



Strategy Document

Dr Michael Neely, Operational Director, Research & Development Office

2007 sees the launch of the new HPSS R&D Strategy for the next five year period. A copy of the new strategy document, Research for Health & Wellbeing 2007-12 is enclosed for your information. The new document builds on the previous strategy but focuses on five strategic priorities:

- developing an enabling infrastructure
- building research capacity
- funding HPSS R&D
- supporting innovation
- ensuring patient and public involvement

The launch of the Strategy comes at a time of considerable change including: the Review of Public Administration; the implementation of the Cooksey Review recommendations; and changes in professional training all impacting on the context within which HPSS R&D takes place. However, despite this backdrop of change, the R&D Office will continue to work with its existing partner organisations and seek out new opportunities to develop partnerships that help HPSS research develop in an all-Ireland, UK and international context. The key strategic priorities will remain valid and will ensure HPSS R&D focuses on the needs of the HPSS and helps build the evidence base that informs decisions about both existing and new health and social care interventions and services.

The development of the Northern Ireland Clinical Research Network (NICRN) presents a real challenge and a great opportunity. The NICRN, once established will be one of the most important elements of enabling HPSS R&D infrastructure. The NICRN will extend the opportunity for involvement in high quality clinical research throughout Northern Ireland and will help link HPSS R&D to the wider context of the new UK Clinical Research Networks. The next issue of R&D Today will provide an update on the establishment of the NICRN and what it will mean for the future of HPSS R&D.

A new and essential aspect of Research for Health & Wellbeing 2007-12 will be increased patient and public involvement. This involvement is essential if we are to positively influence public awareness around health and social care research, improve its quality and relevance and ultimately lead to better treatment and care for service users. The R&D Office will help the HPSS R&D community develop a strategy and systems that support PPI and help:

- identify research that is important and relevant
- researchers ask the right questions the right way
- researchers design research studies
- interpret research results
- promote good research

The new Strategy also sees the introduction of a new way of classifying research activity. In common with

other UK Clinical Research Collaboration partners, the R&D Office is adopting a new Health Research Classification System (HRCS). The HRCS enables research to be classified according to the type of research activity and according to the area of health or disease under investigation. The adoption of this single classification system will enable comparisons to be made within and between different research portfolios and to monitor trends over time. The next issue of R&D Today will look at HRCS in detail but an

initial analysis of the R&D Office's 2004-05 research portfolio using the HRCS is available on our website.

The new Strategy presents new opportunities and sets out the way ahead but it is also important to look at where we have been. The dissemination of research outputs and outcomes is an important aspect of HPSS R&D and much of this newsletter is looking at some of the conferences that have helped that dissemination effort in recent months.

The Cooksey Review of UK Health Research Funding

Professor Robert Stout, Director of Research & Development, for the Northern Ireland Health & Personal Social Services

In March 2006 the Chancellor of the Exchequer and the Secretaries of State for Health and Trade and Industry invited Sir David Cooksey to undertake an independent review to advise on the best design and institutional arrangements for the public funding of health research in the UK. Sir David Cooksey is a venture capitalist and was the chair of the Health Research Delivery Group which co-ordinated the activities of the MRC and the Health Departments. The Chancellor also announced that the Department of Health's R&D budget would be ring-fenced and that the budgets of the MRC and the NHS R&D would be merged into a Single Health Research Fund. Sir David Cooksey's remit was to advise on how this single fund would be managed. The background to this is the view that there are barriers to the translation of research findings from the laboratory into clinical practice and economic benefit. The pharmaceutical and medical devices industries are among the strongest R&D intensive manufacturing industries in the UK and the Chancellor is determined to encourage them to remain in this country. Sir David worked alone supported by officials from Treasury, Department of Health and Department of Trade and Industry. He invited written evidence and made a series of visits, including one to Northern Ireland in July 2006. The recommendations of the Cooksey report have been accepted by Government and are now being implemented.

When the Review was announced our particular concerns were related to the fact that the proposal

meant combining the MRC budget which is UK-wide and to which researchers in Northern Ireland have access, and the NHS R&D budget which is England only. We were not clear whether it was intended to combine all the Health Departments budgets with the MRC budget, and what the implications of combining the budgets would have on the future access of Northern Ireland researchers to whatever followed the MRC. The report of the review which was published in December 2006 is reassuring on both these points. Sir David's remit did not cover the R&D budgets of the devolved administrations. These will remain intact and under the control of their respective R&D Offices or equivalent. Second, the MRC has been left largely unchanged and will continue to be UK-wide body.

Sir David decided against merging the MRC and NHS R&D organisations (the latter is now known as the National Institute for Health Research – NIHR). One of the main recommendations is to set up a new body, the **Office for the Scientific Co-ordination of Health Research** (OSCHR) to facilitate more effective translation of health research into health and economic benefits in the UK. Its key functions will be to:

- work with officials from DH, OSI and the Devolved Administrations (DAs) to set the Government's UK health research strategy, taking into account the advice, priorities and needs set out by NIHR and its equivalents in the Devolved Countries, MRC and the NHS;
- set the budget required to deliver the strategy and the objectives for DH and MRC, including the distribution of the budget between NIHR and MRC;

- submit to the Treasury a single funding bid for the agreed strategy;
- monitor delivery of the strategy against objectives, to report to ministers and Parliament on its progress, and to advise ministers on the effectiveness of maintaining two separate public research bodies; and
- to encourage a stronger partnership with the health industries and charities.

This is a radical proposal. Currently MRC bids to the Treasury have to go through Research Councils UK, the Office of Science and Innovation and the Department of Trade and Industry, and allocations come in the reverse direction with many opportunities for change on the way. NIHR has a similar process through the Department of Health. In Northern Ireland, HPSS R&D is even further from the Comprehensive Spending Review. Under the Cooksey proposals OSCHR will bid directly to Treasury for funds for health research and will control these funds.

OSCHR will be jointly staffed by officials from the Department of Health (DH) and the Office of Science and Innovation (OSI) and will be headed by a non-executive chair. Professor John Bell, Regius Professor of Medicine at Oxford has been appointed to this post on an interim basis. There will be a small governing board which will have one representative from the Devolved Administrations.

The powers of OSCHR are:

- co-ordinating the joint health research bid and concomitant proposed joint health research strategy and spending reviews. Input will come from MRC, NIHR, the NHS, OSI and DH. OSCHR will have a crucial role in amalgamating and prioritising proposals into a single coherent and cost effective strategy. The bid will need to be tensioned against other science priorities (by OSI) and other health priorities by DH (at an early stage in the spending cycle in order to reflect the process);
- overseeing the Translational Medicine Funding Board and having a key role in change management and effecting cultural change, helping to bring NIHR and MRC closer together and ensuring effective cross working on a day to day as well as strategic basis;

- the chair of OSCHR will have a veto on appointments of Chief Executives in NIHR and MRC, the MRC's governing council, NIHR's advisory council and the Translational Medicine Funding Board.
- preparing an annual report to the respective Secretaries of State and to Parliament of progress under the joint strategy.

Discussions are taking place on how DA's can most effectively work with OSCHR.

The Translational Medicine Fund Board (TMFB) will develop a more co-ordinated approach between the MRC, NIHR and its equivalents in the DA's with regard to translational research. It will have a budget from the MRC and NIHR as agreed by OSCHR and set out in the joint health research strategy and will report jointly to MRC and NIHR. It will take the lead in developing a translational research strategy which aims to increase translation into health and economic benefit including:

- commercialisation of the outcomes of research funded by MRC/NIHR
- developing a skills strategy to facilitate more effective translation
- considering new funding mechanisms to ensure that there is adequate funding across the translational pipeline, including follow-on and seed funding, and funding for development of prototypes
- working with industry and the medical charities in a variety of ways (e.g. public private partnerships, co-funding of projects) to meet needs such as: pre-competitive drug development tools (e.g. biomarkers) and technology development (e.g. using stem cells in predictive toxicology). It should also have specific responsibility for R&D to support the redesign of drug development
- feeding in priority areas for funding of clinical trials

A new **Health Research Strategy Board** comprising the UK Departments of Health and Trade and Industry together with the chair of OSCHR, will discuss issues relating to health research and have a particularly important role in ensuring that the view points of the DA's are taken into consideration in the run up to spending reviews or at other times where budgets and strategies are being set.

