

Investing in UK Health and Life Sciences
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**Securing a vibrant research-based
pharmaceutical industry in the UK**

Parliament Launch 27 February
House of Commons



The Journal of the
Parliamentary and
Scientific Committee

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Time to *flourish*

Inside innovation: the medicine development process

Re-investing profits from medicines enables companies to develop new medicines for patients

The pharmaceutical industry develops 90% of medicines¹

Average number of years taken to develop successful medicine²

Average cost to research and develop successful medicine³

Number of medicinal candidates tested to achieve one approved medicine⁴

	4.5 years	5.5 years	7.0 years	8.5 years	11.0 years	12.5 years
	£436 million	£533 million	£710 million	£916 million	£1.1 billion	£1.15 billion
	5,000 - 10,000 candidates	10-20 candidates	5-10 candidates	2-5 candidates	1-2 candidates	1 medicine
Pre discovery Based on their disease focus, companies' scientists work to understand the disease	Drug discovery Researchers select a 'target', such as a gene or protein, then search for a molecule, or compound, that may act on the 'target' to alter the disease	Pre-clinical testing Early safety and efficacy tests are undertaken in computational models, cells and in animals	Phase 1 clinical trial The candidate medicine is tested in people for the first time. Studies are conducted with about 20 to 100 healthy volunteers	Phase 2 clinical trial Researchers evaluate the candidate medicine's efficacy in about 100 to 500 patients with the disease	Phase 3 clinical trial Researchers study the candidate medicine in about 1,000 to 5,000 patients to generate data about safety, efficacy and the overall benefit-risk relationship of the medicine	Licensing approval Information and results from all the studies is compiled and submitted to the regulatory agencies
Medicine available for patients The medicine is now licensed for use and patients may benefit from it, subject to value and cost-effectiveness assessments and local health budget availability						

¹IFPMA analysis of the WHO Model Essential Medicines List (2006)

²Paul S et al How to improve R&D productivity: the pharmaceutical industry's grand challenge, Nature Reviews Drug Discovery, Volume 9 March 2010

³(in 2010 prices based on Bank of England exchange rate)

⁴Paul S et al How to improve R&D productivity: the pharmaceutical industry's grand challenge, Nature Reviews Drug Discovery, Volume 9 March 2010

⁵PhRMA analysis, updated for data per Tufts Center for the Study of Drug Development (CSDD) database (1995)

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⁵PhRMA analysis, updated for data per Tufts Center for the Study of Drug Development (CSDD) database (1995)

With the Chancellor's Budget due next month and the economy top of people's minds both in Westminster and across the UK, it makes sense to start this year's first issue by considering how important science is to the UK's prosperity. Science and innovation hold the key to a competitive UK economy on the world stage.

One 'jewel in the crown', as the Prime Minister called it late last year, is the bio-pharmaceutical industry. Consistently investing more in research and development than any other sector – over four times more than the next biggest, aerospace and defence, the pharmaceutical industry invested £4.4 billion in UK research and development in 2009. Employing more than 67,000 people, including 25,000 highly-trained scientists and doctors, industry earnings from the exports of medicines exceeded imports by £7 billion in 2010 and the industry has been a net earner for Britain throughout all of the past 30 years.

Beyond these striking economic facts, for those of us with an interest in the UK science base it is the industry's collaboration with researchers across our universities, research foundations and charities, the NHS and emerging small- and medium-sized companies that is of greatest value. The UK science base in this area is already strong – over the period 2006 to 2010, UK publications in bioscience received an average of 9.5 citations each, higher than any other country. Collaborations between industry and public and charity researchers help to share expertise and knowledge, and enable discoveries or ideas to be taken forward that perhaps would not otherwise have been developed.

The whole of the UK benefits enormously from all this activity – economically in terms of jobs, GDP and exports, scientifically in terms of R&D investment, science skills and the vibrancy of the science base, and fundamentally the public benefits from medical advances that save lives and improve quality of life for millions.

We can be very proud of the UK's achievements in this field, however growing competition from emerging economies is raising the bar ever higher and the UK needs to run faster just to stay still. There are also major concerns within academia about the availability of research funds as well as the impact of recent changes on future student numbers. These are major challenges and government has an important role to play in facilitating and enabling the UK science base and major research-based industries to prosper. Indeed, with the need for growth and jobs paramount, none of us can afford not to take this seriously.



Andrew Miller MP
Chairman, Parliamentary
and Scientific
Committee

SCIENCE IN PARLIAMENT sip

The Journal of the Parliamentary and Scientific Committee.

The Committee is an Associate Parliamentary Group of members of both Houses of Parliament and British members of the European Parliament, representatives of scientific and technical institutions, industrial organisations and universities.



Science in Parliament has two main objectives:

1. to inform the scientific and industrial communities of activities within Parliament of a scientific nature and of the progress of relevant legislation;
2. to keep Members of Parliament abreast of scientific affairs.

CONTENTS

INVESTING IN UK HEALTH AND LIFE SCIENCES	2	IMPLICATIONS OF THE NEW EU DIRECTIVE REGULATING ANIMAL EXPERIMENTS FOR THE UK	27	STAKEHOLDER PERSPECTIVES ON VALUE-BASED PRICING	43
David Willetts MP		Dr Maggy Jennings OBE		Eric Low	
THE INNOVATION REVIEW AN INDUSTRY RESPONSE	4	WHAT DO YOU NEED TO KNOW ABOUT ANIMAL RESEARCH TODAY	29	ARCTIC METHANE EMERGENCY	44
Nick Burgin		Barbara Davies		Dr Stephen Henley CEng FGS FIMMM	
UNLOCKING PATIENT DATA FOR BETTER CARE AND RESEARCH	7	TRANSPARENCY IN CLINICAL RESEARCH	30	WHAT IS THE PUBLIC UNDERSTANDING OF RISK?	45
Sir Mark Walport FRS		Andy Powrie-Smith		Addresses to the P&SC by Dr Chris Elliott FREng, David Simmons and John Swanson	
PUTTING DATA AT THE HEART OF OUR HEALTHCARE INDUSTRY	9	PUTTING COPD ON THE MAP – COLLABORATING TO FIGHT DISEASE	31	BOOK REVIEW	52
Samantha Marshall		Dr Paul Whittaker and Professor Chris Brightling		Ian Taylor	
'COST-PER-QALY IN THE US AND BRITAIN: DAMNED IF YOU DO AND DAMNED IF YOU DON'T'	11	SOCIETY OF BIOLOGY DEGREE ACCREDITATION PROGRAMME	32	UNDERSTANDING SOCIETY: A LIVING LABORATORY OF LIFE IN THE UK	53
Dr Adrian Towse		Dr Mark Downs FSB, FLS		Professor Patricia Broadfoot	
STANDING UP FOR ORPHANS	12	ASTRAZENECA BRIXHAM	33	HOUSE OF COMMONS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY	55
John Irwin		Paul Duckett		HOUSE OF LORDS SCIENCE AND TECHNOLOGY SELECT COMMITTEE	57
WETTER, WARMER, WINDIER ...WILL THE UK'S INFRASTRUCTURE COPE?	14	VALLEY OF DEATH	34	HOUSE OF COMMONS LIBRARY SCIENCE AND ENVIRONMENT SECTION	58
Addresses to the P&SC by Professor Jim Hall, Professor Will Stewart and Professor Brian Collins		Glyn Edwards		PARLIAMENTARY OFFICE OF SCIENCE AND TECHNOLOGY (POST)	59
IS SCIENTIFIC FREEDOM THE ELIXIR OF CIVILISATION?	20	STRATIFIED MEDICINES: THE FUTURE OF HEALTHCARE	36	SELECTED DEBATES	61
Addresses to the P&SC by Professor Donald Braben, Professor James Ladyman, Professor Benjamin Davis and Professor David Delpy		Louise Leong		SCIENCE DIRECTORY	62
WHAT IS MEDICAL INNOVATION?	26	ANNUAL LUNCHEON OF THE PARLIAMENTARY AND SCIENTIFIC COMMITTEE	38	SCIENCE DIARY	71
Allison Jeynes-Ellis		SIN OFFICERS IN SWITZERLAND: WORKING IN A SMALL RESEARCH PEARL	41		
		Gaby Bloem			
		STEM CELLS FOR SAFER MEDICINES: A PREDICTIVE TOXICOLOGY CONSORTIUM	42		
		Professor Frank Bonner			



INVESTING IN UK HEALTH AND LIFE SCIENCES



The Rt Hon David Willetts MP
Minister of State for
Universities and Science

Government is putting all its efforts into rebalancing the UK economy, and with this the life sciences industry has come sharply into focus. In the last decade the UK pharmaceuticals industry has grown faster than any other sector of the economy, excepting the finance and insurance sector, with an annual turnover of over £50 billion.

Of course with 34 Nobel Prizes in medicine under its belt, the UK has a proven track record of being at the forefront of life sciences discoveries with fantastic health benefits – from Alexander Fleming discovering penicillin in 1928, to James D. Watson and Francis Crick identifying DNA in 1953; from Sir Alec Jeffreys' discovery of DNA finger-printing in 1984 to the first cloning of a mammal at the Roslin Institute (Dolly the sheep) in 1997; from Sir James Whyte Black finding the first clinically significant use of beta blockers in 1962, to the birth of the first 'test tube baby' in 1978.

Now we find ourselves at a crossroads. Global pharmaceutical sales are predicted to grow by up to 6 per cent a year in the coming years, painting an optimistic picture. Emerging markets are creating exciting investment opportunities and western countries such as the US and Germany have developed simpler regulatory processes to approve new therapies. We acknowledge that we have under-utilised our

strengths. To remain competitive we need to up our game in the UK because the challenges facing the industry are real and growing.

Added to this is the changing shape of the industry: the old 'big pharma' model of having thousands of highly-paid researchers working on a pipeline of blockbuster drugs is declining and a new model of collaboration, outsourcing of research and early clinical trials on patients is emerging. But does the UK 'ecosystem' currently support this? And how does innovation fare in the UK regulatory landscape?

The UK has significant areas of excellence, not least its science base, and industry tells us that, yes, the NHS is world-renowned, but it could tempt a lot more investment if we made more of our greatest assets: our talent for discovery and our NHS.

Government recognises that this is the key to ensuring that UK life sciences continue to contribute to sustainable UK

growth. On 5 December 2011 we delivered a radical set of measures in a *Strategy for UK Life Sciences*, alongside the NHS Chief Executive's review, *Innovation health and wealth, accelerating adoption and diffusion in the NHS*.

NHS data is more comprehensive than any other comparable health system in the world, but neither the NHS nor scientists developing new drugs and treatments have been able consistently to make good use of the data to drive further scientific breakthroughs. In the UK we are investing to make it easier for industry to partner with our world-leading scientists and clinicians, and to unlock the power of our unique patient data. That is why the National Institute for Health Research (NIHR) has committed a record investment of £800m over five years to the creation of Biomedical Research Centres and Units within the UK's leading teaching hospital-university partnerships, and the establishment of two new NIHR Translational Research Partnerships. The National Institute for Health Research Office for Clinical Research Infrastructure (NOCRI) provides a single point of entry to these centres for life sciences companies. We are also launching a new secure service to link primary and secondary care data at an unidentifiable

... To remain competitive we need to up our game in the UK because the challenges facing the industry are real and growing. . .

patient level, and investing £60m in a secure Clinical Practice Research Datalink (CPRD) to provide researchers with access to patient data for clinical trials recruitment and observational studies.

Government will support patients to have access to novel treatments, and be part of wider patient benefits, by consulting on an amendment to the NHS constitution. Whilst protecting the right of an individual to opt out, this would assume that data collected as part of NHS care could be used for approved research, with appropriate protection for patient confidentiality. It would also assume that patients are content to be approached about research studies for which they may be eligible, to enable them to decide whether they want a discussion about consenting to be involved.

To complement this, we will invest £75 million to our ELIXIR programme to expand our ability to assemble and manage biological and genetic information generated by research. This will include the provision of a new facility within the existing European Bioinformatics Institute in Cambridge for biological data-storage to support life sciences research and its translation. Furthermore, the NIHR is investing £2.5m pump-priming this year in a new national NIHR Bioresource. This Bioresource will provide a national cohort of healthy volunteers, patients and their relatives who wish to participate in experimental medicine research, and are willing to provide clinical information and samples that will enable them to be recalled for specific studies. It will support companies and researchers in recruiting healthy participants to undertake stratified studies. These studies

will have the potential to rapidly advance the understanding of disease mechanisms, identify potential drug targets, and improve insight into the therapeutic potential and limitations of existing and emerging therapies.

Of course many of the UK's discoveries - potentially the most innovative medicines - will never reach the translation stage from the lab into a commercial venture, falling into the so-called 'valley of death' because small and medium-sized enterprises (SMEs) cannot secure financing in the early years of their R&D.

Building on current investments, we will invest £310 million to support the discovery, development and commercialisation of research into stratified medicine and mechanisms of diseases in people. This will include a £180 million biomedical catalyst fund to tackle the 'valley of death', nurturing the most promising medical treatments from the academic or commercial sector through to companies with products or technology platforms in order to attract private equity. It also includes a £10 million investment by the Medical Research Council (MRC) for collaboration with AstraZeneca to provide academic researchers with unprecedented access to 22 high quality AstraZeneca clinical and pre-clinical compounds which are the building blocks of new medicine. But that is not all. We will make a further investment of up to £50 million over the next 5 years in a Cell Therapy Technology Innovation Centre to focus on the development and commercialisation of cell therapies and advanced therapeutics.

For these investments to have their greatest impact,

... we will invest £310 million to support the discovery, development and commercialisation of research into stratified medicine and mechanisms of diseases in people. . .

industry needs to support new businesses to understand the commercial environment. SMEs are often strong on scientific and research skills but may lack business and management skills. Through Cogent, we will develop and implement a tailored mentoring programme that will provide SMEs with the management skills they need to enhance their competitiveness.

Innovation in life sciences proceeds at an astonishing pace; however, we recognise that this pace is not always mirrored through the regulatory system. Through the MHRA therefore, we will work with industry and other international regulators to develop a progressive regulatory environment that not only supports innovation, but openly promotes it. Furthermore, as part of a major drive to improve innovation and access to medicines in the NHS, Government has announced proposals to consult on a new early access scheme that could allow thousands of the most seriously ill patients to access new cutting-edge drugs up to a year earlier than they can now.

As important as this suite of measures, which includes a raft of tax changes to incentivise R&D, is getting the UK 'house' in order. Granted we have an impressive set of life sciences clusters in the UK but in these global climes we need the UK to be, at the very least, on a par

with the likes of Boston, and the San Francisco Bay area. To ensure that researchers, clinicians, businesses and investors see the UK as the location of choice for life sciences, we are taking steps to build a fully integrated life sciences ecosystem from our world-class research and clinical infrastructure. Building on the Academic Health Science Centre model of adoption and diffusion, the NHS Chief Executive and the Chief Medical Officer will establish a number of Academic Health Science Networks (AHSNs) across the country, with the first going live during 2012/13. The AHSNs will align clinical research, informatics innovation, training and education and healthcare delivery, and will provide industry with clear points of access to the NHS.

We are genuinely committed to this impressive industry and excited by what these comprehensive and far-reaching proposals can offer it. But the proof, so they say, is in the pudding. In our determination to see early results and to ensure these measures deliver to their greatest potential, we have appointed two independent life sciences champions to support delivery against the strategy and we look forward to seeing what we can achieve together in 2012 and beyond.

THE INNOVATION REVIEW

AN INDUSTRY RESPONSE



Nick Burgin
ABPI Board Member

In March 2011, the Government published its Plan for Growth, including a set of measures targeted at strengthening the UK's position as a leading location for life sciences investment. One of these measures called for NHS Chief Executive, Sir David Nicholson, to work together with a range of interested partners including industry representatives, to report on how the adoption and use of medical innovations can be accelerated across the NHS. This resulted in the development of Sir David's *Innovation Review*, which was launched on 5 December, alongside the *Strategy for UK Life Sciences*. These two very important policy documents inform a strategic approach to fostering innovation in a modernised NHS.

Innovation is the lifeblood of our sector, the source of both the breakthrough and the incremental advance; it is that part of our healthcare economy that reinforces the UK as a global destination for investment. But the process for generating pharmaceutical innovations is neither well-defined nor homogenous. Rather, innovations advance in stages, over long periods of time and often with some degree of uncertainty. The innovative process is one that involves search and experimentation, where outcomes cannot be predicted for their clinical impact or economic value. And yet medical innovations hold the potential to transform life-threatening diseases such as HIV/AIDS and certain cancers

into chronic manageable conditions. They can extend life or affect the tolerability of a treatment, thereby boosting patient compliance and saving costs.

Creating an environment where innovation can thrive requires close working between a range of partners, including representatives from academia, clinicians, patients and the NHS. To this end, we applaud the spirit of collaboration and the refreshing leadership of Sir Ian Carruthers and Miles Ayling of the *Innovation Review*, in the approach that was taken to generate insights into these two very important policy instruments.

As the co-leader of the ABPI group invited to work on the initial submission response to Sir David Nicholson's call for evidence, my colleagues and I found the process to be inclusive and flexible. We were offered a range of different settings for meetings where we could engage and share ideas. Some of these included an external advisory board, informal dinners with stakeholder groups, and the secondment of a senior employee from the industry to assist Sir Ian Carruthers and his team whilst also providing excellent communication through the development process.

This joint-working experience presents a successful blueprint and pathway for how the industry and the NHS can work together. We hope that this example will be replicated to assure the effective implementation of the initiatives

generated from this close working.

THE UK AS A LEADING LOCATION FOR LIFE SCIENCES INVESTMENT

The UK and, in particular, the NHS, is already well-regarded globally. The NHS ethos of providing care free at the point of entry is admired across the world, as is the training of our clinical staff.

From a commercial perspective, UK prices are directly referenced in 25 per cent of world markets and then indirectly in a further 15 per cent.¹ This price referencing can take place both at launch and throughout a product's lifecycle. In addition, decisions made by the National Institute for Health and Clinical Excellence (NICE) have influence around the world, with particular importance for British-headquartered companies where NICE is often the first technology assessment body to review a new medicine that the company will then plan to launch globally.

In the midst of a challenging global environment, the UK is increasingly under threat of becoming a mid- or late-tier launch market. An important factor is the issue of delayed local access to market following a positive recommendation by NICE. This is due in part to the structure and governance of the NHS, where there is a culture and tradition of caution regarding new medicines – exacerbated by what might be described as a disconnect between medicines that NICE

considers cost-effective and the reality of local health economies. This disconnect may then compel local NHS budget holders to regard certain medicines as unaffordable despite the national guidance.

These barriers to local market access are tackled directly through initiatives that aim to reduce variation and strengthen compliance with NICE appraisals through automatic yet planned inclusion into the NHS formulary within 90 days of a decision being made. This will be backed up by a NICE Implementation Collaborative to support prompt implementation of NICE guidance. Further support for these initiatives will be in the form of a proposed innovation scorecard designed to track compliance with NICE technology appraisals.

On the supply side, a number of Academic Health Science Networks (AHSNs) are being established to link up the system and drive up innovation. To manage local and regional NHS budget differences that may also act as a barrier to access, a shared savings formula is being introduced to break down NHS silo budgeting and encourage cross-boundary working. Plans to continue work on tariff development, especially in relation to payment for outcomes, are progressing. These initiatives will go a long way to building on the UK's strong global reputation, with more incentives for investors to regard it as a first to market location for their innovation products.

NHS CULTURE CHANGE

Actions to embed innovation in training and education through a range of competency frameworks, coupled with a leadership programme to strengthen board-level

accountability throughout the NHS, are most welcome. These are measures that the industry has used to adapt to changing environments and customers' needs and we believe they will help the NHS to achieve its objectives. Organisational change is never easy, however, and we would like to offer our support, working jointly with NHS partners, to share programmes that we have developed for our own organisations.

Overall, we believe that effective implementation of these initiatives will be the key to improving international confidence in the UK as the fastest adopter of new ideas in the world. For example, my own company Eisai is now more likely to hold the intellectual property for *perampanel* in the UK which will result in sustained investment especially in manufacturing. This is just one small example of where the implementation of targeted initiatives can help to mark out the UK as an attractive site for investment in the midst of increasingly noisy competition from emerging markets.

REGULATION

Innovation has many dimensions, all of which need to be considered by third-party payers designing pricing and reimbursement policies. As such, we welcome the proposals for a fair regulatory process that is proportionate to investment risk. This will enable the UK to take a lead position in attracting research, clinical trials and manufacturing investment. Other plans to simplify regulation, reducing gold plating and unnecessary bureaucracy will help industry move further and faster, again reinforcing the UK as an attractive place to locate business.

The proposal for a group of experts including industry representatives to meet regularly to discuss regulation is in the spirit of fostering an NHS that is open to business and very welcome.

We further welcome the launch of the regulatory audit and Red Tape Challenge in March 2012, and commend the Government's commitment to review the stock of UK regulation that impacts upon the life sciences industry.

ACCELERATING THE USE OF INNOVATIONS ACROSS THE NHS

The commitment to providing earlier access to medicines where appropriate, allowing patients to benefit earlier from promising medicines whilst improving what we know about how these medicines work, is promising. This initiative would allow for patients with severe disease and no other recourse to treatment to have access to innovative medicines. Under these proposals, earlier access will be made available where benefit outweighs the risk. NHS funding must be cost-effective and the UK economy should benefit from the scheme.

The industry welcomes the action for the MHRA to bring forward for consultation proposals for an 'Earlier Access Scheme' as devised by the Ministerial Industry Strategy Group (MISG) New Technologies Advisory Panel. We welcome further detail on this very important proposal.

CLINICAL TRIALS

Clinical trials play a critical role in the cycle of discovery, development and delivery of innovative medicines and we welcome initiatives designed to further ensure that the UK is identified as an attractive site for

clinical trials in the midst of an increasingly competitive global environment.

These initiatives include extending the Academic Health Science Centre (AHSC) model, where a healthcare provider works closely with a university. The industry has noted that organisations with AHSC status have made efforts to align their organisations, thereby integrating the strategy and operation of a medical school with its local NHS Trust. This is good practice and in the spirit of the sort of collaborative working that fosters medical innovations.

Under this initiative, the Cambridge, Oxford and London Biomedical Research Centres (BRCs) will work with the Biomedical Research Unit (BRU) in Leicester to develop a national resource. This will help to seal the UK's position as the 'go-to' location for experimental medicine by providing a national cohort of healthy volunteers, patients and their relatives who wish to participate in experimental medicine research. This will be supported with published information detailing which NHS trusts are involved in clinical research, including information on how they are performing.

Importantly, the National Institute for Health Research (NIHR) Clinical Research Network (CRN) is partnering with *The Guardian* newspaper to create the Clinical Research Zone. This will showcase the research that individual NHS Trusts are taking part in and will be located beneath the existing *Guardian* Healthcare Network site.

Other supporting initiatives include the development of a smartphone app to increase access to information about clinical trials and the re-launch of

an enhanced web-based UK Clinical Trials Gateway in March 2012. These will aim to provide patients and the public with authoritative and accessible information about clinical trials in the UK.

DEVELOPING CAPABILITIES IN eHEALTH AND INFORMATICS

The move towards the integration of health records and data linkages will open up the information created by the NHS as a unique data source of strong interest to industry globally. Furthermore, the introduction of data collected as part of NHS care (with appropriate protection for patient confidentiality) is to be welcomed.

Proposals for the Health and Social Care Information Centre set to open by September 2012 offer a range of options to secure, share and preserve data. Some of these options include a secure data linkage service that will deliver data extracts using linked data from primary and secondary care and other sources on a routine basis. These data will be provided on an unidentifiable, individual level and will be able to be used by the specialist Clinical Practice Research Datalink (CPRD) service. It will also be available to all users of health and care information in order to drive improvements in care, enterprise and innovation. The centre will operate on a self-financing basis where users pay the cost of the linking process.

The Clinical Practice Research Datalink (CPRD), which is a £60 million investment by NIHR and MHRA, will service the specialised needs of the research and life sciences communities by offering data services: providing access to

data for researchers (NHS, social care and others); data matching and linkage services; and data validation to support the clinical trial and observational study work of the life sciences research community. It will also work to support patients to have access to novel treatments and be part of the development of wider patient benefits by consulting on amending the NHS Constitution so that there is a default assumption (with a facility for opt-out) for information collected as part of NHS care to be used for approved research with appropriate protection for patient confidentiality; and that patients are content to be approached about research studies for which they may be eligible, to enable them to decide whether they want a discussion about consenting to be involved in a research study.

This is very welcome as is the drive to ensure leadership in all these instances so that research is a core strand of the NHS's role to drive innovation and develop new medicines.

ECOSYSTEM

We welcome the Government's support for the entire life science ecosystem, including the gap or 'valley of death' funding for early stage research and SMEs. As the pharmaceutical industry comes under new global pressures, the survival of the sector is reliant on this health ecosystem. Recognition of this is very welcome.

FISCAL INCENTIVES

We welcome the fiscal incentives as announced in the Chancellor's statement – reinforcing the Government's commitment to establishing the Patent Box, a measure that will reduce corporation tax on profits

from patents to 10 per cent from April 2013. This will create a competitive tax environment for companies and encourage them to locate high-value jobs and activity associated with the development, manufacture and exploitation of patents in the UK.

Other measures include an R&D tax credit system that will move from super deduction relief to a credit offset against corporation tax in boosting the level of R&D investment in the UK, give this relief to Contract Research Organisations and others when routine R&D testing is subcontracted, and provide a simpler pre-clearance system for smaller companies (such as spin-outs) making their first claim.

The Technology Strategy Board launched a competition to form a Cell Therapy Technology and Innovation Centre which will help to support the development and commercialisation of therapeutics, as well as the underpinning technologies for manufacturing, quality control and addressing safety and efficacy challenges for new treatments.

WHAT THESE ACTIONS COULD MEAN FOR INDUSTRY, THE NHS AND THE UK ECONOMY

The process of innovation is one of search and exploration, where uncertainty and serendipity coincide. Medical innovations confer societal benefits that extend beyond the patient to the economy as a whole. The launch of policy directed at placing innovation at the heart of the NHS marks a positive step forward for the NHS itself and also for industry and patients, and they are most welcome.

Launching the Life Sciences

Strategy, the Prime Minister called for a new paradigm for the life sciences sector where the NHS is open for business and the UK is a 'hotbed of innovation'. He also called for the industry to work hand in hand with the NHS and academia, with better collaboration, more out-sourcing and a greater number of early clinical trials.

We strongly believe that the effective implementation of the actions outlined in the *Life Sciences Strategy* and the *Innovation Review* will go a long way to achieving these aims. The process of designing these reports has been very inclusive. As other negotiations that are crucial to the industry continue – such as those around pricing – the industry hopes to continue to work in the same spirit of collaboration together with Government, academia and the NHS.

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UNLOCKING PATIENT DATA FOR BETTER CARE AND RESEARCH



Sir Mark Walport
Director, Wellcome Trust

On 5 December 2011, the Prime Minister launched the *Life Sciences Strategy*, a comprehensive package of actions that has the potential to transform healthcare innovation in the UK. A series of proposals address funding for translation, streamlining of regulation, and the development of skills and careers. A review of innovation in the NHS, published at the same time, makes a number of much-needed recommendations to encourage the adoption and diffusion of innovative ideas and new technologies in the NHS.

I am delighted to see the Government recognise the importance of the life sciences sector, particularly at a time of economic difficulty. But the recommendations that I am most excited about are those designed to increase access to patient data for research. Research charities have been calling for this for many years.

Using patient information integrated from general practice and hospital clinics to provide and monitor clinical care can be immensely powerful. It can provide rapid and important benefits to patients in improving the quality of care. For example, Scotland has a real-time clinical information system on its diabetes patients. From this we know that there are 246,328 patients with diabetes in Scotland. The database also ensures earlier diagnosis and more targeted treatment. Evidence from Tayside shows a 40 per cent reduction in amputations due to complications with diabetes, over six years; and a 43 per cent reduction of people needing laser treatment for eye

disease that threatens sight.

Patient records can also be an extremely valuable resource for research – research that is essential if the NHS is to deliver the best possible healthcare. Data are used for epidemiological research, to understand more about the causes of disease, to detect outbreaks of infectious diseases, to monitor the safety and efficacy of drugs, and to study the effectiveness of treatments and interventions. Patient records also offer a helpful starting point to identify potential recruits to invite to take part in a clinical trial or cohort study.

Wherever possible, researchers use anonymised, non-identifiable information. But we cannot avoid the fact that sometimes researchers working as part of clinical teams will need to access data from which it may be possible, directly or indirectly, to identify a patient. For example, a study of 33,000 children showed that those who lived close to a power line at birth had an increased risk of leukaemia.¹ This study involved information that a child of a

particular age lived at a particular postcode. Together, these two pieces of information could lead to the identification of individual children, but it would not have been feasible – or proportionate – to seek individual consent from all 33,000 families.

Until now, access to this type of information has been locked up in red tape. Researchers have faced considerable uncertainty, and a lack of consistency, about the processes that should be used when information from patient records is required for research. The issue of inviting patients to take part in research has been particularly problematic. Researchers may need to review medical records to determine whether patients meet the eligibility criteria for the study, such as diagnoses, age or gender. However, because this may involve viewing identifiable information, researchers have often been prevented from accessing the data. Once potential participants have been identified, GPs are sometimes required to contact patients in the first instance to ask whether

they are happy to be contacted at a later time with information about a study. Only after this initial contact can researchers contact patients to invite them to participate in the study. The *Data Sharing Review Report* (Thomas and Walport, 2008) described this need for 'consent to gain consent' as a 'problem that requires a solution'.

We need to ensure that unnecessary and inappropriate bureaucracy such as this does not prevent vital research. Of course, medical records are both personal and sensitive, and everyone agrees there must be safeguards for confidentiality. But mechanisms are already in place to ensure this. An ethics committee assesses the risks and benefits of every individual research study before it can proceed. In situations where it is not possible to seek informed consent to use identifiable records, researchers must apply for special permission to the Ethics and Confidentiality Committee of the National Information Governance Board.

That is why we welcome the actions announced in the Chancellor's *Autumn Statement* and the Government's *Life Sciences Strategy*. The reports commit to the provision of secure data linkage services by the Health and Social Care Information Centre. This service, which will link primary and secondary healthcare datasets, will deliver data extracts at an unidentifiable, individual level. It will be available to all users of health and care information and will operate on a user-pays basis by September 2012. In addition, the Clinical Practice Research Datalink (CPRD), a new secure data service, will be established within the Medicines and Healthcare Products Regulatory Agency (MHRA) to service the

specialised needs of the research and life sciences communities.

Perhaps more importantly, there will also be a consultation on amending the NHS Constitution to introduce a default assumption that patient data can be used for approved research, and patients approached about taking part in research studies. This would be on an 'opt-out' basis and should solve the difficulties of 'consent for consent'.

This is a huge step forward. The aim to make every NHS patient a willing research participant is absolutely the right one. As the NHS *Innovation Review* points out, 'the greater the number of patients involved in research, the wider the public benefit'. But if this aim is to be achieved, we must work together to ensure public trust is maintained. The press coverage immediately after the announcements suggests that this will not be an easy task.

Public attitudes are varied, but do generally appear supportive of research using personal information. A Wellcome Trust Monitor survey in 2009 of 1,179 UK adults found that 74 per cent were willing to allow access to their medical records for medical research.² This is backed up by results in practice. The General Practice Research Database (GPRD) has been collecting data on over 3.6 million patients from more than 450 primary care practices, using an opt-out system similar to that proposed in the NHS Constitution. The opt-out rate is less than 1 per 1000 patients.

The evidence also suggests that patients do not mind being contacted about research projects.

Of nearly 60,000 people invited to take part in the pilot phase of UK Biobank, only 0.1 per cent asked how they had been selected or how their name and address had been obtained. Very few of these people had serious concerns, and the majority of the telephone respondents went on to participate following discussion of their questions. Twenty-five per cent of the people who were invited to participate responded to the primary invitation letter. The situation was similar with the UK Collaborative Trial of Ovarian Cancer Screening. Of 1.2 million women invited to participate, only 32 complained about being contacted. An Ipsos MORI poll earlier this year found that, of 990 people over the age of 15, 80 per cent were definitely or probably happy to be approached about research that would involve allowing a researcher confidential access to their medical records for health research.³

Research charities, clinicians, academics and the Department of Health must work together over the coming months to ensure the importance of research using patient records is communicated effectively, and to reassure patients that the confidentiality of their data will be safeguarded. As a first start, the UK Clinical Research Collaboration has developed leaflets to increase understanding of the use of personal data in research.⁴ These leaflets have been distributed to GP surgeries across England, Wales and Scotland.

The other potential hurdle is a legislative one. We must ensure that the revisions to the European Data Protection Directive, and any resulting

changes to the UK Data Protection Act, do not undermine this progress. The current legislative framework is complex and confusing, and needs urgent simplification. The revisions must develop a clearer definition of 'personal data'; clarify the status of anonymised and pseudonymised data in research; and make adequate provision for research access.

We need to strike a better balance between the right to privacy and the sharing of information for the public good in health research. A cancer patient once said to me, 'giving my anonymous data is the most painless thing I can do to help others get better'. We must work together to ensure that giving data is easier than giving blood. The recent announcements are an excellent step in the right direction.

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PUTTING DATA AT THE HEART OF OUR HEALTHCARE INDUSTRY



Samantha Marshall
PH Associates

David Cameron's keynote speech at the FT Global Pharmaceutical and Biotechnology Conference on 5 December launched a range of initiatives to support the Life Sciences sector, including the *NHS Chief Executive Review of Innovation* and the *Strategy for UK Life Sciences*. Two initiatives of note were the commitment to continue to develop capabilities in electronic health (eHealth) and informatics in the healthcare sector, and the commitment to allow earlier access to innovative medicines through changes in the current regulations. Both are initiatives which have data at their heart.

There are different types of data which fulfil different needs: data from randomised controlled trials (RCTs) is established as the gold standard for evaluation of safety and efficacy of new interventions, while Real World (RW) data refers to data collected to assess healthcare outside the tight constraints of conventional RCTs. These data

are used to evaluate what is happening in normal clinical practice: for instance, the impact on a health economy of the introduction of a new oral chemotherapy agent in terms of reduction of NHS resource use, improvement in patient satisfaction, and time to progression. These data are collected about the wide variety of 'real' patients in 'real' situations, rather than an artificial clinical trial situation where patients are highly selected and which often involve more intensive monitoring and interventions than normal.

The initiatives announced in December 2011 show the value recognised by the government in RW data and the scope that the collection, analysis and use of the data have to drive changes in our healthcare services. The use of RW data from anonymised electronic healthcare records will enable both the NHS to streamline services, and the pharmaceutical industry to streamline development of new products. The proposed earlier access schemes for some new medicines will help NHS patients gain faster access to innovative medicines and, providing current research governance is adapted in parallel, should facilitate the collection of RW data to help reduce any uncertainty regarding the true value of the medicines.

THE IMPORTANCE OF RW DATA

Many people involved in or associated with the pharmaceutical industry will be familiar

with the huge investment required to develop a new pharmaceutical compound and the benefits this brings to countries in which the pharmaceutical companies choose to develop their medicines. From first-in-man studies to test whether a drug is safe to the largest Phase III RCT, the development of novel and innovative medicines is costly and time-consuming and involves large numbers of patients, often in many countries around the world.

