CHIEF SCIENTIST OFFICE

Investing in Research | **Improving Health**

NHS SCOTLAND

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SCOTTISH GOVERNMENT

Investing in Research | **Improving Health**

The research strategy for health and healthcare

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Foreword

by Ms Nicola Sturgeon MSP

RESEARCH AFFECTS US ALL; MANY OF THE TECHNOLOGIES AND THERAPIES THAT WE ASSOCIATE WITH THE DELIVERY OF A MODERN HEALTH SERVICE HAVE THEIR ORIGINS IN RESEARCH.

In Scotland, our healthcare researchers have achieved an international recognition for the excellence of their science. Rapid advances in our understanding of diseases, their causes; treatments that cure or alleviate have largely been generated by their skills. Future progress must be as concerned with the afflictions that cause chronic morbidity as those leading to mortality.

Investing in Research; Improving Health sets out the aims and ambitions we have to sustain and build upon current success. It is only by continuing to invest in our outstanding research talent that we can generate the sound evidence and exciting innovations upon which improvements to healthcare are based. The NHS has supported and conducted research throughout its existence and it is central to achieving these objectives. I encourage NHS boards to give research the importance it deserves. Those responding to the consultations involved in shaping this document emphasised the importance of research activity translating into public benefits. I endorse that view and it is prioritised in this document.

We are committed to tackling disease prevention wherever possible and are excited by the emerging understanding of the biological links between inequalities and health. The benefits to health and healthcare are explicit but we are also alert to the potential for economic benefits. The life sciences have a key part to play and a tradition of excellence on which to build.

There is much to be proud about but I do not underestimate the challenges raised in this document. I believe that its aims will build on our achievements and ensure future benefits to our health and healthcare.

Ms Nicola Sturgeon MSP
Deputy First Minister and Cabinet Secretary for Health and Wellbeing

Preface

by Dr Kevin Woods/Professor Sir John Savill

THE CHIEF SCIENTIST OFFICE WAS ESTABLISHED IN 1973 WITH ITS MAIN MISSION TO *"IDENTIFY, ENCOURAGE, PROMOTE AND SUPPORT"* RESEARCH FOR THE BENEFIT OF THE NHS IN SCOTLAND. THIS RESPONSIBILITY HAS STOOD THE TEST OF TIME AND REMAINS KEY TO THIS STRATEGY.

Over the last year or so, CSO has worked intensively with its many stakeholders to formulate this new strategy, develop high impact research funding partnerships through OSCHR and establish the Scottish Academic Health Sciences Collaboration, with superb support from across Scottish Government. The improvements in both patient care and population health that will result are not the only exciting deliverables, however. The new strategy will also help to drive economic development by fostering Scotland's efforts to develop a world-leading biomedical R&D cluster comprising the NHS, universities and industry. Central to these developments is the unstinting support shown for clinical research by patients and the public in Scotland, for which we should all be very grateful.

There have been major advances in basic scientific knowledge in recent years that offer enormous potential. The need for research that focuses on harnessing those benefits has never been greater. We believe that this document will allow NHSScotland and its research partners to rise to the challenges presented and make a lasting contribution to advances in health and healthcare.

Dr Kevin Woods
Chief Executive, NHSScotland

Professor Sir John Savill
Chief Scientist

Introduction

Introduction

Scotland's strengths in life sciences and healthcare research are well proven. Past investment has helped to train, support and sustain the talented researchers who make the scientific advances in health and healthcare on which progress depends. This strategy describes how we plan to develop and underpin future success.

Patient benefit and ***improving population health*** are central to CSO's new research strategy and the returns on the investment of public money will be measured first and foremost in these terms. However, significant economic benefits are also expected and some successes will be more immediately measured in this way.

The Scottish population is only 8.5 % of the UK but it is estimated that one in eight life scientists work here. Their contribution is key to the growth of the Scottish economy both now and in the future. Public sector investment in research has a major role to play in supporting this achievement. Scotland's researchers in health and healthcare are typically able to attract some 13 % of public and charitable sector awards[1] and a recent analysis for the Chief Scientific Adviser to Scottish Government found that the impact of their research is amongst the very best in the world[2]. These data imply internationally competitive research quality but also suggest that success is significantly driven by volume. These findings have helped to inform our strategy.

The ambition of this strategy is to place Scotland at the international forefront of clinical translational research and the development of systems medicine. To achieve this we must build on past successes, focus on excellence and continue to build capacity and capability in key skills and disciplines. We must ensure strong and productive partnerships amongst funders and funded alike and we must look beyond our borders to work with the best in the world.

We must also improve systems to: ensure smooth and efficient NHS approval processes; draw more effectively on the excellent science base and improve the time taken for research findings to affect practice. While good progress has been made in recent years much remains to be done and will be a focus for effort over the five-year life of this strategy.

This document does not describe aims in terms of disease priorities but as cross-cutting ambitions capable of generating benefits across a broad spectrum of diseases and conditions. Each of these aims is described in more detail in the following sections. The aims are:

1. Securing benefit;
2. Improving population health;
3. Valuing and investing in NHS research; and
4. Building and sustaining skills.

However, CSO will ensure that it retains a proper focus on its investment in healthcare priorities through the Portfolio Steering Groups (PSGs) established in key areas under the previous strategy[3]. Their roles will evolve and are described further under Aim 1.

The funding landscape has changed significantly since the last Strategy was written. Funders increasingly work in partnership and several of the

1 UKCRC Health Research Analysis May 2006 http://www.ukcrc.org/researchcoordination/healthresearchanalysis/ukanalysis/

2 *Metrics for the Scottish Research Base* Scottish Government June 2007

3 *Research Strategy for Health and Healthcare* Scottish Executive July 2003

resulting collaborations are large and multi-sectoral. Following the Cooksey Review (2006[4]), the Office for the Strategic Coordination of Health Research (OSCHR) was formed. This brought greater integration of the activities of the English Health Department's National Institute of Health Research (NIHR) with those of the Medical Research Council. Scotland became an OSCHR partner during 2008 and this strategy reflects our participation.