The report sets out the responsibilities of the MRC and NIHR. The main recommendation is that the MRC will no longer fund Health Technology Assessment, currently largely funded by DH on a UK-wide basis, health services research, applied health research, social care research and clinical research conducted by NHS staff contributing to the better care of patients. At this stage it not known how this is going to be implemented.

The review recommends that the DH together with the health departments of the DA's should undertake an urgent review to understand the impact of diseases and illnesses in the UK and the UK population and economy to determine UK health priorities which will underpin health research priorities set by OSCHR. It then goes on to recommend the establishment of UK Priority Health Research Projects (PHRP) which would be deemed to be of national importance in tackling research priorities identified by OSCHR. The status will reflect a set of suitable criteria to be developed by the Government which could include, for example:

- the relevance of the project to contributing to identified health research priorities in the UK

- the quality of the research being undertaken
- the likelihood of the research resulting in a finding that could have a significant impact, including a positive value for money/affordability assessment at later stages.

PHRP status should confer institutional and procedural advantages for health research that adds real value in tackling the UK's identified health needs. It might include accelerated clinical trials approval and regulatory approval including NICE approval.

Conclusion

The implementation of the Cooksey review could have wide implications for health research in the future and has been generally welcomed by the research community. Although nothing is promised, there is a strong hint that more money will come to health research through OSCHR. We will now have to try to ensure that Northern Ireland participates in and benefits from the new arrangements while pursuing our ability to address our own needs and participate in the all-island activities described by Ruth Barrington later in this issue.

National Cancer Research Institute (NCRI) Conference, Birmingham October 2006

Professor Frederick C Campbell, Professor of Surgery, Department of Surgery Royal Victoria Hospital, Chair Cancer Recognised Research Group

The second annual NCRI Cancer Conference attracted almost 2000 delegates to Birmingham last October, indicating the esteem with which it is considered within academia and beyond. The annual conference focuses on offering both the opportunity and atmosphere to facilitate good cross-disciplinary communication between groups of cancer researchers as well as between the researchers and patients. This unique environment provides excellent opportunities for researchers to share their recent findings, an opportunity which the Cancer RRG (CRRG) was keen to capitalise on. Indeed, the CRRG obtained funding from the R&D Office to support the running of a workshop highlighting their research on metastasis - a major cause of death in cancer patients.

This research theme has grown significantly in recent years as technological advances and new discoveries have provided a scientific basis for novel diagnostic, prognostic and therapeutic modalities available to the clinician. The success of the workshop, which was jointly chaired by Professors Charles Campbell and Stephanie McKeown, exceeded all expectations. Over 300 delegates registered to attend the workshop entitled "Molecular Factors that affect Tumour Growth and Metastasis", representing a four-fold increase in numbers from previous years.

The Northern Ireland CRRG sought to share knowledge and ideas gained from its research portfolio with the wider scientific community. Workshop delegates were impressed by the programme which commenced with a keynote lecture on "**Molecular Mechanisms of Metastasis**" by Professor Philip Rudland, University of Liverpool, an acknowledged international leader in this important area of cancer research. Professor Rudland outlined his seminal discoveries relating to the important concept of *metastasis genes* that may act

alone or synergistically, to promote dissemination of primary tumours. Concepts of specific targeting of critical metastasis-controlling genes by emerging small molecule-, protein- and gene-based therapeutic approaches, were discussed.

In addition to provision of state of the art knowledge, the CRRG has also sought to mentor young investigators and provide opportunities to disseminate findings and this was a perfect example of such an occasion. Thus the remainder of the programme was presented by postdoctoral and predoctoral fellows and students and related to various signal transduction pathways that have a key role in tumour growth and dissemination, as follows:

- Andrea Devlin discussed **“Expression of cytochrome P450 1B1 protein in tumours: role of translational control”** CYP1B1 metabolically activates diverse genotoxic chemicals and may be useful as a marker of tumour progression. Ms Devlin outlined the role of translational processing in regulation of the expression level of CYP1B1.
- Elaine Dunlop presented her work on **“Evidence of abnormal erythropoietin receptor downregulation in non small cell lung carcinoma”**. Erythropoietin (EPO) is a hypoxia-inducible glycoprotein hormone that regulates the production of red blood cells by binding to its

specific cell surface receptor EpoR. Downregulation of EpoR in lung cancer cells, implying a functional role for EpoR signalling in the pathobiology of lung cancer.

- Gavin Collett presented his research on **“Overexpression of p65/RelA potentiates curcumin-induced apoptosis in HCT116 colon cancer cells”**. This work demonstrated a novel pathway for cancer growth inhibition that is independent of NF kappa B inhibition, for the first time. The work provides scientific basis for more accurate targeted therapy for cancer prevention and treatment.
- Haibo Xu discussed modulation of cancer growth, in the topic of **“Ligand-activated vitamin D Receptor (VDR) modulates the neoplastic phenotype through osteopontin (OPN) and beta-catenin/Lef-1/TCF signalling”**. This work concerned the role of nuclear receptors in the initiation and progression of cancer and dealt with the concept of regulatory crosstalk between transcriptional regulators and nuclear receptor signalling.

The breadth of the workshop was such that it could appeal to researchers in all aspects of cancer growth and dissemination and helped provide the necessary insight for the development of future assessment and treatment of cancer metastasis.

The Cochrane Colloquium, Dublin 23 – 26 October 2006

Dr Janice Bailie, Programme Manager Allied Health Professions, R&D Office

The Cochrane Collaboration was set up with the goal of accumulating evidence drawn from good quality research and systematic reviews to help health professionals, policy makers, patients and carers to make more informed decisions about the treatments they may give or receive.

The XIV Cochrane Colloquium was the first to be held in Ireland. In keeping with the commitment of the Health Research Board (HRB), Dublin and the R&D Office to the aims of the Cochrane Collaboration, both were major sponsors of the event and provided support packages for Cochrane enthusiasts throughout Ireland to attend the Colloquium at the Burlington Hotel in October.

The event attracted over 800 participants from 40 different countries and their enthusiasm for the work

of the Cochrane Collaboration was tangible. The Colloquium was a celebration of the achievements of the last fourteen years.



L–R: Dr Ruth Barrington, Professor Robert Stout, Professor Mike Clarke

A special Ireland session on the first day of the Colloquium showed how the partnership between HRB and the R&D Office had brought free access to the Cochrane resources for everyone on the island of Ireland. This has been used to generate new reviews and develop evidence-based interventions. A particular highlight of the session was a presentation by Mr David Bolton, Head of the Trauma Centre in Omagh, whose work with the victims of post-traumatic stress disorder was informed by evidence from the Cochrane Library. Cochrane Fellowships are a benefit offered by the HRB and R&D Office partnership in Ireland, which provide protected time and training for researchers to carry out systematic reviews. A number of Fellows from North and South discussed the ongoing Cochrane work in which they are involved.

The main Colloquium comprised an exciting and challenging programme, looking at how to make Cochrane reviews more accessible, how systematic review could inform policy on HIV/AIDS, developing new content for systematic reviews and how to advance evidence-based policy at a global level. This was accompanied by a comprehensive programme of workshops and entity meetings where individuals and groups could exchange ideas and knowledge. Wednesday 25 October saw an exciting plenary

session, with keynote speaker former Irish President Mary Robinson, who is now President of Realizing Rights: The Ethical Globalization Initiative. Live satellite links to countries most affected by AIDS were set up and presenters discussed the issues they experience in their daily struggle with the pandemic. The session was streamed live on the internet through the R&D Office web site.