However, the story does not stop here. Once a medicine is proven to be safe and efficacious, and a licence to market the medicine is granted, the pharmaceutical industry is also under pressure to show that a product is cost effective in real life and to demonstrate the impact on 'real' patient populations – data that are needed to ensure medicines are accepted by national policymakers and are adopted into practice in the health system.

In the past, studies collecting Real World data have been criticised for lacking the robust scientific methodology of RCTs. However, with the shift in NHS priorities to quality and patient outcomes, it is clear that evaluation of the value of medicines in normal clinical practice is what is required. There is a realisation that it is just not pragmatic or possible to collect all the data which is needed within the constraints of an RCT, and there has been a large shift in mind-set towards RW data as an accepted

standard for collection of evidence.

WHY RW DATA ARE IMPORTANT TO PATIENTS AND THE NHS

As the NHS goes through its most radical changes yet – with the empowerment of healthcare professionals and providers, greater choice and control for patients, and the shifting focus away from targets towards outcomes and quality – its requirements for RW data to inform change will become more demanding. NHS decisions will be based on evidence of value in the commissioning of care, payment for services and, importantly, payment for future new medicines. Even more challenging, these changes are happening against the backdrop of a financial crisis and recent recession, with tight financial management required over the coming years and the likelihood of no real increases in health funding.

WHY RW DATA IS IMPORTANT TO THE UK RESEARCH COMMUNITY

The past decade has seen the UK's share of global commercial clinical trial activity decline significantly. Whilst still attracting between 8 and 10 per cent of global commercial trials, the UK only completes between 2 and 3 per cent of global patient activity, a reduction from 6 per cent in 2000¹. The industry has identified some of the reasons behind this, including slow start-up times, low patient recruitment to time and target, and high and

variable costs. While activities are under way to seek to improve UK performance and make it more attractive for clinical trial activity, an additional strategy to help counteract this shift is to look at other types of research that can be carried out in the UK in a timely and cost-efficient way. A growth in research using RW data is one way to ensure continued growth of the UK in the research arena.

WHY RW DATA ARE IMPORTANT TO THE PHARMACEUTICAL INDUSTRY

2014 will see the introduction of Value Based Pricing (VBP)², a new system for reimbursement of innovative medicines placed on the market. Whilst the details are not yet known, it is likely that rather than applying a standard cost-effectiveness threshold to all medicines as the National Institute for Health and Clinical Excellence (NICE) currently does, weightings will be applied to the benefits provided by new medicines, reflecting a range of price thresholds. These thresholds would be explicitly adjusted to include a broader range of relevant factors such as burden of illness, contribution to NHS service improvement and innovation, and societal costs and benefits, to calculate the full value of a new medicine.

To provide relevant evidence for these evaluations, it will be essential for the pharmaceutical industry to demonstrate the additional benefits of medicines above and beyond the quality, efficacy and safety demonstrated in randomised clinical trials. This will reduce the uncertainty surrounding the value of a medicine at the time of launch, accelerating uptake for the benefit of patients and the industry alike.

Data on unmet medical need, current burden of disease, and wider societal benefits of a medicine, which are reported to be important factors in influencing the cost threshold for pricing and reimbursement, will be best demonstrated through the collection of RW data and could well be supported by the research capabilities offered through the planned expansion of access to healthcare data.

THE OPPORTUNITIES AND IMPLICATIONS

Whilst we can see that RW data are important to the NHS, the UK research community and the pharmaceutical industry, there are two overarching opportunities for the UK to exploit over the coming years.

1. The opportunity to ensure that any UK-specific data are collected in a timely manner for new medicines to facilitate faster uptake by the NHS and access for patients to new innovative medicines.

Non-interventional RW data cannot replace the quality, safety and efficacy data generated by RCTs but can help support those data by allowing actual versus expected efficacy and safety to be evaluated in the context of a normal clinical setting.

It has been recognised that the regulatory frameworks in place for research in the UK currently limit the opportunities for this type of work prior to a new medicine being licensed, and this is now being addressed. However, fears that have been raised concerning the appropriate use of data, and protection of anonymised patient level health-related data need to be addressed. It will be essential for the pharmaceutical industry, NHS and academia to work closely together in order to maximise the opportunity that

the proposed changes afford.

2. The opportunity for the UK to position itself as a centre of excellence for RW data collection, to support its own and other countries' requirements for RW data that can be generalised across a number of healthcare systems.

There are a number of key factors that make the UK a favourable place for the collection of Real World data:

• UK influence on global decision-making in medicine development

It is recognised that the majority of the pharmaceutical companies work in a global market and the UK is only one of the important healthcare sectors. While the UK represents only a small share of the global revenue for a medicine, it nonetheless has a significant influence on access to medicines in other countries. From a Health Technology Assessment (HTA) perspective, recommendations on the most cost-effective use of medicines developed by UK bodies such as NICE are formally or informally used to make coverage decisions in other countries, including emerging markets. In addition, the influence of NICE has been increasing since the establishment of NICE Scientific Advice and NICE International, which are NICE divisions providing assistance to, respectively, companies and payers/governments across the world.

• Attractive NHS environment

The UK has a unique 'cradle to grave' healthcare system, with the General Practitioner being a gatekeeper to most of the health and social care requirements of an individual throughout his or her life. The UK has a wealth of electronic

databases developed over the past 20 years containing patient information with provisions in place to maintain patient confidentiality. The Strategy for UK Life Sciences set out the commitment to have the Health and Social Care Information Centre in place by September 2012. This will provide a secure data linkage service between various data sources with data extracts delivered on a routine basis using un-identifiable patient level linked data from primary and secondary care. The data will be available to all users of health and care information in order to drive improvements in care, enterprise and innovation. In addition, the Clinical Practice Research Datalink (CPRD) will offer data services to the life sciences industry based on the datasets held by the Health and Social Care Information Centre.

• Progress with streamlining the regulatory and governance frameworks for real world research

The Health Research Authority (HRA), launched in December 2011 as a Special Health Authority (SpHA), completed one of the key commitments made by the Government in the Plan for Growth, published in March 2011, towards rationalising and improving health research regulation.

It is proposed that the HRA will co-operate with others to combine and streamline the current approval system and promote consistent, proportionate standards for compliance and inspection. In doing so, it will reduce the regulatory burden on research-active businesses, universities and the NHS, and improve the efficiency and robustness of decisions about research projects.

Current frameworks for

approval, however, cover all types of healthcare research (including RCT and RW data studies) and it is essential that the HRA considers RW data studies specifically, as progress is made towards addressing this important recommendation. This offers an opportunity for the UK to be a more attractive environment for the conduct of RW data studies.

• Skills and education

The strong links that the UK pharmaceutical industry has with the academic community are crucial in ensuring the

appropriate skills are identified and developed to support this growing area of RW research. The pharmaceutical industry has a responsibility to ensure that the personnel involved in RW data projects locally have the appropriate knowledge level or, alternatively, to secure the necessary support for study design and collection, analysis and subsequent use of these data.

SUMMARY

It is well recognised that data about patients' use of medicines in normal clinical practice, or in

settings which reflect the reality of health care delivery – Real World data – are likely to become increasingly important in decisions that affect patients' access to medicines.

The UK is already well placed to lead the world as a centre of excellence for the collection and use of this type of data. The plans announced in December 2011 have been welcomed and help move even closer to this goal. However, it is essential that ongoing consideration is given to the remaining challenges raised here if we are to optimise the benefits to the UK that could

be afforded by this opportunity.

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'COST-PER-QALY IN THE US AND BRITAIN: DAMNED IF YOU DO AND DAMNED IF YOU DON'T'



Dr Adrian Towse

Cost-per-Quality Adjusted Life Years (QALY) is the means by which the value of a medical intervention can be quantified, and is used by the National Institute for Health and Clinical Excellence (NICE) to determine the cost-effectiveness of medicines. This was the subject of the Office of Health Economics' Annual Lecture, given on 15 November in London by Dr Milton Weinstein, Henry J Kaiser Professor of Health Policy and Management at the Harvard School of Public Health.

The lecture was something of a social commentary on the differences in attitudes in the UK and the USA regarding healthcare costs and, in particular, cost-effectiveness analysis costs per QALY. One quote by Dr Weinstein summed this up: 'If you cannot tell from

the title, you are the folks who do and we are the folks who don't ... In my country we do not touch cost-effectiveness analysis with a 10-kilometre pole: in this country you seem to have a love affair with it'.

Dr Weinstein gives a number of arguments deployed in the USA for not using cost-effectiveness analysis. The most prominent of these is that there is no relation between healthcare expenditures and health outcomes across hospitals in the USA. This, according to Dr Weinstein, is actually true – the association between overall expenditures and outcomes tends to be a 'very fuzzy relationship'. Together with Jonathan Skinner of Dartmouth Medical School, Dr Weinstein recently wrote a paper published in the *New England Journal of Medicine* about what

this weak relationship between expenditures and outcomes implies about the need for cost-effectiveness analysis.

What he showed in this paper is that healthcare expenditures are not used most efficiently. There are many situations in which many of the most cost-effective health services and interventions are under-utilised. For example, fewer than half of Americans over the age of 50 have ever had a colorectal screening exam; nor do people get their influenza vaccinations or pneumococcal vaccinations as recommended. For a state to cut its expenditures and improve health outcomes simultaneously, Dr Weinstein concludes it needs to increase the utilisation of highly cost-effective interventions like these and simultaneously cut back on less cost-effective

interventions – and cost-effectiveness analysis is needed to do this.

A study by Skinner and Staiger, available as a National Bureau of Economics research report, looked at the rate of adoption of three highly cost-effective technologies for acute myocardial infarction (MI) – aspirin, beta-blockers and reperfusion. Now almost every hospital is using these to the full, but back in the 1980s and 1990s there was a period where hospitals adopted them at different rates.

Using regression analyses the study looks at the relationship between expenditures and outcomes for acute MI after the hospitals were stratified by their rate of adoption of these cost-effective technologies. The fastest-adopting quintile of hospitals have better outcomes than the slowest and – counter to the opinion that Dr Weinstein spoke of as being widespread in the US – there is a positive relationship between expenditures and outcomes in all the strata. So to cut costs and improve outcomes, hospitals would have had to adopt the cost-effective technologies more rapidly.

Another argument, one that the US Congress has decided to invest in, is that if we do more research on comparative effectiveness of health interventions we can identify the interventions that are useless, leaving enough money saved to pay for everything that is useful. The fact, Dr Weinstein explains, is that it is very hard to prove that something is useless. Randomised trials, if they are feasible, are not intended to prove a negative, and just because you cannot show that an intervention is better than its alternative it is very hard to show that it is exactly equivalent to the alternative. Most interventions do not lend themselves to randomised clinical trials and we have to rely on other sources of evidence, and it is very hard to prove beyond a reasonable doubt that an intervention is absolutely useless.

One argument backed by Dr Weinstein is that QALYs do not reflect everything that people care about in healthcare. For example, there may be value in some genetic testing that tells people what risks they face as they proceed through life, or what risks their child faces. Even if you cannot do anything about

it, there is the psychological value of knowing. Caring does not necessarily manifest itself in more QALYs but it is something that people value. Similarly, access to care, equity, and reducing disparities in society are things that people value but which do not reflect themselves in maximising QALYs.

Dr Weinstein was co-chair of the US Panel on Cost-effectiveness in Health and Medicine which reported to the US Government in the 1990s. One of the most important recommendations the panel made is that cost-effectiveness analysis is an aid to decision-making, not a complete procedure for making resource allocation decisions, because it cannot incorporate all the values relevant to such decisions. Dr Weinstein thought that NICE and Britain should be mindful of this, saying that ‘sometimes in one’s enthusiasm for the cost-effectiveness model – and I am certainly one of the enthusiasts – we need to temper that enthusiasm with the limitations and be mindful of the role that this type of analysis has among many other considerations – ethical, psychological and otherwise’.

Dr Weinstein posed a question – do the British take prescribed guidelines for cost-per-QALY modelling too seriously? The purpose of a model is to inform medical decisions and healthcare resource allocation. Modellers employ quantitative methods to gain qualitative insights. The purpose is not so much the number that comes out as to gain the qualitative insight. The tools of formal analysis are best employed to structure the clinical, epidemiological and economic evidence base in the service of better clinical practice decisions and public health priorities.

Finally, he noted that there is a role for deliberative processes through which individuals and stakeholders, including the general public, can get involved in conversations about how costs and benefits should be traded off against one and another, and with other ethical and psychological factors that people believe should go into decision-making.

STANDING UP FOR ORPHANS



John Irwin
Co-Chair ABPI Orphan Medicines
Industry Group

RARE DISEASES IN THE UK

2012 sees the publication of the UK’s first Plan for Rare Diseases. This represents an important landmark for the estimated 3.5 million patients in the UK believed to be living with a rare disease. This plan has been delivered in response to a commitment made in the response to the Council of the

European Union Recommendation on an action in the field of rare diseases (2009/C 151/02) to ‘establish and implement plans or strategies for rare diseases at the appropriate level ... in order to aim to ensure that patients with rare diseases have access to high quality care, including diagnostics, treatments, habilitation for those living with the disease and, if possible,

effective orphan medicines’.

A rare disease is defined by the European Union as one that affects fewer than 5 in 10,000 of the general population. There are between 6,000 and 8,000 known rare diseases and it is believed that 7 per cent of the population will be affected by a rare disease at some point in their lives. Seventy-five per cent of rare diseases affect children

and 30 per cent of rare disease patients die before their fifth birthday.

MEDICINES FOR RARE DISEASES

Despite the fact that, collectively at least, rare diseases are 'common', there has historically been a dearth of medicines available to ameliorate the situation of those with such conditions. In 2000, the EU enacted orphan medicinal product (OMP) legislation (Regulation (EC) No 141/2000) to offer a package of economic incentives for the R&D and marketing of orphan medicines in recognition of the fact that 'patients with rare conditions should be entitled to the same quality of treatment as other patients'. Since 2000, over 600 medicines have been granted orphan designation, with just over 60 progressing to full European marketing authorisation. Of these, 51 per cent are for the treatment of diseases that affect fewer than 1 in 10,000 patients.

THE AVAILABILITY OF ORPHAN MEDICINES IN THE UK

The EC regulation on orphan medicinal products has clearly stimulated the development of medicines for rare conditions that were previously untreatable, but how successful has this legislation been in increasing the actual availability of medicines for patients with rare disease in the UK?

In England, the majority, but not all, non-cancer rare diseases are defined within the National Specialised Services Definition Set (NSSDS). As a consequence of this, orphan medicines are frequently used in the management of conditions which are commissioned by

specialised commissioners either regionally, in Specialised Commissioning Groups (SCGs), or nationally, by the National Commissioning Group (NCG). The NCG only commissions services that generally impact upon fewer than 500 patients. Where medicines are used as part of a service commissioned by the NCG the medicine is paid for centrally. In contrast, where the medicine is used to treat a condition that is commissioned regionally by SCGs, Primary Care Trusts (PCTs) remain the ultimate payers.

The position of the National Institute for Health and Clinical Excellence (NICE) is that orphan medicines should be appraised in the same way as medicines for more prevalent diseases: although it does not appraise what it terms 'ultra orphan' medicines. However, since only technologies chosen through a topic selection process are referred to NICE, only 3 non-cancer orphan medicines have been appraised and recommended to date. The unintended consequence of the topic selection process has been 'NICE blight' for many orphan medicines in England. In the absence of NICE guidance, the decision of whether or not to pay for orphan medicines has fallen to Individual Funding Request panels considering case by case applications within individual PCTs. This can lead, and has led, to inconsistency in decision-making and geographic health inequalities.

In contrast, the Scottish Medicines Consortium (SMC) appraises all new medicines although it applies 'modifiers' to the cost-per-QALY approach. Despite the use of these 'modifiers', of the 46 orphan medicines appraised by the

SMC by May 2010, 18 were recommended, 17 rejected and 11 recommended for restricted use.

FUTURE CHALLENGES AND OPPORTUNITIES

For patients who are suffering from serious, rare conditions for which no satisfactory treatment exists, undue delay of access to new medicines will always be unacceptable. It is however important that the use of OMPs is considered and a determination of their value to patients treated within the NHS made. The challenge is therefore in determining how both a *timely and appropriate* assessment of OMP value can be made. Judging on the SMC experience, it is evident that where a purely QALY-based approach to Health Technology Assessment (HTA) is applied to OMPs there is a high rate of rejection, but what's the alternative?

One development that represents a step in the right direction is the recent publication of a decision making framework by the Advisory Group for National Specialised Services (AGNSS).¹ This model has been designed to support decisions around which products, services or

technologies should be commissioned and paid for nationally. It evaluates the product against 12 core criteria organised into 4 domains with a holistic view taken across all criteria. (Figure 1)

Although as yet relatively untested, this approach does at least appear to represent a more holistic approach to the evaluation of medicines for rare disease. Unfortunately its application is currently restricted to OMPs that treat no more than 500 patients in England and its future, like that of AGNSS, is by no means certain.

As part of the reforms outlined within the Health Bill, the responsibility for the commissioning (and funding) of specialised services (and the medicines used as part of them) in England will transfer to the NHS Commissioning Board. This represents an opportunity finally to get it right for at least some patients with rare diseases. It is critical, however, that those of us with a stake maintain vigilance and ensure that patients with rare diseases get access to the medicines they need and deserve.

Footnote

¹http://www.specialisedservices.nhs.uk/library/27/Introduction_to_AGNSS_Decision_Making_Framework.pdf

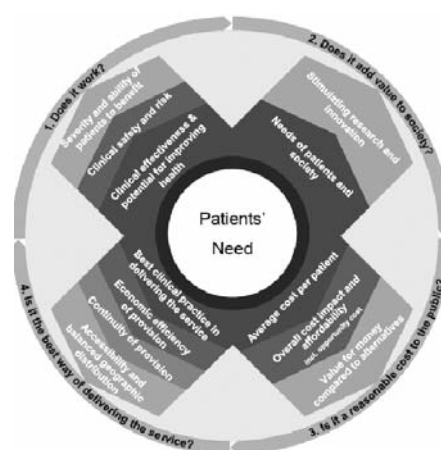


Figure 1: AGNSS Decision-Making Framework

WHAT ARE THE LIKELY IMPACTS OF CLIMATE CHANGE ON INFRASTRUCTURE?



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on Climate Change

The UK's national infrastructure systems will be threatened by the impacts of climate change, including sea level rise, increased temperatures, and changing frequency of droughts and floods. We need to be acting now to ensure that national infrastructure systems are adapted to the climatic conditions they will be experiencing in future.

Recent natural disasters, like the widespread flooding across the UK in the summer of 2007 and again in Cumbria in November 2009, illustrated the vulnerability of infrastructure systems in the UK to climatic extremes. Flooding in New Orleans due to hurricane Katrina demonstrated how fragile modern society is in the face of devastating natural hazards. There are social as well as technical reasons for this fragility. From a technical point of view, there are high levels of inter-dependence between the infrastructure networks that we rely upon for energy, water, transport and telecommunications, which leads to the potential for cascading failures. Meanwhile, an emphasis upon cost reduction and optimising efficiency, in particular in the privatised utilities, has progressively removed redundancy, which was intended to provide fall-back capacity in the event of failure.

Complex systems can be designed to have very high levels of reliability, even when they are occasionally subject to extreme environmental loads – witness the safety record in the civil aerospace industry – but to do so requires careful analysis of the *resistance* of the system to extreme loading, its *robustness* to potential unforeseen loads and the system's capacity to recover from disruption, or in other words its *resilience*. Having originated in ecology and been extensively elaborated in the social sciences, the notion of resilience is rapidly gaining currency in engineering as a motif for the design and management of critical infrastructure systems. The threat of climate change implies the need to extend analysis of system resilience to understand processes of long term change and adapt systems so that they will in future be less vulnerable to failure from natural hazards in a changing climate.

INFRASTRUCTURE VULNERABILITY TO WEATHER-RELATED HAZARDS

A multitude of functions of society and industry are influenced by weather, and thus also potentially by future climate change. Many industries are in a good position to adapt to changing climatic conditions year on year – insurers can modify

the premiums for weather-related hazards and farmers can modify when and what they plant, though even in these instances longer term planning is also necessary. Adaptation, however, becomes of utmost importance in long term climate-sensitive decisions that are hard to reverse. These include major infrastructure investments, such as water supply reservoirs, highways and power stations. Land use planning decisions influence the vulnerability of people and properties to climate-related hazards, such as flooding, now and in the future. Building regulations help to determine how houses and other buildings will cope with future climates.

There have now been many studies that have explored the potential scope of climate impacts on infrastructure. Table 1 (see www.scienceinparliament.org.uk) summarises some of the most important potential impacts. Under the Climate Change Act, infrastructure providers are required to report on the climate risks to which they are exposed and the steps they are taking to reduce those risks. The Climate Change Risk Assessment (published in January 2012) provides a national analysis of risks to the UK, including to national infrastructure systems. The proliferation and diversity of potential impacts can be an

obstacle to well targeted action. Yet in the UK, the top adaptation priorities for infrastructure are now quite well established:

- **Flooding:** The frequency of river flooding, along with surface water flooding from heavy rainfall, is expected to increase. Though mean sea levels around the UK are unlikely to rise by more than a metre before the end of the 21st Century, sea levels will continue to increase for hundreds of years thereafter, with very long term implications for coastal settlements and nuclear facilities.

- **Water scarcity:** Water resources in many UK river basins are already over-exploited. Climate change will exacerbate this problem, especially in the south of England, by reducing summer precipitation and potentially increasing demand.

- **Heat:** The heat wave in 2003 is estimated to have caused 2139 excess deaths in the UK. Excessive heat in buildings and transport systems (including the London Underground) that are not designed for very hot weather causes discomfort that reduces productivity.

At a global scale, Working Group II of the Intergovernmental Panel on Climate Change reports on *Impacts, Adaptation and Vulnerability* including summaries of published literature for various sectors and global regions. The impacts of climate change will vary greatly worldwide. The impacts depend not only on the magnitude of the change in climate but also on the capacity of societies and individuals to cope with climate change, in other words, their adaptive capacity. Hotspots of vulnerability are in low-lying

coastal locations and areas that are already water-stressed. The implications of climate change in these locations has the potential to be felt world-wide via increased disaster relief costs, migration and insecurity.

RECENT PROJECTIONS OF CLIMATE CHANGE FOR THE UK

The latest climate scenarios for the UK were released in June 2009 and are known as the UK Climate Projections (UKCP09). The projections are based upon over 300 runs of the Met Office Hadley Centre's global climate model, combined with more detailed modelling to provide results for the UK on a 25km grid. Each model run was scored by the quality of reproduction of observations of past climate change and weighted accordingly. This procedure enabled the generation of probability distributions that represent the uncertainty surrounding future climate changes.

The science of climate projection has continued to advance since the publication of UKCP09. Improving resolution of climate models will enable more accurate prediction of localised processes like precipitation and wind. Improved modelling is also providing predictions of temperature that include the effect of urban areas. Such developments are to be welcomed, but they do mean that decision makers need to be ready to accommodate intermittent updating of climate information, and to accept that whilst the broad global trends are now well established, predictions of local climatic patterns and associated uncertainties may well change as the science progresses.

DELIVERING ADAPTATION

It is in individuals' and businesses' interests to prepare for a changing climate. Doing so will yield immediate benefit in terms of risk reduction, as well as preparing for longer term changes. However, as Lord Stern observed in his report on the economics of climate change, "in some cases the benefits of adapting could extend beyond those who have paid for them, and provide benefits to the wider economy and society. In this case the private sector is unlikely to invest in the amount of adaptation society would desire, because they cannot

capture the full benefits of the investment." Government therefore has a role in making adaptation happen by:

- Providing of climate information, as has been done in UKCP09, and guidance on adaptation decision making.
- Incorporating adaptation in legal and regulatory arrangements, for example land use planning, building regulations and regulation of privatised utilities.
- Including climate change adaptation in government's own decision making, for example in investments in buildings and infrastructure.

The Climate Change Act 2008

In November 2008, the UK became the first country in the world to introduce a Climate Change Act – a legally binding, long-term framework for both mitigation and adaptation. With respect to adaptation:

- Government is to assess the risks climate change poses to the UK every five years. The first Climate Change Risk Assessment was published in January 2012
- Government is to publish and regularly update a national adaptation programme to address climate risks. The first statutory Programme is expected in 2013
- The Adaptation Sub-Committee of the independent Committee on Climate Change was brought into being in order to monitor and report on progress on the National Adaptation Programme and advise on the Climate Change Risk Assessment
- Government is to require public authorities and statutory undertakers to assess, where necessary, the risks of climate change to their work and set out what action they need to take in response (the "Reporting Power").

In the Climate Change Act and the UKCP09 scenarios the UK has taken purposeful steps to ensure that the country is well adapted to a changing climate. Yet in many respects the UK is still at the outset of a process that will see climate change adaptation becoming embedded in all aspects of decision making. Engineers have particular responsibility with respect to adaptation of infrastructure so as to ensure that these systems are resilient to future threats and adaptable in the face of climate uncertainties.

What are the implications of the Engineering the Future "Infrastructure, engineering and climate change adaptation" report?, February 2011¹



Professor Will Stewart FEng FRET
Southampton University & chair of
the ICT panel

Earlier this year the Engineering the Future group published a report on how infrastructure should be adapted to meet the challenges of climate change and of rapidly-evolving technology.

A major element in the answer to this concern centres on 'smart' infrastructure, which implies the blending of information and communications ('ICT') infrastructures with all others. This is fine and helpful but does mean that all the 'blended' infrastructures will start to see the world more as ICT does. And for ICT, as we are all aware, the world is a highly dynamic place quite apart from climate change. ICT technology is still rapidly developing and all infrastructures are becoming 'smarter', that is more precisely and rapidly monitored, and more swiftly adaptive to changes in user needs and external conditions. This helps efficiency and reduces costs but also increases the interdependencies between the various infrastructures. Essentially, as with any improvement in efficiency,

insofar as smart technology works its effects will get built in to expectations and we will consequently come to depend on it. Less obviously the rapidly-changing technical and demand environment typical of ICT will become typical also of other infrastructures which have traditionally operated on much longer change cycles. But this will also make all smart infrastructures more adaptive to changing conditions, including climate change, which could be very helpful. And in fact the track record for ICT systems in coping with disruptions is generally good – see the later comments on the Japanese tsunami recovery.

But this does need to be considered at the time of design. So future infrastructure systems do need to be overtly designed for adaptation, that is

designed to allow bits of themselves and bits of other infrastructures on which they depend to be changed or improved later without altering the fundamentals of their behaviour in unexpected ways. This tends to involve the use of (international) standard interfaces and a 'modular' approach to the logical (but not necessarily physical) design.

This is one example of the growing interdependencies between the various infrastructures (particularly between all infrastructures and IT & Comms) which can mean that failure in one area can very quickly spread in unexpected ways and in extreme cases can lead to cascade failure. To handle this the infrastructures should be dealt with as a system of systems (as opposed to as independent units).

Although this has nothing particular to do with climate change I note that there are some new hazards associated with smart infrastructures, for example there may be some danger of 'hacking' in mixed infrastructures, as perhaps demonstrated by a recently-reported example². This

... engineers need to develop further their skill in to embracing probabilistic methods and flexible solutions, and in dealing with complex risk scenarios. . .

emphasises the need for a proper approach to security and resilience.

One expected effect of climate change is that **there will be more emergencies**, such as major storms, floods and the like, though of course other things can also cause such events. These will now be more multi-system than in the past because of the growing interdependencies referred to above and thus less easily dealt with within a limited context. The 'system of systems' needs to be resilient. Specifically standards should be adapted to allow resumption of a partial service after an emergency where a full service is still unavailable, and research and experiences from each sector need to be shared.

There is also a need for greater understanding of, and therefore research into, the behavioural changes which are likely as a result of climate change. People are part of the system of systems.

We will be, even more than today, living in a world in which certainty is not possible, but we can aim to know as much as possible about it, and this is easier and cheaper than it was in the past.

Such information as we have is likely to be probabilistic, and this will require some changes of approach. For example engineers need to develop further their skill in embracing probabilistic methods and flexible solutions, and in dealing with complex risk scenarios. And regulations must be developed to deal with probabilistic rather than absolute scenarios. The use of continuous monitoring will allow reactive and timely maintenance across all infrastructure and this can increase resilience.

However, in general getting more resilient is not easy and the best strategies are often counter-intuitive. For example a common reaction to concern over resilience is to set up one's own centralised system under one's own control. But such systems are actually less resilient than dispersed and diverse systems, even when the latter are multi-owned (ask RIM!). A better approach involves careful network design and diversity of supply, even though this may be harder to manage.

But it is not all bad news; modern smart infrastructure is much more adaptable than older 'dumb' versions, and the expected impacts of climate change in the UK will lead to conditions no more extreme than those currently experienced and dealt with elsewhere in the world. And there are other advantages –for example we have ever-greater real-time knowledge of the world in which we live because of an explosion in the number of smart sensing devices ('The Internet of Things'); and this trend has a long way to go. And the UK is already a serious player here. For example in a lecture at the IET on 13th October last ³ Warren East, CEO of ARM, pointed out that there were nearly as many ARM processors shipped last year as there are people in the world, and sales are still rising strongly. About half are for smartphones, but the rest are for other smart devices such as meters.

To maximise resilience we need both smartness and diversity, so that systems can cover for each other. RIM is a lesson here not only because their system was highly centralised but also because people had alternatives, like iPhones & email. Think of smart metering or other infrastructure communications (or health) for

public systems which have diversity issues, any one of which is probably much more critical than RIM.

And as more reassurance it is worth noting that the Japanese tsunami ICT infrastructure recovery experience is in many ways heartening – though complacency would be a mistake. For example, according to a colleague Hiromichi Shinohara of NTT the immediate damage was enormous; 18 offices demolished and 23 flooded, 65,000 poles demolished, 90 routes (~6,300 km total) disrupted and 375 mobile base stations unserviceable. But 90% of the system was recovered in about two weeks and the vast majority within two months (basically almost all except for areas inaccessible because of radiation hazards). But the experience did also highlight interdependency effects – for example the number of failed systems (both mobile and fixed) more than doubled in the 48 hours following the disaster as the backup power systems failed, though these were mostly restored in another few days. And a key 'lesson learned' is the difficulties caused by disruption to other infrastructure such as roads that made repair difficult. But here again there is some

... To maximise resilience we need both smartness and diversity, so that systems can cover for each other. . .

good news – for example in the face of severe congestion in the traditional telephone service (caused by high demand as well as by damage) internet and e-mail services were invaluable. And there are tales of adaptive innovation; for example a colleague Will Franks of Ubiquisys reports that Softbank (a Japanese mobile company) restored some local mobile coverage by combining 'femtocell' technology with satellite phones and generators to create mobile temporary communications base stations.

In conclusion the opportunity exists to react intelligently to climate change and its impact on the increasingly complex, smart, 'system-of-systems' infrastructures. But this will require considerable care and skill, and a meeting of historically very different cultures, even within engineering & science.

Footnotes

1 Available online at www.raeng.org.uk/adaptation

2 <http://www.bbc.co.uk/news/technology-15817335> BBC water pump hacking (US)

3 available for re-viewing at <http://tv.theiet.org/technology/communications/11869.cfm>



"WHAT ARE THE ISSUES AND ACTIONS REQUIRED?"



Brian Collins CB FREng
Professor of Engineering, University
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You will note that the title of this article collapses neatly to “WWW”. That is intended to highlight the World Wide Web as an intrinsic part of what we will need in order to exploit opportunities to deal with a Wetter, Windier and Warmer climate in the future. I will touch on some of the issues raised in the Infrastructure UK plan prepared by the Treasury.

We lack information about infrastructure assets that are between 50 and 150 years old. Collecting data on them has not been at the forefront of anyone's mind. As a result the asset data is inadequate and in some cases inaccurate. And that is causing us a considerable problem in thinking about what we then do with the adaptation of it or the modernization of it in order to cope with climate change. An added complication is that a lot of the infrastructure is regulated and hence data is only collected if either the regulator says so, or it is commercially required; collection for the public good does not happen by default.

The regulatory frameworks are not coherent with regard to resilience. The interdependence between these various infrastructure components means that if one is not resilient it can cause a cascade failure into another, and if you do not have regulations to take this into account before those instances occur, they may indeed occur. The design of infrastructure is disaggregated largely because it is privatized into sectors which are siloed from each other. So the governance of design related to resilience is equally difficult to deal with because of this disaggregation.

We don't do whole life value appraisal. We tend to do cost appraisal of the capital investment (CAPEX) that goes into creating the infrastructure. We don't measure the value of the infrastructure when it is providing a public good and public services. The operational expenditure that is required in order to achieve that is seen as “too difficult”. The whole life value appraisal is therefore not done. We live in a risk-averse culture, so technology, innovation and exploitation is difficult. It is changing, as has been indicated already, but it is changing relatively slowly. The effects of climate change are not slow to have impact.

Academia has been doing a lot of what is called multi-scale modelling for some decades. It has involved taking individual components of infrastructure and aggregating them and taking the aggregated effect in order to extrapolate further and understand the consequences. We have done a lot of that particularly around cities but also in other domains such as transport. There is a lot of knowledge in academia that industry is not taking a huge amount of notice of in this country at the moment. This is not true in other countries.

The economic models need to be more accurate; the financial models, such as public-private partnership funding, seem to be somewhat discredited as a result of recent experience. There is little trust or confidence on how to invest in and pay for all of this. We do not have a mechanism whereby the market knows how to value the public sector. And the public sector is very cautious about what the market may or may not choose to do.

You may think that I am being really negative about all of this. But there is a unanimity of feeling out there that we need to do something about this issue. Everyone is now trying to solve adaptation and modernization at the same time. We need to solve the problems and we need to solve them quickly. I am an optimist. But there is no point in trying to hide from the fact that the list of things to do is not complete and that there is a lot we do not understand. We cannot just tick them off in isolation because they may have relationships between each other. The actions in my view that are now required are holistic, but can be broadly compartmentalized into government, commerce and academia.

Government had firstly to set up Infrastructure UK. It was initiated two and a half years ago and it survived the general election. It is located in the Treasury. It has considerable visibility, not only now in the Treasury but also in the Cabinet Office and increasingly in No.10. So Infrastructure UK is a body that is gaining attention, not only because of what it is doing to deliver the current political agenda, but also because it is moving the agenda ahead more quickly than in the past which is good news.

In the same context is the cost review, carried out by a combination of the Cabinet Office and the Enterprise Reform Group, where we need to look and see why it costs as much as it does to build infrastructure in this country, because we know that it costs more in this country than it does elsewhere. Identifying those factors is one thing. Doing something about them is something else.

There is considerable investment by the Technology Strategy Board (TSB) and by RCUK representing all the Research Councils, of which three are predominant in this field, principally Engineering and the Physical Sciences Research Council (EPSRC), Natural Environment Research Council (NERC) and the Economic and Social Research Council (ESRC), in creating a body of knowledge and some innovative capability to change the way we research infrastructure. That body of knowledge has been invested in already and EPSRC, in particular, is looking to increase its investment. I am talking here about hundreds of millions—not a small amount of money—across a broad range of different areas of science, technology and engineering. In the Department

for Business Innovation and Skills (BIS), across a range of regulatory aspects, there is work to see what reform is feasible and what the migration route would be to deliver more coherent frameworks by making more data available, and to ensure that the data that is available can be exploited.

