

A large, solid blue curved graphic that starts from the left edge and curves downwards towards the right, occupying the middle section of the page.

*Our Inheritance,
Our Future*

Realising the potential of genetics
in the NHS

SUMMARY

June 2003

This document provides a short summary of the Government White Paper '*Our Inheritance, Our Future – Realising the potential of genetics in the NHS*' published in June 2003. The full text can be found at www.doh.gov.uk/genetics/whitepaper.htm



DEPARTMENT OF HEALTH

Our Inheritance, Our Future

**Realising the potential of genetics
in the NHS**

SUMMARY

*Presented to Parliament by the Secretary of State for Health
By Command of Her Majesty
June 2003*

© Crown Copyright 2003

The text in this document (excluding the Royal Arms and departmental logos) may be reproduced free of charge in any format or medium providing that it is reproduced accurately and not used in a misleading context. The material must be acknowledged as Crown copyright and the title of the document specified.

Any enquiries relating to the copyright in this document should be addressed to The Licensing Division, HMSO, St Clements House, 2-16 Colegate, Norwich, NR3 1BQ.
Fax: 01603 723000 or e-mail: licensing@cabinet-office.x.gsi.gov.uk

Foreword by the Prime Minister



Our country has a remarkable scientific tradition. The extraordinary achievements of Newton, Darwin and a host of other eminent scientists have both greatly increased the understanding of our world and improved the quality of life for everyone.

Our record continues to be outstanding; with just one per cent of the world's population, we receive nine per cent of scientific citations. Nowhere has this record been more notable in recent decades than in bio-science and bio-technology.

The discovery in Britain of the structure of DNA 50 years ago – perhaps the biggest single scientific advance of the last century – marked the beginning of a golden age of bio-science in Britain which continues today. It is likely to have as big an impact on our lives in the coming century as the computer had for the last generation.

The more we understand about the human genome, the greater will be the impact on our lives and on our healthcare. As an increasing number of diseases are linked to particular genes or gene sequences, we will be able to target and tailor treatment better to offset their impact and even to avoid the onset of ill-health many years in advance.

I am proud to know that much of this ground-breaking work is already taking place in our country. I am also absolutely determined that the National Health Service should be able to respond to these advances so the benefits of genetics and the more personalised and improved healthcare it will bring are available to all.

It means we must prepare now for the future. We must invest in research and research facilities to drive further discovery. We must ensure the NHS has the skills and expertise to make best use of these advances. And we must also be ready to explain clearly and consistently to patients the new health care choices this will bring. Through the independent experts on the Human Genetics Commission we will ensure that people have access to advice about human genetics and the social and ethical issues involved. This is the best way of easing understandable public anxiety about the coming revolution in health care.



This White Paper sets out how the Government intends to achieve all these goals. It also underlines our determination to ensure the NHS and its patients get the maximum benefit from the pioneering work already under way and the transformation it will bring in the delivery of health care in this country.

A handwritten signature in black ink that reads "Tony Blair". The signature is written in a cursive style and is positioned above a solid black horizontal line.

Tony Blair

Foreword



Advances in human genetics will have a profound impact on healthcare. Over time we will see new ways of predicting and preventing ill health, more targeted and effective use of existing drugs and the development of new gene-based drugs and therapies that treat illness in novel ways. Above all, genetics holds out the promise of more personalised healthcare with prevention and treatment tailored according to a person's individual genetic profile.

The Government recognises and welcomes the potential offered by genetics to improve our health and healthcare. Britain's academic and industrial research prowess means that we are already amongst the leading players in genetics research and development. We are determined to harness that potential and to ensure that the benefits of genetics are realised throughout the NHS.

In April 2001, the Government announced new investment of £30 million to develop our specialised genetics services. This is already enabling them to see more patients and improve genetic testing provision. But there is much more to be done if the NHS is to be ready to cope with future demand and if genetic based healthcare is to expand and permeate every area of medicine as new genetics tests and therapies come on stream.

Our vision is that the NHS should lead the world in taking maximum advantage of the application of the new genetic knowledge for the benefit of all patients. Over the next three years, the Government will invest an additional £50 million in England in developing genetics knowledge, skills and provision within the NHS. This document sets out how that money will be spent. By building on our strengths and starting to prepare now, genetic advances can deliver real and lasting benefits in health and healthcare for all of us.