A lively social programme was provided to support the Colloquium, including a tour of the Guinness Storehouse, an evening of ten-pin bowling, and a Conference Dinner providing an magnificent stage show with a dramatic Irish dancing theme. The enthusiasm that distinguished the whole event pervaded the social programme as well, as those who remained in their seats were in a tiny minority, and the floor was full of delegates dancing the night away.

In summary, the XIV Cochrane Colloquium was a huge success, and it is hoped that it will have given those who attended a renewed inspiration to continue with their work to generate a sound evidence base to underpin the safe and effective delivery of healthcare in the island of Ireland and throughout the world.



3rd All Ireland Cancer Conference

Dr Nicola Armstrong, Programme Manager, Nursing, R&D Office

In Ireland each year there are over 25,000 new cancer cases and 11,000 cancer deaths. It was therefore particularly welcome to Irish researchers and clinicians alike that the 3rd All Ireland Cancer Conference was held at the Waterfront Hall in Belfast 13 – 15 November 2006. Over 470 delegates were provided with an opportunity to reflect upon past accomplishments and to make plans for the future direction of cancer research as they heard presentations from over 50 leading figures in cancer research and care in the USA and Ireland. Presenters discussed the latest developments in cancer, including prevention and cancer control, pharmacogenomics, nursing, biomarkers, biology, radiation, drug developments and palliative care. A considerable number of presentations were given by researchers and clinicians whose research is funded by the R&D Office. The R&D Office was also a major sponsor of the event itself.

The driving force behind the conference, the *Ireland-Northern Ireland-National Cancer Institute (NCI) Consortium* was established in October 1999 by a multilateral partnership between the Department of Health and Children of Ireland, the Department of Health, Social Services and Public Safety of Northern Ireland and



L-R: Dr Michael McBride, CMO, Dr Harry Comber, Irish National Cancer Registry, Dr Anna Gavin, Northern Ireland Cancer Registry, Dr Doug Weed, NCI



the NCI of the USA. The main aim of the Cancer Consortium is to reduce the incidence of cancer in both parts of Ireland which have

among the highest rates of cancer in the Western world. The intensified cooperation which has come from the formal tripartite partnership has resulted in the development of improved scientific programmes in Ireland through joint funding initiatives including Cancer Prevention Fellowships and summer courses eg Principles and Practice of Cancer Prevention and Control Molecular Prevention. Both the R&D Office and the Health Research Board have worked in close partnership to realise the goal of the Cancer Consortium.

In addition to the excellent scientific programme of events, the historic Memorandum of Understanding, which was originally signed by representatives of Ireland, Northern Ireland and the USA in 1999, was formally

renewed at the conference. The newly appointed Director of the NCI, Dr John Niederhuber, was keen to confirm the success of the collaboration and offer his wholehearted support for another 5 years with the signing of an updated Memorandum of Understanding.

To mark the end of the conference a wonderful Irish Night was held at the Ulster Folk and Transport Museum. Attendees were entertained by a medley of traditional music and dance from the Royal Tara Dancers and a spectacular display of acrobatics from the Belfast Community Circus. The evening provided further opportunities to network and exchange ideas in a more informal context. A good night was duly had by all!

All conference presentations are available on the NI Cancer Registry website at www.qub.ac.uk/nicr/



The Belfast Community Circus

Northern Ireland AHP Research Conference

Dr Janice Bailie, Programme Manager Allied Health Professions, R&D Office

Ninety seven Allied Health Professionals (AHPs) from across the professions in Northern Ireland converged on the Comfort Hotel in Antrim for the AHP Research Conference on Tuesday 17 October 2006. The aim of the day was to bring together AHPs who are involved in research and those with an interest in getting involved. The content of the programme provided information on the support available and encouraged AHPs to take up opportunities to carry out patient-centred research. The Conference was organised by the R&D Office for the Health and Personal Social Services (HPSS) in partnership with the Allied Health Professions Centre for Professional Development.

We were delighted that members of the UK Research Forum for Allied Health Professions (RFAHP) were able to schedule their quarterly meeting in Belfast for the 16th October to coincide with the Conference, and five of the members were able to attend the Conference on the following day.

The morning session was chaired by Mrs Nuala McArdle, Officer for the Allied Health Professions in

the Department of Health, Social Services and Public Safety for Northern Ireland. She welcomed local and UK colleagues and emphasised the importance of expanding and using the evidence base to shape the future of AHP services in the province and beyond.

Keynote speaker Wesley Vernon, outgoing Chair of the RFAHP, introduced the Forum, detailing the vision and the work of the Forum in promoting the research interests and profile of AHPs and highlighting the Forum's involvement in helping to shape the national research agenda.

Throughout the day a series of presentations gave up-to-date information about gaining research approvals, seeking ethical opinions and getting help with research design, statistics and protection of intellectual property.

One issue that is often raised by those new to research is the complexity of putting together that first research proposal. The final presentation of the morning focused on one solution. Professor Brendan McCormack, Professor of Nursing Research and Practice Development, Royal Group of Hospitals Trust and University of Ulster, presented his innovative work

on setting up a 'Learning Set for Writing a Research Proposal'. Over 10 months, he facilitated a small group, initially composed of nurses and AHPs, to develop full research proposals from their initial research questions. This was achieved through a process of group discussion and reflective thinking. Two of the AHPs who had been in the group gave participants a candid description of their experiences and told how useful the process had been. The R&D Office was impressed with the outcomes of the work and has now rolled the scheme out to a broader audience. It was hoped that this session would encourage more AHPs to take up this opportunity.

In addition to the oral presentations, there were two poster sessions, during which the 29 submitted posters were judged by Jackie Campbell and Liz White from the RFAHP.

In the afternoon, a session chaired by Janice Bailie from the R&D Office, included a series of short presentations by AHPs, in which they provided a glimpse of their own day-to-day experiences in R&D – pursuing a Doctoral Fellowship, returning to practice post-PhD, working as a research radiographer in a clinical trials unit, supervising Fellows and managing projects as a senior AHP research clinician, sitting on a Trust R&D committee, and conducting a systematic review on a Cochrane Fellowship, as part of the work of a Reader in Physiotherapy in a joint appointment post.

Colleagues from the University of Ulster then described their newly constructed Centre for Rehabilitation Research, the largest in the UK, and the forthcoming meeting of the Rehabilitation and Therapy Research Society to be held in Belfast in Spring 2007. The



Julia Shaw poster winner

importance of links between HPSS and academia was emphasised.

The meeting was brought to a close by Dr Liz White, who congratulated Northern Ireland on the successful meeting, and their achievements in research – and presented the poster prizes. First prize went to Julia Shaw (Podiatry) for her research on diabetic foot ulcers. Runners up were Linda Wray (Dietetics) and Carolee McLaughlin (Speech and Language Therapy).

On behalf of the R&D Office, the organising committee and Mrs Fiona Hodkinson – Head of the Centre for Professional Development, I would like to take this opportunity to sincerely thank the members of RFAHP who came along to the meeting and everyone from the AHPs in Northern Ireland who came along and helped to make the event the success that it was. We hope this event will promote even closer links between the Forum and the AHP research community in Northern Ireland.

Improving Health through Research and Information/Seizing All-island Opportunities for Health Research

Ruth Barrington, Chief Executive, Health Research Board

North-South Research Awards

Dr Orla Hardiman of Beaumont Hospital Dublin and Dr Victor Patterson of the Royal Victoria Hospital, Belfast have discovered that some patients with motor neurone disease have a mutation in a gene called ANG.

Significantly, all the affected patients are Irish or Scottish or of Irish or Scottish descent. The ANG gene codes for a protein involved in forming new blood vessels and while it has been implicated in some other diseases, this is the first time it has been linked to a disorder of the central nervous system. The gene is known to control the body's response to low oxygen levels. The identification of the gene has opened up a new vein of research, and already

a patent has been filed with a view to searching for a potential drug. This outcome is just one of the results of the joint funding programme between the Research and Development Office (R&D Office) and the Health Research Board (HRB).



