

# R&D TODAY

 Public Health  
Agency

The biannual newsletter of the Health and Social Care Research and Development Division

Issue 15 Summer 2011

## Inside this issue:

- *Research in HSC Trusts*
- *Research governance permissions processes*
- *Research and clinical guidelines*
- *Successful innovation*





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# Foreword

**Professor Bernie Hannigan,  
Director of R&D and  
Chief Scientific Advisor**



This issue of our newsletter provides some great answers to the question 'What is research for?' You can read about many different kinds of research and how it leads to innovations and other developments in health and social care.

- Research undertaken in our HSC Trusts directly improves the quality of care for patients and clients. It also allows many different members of staff to contribute to and apply those improvements.
- Through clinical trials, patients get access to potentially better medicines and other new treatments.
- Knowledge-led innovations save money and make money for our Trusts.
- Research provides knowledge to guide decisions that are made every day in clinical practice.
- Research contributes to the wellbeing of our economy.

Each of the UK Health Departments provides funding for research. Locally, our research funding has declined in recent years. But the whole UK population, including those of us who live, work and are cared for in Northern Ireland, should be able to benefit equally from research. It is important for us all to work towards that objective.

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A handwritten signature in black ink that reads "Bernie Hannigan". The signature is written in a cursive, flowing style.

# Supporting research and development

## Northern Health and Social Care Trust



**Dr Des Rooney,  
Director of Research  
and Development**

A range of research projects from a variety of disciplines received support from the research fund. The following projects illustrate the diversity of

research activity that the fund has enabled within the NHSCT.

### **Speech and language therapy: an investigation into the use of The Listening Programme as a therapeutic tool**

Speech and language therapists working in Thornfield House School, Jordanstown, a school for children with a specific language impairment (SLI), wished to investigate the potential benefit of The Listening Programme (TLP) as a therapeutic tool to supplement specialist teaching and intensive speech and language therapy. TLP is a classical music-



based programme which claims to provide advanced auditory training to the ear through the systematic delivery of psycho acoustically modified music. It involves listening through headphones for sessions of between fifteen and thirty minutes five days per week for a minimum of ten weeks.

TLP was delivered to 17 children randomly selected for the intervention group in April/May 2010. Reassessment was completed in June with follow-up assessment in September/October 2010. Results indicated statistically significant differences in the auditory discrimination ability (in both quiet and noise) in the treatment group compared with the other group that did not receive the intervention.

Further funding was given in October 2010 for both staff time and equipment to carry out a profile analysis of the 34 participants in the study and to collaborate with education colleagues to write an evidence-based practice guide for use of TLP in the school setting. The researchers hope also to publish a paper in a good, peer-reviewed journal. Engaging in this research has been a valuable and stimulating process which has helped the team to expand their knowledge and skills.

### **Emergency medicine: an investigation of soluble excipient release from PVA hydro gels intended for wound management**

The NHSCT is collaborating with the University of Ulster to evaluate the performance of an innovative visco-elastic hydro gel that is used to deliver a local anaesthetic during the initial stages of traumatic wound repair, prior to application of sutures. Although the material is a chemically cross-linked structure, a small

## Northern Health and Social Care Trust (continued)

amount of its contents, termed excipients, may be sufficiently soluble to be absorbed by the patient while the gel is applied to the wound. One such material is polyvinyl alcohol (PVA), which forms the scaffold of the hydro gel. If a small proportion of the PVA is not immobilised in the cross-linked network it may be absorbed across both the open wound and across intact healthy skin surrounding the wound.

Using support from last year's fund, an experimental model system was developed and trans-membrane diffusion of soluble excipients from five test formulations was evaluated. The data obtained have allowed the research team to present safety information to ethics and regulatory bodies that confirm the hydro gel does not pose issues for patient safety. Further plans are in place to evaluate the release of other active drug substances, eg antimicrobial agents, from the hydro gel.

### **Microbiology: investigating the possibility of eradicating MRSA from 'graduates' of a special care baby unit**

Methicillin resistant *Staphylococcus aureus* (MRSA) is a widespread problem facing all age groups and clinical settings. Infection with MRSA increases the likelihood of a requirement for more toxic and generally parenteral antibiotics. A patient colonised with MRSA may require isolation from other patients and a higher level of infection control stringency. There is a particularly high incidence of MRSA in neonatal units. The 'graduates' of these units have a higher incidence of hospital readmission and those colonised with MRSA place a significant added burden on paediatric services. A number of regimes have been developed



to eliminate the carriage of MRSA, but with varying success. These generally involve an intensive course of washes and cleansing of the nasal passages, however there is no evidence to support the use of these regimes in children. Also a newborn colonised with MRSA at birth may eliminate this carriage spontaneously or alternatively may respond easily to intervention.

