’ commitment to impartiality, and be a way of dealing with their personal qualms about people’s ability to parent.

Practitioners’ experiences of bureaucracy and their own moral thinking are obviously different, depending upon where they are placed in relation to the rest of the team. The hierarchy between particular professional groups in assisted conception, such as clinicians, nurses and counsellors, and even between different levels of seniority within these groups is not rigid. But there are some clear instances of difference in their experiences of bureaucracy. For example, junior embryologists’ report more positive experiences of ‘double witnessing’ (in which a change made by one clinician is checked by another) to prevent errors in the laboratory than more established professionals, and senior clinicians are especially resistant to overly detailed protocols and standardisation as

compared with nurses’ or laboratory staff’s more positive responses to these new procedures. People rationalise these procedures differently, according to their sense of professionalism, of which a sense of ethics is an important part. This depends upon their social location with respect to the rest of the team and the wider professional groups to which they belong. This means that some bureaucratic measures can enhance professional practice for some groups, or sub-groups, whilst others experience them as a form of disempowerment. Ethics therefore becomes enrolled in negotiations around professional autonomy and authority in the clinic and the laboratory as well as the wider public sphere.

Focusing in particular upon one social issue illustrates how some of these dynamics of professionalism, ethics and bureaucracy play out across the public, local and private realms in which assisted conception is provided and taken up. In the past ten years, there has been a cultural and structural shift within assisted conception services that means that the service is now more available to groups who would previously have been deemed ineligible, for example same-sex couples. This is managed by a range of strategies, including professionals’ reconceptualisation of their needs as medical rather than social; lateral thinking about the ‘the need for a father’ as laid down in the HFE Act (1990); and a strong interpretation of individual’s rights to found a family and not to be discriminated against, on the basis of sexual orientation in particular. At the same time, competing public pressures and moral

ethical, professional dimensions of their work”

sensibilities mean that the traditional heterosexual couple are often the preferred model patients. Practitioners must negotiate their own, their team’s, the couple’s and the public’s responsibilities with respect to treatment of same sex couples and its implications for the future in the course of their routine clinical decisions. This can involve flexibility about treatment protocols or referral to ethics committees for recommendations, as well as considerable moral ambivalence about particular treatments. These are sometimes managed by locating responsibility with another body – the clinic in the local realm, the HFEA in the public realm, or the couple/donor/recipient in the private realm. At other times, lead professionals consciously assume prime responsibility for ‘saying no’ in order to, as they see it, protect their team. Professionals are strongly reflexive about these ethical, bureaucratic and professional dimensions of their work.

Doing Embryo Ethics: Safety and Efficacy in Research and Practice

Professor Anne Kerr, University of Leeds, and Professor Henry Leese, University of York

How do those working in clinics and in research laboratories (involved in IVF) construct systems of ethics (both theoretical and practical) to govern their work?

This project aims to:

- reveal the multiple ways in which ethics are constructed practically during the working day and the relationship between these approaches and the ethical discourses in other professional, political and public domains
- demonstrate how different discourses interact in different contexts: some will legitimise certain ethical concerns while ignoring or rejecting others.

<http://www.sci-soc.net/SciSoc/Projects/Genomics/Doing+embryo+ethics.htm>

“Developments in modern biology pose significant questions regarding how research

Project: Accountability and the Governance of Expertise: Anticipating Genetic Bioweapons

From local to global: after the events of 11 September 2001, countries around the world have had to reassess their security preparedness. In relation to chemical and biological weapons, the immediate response in Western countries has been geared towards countering imminent dangers of established weapons. However, as research in genetics and the life sciences proceeds, the threat is raised that new forms of bioengineered weapons could be produced that either augment or replace existing capabilities.

The principal objective of this project, by Dr Brian Rappert, University of Exeter, and Professor Malcolm Dando, University of Bradford, was to assess how individuals and organisations in the biological and medical sciences were addressing the shared problem of responding to the growing societal concern with the proliferation of weapons-related expertise. A number of more specific key questions underpinned their approach:

- How might current and future bioscience research facilitate the development of new forms of biological weapons?
- What possibilities did bioscience researchers perceive in the development of genetic bioweapons?

- What was the range of advocacy activities undertaken by professional organisations and others in the UK and elsewhere to alert scientists and members of the public regarding the dangers of genetic weapons?