The programme began in 1997, stimulated at the Dublin end by the Wellcome Trust and HRB Matching Funding Agreement which provided an additional £6m over three years for health research south of the border. The suggestion of a joint initiative to stimulate cross-border research partnerships in the interest of better health was well received by Professor Ingrid Allen, then Director of R&D for the HPSS, who at the time was carrying out a major reorganisation of research funding in Northern Ireland. The programme was popular and was always heavily over-subscribed. Twenty two projects were jointly funded under the scheme, with €3m committed by the HRB and £2m by the R&D Office. By 2005, the scheme had achieved its objective of encouraging links between research teams on the island and it was decided to support all-island research activities in different ways. The HRB now welcomes northern partners on all its applications for research funding and a number of research programmes - in general practice, dental health and ageing for example, funded by the HRB have partners in the North. The HRB also funds research fellowships in Queen's University Belfast and the University of Ulster. A recent award by the HRB for ultra sound equipment to fund a perinatal imaging research infrastructure in the eight major maternity hospitals on the island is another example of the advantages of taking an all-island approach to health research.

The Cancer Consortium

The joint programme was the first of a number of joint initiatives between the two offices in the interest of improved health on the island of Ireland. Perhaps the most significant has been the joint approach to

developing cancer research under the Ireland/Northern Ireland/National Cancer Institute Cancer Consortium signed in 1999. With the support and advice of the National Cancer Institute Washington (NCI), the HRB and R&D Office have supported the Clinical Research Support Centre in Belfast and the Irish Clinical Oncology Research Group in Dublin to join together to form the All-island Clinical Oncology Research Group. The Group, after a slow start, is now recruiting approximately five per cent of cancer patients on the island to clinical trials in all the major cancer hospitals on the island, has 270 cancer clinicians and scientists involved as members and has successfully linked with the two major cancer clinical trial networks in the United States. A programme for nurses wishing to develop their skills in clinical trials at the NCI or affiliated hospitals is also helping to expand expertise and deepen links between clinical trial centres. Communication between cancer hospitals in Belfast, Dublin, Cork and Galway and in the United States has been facilitated by state-of-the-art video conferencing or 'Telesynergy' developed at the NCI and made available under the Consortium by the two Departments of Health.

The Consortium has also facilitated investment in the researchers of the future. The R&D Office and the HRB have supported a number of health professionals to deepen their expertise in cancer through supported fellowships at the NCI. Dr Peter McCarron was awarded a Cancer Epidemiology Fellowship in 2000, which gave opportunities to work with investigators from the Division of Cancer Epidemiology and Genetics (DCEG) on newer aetiological aspects of cancer. The Fellowship offered opportunities for international, national and local research, which broadened both the candidate's research understanding and skills. Two other researchers from Northern Ireland – Dr Lesley Anderson and Dr Mandy Black – have been successful in gaining Cancer Prevention Fellowships during which they complete a MPH programme followed by two years research based at the NCI.

One of the most popular Consortium initiatives has been participation in the NCI's summer prevention programme in which some of the world's leading cancer experts share their knowledge and expertise in cancer research. Over 200 cancer professionals on the island have now completed this programme, supported by the HRB and the R&D Office. Each summer, we ask the participants to report on their experience of the NCI course and the value that it adds to their work in cancer. The feedback from participants has been overwhelmingly positive. One major and

lasting benefit is the contacts and friendships across disciplines and across the island that are made during the programme.

The Consortium has also provided a stimulus to support from the R&D Office and the HRB to the research activities of the cancer registries in both parts of the island, which have recorded the similarities and differences in the two health systems as expressed in outcomes for cancer treatment. Cancer Consortium activities are likely to grow stronger over the next few years, stimulated by the new cancer strategies in both jurisdictions and by the new Memorandum of Understanding for the Consortium signed in November 2006 by Mary Harney TD, Minister for Health and Children and Paul Goggins MP, Minister for Health, Social Services and Public Safety and by Dr John Niederhuber, the Director of the NCI.

The Cochrane Collaboration

The development of the Cochrane Collaboration is another example of cooperation on the island of Ireland. In 2001, Mike Clarke, then Chair of Cochrane Collaboration Steering Group and Fiona Alderdice, then a MRC fellow in Belfast, proposed to the R&D Office and the HRB that joint action was needed to promote Cochrane reviewing and the use of the Cochrane Library on the island of Ireland. Conferences held in Dublin and Belfast in May/June 2001 demonstrated the enthusiasm of health and research personnel for systematic reviewing and for easier access to the Cochrane Library. Our two offices responded by purchasing licences that gave everyone on the island of Ireland free access to the Cochrane Library from their personal computers - a world first. From October 2004 to late 2006, there were 211,000 hits on the Cochrane Library from the island of Ireland.

Our two offices also began supporting training in Cochrane systematic reviewing for health professionals. The demand for places on the training courses was overwhelming and we had to run fast in the first few years to catch up with the demand. A number of the initial trainees subsequently went on to develop their expertise in systematic reviewing and have become trainers in turn, thus expanding the number of people on the island who can offer training in Cochrane reviewing. By the end of 2006, more than 400 people on the island had undertaken short three-day training courses. We also initiated the Cochrane Fellowships to promote deeper engagement with the Cochrane review groups and to build up a body of evidence of value to health professionals from the island of Ireland.

Twenty nine fellows have been supported to date, all of whom have or are making a contribution to building the Cochrane evidence base for effective health decision making. We were very pleased that the Cochrane collaboration chose to have its international conference in Dublin in November 2006 and that over 800 delegates from all over the world with a passionate interest in finding and presenting the evidence for health decisions came and participated in the event. A special thanks is due to Mike Clarke, now Director of the UK Cochrane Centre, for his unfailing support for and encouragement of our efforts to develop systematic reviewing and greater accessibility of the Cochrane Library on the island of Ireland.

Clinical Research

The success of the applications from Belfast and Dublin to the call issued by the Wellcome Trust and partners, including the HRB and the R&D Office, for clinical research facilities is a cause for celebration and for great optimism about the future of clinical research on the island of Ireland. Under this call, the Wellcome Trust will fund the building of clinical research centres in Belfast and Dublin and the HRB and the R&D Office have committed to fund the research costs of the centres and associated facilities for a period of five years. The Wellcome Trust proposes to network the clinical research facilities it is funding and Dublin will be participating in this initiative. The HRB and the Health Service Executive is funding the establishment of the Irish Clinical Research Infrastructure Network (ICRIN) to support and coordinate clinical research and to facilitate Irish membership of the European Clinical Research Infrastructure Network. A condition of the funding is that ICRIN will encourage all-island coordination of clinical research. So, we can now see the emergence of a strong clinical research infrastructure on the island of Ireland, a network of clinical research facilities in the UK and Ireland and the possibility of active UK and Ireland participation in European clinical research activities.

Gene Library

The HRB and the R&D Office have also examined other joint initiatives to underpin clinical research on the island of Ireland and to strengthen health research capacity generally. One of the factors that restricts clinical and public health research in Ireland is the absence of a baseline study of the genetic makeup and health status of the population. The HRB and the R&D Office in Northern Ireland have proposed the establishment of GeneLibrary Ireland on an all-island

basis to address this research deficit. A result of a consultation process on the proposal with the research community in the North and South was very positive. The proposal will involve the recruitment of 10,000 adult volunteers who will be invited to donate their blood and information on their health status for the purposes of research. The information will be anonymised at an early stage and will then be made accessible to researchers following peer review of the application. The HRB has received funding to proceed with the proposal in 2007, and we will work closely with the R&D Office in bringing it to the next stage.

Working Together

The staff of the two offices have developed strong working relationships around our shared interest in promoting and supporting health research. Professor Bob Stout is a member of the Board of the Health Research Board and I am a member of the Strategic Advisory Committee of the R&D Office. Among the many areas of expertise that Professor Stout brings to the work of the HRB is his understanding and awareness of health research developments in the UK. As a member of the R&D Office's Strategic Advisory Board, I hope I have been able to add value by bringing to the table information on research developments at an EU level.