Graduates of Antrim neonatal intensive care unit will receive a course of eradication therapy and their MRSA status will be monitored over a period of time to check whether the MRSA has been eradicated fully. If it is, the infectious risk label can be removed from the patients' clinical records so that these patients can be treated normally thereafter. A positive outcome to this study will lead to considerable savings to the NHSCT and dramatically improve the patient experience of those colonised by the bacteria.

### **HSC R&D Doctoral Fellowship working on healthcare-associated infections**

Healthcare-associated infections are a huge burden for patients and for Trusts. Geraldine Conlon, antimicrobial pharmacist in the NHSCT, has been awarded a HSC R&D

# Supporting research and development

## Northern Health and Social Care Trust (continued)

Doctoral Fellowship for a research project to test whether an antibiotic cycling policy, devised using time series analysis, can decrease the incidence of hospital acquired MRSA and *C. difficile* associated diarrhoea (CDAD) in Antrim Hospital. This research will be carried out over a period of three years and will involve studying the relationship between antibiotic use, infection control practices, co-morbidity index and the incidence of MRSA and CDAD from January 2006 until December 2010. The information gained will allow the optimal design for an antibiotic cycling policy to be determined according to effects of different antibiotics on the incidence of healthcare-associated MRSA and CDAD. This research may provide an innovative approach to using antibiotics in a way that will minimise the risk to patients of developing healthcare associated infections.

### **Nursing: an investigation of the suitability and accessibility of services provided to women with a diagnosis of breast cancer in the NHSCT**

This study aims to identify, describe and document current practice in meeting treatment, information and support needs for women diagnosed with breast cancer across the NHSCT. The barriers and facilitators influencing uptake of services will also be detailed, as will the best methods of measuring cost effectiveness

The study aims to recruit more than 30 women diagnosed with breast cancer. A series of focus group interviews will be conducted with patients, one in Causeway, one in Magherafelt, one in Antrim and one in Whiteabbey. Twelve to fourteen women will be invited to each focus group.



## South Eastern Health and Social Care Trust



**Dr David Hill,  
Director of Research  
and Development**

Research activity within the SEHST continues to grow, with an anticipated 83 projects being approved through to the end of April 2011. The

projects themselves represent a wide range of professional and topic areas, including cancer, diabetes, cardiovascular medicine, stroke, nephrology, rheumatology, social work, physiotherapy and nursing.



The SEHST over the last year has continued to support its enabling infrastructure by adding a data administrator and haematology nurse to the staff. It is hoped that these resources will result in research growth for the organisation. Obviously the SEHST does not work in isolation and continues to work closely with HSC R&D, the four other Northern Ireland Trusts, the Northern Ireland Clinical Research Network (NICRN), the

Clinical Research Support Centre (CRSC) and Clinical Trials Unit, both local universities, HSC Innovations and a variety of commercial and individual partners.

The Trust has recently begun a process to reinvigorate its strategic vision for research and is developing a five year plan to set the direction for the Trust, within the overall regional and national context.

The SEHST research office has also sought to develop links with industry and the universities by actively considering the academic, business and clinical (ABC) approach to innovation and partnership. This approach facilitates the identification of real clinical need and the solutions required to meet it. To this end the SEHST will enter at least two of its sponsored and funded projects into the £25,000 awards this year, to enhance the potential scientific and clinical return on its investment.

The SEHST also continues to play its role regionally by contributing to a number of workstreams that aim to enhance service to clinical researchers, eg the Integrated Research Application System (IRAS), the regional research governance permissions process and commitment to the Research Managers Forum (RMF).

# Supporting research and development

## Southern Health and Social Care Trust



**Dr Peter Sharpe,  
Director of Research  
and Development**

In January 2011, two Personal and Public Involvement (PPI) representatives, Eileen Wright and Lee Wilson, were welcomed as new members of the

SHSCT Research Governance Committee. Eileen and Lee were recruited by HSC R&D, working with the Patient and Client Council, and expressed an interest in being involved in R&D in the SHSCT. It is recognised that the personal experiences and contributions of both these members will make an important and valuable contribution to the Research Governance Committee and R&D within the SHSCT.

Having contributed to the Academy of Medical Sciences Review, the SHSCT received with interest the outcome of that review, *A pathway for the regulation and governance of health*



**PPI representatives Lee Wilson and Eileen Wright with Dr Peter Sharpe**

research, issued in January 2011. The review placed much emphasis on the delays in obtaining research governance permissions and the need to embed R&D at SHSCT Board level and have an executive director responsible for that area of service.