There is also a lot of work on planning reform and the issue of planning and localism and how they interact. This has been seen as one of the major impediments to progressing infrastructure investment and the planning reform activity is aimed at trying to do something about it. Of course this is contentious. I am not suggesting that it is not! It is one of those areas that we need to think about from a number of different viewpoints to see where the consensus ends up. That is for government to pursue.

What commerce is doing is gathering data about the assets, because most of them are run by private sector organizations. So they are being persuaded, using a number of mechanisms, that asset data is good for them and on top of that to manage the information they have got in a much more coherent way. If we can do this really well, and we have some of the best information management academics in the world, we could export this know-how in a way that would be very beneficial to our economy.

Programme management is also important, such as how we invest in power stations, utilities, and railways — such as Crossrail for example. Programme managers are required to deliver engineering, civil, mechanical and information technology, both on budget and on time. Sir John Armitt has provided an excellent example with the

Olympic Park and we are learning from John in order to take that message elsewhere.

Understanding where the skills are going to come from is crucial, and commercial organizations are now mounting apprentice training schemes with considerable government encouragement in order to provide themselves with what they need for the future so that they can survive. They are beginning to embrace innovation. So having said that industry is risk averse, it is now moving in a direction to becoming less risk averse.

Academia has a large amount to offer, I believe. We are looking at how you govern these infrastructure activities that are by definition multidisciplinary. We do not know yet how to govern them. And this is not trivial due to the knowledge required, the complexity of their structures, and commercial objectives using value-based economics. What are the social aspects of infrastructure as an emotional as well as a live-able experience is an extant research question.

Many of us live in and around cities. It is one thing to think about the rural economy we used to have in this country—but actually now most of our GDP comes from cities. We also have to continue to think about whether that is where we want to continue to go in lifestyle terms by exploiting our interdependent and networked infrastructure and also deciding where we are internationally. Academic studies of issues such as these add a body of knowledge that provides evidence to politicians and helps leaders of commerce decide what they want to do.

So what are the urgent specifics? How should we manage cities and underground infrastructure? What will be the

effect of (unusually cold) winter weather? The previous Secretary of State for Transport asked me, “How often will this occur in the future?” It was a very easy question for him to ask but it was absolutely impossible to answer. It comes back to questions of probability, uncertainty and distribution. Health, finance and logistics are all influenced by information and communications technology (ICT), which is a crucial part of the infrastructure and affects everything else if it fails, such as the unknown effects of Wetter Warmer Windier (WWW) on the World Wide Web (WWW).

So what are the world wide effects which may mean that our infrastructure closes down? It may mean that available services are reduced, with a repair time that could be days or months. It may be cascade failure that may be un-repairable. We do not know in advance which one of these situations applies as these phenomena have not been modelled at this level of sophistication and complexity. When the snow hit Heathrow three questions were asked by the Secretary of State for Transport: “Who is responsible?” to which the response was: “BAA!” “Who has authority to do something about it?” Again: “BAA!” “Who is accountable?” “Probably in the minds of the general public, the Secretary of State for Transport!” At the end of the day the public like to hold the appropriate Secretary of State accountable for the wellbeing of all of these infrastructural components. The lack of alignment between responsibility, authority and accountability is absolutely crucial for governing resilience in abnormal circumstances and managing and maintaining normal operations. We currently do not have that and we need to do something about it.

IS SCIENTIFIC FREEDOM THE ELIXIR OF CIVILISATION?

Meeting of the Parliamentary and Scientific Committee on Tuesday 22nd November

"SCIENTIFIC FREEDOM: WHY WE MUST PROTECT IT"



Professor Donald W Braben
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SUMMARY

Like much of life, scientific research funding today is dominated by bureaucracy. However, science is concerned with exploring the unknown whereas procedural correctness is paramount in bureaucracy. Most scientists can manage the essential conflicts in this arrangement but it is impossible to do so when the science involves radical challenges to what is known. Such challenges are rare, and so the number of scientists whose work is directly and adversely affected by these new arrangements is very small. Their voices therefore generally go unheard, but they could be answered by modest changes to existing arrangements. Little or no new money would be required, but the national benefits could be substantial as transformative discoveries have often followed such challenges. The Research Councils seem unaware of this significant problem; indeed they are adding new bureaucracy by insisting that applicants also outline the

potential national importance of their work before the work itself will be considered for funding. But crystal balls are unreliable. Recall that Werner von Braun once said: "Research is what I do when I don't know what I'm doing". His ideas subsequently inspired the creation of the space industry. There are proven techniques for identifying such people, but they are incompatible with bureaucracy. Bearing in mind that the boosts they gave to the 20th-century global economy would be measured in \$100s of trillions, my answer to the question posed by the meeting is therefore "yes", but it's under serious threat.

PRESENTATION

The 20th century was dominated by the work of some 500 highly creative scientists. Most were academics. Their discoveries included: nuclear power; penicillin; DNA structure and molecular biology in general enabling much of biotechnology; lasers; magnetic resonance imaging; electronics, computers, and telecommunications; monoclonal antibodies; genetic fingerprinting; carbon-60 and nanotechnology; the internet.

Almost all of them had radically challenged conventional thinking, their work was generally open-ended, and few of their discoveries were immediately accepted. None were predicted. The cumulative global value of the technologies they spawned in real terms would be measured in \$100s of

trillions. Life today would be unthinkable without them.

I call this group, "The Planck Club", named after one of its most prestigious members, Max Planck.

Their work could progress because before about 1970 academic research was essentially unmanaged. Funds available were usually modest, but scientists could explore ideas without external reference. For most of the 20th century, UK-based scientists were exceptionally good at making Planck-Club calibre discoveries as the record shows. (Between 1945 and 1989 the UK, with less than 1% of the world's population, won 19% of scientific Nobel Prizes.) In contrast today, all scientists must compete with each other for funds. Success rates are low - typically ~ 25% or less in some fields. Funding agencies today seem to ignore the question - which Planck-Club member would be funded under today's rules *when they were setting out?* - I call this the "Planck Test". Consequently, they fail to acknowledge the serious problems today's rules are creating.

Robert M Solow (MIT), the American economist, won the Nobel Prize in Economics in 1987 for his discoveries that showed that:

- "technical change" is the main driving force for economic growth
- capital, labour, and resources play much smaller roles

Transformational - Planck Club - discoveries are therefore important stimulants for economic growth. Perhaps investor confidence is boosted by the facts that the fields they create are open with few competitors. Unfortunately, Solow's important discoveries tend to be ignored by funding agencies today.

It is ironic that government now says it wants to make the UK the best place in the world to do science. However, for much of the 20th century the UK indeed had that reputation, as its Nobel-Prize performance alone confirms. The research and funding councils' funding policies have over recent decades seriously eroded that huge advantage, and created the situation that government now seeks to redress.

For example, in 1993 government changed the Research Councils' Royal Charters charging them with contributing to the UK's competitiveness. Hitherto, they had merely been responsible for supporting excellent research - timeliness and promise were the overriding selection criteria. Those who initiated this change ignored the fact that Planck Club members initially had few if any competitors. Their work was unique. The Research Councils have now imposed an additional policy, "Pathways to Impact", which requires applicants to outline in their initial submissions the potential economic or social impact of their research, and the steps they propose to take to realise

this potential. This additional information is then considered as part of a researcher's total submission, graded by peer review, and finally incorporated into an overall assessment using some esoteric formulae. The Research Councils ignore the fact that even industrialists find it almost impossible to predict future potential.

This new policy inhibits creativity because it forces academics to consider factors other than the purely scientific when contemplating what they want to do next. Thus:

- Long-term, open-ended studies are discouraged
- Young people are disadvantaged
- They create distractions and waste taxpayer's money

Difficult and intractable scientific problems not only

require great courage from researchers, but also sustained and total concentration. Possible examples of this type of problem today include aging, consciousness, chemistry-at-a-molecular-address, the nature of gravity, and the origin of life. Many Planck-Club discoveries were similarly inspired. However, it seems most unlikely that proposals to tackle such problems would survive today's bureaucracy. But there are proven techniques for allowing them to do so that have been specifically designed to pass the Planck Test - indeed one is operating at University College London today.

I pose a difficult question for us all: Will the universities (or industry) spawn a 21st-century Planck Club? We had better be confident in our answer. As things stand, the odds are highly against it, whence the

consequences for civilisation could be grave. We must stimulate effective action.

I conclude with a tongue-in-cheek metaphor and a picture of Easter Island in the Pacific Ocean taken from my last book: *Scientific Freedom: The Elixir of Civilization*, Wiley 2008. Before it was inhabited, the Island was lush and tree-covered. The arriving population subsequently split into factions, which

apparently were highly competitive. They accorded the highest priority to stone-statue building. Unfortunately, the trunks of very large numbers of trees were required to place the statues in their final positions. Trees were felled with abandon, and it would seem that nobody asked if the Island's supply of trees could cope. The warning signs were ignored, an inaction that devastated the Island, as the modern picture shows.



IS SCIENTIFIC FREEDOM THE ELIXIR OF CIVILISATION?

HOW ARE HEFCE AND RESEARCH COUNCIL POLICIES UNDERMINING SCIENCE AND THE NATIONAL INTEREST?



Professor James Ladyman
Head of Department of Philosophy,
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IMPACT FACTORS

The research council's charter requires them to promote the economic and other benefits of research. It was pointed out that they are not required to do this on a grant-by-grant or even subject-by-subject basis, but rather as part of their overall activity.

The disagreement between those present was about means, not ends. In particular, everyone agreed that applied science is vital for UK industry and that links between academics and industrialists must be encouraged and nourished.

However, a number of those present argued that some areas of scientific research are necessarily remote from direct

and immediate application, but are nonetheless vital either because they feed into areas of science that are more directly applicable and/or because they may give rise to or be important for future applications of which we can necessarily have no inkling, since they will be based on discoveries that have not yet been made. The research councils might therefore

consider whether it is really appropriate to have the same approach to impact for research applications in synthetic biology as they do to those in pure mathematics.

Everyone agreed that a lot of scientific activity is routine and procedural, rather than the stuff of Nobel prizes and profound changes in theory. However, even routine science only works because of scientific culture and values. If they are undermined,

then even routine science will also suffer. For example, progress is often made by data gathering, fastidious checking, and care and attention to detail, all of which most of the time don't produce any impact, but which are vital to the integrity of the process of science, and occasionally throw up something new.

The research council representatives were at pains to emphasise their continuing

support for pure science, and it is agreed by all that they are not intending to undermine blue skies research in any way. However, it is often the case that institutions and individuals over-respond to incentives and that schemes such as pathways to impact have unintended consequences.

Many of those present expressed concern about doctoral training centres and the overall reduction in postgraduate

grants and the removal of postgraduate funding from responsive mode grants.

Many voices objected to increased research council micro-management of science.

See article by Professor Ladyman in Science in Parliament Summer Issue 2011 (Vol 68 No3)

IS SCIENTIFIC FREEDOM THE ELIXIR OF CIVILISATION?

IS NURTURING THE RESEARCH ENVIRONMENT AN ALTERNATIVE PERSPECTIVE?



Professor Benjamin G Davis
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This analysis of research environment is unashamedly set in the context of science that it might help to enable. We are at a cusp in the development of the UK that will be defined by the opportunities we identify. We have long been scientifically creative and we are well-placed as a nation to embrace science as a possible industry even more heavily. Based on these strengths, we stand at a good point from which to evaluate various potential models for ways forward.

An illustrative burgeoning area stems from a 50-year-old revelation of Biology at the molecular level. Francis Crick powerfully and beautifully analysed the implications of his discovery (along with Watson) of a molecular basis of inheritance. The central upshot: the most important biomolecules – the proteins (the workhorse molecules of biology) – have their function controlled in an

indirect way from the source code, deoxyribonucleic acid (DNA). This indirectness is now being valuably challenged by chemists and biologists – we have a vision of a biology that may be more directly tuned at the molecular level, a Synthetic Biology. This field, and focused examples, can be used to illustrate how properly considered environment might influence outcomes in far-reaching research.

The principle of vaccination has been with us, in essence, for centuries. Nonetheless, striking goals remain, amongst them development of vaccines for many pathogens that lack a 'cure', such as HIV. Proteins on the surface of pathogens can be analysed structurally ("visualised") through various methods. By identifying those that are important to the pathogen, such as the HIV-coat-protein gp120, we can now envisage mimics. These mimics,

given to a patient, might elicit antibodies that recognise key features. This use of mimics 'trains' host immune systems with a potential to recognise and neutralise pathogens. By enabling the creation of such mimics, Synthetic Biology can address such important goals, whilst also testing fundamental hypotheses regarding the molecular nature of Immunology. Such work 'stand[s] on the shoulders of [many] giants'; a timeline of innovation stretches back to the late 18th century and to Jenner, who used intact and mock pathogens for such mimicry. Although, in the early 20th century, this process was partially refined (using instead fragments of pathogens), in many respects currently licensed vaccines are essentially similar in design and strategy. In time we hope that we will be able to apply modern chemical assembly to Synthetic Biology to

fully 'design' mimics as vaccines. However, until that time, examples of the current state-of-the-art are illustrative of both potential and of how environment will be instrumental in the development of this future science.

These advances will test our existing approaches. To my mind, a leading example is a vaccine called *QuimiHib*, sold by Heber Biotechnology. It is used to treat *Haemophilus influenzae* type b (Hib), a pathogen that, before the introduction of Hib vaccines in the late 1980s, was the leading cause of bacterial meningitis in children in the United States of America (since reduced by >95%). Notably, use of the vaccine in developing countries has been slow due to cost and availability. The World Health Organization estimates that in the developing world Hib kills ~350,000 pa, mainly under five-years-old. Heber is a company that few will have heard of; it is Cuban and the model that led to *QuimiHib* is unconventional.

One key portion of *QuimiHib* is entirely synthetic – rather than being isolated from pathogens, it has been chemically assembled before incorporation into the vaccine. It is thus the first of its kind [Verez-Bencomo et al, *Science*, 2004, 305, 522] and was developed by an academic team (led by Vicente - Bencomo-Verez) in Havana in collaboration with a Canadian chemist (René Roy). The 99.7% success rate of *QuimiHib* led to its direct incorporation, in 2004, into Cuba's national vaccination programme.

What were the elements of success that led to such unprecedented translation? Vision was necessary: national centres of excellence were supported (eg CIGB, Finlay Institute) at a bold level given the corresponding national GDP.

There was pressing societal need: only 2% of the world's children were protected by the prior (pre-2004) Hib-vaccination regimes. Prevailing legislative backdrops created an incumbent necessity to avoid developed-world spin-out routes or interaction with large pharmaceutical companies – this created the need for a disruptive business model. *Verez-Bencomo* evoked the associated ethos of academic and social courage for the resulting national collaboration rather than market-driven competition: "It's a collective achievement of the accumulated intelligence of our country". In the backdrop of the UK's climate of 'impact assessment' it is interesting to note that many typical 'metrics' of output were met by Heber: >60 patents, technology transfer, joint industrial projects, extensive exports. Yet Heber's sales are measured in the tens of millions of dollars, a fraction of competitor operations in the developed world: "Our objective is not to make money. Of course, we can't give the vaccine away. We must sell it. But money isn't the objective of our biotech industry, it's the means. We're substantially different from [transnational corporations] TNCs which serve under their own banners, because we work under the same banner as our country and share social and human objectives rather than purely financial ends." (*Carlos Manuel Mella Lizama, Heber Biotech*).

Could this happen elsewhere? One can argue that few countries possess similar (correctly?) integrated systems combining fundamental discovery with appropriate need and ability: in this scenario, advanced fundamental scientific enquiry plus effective socialized medicine; however, in many cases, the UK thankfully does.

Could, therefore, such models emerge in the UK? Synthetic Biology is just one science that could provide a useful disruptive influence (a novelty that demands a reassessment of current systems) that would address current or future crises. What would be needed for an environment that would support it or other parallel disruptive models in other disciplines? It would be trite and intellectually lazy to focus simply on increased resource or even changes in associated regulation. These are important but only part of the issue. I would argue that we also need to consider three things.

Firstly, a long-term and fresh view of the value of fundamentals in science is essential. This may require investment in models that will yield only very distant results e.g., vaccine investment in 1970s treats disease in 2004. We should strongly avoid 'pork barrel' funding in response to lobbying that might (and recently has) led to knee-jerk support of certain narrow scientific topics, no matter their immediate cosmetic attraction. Haldane principles have valuably guarded the UK's intellectual integrity and rigour. Bernal [Bernal, J.D. (1939) *The Social Function of Science*. London: Routledge] and Zuckerman's points on the 'function of science' are equally well-taken; however, all-too-often a false opposition is created between social good and researchers' freedom. We must trust in expert vision, through responsive-mode, peer-reviewed, bottom-up solutions to a challenge and then (plurally) support it. Since creativity can be equated, in some measure, to levels of individuality as well as expertise it should not be micromanaged: we need to nurture future

experts, not generate armies of trainees. Moreover, sciences such as Synthetic Biology that exploit and explore multiple fundamental topics are not handled well by organisational 'silos' – they will break these moulds. We may, therefore, need to question some existing frameworks here in the UK (eg BBSRC+EPSRC+MRC+NERC+S TFC+MHRA...) and elsewhere (eg NIH+NSF+DARPA+BMGF +FDA...).

Secondly, we should aim to more broadly identify how such creativity adds value and where this value lies. We should stop confusing pre-competitive research with competitive; the hallmarks of success are very different. We should learn lessons about the 'icons' of technological impact eg *QuimiHib* cf *Avastin* – what have been the true, associated, global benefits and efficacies. As a nation, for example, we should perhaps be proud that we have grasped the nettle of this analysis in some cases (eg QALYs). We will need to learn the lessons of historical national success and failure (eg Li-ion batteries, monoclonal antibodies are pertinent to the UK). We should create an environment as a 'midwife' to these ideas rather than falsely induce their birth. Boston, MA, oft-cited as an ideal, has strengths that are largely passive (simply clustered). Let us populate that supportive landscape with appropriate people; the model of the CEO as a 'hero' has served many smaller companies poorly and we should encourage the emergence of some genuine *Masters of Business Administration*. This will also need us to clearly distinguish innovation from entrepreneurship. Here, by recognising, that value is not tantamount to monetary reward for many innovators, we will better understand their

motivations. In turn, this will allow us to reward, for example, a desire to add value to the community by creating a better environment for further innovation. Few currently in academia chose their profession for the money.

Finally, all this may necessitate alternative models for addressing pressing challenges (again there are pertinent UK narratives eg

Penicillin's development by Florey, Chain and Heatley). We may need to acknowledge that certain existing institutional models are creaking or even broken eg large pharmaceutical companies as the primary 'drivers' in medicinal research. Aspects of current intellectual property legislation make it a blunt tool. The role of naked competition in solving large-scale problems may need to re-

evaluated in the light of 'national collaboration' or distributive alternatives.

It might be said that far from being an alternative perspective the 'Havana model' is instead one innovative solution that could be taken to fresh and exciting heights. In this context, I wistfully note that the individual (Crick) who has been a scientific inspiration for my own group's perspective on this burgeoning

scientific frontier has also been chosen as the totem for the UK's largest and most bold centre of excellence, which will open in the heart of London in the coming decade. With vision, courage and support, the stage is therefore, in some part, potentially well set.

IS SCIENTIFIC FREEDOM THE ELIXIR OF CIVILISATION?

UK'S APPROACH TO RESEARCH DOES NOT LIMIT THINKING



Professor David Delpy
Chief Executive and Deputy Chair,
Engineering and Physical Sciences
Research Council

The UK has a strong and vibrant research base which continues to produce some of the world's most important scientific discoveries and talented academics, as well as attracting inward investment from global businesses. The UK has only one per cent of the world population but invests in five per cent of the global research and produces 14 per cent of the world's most-cited scientific papers.¹

Government research funding, allocated through the UK's research councils, has consistently supported innovative scientific, sociological and technological developments that have both pushed at the boundaries of conventional thinking and brought change to the everyday lives of people at home and across the world.

However, despite this pedigree, some hold the view that the way research funds are allocated means that imaginative projects are held back. They maintain that the process of

peer review is inherently too conservative in approach and that therefore discovery-led research is less likely to get approved.

This is far from reality. A recent review² of Nobel prize-winning research showed that over 50 per cent had been funded through government sources and agencies which will have been through peer review.

A relevant example is the work of Sir Andre Geim and Sir Konstantin Novoselov, Professors at the University of Manchester, who were awarded the Nobel Prize for Physics for their work with the revolutionary material graphene, which has the potential to replace silicon in integrated circuits and a host of other applications.

The success of Geim and Novoselov would not have been possible without long-term and strategic funding, which began 10 years ago.

Sir Andre says: "The EPSRC grants that got us started

supported curiosity-driven projects, which are generally not expected to have application, certainly not in anything other than the very long term.

"Graphene research is still a very new area, so we are still at the stage of assessing applications for the material – but already the initial investments have been returned in taxes, and in 10 years' time the government will have its investment repaid a thousand times over."

The presumption that applications for funding to carry out discovery-led research fare worse than those for applied research is also baseless. Statistics collected by EPSRC show researchers who succeed in applying for funding tend to be successful in both discovery-led and challenge theme-led research because their projects are excellent per se.

There is a high level of overlap between the populations of researchers supported through both discovery-led and

challenge-led modes. Between 1999–2008 the majority of EPSRC research funding (62%) was allocated to researchers who received both types of funding. Among the top researchers, those who consistently submitted successful applications for funding, 67% were successful across both modes and accounted for 84% of EPSRC funding.

The relative citation impact of the UK research base (1981–2007)⁵



Likewise, it has been suggested that an increased focus on the commercial application of research is detrimental to the health of a research base. Jerry and Marie Thursby³ looked at this very claim in relation to the effects of the Bayh-Dole Act on basic research in the US. The Act ensured that the intellectual property contained in research rested with academics and prompted a worry that only applied research projects would be pursued.

They concluded that at the eight major US universities, while there was growth in applied research, the level of basic research also rose.

Similar concerns were voiced about the introduction of the need to demonstrate the impact of research and inclusion of the criterion of national importance in applications for funding. The research councils and government have monitored the relevance of research to

beneficiaries since 1994. The Research Assessment Exercise shows that the quality of research has consistently risen over the 17 years since then and independent comparisons to other countries show citation rates and impact as consistently high, second only to the USA.⁴

The Natural Environment Research Council commissioned Evidence Ltd to undertake bibliometric analysis in 2008⁶, it showed impact was very similar across research funding modes. The highest quality consistently came from the funding of fellows and in the last year of analysis (2005) directed mode grants had a higher citation impact than responsive mode.

A similar analysis of the impact of EPSRC-funded research in 2009 found no significant difference in citation performance for papers arising from 'Responsive' and 'Targeted' funding modes. The proportion of papers highly cited (cited ≥ 4 times the relevant world average) was 9.2% and 8.6% respectively. The overall citation impact, 1.6 times the world average, was the same for both funding modes.⁷

Maintaining novel approaches and creativity in research is absolutely essential to the long term future of our research

base. The scientific community is monitoring this through the peer review system to ensure creativity flourishes.

In an EPSRC analysis of applications presented to peer review panels since September 2009 reviewers reported that there was no drop in the level of adventure or creativity of those applications receiving funding.

The UK's reputation for high quality researchers and research facilities brings valuable investment into the country. There is a high incidence of multi-national organisations choosing to co-locate their business's R&D with relevant UK university research departments.⁸

Data from the OECD shows international business invests more in research and development based in the UK than anywhere else. Over 20% of business R&D in the UK is funded with investment from abroad.⁹

A recent report¹⁰ commissioned by the Department of Business Innovation and Skills says that "while the UK spends far less in absolute terms on research than the US, China, Japan or Germany, recent trends indicate that it is becoming even more efficient than all four in terms of output per unit spend. The UK is also becoming more efficient over time in terms of output per researcher and per unit of research spend."

The UK is the clear leader among all eight comparator countries (Canada, China, France, Germany, Italy, Japan, UK, US) on citations per unit spend on Gross Expenditure on Research and Development."

It is clear that the UK punches above its weight in terms of research quality and is increasing its reputation in fields in which it already has strength.

To maintain this high reputation and investment income the research community needs to continue to use its robust, proven systems to monitor both the quality of the research it funds and ensure that new ideas have a healthy environment in which to grow.

Footnotes

- 1 International Comparative Performance of the UK Research Base – 2011 by Elsevier on behalf of the Department of Business Innovation and Skills <http://www.bis.gov.uk/policies/science/science-innovation-analysis/uk-research-base>
- 2 Tatsioni, A., Vawva, E., Ioannidis, J.P.A. Sources of funding for Nobel Prize-winning work: public or private? *FASEB J.* 24, 1335–1339 (2010). www.fasebj.org
- 3 Has the Bayh-Dole act compromised basic research? *Research Policy* (2011) Volume: 40, Issue: 8, Publisher: Elsevier B.V., Pages: 1077–1083 ISSN: 00487333
- 4 International Comparative Performance of the UK Research Base – 2011 by Elsevier on behalf of the Department of Business Innovation and Skills <http://www.bis.gov.uk/policies/science/science-innovation-analysis/uk-research-base>
- 5 Funding selectivity, concentration and excellence - how good is the UK's research? Jonathan Adams and Karen Gurney - March 2010 Hepi <http://www.hepi.ac.uk/466-1793/Funding-selectivity-concentration-and-excellence-how-good-is-the-UK-s-research.html>
- 6 NERC Citations Study 2008 NERC Research Outputs Database 2003–2005: Bibliometric baselines September 2008 <http://www.nerc.ac.uk/about/perform/documents/citations-study-2008.pdf>
- 7 EPSRC Citations Study 2009 Evidence, Thomson Reuters www.epsrc.ac.uk/SiteCollectionDocuments/Publications/Other/citationstudy2009.pdf
- 8 University Research and the Location of Business R & D Abramovsky L., Harrison R. and Simpson H. (2007) The Institute for Fiscal Studies WP07/02 <http://www.ifs.org.uk/publications/3829>
- 9 OECD main databases
- 10 International Comparative Performance of the UK Research Base – 2011 by Elsevier on behalf of the Department of Business Innovation and Skills <http://www.bis.gov.uk/policies/science/science-innovation-analysis/uk-research-base>

WHAT IS MEDICAL INNOVATION?



Allison Jaynes-Ellis
Medical & Innovation Director, ABPI

The story of the discovery in 1928 of penicillin – the original ‘wonder-drug’ if ever there was one – is today part of the lore of medicine. Most people know how Sir Alexander Fleming discovered the killing powers of the penicillium mould in an accidentally-contaminated bacterial culture. Fleming received the Nobel prize for medicine for his work in 1945. Yet it is a very long way from a mouldy petri dish to today’s modern armoury of antibiotics. Fleming’s part in the story, though seminal, is but a fraction of it. Moreover, the urgent quest for new antibiotics to combat resistant strains, highlighted by Professor Laura Piddock and Tracey Guise in the Autumn 2011 edition of *Science in Parliament*, shows us that continuous innovation in drug development is both vital and inevitable.

The profound impact antibiotics have had on our lives is no longer the product of

chance discovery but has come about thanks to mankind’s ceaselessly probing nature. Every one of today’s medicines is the result of countless small steps forward: an incessant process of learning and improving so that each new agent takes us further than we have gone before. Innovation is not about eureka moments. There is no switch that puts the bulb on or off. It is more like turning up the dimmer control: gradually intensifying our capacity to understand, overcome and treat.

The Office of Health Economics will shortly publish the second edition of its report *The Many Faces of Innovation*. It will describe how it is this process of incremental innovation that has given us the vast array of medical treatments at our disposal today. Drawing on examples from several therapeutic areas, the report will show how in every case step-by-step improvements have brought important benefits over and above the original concept. These benefits have several dimensions to them. Incremental innovation can lead to a medicine that is more effective than the one before, or which has fewer side-effects. A newer product might be easier to take, making it more convenient for the patient and aiding adherence. It may be more cost-effective. It may have particular value treating specific groups of people with the underlying disease.

These added advantages are seen both in new classes of medicine and within class. Later types of agent for hypertension, for example, have led to

improved health outcomes, with a significantly reduced risk of death from events associated with raised blood pressure. The new generation of anti-epileptic drugs were better tolerated than their predecessors, with less risk of harmful interactions with other medicines. This was particularly important for elderly patients, for example, who are more likely to be taking a variety of medication.

The cholesterol-lowering statins meanwhile provide an excellent example of how innovation expands our options within one class of medicine. Later statins were more potent than the earlier versions, with a corresponding impact on outcomes. If there had only ever been one statin, that would have been good in itself; but nowhere near as good as the spectrum of products available today, allowing doctors to tailor treatment to their patients’ needs.

Incremental innovation is not only the essence of medicine development. It is also important in public policy, and about to become more so as the Government embarks upon reform of how prescription medicines in the UK are paid for. This will be a challenge not just for the pharmaceutical industry, which is under increasing pressure in a finance-dominated environment to justify itself as innovative, but for policy-makers too. They must find ways of providing incentives for the progress and innovation that will help improve NHS productivity in the medium term, while bearing down on costs in the shorter term.

The Government wants a new system of ‘value-based pricing’ to be in place two years from now. The shape of things to come is starting to emerge. The Government’s consultation paper issued in December 2010, for example, states that the new system would ‘[aim] to recognise and reward innovation, in particular by encouraging a focus towards genuine breakthrough drugs, which address areas of significant unmet need’. Later the same document talks about focusing on ‘achieving genuine step changes in clinical performance, rather than seeking just to make incremental changes’. This is in the context of growing reluctance on the part of payers across Europe to recognise and reward innovation beyond a very limited definition of the term.

It is welcome that a paper on pricing recognises innovation as something that matters; however, the nature of some of these comments suggests that a restrictive definition of innovation may be used. How the government defines innovation in the new scheme will be critical to whether it achieves its stated objectives. It is therefore important that the government has a thorough understanding of the nature of pharmaceutical innovation, to inform its policy approach.

Pharmaceutical R&D has four key characteristics: it is highly complex and uncertain due to a significant scientific challenge at early stage and recurrent risk of failure at clinical phases; timelines to develop new products are long (over 12 years

on average); it costs much more than in other sectors to bring a new product to market (£1.15bn per new medicine, including the costs of failure and capital); and there are very close links between the private and academic sectors.

The uncertainty and length of time involved means the outcome of a research project will not be known until many years after the decision to invest has been made, and significant sums have been spent. Companies aim to have a portfolio of high-risk and low-risk projects and the extent of innovation is unpredictable at the point when the investment in R&D is made. Understanding this is important in order to provide the right economic incentives to generate socially valuable R&D.

Pricing systems provide signals to the pharmaceutical industry about whether and where to invest in R&D, depending on what is rewarded and how. The relationship

between pricing mechanisms and rewards for innovation was discussed in the WHO Priority Medicines Report of 2004. This report argues, among other things, that prices in Europe are set at levels that do not fully reward innovation. This, along with delays to reimbursement decisions, leads to uncertainty among stakeholders and encourages companies to launch their products first in non-European markets.

Given the importance of pharmaceutical R&D investment to the UK economy, these considerations should command the attention of policymakers. To encourage continued pharmaceutical investment in innovation, the steady process of incremental advance and the different dimensions of innovation will need to be recognised and rewarded. Looking at the history of medicine development shows that it is just such incremental advances that have led to the considerable improvements in,

for example, antibiotics, anti-epileptics and statins, that have had such major patient benefits.

Therefore, a value-based pricing system will need to allow for a broad definition of innovation. Any policy that does not recognise all aspects of value in a new medicine, including value that accrues outside the health system, and that might increase the uncertainty of reward that companies face, might end up discouraging potential worthwhile R&D investment.

It is still early days for value-based pricing and the new system can – and must – be designed to recognise the reality of incremental innovation. Innovation is a complex, multi-faceted and uncertain matter and valuing it will undoubtedly be a daunting challenge. It is vital we succeed. Whether it is antibiotics or cancer, HIV or heart disease, our success in pushing medicine to its limits is inextricably tied to how well we

recognise and incentivise innovation. Only rewarding eureka moments would choke off that potential.

The stakes are high, not just for our health, but for our pharmaceutical and biopharmaceutical industries as well. Late last year, the Prime Minister launched the Government's life sciences strategy, acknowledging the importance of these industries to growth and jobs. Finding the way through to incentivise incremental innovation in pricing will be an important test of that strategy's durability and strength.

IMPLICATIONS OF THE NEW EU DIRECTIVE REGULATING ANIMAL EXPERIMENTS FOR THE UK

Dr Maggy Jennings OBE
Head of Research Animals Department, RSPCA

On 9 November 2010 a new European Directive on the Protection of Animals used for Scientific Purposes (2010/63/EU)¹ came into force. If this is implemented in line with the intentions encompassed in its recitals, there will be a significant improvement in the regulation of animal experiments in many Member States. However, in the UK, which already has a well-developed law regulating animal use, there could be serious negative consequences.

The Directive is largely based on the UK Animals (Scientific Procedures) Act 1986 (ASPA), but as Home Office Minister Lynne Featherstone MP has acknowledged, a number of its provisions are 'potentially less stringent'.² For example, a higher

level of suffering could be caused than is currently permitted – an exemption clause allows researchers to make a case for using procedures involving long-lasting severe pain, suffering or distress that cannot be ameliorated –

and it could allow animals to be used again after a procedure, causing severe suffering. Minimum cage and pen sizes for some animals may also be reduced, affecting both the space available for animals to move around and the capacity to provide appropriate environmental complexity.

If implemented in the UK, these changes alone would represent a significant retrograde step for animal welfare and humane science. The situation is exacerbated by the fact that current UK law is implemented through Codes of Practice, Guidance and protocols that interpret the Act and set out the expectations of how it should operate in practice. Over the years, these have provided the opportunity to improve on the statute, so that the regulation of animal experimentation in the UK has developed into a system that is commonly stated by successive Governments and spokespersons for industry and academia to provide strict regulation and high welfare standards. However, in transposing the Directive, the Codes of Practice and Guidance will also have to change – and it may not be for the better.

Member States are given some freedom to maintain their current standards where these are higher than in the Directive, so one might expect existing UK standards to be retained. But there is intensive lobbying by some factions within industry and academia to adopt just the minimum standards and reduce the regulation associated with animal experiments.

In transposing the Directive, the Home Office also seems to be considering transferring more control from the Home Office to individual establishments. Whereas there are advantages in the latter bearing greater

responsibility for what they do, it is worrying that controls at a local level could also be significantly reduced if the current local Ethical Review Process (ERP) is replaced by the Directive's 'Animal Welfare Body', which has a reduced membership and remit.

Compounding all of these problems is a recent reduction in the Home Office Inspectorate. Inspectors are central to the functioning of the current UK system; they not only authorise research projects and inspect establishments for compliance, but also provide scientific and welfare advice which is greatly valued by the research community and has provided a driving force in raising UK standards of both welfare and science. Any further reduction in Inspectorate numbers would be especially hard to understand given the universal acclaim within the research community for the work that they do, and the fact that the entire running costs of the Animals in Science Regulation Unit are covered by licensing fees. Given the level of public concern over animal experimentation, it is surely completely unacceptable to reduce the Inspectorate and therefore reduce the safeguards and protection for animals.