And the future?

The EU is moving towards the creation of a common research area in response to the challenge of ensuring that Europe is a world leader in knowledge generation and innovation. What this will mean in practice is still not fully clear but the shape of the future is becoming clearer. The creation of the European Research Council, for example, modelled on the National Institutes of

Health and the National Science Foundation of the US, is a major step forward. A proposal for a European Institute of Technology is also at an advanced stage. The member states have also reached agreement recently on the priority research infrastructures that Europe needs to invest in over the next few years if it is to retain an internationally competitive edge in research. National research funding bodies are being encouraged to work together, to consider joint calls and to open their calls to researchers beyond the boundaries of their member states.

Is it time to follow the European lead and commit to creating a common research area on the island of Ireland? If we are to ensure that the island of Ireland maximises its return from knowledge generation and innovation in an increasingly competitive and globalised world, we need to cooperate and build on our strengths. Should the research funding bodies on the island do more to encourage an all-island approach to building research capacity? Could we envisage, for example, a situation where researchers on the island of Ireland could apply in their own right to research funding bodies in either jurisdiction, the outcome to be decided by international peer review? Or should we consider an all-island research funding body or bodies to which any researcher on the island could apply? Could we organise ourselves better on the island to maximise Irish involvement in the European Framework Programmes and success in European Research Council's calls? These are some of the issues that could be addressed over the next few years. Perhaps those who have shown what can be done to develop an all-island approach to health research can lead the way.

US-Ireland Research & Development Partnership

Professor Robert Stout, Director of Research & Development, for the Northern Ireland Health & Personal Social Services

The US-Ireland R&D Partnership was officially launched at a reception in the residence of the US Ambassador in Dublin on 5 July 2006. The Partnership arose out of a US-Ireland business summit which took place in September 2002 and was attended by high ranking politicians, government officials, business people and

academics from the US and the island of Ireland. One of its outcomes was the establishment of a task force, the US-Ireland R&D Taskforce to explore high level, world class research collaborations between centres of excellence in Ireland (North and South) and the United States. The taskforce agreed that based on the research strengths and priorities in the island of Ireland and in the United States, the priorities emerging as part of the knowledge based global economy, and the potential for knowledge and technology transfer in support of public good and economic development, it

would be appropriate to focus on the broad areas of information and communications technology and biotechnology. The rest of this article will focus on the biotechnology aspect.

It was initially agreed that in biotechnology, potential and existing synergies existed in diabetes and cystic fibrosis. Emerging respiratory infections was later added to this list.

The potential benefits of the proposed US-Ireland collaboration identified by the Task Force are:

- bringing together world class scientists on both parts of the island of Ireland in a shared vision of collaboration
- an increased focus on research areas which all parties have identified as strategic priorities
- the opportunity for the best scientific researchers in Ireland (North and South) to collaborate with their counterparts in the United States through linkages with the National Institutes of Health (NIH) in the best facilities in the world; this opportunity will extend to research students and scientists embarking upon research careers
- access to the more fully developed technology on knowledge transfer programmes in the US, linking the research base with its exploitation for economic and public good
- the opportunity for government agencies, businesses and academics in the island of Ireland to work with their leading counterparts in the US, to protect and exploit the outcomes of joint research, leading to joint business ventures between Ireland (North and South) and the US and to enhancements in health promotion, disease prevention and healthcare
- the establishment of a small scale facilitated mechanism in Ireland (North and South), attached perhaps to an existing organisation, to organise and support the interaction of researchers and the social and commercial exploitation of research in the priority areas.

In order to move this forward, a small overarching Steering Group has been established with the following membership:

Republic of Ireland

- Dr Killian Halpin, Retired Director, Science, Technology and Innovation Policy, Forfas

- Dr Patrick Fottrell, Chairperson, Science Foundation Ireland
- Professor Ferdinand von Prondzynski, President, Dublin City University
- Professor Fabian Monds, Retired Chairman of the Board, Invest Northern Ireland
- Professor Peter Gregson, President and Vice-Chancellor, Queen's University Belfast
- Dr Hugh Cormican, Managing Director, Andor Technology

United States

- The Honorable Alex M Azar II, Deputy Secretary, US Department of Health and Human Services (HHS)
- The Honorable Elias Zerhouni, Director, National Institutes of Health (NIH)/HHS
- Dr Richard Buckius, Acting Assistant Director, Directorate for Engineering, National Science Foundation (NSF)

Co-Chairs

- Dr Killian Halpin, Professor Fabian Monds, The Honorable Alex M Azar II

Three meetings of the Steering Group have been held so far: by teleconference in December 2005; in Washington DC in March 2006; and in Queen's University Belfast in November 2006. The next meeting will take place in Washington in March/April 2007.



The US-Ireland R&D Partnership Steering Group meeting in Washington, D.C. on 14 March 2006. On the left side of the table (from L-R): Dr Killian Halpin, Professor Fabian Monds, Professor Peter Gregson, Professor Bob Stout (in attendance) and on the right side of the table (from R-L): Captain Phil Budashewitz (in attendance), the Honorable Alex M. Azar II and Dr Elias Zerhouni.

Formal workshops have also been held between leading scientists in the island of Ireland and the US to discuss and promote collaboration in diabetes, cystic fibrosis and emerging infections. It is hoped that these workshops will lead to the development of proposals for submission for funding to NIH. After endorsement by the funding bodies in Ireland (North and South), they will be submitted to NIH to process

them through its usual peer review and evaluation systems. Each jurisdiction will fund its own part of the research; for Northern Ireland this will be the R&D Office. Currently the R&D Office will be funding this out of its existing resources, but the Partnership has the support of the Secretary of State and a proposal will go forward to the Comprehensive Spending Review for additional funding to support its activities.

There is a considerable amount of detail still to be worked out on how the process will work. It has therefore been decided to pilot it by selecting one project each in diabetes and cystic fibrosis and submit these as soon as possible to the NIH. Groups, led in

Northern Ireland by Professor Peter Maxwell on the genetics of diabetic renal disease and by Professor Stuart Elborn on cystic fibrosis, together with colleagues in the Irish Republic and the United States, are at an advanced stage of preparation of proposals and it is hoped that these will be submitted by the 5 June 2007 NIH deadline. The NIH process takes 9-12 months so the first projects will not be underway until well into 2008. Once the process has been shown to work it will be opened up for other projects in diabetes and cystic fibrosis, and in time possibly extended to other areas of health research.

Down Lisburn Trust Nursing Research Conference

Victor Robinson - Research Lecturer Practitioner, University of Ulster and Down Lisburn Trust, Chair of the Conference and Mrs Angela Boyle, Principal Nurse, Modernisation and Development, Down Lisburn Trust, Co-organiser of the Conference.

Strategically within Down Lisburn Trust (DLT), we have been concentrating on the 'D' of the Research and Development process through the installation for example of Research Governance policies and procedures as well as the propagation of a nursing research culture whereby the strategic goal is to ensure that all nurses are 'research aware', irrespective of whether they ever generate any research in their own right. Consequently, in terms of creating research and publicising our findings, it's a fair comment perhaps that we are not quite at the point where we are able to 'swim with the research sharks, without being eaten alive'.

Simultaneously, it is also fair to add that the spirit that motivates nursing research within DLT is clearly recognisable and has us moving forward in the right direction. Despite any of the challenges the future may hold, those of us charged with the responsibility of supporting the cause of nursing research within DLT are of the strong belief that as long as that spirit is there' we will continue to repair it and tend its shrine. In partnership with the team from the Ulster Community and Hospitals Trust, this can only auger well therefore for the future direction of nursing



L-R: Maurice Devine - Nurse Consultant for Learning Disabilities, Dr Nicola Armstrong - Programme Manager Nursing, R&D Office, Victor Robinson - Research Lecture Practitioner, University of Ulster and Down Lisburn Trust (DLT), Alan Finn - Director of Nursing and Acute Services for DLT, Denise Fitzimmons - Chairman of DLT, Professor Martin Bradley - Chief Nurse for Northern Ireland (DHSS&PS) and Angela Boyle - Senior Nurse for Modernisation and Management DLT.

research within the newly hybridised organisation of South Eastern Health and Social Services Trust, as both agencies will share a mutual need for self fulfilment in this regard.