For Northern Ireland, there now are agreed metrics for the research governance permissions process. Examination of the 20 research applications received by the SHSCT during the first quarter of 2010/2011 revealed:

Calendar days to approval	Proportion of applications
30	70%
30 - 60	15%
60 - 84	5%
> 4	10%

For those applications where there was a delay in granting research governance permission, the primary cause was finalisation of clinical trial agreements especially in relation to the governing law (eg Northern Ireland instead of England).

In relation to the need to embed R&D at Board level, in the SHSCT, there is tangible commitment to R&D by the chief executive, executive director and SHSCT Board. The medical director has responsibility for research and development, and meets monthly with the SHSCT's Director for R&D – Dr Sharpe. On an annual basis, Dr Sharpe is invited to present the Annual Report for R&D to the Board and did so most recently on 27 January 2011. The SHSCT Board expressed its satisfaction with the R&D activity. Controls Assurance Standards for Research Governance for 2010/2011 have recently been submitted to the SHSCT and have again met the required substantive compliance and



## Southern Health and Social Care Trust (continued)



Dr Patricia McCaffrey, Consultant Geriatrician, Mary McParland, NICRN Clinical Research Nurse (Stroke), Jane Greene, Nurse Consultant Older People, Irene Knox, Research Manager, Dr Peter Sharpe, and Angela McVeigh, Director Older People and Primary Care, reviewing the achievement of the LoTS Care Trial.

exceeded the level achieved in 2009/2010 by a further 7%.

For the year 2010/2011, research applications totalled 84 and originated in a wide range of professional disciplines, a significant increase on the 62 received in 2009/2010. The following are examples of studies which made specific achievements:

- **LoTS Care – Stroke system of care trial: Cluster randomised trial evaluation of a patient and carer-centred system for longer term stroke care.** The initial recruitment figure was 50 patients; when 45 was achieved the site was asked to extend to 90 due to the successful recruitment within the SHSCT. Mary McParland, Northern Ireland Clinical Research Nurse (Stroke) achieved the highest recruitment in the UK for this trial.

- **NOBLE Study – coronary artery bypass grafting versus drug eluting stent percutaneous coronary angioplasty in the treatment of unprotected left main stenosis – a randomised clinical study.** Dr Ian Menown, consultant cardiologist, was the local principal investigator and had the fourth highest recruitment centre for the study.

The availability of the £50,000 Research Fund for 2010/2011 has been invaluable and enabled many research projects to commence, with some developing into large clinical trials. Nineteen projects were funded. The successful applications were received from many different areas of the SHSCT, but, for the past two years, nursing, social services and allied health professions have been the priority areas in which every effort has been made to encourage and promote research. Three applications related to the use of prism glasses in occupational therapy stroke rehabilitation; the use of the 'Kinect' gaming console within occupational therapy stroke rehabilitation and the development of a dual dynamic forearm supination and composite finger flexion splint after distal radius fracture. The latter was selected for an oral presentation at the All-Ireland Occupational Therapy Conference in April 2011, while the other two were accepted as poster presentations at the same conference.

A workshop organised between HSC Innovations and the SHSCT entitled 'Innovation to improve patient care' was held in January 2011. The workshop was facilitated by Dr David Brownlee, HSC Innovations, and Professor Alistair Fee, Queen's University visiting professor of marketing and innovation and European Business School visiting professor. An introduction to intellectual

# Supporting research and development

## Southern Health and Social Care Trust (continued)



Dr Peter Sharpe with Charlotte Greene and Tina Hughes, occupational therapists, and Irene Knox, Research Manager, Dr Michael McCormick, Consultant Physician and Tracey Gibbs, Occupational Therapy Manager, reviewing the posters for the All-Ireland Occupational Therapy Conference.

property (IP) was presented including its value within research and the associated IP policy. Those who attended were invited to submit their suggestions for innovation, some of which appear to be very novel and arrangements are being made to develop those innovative ideas further.

The homepage of the SHSCT intranet already had a link for R&D but in December 2010 an additional link for clinical trials was added. Links are organised by specialty to the name of the trial, what the trial involves, any emergency management arrangements and contact telephone numbers of relevant staff for further advice on patient management. In February 2011, the induction training for junior medical staff at both Craigavon Area Hospital and Daisy Hill Hospital sites included a presentation on how to access information on the management of patients enrolled in clinical trials and also directed them to the SHSCT's intranet links. This presentation was facilitated by SHSCT R&D staff and will continue at future induction sessions for junior medical staff.