Animal welfare organisations such as the RSPCA are not alone in these concerns about the future regulation of animal experiments within the UK. Many of our colleagues at the 'coal face' in industry and academia are also deeply worried. Pressure to reduce regulation of animal use often cites the need to maintain a competitive science base for the UK. But competitive science has to be good science, and this is now widely recognised as depending on good animal welfare. There are many factors that affect competitive science

that have nothing to do with 'bureaucracy'. These include the poor standard of experimental design and reporting and questionable validity of some animal models increasingly acknowledged in the scientific literature,^{3,4} together with a lack of basic understanding and respect for animal behaviour and biology. In the RSPCA's view, the scientific community ought to address these issues if it is truly concerned about the quality and competitiveness of UK science.

To conclude, choosing to adopt the new minimum baseline regulations set by Europe, whilst at the same time reducing the Home Office Inspectorate, would be a false economy that could have serious implications for the welfare of animals, the quality of science, and for public confidence that animal experiments are appropriately regulated and controlled. It is difficult to see how this would equate with the declaration of the House of Lords European Union Committee that there should be 'no weakening of standards in the UK'⁵ and with statements by Home Office Minister Lord Henley giving 'an absolute and categorical assurance that we will not be dropping our standards in any way whatever'.⁶ However, the devil is in the detail, and there are conflicting opinions amongst different stakeholders as to what might actually constitute a 'weakening' or 'reduction' of standards. As we have heard delegates in expert working group meetings significantly downplaying animal suffering, and even arguing about whether animals can experience suffering at all, the RSPCA would argue that the need to protect laboratory animals and give them the benefit of the doubt is as strong as ever – and it is

important that the new system of regulation reflects this.

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WHAT YOU NEED TO KNOW ABOUT ANIMAL RESEARCH TODAY



Barbara Davies
Communications Director, Understanding Animal Research

When the FGF20 gene was 'knocked out' of mice, the animals appeared perfectly healthy but had absolutely no ability to hear. This single gene may provide important clues to the causes of some types of deafness. In humans, the gene has already been associated with inherited deafness in otherwise healthy families.

This research was reported recently in an online scientific journal¹ and picked up by the national media.

Three-quarters of animal research taking place in the UK today uses mice, more than half of them genetically modified. A precise and targeted mutation can lead to better understanding of a human condition, in this case deafness, and ultimately to improved treatments.

Research involving animals is essential for scientific progress. It helps us to understand the body in health and disease, and to develop and test medical treatments. Medicines for serious conditions such as diabetes and asthma mean that patients can now live with them, where once prognosis was poor. Remarkable progress in stem cell technology and monoclonal antibody treatments (eg for cancers and arthritis) has depended on mouse research. Animals may also be used to test chemicals for safety, and in wildlife research.

Over the last decade, the total numbers of animals used in UK research have risen,

mainly because of the increased use of GM mice². The number of normal (ie not genetically modified) animals has declined. Following decoding of both human and mouse genomes, GM mice can provide valuable insights into human biology and medicine.

Numbers of animals used in research are rising in virtually all modern economies across the world. The UK is particularly successful in biomedical research, and attracts considerable investment in this area, even in difficult economic times. Although the number of animal procedures has increased by one million (over one third) since the late 1990s, UK expenditure on biomedical research rose considerably more; it has doubled in real terms over the same period. This reflects the commitment within bioscience to developing and using non-animal replacement and reduction techniques and the use of alternative resources such as human cell lines.

Several international initiatives ensure that maximum knowledge is gained from these animals, whilst minimising animal use by avoiding duplication. Examples include the European Mouse Mutant Archive, providing open access to mutant mouse lines, and the International Mouse Phenotyping Consortium (IMPC), which aims to explain and share the functions of genes in mice. Such projects

mean that all scientists will have comparable models, procedures and data.

Animal research which may cause pain, suffering, distress or lasting harm is regulated in the UK under the Animals (Scientific Procedures) Act 1986³. This Act requires every research project involving a vertebrate animal to be thoroughly assessed by the Home Office before a licence is granted. The legislation strikes a balance between the legitimate needs of science and medical progress, and genuine concerns about animal welfare.

The application process for a licence is very detailed, involving considerable scrutiny; each application is subject to a 'cost-benefit assessment' which weighs up the potential harms to the animals against the intended benefits of the research. Proposed research projects are also normally peer-reviewed.

In October 2010 a new European Directive 2010/63/EU concerning the use of animals in research was published⁴. Member states are now in a period of transposition; all must incorporate the Directive into national legislation by January 2013.

The incorporation of new European regulations into UK law will define how animal research is regulated in the UK for years to come. Because animal welfare is vitally important in science and medicine, the UK bioscience

sector wants to be sure that the new legislation has high animal welfare standards at its core⁵, at the same time as enabling real patient benefits.

The bioscience sector wishes to see a continuing emphasis on reduction, refinement and replacement of animals in research, while encouraging high quality science. Controls should also be harmonised across Europe so that the UK does not work under significantly different rules from those of other member states.

Understanding Animal Research is currently co-ordinating a programme of visits for MPs to animal research facilities so that you can find out how and why animal research is conducted in the UK and what the new Directive means for UK bioscience. To arrange a visit please contact info@uar.org.uk.

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TRANSPARENCY IN CLINICAL RESEARCH



Andy Powrie-Smith, Director, ABPI

INTRODUCTION

Transparency, in the context of openness, communication and accountability, is an important subject for the pharmaceutical industry, both in clinical research and in its relationships with patients, clinicians, the research community and government. It is something we are continually striving to improve.

Transparency in clinical research and reporting of research results is highly important to the industry, to other researchers and academics, and to patients and the public. It contributes to medical education, to the collective knowledge of the research community, to public health and ultimately benefits patients. For example, it can help in the understanding of disease mechanisms, improved protocol design and help avoid duplication of research studies. This is particularly important when reporting on research of significant medical importance, even when the research has failed to produce a viable healthcare product.

WHAT WE ARE DOING ALREADY

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is the global non-profit Non-Governmental Organisation (NGO) representing the

research-based pharmaceutical, biotech and vaccine sectors. The IFPMA Clinical Trials Portal is one example of a number of global resources set up to help stakeholders access clinical research information and results, both positive and negative, from around the world. It is accessible to all – healthcare professionals and the public – and is easily searchable, providing accurate, non-promotional information. The advantage of this Portal is that information on negative research results – where results show that research was not continued as it would not lead to a viable safe healthcare product – is also published. Journals are often reluctant to publish negative research data as it is not as interesting as positive research information and results. This means it can be very difficult to get negative trial data published in peer reviewed journals and so it often goes unpublished. The Portal provides an avenue through which information on both negative and positive research results is publicly available.

The pharmaceutical industry, as a sponsor of clinical research, is proactive in ensuring transparency in clinical research and has signed up to guidelines and principles of reporting set out in the IFPMA Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases, agreed in 2005. Companies committed to a number of principles regarding the disclosure of information relating to clinical research, such as the timeline for reporting and the nature of the information to be disclosed. The Joint Position was referred to in the 2006 ABPI Code of Practice for the Pharmaceutical Industry, and since 2008 the Code has required companies to disclose details of clinical trials in line with the IFPMA Joint Position. The Joint Position itself was

updated in 2008, then 2009¹, with a subsequent Joint Position on the Publication of Clinical Trial Results in the Scientific Literature agreed in 2010².

In addition to this, there is a legal requirement in the UK for industry and others in the research community to disclose information on clinical trials involving investigational medicinal products. The European Union Drug Regulating Authorities Clinical Trials (EudraCT) database established by the European Medicines Agency (EMA) is a database of all clinical trials commencing in the EU from 1 May 2004 onwards. Prospective registration of trial details on EudraCT is required in order to apply to the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for authorisation to conduct a clinical trial in the UK, and to apply for Research Ethics Committee (REC) approval for a study. Data extracted directly from EudraCT was made available to the public in March 2011 as the fully searchable EU Clinical Trials Register.

Guidelines issued by the European Commission cover not only which data are stored in the EudraCT database, but also which of these data should be made available to view by the public. As a result, comprehensive information about trials conducted in the UK is collected, including descriptive data about the study. Plans for the future include the publication of summaries of results, planned for late 2012.

WHAT ELSE ARE WE DOING?

As already noted, this is an important area not just for pharmaceutical companies, but for the wider research community (including devices and diagnostics companies) and patients. All stakeholders need to work together to improve

openness, communication and accountability.

ABPI is a partner in a multi-stakeholder group which includes the medical Royal Colleges, regulatory and professional bodies of the medical community, and trade bodies representing other healthcare industries such as diagnostics and devices. This group is working to improve awareness of best practice in the reporting of clinical research information across the entire research community, both commercial and academic. It aims to ensure that the relationship between healthcare professionals and industry benefits patients and meets the expectations of stakeholders.

Part of the group's work is looking at clinical research transparency. The group is seeking to increase best practice across all trials, be they commercial, non-commercial, surgical, academic or devices. The group is working on a set of mutually agreed principles to apply across the research community. These principles will be aligned to the IFPMA Joint Position already established by the pharmaceutical industry and will be published shortly.

The pharmaceutical industry is committed to clear and open communication and we believe the solution is to work together as a whole research community. Consequently, we are committed to working with all the stakeholders to increase transparency to the benefit of patients.

Footnotes

1 http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/EN/November_10_2009_Updated_Joint_Position_on_the_Disclosure_of_Clinical_Trial_Information_via_Clinical_Trial_Registries_and_Databases.pdf

2 http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/20100610_Joint_Position_Publication_10Jun2010.pdf

PUTTING COPD ON THE MAP - COLLABORATING TO FIGHT DISEASE

Dr Paul Whittaker, Director, Respiratory Diseases Area, Novartis Institutes for Biomedical Research

Professor Chris Brightling, Wellcome Senior Clinical Fellow, Honorary Consultant, Institute for Lung Health, Leicester

Chronic obstructive pulmonary disease (COPD) is a disease that slowly and insidiously destroys the lungs of sufferers and robs them of their ability to breathe. Every 15 seconds someone in the world dies of COPD. It will be the third commonest cause of death globally by 2020 (WHO) and the fifth commonest cause of disability. COPD is a bigger killer than bowel, breast or prostate cancer (British Lung Foundation). Indeed more women die of COPD in the UK than breast cancer. Yet despite decades of research by both academia and industry, the available treatments are very limited. The real impact of this disease can be felt by the social and economic wellbeing of those affected and the burden it places on the NHS and business. As well as being debilitating and unpleasant for patients, it can be socially isolating and reduce the earnings of individuals who should be at their peak, and who may even end up claiming benefits.

So why the lack of success? The main reason is the underlying complexity of the disease, which is the clinical manifestation of a subtle interplay between environmental factors (mainly cigarette smoking) and genetic susceptibility factors (the development of COPD among smokers is not uniform and a minority of smokers develops the disease). COPD is at best an umbrella term that describes a number of different disease subtypes, rather than a single

disease.¹ It is this complexity that has been a key barrier to the development of new therapies. The identification of groups of patients all with the same disease type would facilitate both research on COPD and the development of new drugs.

We need to understand more about the underlying biology and pathology of COPD, as effective future therapies will require defining each type first, then matching the relevant drug(s) to it. We also need to be better at selecting 'the right patient' for the 'right intervention' and measure 'the right outcome'. It can take decades to develop COPD, so using standard clinical tests it could take a very long time to prove the effectiveness of a new therapy. This is even more important when targeting aspects of the disease that cannot be measured by the available clinical tests. Trials need to be large and run over several years to see a statistically significant effect of a drug, which also makes them expensive.

The benefits to the UK of fostering good research are improved patient outcomes and commercial investment. A complex, costly and slow research environment, underpinned by a historic lack of inter-centre collaboration, often impedes investment, although the Government has made significant and welcome strides in addressing this.

It is clear that no single pharmaceutical company or academic group can provide all the resources, expertise and know-how needed to make the required progress to develop new therapies for COPD. It has been increasingly recognised on both sides of the Atlantic that in order to do this, there is a need for Government, academia and industry to work together to make progress in our understanding of COPD and kick-start the identification of new drug targets and biomarkers. In the UK, the leading academic experts in COPD and industry have joined forces to address this 'grand challenge' and formed the Medical Research Council (MRC) and the Association of the British Pharmaceutical Industry (ABPI) COPDMAP consortium.

Following a workshop and grant, the COPDMAP consortium looked at areas identified by industry as being key to target research. Crucially, representatives from four major pharmaceutical companies (Novartis, Pfizer, GlaxoSmith-Kline and AstraZeneca) are closely involved in managing and developing the strategic direction for the work, as well as

providing 'in kind' resources such as research tools to aid it.

The belief from industry is that a pre-competitive consortium such as this is the only way to make effective progress in the development of new therapies for COPD, and represents a unique opportunity to make a step change in our understanding of COPD and how to tackle it therapeutically. It will enable the faster development of better therapies to benefit patients, and open up more innovative and diverse avenues of research. Key to this whole approach is using groups of patients with the same type of disease to help us understand and tackle the disease complexity that has frustrated drug discovery research in the past.

The COPDMAP consortium is an exemplar of how academic and industry partners can work together effectively, united in pursuing a common vision and goal – better treatments for COPD patients. It can also act as a catalyst for tapping into the potential research and development talent within the UK, and allow the UK to compete as an international research centre.

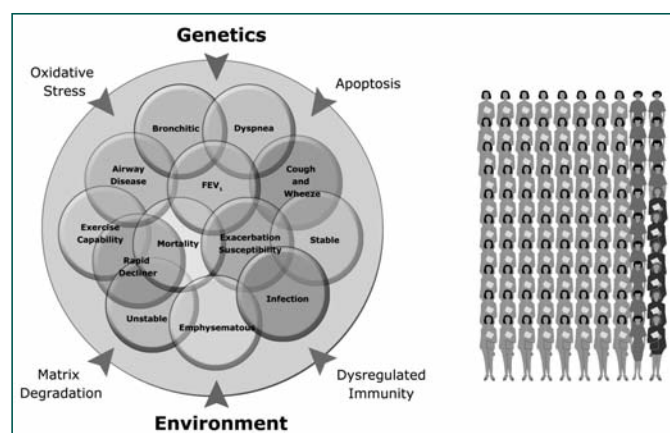


Figure: The clinical complexity of COPD means that effective therapies will have to be tailored to specific subgroups of patients (dark grey)

Footnote: 1 Chest 2008 Sep;134(3): 623-7

SOCIETY OF BIOLOGY DEGREE ACCREDITATION PROGRAMME



Dr Mark Downs FSB, FLS
Chief Executive, Society of Biology

With a more market-based approach to university finance, students are likely to become increasingly demanding in return for the investment they make in their education. Among other things, their interest in employability will grow. The Society of Biology is keen to enable students to make informed choices and to be more certain of the employability prospects they can expect from their university education. This has been one of the contributing factors to the development of the Society of Biology's Degree Accreditation Programme for the biosciences.

With a strong emphasis on academic rigor and research experience, the Society's Accreditation Programme is specific in its aims:

- to highlight degrees that provide graduates with the skills and experience required to progress to employment in academic or industrial research, and

- to ensure a pipeline of skilled graduates into areas of particular national need and international importance.

The rigorous assessment procedure will recognise outstanding courses across the UK that focus not only on core knowledge but also on experimental and analytical skills. The accreditation criteria put a strong emphasis on academic excellence and, critically, time spent in an active research environment. We recognise that higher-level research skills can only be gained through a period of practice, and so the scheme focuses on four year undergraduate degrees with substantial research placements either in academic or industrial research groups, eg a BSc with Year in Industry course or Integrated Masters programme.

Through the Accreditation Programme we hope to highlight and share best practice and we see that accreditation has the potential to drive up the already high standards of teaching and learning in biology higher education, cementing the UK's position as a leader in life science training and research.

This scheme doesn't only stand to benefit students. The Society of Biology has consulted a full range of stakeholders in the biosciences, including academics and universities, industry, learned societies, funding bodies, sector skills councils and students. A survey carried out by the Society of Biology¹ indicated that employers ranked 'lack of work experience' as the main reason for not employing a graduate with a BSc or MSc qualification.

The Accreditation Programme will enable employers in both industry and academia to better identify graduates with the required research experience, skills and interest. Sarah Jones of the Association of British Pharmaceutical Industry, said: 'We believe that accreditation of bioscience degrees will enable employers to feel confident that recruits from UK universities will have the skills and knowledge required to make substantial contributions to the research and development of new medicines'. The Accreditation Programme also benefits employers by targeting bioscience disciplines where reports^{2,3} have highlighted national graduate skills gaps. The project has the backing of the Department for Business, Innovation and Skills (BIS) and the Biotechnology and Biological Sciences Research Council (BBSRC), and was highlighted in HM Treasury's Plan for Growth⁴ as a key strategy for growth of UK industry.

In June 2011, the Society launched a pilot of the Accreditation Programme, initially focusing on two key areas of graduate skill shortages - biochemistry and *in vivo* (animal) sciences. The pilot is due to finish in February 2012 and the degree courses which have successfully achieved accreditation will be announced at an award ceremony on the 20 March in the Members' Dining Room, 4-6pm. The first students will graduate from accredited degrees in summer 2012. This will help ensure that skills demands are better met in both academia and industry, and

supports the Government's recommendations for a growth agenda.

Since the early stages of development of the Accreditation Programme, we have received much interest from higher education institutes in taking part. Following a successful outcome from the pilot, we will open the scheme to all UK higher education institutions in 2012. In-built flexibility ensures that the Accreditation Programme also remains inclusive of a range of the bioscience disciplines, and we aim to expand it into a wider range of strategically important research disciplines with identified skill shortages in the future, covering a wide range of the biosciences.

For more information please visit www.societyofbiology.org/education/hei/accreditation.

We look forward to celebrating the announcement of the first courses to be awarded Accreditation by the Society of Biology in March 2012.

Footnotes

1 Report of the 2010 Industry survey on bioscience graduates, Society of Biology (2011)
<http://www.societyofbiology.org/documents/view/832>

2 Skills needs for biomedical research, ABPI (2008)
<http://www.abpi.org.uk/our-work/library/industry/Pages/skills-biomedical-research.aspx>

3 Life Sciences and Pharmaceuticals: A Future Skills Review with Recommendations to Sustain Growth in Emerging Technologies, Semta, Cogent, Skills for Health (2010)
<http://www.cogent-ssc.com/research/Publications/LSPReport.pdf>

4 Plan for Growth, HM Treasury (2011) - http://cdn.hm-treasury.gov.uk/2011_budget_growth.pdf

Spotlight on the Brixham Environmental Laboratory

ASTRAZENECA BRIXHAM

**Paul Duckett, Site Manager,
Brixham Environmental Laboratory.**

Minimising the environmental impact of creating life-changing medicines – this is the role of Brixham Environmental Laboratory, AstraZeneca’s multi-disciplinary research centre on the Devon coast.

In 1948 Brixham Environmental Laboratory (BEL) began life as a testing facility for ICI Paints, with the laboratory moving to its current site on the Brixham seafront in 1957. During the 1960s the remit of the laboratory gradually changed from the testing of the efficacy of marine antifouling paints, to testing and predicting the fate and effects of products and effluents in the environment. By the late 1980s, Brixham had gained a worldwide reputation. The laboratory transferred to Zeneca Limited following the demerger of ICI in 1993 and in 1999 the laboratory became part of AstraZeneca Pharmaceuticals.

Throughout its history the laboratory has worked for both its parent company and external clients, who have included a wide range of companies from across the international chemical industry.

At Brixham, AstraZeneca scientists test and assess the environmental impact of pharmaceutical products and processes to increase understanding of their environmental effects, as well as ensuring they meet the required regulatory approval standard. The objective is to deliver fit-for-purpose environmental support to the chemical industry worldwide, providing assessments of the environmental fate and effects of new and existing products and intermediates. The laboratory can also offer environmental support for the manufacturing processes that produce those products.

Understanding and minimising the environmental impact of pharmaceutical products is essential. That’s why, in 2008, AstraZeneca invested £13.1 million in new facilities at Brixham to support research into the environmental effects of potential medicines, prior to their approval for general use.

Ecotoxicology is the study of how chemicals affect the environment and the organisms living in it, and is a long-standing well-developed discipline at Brixham. The Ecotoxicology team of 15 scientists works in an area with 23 laboratories and a husbandry facility. These ‘state of the art’ high-specification facilities offer instant room water control, able to dial up any salinity and temperature, and room temperature control.



Another specialism is environmental monitoring, ie the measurement of chemical exposures and effects in the receiving environment, a valuable tool for environmental risk assessment (ERA), environmental impact assessment (EIA), and environmental performance assessment. While ERA predicts the environmental impact of an effluent, chemical release or product use, the only way of validating that prediction is to study the actual receiving environment. Monitoring the receiving environment takes into account the interaction of chemical mixtures effluents, environmental amelioration, and their long-term effects on exposed organisms.

Brixham’s areas of expertise include:

- Industrial chemicals
- Human pharmaceuticals
- Biocidal products
- Plant protection products
- Veterinary medicines

Brixham employs around 80 people, nearly half of whom are bench scientists. The site has an excellent reputation and a commitment to the future of applied environmental science education. Through AstraZeneca’s continued investment in research in the UK, Brixham is now a global leader in the study of industrial environmental science, with some of the most advanced equipment available in the world.



VALLEY OF DEATH



Glyn Edwards
Interim Chief Executive,
BioIndustry Association

The UK is rightly considered a world leader in life sciences with a research base second to none and a long list of success stories. However, a deteriorating funding environment is threatening to starve small and emerging bioscience companies and constrain growth, particularly through the toughest part of R&D to navigate – the ‘valley of death’. Government should look to diversify funding opportunities and engage the public in supporting UK technology by launching Citizens’ Innovation Funds.

Around this time last year Amgen, a large multinational biotechnology company, bought Biovex, a Massachusetts-based company researching and developing speciality cancer drugs, in a deal that could eventually be worth \$1bn. It was one of the largest biotech Venture Capital (VC) sales in history.

Why does the story of one large company buying another in the US have relevance to the UK? Because Biovex was originally spun out of University College London and was based in Oxford until 2005. It represents a success of British science but also highlights a persistent issue, long recognised but not yet adequately tackled – namely, the UK’s poor record at translating science research into market-ready products.

Biovex relocated for a number of reasons but the readier access to finance and a more favourable public market

was clearly a factor. It is not an isolated case, with other UK-founded companies moving, often to the US, to access capital.

A key consideration in all such relocation decisions is a company’s ability to raise finance to develop new, innovative healthcare products. Research and development of a new medicine is time-consuming (on average around 10-15 years) and expensive (on average costing around \$1bn), but is a vital endeavour to meet areas of unmet medical need.

Access to finance remains the key concern for BioIndustry Association (BIA) members and many warn of further relocations to come if we don’t help small companies bridge the so called ‘valley of death’ – the gap between translating basic research into a viable potential product, or to what’s called ‘proof of concept’. By proof of concept a company has

demonstrated that its research is more than just an idea in a lab and can often then attract further funding, not to mention large companies as partners, to begin the hard work of demonstrating the efficacy and safety of its product for patients.

Some, in fact many, potential new products will fail to get to proof of concept stage; that is the nature of experimental medical research. This is a healthy thing because it means that those innovative products that do successfully vault the many hurdles and make it to patients have been thoroughly and exhaustively tested for safety and efficacy. There comes a tipping point, however, where sound research prospects are being left the wrong side of this valley because a company simply cannot afford to explore it further. When research projects are being abandoned due to financial considerations, not the strength of the science, then restorative action becomes justified.

To remain competitive, therefore, the UK must tackle this funding gap or risk losing the continued financial benefits of a thriving bioscience community. While much good work exists and the UK remains amongst the leaders in the

... the BIA believes that enacting a CIF would be of benefit to innovative UK companies and, in our own space, provide bioscience companies with a better chance of attracting finance to bridge the valley of death ...

sector, it is a great shame that we do not fully capitalise on the world-leading science base, which really is second to none, and other assets we can boast. The valley of death is now the subject of a House of Commons Science and Technology committee inquiry which comes at an opportune moment.

Bridging the gap is more difficult than ever, in part because the traditional funding model for small and emerging bioscience companies, of the type the BIA represents, has been under increasing strain over recent years. At the risk of over-simplifying, traditionally a company, perhaps recently spun-out from a university around a promising bit of research, would seek angel and seed funding to get off the ground with more significant VC funds required to reach the clinical trial stage. Investors set the company certain targets, or 'milestones', to reach along the clinical development pathway whereby additional funding would be provided.

In the past, at this stage, a bioscience company would often make an Initial Public Offering (IPO) and list on the market enabling it to source significant public funding to develop its product further (often with many more now on the way as well). For investors, this IPO was the stage by which they could expect a return on their investment, which, in all likelihood, would then be reinvested in the next new company with promising research starting on its journey.

It is therefore deeply worrying that over the past two years there have been no bioscience company IPOs in the UK, which has had a knock-on effect on those VCs willing to invest in the sector. Many VCs look at a bioscience company in 2012, without realistic IPO

opportunities in the UK, and shy away from investing their money for the length of time it takes to develop a new medicine.

Equity is still available but is increasingly being channelled into a smaller pool of companies seen as safe bets or those whose products are nearer to market and the perceived risk is lower. Numerous highly innovative companies are struggling to continue their development in the UK.

It is true that the medical research environment is changing for small and large companies alike. Pharmaceutical companies themselves are directly acquiring more bioscience companies to stock their own development pipelines, for example. The industry is responding in other ways also. There is greater collaboration and partnering across the board to de-risk earlier stage research. Large companies are investing into promising small companies directly through Corporate Venture Capital arms or sharing this investment with established VCs. It is increasingly recognised that different players in the development chain – academics, investors, small and large companies – bring different and complementary expertise to the table.

Greater collaboration is welcome and will, in all probability, continue to be the direction of travel for the sector. But all these new models of working are not, on their own, enough to shallow the valley satisfactorily. Without VC money being recycled into the sector, companies will continue to struggle. BIA members tell us that by necessity they are spending more of their time on identifying funding opportunities, almost to the detriment of the science itself. Promising research

is being jettisoned as investors urge a narrow focus. Bioscience companies are renowned as lean and effective machines that can operate on a shoestring – but even this tradition can only be stretched so far.

The current Government recognises, as did its predecessor, the competitive advantage the UK holds in life sciences, and as such the recent Strategy for UK Life Sciences is warmly welcomed, containing as it does a package of actions to improve the attractiveness of the UK. Specific new sources of funding, such as the BioMedical Catalyst fund, are particularly important and are aimed at that tough and highly risky point of R&D – the valley of death. Taken alongside other initiatives such as the Patent Box, it is clear we are moving in the right direction, although the impact of these will only be felt in the medium to long term.

However, the government has other levers available to it to create the optimum environment for private investment into highly innovative UK technology companies. Alongside traditional fiscal incentives for high-net-worth individuals, the BIA is urging Government to consider policies that will diversify the sources of available funding. One such policy would be the introduction of Citizens' Innovation Funds (CIF).

The CIF would be based on the French FCPI funds, which have been in existence for around 10 years, raising almost €6bn and investing in over 1,000 high tech companies. The concept is very simple – provide a tax incentive of up to £15,000 for mid-net-worth individuals through a simple 'over-the-counter' retail product sold in high street banks, the Post Office, and others. The money is then pooled together into VC

funds and invested directly into eligible innovative high-growth companies in all technologies, not just bioscience. Companies must be performing R&D in the UK to benefit from the investment, and this could be gauged simply by ascertaining whether they are eligible to claim an R&D Tax Credit, for example.

The CIF has a number of attractive qualities. Firstly, it relies not on public money but merely creates the space to encourage private investment. It opens up a new source of funding for the UK's innovative companies, thus diversifying the funding base and providing a boost to growth. It also engages the British public in UK R&D, providing the connection between investment, research and medical advancement, in the case of bioscience for example. Opening up such investment opportunities to the public without the need to study the markets daily debunks the myth that direct funding of companies is something that 'someone else' does.

The CIF is not a panacea: it will not solve the funding gap on its own and should be considered in conjunction with other fiscal and growth supporting policies. However, the BIA believes that enacting a CIF would be of benefit to innovative UK companies and, in our own space, provide bioscience companies with a better chance of attracting finance to bridge the valley of death and capitalise on the world-leading science and assets we possess. More medicines for patients in the UK and worldwide could be developed here from lab bench to market, and perhaps then the next Biovex will be a UK story from start to finish.

STRATIFIED MEDICINES: THE FUTURE OF HEALTHCARE



Louise Leong
Head of Research and
Development, ABPI

Today if you are unlucky enough to develop an epileptic seizure you and your doctor will be left with a dilemma. You have a 1 in 3 chance of having another one. Is it worth treating you? The first line medicines were discovered over 20 years ago and have significant side-effects. On balance you will probably not be treated but if you do have a second seizure you will get one of the first-line medicines. You could spend the next 18 months trying different medicines and combinations until you get the one that works for you. That's two and a half years where your disease is not being treated and you could have more seizures.

That is the reality today: but imagine a day when, after the first seizure, you get a blood test in the hospital and you are told that your risk of having another seizure is 90 per cent and that there is a medicine which will best treat you (say, levitiracetam) for which you need the normal dose. Yes you have epilepsy, but the uncertainty is removed and you can be sure you have the most likely treatment to work. Your risk of having a seizure and hurting yourself is as low as it can be, leading to greater quality of

life for you and minimum impact on the healthcare system.

Stratified medicines will allow us to do just that. Along with significant discoveries such as antibiotics, statins and HIV therapies, stratified medicines are set to transform healthcare in the next wave of pharmaceutical innovation. Alongside the next generation of innovative medicines will come diagnostic tests, which will much more accurately predict to whom the medicine should be given. This future is not far away, as we are already seeing the first wave of these stratified medicines come into the NHS – mainly to treat cancer, but therapies in other areas such as neuroscience are also being developed.

PERSONALISED OR STRATIFIED MEDICINES

Stratified medicines enable us to target treatments specifically to patient subpopulations, identifying those with the greatest chance of benefit and the lowest risk of suffering adverse events. Called personalised medicine or personalised healthcare in the US, it is better known as stratified medicine in the UK, to avoid confusion with individualised healthcare. Many organisations here have adopted the definition by PCAST: it is 'not about creating medicines unique to a patient, but rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventive or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side-effects for those who will not'.¹

It also involves the development and use of companion diagnostics to achieve the best outcomes in the management of a patient's disease.

Why the excitement? Current treatments can often only be designed to work across the board – in, say, between 30 and 60 per cent of patients on average. However as our insight into human biology in health and disease advances, we come to understand on the one hand, the heterogeneity of disease conditions, and on the other hand, heterogeneity amongst human population in response to medicine based on their physiological makeup, which can be defined at the pharmacological level. With this understanding comes the opportunity to use our medicines much more effectively, benefiting patients, the NHS and paving the way for further research.

Many pharmaceutical companies are embracing a stratified approach in medicine development, and we predict that analysts will see an increasing proportion of stratification emerging through the pipeline. This is made possible by the advancement of technology and the ability to build in predictive and stratifying biomarkers, as well as improved molecular understanding of disease pathways.

RIGHT MEDICINE, RIGHT PATIENT, RIGHT TIME, RIGHT DOSE

Simply put, whether patients respond to a particular treatment,

may in part depend on the subtype of disease that they have (and therefore whether the target in the disease pathway that the medicine was designed to attack is relevant to the disease subtype); or their response to treatment, as in the example above; or their propensity to an adverse reaction. Therefore any that can target treatment more precisely would mean patients taking the right medicine at the right time that will give the best therapeutic benefit and avoid unnecessary side-effects.

BIOMARKERS

The advent of stratified medicine is due to advances in science and technology, which is leading to an increase in the discovery of biomarkers – simply, biological measures of patient samples that can indicate disease progression, prognosis, or treatment response, for example. Some are physiological functions that can be detected by imaging scans. There are many types of biomarkers, and many ways in which they can be deployed in medicine development. Their central role in stratified medicine centres around predicting response to treatment. Biomarkers can also be developed into companion diagnostics for use with stratified medicines. Biomarker science is a highly complex area of research and for any promising avenue, thousands of possible biomarkers

Today if you develop Non-Small Cell Lung Cancer (NSCLC) you will have a choice of traditional chemotherapy with carboplatin/paclitaxel or newer therapies which are targeted against a protein called epidermal growth factor receptor (EGFR). The choice is vital as, when the new medicine works, it is significantly better than chemotherapy and has fewer side-effects. However get the choice wrong and the medicine may not help you at all. The decision is based on a change (mutation) in the gene for EGFR which switches the receptor to a permanently on state. The activating mutations are only present in 10-15 per cent of patients with NSCLC, but if they are you can now get a better safer medicine.

emerge. The challenge is to identify, qualify and validate the right ones that will prove useful. Hence, continued investment is vital to ensure that the science develops.

Researchers investigating biomarkers to establish specificity and relevance require access to tissue samples and well-phenotyped patient cohorts. Many tissue samples donated by patients sit in individual laboratory collections, and there would be value in creating a nationwide register, with the appropriate governance and consents, to enable researchers to know where to look for them. Continued investment in biomarker science is vital in order to drive the science base needed to enable stratified medicine.

SMARTER WIRING-UP

Integrated health informatics offers rich potential for research in stratified medicine, with the right governance, anonymisation and controls. For example, better data linkages would enable researchers to establish associations between genotype and clinical phenotype. Talent in informatics and biostatistics in the UK must be built up to harness this potential. Government's recent commitment to link primary, secondary and tertiary electronic health records is encouraging in this regard. Access to biological databases (eg – omics, imaging information) would similarly be helpful. Further, a larger linking up of systems with pharmacies, such as has been done by a number of health systems in the US, would expedite use of stratified medicines in the real world.

The use of stratified medicines in the clinic is multidisciplinary, beyond a linear physician-patient relationship. Other experts in the healthcare chain are required to work with the clinician, such as experts in pathology and diagnostics. A good illustration of how this can work in practice has been demonstrated by INCa (Institut National du Cancer) in France, along with indicators of value derived for the health provider.²

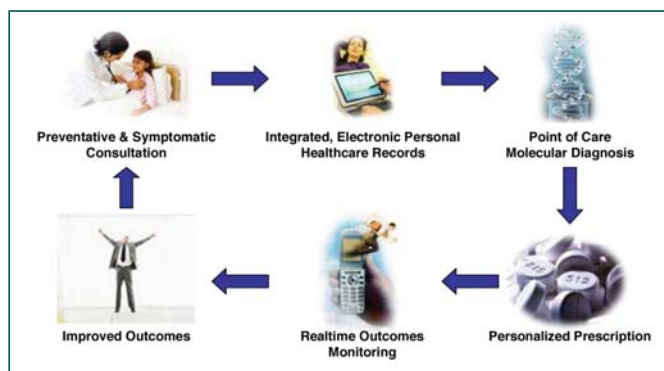


Figure 1 – What it's all about: Integrated healthcare in the service of the patient³

PARTNERSHIPS

Improved understanding of biological pathways and biomarkers is crucial to enable stratification. The knowledge base underpinning this comes from scientific research in both academia and industry. Enhanced collaboration across sectors will be key to accelerating the development of stratified medicine. To this end, a number of multi-partner initiatives have been launched recently:

- The 5-year £50 million Stratified Medicine innovation platform coordinated by the Technology Strategy Board;
- MRC-ABPI research consortia in respiratory and inflammatory joint disease, and in diabetes;
- MRC £60 million 4-year research initiative in stratified medicine;
- Cancer Research UK Stratified Medicine initiative with AstraZeneca, Pfizer and TSB to lay foundations for standardised, high quality, cost-effective genetic testing of tumours.