New members contribute pro rata to those NIHR programmes in which they wish to be involved. Thus Scotland is participating in the Health Technology Assessment programme and related programmes in public health and health services research. Our own grant award structures will be modified to articulate more effectively with these programmes and some evolution of the committees will also result. The section "*Securing Benefit*" provides further detail.

Other important changes in funding arrangements have a general industry focus that is much wider than healthcare. The UK Technology Strategy Board was given a broader role in 2006 and has objectives that align well with ours and funding initiatives that support knowledge transfer activity. More recently, the Office for Life Sciences was created in 2009 and its initial commentary published in June[5]. There is a wish to secure UK-wide benefits drawing on the different structures and experience across the UK nations and we shall work with the Office for Life Sciences to help achieve this goal.

Our consultation provided emphatic support for a programme targeting healthcare quality improvement and some wish that it be well aligned with the English Service Delivery and Organisation programme. The focus of our programme will be complementary but distinctive. It will focus on systems and issues that are a priority for health and healthcare and the policies and structures that have been developed in Scotland. It will aim to learn from international best practice, explore necessary adaptation and understand the processes required for successful adoption. We shall work in close collaboration with NHS Quality Improvement Scotland to shape and assess activity. This new programme is described in greater detail in the section "*Securing benefit*".

Exciting and innovative partnerships have been established in public health, seeking to secure research translation, often in non-healthcare settings. Scotland has uniquely rich NHS datasets that when combined with other information can yield new insights into problems or their remedy. However, the public must be confident that their data is being used appropriately and with sufficient regard to issues of privacy. Our ambitions to improve population health are described in Aim 3.

Competition is growing and increasingly researchers must collaborate effectively if they are to remain at the front of their field internationally. For some ten years, CSO and the Scottish Funding Council have both pursued strategies that emphasised collaboration within Scotland; as a result the practice is now well established. Similarly, in recent years CSO has fostered national co-ordinated systems for the NHS research approvals processes. These are now in routine use and expected to deliver consistently and efficiently to nationally accepted performance standards. Further development of research infrastructure is described in the section "*Valuing and Investing in NHS Research*". The evident ease and strength of the cooperative approach was influential in attracting Wyeth Pharmaceuticals Inc to invest $50m in Scottish translational medicine, a success on which we need to build.

4 *A review of UK health research funding* HM Government 2006 http://www.hm-treasury.gov.uk/d/pbr06_cooksey_final_report_636.pdf

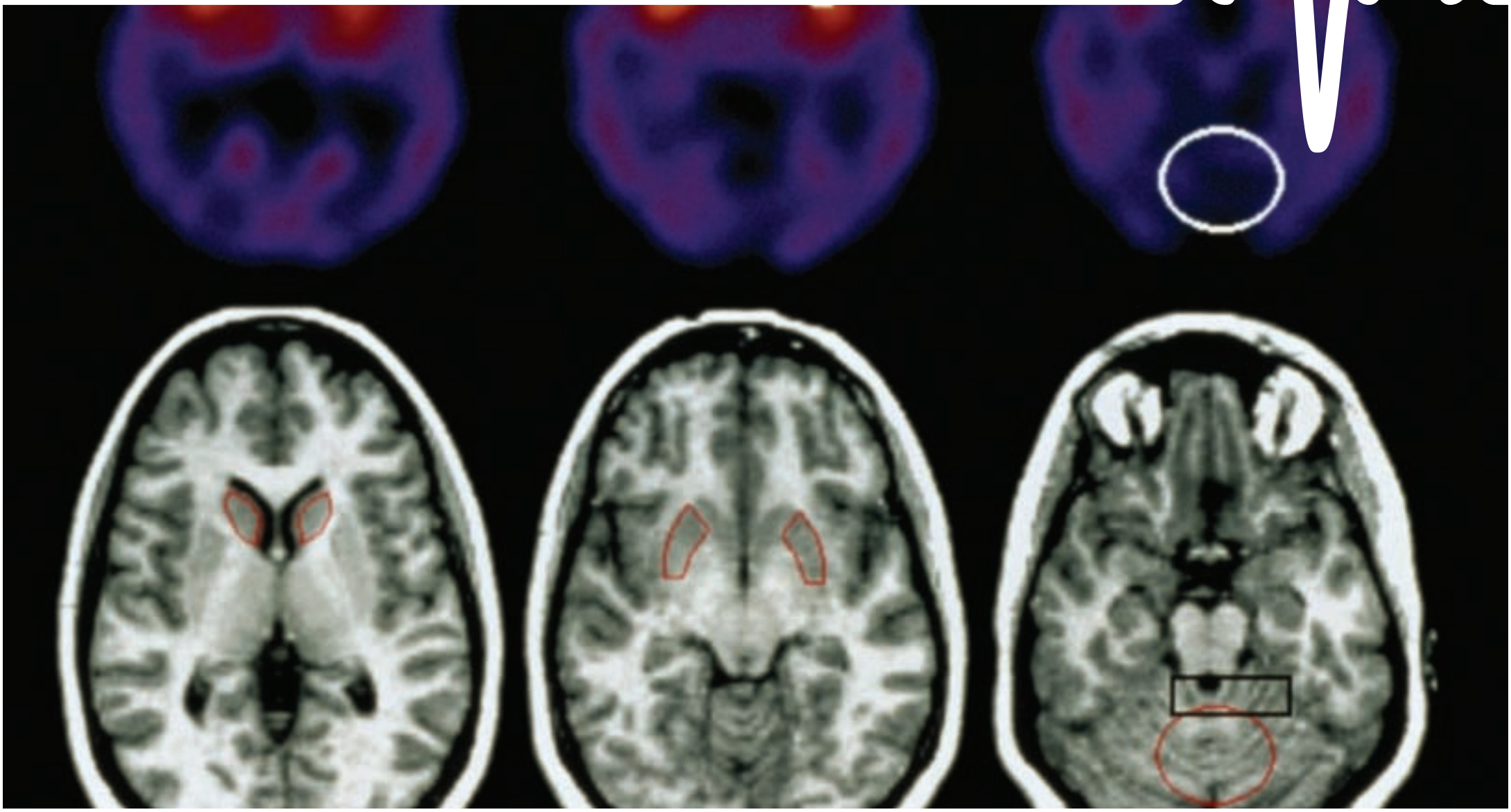
5 *Life Sciences Blueprint* HM Government 2009 http://www.dius.gov.uk/~/media/publications/O/ols-blueprint