Dr Peter Sharpe and Irene Knox, Research Manager, with Daniel Harte, Clinical Lead Occupational Therapist and Emma McKillion, Senior Occupational Therapist viewing the dynamic splint.



**Dr Maurice O'Kane,  
Director of Research  
and Development**

The WHSCT continues to develop its depth and focus of research activity. Under the Research Director's £50,000 allocation, a range of research

projects received funding. Some of these were collaborative projects with the University of Ulster, for which matched funding was provided. This allowed an increase of about 50% in the total funding awarded.

The £50,000 award plays an important strategic role in allowing researchers to perform preliminary work and generate results which can then support larger external funding applications. The projects funded in the 2010/11 round covered a range of areas and built on research themes and projects developed in previous years. Examples of funded projects included:

- **An investigation of psychological barriers and resistance to injectable treatment for type 2 diabetes** (funded jointly with University of Ulster). In patients with type 2 diabetes the use of injectable treatments (insulin and GLP-1 mimetics) is necessary when oral therapy has failed to provide adequate control of blood glucose levels. However, the commencement of injectable therapy may cause considerable anxiety in patients, often resulting in a delay in its introduction. This project is investigating the psychological barriers to injectable therapies and will gather baseline data on patient experiences. It will form the
- **Study of the experiences of gynaecology patients in the WHSCT cancer pathway.** Patients with gynaecological cancers may undergo complex treatments involving both the cancer centre and local cancer unit. This project will explore the experiences of patients on their cancer journey and will generate data to inform service development.
- **An investigation of prescriber perceptions and the benefits of, and barriers to, the successful implementation of antimicrobial prescribing guidelines** (funded jointly with the University of Ulster). Appropriate antimicrobial prescribing is essential for effective treatment and reducing the risks of unwanted sequelae. In practice it has proved challenging to implement antimicrobial prescribing guidelines. This study will examine the perceptions of prescribers on the use of guidelines and guideline implementation. This research project will generate valuable information on how such guidelines can be integrated most effectively into clinical care.
- **Usability study of novel asthma drug dosage device** (jointly funded with the University of Ulster). Although inhaled drug therapy is the mainstay of asthma treatment, challenges continue to ensure optimum and effective delivery of drugs into the airways. This project brings together a team of respiratory physicians, academic designers and psychologists to assess the efficacy of the novel drug dosage device in the treatment of asthma.

# Supporting research and development

## Western Health and Social Care Trust (continued)

- **The assessment of dietary intake in maintenance haemodialysis patients and the impact of micronutrient supplements.** End-stage kidney disease requiring dialysis treatment is associated with greatly increased morbidity and mortality. This may be mediated in part by oxidative damage to tissues. This study builds on the work of a previous research project and will assess micronutrient dietary intake and the effect of micronutrient supplements on markers of oxidative damage. A related project (jointly funded with the University of Ulster) will study oxidative DNA damage in haemodialysis patients.
- **Use of bioimpedance for the longitudinal assessment of nutrition, hydration and residual renal function in a haemodialysis population.** Patients with end stage kidney disease who are on haemodialysis have complex fluid and nutritional requirements and are at risk of suboptimal fluid balance and nutrition. This may be an important factor contributing to increased morbidity and mortality in this patient group. However the assessment of nutritional status (and therefore nutritional requirements) poses particular challenges. This research project will compare use of technology to measure bioimpedance with conventional clinical and biochemical markers in the assessment of hydration and nutritional status.

## Clinical Translation and Research and Innovation Centre (C-TRIC)

Much of the clinical research within the WHSCT is based in C-TRIC. C-TRIC was one of three all Ireland recruitment sites for the TUDA study (Trinity College/University of Ulster/Department of Agriculture) which is investigating gene/

nutrient interaction in degenerative disease. In excess of 1000 patients were recruited from C-TRIC ahead of schedule.

C-TRIC is currently working with a US-based company in a laboratory and clinical evaluation of a new point of care testing device.

One of the functions of C-TRIC is to provide incubation space for biotechnology companies. C-TRIC has recently launched a second bio-entrepreneur programme and is working with five biotechnology companies in the areas of infection control, point of care testing technology and health care product design. The bio-entrepreneur programme stimulates interaction between the biotechnology, clinical and academic sectors to expedite the development of healthcare products that can have a direct impact on patients.

In the last year C-TRIC has hosted and coordinated the development of collaborative networks of bio-business, clinical and academic staff in the areas of infection control and respiratory health.