REGULATORY IMPLICATIONS

In line with stratified medicine, recruitment into clinical trials of the appropriate patient subpopulations most likely to respond to the treatment under investigation will involve enriched but smaller trial populations. While it is hoped that this would generate more efficient trials, it will nonetheless impact on trial design and statistical analysis. Regulatory (MHRA) data requirements for trial and licensing dossiers for more

traditionally designed drugs will need to be adjusted to be relevant to stratified medicine. Regulator engagement with new science and technology is therefore critical, to provide clear and appropriate guidance to trial developers. At EU level, we anticipate draft revision of the IVD (*in vitro* diagnostic) Directive. The commitment to an earlier access scheme announced by Government in December's *Strategy for UK Life Sciences* will be helpful.

Unsurprisingly, most experience thus far lies in retrospective qualification of companion biomarkers after the launch of a new medicine. This is a fast-moving field with multiple tests and it is here that medicine developers face burdensome hurdles to regulatory acceptance. Streamlined and harmonised regulatory requirements would help to benefit patients by removing the barriers to stratified medicines getting onto the market.

THE FUTURE

It is clear that concerted action is needed across multiple policy areas for the UK to be an attractive location to develop and use stratified medicine. We are seeing new developmental models, with a range of alliances of pharmaceutical and diagnostic companies and academics across life science sectors to develop stratified medicines (eg the cancer drugs crizotinib, developed by Pfizer with a companion diagnostic co-developed by Abbott; and gefitinib developed by AstraZeneca and companion test developed by DxS).

In the UK, the development and implementation of an integrated stakeholder strategy in stratified medicine will bring benefits to patients, but also prescribers, payers, and regulators; it may also improve the efficiency and productivity of developing new treatments, and enhance UK competitiveness and attractiveness for drug and diagnostic research and development. On this front, we have intensively engaged on the development of an integrated stratified medicine approach over an extended period, working closely with a range of partners such as:

- The diagnostics sector
- Research funders
- Regulators
- Healthcare providers and policymakers
- Health informatics programmes
- Health economists

In summary, medicines can only be of use if they actually get to patients. With stratified medicines set to become a reality, we must ensure that we have the appropriate reimbursement frameworks in place. The cost of developing these medicines will reflect the additional complexity of stratification in combination with the development of companion diagnostics, and stratified medicines will be used by a smaller patient base. Future Health Technology Assessment (HTA) and reimbursement systems will need to be sensitised to this in order to value these developments appropriately and incentivise future research.

Footnotes:

- 1 US President's Council of Advisors on Science & Technology (PCAST).
- 2 *Personalized medicine – a nationwide initiative for an equal access to cancer treatment in France.* http://ec.europa.eu/research/health/pdf/event06/13052011/fabien-calvo_en.pdf
- 3 *The stratification of disease for personalised medicines: Research driven recommendations and the rationale for a UK stakeholder alliance.* April 2009 <http://www.abpi.org.uk/industry-info/future/Documents/SDfPM%20final%202009-04-16%20.pdf>

ANNUAL LUNCHEON OF THE PARLIAMENTARY AND SCIENTIFIC COMMITTEE

The Annual Lunch of the Parliamentary and Scientific Committee was held on Tuesday 8th November 2011 in the Cholmondeley Room and Terrace, House of Lords.



Lord Jenkin opened proceedings by welcoming Lord Soulsby, past President, and past Chairmen including Ian Taylor, and the many other distinguished guests, scientists and especially the engineers present which has arisen due to the recent merger with the All Party Parliamentary Group on Engineering (APEG). He also referred to the Committee's current programme of events and activities which include a much greater contribution from Engineering. "It is hugely important that people should understand that if you want to make things happen – it is the Engineers that do that! And that

is why I am particularly pleased to be able to introduce the speaker, Dr Mike Weightman, HM Chief Inspector of Nuclear Installations and Executive Head of the Office of Nuclear Regulation, who has spent his life as an engineer in the nuclear industry – and long before regulation commenced! His career evolved from working in BNFL, then Principal Inspector of Nuclear Installations in 1988, and he has now become a figure of both national and international distinction this year, with his work following the disaster that struck Fukushima Daiichi, where the safest place to be was in a nuclear power

station. Not one life was lost from radiation – a fact that needs to be very widely known indeed. The Japanese handled it with extreme skill and courage. He accepted the remit from the Secretary of State to prepare a report as to what should be the consequences for the UK Nuclear Power Industry. It is to his enormous credit that he was subsequently invited by the IAEA to undertake a similar task for them – thus demonstrating this country's outstanding reputation in the regulation and safety of nuclear power stations. We are very proud to have him here to speak today!"

Dr Mike Weightman rose to respond with the comment "As they say, "Follow that!". "Whenever I am asked difficult questions in Select Committees, the response I usually give is – "I am just a Simple Engineer". However Engineering is what Fukushima is all about, and I am therefore very grateful for the opportunity to address this august group, comprising engineers, scientists and parliamentarians. As HM Chief Inspector of Nuclear Installations one of my prime aims is to embrace openness and transparency. Not only as a Regulator, but also because people deserve to know what is around them, what decisions we take on their behalf, and how they are being protected. It is only by doing that, which enables you to earn the trust and confidence of the people who we serve."

"Let me begin relating the

Fukushima Daiichi event by telling you about the Office for Nuclear Regulation (ONR) as this is relevant to one of the prime institutional lessons to come from Fukushima. The ONR was created on 1 April 2011 as an Agency of the Health and Safety Executive (HSE). This is an interim step towards the Government's intention through primary legislation, to set up an Independent Nuclear Regulator as a Statutory Corporation outside the HSE."

"It is intended to provide flexibility to enable us to sustain ourselves as an expert well-resourced, world-leading nuclear regulator for future challenges. It would also bring more independence if the Chief Inspectors role is established by Statute and through our own Board resulting in openness and transparency. This has been praised by the Deputy Director General of the IAEA, with the UK once again, demonstrating world leadership in facing up to future challenges."

"The ONR is deployed across all sectors of the nuclear industry, for regulating nuclear safety, we are also responsible for nuclear security at civil sites and for the safeguarding of nuclear material that otherwise might be used in atomic weapons. To fulfil those responsibilities we have a staff of 450 people, half of whom are very well qualified engineers and scientists and you will perhaps, also be pleased to know that over 95% of the costs are recovered from industry!"

"Let me now provide you with a brief review of the Fukushima Nuclear Accident and what it means for the UK nuclear industry. Eight months ago Japan's east coast suffered the sixth largest earthquake the world has ever seen and Japan within an hour was hit by a series of tsunami waves. Whole towns and villages were swept away. Over 100,000 homes were damaged or destroyed, and tragically some 20,000 people are dead or missing. Severe damage to the Japanese infrastructure also resulted from the impacts of the earthquake and tsunami".

"All the nuclear plants on the east coast of Japan were affected to a lesser or greater extent, with the Fukushima Daiichi site the most affected of all. At this site three reactors were operating, and another three were shut down for maintenance. The operating reactors shut down automatically in response to the earthquake, as they are designed to do. To keep them safe, cooling had to be maintained because of the large amount of heat generated by radioactive decay from the fission products in the fuel. The heat on shutdown would be equivalent to some 20,000 electric fires in a volume equivalent to a couple of double decker buses. However the cooling systems designed to operate during shutdown failed to operate. Six electric grid lines serving the site had been destroyed by the earthquake. The emergency electrical supply was provided by twelve large diesel engines on the site."

"Within an hour the tsunami waves hit the site, inundating it to a depth of 14 to 15 metres. The waves hit the turbine buildings and then splashed into the air half a rugby pitch in height resulting in the loss of all AC power excepting Reactor 6

which is located on higher ground. The diesel electric generators and their electrical controls are all located beneath turbine halls which became flooded and inoperable."

"The operators then faced a nightmare situation due to the loss of AC electric power supply to the reactors, fuels ponds and the loss of the heat sink that is required to remove excess heat. Instrumentation indicating the physical state of the reactors and communications, all broke down. And difficulty of access was caused by the tsunami with cars slung around like driftwood and only the staff they had on site available to help with little hope of outside assistance in the short term."

"The operators did what they could in very difficult circumstances by attempting to vent reactors to stop over-pressurisation and putting in alternative cooling through fire tenders, which included the use of seawater. However, during the next couple of days at Daiichi all effective cooling was lost, with the fuel heating up to over 1000 Degrees C. The Zr-cladded fuel reacted with water which generated hydrogen that rose to the top of Reactor Buildings 1, 3 and 4 in sufficient quantities to cause extensive, massive explosions, with Reactor 2 also causing an explosive event inside containment. A large quantity of radioactive material was released to the atmosphere. The authorities had however simultaneously responded in the environs by evacuating people to safety, firstly those within 3km and then within 20km of the site. As time progressed, large quantities of contaminated water from efforts designed to help cool the reactors began flowing into the sea. Further efforts to stabilise the reactors continue today, but the risk of additional radioactive release has been

significantly reduced. Despite all these events there is no evidence of any related public health detriments arising from the accident. However it has caused widespread social impacts and alarm, and billions in damage. So what has our response been as the UK Nuclear Regulator?"

"The first priority was to provide advice to Government on how to protect the 17,000 UK Citizens in Japan. This involved making predictions from limited information of reasonable worst case scenarios in order to feed data into models in order to determine the dispersion of radioactive materials from Fukushima and the likely impact they might have in places like Tokyo. With help from our colleagues in the Met Office and other agencies we were then able to produce four-hourly predictions to John Beddington's Group on Scientific Advice and COBRA."

have issued two reports, one in May and one in September, on lessons that have been learnt for the UK Nuclear Industry. These include 17 Conclusions and 38 Recommendations. The final report took account of Japanese Government reports, and the IAEA mission report as well as deliberations of the Advisory Panel that I set up."

"WHAT DID WE LEARN?"

- 1) Need for a robust design basis and periodic safety review of nuclear facilities.
- 2) They can be made safe from earthquake and flooding risks
- 3) This is what we do in the UK
- 4) Continuously review safety of all facilities, as knowledge accumulates and standards improve.
- 5) Regulatory System in the UK requires this through conditions we attach to nuclear site licences



"The UK Government subsequently adopted a measured approach and decided NOT to evacuate people from Tokyo. Additionally, we sought and received assurances about the UK fleet of nuclear reactors and UK nuclear experts were also required to confirm that all safety systems were operating successfully. I

- 6) Should prepare on and off site for even more severe events – we can do more
- 7) Strong independent technically expert Nuclear Industry Regulator required
- 8) Continue to fulfil duties and responsibilities in line with UK Government intentions for safety"



"Given the differences between the UK and Japanese regulatory systems and the level of external hazards, there is no need to curtail operations of nuclear facilities in the UK and no fundamental weaknesses exist in the UK systems and their regulation."

"However there is no room for complacency and we must seek to learn from events as a fundamental feature of the UK nuclear industry. This is why 38 recommendations have been made with openness and transparency that are based on continuous learning and a strong independent Nuclear Regulator as with this in place, with this the ultimate overall benefit of nuclear power to society remains an option. Thank you!"

QUESTIONS

Q1. Was there any investigation of costs as Nuclear related activities are uninsurable in the UK?

A. The remit of the Regulator is not to examine financial but safety aspects. The market will decide on costs.

Q2. We do have strong links with Japan where people are in fear and terror of everything that has happened. How can the UK help respond to attacks of panic?

A. Sir John Beddington did visit Japan to provide the scientific facts and help with advice on behalf of the British Government.

Q3. How are the costs of energy production linked to costs to human health?

A. These are provided in OECD nea pubs Reports and people also have their own ideas as exemplified by Electricite de France (EDF).

Q4. We live on Risk, what are dangerous levels of radiation and who sets these?

A. For workers in the nuclear industry the annual upper limit is 20 millisieverts (mSv), whereas the worldwide average dose for a human being is about 2.4 mSv per year from the natural radiation background. These data are provided by IAEA and the EU. Evacuees from Japan would have received more radiation from flying to the UK than from nuclear installations.

Andrew Miller MP gave a vote of thanks to the Speaker:

"It is great to be here again after an excellent year due in large part to the contribution from our President, Patrick Jenkin and thanks are therefore due to him for everything that he does to make our work so successful. Thank you also to the members in the audience for their valuable contributions to discussion meetings, *Science in Parliament* and SET for BRITAIN. Transparency is the order of the day, especially the need to inform and provide public confidence in what scientists and engineers do. Thank you all for coming here today and look forward to seeing you all in future meetings."



SIN OFFICERS IN SWITZERLAND: WORKING IN A SMALL RESEARCH PEARL



Gaby Bloem
Senior Science and Innovation
Adviser, Switzerland

The UK Science and Innovation Network (SIN) is jointly funded by the FCO and BIS and has a remit to cover international science and innovation. Represented in around 25 countries globally, it is also present in Switzerland. Senior Science Officer gives an overview of the team's recent work in supporting UK Nuclear Research capability, and bilateral projects taken forward, building on Swiss strengths in R&D.

In October 2011 SIN Switzerland organised a UK Nuclear Tour together with UK stakeholders in support of further development of the UK's nuclear research ambitions; an issue which was highlighted in the contributions on nuclear energy in the last edition of SiP and in final report of the House of Lords enquiry on nuclear energy.

From 24 to 27 October nine nuclear scientists from eight different European countries visited the just opened Dalton Cumbria Facility for nuclear research and education, the nuclear site in Sellafield, Manchester University, the (Nuclear) Advanced Materials Research Center in Sheffield and finally Imperial College in London. The aim of the tour

was to inform the European Fission Research Community of the latest UK initiatives in the area of education, training and innovation to support its Nuclear Renaissance, thereby opening up new possibilities for collaborations between the UK and other European countries.

The Tour followed up from a *Pan-European Nuclear Workshop*, which took place in Zurich in January 2011, jointly organised by our team and the EPSRC. The workshop showed that in wider Europe, some areas of British expertise are recognised but generally the size of the UK activity and its facilities are under appreciated or even unknown.

At the end of the tour, the European delegates left with an increased understanding of the UK strengths and its ambitions for nuclear research, taking this recognition back to their home country. Furthermore, the delegation formulated recommendations that closely reflect the results of the HoL enquiry addressing the UK government's strategy on nuclear research and the need to involve all bodies from academia, industry and government agencies in implementing that strategy.

In the recommendations, European delegates also expressed their wish to collaborate with the UK. That they were serious shows the concrete negotiations for bilateral collaboration between the UK and the individual European partners already happening just shortly after the tour. Furthermore, Neil Hyatt, University of Sheffield, and Tim Abrams, University of Manchester, will be working closely together with the Laboratory of Reactor Physics

The 5 recommendations as formulated by the European Delegation for the UK Nuclear Tour 2011

- To involve the end-users (utilities, industries, manufacturers, designers, etc) in guiding the R&D towards the final application needs;
- To foresee a Public-Private co-funding mechanism for applied research;
- To involve the safety and licensing authorities from the very beginning of the innovative qualification and validation processes;
- To consider rapidly the use of the NNL facilities for R&D on irradiated materials;
- To consider collaborations with European partners well equipped with neutron-irradiation capabilities and associated equipment for R&D on irradiated materials and fuels.

and Systems Behaviour of the Swiss Paul Scherrer Institute.

Apart from such a large project, SIN Switzerland also acts upon opportunities for bilateral research collaboration offered by the excellent R&D landscape in the host country.

Switzerland with a population of 7 million people and a yearly R&D budget of around 3% of GDP can be characterised as "klein aber fein", a small gem in global research and innovation. High quality and innovative research, stable high-level and long-term funding (which does not seem to have been affected by the financial crisis) and the keenness to collaborate with foreign partners make Switzerland a robust collaboration partner.

Against this favourable background, the Swiss S&I team organised niche activities with a small budget resulting in fruitful UK-Swiss collaborations. Just to name a few examples from the last 12 months/2011:

- The meeting initiated by our team in January between a delegation from the STFC interested in Intense Free Electron Light Source facilities

and the Paul Scherrer Institute in Switzerland led to a Memorandum of Understanding for collaboration in areas of mutual strategic importance covering accelerators, detectors and exchange of science.

- Our team initiated and facilitated a meeting between the Environmental Sustainability KTN and the Swiss Centre for Aquatic Sciences, resulting in a joint FP7 bid.
- Our visit to Disney Research Lab in Zürich in November generated strong mutual interest between Disney and UK stakeholders, including the Creative Industries KTN and Bristol University.
- Finally we organised visits by UK delegations to Switzerland in the areas of nanomedicine (May 2011) and Clean Tech (Sept 2011) which led to several bilateral collaborations.

If you would like to know more about the work of the UK Science and Innovation team in Switzerland or the projects mentioned, please contact Elisabeth Wallace, elisabeth.wallace@fco.gov.uk or 0041 31 359 7754.

STEM CELLS FOR SAFER MEDICINES: A PREDICTIVE TOXICOLOGY CONSORTIUM



Professor Frank W Bonner, PhD, FBTS
Chief Executive, Stem Cells for Safer Medicines

THE OPPORTUNITY TO IMPROVE PHARMACEUTICAL RESEARCH AND DEVELOPMENT

The pharmaceutical industry is facing many challenges, not least the substantial loss of revenue as a consequence of a number of products coming off patent. We are witnessing escalating drug development costs combined with reduced numbers of products gaining regulatory approval and hence introduction into clinical practice. Too many drugs fail in development and a significant proportion (around 25 per cent) of drug attrition is due to toxicity issues. It is recognised therefore that improved drug screening models are urgently needed for the identification of potential toxicity, which should result in an increased success rate as 'flawed' candidate drugs are eliminated early.

Stem Cells for Safer Medicines, SC4SM, is a public-private partnership that was founded as a direct recommendation of the UK Stem Cell Initiative (Sir John Pattison Report, 2005) to develop predictive toxicology tools from human embryonic stem cell (hESC) lines. The

partnership capitalises upon the emerging strength of stem cell science in the UK, with its strong ethical and governance framework combined with the enabling environment, both politically and socially, to generate and validate novel *in vitro* models that can be used to predict risk for many of the potential adverse effects of new drugs and chemicals.

AIMS AND OBJECTIVES OF THE CONSORTIUM

To address the challenges in the development of new medicines, we need to generate and validate more innovative, preferably cellular (in vitro), tools. One way is the development of models for toxicity testing that are reliable, high throughput and above all, predictive of risk for man.

The aim of the SC4SM partnership is to produce optimised methods for the preparation of particular cell types (initially, the liver as the major organ affected by drug toxicity) from hESC lines with well-defined and 'fit for purpose' functionality. Differentiated cell types derived from hESCs offer significant benefits in terms of unlimited supply, the opportunity for standardisation and potentially improved predictiveness. Following scale-up and manufacture, the derived liver cells would then be incorporated into high throughput toxicity screening platforms and subjected to comprehensive validation and benchmarking against current existing cellular models. A successful outcome would be confirmation of the reliability and utility of the stem cell model to identify those compounds with potential risk of toxicity for man.

In this case, it would be anticipated that pharmaceutical companies would integrate the new stem cell model into the range of screening procedures that are required to test the efficacy and safety of new medicines.

OPERATING MODEL FOR THE PARTNERSHIP

SC4SM, as one of the earliest public-private partnerships (PPPs) focused on generating predictive toxicology tools, was a pioneering model in how pre-competitive collaborations between companies, government and academia could be used to drive innovation in a technically challenging area such as hESCs. This collaboration reflects wider changes in the industry which are now increasingly entering into pre-competitive PPPs (eg the Innovative Medicines Initiative in the EU) to tackle major challenges where collaboration allows both the knowledge and the risk to be shared.

SC4SM operates as a not-for-profit company with its ethical policies and a strong governance framework agreed upfront. Operating as a pre-competitive consortium of industrial members and public sector partners, the company's funds support a range of academic collaborators. Currently, SC4SM industrial members include AstraZeneca, GSK, Roche and UCB, and in addition to providing funds, the companies make a major contribution to the project through scientific input and availability of their expertise, data and other resources, for example technology platforms. Recognition of the importance in improving predictive tools was demonstrated by public funding

being made available by a number of government agencies including the Medical Research Council, Biotechnology and Biological Sciences Research Council, and the Department of Health and Technology Strategy Board.

The research programme is being conducted through academic collaborations with the universities of Bath, Liverpool and Manchester and is project-managed directly by SC4SM. A Scientific Advisory Board (SAB) provides external peer review and overall scientific guidance and includes a range of relevant academic experts plus representatives from the industrial partners. An Executive Board is responsible for overall corporate governance and approves scientific strategy and direction.

BENEFITS AND CHALLENGES

The formation of SC4SM as a public-private partnership facilitates collaboration between cutting-edge academic science in the UK and the vitally important research-based pharmaceutical industry. The opportunity for risk, cost and pre-competitive data sharing is a clear benefit for the industrial members and at the same time, access to company R&D know-how and experience is of great value to support the activities of the network of academic collaborators who are working in a highly competitive and challenging scientific environment.

Through these combined resources, a successful pilot phase project has been completed (with IP generated and a patent filed) and a three-year research programme is currently underway.

STAKEHOLDER PERSPECTIVES ON VALUE-BASED PRICING



Eric Low
Chief Executive, Myeloma UK

After more than fifty years of regulating the cost of medicines through the Pharmaceutical Price Regulation Scheme (PPRS), the Government has embarked on an ambitious plan to move towards a system of value-based pricing (VBP) for new branded medicines from 2014 onwards.

Whilst the Government's intentions behind introducing VBP have been broadly welcomed, stakeholder opinion has divided substantially over the complexities of how to design and implement such a system – accentuated by the lack of detail in the Government's response to the initial consultation on VBP.

One of the biggest frustrations in this process is that there has been no forum available for stakeholders to come together to exchange their views on VBP. Stakeholders have been thinking in isolation and 'lobbying' Government independently rather than working together to ensure 'win-win' solutions to some of the underlying issues and disagreements.

To address this, and because VBP offers such an important opportunity, Myeloma UK decided to host a roundtable discussion to create such a forum.

Attendees at the discussion, including patient groups, health economists and industry

representatives, examined the issues and 'critical success factors' fundamental to a new system of drug pricing, the 'fault-lines' in the VBP debate, and possible areas of consensus. Attendees also contributed to clear recommendations, summarised below, that we hope will move the VBP debate forward.

PRICE SETTING

In establishing a system of VBP one of the most critical issues that needs to be addressed is how prices are set.

Attendees agreed that value-based prices for new branded medicines should be arrived at through a clear and fully transparent process, able to withstand judicial review. However, in order to protect against the negative effects of international reference pricing, the actual reimbursement price reached through this process should remain undisclosed when necessary.

It was also recognised that the new system should include a mechanism for the price of a medicine to be adjusted to take account of new indications, thus representing its overall value to the NHS. This should not mean, however, that different indications of the same medicine should be priced differently, as this is impractical.

The question of the relationship between pricing and reimbursement arrangements and industry's location of research and clinical trials proved particularly controversial during the discussions.

Whilst some stakeholders perceived the two issues as unrelated, others feared that applying a downward pressure on prices would damage the existing 'ecosystem' and drive companies to relocate their clinical trials elsewhere.

In taking VBP forward, if stakeholders do consider this pivotal to the debate they should be explicit about why.

VOLUME AND UPTAKE

A primary objective of VBP is to ensure better access to effective drugs and innovative medicines on the NHS.

Whilst this is a laudable objective, attendees struggled to see a strong link between VBP as presently proposed and improved patient access to medicines. The issues surrounding patient access are complex, and drug-pricing only forms part of this bigger picture.

It was concluded therefore that additional policy initiatives would be required as part of VBP to ensure that approved new medicines are prescribed and available throughout the UK.

Furthermore, in order to understand the current problems with access and uptake, attendees called for improvements in data collection techniques across the NHS.

THRESHOLD SETTING

In light of the long-standing criticism of the National Institute for Health and Clinical Excellence (NICE) cost-effectiveness threshold (the cost/QALY threshold), attendees were asked to consider how thresholds should be set under VBP. This is particularly important as the Government has outlined its intention to create maximum prices for medicines based on a range of thresholds – depending on factors such as innovation, societal costs and benefits, disease severity, and unmet need.

Attendees agreed that thresholds should, for the first time, be based and set by a new, independent advisory body that would sit outside of the existing HTA organisations in the UK.

Attendees also recognised the value of wider Government engagement with patient groups and the public on threshold setting, since the potential application of varying thresholds has already proved one of the most controversial elements of the Government's proposals.

DEALING WITH UNCERTAINTY

The design of the new pricing system will have to address the challenges in certain cases of dealing with uncertainty regarding the clinical and cost effectiveness of new medicines at their launch.

Attendees agreed that through the use of different cost-effectiveness thresholds the Government should be able to accept a lower price in certain circumstances for medicines when there is uncertainty around the data.

To reduce uncertainty the Government needs to agree with industry the level of evidence that needs to be collected prior to launch to ensure that companies reach higher price thresholds with their medicines.

To address further the issue of uncertainty, after a medicine has been approved by NICE, it was agreed that the Government needs to ensure that NICE works with Commissioners to specify clearly how the new medicine will fit into clinically relevant commissioning pathways on the NHS.

NEXT STEPS

Myeloma UK believes that the best way towards resolving some of the outstanding issues and differences of opinion relating to VBP is through multi-stakeholder dialogue. It is our hope that discussions such as those we have outlined will provide a valuable contribution to inform the development of the Government's policy. We are keen to continue to provide stakeholders a forum to discuss these issues and look forward to holding further meetings to address the policy detail in the lead-up to 2014.

You can order a full copy of the report by emailing VBP@myeloma.org.uk

ARCTIC METHANE EMERGENCY



Dr Stephen Henley
CEng FGS FIMMM
Parliamentary & Scientific
Committee website manager

At the Fall Meeting of the American Geophysical Union in San Francisco from 5-9 December 2011, there was a session on **Arctic Gas Hydrate Methane Release and Climate Change** at which Dr Semiletov of the Far Eastern branch of Russian Academy of Sciences reported dramatic and unprecedented plumes of methane – a greenhouse gas about 72 times more potent than carbon dioxide over 20 years – were seen bubbling to the surface of the Arctic Ocean by scientists undertaking an extensive survey of the region.

So far this has been reported in *The Independent* and in a number of online blogs, but the background is explained in detail by a website set up by the Arctic Methane Emergency Group. Essentially the problem they have identified is the following:

This emergency to our planet's biosphere comes from multiple mutually reinforcing positive feedbacks now affecting the Arctic climate. Each of these feedbacks alone would affect the entire biosphere, however, when working in concert with each other will exponentially increase global warming, leading to abrupt and catastrophic climate change. Numerous scientific sources show atmospheric temperatures are rising much faster in the Arctic than in temperate or tropical regions.

The Arctic summer sea ice is in a rapid, self-reinforcing collapse, causing a most dangerous feedback: an albedo flip from a highly reflective state to a highly light absorbing state. (Open sea absorbs 90% of incoming solar radiation and converts it to heat, while sea ice harmlessly reflects 90% of incoming solar radiation back out to space) In hindsight, Arctic summer sea ice clearly passed its tipping point in 2007 – many decades earlier than models projected, meaning that it is now highly likely that the Arctic will become ice free in summer within the next two to seven years. Models, based on measurements going back to 1979, of sea ice volume indicate a seasonally ice free Arctic likely by 2015, with the possibility of a collapse to a small amount of residual ice as soon as summer 2013. Such a collapse will inexorably lead to a number of

positive feedbacks, among which will be a change of today's carbon sinks such as permafrost, peat bogs, and rainforests worldwide to become net sources of atmospheric carbon. The net effect of these positive feedbacks will be planetary catastrophe.

The retreat of sea ice could establish the most catastrophic feedback process of all, which may already have started many decades ahead of projections. This involves the venting of methane to the atmosphere from vast stores of methane capped by sub-sea permafrost that is now thawing and perforating all across the East Siberian Arctic Shelf – the world's widest continental shelf. Such venting can lead to greenhouse warming and further venting in a vicious cycle where global warming spirals out of control towards a hothouse planet.

All of these Arctic feedbacks are described in detail in the 2009 World Wildlife Fund (WWF) report, *Arctic Climate Feedbacks: Global Implications* (<http://en.wwfchina.org/en/publications/?3265/Arctic-Climate-Feedbacks>)

If substantiated as happening on a large scale – and this year's reports suggest that it will be – then this situation can start an uncontrollable sequence of events that would cause worldwide modern agriculture to fail and civilisation to collapse. Change in the Arctic is occurring at an accelerating rate, and when presented with the most recent evidence it is not alarmist to say that it is an all too real threat to the survival of humanity and much other life on Earth.

Emergencies always happen at the worst times – but it doesn't mean that there is any excuse to scrimp in funding whatever it takes. After all, World War II came at the end of ten years of depression, yet the country had to respond to the threat. If the AMEG analysis is right, then the present threat not only to the UK, but to all humankind, is far greater than we faced in 1939, and demands an appropriate response. It requires rapid mobilisation on national and international scales.

The first part of such a response should be the urgent formation of an independent, international team of scientists and engineers to assess the real

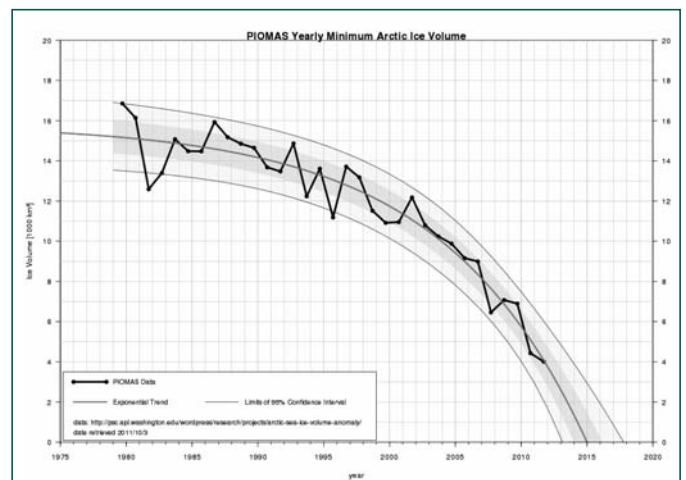


Figure 1: Trend of minimum summer Arctic ice volume. Data from PIOMAS (Polar Science Center, Washington DC, USA)

scale of the problem. This clearly cannot be done by any one nation alone – even Russia, on whose doorstep the most serious symptoms have been seen.

If the AMEG analysis is confirmed, then the second stage is urgently to identify and implement the necessary counter-measures, which also need to be carried out as an international project. There are a number of methods to tackle the problem if action is not delayed: they may be grouped as either geo-engineering or local intervention solutions. Financing these is something which simply has to be done – without long delays and political wrangles. It is an almost

impossible challenge to implement the counter-measures quickly enough to prevent the possible collapse of the Arctic sea ice in summer 2013, but this challenge has to be faced as an international emergency.

It should be added that there have been other reports which suggest that there may be less urgency – though they do not disagree with the existence of the problem. However, this is a case where I believe the precautionary principle must override such doubts. The precautionary principle was invoked during the 1990s to justify international action (such as the Kyoto Protocol) on global warming at a time when the

scientific evidence for man-induced warming, though strong, was not totally certain (at that time, for instance, only CO₂ was being monitored, not methane or nitrogen oxides). The wisdom of that was borne out by the fact that the scientific evidence has become absolutely overwhelming. Doing nothing, in my opinion, is not an option. Delaying action is as bad as doing nothing. If we take action and it proves to have been unnecessary then a lot of money will have been spent – but not altogether wasted even so, as we shall understand these feedback processes much better. If we do nothing and find that action was required, then the future of civilisation is at serious risk, if not worse.

The Arctic Methane Emergency Group is an ad hoc international group, chaired by geoengineering expert John Nissen, whose members include Peter Wadhams, Professor of ocean physics at Cambridge University, Stephen Salter, Emeritus Professor of Engineering Design at Edinburgh University, and Dr Brian Orr, former Principal Scientific Officer, Department of the Environment. Further information can be obtained from <http://www.arctic-methane-emergency-group.org>

A document from AMEG has also been placed on the P&SC web site giving much more information, in language that should be accessible to non-scientists.

WHAT IS THE PUBLIC UNDERSTANDING OF RISK?

Meeting of the Parliamentary and Scientific Committee on Tuesday 13th December

ENGINEERING, ETHICS AND RISK



Dr Chris Elliott FREng
Pitchill Consulting Ltd

The public has no difficulty understanding risk. My evidence for that assertion is to look at how people deal with, for example, a three horse accumulator bet. People are quite capable of understanding odds and alternative outcomes, provided they have trustworthy, accurate and impartial information. For horse racing, all they have to do is pick up the Racing Post.

However, the question is not whether the public is capable of understanding risk but whether they do actually understand it. For many of the risks that they have to deal with, there is no equivalent of the Racing Post.

An extreme example was Andrew Wakefield's allegation of a link between autism and the MMR vaccination. Wakefield was at least incompetent and possibly dishonest but the real harm was done by the news media that reported his work sensationally. Poor risk decisions by parents meant that children

were not vaccinated, with a consequent loss of "herd immunity", and it is highly likely that some have died as a result. Did any of those newspapers print as big headlines after his work was discredited? How can lay parents take a sensible risk-based decision when confronted with such poor information?

My understanding of juries and work I have done with focus groups leads me to trust the proverbial "man on the Clapham omnibus" provided we treat him or her like a grown-up. That leads to my first

conclusion: The public is perfectly capable of understanding risk – if given trustworthy, accurate and impartial information on which to make an informed decision.

The following cutting from the London Evening Standard quotes an Assembly spokesman saying that driverless trains are "perfectly safe". That is nonsense; nothing is perfectly safe. Every human activity brings good and bad consequences, not all of which can be accurately predicted. We decide

Underground could be running driverless trains as early as 2018

Dick Murray

THREE out of four Tube trains will be able to operate without drivers by 2018, Transport for London directors have been told.

These include trains on all lines except Piccadilly, Bakerloo and Waterloo and City. A report presented to the TfL board said that once the new stock of trains for the sub-surface lines is complete it is "unlikely" Tube bosses "will ever again buy a fleet of passenger trains with conventional drivers' cabs", and upgrading the signalling systems

meant "by 2018 ... some 70 per cent of the network will be automatic".

Plans for driverless trains across the network from 2020 were revealed by the Evening Standard last week.

London Assembly Tory group transport spokesman Richard Stacey said: "It makes total sense. Thirty cities around the world have driverless trains. They are perfectly safe."

But Caroline Pidgeon, leader of the Assembly Lib-Dem group and the transport committee, said the Assembly would need "absolute guarantees" about safety.

that a risk is acceptable if the likely harm is outweighed by the likely good.

Equally absurd is the call in the final paragraph for "absolute guarantees". Safety is a result of a trade-off. When you hear a Managing Director or a Minister after an accident saying, "safety is our highest priority", you can be sure of one thing. She or he is lying. If safety were the highest priority they would not fly the plane, drive the train or sell the medicine. Safety has to be traded with speed, effectiveness, comfort and many other properties *including* cost.