A natural evolution of this approach has helped to establish the Scottish Academic Health Sciences Collaboration (SAHSC). Founder membership is the same four University clinical medical schools and health boards that partnered Wyeth, with Scottish Enterprise as the ninth partner. This critical mass of expertise is confidently expected to extend beyond founder members through existing alliances in each region. In future, the Collaboration's capabilities will include other disciplines and professions from across Scotland. It will harness the clinical skills, intellectual leadership and research talents of the country to improve healthcare and help attract further inward investment. Increasingly it will be the vehicle to deliver co-ordinated activity on topics such as tissue collection and informatics.

Ensuring that the necessary skills and capabilities are available is as important today as it was when CSO was established in 1973. Building capacity and capability has been an enduring priority and will remain for the life of this strategy. Support mechanisms have evolved, specific to the needs and ambitions of different topics and professions. These are often only able to be delivered in partnership with others. Most recently, schemes to support for example the Nursing, Midwifery and Allied Health Professions have involved NHS Education for Scotland, the Scottish Funding Council and the Health Foundation. We shall continue to develop schemes in partnership with others to foster research capacity in key areas; our plans are given in greater detail in the section "*Building and Sustaining Skills*".

We need to measure progress achieving the aims and objectives we have identified. Key success indicators are outlined in the final section.

AIM 1:
Securing Benefit



Background

The Cooksey review highlighted the need for concerted action to ensure a step change in the translation of research findings into health and economic benefits. Although published nearly three years ago this emphasis remains essential and is a key objective. Under the auspices of OSCHR's Translational Medicine Board, specific calls have already targeted some recognised bottlenecks. Similarly, we have focused a small grant scheme on translational objectives in recent years. However, translational research starts from a relatively low baseline and new skills sets and effective partnerships need to be developed.

The Cooksey report identified two gaps in translation; both are highly relevant to CSO's mission to improve the health of the people of Scotland and the quality and cost-effectiveness of health services. For the purposes of this document they are defined as:

Gap 1 Laboratory to clinical relevance – The explosion of new knowledge of biological systems at a molecular and cellular level needs to be translated into clinically useful deliverables. The key difference for future funding decisions will be greater focus on a tangible outcome of the research reflected in terms of potential patient or service benefit.

Gap 1 Examples

Patients are at the centre of this type of translational research and access to well characterised patient cohorts, patient material and/or patient data is critical to speed up the transition to more personalised medicine. The availability of well characterised tissue specimens is essential to support translational research in both the academic and biotechnology sectors.

Understanding individual differences in responses to therapy, risk of disease and the heterogeneity of the disease phenotype should lead to more sophisticated diagnostic and prognostic tests as the basis of better targeted therapies. In addition, the drug development pathway can be radically streamlined (and costs reduced) by identifying biomarkers of drug efficacy and toxicity in pre-clinical studies. Validated biomarkers can be incorporated into clinical trials as useful surrogate clinical endpoints to optimise the evaluation of targeted drugs.

Gap 2 Clinical findings to improved practice – Patients can only benefit once clinical research findings are translated into real-world practice. Moreover, research findings from public health, behavioural sciences and health services research need to make a stronger and earlier impact on the delivery of health services and population health. We shall interpret this broadly. There is a need for research that embraces a greater range of methodologies to address issues about both health technologies and change management. This will include not only individual professionals but clinical teams through to the level of the large complex organisation that is the NHS.

CSO has always expected its research to demonstrate the potential for 'health gain'. This will become even more explicit. CSO funding will be directed towards research that will make a measurable difference.

Objectives:

To stimulate and support translational research leading to patient or population benefit;

To increase the success of the Scottish research community in winning awards from UK and other funding streams;

To foster effective partnership working between academia, industry and the NHS for the benefit of patients through translational research.

Action:

CSO funding streams will address these strategic gaps through two broad objectives: to secure the necessary skills base of the Scottish healthcare research community and to help them to attract longer term support from other funders. Our funding streams will aim to articulate smoothly with other OSCHR partners and larger studies will only be supported as part of a targeted call. It will be of greater importance to work with the funding partners and other agencies to ensure that key areas of translational research do not fall between funding streams.

Driven by increased research costs there has been a progressive shortening of grant duration which we view as detrimental to effective capacity building. We shall aim to keep grant ceilings under review with an ambition that as early as possible in the life of this strategy we shall increase the project grant limit to £100k/yr for a maximum of 3 years.

Two strands of activity will address the strategic gaps identified.

(1) Translating biological discovery into clinical application

We shall replace the Biomedicine and Therapeutics Research Committee (BTRC) with an Experimental and Translational Medicine Research Committee (ETMRC) to enhance further our focus on translational research (Gap 1 above). Working practices of the committee will be reviewed and revised to support the research community to increase the translational impact of their research. We shall continue to make periodic targeted calls for small translational grants (£75k) as these have attracted high-quality, novel proposals.