A recent clinical trial event, organised by Invest NI, was hosted at C-TRIC. This event provided an overview of the resources and services available to support clinical trials and to initiate discussion on how HSC Trusts and companies may work better together. Four companies participated: Bio-Kinetic Europe Ltd, Medevol Ltd, Celerion Ltd, and O4 Research Ltd. Each company provided an overview of the clinical trial areas and phases they facilitate and how they currently engage with local Trusts and the Northern Ireland Clinical Research Network (NICRN).

C-TRIC also hosted the 2011 3rd Translational Medicine Conference – see the report on page 18.

# Navigating the research governance permissions process

Achieving the research governance permissions and regulatory approvals to get research underway need not be a nightmare.

HSC R&D spoke to some researchers who have recently commenced their research, and asked them about their experience of the permissions process. The researchers we spoke to were from different health and social care professions and had varying amounts of research experience. The projects they had submitted for research governance permission were a mixture of academic and commercial studies.

HSC R&D asked the researchers the following questions:

- How easy was it to understand and navigate the permissions process?
- Were you happy with the support you received from your Trust R&D office?

- Was the time to obtain governance permission satisfactory?

Researchers were also asked what advice they would give to others about to go through the process. Below we explain some of the general findings as well as direct quotes from researchers.

The Integrated Research Applications System (IRAS)\* is designed to avoid unnecessary duplication of information. As all research projects are different, the permissions and approvals required will vary depending on the type of study.

On IRAS, a master dataset is created and a series of forms is then cross-populated as required for the specific study being undertaken. Most researchers agreed that the first time completing the IRAS forms was the most daunting, and some felt that navigating



# Supporting research and development

## Navigating the research governance permissions process (continued)

the website for the first time was possibly best done with help from someone who was familiar with the forms and the process. However, time could be saved by making sure to get some processes underway in parallel, while other parts of the process were sequential.

During completion of the forms, researchers felt they were prompted to consider important issues and take appropriate action in preparation for starting their study, and a number felt that this avoided problems that could have arisen after the project began. Those who had completed the process more than once felt that they had quickly become familiar with it and found it quite straightforward.

### Comment from Trust-based researcher

*"I found the process easy to understand, I had all the help I needed from the research and development office and am satisfied with the time taken to receive permission."*

### Comment from university-based researcher

*"The permissions process is actually quite difficult to navigate even with IRAS. ....The office were quite proactive in terms of helping me through the process and even obtaining the required signatures. They processed everything actually pretty quickly and were quite explicit about what was needed at each stage."*

All of those we spoke to agreed that, in developing a research project, it was important to get in touch with the Trust R&D office at the earliest possible stage. Those who had done this were very happy with the advice and support they had received. Where projects involved more than one institution, HSC R&D heard evidence from the researchers of effective communication between the Trust R&D offices, the Office for Research Ethics Committees Northern Ireland (ORECNI) and the university research governance offices.

With regard to the time taken to receive research governance permission, most of those we spoke to were content. Recent cumulative statistics collected by the five Trust R&D offices show that over 75% of studies presented for governance permissions now complete the process within the 60 day recommended time limit.

However, HSC R&D acknowledges that there still are instances of long delays in obtaining governance permissions. HSC R&D is working with the Trusts and universities to further improve the permissions performance locally and in line with UK-wide permissions processes. This involves local staff devoting time to a number of workstreams that aim to minimise bureaucracy and dispense with duplication. While much progress has already been made, significant improvements will only result from effective interactions and communication between the research community and those involved in research governance. HSC R&D sees this as vital in helping Northern Ireland build a stronger reputation as a viable global location for clinical research, thus bringing greater benefits to service users and the HSC as a whole.

## Navigating the research governance permissions process (continued)

### Comments from Trust-based researchers

*“The support and flexibility shown by the staff in the (Trust) R&D office in fast tracking our application at short notice was vital and has enabled our participation in this important international study... We have been delighted with the level of service and assistance received. The net approval time for this study was five days.”*

*“The net approval time for this study was 20 days. A feasibility questionnaire was initially completed in advance of a site visit... Discussions at this time included documentation required for research and development submissions, closing dates for submissions, costings for the study and the need for the Northern Ireland version of the Clinical Trial Agreement. The required documentation was provided in a timely fashion and approval to start the study followed shortly after this.”*

*“For our current project we were contacting health service staff to complete a questionnaire – I was unaware that this would require ethical approval but the research and development team in the .. Trust helped me through the process. Their comments included advice on sponsorship, local collaborators, lead Trusts and the application to ORECNI. The staff within the Trust R&D office have been prompt to respond to any questions or queries no matter how many times the same question is asked. Their advice allowed for a successful application.”*