That leads to my second conclusion: **Risk has to be managed, it cannot be avoided**

We are seeing attempts to avoid it in the response to Fukushima. Much of that has been driven by fear of the hazard without consideration of the actual risk. A hazard is something that has the potential to cause harm; risk is a measure of the likelihood that it will arise and the consequence that would follow. For example, a penknife blade is a hazard but, if I fold it into the handle, the risk that it presents in my pocket is tiny. Nuclear hazards are very easy to detect but what is the level of risk? Let's be clear – no-one was killed by the nuclear failure (compared with over 25,000 in the tsunami). The worst affected people were probably the fire-fighters. On

average 25% of us die of cancer (1 in 4); according to the WHO those fire-fighters now have a risk of 26%. That is about the same risk of dying at work as "white van man" in the UK. I'm not dismissing a 1% risk of death and I hope they were well rewarded but the reaction of many governments, to end nuclear power, is hardly rational.

It's even less rational when they do not also do anything to reduce demand. We still want our air conditioning and dishwashers, which need electricity. We can generate it with oil – the Macondo accident killed eleven people, as well as its environmental impact. We can use coal, maybe for the Japanese from China, but last year the Chinese authorities admitted to 2433 mining fatalities. Coal mining also has collateral damage – remember Aberfan?

Objectively nuclear power is one of the safest ways of generating electricity, and it does not release carbon from fossil fuel, so why aren't we clamouring for it? Maybe we are not receiving trustworthy, accurate and impartial information. There is an interesting exception. I usually rely on the Daily Mail for examples of sensationalising and distorting risk, for example in its outrageous coverage of the impact of road safety on speed cameras, but its reporting post-Fukushima has been balanced and calm.

We, by whom I mean engineers *and* politicians, have an ethical duty to deal properly with risk, delegated to us by the public because engineers have expertise and knowledge to assess benefit and harm and politicians have the responsibility to choose the "least-bad" option. It is not easy to choose between unpleasant options – nuclear power, coal mines or lights out – but we have to do so, ethically and courageously. For me, the ethical test is quite simple: would you be happy if someone whom you respect saw how you had decided? If you like, what would Jiminy Cricket say? If for example nuclear power is the right solution, it then takes political courage to say so in the face of hostile fear of the hazard and to do what you believe is right, not just popular.

Adam Smith is quoted on the £20 note explaining that society is built on the division of labour. The public, who can and do understand risk, has delegated to engineers the duty to find out the best way to solve practical technological problems and delegated to politicians the duty to put them into effect. That is the third conclusion: **We have a duty to take decisions about risk on behalf of other people.**

Let me return to automation; it's an emerging risk issue that has not been thought through. Despite the whipped-up concerns about driverless tube trains, the public is very comfortable with automatic transport. The picture is the Heathrow Pod. I signed its Safety Verification Certificate before it entered service. Since then, we have found that people love it and they're intrigued, not frightened, by the lack of a driver.

But what about what the Press calls "killer drones", pilotless military aircraft or vehicles? REAPER is an unpiloted surveillance aircraft in service in Afghanistan and under

development are so-called mules – driverless trucks that can resupply troops under fire or evacuate casualties. Why should we not want to keep our troops out of harm's way? Is there a real issue, perhaps about where we should draw the line?

Is ground support by a piloted Tornado different from support by a remotely controlled aircraft, where the "pilot" in a bunker in Nevada orders the weapon to be released? What if an autonomous aircraft is told what a target looks like and then finds and engages the enemy with no further control?

This raises legal as well as ethical questions. If that autonomous aircraft mistakenly attacks an ambulance, is it a war crime and who committed it? An enemy combatant who shoots down one of our pilots hasn't committed a crime, but what if he shoots the "pilot" going off duty in Nevada where he's been "flying" a drone 5000 miles way?

The challenge is not just about weapons. What about a robot surgeon? Do we want a remotely controlled knife that's more accurate and doesn't get the shakes but which has a real surgeon on the other end of the joystick? How about taking away the surgeon and tell the robot to take out the appendix? What about self-driving cars? 95% of road accidents are caused wholly or in part by human error. Wouldn't it be better to eliminate the least reliable component, the nut on the steering wheel?

These are difficult ethical questions and they are no longer theoretical. All those technologies are either with us now or credible in the foreseeable future. How do we – the engineers and politicians to whom the public has delegated responsibility – reach ethical decisions about the risks?

RISKY BUSINESS: RISK AND REWARD ASSESSMENT IN BUSINESS DECISION MAKING



David Simmons, Managing Director, Analytics, Willis Re

INTRODUCTION

As a young maths graduate in 1980 I looked around for a career that would offer general business experience but with an element of mathematics. I rejected being an actuary, then life and pensions only – too many exams and too dull, but general insurance seemed ideal, “the risk business”. It was a big mistake. I found myself in a bloated bureaucracy where insurance rates came out of a dusty book that looked as if it had been handed to Moses on Mount Sinai; in truth parts probably dated back over 50 years. Over time I drifted towards a more actuarial career, moving to Head Office to get involved in reserve setting and budgeting. But even there, the understanding of risk was low. I recall one early report written for the board which mentioned standard deviation, a common measure of volatility. The paper was returned as the board could not be expected to understand such a term.

By 1985 I had moved to the reinsurance market, the insurance of insurance companies, partially motivated by the higher salaries it offered but mainly because I thought it must offer a more rigorous analysis of risk – the amounts of cover bought were in the hundreds of millions, the premiums huge, the risks very uncertain. But I was wrong. The market worked on shared knowledge and used simple rating algorithms. But quickly things would change and that change would be profound. The market now is unrecognisable from the one I joined. Twenty-five years ago I was the only

mathematician working for a London market reinsurance broker developing risk analysis systems. Now my company alone has over four hundred analytical staff, approaching twenty per cent of the overall personnel total.

Risk is now embedded in the decision making processes of all UK insurers, from the smallest to the largest. Directors of insurance companies are now expected not only to understand what standard deviation means but also to have a broad understanding of the risk models used in their business: their assumptions, strengths and limitations. The relationship

between risk and reward is considered before every major decision is made – is the cost of this strategy worth the reduction in risk it brings? The cultural change has been enormous. I will seek to explore why this happened, what the benefits have been, what problems have been encountered and what lessons there are, if any, for government and wider society.

WHY HAS THIS HAPPENED?

Technology

The mid-1980s saw the emergence of the IBM PC. By the early 1990s the power of these machines had increased,

and software had emerged, to make stochastic simulation modelling possible on the desktop. More data about the risks was gathered and that data was more easily accessible. For the first time, rather than modelling a best estimate or worst case, it was possible to attempt to model all possible outcomes of loss causing events, individually and in combination with each other. It was thus possible to show the impact of a particular strategy, for example the purchase of a reinsurance treaty, on an insurer's results not only on average but also at extremes. This opened the door to new pricing and decision making algorithms.

National Competition

New firms developed to take advantage of the new technology and better data to, for example, target properties in low risk areas which the crude rating models of existing companies systemically over-rated, cherry-picking the best risks. This led to a drive by all UK insurers to improve their data, their risk understanding and their analytical techniques. Reinsurance brokers were at the forefront of this revolution, developing the first probabilistic UK windstorm and flood models and decision support systems for their clients use.

International Competition

The Lloyd's market, the world's predominant reinsurance market in the 1980's, was coming under attack from "professional reinsurers" in Europe and then Bermuda. These companies aggressively used risk analysis and technology to accept and rate business. For example, by the

mid 1990's Bermuda reinsurers were beginning to use marginal capital methods. The impact of each new catastrophe risk presented, for example hurricane reinsurance, would be assessed not only in terms of expected profit but also in terms of how much additional capital it would require. The London market had to up its game if once again it were not to lose the better risks to competitors.

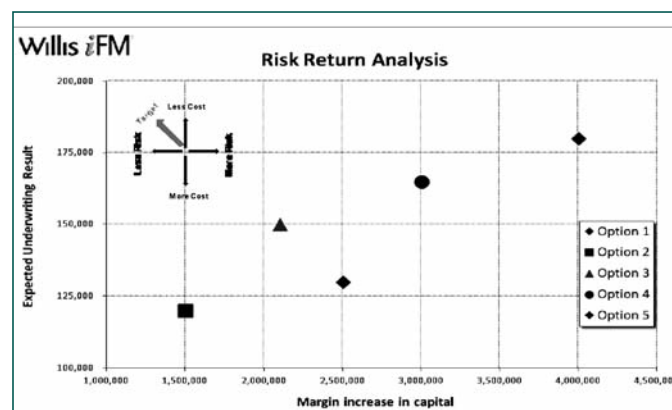
Regulation

Risk based insurance regulation began to emerge. In some cases such as Australia, this was prompted by market

HOW DOES IT WORK?

Risk/return analysis

The aim is to compare the cost of an action or a strategy with its impact. A common tool for doing this is a risk/return chart. Typically on the vertical axis is a measure of average return, for example how much money is made or how much the action costs. On the horizontal axis is a measure of risk, something which needs to be minimised. That risk could be the probability of missing a target, the probability of a loss exceeding £x or y lives etc. An example is given below:



failure, in others by advances in banking regulation. With the formation of the FSA, a unitary regulator, a Basel II type regime, Individual Capital Assessment (ICAS), was introduced in 2005. Insurers were required to identify, manage and quantify their risks; most interpreted this as a need to build a stochastic capital model. Solvency II, the European risk adjusted insurance solvency regime was announced around the same time and should go live in 2014. The ICAS experience leaves the UK industry much better prepared than its continental rivals but it remains to be seen how level a playing field Solvency II will be.

In this example, the return measure is expected underwriting result, the y axis marginal increase in capital (perhaps measured by increase in the 1 in 200 year loss expectation). Ideally the insurer would want to be at the top left of the chart, high return but low risk. Sadly, that is impossible unless within a monopoly. To make money an enterprise needs to take risk (and so have higher capital), to minimise risk (and resultant capital) they must accept a lower return.

On this chart 5 options are plotted as possible strategies. What does the chart tell us? Firstly it tells us that option 5 is

sub-optimal. Assuming (and we will return to this) we are happy that our model is correct, why follow option 5 when option 3 has a better return and lower risk/capital? But which of options 1 to 4 should the company follow. It depends on its relative attitude to return and risk. Option 1 provides maximum additional income but for maximum capital usage. Option 2 gives a much lower return but also much lower additional risk and thus capital usage. The modelling does not provide the answer but provides the framework for discussion.

HOW DOES IT WORK?

Marginal capital analysis

In this example, assuming each option is a contract which we could accept onto our books, we can use marginal capital methods. Say the company's return on capital target is 10%. We can look at each contract to see if it meets or exceeds that target.

All options fail the 10% target, though option 2 is the closest, option 1 the worst. Based on this test all contracts would be rejected. In reality of course other considerations may apply: existing client relationships, market condition etc. Again, the model provides a framework for discussion.

WHAT BENEFITS HAVE ACCRUED?

Undoubtedly there is now a much greater transparency about the decision-making process. To model risk, assumptions about risk behaviour have to be captured, perhaps assumptions that have been commonly assumed but

never previously been open to examination and challenge. Arguably, the UK insurance industry is stronger, certainly more professional, probably better capitalised and more resilient. It is true that in the early days of modelling a “the computer says no” attitude prevailed, models were often allowed to lead decision making rather than inform them. However, now a more adult and mature attitude prevails. Models advise, but models do not, and should not, decide. A balance between model complexity and model comprehensibility has to be struck. Better a simple model where the flaws are known to all than an apparently more comprehensive one where the flaws are buried deep and understood by no one.

WHAT HAS THE ORGANISATIONAL IMPACT BEEN?

There are not enough actuaries in the world to meet global demand. The insurance industry has become far, far more technical. The staffing profile of insurers and brokers has changed radically and continues to change. Numerate science graduates are now sought. Every significant UK insurer now has a board level Chief Risk Officer – a position unknown 10 years ago. Boards now need to be numerate to meet regulatory demands, there are too few grey-hairs of the right background to meet demand for appropriate non-executive directors. But the UK is in a good position. We are a net importer of actuaries but are now arguably the global centre of insurance capital

modelling expertise. There is concern about the cost of the risk management and Solvency II compliance, estimated at over £400m for the Lloyd’s market alone, but at least UK insurers have the people and the systems in place. Many in Europe do not. Solvency II is a European initiative, but Solvency II-like risk regulation is spreading world-wide through the International association of Insurance Supervisors. The UK is well positioned to be a global centre of excellence.

DOES THIS BENEFIT THE CONSUMER AND UK POPULATION?

Undoubtedly yes. Insurers are stronger, better capitalised, more fit for purpose. Regulators are more efficient and better informed. More internationally competitive insurers, brokers and consultants benefit the UK economy and create UK jobs. But not everybody is a winner. Greater risk analysis means that some lose. Insurers can more readily identify poor risks. Premiums, say, for those in a flood plan with poor flood protection may increase. Some countries, such as France, nationalise some areas of risk to ensure “solidarity” with the same flood premium regardless of whether you live at the top of a mountain or the bottom of a valley. But appropriate risk pricing encourages appropriate risk behaviour. For example, should local authorities grant planning permission to properties in a flood plain with inadequate protection? The lack of availability of insurance will surely concentrate minds. Similarly pollution risk insurance rate analysis allows well

managed companies to reap immediate benefit for demonstrably better risk management.

WHAT LESSONS ARE THERE FOR WIDER SOCIETY?

As a mathematician I have big problems with woolly thinking. For example, what on earth does reasonable doubt mean in law? Does it mean there is a 1 in 1000 chance the defendant is not guilty, a 1 in 100 chance, a 1 in 10 chance, a 1 in 5? Now clearly we cannot measure probability of guilt to these levels of accuracy, but we should be clear which target we are aiming at. The chance of any two jurors having the same understanding of reasonable doubt is virtually zero. Now business is not the law, but the insurance industry’s adoption of probabilistic decision making tools has certainly brought more objectivity and transparency to decision making. In truth it is equally difficult to quantify capital requirements at the 1 in 200 level, as regulators require, but at least everybody is aiming at the same target and forced to explain their thinking.

There is no reason why such tools should not be used in government. Is it better to spend £x to make the railways safer, saving 5 lives a year on average, reducing the risk of a media friendly crash with multiple fatalities, or spend the same money on road improvements saving 20 lives a year, although these will be mostly single fatalities which are missed by the news media. For politicians this is a difficult call, but being able to call on an unbiased

risk/return analysis can only improve decision making and justify where the taxpayers’ money is best spent. Arms procurement is another area which would seem ideal for such an approach.

But it must be emphasised that all models are hugely assumption-dependent. Resist the temptation to say “the computer says no”. Politicians, like insurance company executives, cannot hide behind experts. They need to judge the advice they get and make a decision; it is their decision, they are responsible. Models advise, they do not decide.

There are clearly implications here for educational policy. Are we turning out school-leavers and graduates with appropriate levels of numeracy to understand basic concepts of risk? How do we encourage more students to study mathematical and scientific subjects?

The real value of a risk/return approach derives from the transparency, understanding and challenge which should flow from the risk quantification process. Objectives should be clearly stated and options compared to these objectives. All assumptions behind a decision can be seen, discussed, challenged and stressed. Stakeholders can understand how and why decisions have been made. In this brave new world there can be no more hiding behind woolly assessments and woolly thinking.

POWER LINES AND PEOPLE

A case study in differing assessments of risk



John Swanson
National Grid

Academic research on risk psychology has established a good understanding of how the public perceive risk. Can this understanding be successfully applied to a practical, and pressing, real-life example, that of high-voltage electricity power lines?

Many coal-fired and oil-fired power stations are reaching the end of their useful lives, and the UK is connecting new renewable energy and nuclear power stations as low-carbon alternatives. This requires a programme of investment in new infrastructure and extensions to the National Grid on a scale comparable only to the initial building of the supergrid in the 1960s. The resultant requirement for new routes and especially for new overhead power lines creates public opposition (not forgetting the opposition to existing power lines, either).

Some of the opposition is on visual grounds, but some is on grounds of health concerns over the magnetic and electric fields produced by power lines (along with all other uses of electricity). Thirty years of research has not established that there is any risk from these fields; it is probably fair to say the weight of evidence is against health effects; but research has found a persistent statistical association with, in particular, childhood leukaemia. The World Health Organization classified magnetic

fields in 2001 as “possibly” carcinogenic as a result. The Health Protection Agency state “the overall evidence for adverse effects of EMFs on health at levels of exposure normally experienced by the general public is weak. The least weak evidence is for the exposure of children to power frequency magnetic fields and childhood leukaemia.”

It is, however, no surprise that members of the public generally regard the risk as greater than this scientific assessment would suggest, both the likelihood of its being real and its potential severity. We know from the previously mentioned research on risk psychology, by Slovic and others, that there are well established “fright factors”. These are attributes of a risk that lead the public to regard it as more serious; and power lines, and the magnetic fields they produce, trigger many of these fright factors:

- It is not found in the natural environment and is seen as something new, unfamiliar and invisible.

- It is seen as imposed, in that people perceive they have limited choice over the presence of a power line close to their home.
- It is seen as not bringing any direct personal benefit. While electricity networks as a whole bring the benefits of secure and affordable electricity supplies to society, the link is not a direct one between a power line carrying bulk power long distances and the person living near it.
- It is seen as inequitable, in that only a small fraction of the population live near high-voltage lines, and that may further be seen as a consequence of decisions made against local wishes by more powerful sections of society.
- There is uncertainty in the science of health effects.
- There is disagreement among supposed experts, with scientists adopting views to both sides of the mainstream.
- Any risk involving childhood leukaemia would affect children and involve a dread disease.

These “fright factors” are deeply embedded in human culture. Regardless of our scientific education, we probably all unwittingly as well as consciously accept higher risks, whether in transport, leisure activities, or food and drink, if we feel it is something we have chosen because it brings us a benefit and that we have control over. So it is unavoidable that there will be considerable public concern at power lines, more than the scientific evidence on its own might justify.

However, it would be foolish to respond to this by saying that we scientists come up with the true magnitude of a risk, and that if the public disagree, then they are wrong. It is foolish because at one level, in a democracy, the public are right, if not about the facts of a risk, then certainly about whether it is deemed acceptable or not. But it is also foolish because it ignores the reasons why the public treat risk differently from scientists. It should be a good assumption that, as the product of evolution, there are often sound reasons for human instincts, and that includes our perception of risk. The public perhaps have, not a deficient understanding of risk, but a richer understanding.

So the wiser approach is to engage in a dialogue with the public about how the risk looks from where they are. In the course of that dialogue we may well be able to provide better information, which may help to better inform their understanding of the risk. But we will be successful in this only if we start by listening, not by lecturing, and we will certainly

fail if any sense that the public are wrong or do not deserve to have a voice comes through from our approach. In the words of Thomas Jefferson: “I know no safe depository of the ultimate powers of the society but the people themselves; and if we think them not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them but to inform their discretion by education.”

Examples of how National Grid have tried to do this in the context of proposed new power lines include:

- **Uncertainty:** it is human psychology to dislike uncertainties and instead to see them more as “definitely yes” or “definitely no”. But there are also too many examples of reassurances given about supposedly unlikely risks that turned out to be unjustified. There is some basis for the public presuming that risks will often turn out to be more serious than they are told by authorities. As far as we are able we try to work with and from the public perception, specifically when it comes to adopting appropriate precautionary policies.
- **Risk comparisons:** comparisons are effective only if the public view the risks as comparable. A comparison to an exposure to magnetic fields (e.g. from a domestic appliance) that is chosen by the individual will not provide reassurance about an exposure seen as imposed (the power line), even though the former can be bigger. Likewise, telling people that exposure to magnetic fields is like drinking

coffee (both classified in the same category on strength of the evidence for carcinogenicity by WHO) is ineffective. Enabling people to place things in context is valid and helpful, but it is ineffective to force it on them.

- **Choice, benefit and control:**

We may never be able to produce a direct benefit for a person living near a high-voltage power line from that specific line. But at the societal level, electricity networks are integral to the incalculable benefits that secure and affordable electricity brings to quality of life, health, communications etc, and increasingly, through enabling low-carbon electricity, to the nature of the lives our children will be able to live. Given how central these attributes of risk are to risk perception, we have to get better at telling that story at the societal level.

Some people affected by one of our proposals will inevitably still feel disempowered and may well dispute that communications have improved. However, we, while recognising that the decisions that finally have to be made are often still unpopular ones, believe that progress has been made away from “decide, inform, defend” to more genuinely consultative approaches. This is very much encouraged by the new planning regime for major infrastructure projects, which emphasises more consultation and at a much earlier stage.

We will never persuade the majority of people to like power lines. Nor can we eliminate health concerns; indeed, nor should we even try, as long as

the scientific uncertainty remains, and a separate strand of National Grid’s approach to this issue is to support high quality scientific research to try to resolve the issue. But we can make a difference by the style and approach of our communications about risk. As with so many risk issues, we tend to start by thinking that the correct outcome is determined solely by the facts: all that matters is to “get the numbers right”. We progress to realising that we need not just to get the numbers right ourselves, but to communicate the numbers. Then we realise that for this communication to be effective, we have to explain the numbers and to put them in context. All of these stages are necessary, but in our experience with power lines, reinforcing experience from many other issues, risk communication only becomes its most effective when, rather than “telling” people anything, we trust people and let them arrive at the answers for themselves, with us assisting but not directing.

Managing a scientific risk in a societal context is as much, if not more, an issue about people rather than about numbers.

BOOK REVIEW

LGC: The Making of a Company. From government agency to international business.

By Richard Worswick. Carrick Press

Review by Ian Taylor (Minister for Science & Technology 1994-97).

The Laboratory of the Government Chemist (LGC) was an early focus of my attention when becoming a DTI Minister in 1994. I had a glimpse of what was to be in store during a previous spell as PPS to William Waldegrave, who was responsible for the Cabinet Office and Minister for Science in 1992. The seminal White Paper 'Realising our Potential' had promised a systematic examination of all Government science and technology Agencies. I soon found that this was a challenge that had landed on my Ministerial desk.

Michael Heseltine as President of the Board of Trade had decreed that all the Next Steps Agencies should not only be subject to market testing of their contracts with government but should in principle be more commercially independent of government and even privatised. This was not straightforward, as I soon learned that every Agency had to be considered separately for all sorts of complicated reasons. There were frustrations – the ever unhelpful Home Office blocked our efforts to merge the Forensic Science Laboratory with LGC to the former's eventual disadvantage. That we succeeded overall – with often significant resistance within the Agencies and their friends in Parliament – was a notable achievement by a dedicated team of DTI officials. Once enthused about a clarified task (and with the right team assembled) the Civil Service is splendidly effective.

Richard Worswick provides an excellent reminder of just how transformational the complicated process could be and how 'insuperable' obstacles could

dissolve under pressure. The Laboratory of the Government Chemist, sold in 1996, was one of the last to be privatised, and as he says, possibly the least expected, partly because of the historic role of the Government Chemist. The latter post (which he held over a long period) involved the statutory role in disputes (such as about chemical content in food or originally the adulteration of gin and tobacco) as a referee technical analyst and dated back to the 19th Century. LGC also had little commercial experience, however impressive the scientific expertise.

Yet privatised it was, with Worswick himself leading a £5m buy-out in conjunction with the Royal Society of Chemistry (RSC) and 3i. The privatisation agreements included a 'framework contract' with DTI under which support for the 'National Measurement System' in relation to developing analytical standards was contracted to LGC. The book tells you all you need to know about the complicated history of negotiations from Worswick's point of view – warts and all.

What it does not really reflect is the context of the discussions within my team at the DTI and the lively input from Bob (now Lord) May, the Chief Scientific Advisor to the Government with whom I worked closely and constructively. One of our motivations as part of an overall stimulus for innovation was to enhance analytical science in the UK, as we saw it as a key part of exploitation of novel science. We realised that this required that Agencies such as the LGC become connected with industrial and international

activity. LGC itself needed to seek out new scientific applications or methodologies and fresh market opportunities, encompassing reference standards and analysis for the approaching age of genetics and forensic science. Science as a solution provider. In other words, there was a wider agenda than just saving money or following an ideological principle of privatisation.

In a visit 4 years ago to LGC at Teddington, I was impressed with all the technical progress, investment in laboratory equipment and width of sectors covered (including giving me a genetic scan from my saliva taken on my arrival). It has become a highly successful international company providing analytical and diagnostic services to clients in the private and public sectors throughout Europe and in India. I can claim only to have been a godfather to the success that Richard Worswick and his team achieved. The managerial strains and changes, the acquisitions, the investor negotiations, the managerial philosophy and culture were all challenges well-handled which is a tribute to their efforts. Staff numbers have risen from 250 to around 1500 in around 30 locations.

In 2004 a refinancing allowed 3i to exit (the RSC had done so earlier with a healthy cash benefit) and Legal & General Ventures became the majority shareholder. In February 2010 – after he had left – the company was sold to Bridgepoint for £257 million making the many employee shareholders considerable sums of money.

How this was done is explained clearly by Worswick and is worth careful attention by all those interested in how an Agency slowly disentangles itself from 'cushioning' within the public sector and faces the challenges of a competitive environment. He has written this very much in the first person – and as he ended up after all his considerable efforts substantially wealthier who can blame him. Any irritation for the reader is balanced by enjoyment of the deliberate indiscretions he makes about people or institutions he did not respect – you will have to find out who and which by reading the book!

This is a valuable insight into the process of extracting an Agency from the bosom of government and building a successful international commercial science based venture. There are many lessons to be learned. Richard Worswick deserves the tributes and is to be wished further success in his new ventures – one of which is chairing a spin out company from the Rutherford Appleton Laboratories, Cobalt Light Systems Limited.

The book is available post free via www.lgcthemakingofacompany.com

Ian Taylor is a former chairman of the Parliamentary & Scientific Committee. He decided to stand down from Parliament in 2010 to pursue a business career. He is now also on the Science & Technology Facilities Council and an ESA advisory committee.

The P&SC Committee visited LGC last June and the informative report is in SIP Autumn 2011.

UNDERSTANDING SOCIETY: A LIVING LABORATORY OF LIFE IN THE UK



Professor Patricia Broadfoot
Chair, *Understanding Society*
Governing Board, Economic
and Social Research Council

How are people in the UK coping with increasing unemployment? Do current economic pressures weigh particularly heavily on some groups? How far does your gender, age or ethnicity make a difference? What do young people who are not in education, employment or training – the so-called ‘NEETS’ – feel about their situation and prospects? To what extent is stress increasing as people face potential unemployment and rising living costs? Are the increasing pressures in the workplace resulting in more bullying and harassment at work? Who do people turn to for support when under pressure?

These and hundreds of other questions about life in Britain today will be reported on when the second round of findings from *Understanding Society* are published on 27th February 2012. *Understanding Society* is the world's most comprehensive longitudinal household panel survey. Building on the long-standing British Household Panel Survey (BHPS) which has been providing insights into life in the UK for the last 20 years, *Understanding Society* will record the experiences, views and aspirations of the national population on a scale unprecedented anywhere in the world. Launched in 2008, the survey collects data on a longitudinal basis from a sample of 40,000 households drawn from all parts of the UK. The households have been carefully

selected to reflect social and economic differences among the population and a range of geographic areas. Its unique ethnic minority boost sample will provide as never before, particular insights into the life experiences of different racial communities including family life, employment and social integration.

Understanding Society will also be pioneering new methods of data-collection. Because of its unprecedented scale, it will be vital to keep data-collection costs down. Equally, it is vital to the longitudinal character of the survey that those households currently selected for study, continue to be willing to participate. To meet these dual challenges, the researchers are incorporating new methods of data collection including on-line questionnaires and telephone interviews.

As well as providing data on the 100,000 or so individuals who live in the selected households, *Understanding Society* is designed to track the vitally-important reality of relationships *within* the household. When the ‘First Findings’ of *Understanding Society* were published in February 2011, much was made, for example, of the revelation, that more than half of all siblings were involved in bullying in one form or another within the home. It was also found that married individuals were happier than those in cohabiting couples.

Other potentially important themes for future analysis that emerged from these early data included the fact that many people felt they experienced poor or short sleep and that this tended to affect both their work and their happiness. It also emerged that in relation to the perceived threat of climate change, whilst 60 per cent of respondents felt that current lifestyles would be likely soon to result in a major environmental disaster, they would only change their behavior patterns if it fitted with their existing lifestyle.

Interesting as these initial findings are however, the true potential of *Understanding Society* lies in the fact that it will follow the same households and the individuals within them over many years. Providing that funding continues to be available, it will follow the children growing up in the sample households today, through adolescence, school and further and higher education. It will document their entry or otherwise, into the labour market and the process of establishing their own households and families. Because it will collect data over time, *Understanding Society* will also be able to report on the lifestyles of the ever growing numbers of older people and the links between the health problems they may experience in later life with their earlier education and employment, as well as previous patterns of diet and exercise and the health of other household members.

Another pioneering aspect of *Understanding Society* is the collection of 'bio-marker' data based on biometrics, blood and saliva samples provided by volunteers from within the main sample. This means that, in due course, it will be possible to link information about people's life experiences and events to aspects of their genetic make-up and health behaviours. The collection of both individual and family health and social data across such a large sample and over time will provide powerful new insights into fields such as education and aging. Challenging as the collection of this kind of information undoubtedly is, given the serious ethical and privacy concerns involved, it is to be welcomed that *Understanding Society* has received the agreement of participants to help create this unique scientific resource for the nation.

Understanding Society will thus be nothing less than a living laboratory of life in the UK, providing policy-makers, researchers, the media and the population as a whole with a comprehensive picture of life in the many different communities that make up life in Britain today. Because of its scale, the collection of information from the same individuals over time and its focus on households, *Understanding Society* is not like other surveys. It will not merely report respondents' experiences; it will also provide understanding about some of the drivers behind these lived experiences and hence useful insights about potentially -fruitful policy responses.

Clearly, such a 'laboratory' has great potential value for informing policy-making. It is this potential that has encouraged a significant number of Government Departments to provide co-funding for the study

alongside the Economic and Social Research Council, including the Department for Education, the Department for Work and Pensions, the Department of the Environment, the Department of Transport, the Department of Communities and Local Government and the Department of Health. This collaboration across such a wide span of Government departments and academic researchers will help to ensure that both the questions included in the survey and the subsequent analysis of the data generated will be genuinely useful in the development of Government policy.

Since November 2011, both academic and Government researchers have had access to the first full Wave of information collected across a 24 month period from January 2009 - January 2011. For the Department of Health and the Department for Education, for example, there is extensive data on young people's health related behaviours including their levels of drinking and smoking and patterns of diet and exercise. Over time, of course, it will be possible to trace the impact of these early adolescent behaviours on health and well-being later in life. Data from the special youth questionnaire documents other patterns in young people's behaviour in relation to, for example, how much freedom young people are allowed to stay out late without their parents' knowledge, in different socioeconomic and ethnic communities.

For many adults, these are challenging times in terms of managing the family budget, worries about pensions and employment prospects for the future. *Understanding Society: Findings 2012* will help to inform the work of the Department for

Work and Pensions and the Department for Health as well as the Department for Education in documenting changing patterns of unemployment across the different regions of the UK. How is the current economic crisis impacting on those claiming benefits? In what ways is the current employment situation affecting people's health and sense of well-being? Are attitudes to work and to finding work changing among young people in particular? Not only will *Understanding Society* provide Government with timely answers to some of these vitally important questions, it will also, crucially, trace the longer-term effects on both individuals and households of redundancy, poverty and for young people, of never having been able to enter the labour market. It will also provide insights into the current extent of debt in relation to mortgage payments and household bills and the factors associated with moving into or out of debt.

In difficult times, support networks are particularly important. *Understanding Society: Findings 2012* will document the distribution of perceived social support across the population and how this varies by individual and household characteristics. Do particular ethnic groups, for example, differ in the way they support each other? Or how does having someone to confide in affect overall life-satisfaction? Does this vary at different times of life?

Up to now, there has been a shortage of information about the particular experiences of ethnic minority groups. Most social surveys do not have samples that are big enough to provide for separate analyses of ethnic minority groups. *Understanding Society* by contrast, with its ethnic minority

boost sample, will uniquely make it possible to analyse diversity in the UK over time, exploring the degree to which particular cultures are being transmitted through the generations. *Understanding Society: Findings 2012* will provide a preliminary taste of the emerging picture concerning experiences among particular minorities, experiences of discrimination and harassment for example, as well as patterns of segregation and migration in different parts of the country and in different social classes.

As the data from *Understanding Society* accumulate over the years, they will provide ever more important insights into the factors that impact upon individuals, families and communities over time. It will provide insights into life in Britain today as never before in terms of the size of the sample, the range of topics covered and above all, the connection between various aspects of life in the home. For perhaps the first time, researchers across the spectrum of policy concerns from public health and the environment, to social policy, education and economics, will be able to work collaboratively to explore the ways in which different aspects of our lives are interrelated. In the creation of *Understanding Society*, social science now has the capacity to answer some of the most pressing questions of our age.



HOUSE OF COMMONS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY

The Science and Technology Committee is established under Standing Order No 152, and charged with the scrutiny of the expenditure, administration and policy of the Government Office for Science, a semi-autonomous organisation based within the Department for Business, Innovation and Skills.

The current members of the Science and Technology Committee are:

Gavin Barwell (Conservative, Croydon Central), Gregg McClymont (Labour, Cumbernauld, Kilsyth and Kirkintilloch East), Stephen McPartland (Conservative, Stevenage), Stephen Metcalfe (Conservative, South Basildon and East Thurrock), Andrew Miller (Labour, Ellesmere Port and Neston), David Morris (Conservative, Morecambe and Lunesdale), Stephen Mosley (Conservative, City of Chester), Pamela Nash (Labour, Airdrie and Shotts), Jonathan Reynolds (Labour/Co-operative, Stalybridge and Hyde), Graham Stringer (Labour, Blackley and Broughton) and Roger Williams (Liberal Democrat, Brecon and Radnorshire).

Andrew Miller was elected by the House of Commons to be the Chair of the Committee on 9 June 2010. The remaining Members were formally appointed to the Committee on 12 July 2010. Stephen McPartland was formally appointed to the Committee on 14 February 2011 in the place of Alok Sharma.

CURRENT INQUIRIES

Alcohol guidelines

On 19 July 2011 the Committee announced an inquiry into Alcohol guidelines. The Committee invited written submissions by 14 September 2011.

On 12 October 2011 the Committee took evidence from: Professor Sir Ian Gilmore, Royal College of Physicians, Dr Richard Harding, Member of the 1995 Interdepartmental Working Group on Sensible Drinking, Professor Nick Heather, Alcohol Research UK, and Dr Marsha Morgan, Institute of Alcohol Studies; Jeremy Beadles, Chief Executive, Wine and Spirits Trade Association, Professor Averil Mansfield, British Medical Association, and Chris Sorek, Chief Executive Officer, Drinkaware.

On 26 October 2011 the Committee took evidence from: Anne Milton MP, Parliamentary Under Secretary of State for Public Health, Dr Mark Prunty, Senior Medical Officer for Substance Misuse Policy, and Chris Heffer, Deputy Director, Alcohol & Drugs, Department of Health.

The written evidence received in this inquiry is on the Committee's website. The Committee's Report was published on 9 January 2012.

Science in the Met Office

On 19 July 2011 the Committee announced an inquiry into Science in the Met Office. The Committee invited written submissions by 14 September 2011.