We shall fulfil the aspirations for a population-based tissue bank, as outlined in *Better Cancer Care*[6], by integrating local tissue collection through histopathology departments with the SAHSC biobanks. The aim will be to use this as an exemplar to develop the ethical infrastructure able to gain appropriate consent to link dedicated research tissue to patient-specific pathology, clinical and outcome data. Only through such a population-based resource, can the influence of factors such as socioeconomic status, ethnicity and co-morbidities be related to the molecular features of tumours and the effect on disease causation and outcome be studied.

6 Scottish Government, October 2008; http://www.scotland.gov.uk/Publications/2008/10/24140351/0

Learning from our Viking genes

Isolated populations such as Orkney offer a unique insight into the genetic determinants of complex disorders. The Orcades study has expanded from the original study of cardio-vascular disease traits to include multiple phenotypes (osteoporosis, arthritis, glaucoma, multiple sclerosis); securing funding from various agencies. CSO has provided further funding to both expand the resource and enable rarer genetic variants to be studied. The ultimate goal is to act as a drug discovery platform by understanding the protein and glycoprotein targets of the genes involved. Patients will benefit through improved understanding of disease risk as well as the potential to stratify disease and thus target future therapies.

Scotland has an enviable NHS dataset recording healthcare activity. We shall work in partnership with colleagues in NHS Information Services to expand the use of patient clinical information systems through the disease-specific research networks already established. We wish to:

- Lead development of an ethical method of approaching patients about participation in future clinical trials and
- Foster a platform to evaluate healthcare interventions or services, drug safety surveillance and gain a better understanding of the determinants and occurrence of disease. Our Portfolio Steering Groups (PSGs) will provide this additional strategic advice.

We shall re-focus the work of the cardiovascular PSG on building research functionality into the new Coronary Heart Disease register (SCI-CHD; previously the acute coronary syndrome register SCI-CHD_ACS). It will be able to draw upon the experience and expertise of the Diabetes Research Network and the clinical information system used for diabetes, primarily due to the links to the national Community Health Index (CHI). We shall

also aim to couple such a register to tissue samples obtained via the new SAHSC investment in bio-resources. This would offer considerable translational research opportunities for academia and industry.

Improving the infrastructure to support clinical research has attracted significant new resources over the last five years. There are now networks for research in cancer, stroke, diabetes, paediatrics/medicines for children, mental health and dementia. The networks not only provide the support necessary to manage high quality clinical studies but they will increasingly offer an ideal environment to help ensure that findings influence future care in a timely and appropriate way. Under the last strategy, CSO invested large sums to establish "Generation Scotland", a programme of work aiming to enrich NHS datasets with detailed genetic information. We shall adopt a systems medicine approach to its second phase and see a shift in emphasis from individual molecules to complex genetic and biochemical networks. It will be essential to this ambition that a broader partnership be established; we welcome the emerging collaboration with the Scottish Universities Life Sciences Alliance (SULSA) to build on the associated investment in systems biology infrastructure.

Generation Scotland, a systems medicine platform

Through a consortium of research funders and providers, CSO aims to secure a key biomedical R&D resource focused on high throughput technologies to develop predictive and personalised medicine. Past investment by Scottish Government of c.£9m has established a well characterised cohort of Scottish families to explore the complex interactions between genes, environment and lifestyle factors. This platform will place Scotland in a world-leading position that should also attract inward investment from Biotech and Pharma.

Partnership with industry will be key to unlocking the potential from our investment. Experience of working with Wyeth Pharmaceuticals Inc and other large pharmaceutical companies has helped to achieve the focus and support necessary for SAHSC to thrive. Similarly the Life Sciences Alliance Board, established this year, provides a forum for crucial strategic feedback from industry stakeholders in pharma, biotech and medical devices. Its work complements the "Chatham house" debate of the Pharmaceutical Liaison group established a decade ago to help ensure understanding of the distinctive structures and approaches in a devolved Scotland.

Until recently, most industry partnerships involved pharma. However, the development of new innovative technologies able to deliver significant patient and health service benefit also require the creation of effective partnerships across the NHS, academia and industry. To support this, we will provide the resources to enable Scotland's NHS and academic researchers to collaborate with industry through the *Invention 4 Innovation* Programme established by NIHR but able to operate across the UK. This supplements schemes already available through NHSScotland to assist small device companies with clinical assessments of their product.

(2) Fostering evidence-based healthcare through the translation of knowledge into practice

We shall also re-focus the work of the Health Services Research Committee (HSRC) to serve as the Health Services and Population Health Research Committee (HSPHRC). There will be a stronger emphasis on the development of the evidence-base for health improvement through population-based programmes as well as through health services. We shall attach greater importance to applications demonstrating the relevance and significance of their research questions. In addition, applicants will need to indicate more clearly how findings will be used to improve health or the delivery of health services. We shall also work with applicants to ensure that they access the major HTA-related funding streams when appropriate.

We recognise the challenges this will create and shall establish a new initiative for healthcare improvement science to address the skills gap. We shall make occasional targeted calls for proposals, such as our current programme of small grants in healthcare improvement (see box). We plan that this activity will grow over the duration of this strategy to justify an annual commitment of up to £1m. NHS Quality Improvement Scotland plays a major role in monitoring and supporting clinical progress in the health service and will be a key collaborator for this programme.

Scotland's geography can create challenges to health services' configuration and delivery; its scattered island communities and the challenges of climate and access are unique in the UK and require innovative solutions. Such imaginative steps can often point the way to more efficient and effective services elsewhere. These remote and rural issues will be of particular interest to the new programme.