This project found significant reason for concern about the potential for current civilian bioscience research to facilitate the development of novel forms of bioweapons. Through a review of scientific and medical literature, the research team identified the role of bioregulators – chemicals produced by living organisms that have regulatory effects on life processes – in the central nervous system as a particular area of concern. The tremendous advances in neuroscience, linked to the whole biotechnology revolution, are providing the opportunity to make major strides in the understanding of the central nervous system, and thus in our ability to treat mental illnesses. However, such beneficial advances may also enable both the more effective targeting of the central nervous system and the ability to achieve specific types of effects. The situation is particularly worrying because the researchers were able to document the current US government interest in evaluating so-called incapacitating chemical/biological agents – eg, toxins, peptides, and cell signalling molecules – for altering body temperature, mood and hormone release.

questions might facilitate the hostile use of biological agents”

Despite the technical possibilities mentioned previously, by 2003 when the project ended, there had been limited discussion in scientific and policy communities regarding the possible long-term implications of modern bioresearch and little recognition of the possible implications of civilian research. While many scientists and policymakers shared an assessment of the abhorrence of biological weapons, just what this should mean for research controls was not agreed. Deciding on the nature of controls involves considering the identity of would-be users, the nature of scientific research, the bounds of technical expertise, and the public or private status of knowledge. The different ways in which these are characterised and defined indicate different ways of thinking about and allocating social and professional responsibility for minimising the threats associated with bioweapons. The extent to which the question of appropriate conduct is debated suggests that attempts to strengthen the international norm against the use of biological research for the development of weaponry requires more than just gaining abstract agreement about this principle. Rather, attempts to foster the norm should be treated as a practical activity, which allows the meaning of norms, definitions of the identity of individuals, and the context of research must be negotiated and practically secured.

Much of the past UK public policy response to anticipated threats associated with bioweapons has focused on concerns about the physical control of pathogens and, to a lesser extent, those handling such material. The relatively stringent state of British health and safety provisions in place for the handling and protection of dangerous pathogens and toxins in relation to biosafety have been taken by many as largely sufficient to address biosecurity concerns associated with bioscience research. The work undertaken as part of this project would suggest that such measures, while important, are not adequate to address the range of considerations and associated future possibilities.

In considering policy options, the continuing developments in modern biology pose significant questions regarding how research might facilitate the hostile use of biological agents. Yet, all the available evidence suggests that it is very difficult to cause mass casualties with biological agents. Whilst it may be possible decades into the future for some individuals or groups to threaten society with a mass casualty agent, it is not a likely possibility today. From the understanding formed through this project, the current threat from biological weapons in general is limited. However, that threat is likely to increase, both through the spread of technological capabilities and the development of greater technological capabilities. Policy options therefore have to be chosen with this timeframe in mind.

“Many of the technologies required to produce

Whilst concentrating today on preventing illegal state programmes, at the conclusion of the project in 2003, Dr Rappert and Professor Dando argued that we must also begin to put in place an integrated international approach more appropriate for dealing with the more dispersed threat we almost certainly will face from the types of bioweapons examined in this project. If strong, positive, integrated action is not taken in the years ahead, we could face a situation some decades hence (and maybe not too many decades hence) where many people will have the capabilities required to cause mayhem. That response should include engaging scientists and others in initiatives that will steadily enact, elaborate and reinforce the widespread belief that the biotechnology revolution is not to be used for the production of weaponry.

Accountability and the Governance of Expertise: Anticipating Genetic Bioweapons

Dr Brian Rappert, University of Exeter and Professor Malcolm Dando, University of Bradford

How do individuals and organisations in the biological and medical sciences address the shared problem of responding to the growing societal concern with the proliferation of weapons-related expertise?

This project explored:

- How might current and future bioscience research facilitate the development of new forms of biological weapons?
- What possibilities did bioscience researchers perceive in the development of genetic bioweapons?
- How was 'professionalism' defined, articulated, and negotiated in relation to the development of biological weapons? What implications did such considerations have for the communication of research?
- What was the range of advocacy activities undertaken by professional organisations and individual scientists in the UK and elsewhere to alert experts and members of the public regarding the dangers of genetic weapons?

<http://www.sci-soc.net/SciSoc/Projects/Governance/Accountability+and+the+governance+of+expertise.htm>

biological weapons
also have legitimate peaceful applications”

Project: Dual Use Controls and Genomics Research

The final project in this theme, by Dr Paul Nightingale at the University of Sussex, combined both global and local perspectives, exploring the effects of global regulations on local research.

This project, conducted in 2004, focused on balancing the risks and benefits of research and of finding solutions to biosecurity problems by providing feedback to policymakers about the local impact of security controls. It was different from most in that it explored scientists as subjects rather than originators of policy. The aim of the project was to develop innovative methodologies for creating policy networks – thereby using the process of research to create the dissemination paths for the research findings.