A handwritten signature in black ink, appearing to read 'John Reid'.

Secretary of State for Health



Chapter one – Recognising the potential

Looking to the future and laying the foundations – the NHS to be a world leader in genetics based healthcare

A greater understanding of the part played by our genes in the development of disease will result in a step-change in disease prevention, diagnosis and treatment. The Government's vision is for the NHS to lead the world in harnessing the potential of genetics in healthcare and for NHS patients to benefit from the safe, effective and ethical application of the new genetic knowledge and technologies.

Chapter one sets out where advances in knowledge and understanding are taking us. Genetics knowledge will permeate healthcare bringing more accurate diagnosis, more personalised prediction of risk, new drugs and therapies, and prevention and treatment better targeted to the disease and tailored according to a person's individual genetic profile.

We are building on the present, where NHS genetics services care for patients and their families who have, or might be at risk of, an inherited disorder. Examples are cystic fibrosis, haemophilia and muscular dystrophy. Genetic testing can be used to help predict whether someone with a strong family history is likely to develop the disease in future. Genetic testing is also used to aid diagnosis, to check for carrier status and in antenatal and neonatal screening programmes.

We are looking to the future. Over time we will learn more about the genetic features of common diseases such as heart disease and diabetes and the way external factors such as diet and smoking interact with our genes to increase the likelihood of developing a given disease. There will then be the option to test people for a predisposition to disease, or a higher than normal risk. Treatment, lifestyle advice and monitoring aimed at disease prevention could then be tailored appropriately to suit each individual.

The greatest impact of genetics on healthcare in the shorter term is likely to come from pharmacogenetics. Variations in our genes mean that patients can respond differently to drugs. As our understanding grows about how genes and drugs interact, patients could undergo a genetic test to predict their response and help ensure that the medicine and dose is right first time. This should improve outcomes, reduce wastage and help avoid serious side effects. New pharmaceutical products linked to a genetic test are likely to become available within the next five years.



Advances in genetics will lead to new drugs and novel therapies. It will allow the development of gene based drugs and treatments targeted at the disease-causing fault rather than at the control of symptoms. An example is gene therapy. This is the deliberate introduction of genetic material into a patient's cells to treat diseases. As well as replacing defective copies of genes, techniques are being developed which aim to switch helpful genes on or harmful genes off. Although this new branch of medicine is still at the research stage, more than 600 trials have been approved world-wide. Gene therapy holds out the prospect of new treatments for a wide range of common conditions such as cancer and coronary artery disease. At the current rate of development we can expect to see the first licensed gene therapy medicines coming on stream within five to ten years.

The exact timing for different genetic advances is uncertain and it is too early to accurately predict all our requirements for the next decade. But unless we act now to ensure we have firm foundations to build on, the NHS will be left trailing. The White Paper sets out a detailed plan of action and investment for the next three years together with a commitment to review and respond to the needs of the NHS beyond that time. The steps we outline in the White Paper will:

- Strengthen specialist genetics services
- Build genetics into mainstream services
- Spread genetics knowledge across the NHS
- Generate new knowledge and applications
- Ensure public confidence.

Chapter two – Strengthening specialised services

Increasing the capacity of laboratory and clinical genetics services

Developing our existing centres of expertise is a critical first step to realising our vision for the NHS to be the world leader in maximising the benefits of the new genetic knowledge in healthcare for all patients. Specialist NHS genetics centres bring together clinical geneticists, genetic counsellors and genetics laboratories. These specialist centres will need to play a lead role in diffusing genetics knowledge and expertise across the NHS. They must also be prepared for the increased demand for genetic testing from other clinicians.