The science of healthcare improvement

Achieving a healthcare system of the highest quality is a key theme in Scottish Government health policy. CSO is developing a five year initiative, with partners to support a range of research activities which will:

- focus on management, organisations, services and systems responsible for healthcare delivery in Scotland
- show strong knowledge transfer potential for improving the quality of healthcare, and
- contribute to the advancement of healthcare improvement science.

Scottish Health Innovations Ltd (SHIL) was incorporated in 2002 to support NHSScotland to identify, protect and exploit its intellectual property. Since its inception it has examined over a thousand ideas and supported inventors taking a number of them to market. Income is now being generated by the earliest to market and companies 'spun out' of NHSScotland are also adding value to the Scottish economy. When this is less appropriate SHIL ensures a greater awareness of the technology across the NHS since there can be potential to save money or address practical problems. CSO with the NHS has been a major funder of SHIL alongside both Scottish Enterprise and Highlands and Islands Enterprise and supports its 'translational' role.

Touch Bionics: the first spin out from NHSScotland

The history of Touch Bionics goes back to a program of work conducted at the Princess Margaret Rose Hospital in Edinburgh from 1963, starting with comprehensive research into developing prosthetic solutions for children affected by Thalidomide.

Spun out from the NHS in 2003, Touch Bionics is launching two key products, the i-LIMB Hand and ProDigits. The hand is the world's first commercially available multi-articulating bionic hand. It has five independently powered digits that open and close around objects. It supports amputees in going about their everyday lives. In medicine, bionics means the replacement or enhancement of organs or other body parts by mechanical means.

ProDigits, short for Prosthetic Digits, are the self-contained fingers that are individually powered and controlled to provide new fingers for partial-hand patients. The i-LIMB Hand is effectively a chassis for five ProDigits. Individual ProDigits are used for patients who have lost part of their hand or a whole finger or fingers.

AIM 2:
Improving Population Health

Background

A Healthier Scotland is one of five strategic objectives of the Scottish Government. To strengthen the evidence base for effective strategies to sustain and improve health we need to ensure that researchers in Scotland have access to a flexible array of support to build research capacity, develop multidisciplinary collaborations, carry out early-phase development and testing of interventions, and go on to well-designed, large scale intervention studies that will make a convincing and influential contribution to the evidence base.

Objectives

To strengthen the evidence base for improving health in Scotland; and

To support research to develop and test population health interventions.

Action

There will be two strands of activity to address these objectives.

(1) Research Partnerships

We shall work with other funders to sustain and increase population health research capacity in Scotland. Specifically, we shall maintain our highly productive joint investment with the MRC in the internationally-renowned Social and Public Health Sciences Unit (see box), and the path-breaking new Scottish Collaboration for Public Health Research and Policy (see box). We share the ambition of the Scottish Universities to establish a Scottish School of Public Health Research, and have expressed our support for their bid.

The MRC/CSO Social and Public Health Sciences Unit has recently been awarded a total of £19m over the next five years. The award includes £3.5m from the CSO towards the Unit's programmes of work to understand the social patterning of health in Scotland, and to develop and test non-health sector interventions to improve health. Commenting on the award, the Unit's Director, Professor Sally Macintyre CBE said, 'It is really important that social and public health policies (which often affect many people and cost a lot of money) are based on the best possible evidence. Renewed funding will help us provide that.'

We shall contribute to the UK National Prevention Research Initiative and the NIHR Public Health Research Programme so that researchers based in Scotland can bid for grants large enough to support well-designed, adequately powered intervention studies. We shall work with our UK partners to ensure that these funding streams are aligned with Scottish research needs and well-publicised among the research community in Scotland.

We shall provide flexible support for the development and early testing of public health interventions through our own grant funding streams. As explained in Aim 1, the Health Services Research Committee will be re-focused to become the Health Services and Population Health Research Committee. This will emphasise its role in supporting work on the whole range of population and health service based approaches to improving health. Large scale intervention studies should target UK funding streams, but we shall keep our grant ceilings under review, retaining the flexibility to invite grants for high quality, high priority studies that are unlikely to be funded through UK sources.

The Scottish Collaboration for Public Health Research and Policy (SCPHRP) was formally established in July 2008, with £3.5m of funding over five years from the CSO and the MRC. Headed by Professor John Frank, formerly Director of the Canadian Institute of Population and Public Health, its aims are to (1) strengthen the evidence base for public health by developing and testing complex interventions for improving population health, using the best available theory and methods; (2) facilitate rapid uptake of research evidence in the development and implementation of policy by engaging policy makers and practitioners at all stages of the research process, from priority setting through to knowledge transfer. Commenting shortly after his appointment, Professor Frank noted that 'The more I've talked to people about the initiative, the more support I've been offered. Many public health problems are biologically completely reversible, and that's a very compelling argument for involvement.'

(2) Linking records for research

As noted under Aim 1, Scotland has a long tradition of effective use of linked health service data for clinical and epidemiological research, and methods have recently been pioneered for linking health service datasets to other data sources such as the Census and population surveys. Data linkage is a highly efficient way both of assessing the capacity of interventions to deliver patient benefit, for example through measuring long term outcomes in clinical trials, and of understanding patterns of health and illness in the population. It is therefore key to delivering our objectives.

Record linkage capability is being developed rapidly throughout the UK, opening up new opportunities for research using federated datasets from

more than one country. To ensure that Scotland plays a full part in these developments, we need to build on initiatives such as the Scottish Health Informatics Programme and the Scottish Academic Health Sciences Collaboration, to create a secure and efficient system of linking health and relevant non-health records, which encourages research use while maintaining the highest standards of data security. We shall work with our partners in the Information Services Division of NHSScotland, the Health Service as a whole and the Universities to support the creation of a world-leading system of data linkage for health research (see box).