'Research awareness' has been alluded to previously as one of our strategic aims. One medium in the creation of such a culture is to hold a conference for the purpose - amongst many other reasons, of showcasing whichever research projects our staff have become involved with, in cross-fertilisation of ideas in constructive dialogue and in networking generally. 'Research Matters' is a multi-disciplinary research conference that is held annually within DLT at some

stage during the autumn months. For varying reasons however, it was not possible for this event to run as normal this year and this created a void that inadvertently provided an opportunity for a nursing research conference in particular to be organised, as no such conference had ever been held before within the Trust.

Consequently, at the authentic venue of the Great Hall, Downshire Hospital, Downpatrick, Thursday 28th September 2006 marked the origin of what is hoped to be an annual event. The conference entitled 'Many Outlooks - Single Vision' was designed around the theme of 'outlooks' and therein attempted to reflect the multiplicity of such outlooks from statutory and non-statutory sources that connect with nursing research.

A colourful display of posters as well as many exhibition stands from the various agencies exemplified this reflection and created the back-drop for the conference event. Amongst those with quite differing outlooks on healthcare in general and nursing in particular who generously contributed were the following:

Northern Ireland Chest Heart and Stroke, University of Ulster, the RCN, Unison, The Queens Nursing Institute, The Open University, The Florence Nightingale Foundation, Clinical Research Support Centre, The Health Research Board from Dublin, The Research and Development Office from Belfast, The Smith and Nephew Foundation and not least our own Quality

Support Team who administer the funding for our annual Chairman's Prize competition. To all of these agencies we owe a debt of gratitude.

Not least of those extolling the virtues of nursing research was Professor Martin Bradley, the Chief Nursing Officer in Northern Ireland who offered the 'Department's outlook' as part of his keynote address in the afternoon. The morning keynote address was given by Mrs Sara Condell Nursing Research Advisor from the Health Research Board in Dublin who provided us with a very informed 'outlook from the South of Ireland'.

From both keynote addresses as well as many of the other presenters, one could quite clearly glean that the research landscape has changed. No longer then should research be perceived as a 'Cinderella' part of the service as far as nursing is concerned, as nurses have now shifted in many instances from being the data collectors for other professions and created meaningful research roles in their own right.

Notwithstanding the usual high standard of Catering Services, Information Technology and the organising team associated with the Great Hall venue, thanks and appreciation must also go to all those within and outwith the Trust who contributed either by way of their attendance, their nursing research presentations or through the medium of nursing research workshops. All of these contributions added to the general sophistication and all-round success of the day.

Boost For Cancer Trials Across Northern Ireland

Dr Michael Neely, Operational Director, Research & Development Office

A new team of nurses will improve access to cancer clinical trials across Northern Ireland-addressing the current concentration on Belfast. Cancer Research Northern Ireland and the R&D Office are placing five new research nurses in cancer units to co-ordinate and help run cancer clinical trials in breast, lung, colorectal, prostate, bladder and haematological cancers. Funding has been confirmed initially for six years to allow the nurses to focus completely on cancer clinical trials. The investment will help Northern Ireland continue its world class research while improving treatment for all

cancer patients and building on the success of the current trials unit in Belfast.

The nurses will help raise awareness of new cancer clinical trials among medical teams and cancer patients. It is hoped this increased awareness will translate into improved recruitment into clinical trials. Patients throughout Northern Ireland will now have a greater opportunity to learn about new clinical trials and receive better support if they choose to participate in a trial.

Improved recruitment into clinical trials speeds the pace of research. Clinical trials that recruit patients faster can report their findings sooner. New knowledge from trials develops better treatments more quickly.

Taking part in a clinical trial means patients may be able to receive a new treatment not available outside the trial. Cancer patients taking part in a trial often find the experience rewarding, knowing they are helping to shape the best treatment for patients in the future.

Ruth Boyd, Cancer Research Northern Ireland Senior Nurse at the NI Cancer Clinical Trials Unit, Belfast City Hospital, said "This is great progress for cancer patients across Northern Ireland. More patients should have the opportunity to take part in new trials. These new nurses will provide information, care and support for cancer patients who want to take part in a clinical trial based at a Cancer Unit close to their home. The nurses will be an excellent resource for cancer patients".

Kate Law, clinical trials director at Cancer Research Northern Ireland, said "Clinical trials are vital in cancer research. All potential new treatments are thoroughly tested in the lab first but we then need to find out how well they work in people. Without clinical trials, we wouldn't know which drugs work best to prevent and treat cancer."

"Cancer Research Northern Ireland is committed to increasing the number of patients offered the opportunity to join a clinical trial. By participating in trials, individuals can play a more active role in their own care and help others by contributing to research".

Professor Robert Stout, Director of Research and Development for the Health and Personal Social Services, said "Clinical trials play an essential role in health and social care research. We are delighted to work in partnership with Cancer Research Northern Ireland to increase research capacity and to improve patient care. Cancer is one of a number of new clinical research networks we are building and these new cancer research nursing posts provide a great boost for health and social care research and the creation of our new research networks".

For more information about clinical trials visit Cancer Research Northern Ireland's clinical trials database at www.cancerhelp.org.uk.

GP Prescribing – A New Perspective

**Dr Edward G.J. O'Neill, Research Fellow,
Queen's University Belfast**



In his August 2005 "Independent Review of Health and Social Care Services in Northern Ireland" Professor John Appleby¹ recommended a "... greater use of sanctions ... to tackle high prescribing costs and to encourage greater use of generic drugs" to reduce the significantly higher level of spend on prescription

drugs in Northern Ireland (NI) compared with England. New collaborative research, conducted by researchers from the School of Pharmacy and the Department of General Practice at Queen's University Belfast (QUB) on ulcer healing drugs, suggests that the situation is more complex. The findings of this new study indicate that

there are major factors influencing GP prescribing that are not directly amenable to sanctions.

The most commonly prescribed ulcer healing drugs are Proton Pump Inhibitors (PPIs). They are expensive agents and prescribing of them has nearly doubled over the last 5 years. The prescribing costs in NI are proportionately higher than in England e.g. in 2001, (the year before this research was commenced) the average expenditure on medication within this class in NI was £17,000/1000 patients per annum, compared with £8,000/ 1000 patients in England. The purpose of the research was to identify reasons for the higher expenditure in NI.

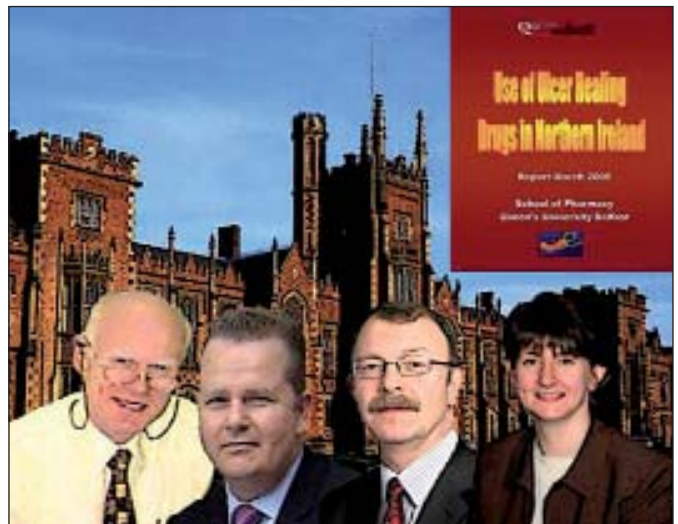
In the first phase of the research the influence of a number of factors in NI on prescribing was assessed. It was difficult to find anything unique about the NI population to explain the difference observed e.g. elderly patients usually require greater amounts of prescribed medication, yet in NI, compared with England, the population is proportionately younger.