Chapter two describes the steps the Government will take to boost the capacity of clinical and laboratory genetics. Over the next three years we will:

- increase our investment in expanding the specialist genetics workforce. We will fund new clinical training posts to train over 50 new genetics counsellors over the next five years. And we will make available up to £3.5 million to fund up to 90 new Grade A trainees in laboratory genetics, and the equivalent of ten full-time trainer posts
- invest up to £18 million capital on upgrading NHS genetics laboratory facilities in England. As a result of this investment, by 2006 genetic testing times will be cut and the results should be available to the following standards:
 - within three days where the result is needed urgently (eg. for prenatal diagnosis)
 - within two weeks where the potential genetic mutation is already known (e.g. because another family member has already been tested)
 - within eight weeks for unknown mutations in a large gene
- invest up to £1 million in IT for genetics laboratories in the Genetics Testing Network. This will enable better handling of work and communications within and between participating laboratories.

Chapter three – Building genetics into mainstream services

Incorporating genetic advances into everyday clinical practice

As the relevance of genetics across the spectrum of other medical specialties becomes apparent, mainstream NHS services will increasingly be able to take advantage of genetic knowledge and tools in diagnosing, preventing and treating disease.

Chapter three sets out how the Government will assist the take-up of genetics by other specialties by supporting new initiatives in genetics based care both in hospital and primary care settings. And how we will ensure that screening programmes for genetic disorders are rolled out, where appropriate. The Government will:



- co-fund with Macmillan Cancer Relief pilots in six cancer network areas of a model of service delivery for people at risk of familial cancer
- pilot a systematic programme to identify and treat people with a genetic disorder known as familial hypercholesterolaemia in order to reduce their risk of dying of a heart attack at an early age
- provide up to £2 million of start-up funding over three years for other initiatives to bring the benefits of genetics into mainstream clinical areas
- provide up to £2 million of start-up funding over three years specifically for primary care genetics initiatives
- provide start-up funding to allow up to ten GPs with a special interest in genetics to be established over the next three years
- ensure that by 2004/5, all pregnant women are offered antenatal screening for Down's syndrome and then counselled by midwives to help them make an informed choice
- ask the Human Genetics Commission to work with the National Screening Committee to consider the case for screening babies at birth and storing information about their genetic profile for future use in tailoring healthcare according to their needs and their genetic make-up. The HGC will be asked to report by the end of 2004.

Chapter four – Spreading knowledge across the NHS

Enabling healthcare professionals to be confident and effective in dealing with inherited disease and using new genetics based technologies and treatments

If advances in genetics are to be translated into effective health care applications across the NHS then genetic education for a wide range of non-specialist health professionals will be vital. Education in genetics will be needed at all levels: undergraduate, general professional training, specialist training and continuing professional development. Some work has already begun but the agenda is enormous. Chapter four sets out how the Government will:



- invest in education and training
- support evidence-based care
- invest in information systems
- support commissioners of NHS services.

The pace of scientific and clinical discovery in genetics makes it difficult for individual healthcare professionals to keep abreast of developments and apply them for maximum patient benefit. Information to support clinical decision making and ensure that genetic technologies are implemented in a safe, systematic and evidence based way will be essential. Commissioners of genetic services will also need support. And information systems will need to be adapted to cope with new demands for recording, storing and retrieving genetic information.

The Government will support the integration of genetics throughout the NHS by:

- setting up an NHS Genetics Education and Development Centre which will act as a catalyst to bring education and training in genetics for all healthcare staff. An early priority for the Centre will be to ensure that all GPs have access to appropriate genetics education and training when they need it to support effective practice
- setting up a Genetics Visiting Fellowships Fund to allow NHS clinicians and scientists to travel abroad to acquire new genetics knowledge and expertise. The Fund will also be open to bids to invite international experts to come to Britain to share their knowledge and expertise with the host organisation
- developing a genetics portal on the National Electronic Library for Health and funding the production of specially written material for this website to ensure that all GPs and other healthcare staff have access to up-to-date genetics information to assist them in clinical decision making
- ensuring that NHS Direct keeps abreast of developments in genetics so that patients and the public will always be able to access up-to-the-minute information about genetic influences on health and what these might mean for them and their families



- supporting evidence based care. The National Horizon Scanning Centre will be including genetics in its regular programme of work. The National Genetics Reference Laboratories will undertake health technology assessments as will the National Health Technology Assessment programme. The National Institute for Clinical Excellence will be asked to consider developments in genetics as the evidence base develops
- investing in training for commissioners. The Public Health Genetics Unit and the Genetic Testing Network team will identify commissioners' needs in genetics and provide a rolling programme of training to meet them.