We shall look for ways to clarify, strengthen and, where possible, simplify the legal and governance framework. Much work has already been done by ourselves and others but the need for greater clarity and simplicity remains. This must strike an appropriate balance with the requirement to respect consents and patients' wishes for privacy.

We shall invest further in strengthening the infrastructure for record linkage and increasing capacity to carry out and exploit novel linkages. This will build on past CSO investments and the Scottish Health Informatics Programme (SHIP), funded by the Wellcome Trust, which aims to establish a Scotland-wide platform to enhance the use of patient records for research purposes.

We shall play a full part in UK developments via the OSCHR e-Health Research Resources Board. This major piece of work seeks to coordinate cross UK activity and learn from the experience and expertise available in each of the four countries as they develop their own systems.

We shall establish a health information advisory group in Autumn 2009 to reach consensus with our partners on the best way to achieve these goals, and to enable effective dialogue with the new UK structures.

Vision for a world leading system of record linkage

To work in partnership with NHS Information Services to create a world-leading research information linkage and data exchange programme within NHSScotland, supported by an infrastructure that is adaptable and developed in response to the research needs of the NHS, academia and industry.

We shall:

- Ensure that the underlying principles, processes and approaches related to research access to data and associated approvals and governance have broad public support and an appropriate legal basis.
- Ensure information is treated and handled in a safe and secure way to protect the rights and confidentiality of patients and individuals under the law, and also meet researchers' needs effectively.
- Provide access to a comprehensive range of technical resources for accessing health and other relevant data sets, under strict protocols of information governance that will aid the research community to access the data needed to prosecute research of the highest methodological standard.
- Provide high quality training for researchers and NHS staff on technical and applied aspects of data linkage research and the associated legal and ethical principles on which it is founded.
- Maintain Scotland's position as a leader in record linkage based research and in the provision of research support services to academia and industry.

AIM 3:
Valuing and Investing in NHS Research

Background

We must ensure that our academic research strengths are complemented by an NHS both capable and willing to support the full range of NHS research activities from early inception through to implementation. A strong NHS infrastructure is needed to deliver on that ambition and in recent years significant progress has been made on which we now seek to build.

The Scotland-wide NHS research infrastructure comprises all of Scotland's Health Boards but acts as a single entity. Key features of such an approach are nationally delivered system of approvals, costings, and negotiation underpinned with a co-ordinated investment in NHS clinical infrastructure (in particular staff), to ensure prompt study start-up and increased capacity to support additional research. The funding system will continue to target funds more closely with activity.

In addition to having an efficient national infrastructure to support research across Scotland, we must also ensure that those leading the research across Scotland behave in a similarly co-ordinated way. Although the research networks mentioned above fulfil this role in key research areas, CSO has no plans to extend the number of formal networks it funds. There is therefore a need to ensure that researchers in other specialty areas have similar supports in place. The NIHR Specialty Groups are well placed to fulfil that role, bringing together key researchers in specific topic areas from across the UK to provide oversight of the management and delivery of priority research studies. There are 26 such Groups covering a wide range of research activities, all with Scottish representation. CSO proposes to use the Scottish representatives on these NIHR Specialty Groups as the focus for co-ordinating research activity across Scotland. Funding towards the clinical time associated with that function will be met from the CSO allocations to the Health Boards.

It is now recognised that the autonomous Health Boards structures designed to provide clinical services across Scotland do not always achieve efficient R&D approvals. This is particularly noticeable for multi-centre studies, where in the past the need to seek separate ethics and R&D approvals from each Board has been time consuming, bureaucratic and has acted as a significant barrier to busy researchers and industry.

The difficulties researchers may have had in securing funded research time from the R&D budget allocated to Boards can be a further disincentive. Although the introduction of the Support for Science funding formula distributes funds to Boards in relation to their recent research activity, these funds do not always find their way back to buy time prospectively for research. There is also a view that collaborating in research, as opposed to leading it, is insufficiently recognised in the funding formula. This may act as a further disincentive to participation particularly for less research-active Health Boards.

Objectives

To create an efficient and effective national portal through which clinical trials may be negotiated, costed and progressed on a Scotland-wide basis;

To strengthen the system of co-ordinated R&D management approval, under which the decision of any Health Board is accepted and not revisited by others;

To ensure the efficient and equitable bases of funding formulae that link activity to resources.

Action

Our aim is to create an efficient and resilient infrastructure that allows patients from all Scottish Health Board areas to be recruited to well designed studies. In recent years there have been a number of changes introduced to make the various research approval systems more efficient. This progress must be sustained and address the needs and concerns of sponsors for whom delay may create significant extra cost. The emphasis will be upon improved service and support to clinicians, researchers and sponsors with simplified processes focusing on efficiency, effectiveness and greater ability to operate Scotland-wide.

Improving ethical appraisal structures and timescales

The removal of the distinction between single site and multisite approval Research Ethics Committees (RECs) means that most decisions[7] taken by any REC in the UK have UK-wide recognition. Focusing the Scottish Research Ethics Service in four regional hubs has significantly improved the delivery of ethics approval and support in Scotland, and the recent transfer of responsibility for Site Specific Assessment from local RECs to Health Board R&D Departments points the way to how closer inter-agency operating can reduce duplication and streamline handling. Current ethics approval times are now averaging 49 days; well within the 60 days target.

Building on the success of the ethics regional model (see box), a new system for R&D approval of multicentre studies is now in place in Scotland. Operating under the title of NHS Research Scotland (NRS) (see box), Scotland wide approval is arranged through the same four centres as for ethics, each working in collaboration with their neighbouring Boards. Consideration and approval of generic issues is undertaken once on behalf of all Boards and is co-ordinated for the researchers through a NRS Co-ordinating Centre (NRS CC) based in Aberdeen. This new development, widely welcomed by partners in pharma and biotech is a key component of the recently created Scottish Academic Health Sciences Collaboration (SAHSC) (see box), that will further enhance such Scotland-wide working.