Its specific focus was biological weapons. Although they are banned by international law, they are still described as a major threat to international security. Many of the technologies required to produce biological weapons also have legitimate peaceful applications. This 'dual use' phenomenon creates a dilemma as attempts to control the generation, diffusion and application of these technologies for prohibited purposes can have unintended impacts on their socially beneficial uses. This project explored how concerns about biosecurity were changing the governance of technology in general and scientific research in particular:

Since 2001, governments have introduced additional policies designed to frustrate the misuse of the biological sciences. In the US, for example, legislation such as the 2001 Patriot Act and the 2002 Public Health Security and Bioterrorism Preparedness and Response Act, and in the UK, the 2001 Anti Terrorism Crime and Security Act and the secondary legislation to the 2002 Export Control Act, has been passed.

These new pieces of legislation build upon previous measures so that behaviour in and around the laboratory is now governed more than ever before. So, in both the US and UK, work with certain pathogens and toxins, known as 'Schedule 5 pathogens and toxins' in the UK and 'select agents' in the US, is now performed under strict rules. For example, scientists working with these pathogens and toxins in the US must now undergo background checks, including having their fingerprints screened by the FBI against criminal, immigration, terrorism, and national security databases. Research in the US and Germany has suggested that these controls are having an adverse impact on science.

Given the importance of the biosciences to the UK economy, the project started with a pilot study whose results suggest that, so far, UK biosecurity regulations are having a less disruptive impact on the practice of science. Indeed, 79 per cent of the sample judged the current balance between scientific freedom and security considerations to be satisfactory. Although the research was performed only three years since implementation of the Anti Terrorism Crime and Security Act began, the

results from the pilot project seem to suggest that UK policymakers may have found a formula that improves bio-security without adversely affecting the practice of science.

The researchers systematically gathered information from a sample of UK scientists, funders of science and biosafety and security officials. They found that 41 per cent of them reported no 'major complications and setbacks' to their practice of science since the introduction of the new national controls. However, others did report experiencing 'major complications and setbacks', and their main reported difficulty was obtaining pathogens and toxins. When asked, these members of the sample believed the difficulties were as much the result of changes in US biosecurity controls as changes in UK law that national biosecurity regulations have international implications. The results also showed that four research projects have had to be abandoned since 2001 as a direct result of the increased national and international attention to the biological weapons/bioterrorism problem.

Dual Use Controls and Genomics Research

Dr Paul Nightingale, Science and Technology Policy Research, University of Sussex

What kind of impact do government policies in the biological arms control environment have on the practice of science?

This project aims to examine:

- the impact of the complex and extensive UK controls on dual use technologies on scientific research
- whether scientists are finding dual use policies are redirecting research priorities
- how the costs of dual use controls are being distributed between large and small, public and private research organisations
- the extent of variation in costs and benefits between institutions and what the causes of this variation are.

<http://www.sci-soc.net/SciSoc/Projects/Genomics/Dual+use+controls+and+genomic+research.htm>





Conclusion: Understanding Practice, Makes Perfect

"Understanding may mean the ability to use technical knowledge effectively, but inability to use such knowledge does not necessarily mean lack of understanding. Understanding science may also mean understanding its methods rather than its specific content... and it may mean understanding its institutional characteristics, its forms of patronage and control, and its social implications." Brian Wynne 1995

As it becomes possible to screen for an increasing number of foetal conditions, some researchers are questioning the ways in which this technology is being put to use (eg, Abramsky et al. 2001, Lippman 1999, Williams et al. 2002, see further Kerr 2004). They explore the ways in which healthcare professionals understand and communicate diagnoses of foetal abnormalities, when and why they might recommend selective terminations. They are asking questions such as: How do we define the conditions that are to be screened for, and why? Should the provision of prenatal screening automatically be regarded as a 'good thing' that should be offered to as many women as possible? Some critics of current practice have used stronger language. Considering the rising numbers of terminations on the basis of a diagnosis of Down's syndrome (Ridley 2004), they ask for example, what kind of vision of genetic welfare 'discounts individuals on the basis of their inborn characteristics', narrowing 'the range of desirable human beings, identifying the different, the diseased, or the disabled as those we wish to root out.' (Miringoff 1991).

In trying to find answers to these questions, most of the current research on genomics, the life sciences, and society emphasises the moral and ethical concerns surrounding advances in such areas. In doing so, they tend to draw particular attention to the ways in which technological innovations based on genomics are a force for social change, and how they are likely to transform our daily lives, in terms of both our behaviour and our ways of seeing the world.

These are certainly worthwhile areas for further research, but does this focus on visions of future change mean that we are not giving sufficient attention to what is going on now? As the research on pre-natal screening suggests, although our new knowledge may lead us to discover revolutionary new tools, the ways we use those tools are firmly rooted in our current system of values and beliefs – in this particular case, views of disability and the authority of 'the scientific expert'. As science lays siege to the secrets of the universe and our knowledge steadily grows, we have to

“Introduction of new technologies is far from technical

a simple process, in which science can be neutral”

wonder, who is making the crucial decisions, with what authority and on what basis? As Professor Wynne says in the opening quotation: What are their methods and how are they shaped by institutional culture? Who are their patrons and what kind of control do they wield? And what will be the implications of these activities for society?