Chapter five – Generating new knowledge and applications

Translating genetics research and development into improved health and healthcare

The UK is at the leading edge of genetic research and development. The Government will continue to facilitate and foster the extensive range of genetics research initiatives underway in the UK, both in the public sector and in our biotechnology and pharmaceutical industries.

Chapter five explores ways to realise the benefits of genetic research. This will be a key challenge for the NHS over the coming decades. The Government is investing around £15 million to support the development of six genetics knowledge parks. They will bring together a powerful combination of expertise to create an overlapping and complementary network of centres of excellence. They will be able to work in partnership with the private sector to develop new genetic medicines and treatments and an extended range of diagnostic and predictive genetic tests.

The Government is also co-sponsoring the UK Biobank project. This unique project will begin later in 2003 and will collect data and blood samples for genetic analysis from 500,000 men and women volunteers aged between 45 and 69. It will provide an invaluable resource for researchers seeking to establish the effects of our genes, combined with lifestyle factors, on our risk of developing the common diseases of later life.



The Government will also sponsor new research initiatives to help convert genetic discoveries into improved patient care. We will:

- invest up to £4 million to fund pharmacogenetic research on existing medicines
- provide funding to set up the first university Chair in pharmacogenetics, supported by a small department of two to three full-time researchers
- when the technology becomes available, provide up to £500,000 to support piloting of near patient genetic testing in the NHS to help evaluate its reliability, utility and validity in clinical settings
- invest up to £1.5 million to fund a range of research projects in the area of genetics based health services
- invest up to £3 million to support gene therapy research on single gene disorders
- in addition, provide £2.5 million over 5 years to support gene therapy research for cystic fibrosis, the most common single gene disorder in the UK
- invest up to £4 million to provide greater access to facilities for gene therapy vector production for NHS and public sector researchers.

Chapter six – Ensuring public confidence

Promoting public understanding of genetics, a robust regulatory framework responsive to public concerns and transparency in genetic policy making

Realising the full benefits of human genetics will require public acceptance and public confidence. Fundamental to this is greater public understanding of genetics. The Government is committed to ensuring openness and transparency in genetic policy making. We want to engage in a genuine dialogue on genetics issues. We recognise that developments in genetics will present new ethical and social challenges. We need to be alert to the potential adverse consequences and prepared to take action where necessary.



As set out in chapter six, the Government:

- has developed a robust and proportionate regulatory framework around genetics and health. We have already introduced key safeguards – the moratorium on unacceptable use of genetic tests by insurers, banning human reproductive cloning, and regulating the use of genetics in reproductive medicine and clinical trials of gene therapy
- will ensure that the regulatory framework anticipates and continues to address public concerns
- will continue to promote public understanding of genetics, including through providing additional financial support to the Progress Educational Trust and providing around £1,000,000 to support a programme of events and initiatives in 2003 to celebrate the 50th anniversary of the discovery of the structure of DNA. A key aim will be to increase people's awareness and understanding of genetics
- has established the independent Human Genetics Commission to provide expert advice on developments in human genetics and the social and ethical issues raised. The Government welcomes their report *Inside Information* on the uses of personal genetic information, and in particular the ethical principles it sets out
- will introduce legislation making it an offence to test a person's DNA without their knowledge or consent, except as part of their medical treatment where consent is impossible to obtain, and use by the police and courts
- will consider the evidence for unfair discrimination against people on the basis of their genetic characteristics and the appropriate means of addressing any concerns in this area.



Conclusion

The White Paper sets out the Government's strategy for maximising the potential of genetics in the NHS so that all patients can benefit from new genetic advances in disease prevention, diagnosis and treatment.

It was developed with advice from an Advisory Panel chaired by Lord Turnberg, former President of the Royal College of Physicians. Its membership was drawn widely from genetics healthcare professionals, industry, academia and patient groups (see Annex).

Any comments or queries on the White Paper should be addressed to Genetics White Paper, Genetics Branch, Department of Health, Room 651C Skipton House, 80 London Road, London SE1 6LH. Email: Geneticswhitepaper@doh.gsi.gov.uk.