NHS Research Scotland (NRS) is an initiative developed to streamline the process of obtaining R&D approval for multicentre research studies in Scotland. The process is managed by the NRS coordinating centre (NRS CC), which is the main point of contact for applicants undertaking such studies, and is responsible for liaising with Health Board R&D offices to facilitate Board and management approval prior to study initiation.

The NRS CC receives and collates the valid national document set; the researcher therefore only has to provide the information on their study once. NRS CC then assigns an Health Board as the generic review site – which assesses issues including legal and research governance criteria – before alerting the other participating Health Board R&D offices to initiate the local review. The NRS CC tracks the progress of the study through the approval steps and helps maintain adherence to timelines.

7 Exceptions are studies involving incapacitated adults, and only designated RECs can consider studies of clinical trials of investigational medicinal products

This co-ordinated approval system has already reduced duplication of function and has made a start at improving R&D approval times. The initial aim is to approve 95% of multicentre studies within 60 days of receipt of the complete document set, falling to 30 days by June 2010. Such co-ordinated working has highlighted variation in practice in different Boards; key differences will be harmonised as an early priority. Additionally, while the Integrated Research Application System (IRAS) has combined the process of applying for both ethics and local R&D approval, there is scope for further integration of ethics and R&D support services for the benefit of the researcher.

We will continue to rationalise R&D management across Scotland, focused on four regional R&D centres. All other Health Board R&D offices in Scotland will become satellites of these centres, working closely to the same processes and procedures. This should also facilitate their participation in the SAHSC. The operation and management of the Research Ethics Service in Scotland will be closely integrated with these R&D centres, providing a seamless service to researchers.

The four regional ethics and R&D centres will operate under new titles intended to capture role and scope more explicitly: NRS West, NRS East, NRS South East and NRS North. Work will start on this change immediately. From April 2012, all CSO R&D funding will be paid to Scottish Boards through one of these four regional nodes. Contracts will clearly set out funding to be distributed to collaborating Boards within each node.

Scottish Academic Health Sciences Collaboration (SAHSC)

The Scottish Academic Health Sciences Collaboration is a unique partnership bringing together the talents of the Health Boards and associated university medical schools in Aberdeen, Dundee, Edinburgh and Glasgow. It will deliver 250 posts assigned across a range of clinical disciplines, including imaging, pharmacy, radiology and tissue banks over the next three years. This investment in research infrastructure will place Scotland at the forefront of turning the latest scientific research into real health benefits for patients, including clinical trials and, hopefully, new drugs and treatments. It also puts Scotland in a strong position to win increased international health research funding and create stronger collaborative links with industry.

After many years of successful operation it is now time to review the Support for Science Funding Formula to embrace new needs. This will commence in January 2010 and conclude in sufficient time for new arrangements to be in place from April 2012. During this period there will be no changes to the Support for Science allocations based on the Formula. The review will consider any current and proposed changes to the UK funding of research and determine which categories of research should be funded through the Support for Science funding arrangements, either directly or indirectly. The review will also make recommendations on how clinician time spent on research should be deployed to better support researchers. All NHS programmes will terminate by March 2012.

New governance requirements will be introduced for CSO R&D funding to complement these new structural arrangements. The changes will be phased in over two years from April 2010.

Key features will be –

- Funding allocated for researcher time will only be used for that purpose.
- R&D management will be separately contracted, with clear performance targets.
- Formal annual performance reviews will be undertaken with senior Health Board management.

Although these changes will be implemented progressively we expect to see early benefits being achieved; these are reflected in the Measures proposed for this Aim.

AIM 4:
Building and Sustaining Skills

Background

CSO supports the development and retention of skilled health researchers through a hierarchy of mechanisms from its core-funded research units, strategic initiatives, personal awards and visiting fellowships. Skills and capacity-building are also enhanced through our Research Committee awards which provide opportunities for early career researchers to work on research projects with more senior investigators. Our Clinical Research Networks also have a strong focus on skills and capacity building.

The OSCHR partners also recognised at an early stage that human capital was a necessary strand of activity to be co-ordinated across the UK. This work has now completed its first report and collates the many opportunities available. The exercise did not identify gaps for urgent attention but will keep matters under review particularly in relation to the rather different skills necessary for effective research translation. This is a view shared by CSO.

Objectives

To sustain and grow Scotland's strong research performance in health by developing and retaining talented researchers and research support staff;

To build capacity focusing on clinical and translational research;

To enhance the knowledge and evidence base to support NHSScotland.

Actions

CSO offers capacity and capability building awards that range from personal awards to promising young graduates through to larger awards to groups and multi-institution collaborations. Past evaluations have demonstrated the merits of each approach in helping to develop skills, methodologies and critical mass in priority subjects. We shall retain this range of support.

Training Fellowships Build Careers

In 2000 Stewart Mercer, now Professor of Primary Care Research at the University of Glasgow, was an early recipient of a CSO Research Training Fellowship. His study of factors influencing patient enablement in areas of high deprivation in the west of Scotland was followed by a programme of research on consultation quality and outcomes in areas of high deprivation, supported by CSO through a Career Award. Stewart now works closely with the Scottish School of Primary Care, as national lead for research into the problems of multi-morbidity in primary care in Scotland, as well as continuing his interests in inequalities and primary care in different cultures. He says that the awards "…were crucial to my development as a clinical researcher and without them I really don't know if and how I would have progressed through an academic career in primary care research, given the lack of a career structure for general practitioners interested in academic work. Throughout the period of support I combined research work with clinical sessions as a GP, which I feel is essential."