Risk factors for dyspepsia include smoking, obesity and excess alcohol consumption, though there is little difference in prevalence between the two jurisdictions to explain the prescribing differences observed. The most consistent factors influencing the prescribing of ulcer healing drugs in NI, were found to be the level of non-steroidal anti-inflammatory drugs (NSAIDs) being prescribed and the level of deprivation at practice level. Aspirin prescribing and practice list size were also important factors (with list size, the relationship was inverse). PPI prescribing was demonstrated to be influenced by the proportion of Nexium[®] prescribed at a practice level. Nexium[®] was a relatively new product at the time of the study. It did not have any significant therapeutic or cost advantage over products already available and so it was considered that the extent to which it was prescribed was a useful measure of the influence of pharmaceutical company marketing.

Having identified broad factors that influenced prescribing of ulcer healing drugs in NI, the researchers matched the NI practices with a series of English practices on demographic data / levels of deprivation (thus eliminating their influence), in an attempt to examine the situation in more depth. Even after careful matching of practices, the level of prescribing of ulcer healing drugs was still much higher for the NI practices. However, when the cost per defined daily dose (DDD), (an indicator used to assess the quality of prescribing in terms of cost) was examined, there was no significant difference between NI and England across the two years of analysis. This indicated that it was the volume of prescribing rather than the proprietary /generic mix that was having the greatest influence on cost differentials.

A much higher level of NSAID and Aspirin prescribing was observed in the matched practices in NI, as evidenced in the first analysis. Aspirin is prescribed most frequently to prevent complications of cardiovascular disease such as 'stroke' and 'heart attacks'. These conditions are more common in NI. NSAIDs are largely used to help patients with musculo-skeletal and joint problems. Gastrointestinal side-effects are common with NSAID and Aspirin use and hence the data suggested that NI GPs were prescribing ulcer-healing drugs to provide gastroprotection / overcome dyspeptic side-effects in their patients.

One has to question why the level of NSAID prescribing should be so much higher in NI matched practices. The age profile of the population is lower in



L - R: Prof. Philip Reilly, Professor of General Practice, Queen's University Belfast. Dr Edward O'Neill, Research Fellow, Queen's University Belfast, Professor James Mc Elnay, Professor of Pharmacy Practice, Queen's University Belfast. (PI) Professor Carmel Hughes, Professor of Primary Care Pharmacy, Queen's University Belfast.

NI and an Arthritis Research Campaign publication in 2002 indicated a lower incidence of musculoskeletal disorders in NI. There are, however, very much longer waiting times to access Orthopaedic and Rheumatology secondary care services in NI¹. Access to these services is essential to receive effective disease modifying medication for inflammatory arthritis or operations to replace painful joints. We suggest that this difficulty with access is likely to have led to a higher prevalence of patients requiring medication such as NSAIDs to relieve pain. There is also a lack of Occupational Therapy and Physiotherapy services in NI² that might provide alternative methods of pain relief. Lack of access to secondary care and other key services places a higher burden of work on GPs in NI, as evidenced by the Continuous and General Household surveys, with patients in NI 40% more likely to have seen their GP in the 14 days preceding survey¹.

An additional observation was possible since the period of study coincided with the introduction of a new ulcer healing drug and two new NSAIDs to the UK. These new medications were represented in much higher levels at an earlier stage in the prescribing data of the NI matched practices, indicating a greater market penetration.

As part of the research study, interviews were conducted with GPs (from high and low cost prescribing practices for ulcer healing drugs) and hospital Consultants. Analysis of these data indicated that neither GPs nor Consultants were strictly following published guidelines on the prescribing of ulcer

healing drugs. Most GPs reported high levels of contact with pharmaceutical company representatives through educational activity or practice support activities such as audit. In addition, higher cost prescribers also appeared less critical of representatives and the literature they provided to support the use of their products. Higher cost prescribers appeared to be more likely to follow hospital consultant therapeutic recommendations for patients with dyspepsia, without substituting a cheaper alternative if one was available. The higher cost prescribers also reported greater difficulty in challenging patients to undertake dose reduction of ulcer healing medication.

Consultants interviewed favoured use of PPIs and did not advocate use of less expensive alternative ulcer healing drugs. The consultants reported that their hospitals had negotiated contracts with the pharmaceutical industry to provide a particular PPI, which they would have routinely used, at a reduced cost. Such a contract represents a product placement 'loss-leader'. Patients were started on medication in hospital where the price was lower than in the community, where cheaper alternatives were available, and this was carried through to primary care prescribing. Consultants participating reported regular contact with pharmaceutical company sales representatives and that significant access was gained by these representatives to junior and senior hospital staff through the support or provision of educational activity, though all reported that they were not influenced by such contact.

The main conclusions that can be drawn from this work are that prescribing of ulcer healing medications by GPs is influenced by a number of factors that are beyond their control. Detailed analysis of the prescribing data suggests that musculo-skeletal and articular morbidity contribute significantly to the prescribing of ulcer healing drugs (and the clinical rationale is also clear). However, were secondary care services more developed, this reason for this local pattern of GP prescribing would diminish. Service development is probably more important, and certainly more urgent, than simply focusing all efforts on GPs to adopt a range of limited prescribing initiatives. Cardiovascular morbidity also contributes to the prescribing of ulcer healing drugs through use of Aspirin. Pharmaceutical marketing also has an important influence on prescribing. The ongoing work on joint primary/secondary care formularies within NI is likely to have a significant impact on this latter influence. Tangentially the research also questions the adequacy of funding of postgraduate education and continuing professional development for hospital doctors and GPs within N. Ireland, with currently much reliance being placed on input from pharmaceutical manufacturers.

- 1 Professor John Appleby (2005) "Independent Review of Health and Social Care Services in Northern Ireland" DHSSPS.
- 2 "Strategic Review of Rheumatology Services in Northern Ireland" DHSSPS 2005.

Launch of Northern Ireland Clinical Research Monitoring Service

Dr Paul Biagioni, Clinical Trials Manager, Clinical Research Support Centre

The R&D Office and the Clinical Research Support Centre (CRSC) are pleased to announce the launch of a regional Clinical Research Monitoring Service (CRMS). This Service, based at the CRSC, will help HSS Trusts and other HSS bodies discharge their clinical research governance and management

responsibilities and help protect the rights, safety and wellbeing of research participants.

Whether an HSS Trust is a sponsor and /or an employer and/or a care organisation they need to ensure arrangements are in place to monitor ongoing research activity in their organisation. The appropriate level of monitoring required for each research study is established by the risk assessment carried out as part of the R&D approvals process.



L-R: Dr Paul Biagioni, Mrs Judith Storey and Mr Gareth Harry

The monitoring schedule may include initiation, interim and close-out visits or one-off on-site visits, depending on the amount of risk associated with the research project. In the case of investigational medicinal products, the monitoring requirements under the Medicines for Human Use (Clinical Trial) Regulations 2004 are potentially more onerous. For these studies working with the CRMS will provide reassurance that research is conducted to the appropriate regulatory and professional standards, help HSS organisations prepare for MHRA inspections, facilitate the development of GCP compliant research teams, along with its core function of verifying the accuracy and completeness of reported clinical trials data. Following the completion of a successful pilot phase at the Belfast City Hospital Trust (BCHT), the CRMS is now available regionally to all HSS bodies.

Professor Stuart Elborn, Director of Medical Education and Research (BCHT), said

“The pilot at BCHT was a useful exercise that identified areas for improvement to meet GCP requirements. The level of monitoring required will be based on an appropriate risk assessment for each study. The CRMS will help standardise quality control between commercial and non-commercial studies, this will help improve the quality of study documentation and improve patient safety”.