Annex

Advisory Panel

This document was informed by the work of an Advisory Panel. The Government is grateful to the members of the Advisory Panel for their contribution.

Membership

Lord Turnberg	Former President of the Royal College of Physicians (Chair)
Prof Martin Bobrow	Professor of Medical Genetics, Cambridge
Prof John Burn	Professor of Clinical Genetics, Northern Genetics Service and Director, Newcastle Genetics Knowledge Park
Dr Paul Debenham	Head of Life Sciences and Forensics, LGC
Joanie Dimavicius	Former Chair of the Genetic Interest Group
Prof Peter Farndon	Professor of Clinical Genetics, Birmingham and former chair of the Joint Committee on Medical Genetics
Penny Guilbert	Nurse/Counsellor, Nottingham City Hospital
Prof Sir David King	Government Chief Scientific Adviser, Office of Science and Technology
Crispin Kirkham	Former Chief Executive, Bioindustry Association
Delyth Morgan	Chief Executive, Breakthrough Breast Cancer
Baroness Onora O'Neill	Former Chair of the Nuffield Council on Bioethics and of the Human Genetics Advisory Commission; Principal of Newnham College, Cambridge
Dr Allen D Roses	Senior Vice-President, Genetics Research, GlaxoSmithKline; nominated by the Association of the British Pharmaceutical Industry
Dr Nigel Starey	GP and Director of the Centre for Primary Care, University of Derby
Dr Ron Zimmern	Director, Public Health Genetics Unit and Director, Cambridge Genetics Knowledge Park

Annex

Advisory Panel

This document was informed by the work of an Advisory Panel. The Government is grateful to the members of the Advisory Panel for their contribution.

Membership

Lord Turnberg	Former President of the Royal College of Physicians (Chair)
Prof Martin Bobrow	Professor of Medical Genetics, Cambridge
Prof John Burn	Professor of Clinical Genetics, Northern Genetics Service and Director, Newcastle Genetics Knowledge Park
Dr Paul Debenham	Head of Life Sciences and Forensics, LGC
Joanie Dimavicius	Former Chair of the Genetic Interest Group
Prof Peter Farndon	Professor of Clinical Genetics, Birmingham and former chair of the Joint Committee on Medical Genetics
Penny Guilbert	Nurse/Counsellor, Nottingham City Hospital
Prof Sir David King	Government Chief Scientific Adviser, Office of Science and Technology
Crispin Kirkham	Former Chief Executive, Bioindustry Association
Delyth Morgan	Chief Executive, Breakthrough Breast Cancer
Baroness Onora O'Neill	Former Chair of the Nuffield Council on Bioethics and of the Human Genetics Advisory Commission; Principal of Newnham College, Cambridge
Dr Allen D Roses	Senior Vice-President, Genetics Research, GlaxoSmithKline; nominated by the Association of the British Pharmaceutical Industry
Dr Nigel Starey	GP and Director of the Centre for Primary Care, University of Derby
Dr Ron Zimmern	Director, Public Health Genetics Unit and Director, Cambridge Genetics Knowledge Park



Published by TSO (The Stationery Office) and available from:

Online

www.tso.co.uk/bookshop

Mail, Telephone, Fax & E-mail

TSO

PO Box 29, Norwich, NR3 1GN

Telephone orders/General enquiries: 0870 600 5522

Order through the Parliamentary Hotline Lo-call 0845 7 023474

Fax orders: 0870 600 5533

E-mail: book.orders@tso.co.uk

Textphone 0870 240 3701

TSO Shops

123 Kingsway, London, WC2B 6PQ

020 7242 6393 Fax 020 7242 6394

68-69 Bull Street, Birmingham B4 6AD

0121 236 9696 Fax 0121 236 9699

9-21 Princess Street, Manchester M60 8AS

0161 834 7201 Fax 0161 833 0634

16 Arthur Street, Belfast BT1 4GD

028 9023 8451 Fax 028 9023 5401

18-19 High Street, Cardiff CF10 1PT

029 2039 5548 Fax 029 2038 4347

71 Lothian Road, Edinburgh EH3 9AZ

0870 606 5566 Fax 0870 606 5588

TSO Accredited Agents

(see Yellow Pages)

and through good booksellers

0 10 157912 8