Such questions may also underlie some of the widespread assumptions about genomics that are commonly held, or assumed to be held, about advances in genomics. As discussed previously, although a number of these are misunderstandings that can be explained away, they may also draw attention to people's attitudes to this new technology, and their hopes and fears about the benefits and risks that scientific advances may bring. In particular, they seem to illuminate a widespread concern about the stewardship of these innovations.

Surprisingly, the activities of experts in this field – be they scientists or policymakers – and the influences that shape their work have, so far received little analysis. Most of the literature in this area, despite a thorough discussion of the ethical questions and concerns, reveal little sign that the scientific research done in this area, and the knowledge that results, can be anything other than neutral in both its nature and process.

In contrast, all the projects collected under this theme and in this brochure challenge this idea of scientific neutrality and the all-encompassing expertise of scientists or policymakers. They focus on the many different factors that influence those involved in the development, uptake and use of these technologies in various settings, taking as the subjects of their research: professional users, clinicians, regulators and policymakers.

As these projects reveal, it is all too easy to make assumptions about how particular social groups will respond to new technologies. For example, it might be easy to assume a simple division between experts and non-experts, in which those involved in scientific research are more likely to be objective about their work, while non-scientists are uninformed about new technologies. But such assumptions are misplaced: for example, Professor Lane's work reveals that farmers involved in implementing GM crops adopt a practical, experience-based approach, rather than being influenced by the concerns of their local public community. The responses of this group also underline another important observation, that is, that there are many different levels of expertise that must be involved in the process of technological innovation and development. Farmers are neither scientific experts nor members of an uninvolved 'general public', but their tacit knowledge and professional experience is essential in the successful implementation of GM crops.

As the projects demonstrate, a wide variety of social, cultural and individual factors may influence any particular group's attitudes to genomics, including experts. In particular, a number of these projects explore the consequences, both intended and unintended, of attempts at regulation – both national and international.

At a local level, Professor Kerr's research explores practitioners' own accounts of the 'unintended consequences' of regulation, in relation to professional norms of disinterested scientific practice and their informal 'moral thinking' in particular. Dr Lewis' work considers regulation, both national and international, as one of many different factors influencing the question of the incorporation of pharmacogenetics into clinical practice. At the international level, Dr Rappert's and Dr Nightingale's research on the regulation of genetic bioweapons reveal different dimensions of concern: that the regulations intended to promote biosecurity are endangering other forms of research that use the same basic technology as for the development of biological weapons. Dr Rappert's work draws attention to the ways in which, just as the science is continually developing, so must regulation. The process should be treated as a practical activity based on experience, in which the meaning of norms, the definitions of the identity of

individuals, and the context of research must be negotiated and practically secured. This project draws explicit attention to the importance of acknowledging how current attitudes of scientists and policymakers may influence developments in the future.

These projects provide robust evidence for the fact that the introduction of new technologies is far from a simple technical process, in which science can be neutral. Gaining a fuller understanding of practical, real-life responses to genomic knowledge and technologies is essential for the development of appropriate policies, but it is also essential for us, as a society, to pay attention to the ways in which those involved in the development and implementation of genomics research and related technologies engage with their work.

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Research projects listed under topical themes

The Science in Society Programme is one of the ESRC's major investments and is a six year commitment running from 2002 to 2007. The Programme, originally conceived following a parliamentary report on science and technology, is both broad in scope and diverse in its research focus and has been host to 45 different research projects during its lifetime. The Programme is separated into six themes, each one acting as an umbrella for a variety of projects, all of which consider a different aspect of the science-society relationship.

Science in Governance and the Governance of Science

Social and Human Rights Impact Assessment and the Governance of Technology

Dr Andrew Barry, research undertaken at Goldsmiths College, London – now based at the University of Oxford
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Interdisciplinarity and Society: A Critical Comparative Study

Dr Andrew Barry, University of Oxford andrew.barry@ouce.ox.ac.uk

Using Public Environmental Knowledge in Industry

Dr Kate Burningham, University of Surrey k.burningham@surrey.ac.uk

Childhood Cancer Tissue Donations: A Gift Relationship?

Professor Mary Dixon-Woods, University of Leicester md11@le.ac.uk

Contesting Environmental Science: Business and Environmentalist NGOs

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Credibility Claims as Scientific Commodities

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Public Perceptions of Risk, Science and Governance

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Simulation Modelling of Contentious Scientific Knowledge Claims in Society

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