The Monitoring Service is led by Dr Paul Biagioni, with Mrs Judith Storey and Mr Gareth Harry working as monitors. Following graduation in 1987 Paul has worked almost exclusively within the clinical trials arena, primarily as a research assistant within the Contact Dermatitis Research Group in Belvidere Hospital, Glasgow and the Pharmacology

department of Strathclyde University. He gained his PhD at Queens University Belfast (QUB). Paul is chair of the Northern Ireland Research Management System Users Group and represents the R&D office on the MHRA’s GCP Consultative Committee as well as acting as the Northern Ireland Clinical Research Network (NICRN) representative on the UK Clinical Research Network (UKCRN) Industry Core Working Group. Judith has a nursing background; she graduated from QUB in Health Studies, followed by a post-graduate diploma in Computing and Information Systems from UUJ. Judith has monitoring experience from her previous employment as a research nurse within the commercial sector. Gareth completed his primary degree from Queen’s followed by a Master’s degree in Medical Ethics & Law, Diploma in Nursing Studies, a Master’s degree in Medical Science (all at QUB), and a Certificate of Professional Development in Clinical Research from the Institute of Clinical Research and John Moores University, Liverpool. He has over twelve years experience working within the HPSS and four years experience working for a Commercial Contract Research Organisation specialising in Phase I and II International Pharmaceutical Research. All CRMS staff are fully trained and follow specifically developed Standard Operating Procedures ensuring the service is delivered via rigorous quality standards in line with the commercial sector.

The introduction of the CRMS adds to a number of regional research support services provided by the CRSC and funded by the R&D Office. HSS bodies should contact Dr Biagioni during the pre-study initiation phase, to discuss and agree their monitoring requirements.

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Research and Development Office

Research Sabbatical Training Scheme

Professor Usha Chakravarthy, Ophthalmic Research Centre, Institute of Clinical Science, Queen's University Belfast



After 15 years in Academia with clinical, research and teaching responsibilities where life is an endless series of deadlines and fixed commitments, it is time to have a break from it all. Apart from simply taking a year's unpaid leave to go walking in the rain forest of Borneo or just living it up in the night clubs of Monaco, the alternative was a rest cure in the form of a sabbatical. Well, there were many obstacles. First of all I

had to find an appropriate organisation which could provide the funding. Then I had to locate the right person who had the qualifications to take on my clinical responsibilities. Finally I had to find the host environment that would give me the opportunity to learn new skills while contributing with my own skills.

In September 04, I was visited by Professor Steve Ryan, Dean of the University of Southern California and President of the Doheny Eye Institute. Steve is a retinal surgeon par excellence and well recognised for his extensive contributions to the literature in retinal disorders. Following his visit to my unit, Steve was enthused with the idea of a collaboration and invited me to go and spend time in the Doheny in Los Angeles on the West Coast of the USA. With its wonderful equable climate and superb opportunities to interact with a world class team in one of the most well equipped retinal Institutes, I didn't need a second invitation.

The next job was to obtain grant funding. This was actually the easiest obstacle to overcome. Within weeks I had identified an area of research where there was some commonality and where there were opportunities to learn improve and refine on my existing knowledge. A collaborative proposal allowing me to undertake a 6 month sabbatical was generated and sent to the R&D Office in Northern Ireland. Following a highly positive peer review in the spring of 2005, the offer of a sabbatical was in the bag.

Well then, the real difficulties began. Firstly family commitments meant that I was unable to take my entire 6 months in one tranche. Both my host Foundation and the R&D Office proved extremely helpful and flexible and I

was allowed to undertake the work over two summers. The next problem was probably the hardest. I provide a highly specialised macular retinal service so finding a locum with these skills was problematic. While Queen's University is used to requests for sabbatical and automatically provides cover, the Royal Hospitals will refuse such requests unless clinical cover can be found. Fortunately splitting the sabbatical proved to be helpful as my colleague Olivia Earley from the Mater Hospital in Belfast stepped into the breach in the summer of 2005. Likewise in the summer of 2006, Ms Clara McEvoy a retina trained ophthalmologist was able to provide the locum cover.

Now for the actual time in LA. My hosts were most accommodating and hospitable. I was provided with an office, a secretary and a team. Having protected time meant that I was able to indulge in some creative thought¹⁻². We worked on developing, testing and validating a new platform to dynamically assess fluorescence patterns in retinal macular disease. The novelty of the work lay in the use of artificial intelligence to assess the nature and extent of abnormalities of



fluorescence arising in the different tissue layers of the posterior pole of the eye and mathematically create the models that described it numerically. We used the software to analyse a database of retinal images that I had created in Belfast. The value lay in its construction as part of a longitudinal controlled clinical trial where retinal imaging data were acquired to the highest specification along with an accompanying systematically collected clinical database. This allowed the software to be validated and tested against measures of vision to show that the new methodology was clinically robust³. We also began to undertake the initial testing of a spectral imaging system which detects levels of oxygen saturation in the retina of the living eye with huge implications for

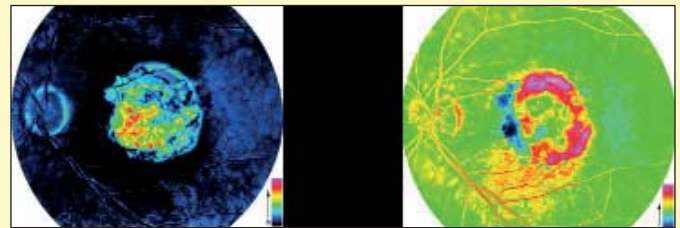
managing conditions like diabetic retinopathy. Within weeks we had undertaken sufficient work to generate two publications in the top ranked journal in the ophthalmic scientific literature. Collaboration also allowed me to work with other members of the Doheny Institute⁴. Although I spent only 10 weeks in total in California I was left with a feeling of enormous achievement. We have a new ongoing collaboration which will examine the role of epigenetics in macular disease and a continuing process of working together on multimodal retinal imaging. The sharing of experiences was most rewarding and I was able to come back refreshed with new ideas. My family too had a wonderful time visiting me while I was in California. We made a number of new friends and the invitations to go back to LA come thick and fast. I would recommend a sabbatical in this wonderful part of the world.

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4. Chakravarthy U and Lim J. New treatments for age-related macular degeneration. *British Medical Journal*. 2007; 334: 269-270.

5. Esmaili DD, Ghafouri RH, Chakravarthy U, Lim JJ. Quantitative retinal imaging. In Press



A case (A) of choroidal neovascularization (CNV) following training (B) of classic CNV (blue), hemorrhage (red) and surrounding fluorescein dye leakage (cyan) appearing in the later phases. Following training, the computer software can 'guess' (C) the identity of the image pixels based on the training data



Color maps of: (A) the Integrated Intensity (II) obtained by summing the pixel intensity at each pixel location across all five phases of the angiogram, and (B) the Positive Fluorescence (PF) obtained by summing the positive change in fluorescence in only those angiographic frames taken after the arteriovenous laminar phase. As shown in the color bar, red-purple indicates higher values and blue-black are lower values.

Mrs Lillian Bradley



We were saddened to learn of the death on the 13 November 2006 of Mrs Lillian Bradley, a Principal Investigator in the RRG project. "The effect of phenytoin in the treatment of chronic wounds". Mrs Bradley was a qualified nurse who had a long term interest in tissue viability and for a period

took on the role of convenor of the Trauma and Rehabilitation RRG wound healing sub-group. She initiated the first nurse-led leg ulcer clinic in Northern Ireland in

1995 in the Ulster Community and Hospitals Trust and introduced modules in tissue viability in the curriculum of the School of Nursing and Midwifery in Queen's University. She was a founder member of the Leg Ulcer Forum Ireland, member of the National Executive of the Leg Ulcer Forum London and of the European Wound Management Association. In 2004 she was awarded a degree of Master of Science in Wound Healing and Tissue Repair in the University of Wales and through all these activities had been very active in promoting the cause of wound healing in Northern Ireland and further afield. We send our sympathy to her colleagues and in particular to her husband, the Reverend Ken Bradley and her family.

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