On 26 October 2011 the Committee took evidence from: Professor Paul Hardaker, Chief Executive, Royal Meteorological Society, Professor Ed Hill OBE, Director, National Oceanography Centre, and Professor Alan Thorpe, Director General, European Centre for Medium-Range Weather Forecasts.

On 2 November 2011 the Committee took evidence from: Nick Baldwin, Independent Chairman, Public Weather Service Customer Group, Professor Sir Brian Hoskins CBE, Chair, Met Office Science Advisory Council, and Professor John Pyle, Chair, Hadley Centre Science Review Group; Phil Evans, Government Services Director, John Hirst, Chief Executive, and Professor Julia Slingo OBE, Chief Scientist, Met Office.

On 9 November 2011 the Committee took evidence from: Edward Davey MP, Minister for Employment Relations, Consumer and Postal Affairs, Department for Business, Innovation and Skills.

The written evidence received in this inquiry is on the Committee's website. A Report is being prepared.

Malware and Cyber-crime

On 19 July 2011 the Committee announced an inquiry into Malware and Cyber-crime. The Committee invited written submissions by 7 September 2011.

On 9 November 2011 the Committee took evidence from: Dr Richard Clayton, Senior Research Assistant, University of Cambridge, Professor Peter Sommer, Visiting Professor in the Department of Management, London School of Economics, and Dr Michael Westmacott, BCS, The Chartered Institute for IT, but also representing Royal Academy of Engineering & Institution of Engineering and Technology.

On 14 November 2011 the Committee took evidence from: Gordon Morrison, Director of Defence and Security, Intellect, Janet Williams, Deputy Assistant Commissioner, Charlie McMurdie, Detective Superintendent, Head of Police Central e-Crime Unit, Metropolitan Police, and Lesley Cowley OBE, Chief Executive, Nominet; James Brokenshire MP, Parliamentary Under-Secretary of State for Crime and Security, Home Office.

The written evidence received in this inquiry is on the Committee's website. A Report is being prepared.

Engineering in government: follow-up

On 14 September 2011 the Committee announced an inquiry following up its predecessor Committee's inquiry into Engineering in government. The Committee invited written submissions by 1 November 2011.

On 7 December 2011 the Committee took evidence from: Chris Aylett, Chief Executive, Motorsport Industry Association, and Philip Greenish, Chief Executive, Royal Academy of Engineering.

On 14 December 2011 the Committee took evidence from: Sir John Beddington, Government Chief Scientific Adviser.

The written evidence received in this inquiry is on the Committee's website. A Report is being prepared.

The Census and social science

On 9 November 2011 the Committee announced an inquiry into The Census and social science. The Committee invited written submissions by 30 November 2011.

On 7 December 2011 the Committee took evidence from: Professor David Blane, Deputy Director, ESRC International Centre for Life Course Studies, Professor Heather Joshi, President, Society for Lifecourse and Longitudinal Studies, and Professor Les Mayhew, City University.

On 14 December 2011 the Committee took evidence from: Professor Tim Allen, Local Government Association, Aleks Collingwood, Joseph Rowntree Foundation, Professor David Martin, Royal Statistical Society, and Professor Phil Rees, Royal Geographical Society; Adrian Alsop, Director of Research and International Strategy, and Jeremy



Neathey, Deputy Director of Policy, Economic and Social Research Council, Glen Watson, Census Director, and Peter Benton, Deputy Director, Office for National Statistics.

The Committee expects to hold a further oral evidence session in January. The written evidence received in this inquiry is on the Committee's website.

Risk perception and energy infrastructure

On 9 November 2011 the Committee announced an inquiry into Risk perception and energy infrastructure. The Committee invited written submissions on the following issues by 14 December 2011:

1. What are the key factors influencing public risk perception and tolerability of energy infrastructure facilities and projects?
2. How are public risk perceptions taken into account in the planning process for energy infrastructure?
3. How effectively does local and central Government communicate risk and could it be improved?
4. To what extent can public perceptions be changed by improving risk communication? (please provide examples)
5. How does and should the Government work with the private sector to understand public perceptions of risk and address them?
6. How do risk perceptions and communication issues in the UK compare to those of other countries?

The Committee expects to announce dates for oral evidence sessions in due course. The written evidence received in this inquiry is on the Committee's website.

Science and international development

On 11 November 2011 the Committee announced an inquiry into Science and international development. The Committee invited written submissions on the following issues by 16 December 2011:

1. How does the UK Government support scientific capacity building in developing countries and how should it improve?
2. What are the most effective models and mechanisms for supporting research capacity in developing countries?
3. How does the Government monitor and evaluate the effectiveness of the scientific capacity building activities it supports? Is further assessment or oversight required?
4. What role does DfID's Chief Scientific Adviser play in determining priorities and in the development and assessment of capacity building policies?
5. How are government activities co-ordinated with the private and voluntary sectors?

The Committee expects to announce dates for oral evidence sessions in due course. The written evidence received in this inquiry is on the Committee's website.

Bridging the "valley of death": improving the commercialisation of research

On 16 December 2011 the Committee announced an inquiry: Bridging the "valley of death": improving the commercialisation of research. The Committee invited written submissions on the following issues by 8 February 2012:

1. What are the difficulties of funding the commercialisation of research, and how can they be overcome?
2. Are there specific science and engineering sectors where it is particularly difficult to commercialise research? Are there common difficulties and common solutions across sectors?
3. What, if any, examples are there of UK-based research having to be transferred outside the UK for commercialisation? Why did this occur?
4. What evidence is there that Government and Technology Strategy Board initiatives to date have improved the commercialisation of research?

5. What impact will the Government's innovation, research and growth strategies have on bridging the valley of death?
6. Should the UK seek to encourage more private equity investment (including venture capital and angel investment) into science and engineering sectors and if so, how can this be achieved?
7. What other types of investment or support should the Government develop?

The Committee expects to announce dates for oral evidence sessions in due course. The written evidence received in this inquiry is on the Committee's website.

ORAL EVIDENCE

The transcripts of the evidence sessions described above and below are available on the Science and Technology Committee's website [www.parliament.uk/science].

The Forensic Science Service: Government Response

On 19 December the Committee took evidence from James Brokenshire MP, Parliamentary Under-Secretary of State for Crime Prevention, Professor Bernard Silverman, Chief Scientific Adviser, Home Office, and Andrew Rennison, Forensic Science Regulator, on the Forensic Science Service: Government Response.

REPORTS

Pre-appointment hearing with the Government's preferred candidate for Chair of the Technology Strategy Board

On 26 October 2011, the Committee published its Tenth Report of Session 2010-12, *Pre-appointment hearing with the Government's preferred candidate for Chair of the Technology Strategy Board*, HC 1539.

Alcohol guidelines

On 9 January 2012, the Committee published its Eleventh Report of Session 2010-12, *Alcohol guidelines*, HC 1536.

GOVERNMENT RESPONSES

Government and Research Councils UK Responses to the Science and Technology Committee report 'Peer review in scientific publications'

On 18 October 2011, the Committee published the Government and Research Councils UK's Responses to the Committee's Report on Peer review in scientific publications, HC 1535.

Government and Ofqual Responses to the Science and Technology Committee report 'Practical experiments in school science lessons and science field trips'

On 29 November 2011, the Committee published the Government and Ofqual's Responses to the Committee's Report on Practical experiments in school science lessons and science field trips, HC 1655.

FURTHER INFORMATION

Further information about the work of the Science and Technology Committee or its current inquiries can be obtained from the Clerk of the Committee, Elizabeth Flood, the Second Clerk, Stephen McGinness, or from the Senior Committee Assistant, Andy Boyd, on 020 7219 8367/2792/2793 respectively; or by writing to: The Clerk of the Committee, Science and Technology Committee, House of Commons, 7 Millbank, London SW1P 3JA. Enquiries can also be e-mailed to scitechcom@parliament.uk. Anyone wishing to be included on the Committee's mailing list should contact the staff of the Committee. Anyone wishing to submit evidence to the Committee is strongly recommended to obtain a copy of the guidance note first. Guidance on the submission of evidence can be found at www.parliament.uk/commons/selcom/witguide.htm. The Committee has a website, www.parliament.uk/science, where all recent publications, terms of reference for all inquiries and press notices are available.



HOUSE OF LORDS SCIENCE AND TECHNOLOGY SELECT COMMITTEE

The members of the Committee (appointed 22 June 2010) are Lord Broers, Lord Crickhowell, Lord Cunningham of Felling, Baroness Hilton of Eggardon, Lord Krebs (Chairman), Baroness Neuberger, Lord Patel, Baroness Perry of Southwark, Lord Rees of Ludlow, the Earl of Selborne, Lord Wade of Chorley, Lord Warner, Lord Willis of Knaresborough and Lord Winston. Lord Jenkin of Roding and Lord Oxburgh were co-opted to the Committee for the purposes of its inquiry into nuclear research and development capabilities and Baroness Sharp of Guildford has been co-opted for the science and heritage inquiry. Lord Lucas of Crudwell and Dingwall has been co-opted to Sub-Committee 1 for the purposes of the inquiry on Higher Education in STEM subjects.

Higher Education in Science, Technology, Engineering and Maths (STEM) subjects

In September 2011, the Select Committee appointed a Sub-Committee, under the chairmanship of Lord Willis of Knaresborough, to conduct an inquiry into higher education in STEM subjects. The purpose of the inquiry is to consider how the UK can ensure that the supply of graduates in STEM subjects meets current and future needs, looking at 16-18 supply, undergraduate and postgraduate education and at what can be learnt from the experience of other countries. A call for evidence was released on 13 September 2011 with a deadline for written submissions of 16 December. Oral evidence sessions began in December and will continue until March 2012. It is anticipated that the Committee will report in the summer.

Science and Heritage Follow-up

In December 2011, the Select Committee launched a short follow-up inquiry to its report into science and heritage in session 2005-06. The Committee wrote to Government and contributors to the original inquiry to provide an update of developments since the publication of the original report in 2006 and the update in October 2007. The deadline for written submission is 31 January 2012. Oral evidence sessions will be held in the spring.

The role and function of departmental Chief Scientific Advisers (CSAs)

In July 2011, the Select Committee, under the chairmanship of Lord Krebs, launched an inquiry into the role and functions of Chief Scientific Advisers. The inquiry will be looking at a number of aspects concerning the role of CSAs including: the ability of CSAs to provide independent advice to ministers and policy makers; the extent of their influence over research spend; and their role in providing independent challenge and ensuring that departmental policies are evidenced-based. A call for evidence was released on the 20 July 2011 with a deadline for submissions of 16 September. The Committee took oral evidence from October to December and will be reporting in spring 2012.

Nuclear research and development capabilities

In March 2011, the Select Committee, under the chairmanship of Lord Krebs, launched an inquiry to investigate whether the UK's nuclear research and development (R&D) capabilities are sufficient to meet its future nuclear energy requirements to 2050.

The inquiry was focused on what the Government should be doing if they are to ensure that the UK's R&D capabilities are sufficient to meet our nuclear energy requirements into the future. It examined, amongst other things, the R&D implications of future scenarios up to 2050 and whether the UK has adequate R&D capabilities, including infrastructure, to meet its current and future needs for a safe and secure supply of nuclear energy.

The report was published on 22 November 2011. It is likely to be debated in the House in the current session or early in the next session, following receipt of the Government's response.

Behaviour change policy interventions

In June 2010, the Select Committee appointed a Sub-Committee, under the chairmanship of Baroness Neuberger, to conduct an inquiry into the effectiveness of behaviour change interventions in achieving government policy goals and helping to meet societal challenges.

The Committee considered the current state of knowledge about which behaviour change interventions are effective, whether the Government's current behaviour change interventions are evidence-based and subject to robust evaluation, and how such interventions are coordinated across departments. The Committee also looked at the role of industry and the voluntary sector in shaping behaviour patterns and the social and ethical issues surrounding behaviour change interventions by government. The inquiry included two case studies, one on obesity and the other on reducing car use in towns and cities. The Committee published its report on 19 July 2011. The Government response was published on 15 September. It is anticipated that the report will be debated in the House in the current session or early in the next session.

FURTHER INFORMATION

The written and oral evidence to the Committee's inquiries mentioned above, as well as the Calls for Evidence and other documents can be found on the Committee's website www.parliament.uk/hlscience. Further information about the work of the Committee can be obtained from Christine Salmon Percival, Committee Clerk, salmonc@parliament.uk or 020 7219 6072. The Committee's email address is hlscience@parliament.uk.





HOUSE OF COMMONS LIBRARY SCIENCE AND ENVIRONMENT SECTION

A Research Paper produced for Members of Parliament is summarised opposite. Papers can be accessed at <http://www.parliament.uk/briefing-papers/commons-research-papers/>

The Section produces a series of frequently updated notes on a wide of topics. Opposite are summaries of some recently updated notes.

The notes can be accessed online at <http://www.parliament.uk/topics/Topical-Issues.htm>

For further information contact Christopher Barclay Head of Section
Tel: 020 7219 3624 email: barclaycr@parliament.uk

Daylight Saving Bill: Committee Stage Report Research Paper 12/3

This is a report on the House of Commons Committee Stage of the Daylight Saving Bill. It complements Library Research Paper 10/78 (Daylight Saving Bill) prepared for the Commons Second Reading.

The Bill is a Private Member's Bill sponsored by Rebecca Harris. It would require the Government to prepare a report on the potential costs and benefits of advancing clocks in the UK by one hour. Depending on the outcome of the report, and the degree of consensus, the Bill will allow a trial clock change to be initiated. A trial would be subject to an affirmative resolution in both Houses. The trial could last up to three years and could be made permanent.

The Bill was extensively amended in Committee by the Government and the Bill's sponsor.

Durban Climate Conference SN/SC/6140

The 17th meeting of the Conference of the Parties (COP 17) to the UN Framework on Climate Change took place in Durban between 28 November and 11 December 2011.

Many of the decisions that were not taken in Cancun – such as what would succeed the Kyoto Protocol – were no nearer to being resolved when the conference began, with little progress during preparatory meetings. Despite this, consensus was reached on drawing up an agreement by 2015, that would include all developed and developing countries making some kind of commitment to reduce emissions, which would come into force from 2020. The EU also agreed to a second commitment period of the Kyoto Protocol.

There was also progress in other areas, such as climate finance for developing countries, forestry, and inclusion of carbon capture and storage in the Clean Development Mechanism.

Feed-in Tariffs: Solar PV SN/SC/6112

This note covers feed-in tariffs for solar photovoltaic electricity generation, including the review of tariffs announced in October 2011 for installations of 250kW or smaller. This follows on from a review earlier in 2011 which covered all solar projects larger than 50kW.

The reason for the latest review of tariffs for Solar PV of installations of 250kW or smaller, is the unexpectedly high uptake of the scheme. This follows on from a review earlier in 2011 which covered all solar projects larger than 50kW. The Government is concerned that the rates of return

for generators are much higher than were projected and about the impact high uptake may have on energy bills. Critics, including the industry, are unhappy at the short timescale involved, as any new tariffs would be applicable from 12 December 2011, two weeks before the consultation closed.

There are also proposals to reduce the level of return for generators who own multiple installations and proposals to link the ability to qualify for tariffs to the energy performance of a building.

The High Court and the Court of Appeal have ruled that the proposal to cut from 12 December was a retrospective cut in tariffs and therefore illegal but the Government is now seeking leave to appeal to the Supreme Court. As a contingency, it has produced draft regulations that would reduce the tariffs for solar from 3 March 2012 instead.

Shale gas and fracking SN/SC/6073

In September 2011 the company Cuadrilla announced the results of test drills that indicate substantial shale gas reserves in the UK, although there are doubts about how much of the reserves can be exploited. Concerns have also been raised regarding resource use, net effects on greenhouse gas emissions and risk of groundwater contamination. The US Environmental Protection Agency is conducting a long-term study. The UK Government has declined to place a moratorium on fracking, and the Energy and Climate Change Select Committee supported this.

Following small seismic tremors in April and May 2011, drilling is temporarily suspended. A seismicity study shows it is 'highly probable' that fracking triggered these, but the British Geological Survey has said that such small earthquakes associated with mining or occurring naturally are not uncommon. The Government has yet to decide about resuming fracking at the site. The 14th onshore licensing round is forthcoming.

Electricity substations and health SN/SC/6151

Electricity substations, like overhead power lines and electrical appliances in the home, are sources of extremely low frequency (ELF) electromagnetic fields.

The electric and magnetic fields in the vicinity of electricity substations are well below the levels associated with established health effects. A large number of studies have so far failed to establish adverse health effects associated with exposure to low level electromagnetic fields – with the exception of a possible doubling of the risk of childhood leukaemia.



Bodies such as the Government-backed SAGE and the independent group Powerwatch have recommended precautionary approaches. EU legislation, derived from pre-existing guidelines on exposure to non-ionising radiation, is in train.

Marine Conservation Zones SN/SC/6129

New powers to designate Marine Conservation Zones (MCZs) in UK waters were introduced under the Marine and Coastal Access Act 2009. MCZs will be used to protect nationally important marine wildlife, habitats, geology and geomorphology. Different levels of protection will be applied to each MCZ, from voluntary controls to "Reference Areas", where no damaging activities will be allowed. As a result their designation may be controversial in some circumstances.

The locations of the proposed MCZs were announced on 8 September 2011. An independent Science Advisory Panel concluded that the recommended sites would contribute to an ecologically coherent network of marine protected areas, but that the network would need to be strengthened. The proposed sites are now being assessed for their economic, social and environmental costs and benefits. A public consultation on the site proposals will be launched in 2012.

Surface water drainage charge (rain tax) SN/SC/5130

This note introduces the debate surrounding the surface water drainage charge, or "rain tax".

Following a change in legislation, water companies are now permitted to introduce surface water drainage charge concessionary rates for community groups.

Internet regulation SN/SC/6145

The practicalities of blocking and filtering harmful material on the internet have generated interest in a range of contexts: the misuse of social media during the August 2011 riots, child sexual abuse images and copyright infringement.

The communications regulator, Ofcom, considered a range of blocking techniques in the context of combating copyright infringement. Ofcom reported in May 2011. In August 2011, the Department for Culture, Media and Sport published Next steps for implementation of the Digital Economy Act. This referred to Ofcom's assessment of website blocking and the fact that the Government would not be proceeding with this for the time being.

Other legislation can also be invoked to control internet content.

Section 127 of the Communications Act 2003 proscribes the improper use of a public electronic communications network. It has recently been applied, apparently for the first time, to a social networking site (Twitter).

Cloud computing SN/SC/6085

The cloud is a reference to the internet, and cloud computing means relocating computer resources and activities on to the internet. This note considers the potential for cloud computing, its applications and risks. Among the latter could be dependency on external providers of cloud computing services. Consideration also has to be given to implications for data security and compliance with data protection law.

Started under the Labour Government, the present administration is taking forward a programme that will see cloud computing contribute to the delivery of public sector services. This government cloud, called the G-cloud, provides an example of the use of so-called private cloud services that seek to ensure, among other things, the security of personal data.

Badger culling SN/SC/5873

The previous Government decided in 2008 not to introduce a badger cull as part of bovine TB control measures in light of the findings of the UK Randomised Badger Culling Trial. This concluded that a reactive cull of badgers resulted in significant increases in Bovine TB and a proactive cull, whilst controlling TB in the cull area, contributed to an increase in TB in surrounding areas, and would not be cost effective. Not all agreed. Sir David King, the chief Scientific Adviser at the time, concluded that a proactive cull would be cost effective.

The Coalition Government announced a consultation in September 2010, which set out its proposals for culling. These include introducing proactive culls over 150km² areas where farmers would be licensed to shoot badgers. Farmers would have to bear the costs of any culls. In December 2011 the Government announced that it intended to go forward with a badger cull trial. The trial will be carried out in two pilot areas. Results from the trial will be considered before culling is rolled-out more widely.

The Welsh Assembly was also in the process of introducing a badger cull in Wales, although the process was temporarily halted by the courts. There has now been an election and the new Labour Government has suspended a cull until a review of the science is carried out.



PARLIAMENTARY OFFICE OF SCIENCE AND TECHNOLOGY (POST)

RECENT POST PUBLICATIONS

Clinical Trials

October 2011

POSTnote 390

Clinical trials benefit the health and safety of patients by making proven new treatments available more quickly. This industry is also very important for the UK economy. However, recent years have seen a drop in the number of trials held in the UK. This POSTnote summarises some of the most important reasons behind this decline, and the actions being taken to improve the situation. It also

highlights areas identified by key industry partners as opportunities for growth.

An Ageing Workforce

October 2011

POSTnote 391

Over the next decade, the changing age profile of the workforce will be the most significant development in the UK labour market, as a third of workers will be over 50 by 2020. Employers will be expected to respond to this demographic shift by making work more attractive and feasible for older workers, enabling them to work up to and beyond State Pension Age (SPA) if they are



capable. This POSTnote examines the main challenges to the participation and productivity of older people in the workforce.

Livestock Disease

October 2011

POSTnote 392

The 2001 Foot and Mouth Disease outbreak cost the UK £6-9 billion. In 2010/11, the government spent £91 million compensating farmers for bovine TB. It is considering proposals for sharing costs and responsibilities for preventing and controlling disease with the livestock industry. This POSTnote examines disease threats to UK livestock, outlines prevention and control measures, and looks at factors likely to contribute to future disease.

Improving Livestock

October 2011

POSTnote 393

Selective breeding has long been used by farmers to improve the quality of livestock. Over the past 10-15 years breeders have worked on developing broader breeding goals that incorporate animal health and welfare traits, as well as productivity. This POSTnote describes current technologies used in livestock breeding, research into future technologies and how the improvement of livestock can contribute towards future food security.

Invasive Tree Pests and Diseases

October 2011

POSTnote 394

The risk to UK trees from invasive diseases and pests is growing with the expansion of international trade and travel and transport of live trees and timber products, along with environmental changes. This POSTnote summarises the difficulties in regulating the threat of imported pests and diseases, and for managing them if they become established in the UK.

Explosive Injuries

December 2011

POSTnote 395

Explosives can cause multiple severely-injured casualties in a single incident. They currently pose the most prevalent threat to troops operating in conflict regions. However, recent explosive events on UK mainland have ensured these injuries are no longer solely the signature of military conflict. This POSTnote provides a background to explosive injury, explores developments in mitigation science, and highlights research priorities.

Natural Flood Management

December 2011

POSTnote 396

Natural flood management, defined here as the alteration, restoration or use of landscape features, is being promoted as a novel way of reducing flood risk. This POSTnote reviews the policy drivers of this approach, as well as the scientific basis, and implementation, of inland natural flood management strategies.

CURRENT WORK

Biological Sciences – Review of Stem Cell Research, Computer Games and Violence, Biotechnology Patents, Personalised Cancer Treatments, Superfarms, Personal Genomics.

Environment and Energy – Measuring Energy Security, Climate Variability and Weather, Sustainability, Bioenergy, Energy Efficiency.

Physical sciences and IT – Solar Technologies, Clean Water and the MDGs, Open Public Sector Data, Preparing for Natural Disasters in Developing Countries, Low Carbon Technologies for Energy Intensive Industries, Open Access to Scientific Data.

Science Policy – STEM Education for 14-19 years old

CONFERENCES AND SEMINARS

Annual Review of Climate Change

On 13th December, POST and the Westminster Energy Forum hosted a seminar to discuss recent developments in climate

change policy. The event followed the UN Climate Change Conference in Durban, South Africa, and was intended to give parliamentarians and their staff together with other invited guests the opportunity to discuss topical issues with experts in the field. Lord Giddens, Member of the House of Lords EU Sub-Committee D, and Neil Hirst, Senior Policy Fellow at the Grantham Institute, each chaired a session. Around 135 guests heard presentations from Prof David Mackay, Chief Scientific Advisor of the Department of Energy and Climate Change; Luciana Berger MP, Shadow Minister for Energy and Climate Change; Matthew Spencer, Director of Green Alliance; Malcolm Hutton, Global Head of Risk Practice for Environmental Resources Management (ERM); Miles Austin, Director of Climate Markets & Investors Association; Dr Guy Doyle, Chief Economist of Mott MacDonald.

Show Me the Evidence

On 8th December, POST organised a seminar to discuss the extent to which policy making processes are informed by evidence, focusing on research in developing countries. There is a limited but growing body of research in this area, from both the developed and the developing world. In this seminar a panel of parliamentarians, parliamentary staff and external experts discussed what lessons could be learned from research into evidence informed policy making, focusing mainly on the developing world. The seminar looked at the work of both legislatures and governments and asked how such research could help guide the work of researchers as well as organisations whose role is to provide policymakers with reliable information. Martin Belcher, head of programmes at the International Network for the Availability of Scientific Publications (INASP), chaired the seminar at which Dr Chandrika Nath presented results from the October 2011 joint report by POST, the Parliament of Uganda and the Ugandan National Academy of Sciences, on "Use of Scientific and Technological Evidence in the Parliament of Uganda". Invited guests also heard presentations from the Hon Obua Denis Hamsom MP, Chair, Standing Committee on Science and Technology, Parliament of Uganda; Ajoy Datta, Research and Policy in Development (RAPID), Overseas Development Institute; Dr Kirsty Newman, Head of Evidence Informed Policy Making, International Network for the Availability of Scientific Publications and Bryn Morgan, Director of Research, Department of Information Services, House of Commons.

Foresight Project on Migration and Global Environmental Change

On 26th October, POST hosted the Government Office for Science parliamentary launch of the most recent foresight project, addressing the issues of global environmental change and human migration over the next 50 years. Existing environmental change-migration literature tends to focus on estimating numbers of potential migrants. The Foresight project assembled and analysed the latest evidence and research on global environmental migration to fill a gap in the current literature/knowledge base; to analyse why people move, how long for and what kind of challenges or opportunities this movement presents. This was to provide a more informed platform for understanding policy implications and for developing possible responses. This meeting, chaired by Baroness Miller of Chilthorne Domer, was an opportunity for parliamentarians to discuss the project's final conclusions and options for policy in the UK and internationally with key experts from the project. Invited guests heard presentations from Professor Sir John Beddington, Government Chief Scientific Adviser; Professor David Thomas, Head of School of Geography and the Environment and Professor of Geography at the University of Oxford; Professor Nigel Arnell, Director of the Walker Institute for Climate System Research at the University of Reading and Professor Neil Adger, Professor of

Environmental Economics at the University of East Anglia, and Programme leader at the Tyndall Centre.

STAFF, FELLOWS AND INTERNS AT POST

Conventional Fellows

Oliver Pescott, Sheffield University, British Ecological Society
Matthew Ashfold, Cambridge University, Natural Environment Research Council

Martin Goodfellow, University of Manchester, Engineering and Physical Sciences Research Council

Hannah Swift, University of Kent, British Psychological Society

Hollie Chandler, Cancer Research UK, Cancer Research UK

Kate Hamer, University of Nottingham, Biotechnology and Biological Sciences Research Council

Anne Richmond, University of Dundee, Institute of Food Science and Technology

Iwan Roberts, University College London, Institution of Chemical Engineers/North East Industry Processing Cluster

INTERNATIONAL ACTIVITIES

In November, the Director, along with other EPTA member parliamentarians and directors attended and made a presentation at

a special one day seminar at the Assemblée Nationale in Paris on Innovation in the Face of Risks and Fears, organised by OPECST, POST's sister organisation at the French Parliament.

POST African Parliaments Programme

In December, Dr Chandrika Nath helped the overseas office co-ordinate a week-long visit of 5 MPs from the Standing Committee on Science and Technology, Parliament of Uganda. The aim of the visit was for the MPs to learn more about how science was handled in the UK Parliament. The schedule included meetings with the members and officials of the science and technology committees in both Houses as well as with Mr John Pullinger, Lord Papat (APPG on Uganda) and with the Government Office for Science and the Royal Society.

On 23rd January 2012, Chandrika Nath was invited to meet Professor Sir David King to brief him about POST's activities in Uganda.

As part of the African Parliaments programme Dr Nath is also helping to organise an international conference on Evidence Informed Policy Making along with UK NGO INASP and Nigerian governmental science organisation NACETEM (with support from the Wellcome Trust). The conference will be attended by researchers, government and parliamentary officials from the UK as well as Latin America, South East Asia and Africa.



SELECTED DEBATES

Listed opposite (grouped by subject area) is a selection of Debates on matters of scientific interest which took place in the House of Commons, the House of Lords or Westminster Hall between 3rd October and 21st December 2011.

A Digest of Parliamentary Questions and Answers for the same period can be found at www.scienceinparliament.org.uk

Animal Health and Welfare

Animal Experimentation – 24.10.11 HoL 618
and 7.12.11 HoC 366
Animal Feed – 6.12.11 HoL 697
Badgers and Bovine TB – 18.10.11 HoC 216WH
Live Animal Exports
(Port of Ramsgate) – 24.10.11 HoC 146
Welfare of Laying Hens
Directive – 13.12.11 HoC 224WH
Zoos (Regional Economic
Development) – 14.12.11 HoC 273WH

Defence
BAE Systems – 24.11.11 HoC 472
Education
Dyslexia – 14.12.11 HoC 305WH
Universities: Impact of
Government Policy – 13.10.11 HoL 1870
University Technical Colleges 2.11.11 HoC 1058

Energy
Energy Prices – 19.10.11 HoC 929
Shale Gas – 3.11.11 HoC 339WH
Nuclear Power Production
(Sellafield) – 11.10.11 HoC 307
Wind Farms – 9.11.11 HoL 309

Environment
Dalgety Bay (Radiation) – 30.11.11 HoC 1053
Environmental Protection
and Green Growth – 26.10.11 HoC 382
Hazardous Waste – 12.10.11 HoL GC472
Marine Management
Organisation – 18.10.11 HoC 870

Fisheries
Fisheries – 15.11.11 HoC 711
Food
World Vegan Day –
adjournment debate – 1.11.11 HoC 895

Health

Alcohol Taxation – 14.12.11 HoC 334WH
Bowel Cancer Screening – 23.11.11 HoC 419
Digital Technology
(effect on the mind) – 5.12.11 HoL 573
HIV – 29.11.11 HoC 254WH
Innovation (NHS) – 12.10.11 HoC 96WH
Low Dose Naltrexone – 8.12.11 HoC 490
Malnutrition: Costs – 21.10.11 HoC 1189WH
Neurological Conditions – 8.12.11 HoL 868
NHS Care of Older People
Non-communicable
Diseases – 6.10.11 HoL 1223
Organ Donation – 30.11.11 HoC 263WH
Ovarian Cancer – 12.10.11 HoC 73WH
Phenylketonuria (Kuvan) – 1.12.11 HoC 1190
Ritalin – 25.10.11 HoC 64WH

Industry

Apprenticeships – 19.12.11 HoC 1105
Manufacturing – 24.11.11 HoC 510
UK Manufacturing Industry 8.12.11 HoL 830

IT, Telecommunications and Broadcasting

Internet (Governance) – 26.10.11 HoC 109WH

Science Policy

UN: Specialised Agencies – 22.11.11 HoC 1027

Transport

Aviation – 13.10.11 HoL 1908
and 15.11.11 HoC
217WH
HGV Wheels (Safety) – 29.11.11 HoC 214WH
High-Speed Rail – 13.10.11 HoC 556,
2.11.11 HoC 298WH
and 8.11.11 HoC 213
London and the Regions 15.11.11 HoL GC240



SCIENCE DIRECTORY

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Institution of Engineering Designers
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Animal Health and Welfare, Veterinary Research

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Brain Research

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Cancer Research

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Chemistry

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Colloid Science

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Construction and Building

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Cosmetic Science

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Society of Cosmetic Scientists

Earth Sciences

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Ecology, Environment and Biodiversity

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Economic and Social Research

Economic and Social Research Council

Education, Training and Skills

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British Nutrition Foundation
British Pharmacological Society
British Society for Antimicrobial Chemotherapy
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Clifton Scientific Trust
C-Tech Innovation
Economic and Social Research Council
EPSRC
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Institution of Chemical Engineers
Institution of Civil Engineers
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Royal Society of Chemistry
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Energy

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Institution of Engineering and Technology
Institution of Mechanical Engineers

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Engineering

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Fisheries Research

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Food and Food Technology

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Forensics

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Genetics

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Geology and Geoscience

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Hazard and Risk Mitigation

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Health

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British Nutrition Foundation
British Pharmacological Society
British Society for Antimicrobial Chemotherapy
Economic and Social Research Council
Eli Lilly and Company Ltd
EPSRC
The Food and Environment Research Agency
GAMBICA Association Ltd
Institute of Physics and Engineering in Medicine
LGC

Medical Research Council
National Physical Laboratory
The Nutrition Society
The Physiological Society
The Royal Institution
Royal Society of Chemistry
Society for Applied Microbiology
Society for General Microbiology
Society of Biology
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Heart Research

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Hydrocarbons and Petroleum

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Industrial Policy and Research

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Institution of Engineering and Technology
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Information Services

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CABI
The Welding Institute

IT, Internet, Telecommunications, Computing and Electronics

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Institution of Engineering and Technology
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Intellectual Property

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NESTA
Society of Biology

Large-Scale Research Facilities

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Lasers

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Manufacturing

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Institution of Engineering and Technology
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Materials

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Royal Society of Chemistry
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Mathematical Sciences

Council for the Mathematical Sciences:
Institute of Mathematics and its Applications
London Mathematical Society
Royal Statistical Society
Operational Research Society
Edinburgh Mathematical Society

Medical and Biomedical Research

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Academy of Medical Sciences
Biochemical Society
British Pharmacological Society
British Society for Antimicrobial Chemotherapy
CABI
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Medical Research Council
MSD
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The Royal Institution
Society of Biology
UFAW
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Motor Vehicles

Institution of Engineering Designers
The Welding Institute

Oceanography

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Society of Biology
Society of Maritime Industries

Oil

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Particle Physics

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Physics

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Pollution and Waste

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Psychology

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Public Policy

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Quality Management

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Radiation Hazards

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Science Policy

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SSSIs

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EngineeringUK

Surface Science

C-Tech Innovation
STFC

Sustainability

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Society of Biology
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Technology Transfer

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Society of Biology
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Tropical Medicine

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Society for General Microbiology
Society of Biology

Viruses, Fungi and Bacteria

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Society for General Microbiology
Society of Biology

Water

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Society of Maritime Industries

Wildlife

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The Food and Environment Research Agency
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Marine Biological Association
Natural History Museum
Royal Botanic Gardens, Kew
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The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. The Academy's Fellows are the United Kingdom's leading medical scientists and scholars from hospitals, academia, industry and the public service. The Academy provides independent, authoritative advice on public policy issues in medical science and healthcare.

Association of the British Pharmaceutical Industry



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The ABPI is the voice of the innovative pharmaceutical industry, working with Government, regulators and other stakeholders to promote a receptive environment for a strong and progressive industry in the UK, one capable of providing the best medicines to patients.

The ABPI's mission is to represent the pharmaceutical industry operating in the UK in a way that:

- assures patient access to the best available medicine;
- creates a favourable political and economic environment;
- encourages innovative research and development;
- affords fair commercial returns

AIRTO



Contact: Professor Richard Brook OBE FREng
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Website: www.airto.co.uk

AIRTO – The Association for Independent Research and Technology Organisations – is the foremost membership body for organisations operating in the UK's intermediate research and technology sector. AIRTO's members deliver vital innovation and knowledge transfer services which include applied and collaborative R&D, frequently in conjunction with universities, consultancy, technology validation and testing, incubation of commercialisation opportunities and early stage financing. AIRTO members have a combined turnover of over £2Bn from clients both at home and outside the UK, and employ over 20,000 scientists, technologists and engineers.