### Comments from university-based researchers

*“Given that Trusts are large organisations and locating the relevant contact information can be difficult, it is especially helpful to have a supportive research and development office that are willing to facilitate and coordinate the wider process.”*

*“.. the interaction with Trust finance can be very slow and it is not always apparent to an investigator what stage their application is at and what things are causing delay. I do feel that Trust offices should be allowed to show some leeway in terms of proportionality – even small low risk studies can take several weeks.”*

*“Due to the fact that I was a researcher at the university I did not hold an honorary contract and I was impressed with how promptly the (Trust) was able to deal with my application. Another positive aspect was the promotion of training requirements for researchers including training on good clinical practice and the Human Tissue Act.”*

*“Due to the efficient way our application was dealt with, particularly at a time when the application process was changing to IRAS, we have completed the recruitment phase of the ...study on time and with all targets met.”*

\* A list of the approvals/permissions covered by the IRAS form is available at [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk)

HSC R&D wishes to thank the researchers who contributed to this brief study.

# Supporting research and development

## Using research: developing and using clinical guidelines

The traditional formats for written outputs from research include peer reviewed papers in journals or systematic reviews of multiple studies, but these formats are not always either accessible or sufficient for use in healthcare. In this article, Professor Mike Clarke provides some insights into the links between reported research, guidelines for clinical practice and the use of the guidelines.

A healthcare practitioner or policy maker might make dozens of decisions every day about the care of others. These decisions may be for an individual patient; for small groups of people, such as families; or for larger groups or whole populations on a regional, national or international scale. The decisions should be informed by reliable evidence, and this evidence needs to come from a variety of sources.

In the context of choices between interventions, the evidence needs to balance knowledge about the effects of the interventions with information on the feasibility of implementing the interventions and the local values and preferences for the outcomes that might be more, or less, likely following the different interventions. Systematic reviews of randomised trials might be most useful as the source of an estimate of the relative effects of the interventions but will probably not be sufficient for the knowledge needed on issues such as values and feasibility. In such circumstances, rather than gathering all the elements personally, the decision maker might prefer to rely on relevant guidelines.

The complexity of the inputs needed for a well-informed decision might mean that the recommendations in a guideline

do not match perfectly with the findings of a review of randomised trials but that is not a failing. It is a virtue of the whole process for compiling the guidelines, allowing the practice of evidence-based health care to rely on more than the 'simple' implementation of the findings from research studies.

In considering differences between recommendations in guidelines and the findings of a systematic review of research, it is worth remembering some of the reasons behind the need for guidelines. These include diversity of practice and uncertainty about what is best, reflecting that different decision makers have interpreted the existing research in different ways; and a volume of 'evidence' that is overwhelming and too diverse for easy or timely interpretation by a single decision





## Using research: developing and using clinical guidelines (continued)

maker. In the same way that systematic reviews help avoid undue emphasis on any single study, so guidelines can help ensure that undue emphasis is not placed on any single piece of evidence or interpretation of it. They provide a full and transparent process for identifying the evidence and assessing its relevance and reliability.

Guidelines should seek all relevant evidence on the topic, appraise and summarise it, and interpret it to make recommendations for the setting in question. This might involve multiple systematic reviews of different types of evidence, covering, for example, the most appropriate ways to diagnose a condition, the options for treating it, and the means to assess

outcomes; as well as information about the scale of the problem and the value judgements used to support the recommendations.

The recommendations in a guideline are likely to seek to achieve more good than harm, on average, within the relevant setting. Although they will often lead to decisions at the level of an individual patient, guidelines are rarely able to take all of the circumstances for that individual into account. If they are seen as guidance rather than unbending rules, they leave the way open for individual decisions to differ; but they provide a baseline for those decisions and the standard against which any decision to go against their recommendations should be justified.



### Professor Mike Clarke

Professor Mike Clarke became Chair of Research Methodology at Queen's University in Belfast and Director of the All-Ireland Hub for Trials Methodology Research in March this year, after being Director of the UK Cochrane Centre since 2002. Mike has worked actively on more than 30 systematic reviews in a wide range of areas, as well as on large randomised trials in topics such as maternity care, breast cancer, poisoning and stroke. He is podcast and journal club editor for The Cochrane Library, and has a strong interest in increasing capacity for the conduct of clinical trials and systematic reviews and in improving their

accessibility. His work on accessibility includes Evidence Aid, which is seeking to make it easier for people and organisations planning for and responding to natural disasters and other humanitarian emergencies to use systematic reviews in their decision making. Mike will be working with partners here in Northern Ireland and elsewhere to strengthen the portfolio of research that is directly relevant to practitioners, patients and the public.