(1) Research Units

We will continue to support, subject to regular strategic and scientific review, core-funded Research Units, which undertake research in areas of strategic need, provide policy advice and train researchers. The Units' chief role is as centres of excellence for research disciplines that are central to Scotland's health needs. Our current research units are the Health Economics Research Unit, University of Aberdeen, Health Services Research Unit, University of Aberdeen, Nursing Midwifery and Allied Health Professionals Research Unit, Glasgow Caledonian and University of Stirling. We also co-fund the MRC Social and Public Health Sciences Unit, and the Scottish Section of the MRC Institute of Hearing Research, both based in Glasgow.

(2) Collaborative initiatives

These have become the focus for recent research development spending. Typically funded in partnership, they are created with a focused and specific objective and tight timelines for delivery. CSO co-funded, along with the Scottish Funding Council (SFC), NHS Education Scotland (NES) and the Chief Nursing Office, three consortia for nursing, midwifery and allied health profession research. We also funded the Scottish School of Primary Care on this basis and more recently, the Scottish Collaboration for Public Health Research and Policy, which we continue to support (see Aim 2).

Research Assessment Exercise demonstrates value of sustained investment

The Health Economics Research Unit, University of Aberdeen, as with all CSO Research Units, includes capacity-building in its remit. Demand for health economists routinely exceeds supply, both as practitioners and researchers. HERU makes efforts to build capacity across the career pathway, teaching in undergraduate and graduate programmes to expose them to health economics, running a distance Postgraduate Certificate, supervising MPhils and PhDs (including two new students on MRC capacity building studentships), mentoring postdoctoral fellows, encouraging early career researchers and contributing to UK-wide and international initiatives to build health economics capacity. In a year when HERU contributed to an outstanding result in the Research Assessment Exercise, its Director, Professor Bob Elliott, says: "capacity building is a key to sustaining excellence."

(3) Researching healthcare improvement

Researching healthcare improvement in Scotland and in comparison with other countries will be the focus of a new strand of work. Advances in understanding quality healthcare have been rapid in recent times, but the evidence base for new initiatives could be stronger. CSO has begun a five year initiative, involving small grants and larger programme activity, around a range of activities which will:

- involve research on management, organisations, services and systems responsible for healthcare delivery in Scotland
- contribute to the advancement of healthcare improvement science, and
- show strong knowledge transfer potential for improving the quality of healthcare services, organisations and systems in Scotland.

(4) Personal awards

Clinical relevance and potential for translation of the proposed activities will have an increasing emphasis in determining success for personal awards. Recently CSO, along with our OSCHR partners, conducted a strategic review of "human capital" in UK research, focusing on personal awards. This review has made more explicit how our schemes complement those of partner organisations, and has given us more detailed information on which research disciplines and specialties attract or require to be supported at UK level.

CSO personal awards schemes will continue to offer opportunities for research training at the doctoral level, with other funders responsible for educational programmes with research components at Masters and below. Current schemes are continually reviewed and CSO aims to strike a balance between generic and targeted schemes.

Current schemes include:

- Health Services and Health of the Public Personal Awards
- Clinical Academic Training Fellowships
- Primary Care Research Career Awards, and
- Scottish Clinical Research Excellence Development scheme (jointly funded with NHS Education for Scotland, Scottish Funding Council and Higher Education Institution partners).

CSO will continue to work with other funders to ensure that research is embraced in the progress made towards modernising the many clinical professions. Our aim is to increase the opportunities for the non-medical professions to pursue roles that mix clinical and academic responsibilities. CSO is working with the Chief Officers for the different health professions whose leadership in this activity will be essential. CSO's targeted support to Nurses Midwives and the Allied Health Professions is being reviewed in 2009 and we shall build on its findings to ensure that future investment in this area is suitably targeted.

(5) Visiting Fellowships

CSO recognises the value that can be gained by even short periods of co-working, through knowledge of new techniques or technologies, embracing new collaborations and contact with different healthcare systems. CSO offers support to develop capacity in Scotland by bringing in researchers of the highest international standing to transfer topic-specific or methodological knowledge to researchers, practitioners and policy makers.

The range of opportunities funded by CSO represent a significant commitment by Government to the training and career development of key disciplines and professional groups. The typical annual cost draws on some 14% of the overall budget. Thus schemes will be kept under review during the life of this strategy to ensure that they remain relevant and that they remain the best means to secure the science and skills base Scotland needs.

Measuring Benefits

We will measure progress towards our Aims during the life of this strategy; key indicators will be:

Aim	In next 5 years	Longer-term
1 – Securing benefit	Increase proportion of investment in translational awards; Scottish success rates in UK-wide funding sustained and improved; Deliver value for money through partnerships with other funding agencies; Develop, in consultation with grant-holders, means to evaluate outputs of CSO research; Increased skills in healthcare improvement science.	Investment in healthcare research delivers economic benefits; Stratified medicine research starts to deliver patient benefits; Evidence of more efficient and effective service delivery, e.g. new standards developed.
2 – Improving population health	Pilot and development work leads to full-scale evaluations of public health interventions; Improved systems for using health records for research and increased volume of high quality linkage-based research.	Stronger evidence base for population health improvement; Public and researchers confident that systems are safe and efficient.
3 – Valuing and investing in NHS research	An increase of 100% of subjects recruited to participate in clinical trials of investigational medical products by 2012; R&D approval times 95% completed within 30 days by June 2010.	NHSScotland regarded as first-choice partner by international pharmaceutical, biotechnology and medical devices industries.
4 – Building and sustaining skills	Increased numbers of personal translational awards; Increased capacity evidenced in surveys of Chief Investigators; CSO funded groups deliver excellence in key areas of strategic investment.	Sustaining the skills and vigour in the science base and an outstanding environment for career progression.

This document is also available on the Scottish Government website:
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