AMPS

AMPS

The Association of
Management and
Professional Staffs.

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Website: www.amps-tradeunion.com

Trades Union for Management and Professional
staffs working in the pharmaceutical and chemical
industries also includes professional divers section.

Biochemical Society



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The Biochemical Society exists to promote and support the Molecular and Cellular Biosciences. We have nearly 6000 members in the UK and abroad, mostly research bioscientists in Universities or in Industry. The Society is also a major scientific publisher. In addition, we promote Science Policy debate and provide resources, for teachers and pupils, to support the bioscience curriculum in schools. Our membership supports our mission by organizing scientific meetings, sustaining our publications through authorship and peer review and by supporting our educational and policy initiatives.

The British Ecological Society



The British Ecological Society
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British Ecological Society
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Tel: 020 7685 2500 Fax : 020 7685 2501
Website: www.BritishEcologicalSociety.org
Ecology into Policy Blog
<http://britishecologicalsociety.org/blog/>

The British Ecological Society's mission is to advance ecology and make it count. The Society has 4,000 members worldwide. The BES publishes five internationally renowned scientific journals and organises the largest scientific meeting for ecologists in Europe. Through its grants, the BES also supports ecologists in developing countries and the provision of fieldwork in schools. The BES informs and advises Parliament and Government on ecological issues and welcomes requests for assistance from parliamentarians.

British In Vitro Diagnostics Association (BIVDA)

BIVDA

Contact: Doris-Ann Williams MBE
British In Vitro Diagnostics Association
(BIVDA), 1 Queen Anne's Gate,
London SW1H 9BT

Tel: 020 7957 4633
Fax: 020 7957 4644
E-mail: doris-ann@bivda.co.uk
Website: www.bivda.co.uk

BIVDA is the UK industry association representing companies who manufacture and/or distribute the diagnostics tests and equipment to diagnose, monitor and manage disease largely through the NHS pathology services. Increasingly diagnostics are used outside the laboratory in community settings and also to identify those patients who would benefit from specific drug treatment particularly for cancer.

British Nutrition Foundation



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Director General
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Fax: 020 7404 6747
Email: postbox@nutrition.org.uk
Websites: www.nutrition.org.uk
www.foodafactoflife.org.uk

The British Nutrition Foundation (BNF) was established over 40 years ago and exists to deliver authoritative, evidence-based information on food and nutrition in the context of health and lifestyle. The Foundation's work is conducted and communicated through a unique blend of nutrition science, education and media activities.

BPS BRITISH PHARMACOLOGICAL SOCIETY

Today's science, tomorrow's medicines

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Chief Executive
British Pharmacological Society
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London EC1V 2PT
Tel: 020 7417 0110
Fax: 020 7417 0114
Email: kb@bps.ac.uk
Website: www.bps.ac.uk

The British Pharmacological Society has been supporting pharmacology and pharmacologists for over 80 years. Our 3,000+ members, from academia, industry and clinical practice, are trained to study drug action from the laboratory bench to the patient's bedside. Our aim is to improve quality of life by developing new medicines to treat and prevent the diseases and conditions that affect millions of people and animals. Inquiries about drugs and how they work are welcome.

The British Psychological Society



The
British
Psychological
Society

Contact: Lucy Chaplin
PR & Marketing Manager
The British Psychological Society
St Andrews House
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Leicester LE1 7DR
Tel: 0116 252 9910
Email: lucy.chaplin@bps.org.uk
Website: www.bps.org.uk

The British Psychological Society is an organisation of over 48,000 members governed by Royal Charter. It maintains the Register of Chartered Psychologists, publishes books, 11 primary science Journals and organises conferences. Requests for information about psychology and psychologists from parliamentarians are welcome.

British Science Association



Contact: Sir Roland Jackson Bt,
Chief Executive
British Science Association,
Wellcome Wolfson Building, 165 Queen's Gate,
London SW7 5HD.

E-mail:
Roland.Jackson@britishscienceassociation.org
Website: www.britishscienceassociation.org

Our vision is a society in which people are able to access science, engage with it and feel a sense of ownership about its direction. In such a society science advances with, and because of, the involvement and active support of the public.

Established in 1831, the British Science Association is a registered charity which organises major initiatives across the UK, including National Science and Engineering Week, the British Science Festival, programmes of regional and local events and the CREST programme for young people in schools and colleges. We provide opportunities for all ages to discuss, investigate, explore and challenge science.

British Society for Antimicrobial Chemotherapy

Mrs Tracey Guise
Executive Director
British Society for Antimicrobial Chemotherapy
Griffin House
53 Regent Place
Birmingham B1 3NJ
T: 0121 236 1988
W: www.bsac.org.uk

Founded in 1971, and with 800 members worldwide, the Society exists to facilitate the acquisition and dissemination of knowledge in the field of antimicrobial chemotherapy. The BSAC publishes the *Journal of Antimicrobial Chemotherapy* (JAC), internationally renowned for its scientific excellence, undertakes a range of educational activities, awards grants for research and has active relationships with its peer groups and government.



CABI

Science and development organization



www.cabi.org

Contact: Dr Joan Kelley, Executive Director, Global Operations, CABI
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Email: c.scotter-mainprize@cabi.org
Website: www.cabi.org

CABI is an international not-for-profit development organization, specializing in scientific publishing, research and communication. We create, communicate, and apply knowledge in order to improve people's lives by finding sustainable solutions to agricultural and environmental issues.

We work for and with universities, national research and extension institutions, development agencies, the private sector, governments, charities and foundations, farmers, and non-governmental organizations. We also manage one of the world's largest genetic resource collections: the UK's National Collection of Fungus Cultures.

Cavendish Laboratory



The Administrative Secretary, The Cavendish Laboratory,
J J Thomson Avenue, Cambridge CB3 0HE, UK.
E-mail: dhp24@cam.ac.uk
http://www.phy.cam.ac.uk

The Cavendish Laboratory houses the Department of Physics of the University of Cambridge.

The research programme covers the breadth of contemporary physics

Extreme Universe: Astrophysics, cosmology and high energy physics

Quantum Universe: Cold atoms, condensed matter theory, scientific computing, quantum matter and semiconductor physics

Materials Universe: Optoelectronics, nanophotonics, detector physics, thin film magnetism, surface physics and the Winton programme for the physics of sustainability

Biological Universe: Physics of medicine, biological systems and soft matter

The Laboratory has world-wide collaborations with other universities and industry

Chartered Institute of Patent Attorneys



Founded 1882
Royal Charter 1891

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CIPA's members practise in intellectual property, especially patents, trade marks, designs, and copyright, either in private partnerships or industrial companies. Through its new regulatory Board, CIPA maintains the statutory Register. It advises government and international circles on policy issues and provides information services, promoting the benefits to UK industry of obtaining IP protection, and to overseas industry of using British attorneys to obtain international protection.

Clifton Scientific Trust



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- bringing school science added meaning and motivation, from primary to post-16
- locally, nationally, internationally (currently between Britain and Japan)

Clifton Scientific Trust Ltd is registered charity 1086933

The Council for the Mathematical Sciences



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The Council for the Mathematical Sciences is an authoritative and objective body that works to develop, influence and respond to UK policy issues affecting mathematical sciences in higher education and research, and therefore the UK economy and society by:

- providing expert advice;
- engaging with government, funding agencies and other decision makers;
- raising public awareness; and
- facilitating communication between the mathematical sciences community and other stakeholders

C-Tech Innovation Limited



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Lilly UK is the UK affiliate of a major American pharmaceutical manufacturer, Eli Lilly and Company of Indianapolis. This affiliate is one of the UK's top pharmaceutical companies with significant investment in science and technology including a neuroscience research and development centre and bulk biotechnology manufacturing operations.

Lilly medicines treat schizophrenia, diabetes, cancer, osteoporosis, attention deficit hyperactivity disorder, erectile dysfunction, severe sepsis, depression, bipolar disorder, heart disease and many other diseases.

EngineeringUK



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EngineeringUK is an independent organisation that promotes the vital role of engineers, engineering and technology in our society. EngineeringUK partners business and industry, Government and the wider science and technology community: producing evidence on the state of engineering; sharing knowledge within engineering; and inspiring young people to choose a career in engineering, matching employers' demand for skills.

The Food and Environment Research Agency



The Food and Environment Research Agency

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The Food and Environment Research Agency's overarching purpose is to support and develop a sustainable food chain, a healthy natural environment, and to protect the global community from biological and chemical risks.

Our role within that is to provide robust evidence, rigorous analysis and professional advice to Government, international organisations and the private sector.

GAMBICA Association Ltd



AUTOMATION
INSTRUMENTATION & CONTROL
LABORATORY TECHNOLOGY

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GAMBICA Association is the UK trade association for instrumentation, control, automation and laboratory technology. The association seeks to promote the successful development of the industry and assist its member companies through a broad range of services, including technical policy and standards, commercial issues, market data and export services.

The Geological Society



The Geological Society

serving science & profession

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The Geological Society is the national learned and professional body for Earth sciences, with 10,000 Fellows (members) worldwide. The Fellowship encompasses those working in industry, academia and government, with a wide range of perspectives and views on policy-relevant science, and the Society is a leading communicator of this science to government bodies and other non-technical audiences.

Institute of Food Science & Technology



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IFST is the independent qualifying body for food professionals in Europe. Membership is drawn from all over the world from backgrounds including industry, universities, government, research and development and food law enforcement.

IFST's activities focus on disseminating knowledge relating to food science and technology and promoting its application. Another important element of our work is to promote and uphold standards amongst food professionals.

Institute of Marine Engineering, Science and Technology (IMarEST)



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Established in London in 1889, the IMarEST is a leading international membership body and learned society for marine professionals, with over 15,000 members worldwide. The IMarEST has an extensive marine network of 50 international branches, affiliations with major marine societies around the world, representation on the key marine technical committees and non-governmental status at the International Maritime Organization (IMO) as well as other intergovernmental organisations.

The Institute of Measurement and Control



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The Institute of Measurement and Control provides a forum for personal contact amongst practitioners, publishes learned papers and is a professional examining and qualifying organisation able to confer the titles Eurlng, CEng, IEng, EngTech; Companies and Universities may apply to become Companions. Headquartered in London, the Institute has a strong regional base with 15 UK, 1 Hong Kong and 1 Malaysia Local Section, a bilateral agreement with the China Instrument Society and other major international links.

IOP Institute of Physics

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The Institute of Physics is a leading scientific society promoting physics and bringing physicists together for the benefit of all.

It has a worldwide membership of around 40,000 comprising physicists from all sectors, as well as those with an interest in physics. It works to advance physics research, application and education; and engages with policymakers and the public to develop awareness and understanding of physics. Its publishing company, IOP Publishing, is a world leader in professional scientific publishing and the electronic dissemination of physics. Go to www.iop.org



Institute of Physics and Engineering in Medicine

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IPEM is a registered, incorporated charity for the advancement, in the public interest, of physics and engineering applied to medicine and biology. It accredits medical physicists, clinical engineers and clinical technologists through its membership register, organises training and CPD for them, and provides opportunities for the dissemination of knowledge through publications and scientific meetings. IPEM is licensed by the Science Council to award CSci, RSci and RSciTech, and by the Engineering Council to award CEng, IEng and EngTech.

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The Institution of Chemical Engineers

With over 33,000 members in 120 countries, IChemE is the global membership organisation for chemical engineers. A not for profit organisation, we serve the public interest by building and sustaining an active professional community and promoting the development, understanding and application of chemical engineering worldwide.

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Institution of Civil Engineers



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ICE aims to be a leading voice in infrastructure issues. With over 80,000 members, ICE acts as a knowledge exchange for all aspects of civil engineering. As a Learned Society, the Institution provides expertise, in the form of reports, evidence and comment, on a wide range of subjects including infrastructure, energy generation and supply, climate change and sustainable development.



Institution of Engineering Designers



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The only professional membership body solely for those working in engineering and technological product design. Engineering Council and Chartered Environmentalist registration for suitably qualified members. Membership includes experts on a wide range of engineering and product design disciplines, all of whom practise, manage or educate in design.



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The IET is a world leading professional organisation, sharing and advancing knowledge to promote science, engineering and technology across the world. Dating back to 1871, the IET has 150,000 members in 127 countries with offices in Europe, North America, and Asia-Pacific.

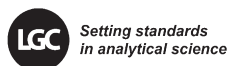
Institution of Mechanical Engineers



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The Institution provides politicians and civil servants with information, expertise and advice on a diverse range of subjects, focusing on manufacturing, energy, environment, transport and education policy. We regularly publish policy statements and host political briefings and policy events to establish a working relationship between the engineering profession and parliament.

LGC



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LGC is an international science-based company and market leader in the provision of analytical, forensic and diagnostic services and reference standards to customers in the public and private sectors.

Under the Government Chemist function, LGC fulfils specific statutory duties as the referee analyst and provides advice for Government and the wider analytical community on the implications of analytical chemistry for matters of policy, standards and regulation. LGC is also the UK's designated National Measurement Institute for chemical and biochemical analysis.

With headquarters in Teddington, South West London, LGC has 36 laboratories and centres across Europe and at sites in China, Brazil, India and the US.



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The Linnean Society of London is a professional learned body which promotes natural history in all its branches, and was founded in 1788. The Society is particularly active in the areas of biodiversity, conservation and sustainability, supporting its mission through organising open scientific meetings and publishing peer-reviewed journals, as well as undertaking educational initiatives. The Society's Fellows have a considerable range of biological expertise that can be harnessed to inform and advise on scientific and public policy issues.

A Forum for Natural History

Marine Biological Association



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For over 125 years the Marine Biological Association has been delivering its mission 'to promote scientific research into all aspects of life in the sea, including the environment on which it depends, and to disseminate to the public the knowledge gained.' The MBA has extensive research and knowledge exchange programmes and a long history of providing evidence to support policy. It represents its members in providing a clear independent voice to government on behalf of the marine biological community.



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The National Endowment for Science, Technology and the Arts



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NESTA is the National Endowment for Science, Technology and the Arts – an independent organisation with a mission to make the UK more innovative. It operates in three main ways: by investing in early-stage companies; informing and shaping policy; and delivering practical programmes that inspire others to solve the big challenges of the future. NESTA's expertise in this field makes it uniquely qualified to understand how the application of innovative approaches can help the UK to tackle two of the biggest challenges it faces: the economic downturn and the radical reform of public services.

National Physical Laboratory



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The National Physical Laboratory (NPL) is the United Kingdom's national measurement institute, an internationally respected and independent centre of excellence in research, development and knowledge transfer in measurement and materials science. For more than a century, NPL has developed and maintained the nation's primary measurement standards – the heart of an infrastructure designed to ensure accuracy, consistency and innovation in physical measurement.



Natural History Museum



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The Nutrition Society



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Founded in 1941, The Nutrition Society is the premier scientific body dedicated to advance the scientific study of nutrition and its application to the maintenance of human and animal health.

Highly regarded by the scientific community, the Society is the largest learned society for nutrition in Europe. Membership is worldwide and is open to those with a genuine interest in the science of human or animal nutrition. Principal activities include:

1. Disseminating scientific information through its programme of scientific meetings and publications
2. Publishing internationally renowned scientific learned journals, and textbooks
3. Promoting the education and training of nutritionists
4. Engaging with external organisations and the public to promote good nutritional science

PHARMAQ

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PHARMAQ is the only global pharmaceutical company with a primary focus on aquaculture. Specialising in the manufacture and supply of veterinary pharmaceuticals for the global aquaculture industry including vaccines, anaesthetics, antibiotics, sea lice treatments and biocide disinfectants.



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The Physiological Society brings together over 3000 scientists from over 60 countries. Since its foundation in 1876, our Members have made significant contributions to the understanding of biological systems and the treatment of disease. The Society promotes physiology with the public and Parliament alike, and actively engages with policy makers. It supports physiologists by organising world-class conferences and offering grants for research. It also publishes the latest developments in the field in its two leading scientific journals, The Journal of Physiology and Experimental Physiology.

Prospect



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Prospect is an independent, thriving and forward-looking trade union with 122,000 members across the private and public sectors and a diverse range of occupations. We represent scientists, technologists and other professions in the civil service, research councils and private sector.

Prospect's collective voice champions the interests of the engineering and scientific community to key opinion-formers and policy makers. With negotiating rights with over 300 employers, we seek to secure a better life at work by putting members' pay, conditions and careers first.



The Royal Academy of Engineering

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Royal Botanic Gardens, Kew



RBG Kew is a centre of global expertise in plant and fungal diversity, conservation and sustainable use housed in two world-class gardens. Kew receives approximately half of its funding from government through Defra. Kew's Breathing Planet Programme has seven key priorities:

- Accelerating discovery and global access to plant and fungal diversity information
- Mapping and prioritising habitats most at risk
- Conserving what remains
- Sustainable local use
- Banking 25% of plant species in the Millennium Seed Bank Partnership
- Restoration ecology
- Inspiring through botanic gardens

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Inspiring and delivering science-based plant conservation worldwide, enhancing the quality of life

The Royal Institution



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The core activities of the Royal Institution centre around four main themes: science education, science communication, research and heritage. It is perhaps best known for the Ri Christmas Lectures, but it also has a major Public Events Programme designed to connect people to the world of science, as well as a UK-wide Young People's Programme of science and mathematics enrichment activities. Internationally recognised research programmes in bio- and nanomagnetism take place in the Davy Faraday Research Laboratory.

The Royal Society



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The Royal Society is the UK academy of science comprising 1400 outstanding individuals representing the sciences, engineering and medicine. It has had a hand in some of the most innovative and life-changing discoveries in scientific history. Through its Fellowship and permanent staff, it seeks to ensure that its contribution to shaping the future of science in the UK and beyond has a deep and enduring impact.



RSC | Advancing the Chemical Sciences The Royal Society of Chemistry

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The Royal Society of Chemistry is a learned, professional and scientific body of over 46,000 members with a duty under its Royal Charter "to serve the public interest". It is active in the areas of education and qualifications, science policy, publishing, Europe, information and internet services, media relations, public understanding of science, advice and assistance to Parliament and Government.

Society for Applied Microbiology



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SfAM is the oldest UK microbiological society and aims to advance, for the benefit of the public, the science of microbiology in its application to the environment, human and animal health, agriculture and industry.

SfAM is the voice of applied microbiology with members across the globe and works in partnership with sister organisations to exert influence on policy-makers world-wide.

society for general Microbiology

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SGM is the largest microbiological society in Europe. The Society publishes four journals of international standing, and organises regular scientific meetings.

SGM also promotes education and careers in microbiology, and it is committed to represent microbiology to government, the media and the public.

An information service on microbiological issues concerning aspects of medicine, agriculture, food safety, biotechnology and the environment is available on request.

Society of Biology



SOCIETY OF
Biology

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The Society of Biology has a duty under its Royal Charter "to serve the public benefit" by advising Parliament and Government is a single unified voice for biology: advising Government and influencing policy; advancing education and professional development; supporting our members, and engaging and encouraging public interest in the life sciences. The Society represents a diverse membership of over 80,000 - including, students, practising scientists and interested non-professionals - as individuals, or through learned societies and other organisations.

Society of Cosmetic Scientists

SOCIETY OF
COSMETIC
SCIENTISTS



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Advancing the science of cosmetics is the primary objective of the SCS. Cosmetic science covers a wide range of disciplines from organic and physical chemistry to biology and photo-biology, dermatology, microbiology, physical sciences and psychology.

Members are scientists and the SCS helps them progress their careers and the science of cosmetics ethically and responsibly. Services include publications, educational courses and scientific meetings.

Society of Maritime Industries



Society of
Maritime
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The Society of Maritime Industries is the voice of the UK's maritime engineering and business sector promoting and supporting companies which design, build, refit and modernise ships, and supply equipment and services for all types of commercial and naval ships, ports and terminals infrastructure, offshore oil & gas, maritime security & safety, marine science and technology and marine renewable energy.

Universities Federation for Animal Welfare



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UFAW is an international, independent scientific and educational animal welfare charity. It works to improve animal lives by:

- supporting animal welfare research.
- educating and raising awareness of welfare issues in the UK and overseas.
- producing the leading journal Animal Welfare and other high-quality publications on animal care and welfare.
- providing expert advice to government departments and other concerned bodies.



The
Welding
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The Welding Institute creates value and enhances quality of life for Members and stakeholders through engineering, materials and joining technologies.



Research Councils UK

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Each year the Research Councils invest around £3 billion in research covering the full spectrum of academic disciplines from the medical and biological sciences to astronomy, physics, chemistry and engineering, social sciences, economics, environmental sciences and the arts and humanities.

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- lead in shaping the overall portfolio of research funded by the Research Councils to maximise the excellence and impact of UK research, and help to ensure that the UK gets the best value for money from its investment;
- ensure joined-up operations between the Research Councils to achieve its goals and improve services to the communities it sponsors and works with.

Biotechnology and Biological Sciences Research Council (BBSRC)



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BBSRC invests in world-class bioscience research and training on behalf of the UK public. Our aim is to further scientific knowledge to promote economic growth, wealth and job creation and to improve quality of life in the UK and beyond. BBSRC research is helping society to meet major challenges, including food security, green energy and healthier, longer lives and underpins important UK economic sectors, such as farming, food, industrial biotechnology and pharmaceuticals.

Economic and Social Research Council



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EPSRC

Engineering and Physical Sciences
Research Council

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EPSRC is the UK's main agency for funding research in engineering and physical sciences, investing around £800m a year in research and postgraduate training, to help the nation handle the next generation of technological change.

The areas covered range from information technology to structural engineering, and mathematics to materials science. This research forms the basis for future economic development in the UK and improvements for everyone's health, lifestyle and culture. EPSRC works alongside other Research Councils with responsibility for other areas of research.

Medical Research Council



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Website: www.mrc.ac.uk

For almost 100 years, the MRC has been improving the health of people in the UK and around the world by supporting the highest quality science on behalf of UK taxpayers. We work closely with the UK's Health Departments, the NHS, medical research charities and industry to ensure our research achieves maximum impact as well as being of excellent scientific quality. MRC-funded scientists have made some of the most significant discoveries in medical science – from the link between smoking and cancer to the invention of therapeutic antibodies – benefiting millions of people.

Natural Environment Research Council



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The UK's Natural Environment Research Council funds and carries out impartial scientific research in the sciences of the environment. NERC trains the next generation of independent environmental scientists.

NERC funds research in universities and in a network of its own centres, which include:

British Antarctic Survey, British Geological Survey, Centre for Ecology and Hydrology, and National Oceanography Centre.

Science & Technology Facilities Council



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The Science and Technology Facilities Council is one of Europe's largest multidisciplinary research organisations supporting scientists and engineers world-wide. The Research Council operates world-class, large-scale research facilities and provides strategic advice to the UK Government on their development. The STFC partners in two of the UK's Science and Innovation Campuses. It also manages international research projects in support of a broad cross-section of the UK research community, particularly in the fields of astronomy, nuclear physics and particle physics. The Council directs, co-ordinates and funds research, education and training.



SCIENCE DIARY

THE PARLIAMENTARY AND SCIENTIFIC COMMITTEE

Tel: 020 7222 7085
parliamentaryandscientificcommittee@hotmail.co.uk
lloyda@pandsccte.demon.co.uk
www.scienceinparliament.org.uk

Tuesday 28 February 17.30

Discussion Meeting

Ground Engineering - why it matters

Speakers: Professor Barry Clarke, Rodney Chartres and Professor John Burland.

Monday 12 March

SET for BRITAIN

Poster Competition and Exhibition for early-stage researchers

12.30 – 14.30 Biological and Biomedical Science

15.30 – 17.30 Physical Sciences
(Chemistry and Physics)

18.30 – 20.30 Engineering

Tuesday 13 – Thursday 15 March

Oceanology International Exhibition at Excel

The Committee will have a stand

Thursday 15 March 10.00 - 13.00

National Science and Engineering Week Seminar in collaboration with the Council for the Mathematical Sciences

Mathematics Matters - a Crucial

Contribution to the Country's Economy

This will be followed by a Reception and buffet lunch in the Jubilee Room.
Details available at

www.scienceinparliament.org.uk

THE ROYAL SOCIETY

Website: royalsociety.org

The Royal Society hosts a series of free events, including evening lectures and conferences, covering the whole breadth of science, engineering and technology for public, policy and scientific audiences. Events are held at the Royal Society's offices in London, at the Kavli Royal Society International Centre at Chicheley Hall, Buckinghamshire and other venues.

Many past events are available to watch or listen to online at <http://royalsociety.tv> The collection includes events with speakers such as David Attenborough, Margaret Atwood and Lord Rees FRS.

Highlights in the next few months include the following. Details of how to attend all these, plus information on many more

events can be found on our website at royalsociety.org/events:

Monday 13 February 18.30 – 19.30

How new science is transforming the optical microscope

Dr Brad Amos FRS

at The Royal Society, London

Thursday 23 and Friday 24 February

Rigidity of periodic and symmetric structures in nature and engineering

at Kavli Royal Society International Centre, Buckinghamshire

Monday 27 February 18.30 – 20.00

What's left to explore in our solar system?

Dr Zita Martins

at The Royal Society, London

Friday 2 March 13.00 - 14.00

Shakespeare the metallurgist, Eliot the spectroscopist: the cultural journey of the chemical elements

Hugh Aldersey-Williams

at The Royal Society, London

Friday 9 March 13.00 – 14.00

The first ornithologist: Francis Willughby

Professor Tim Birkhead FRS

at The Royal Society, London

Thursday 15 and Friday 16 March

Nanolaboratories: physics and chemistry of small-molecule endofullerenes

at Kavli Royal Society International Centre

Friday 16 March 13.00 – 14.00

'Against images made by hands': Florence Nightingale's reluctant life in portraiture

Dr Natasha McEnroe

at The Royal Society, London

Wednesday 28 and Thursday 29 March

Signal processing for the physical sciences

at Kavli Royal Society International Centre

Friday 30 March 13.00 – 14.00

Dream to reality?

Dr Susan Mossman

at The Royal Society, London

Friday 13 April 13.00 – 14.00

'How should a chemist understand brewing?' Beer and theory around 1800

Dr James Sumner

at The Royal Society, London

Friday 20 April 13.00 – 14.00

Hero or villain? Nevil Maskelyne's posthumous reputation

Dr Rebekah Higgitt

at The Royal Society, London

Monday 23 and Tuesday 24 April

New windows on transients across the Universe

at The Royal Society, London

Monday 23 April 18.30 – 20.00

Hiding in plain site?

Dr Andrew Ker on steganography

at The Royal Society, London

Friday 27 April 9.30 – 17.00

History Comes to Life: Seventeenth-Century Natural History, Medicine and the 'New Science'

at The Royal Society, London

Friday 27 April 13.00 – 14.00

Sir George Cayley (1773-1857), the father of flight

Dr Alan Morrison

at The Royal Society, London

Thursday 3 and Friday 4 May

Structure and dynamics of the thylakoid membrane

at Kavli Royal Society International Centre

Friday 4 May 13.00 – 14.00

Chasing Venus: the race to measure the heavens

Andrea Wulf

at The Royal Society, London

Friday 11 May 13.00 – 14.00

Triangulating positions: Hevelius, Halley and the management of the open-sights controversy

Dr Noah Moxham

at The Royal Society, London

Monday 14 and Tuesday 15 May

Next-generation molecular and evolutionary epidemiology of infectious disease

at The Royal Society, London

Monday 28 May 18.30 – 20.00

Do we need friends?

Professor Neil Macrae

at The Royal Society, London

THE ROYAL INSTITUTION

21 Albemarle Street

London W1S 4BS.

All events take place at the Royal Institution. For information and to book tickets visit www.rigb.org

Tuesday 21 February 19.00 – 20.30

Waking the giant: How a changing climate triggers earthquakes, tsunamis, and volcanoes

Bill McGuire



Thursday 23 February 19.00 – 20.30

Does innovation begin with the entrepreneur or the technology?

Friday 24 February 20.00 – 21.15

Alzheimer's disease: treatments and tests on the horizon

Simon Lovestone, Director of the NIHR Biomedical Research Centre for Mental Health and Unit for Dementia

Tuesday 28 February 19.00 – 20.30

From Iron lungs to intensive care

Wednesday 29 February 19.00 – 20.30

Wired for culture

Mark Pagel

Wednesday 7 March 19.00 – 20.30

Consciousness: the hard problem?

Tuesday 13 March 19.00 – 20.30

Scientists and journalists need different things from science. Discuss

Wednesday 21 March 19.00

Famelab UK Final

Wednesday 28 March 19.00start

Science Weekly Live

Friday 30 March 20.00 – 21.15

The social brain in adolescence

Sarah-Jayne Blakemore

Thursday 5 April 19.00 – 20.30

The reason why: the miracle of life on Earth

John Gribbin

Tuesday 10 April 19.00 – 20.30

The righteous mind

Jonathan Haidt

Saturday 14 April 11.00 – 16.00

Family Fun Day: A bug's life

Friday 27 April 20.00 – 21.15

Probability does not exist. Probably

David Spiegelhalter

BRITISH SCIENCE ASSOCIATION

Friday 9 – Sunday 18 March

National Science & Engineering Week

Theme: "our world in motion"

With over 4,500 events and activities attended by 1.7 million people in 2011, this is the UK's widest grassroots celebration of all things science and engineering. For more information, please visit www.nsew.org.uk

Monday 14 and Tuesday 15 May

The 2012 Science Communication Conference

This year's Conference theme is 'Impact' which aims to discuss the various ways to measure the impacts of public engagement activities as well as how research scientists and engineers will consider the impact agenda of their research.

at Kings Place, London

For more information, please visit

www.britishtscienceassociation.org/sciencecommunicationconference

HOUSES OF PARLIAMENT OUTREACH SERVICE

Monday 12 March 18.30-20.30

"Parliament Talks... Science"

Discussion on Parliament's use of scientific expertise

Organised by the Houses of Parliament Outreach Service, in partnership with the University of Leeds, as part of National Science and Engineering Week.

Further information:

<http://www.parliament.uk/talks>

THE LINNEAN SOCIETY OF LONDON

Burlington House

Piccadilly

London W1J 0BF

Tel: +44 (0)20 7434 4479 ext 11

Visit www.linnean.org for further details

Unless otherwise stated events are held at the Linnean Society of London and are free and open to all

Thursday 15 March 18.00

Flora of Tropical East Africa: a very slow cutting edge

Henk Beentje

Free Evening Lecture

Thursday 19 April 18.00

Biodiversity Lecture - Marine Protected Areas in English Waters

James Marsden, Director Marine, Natural England

Free Evening Lecture

Thursday 26 and Friday 27 April

Meeting the challenges of Neglected Tropical Diseases

Joint meeting with the Royal Society of Medicine, organised by Vaughan Southgate PLS and John Betteridge

Two-day meeting which will require

registration, details from www.linnean.org



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The production of this issue has been supported by contributions from the Association of the British Pharmaceutical Industry and those organisations who have entries in the Science Directory (pages 62-70).

Published by the Parliamentary and Scientific Committee, 3 Birdcage Walk, London SW1H 9JJ.

Published four times a year. The 2012 subscription rate is £70.00. Single numbers £17.50

ISSN 0263-6271

All enquiries, including those from members wishing to take the front or back covers, advertise in the journal or appear in the directory to Mrs Annabel Lloyd, Tel 020 7222 7085

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Typeset and printed by The Bridge Press.





Bringing medicines to *life*

About the ABPI

Who We Are

We represent innovative research-based biopharmaceutical companies, both large and small, leading an exciting new era of biosciences in the UK. Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. Our members supply 90 per cent by value of all medicines used by the NHS, and are researching and developing 90 per cent of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

We are the Government recognised body negotiating the pricing of branded medicines on behalf of the entire industry. Working with our Research Affiliate Members, we promote the UK as a destination of choice for international life sciences investment.

Britain's future economic prosperity depends on fostering strong, vigorous and well-supported knowledge-intensive industries. By most measures, the pharmaceutical sector is Britain's most successful research-based industry and remains a jewel in the UK's scientific and industrial crown.

- 29% of all research and development (R&D) investment in the UK is invested by the pharmaceutical sector¹
- the industry generated a £7billion trade surplus for the UK in 2009²
- the industry directly provides 67,000 jobs, of which 25,000 are in R&D³

¹ Research and Development in UK Businesses 2010

² HM Revenue and Customs

³ ONS Annual Business Survey (November release) and ONS Research and Development in UK Business 2010

What We Do

We are the single voice of our industry from bench to patient, engaging with all stakeholders in the process of discovery, development, manufacturing, licence, price, access and uptake. As the trade association for the research-based biopharmaceutical industry in the UK, we work with policy-makers and stakeholders to ensure that patients are able to benefit from the latest and most advanced medicines.

The pivotal role that the pharmaceutical industry has played, and continues to play, in improving the health, wellbeing and productivity of the UK population is often underestimated. Whilst good health is something that most people take for granted, it is a vitally important personal and societal requirement. The impact of poor health on the UK population is hard to quantify, but the pharmaceutical industry has been shown to contribute significantly – both directly and indirectly – to the welfare of the UK population as a whole. Our objective is to ensure that this is better understood.

Contact for Further Information

If you would like more information or have any questions, please contact: Government Affairs on 020 7747 7136 or abpicomms@abpi.org.uk

Bringing leadership to *life*

abpi.org.uk

key facts on the cost of medicines

1. The UK spends only 0.9% of GDP on medicines – less than the European average of 1.2%¹.
2. In the last published PPRS report to Parliament, the UK was shown to have amongst the lowest priced medicines in Europe².
3. The proportion of the NHS budget spent on medicines has fallen since 1999 – down from 13% to a little under 10% today⁴.
4. 65% of prescriptions are written for the over 65s⁵. With 172,000 additional over 65s added to our population each year⁶, the medicines bill is only going to increase.
5. The UK is very cost-efficient when it comes to paying for medicines, as around two-thirds of all prescriptions dispensed in the UK are for cheaper generic medicines⁷.
6. Due to a growing number of elderly people the total amount spent by the NHS on medicines is likely to grow. According to industry forecasts, by around £400m per year, reaching a projected total of around £15bn by 2014³.
7. New medicines⁸ only account for 10% of the NHS's total spending on medicines⁹.
8. In the UK uptake of new medicines is significantly slower than the European average. In the UK the use of new cancer medicines is 33% lower than the European average¹⁰.
9. Due to the number of products coming off patent between 2009 and 2015 the NHS is set to save well over £3bn¹¹.
10. The rate of secondary care growth is slowing. Our forecast suggests projected growth of 1% per year in primary care and 7% per year in secondary care between now and 2014¹². This compares to the trend over the last two years where primary care grew at 2% and secondary care at 11%¹³.

References

1 EU 15 countries – ABPI Calculation, IMS, OECD, (2010 Figures)

2 PPRS, Tenth Report to Parliament, December (2009)

3 ABPI forecast (2010)

4 At manufacturers prices - Office of Health Economics (2011)

5 NHS Information Centre (2009)

6 ONS (2008-2009)

7 NHS Information Centre (2009)

8 Branded medicines introduced within the past 5 years

9 IMS (2010)

10 EU 15 countries, cancer therapy area – up to 5 years after the medicines launch (2009) – ABPI Analysis

11 ABPI Forecast (2010)

12 ABPI Forecast (2010)

13 IMS