# Success in research and development

## C-TRIC's 3rd Annual Translational Medical Conference



Pre-conference discussions: Dr Susan Whoriskey, Professor Paddy Johnston

In March 2011 clinicians, academics and businesses from the UK, Ireland, the US and from across Europe came to the City Hotel, in Londonderry for C-TRIC's 3rd Annual Translational Medical Conference.

C-TRIC, the Clinical Translational Research and Innovation Centre, based at Altnagelvin Hospital, holds the annual conference to showcase progress and developments at the facility and to promote life sciences within Northern Ireland. Conference sponsors



Mental Health Leaders (L-R): Professor Brendan Bunting, Dr Ciaran Mulholland, Professor Gerry Leavey

included Invest Northern Ireland, Partners Healthcare from the US and HSC R&D.

Over 150 delegates heard presentations from leading clinicians who identified areas of unmet need within healthcare. Industry and academic researchers presented possible solutions and approaches to address these key challenges. Such solutions can lead to improved patient care and reduced inefficiencies in the diagnosis, treatment and management of chronic illness.

The conference focused particularly on diabetes and mental health, as they are significant health problems affecting large sections of the population in the UK and Ireland, and a growing drain on the resources of healthcare systems globally. Northern Ireland boasts internationally leading researchers in mental health and diabetes who can promote engagement and collaboration among academics, business and clinicians to address clinical needs.

The Northern Ireland Public Accounts Committee has reported that the incidence of diabetes is rising, costing the health service more than £1m per day. Recent figures from the University of Ulster's Bamford Centre for Mental Health and Wellbeing demonstrate that the proportion of people in Northern Ireland with a mental disorder is among the highest worldwide.



Conducting the show: Professor Hugh McKenna

## C-TRIC's 3rd Annual Translational Medical Conference (continued)



Diabetes Leaders (L-R): Dr Sara Flatt, Dr Caroline Day, Professor Clifford Bailey, Professor Peter Flatt



Enjoying a great conference dinner (L-R): Bridgeen Rutherford and Nadine McDermott (WHSCT R&D Office), Marion Fay (SEHSCT R&D Office).

Dr Maurice O’Kane, R&D Director for the Western Health and Social Care Trust and CEO of C-TRIC, outlined how the event would steer future R&D efforts: “This was an excellent conference with an array of international experts in diabetes and mental health outlining the challenges posed by these conditions. Diabetes and mental health have been identified as research themes to be developed in C-TRIC.”

Keynote speaker Dr Susan Whoriskey, a member of the founding executive teams of both Momenta Pharmaceuticals. Inc. and Cubist Pharmaceuticals Inc. (now valued at around \$3 billion), endorsed the facility. She said: “I was very impressed by my C-TRIC visit and Northern Ireland is lucky to have

such a centre. I have never seen such an excellent convergence of facilities, expertise and partnership under one roof as is present in C-TRIC.”

The 4th Annual Translational Medical Conference in early May 2012 will focus on inflammation and cardiovascular disease.

C-TRIC is a partnership of the University of Ulster, the Western Health and Social Care Trust and Derry City Council, with funding provided by ILEX urban regeneration company and Invest Northern Ireland. C-TRIC is a healthcare innovation hub and Northern Ireland’s only purpose-built clinical research facility. It is the only facility of its type in Great Britain or Ireland.

# Success in research and development

## A second successful year for the Northern Ireland Clinical Research Network

The Northern Ireland Clinical Research Network (NICRN) has now enabled almost 10,000 patients in Northern Ireland to participate in clinical trials of new, innovative treatments. Thanks are due to all of the staff who contribute to this success and to the patients who agree to take part in studies.

The aim of NICRN is to facilitate the delivery of clinical trials and other high quality clinical research in the HSC. NICRN is essential to ensure that patients across Northern Ireland have access to new and innovative treatments in the same way as patients elsewhere in the UK.

The second annual NICRN report shows that, during calendar year 2010, a total of 95 studies were adopted or run by the nine NICRN clinical interest groups, involving 6,876 patients. This brings to 9,850 the number of patients who participated in trials since the NICRN was established. While these figures

are impressive, the network is now running at close to saturation and further expansion will require the re-investment of income. The primary source of new funding is likely to be commercial funders. This is a significant goal for 2011.

The full complement of NICRN staff is funded through some £1.4 million from HSC R&D and is now in place across the five Trusts. This comprises 18 clinical programmed activities (PAs) for clinical leads, 32.5 support staff (mainly nurses and allied health professionals) distributed across the network and there are four posts in the coordinating centre. For efficiency, there is scope to re-deploy support staff in line with activity levels of each interest group. HSC R&D also funds core staff in all Trust R&D offices – to manage research governance processes and monitor the achievement of objectives – along with contributions to pharmacy and finance services. All staff are direct employees of the HSCTs.

There is copious evidence that participation in clinical research improves outcomes for patients, creating an environment which attracts and retains high quality healthcare staff. In addition, a strong clinical trials infrastructure helps to attract inward investment and assists the development of local enterprises. Many studies are ongoing that will not have their full impact for some time, but already patients have been able to access treatments that were not otherwise available.

The NICRN brings together existing Trust-based R&D structures and personnel with proven clinical research track records. This approach, along with other HSC R&D enabling infrastructure, such as the Northern Ireland

The screenshot shows the NICRN website with the following content:

- Navigation Links:** About Us, Areas of Interest, Involving People, Frequently Asked Questions, Contact Us.
- Areas of Interest:** The following is a list of areas of interest for the NICRN. However this list is not exhaustive as the NICRN will consider good quality studies from other areas.
  - Dementia
  - Diabetes
  - Cardiovascular
  - Childrens
  - Critical Care
  - Primary Care
  - Respiratory
  - Stroke
  - Vision
- Formal Process:** A formal process is required to ensure that the finite resources of the NICRN are used in a coherent and strategic manner for the benefit of the HSC. Therefore before a study is included in the NICRN portfolio it will have to be assessed against the following criteria:
  - Is the study fully funded?
  - Has a sponsor been identified?
  - Has the study had robust Peer Review?
  - Is the clinical research of clear value to the Health Service?
  - Does the study align with NICRN clinical and strategic priorities?
  - Is it feasible for the study to be conducted at one or more NICRN centres?
- Footer:** Return to the NICRN Home Page (with a house icon) and the r&d office logo.

## A second successful year for the Northern Ireland Clinical Research Network (continued)

Cancer Trials Centre and Network, an accredited clinical trials unit, and clinical research facilities all aid Northern Ireland-based researchers to design and conduct clinical research of the highest national standards within the HSC environment.

To ensure a strong programme of activity and efficient use of the core staffing resource, each interest group agrees a series of annual objectives that are based on activity, staffing levels, previous outcomes and planned

developments. Study portfolio and patient accrual are the key performance targets applied and are broadly in line with metrics used elsewhere in the UK.

The table below illustrates the overall NICRN portfolio and accrual for each interest group. In 2010 a total of 95 studies were run by NICRN staff of which 32 were newly adopted during the year. Of the 9850 patients who have been accrued in total into these studies, 6876 were accrued during 2010.

Interest group	No. studies adopted	Total patients accrued
Cardiovascular	17	1123
Children's	12	1136
Critical care	9	1344
Dementia	5	529
Diabetes	13	3540
Primary care	9	836
Respiratory	13	183
Stroke	10	289
Vision	7	870
<b>Total</b>	<b>95</b>	<b>9850</b>

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## Benefits of Personal and Public Involvement in research

HSC R&D is implementing its Personal and Public Involvement (PPI) strategy. As we encourage researchers to work closely with service users and encourage people to get involved, it is important to understand how PPI can be organised to benefit research.

The Northern Ireland Cancer Trials Centre (NICTC), based at the Belfast Cancer Centre, has been at the forefront of implementing PPI. The feedback below was provided by Sister Ruth Boyd and contains some great insights into the value that can be contributed by consumers.

She said: "Having consumer involvement in the research activities coordinated by the NICTC has not only enhanced the work we're doing, but brought about a new culture. In fact, it would be true to say that while we always knew we needed consumer involvement in cancer research, we hadn't foreseen just what we'd been missing out on!

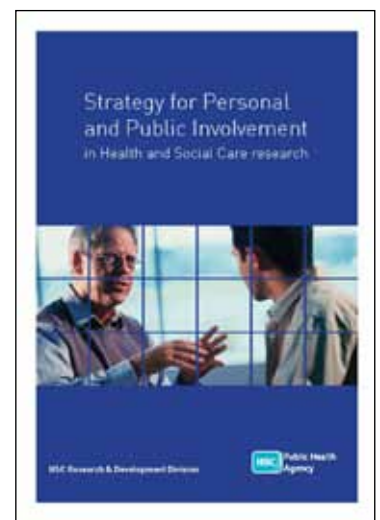
"The patient perspective is now more central at meetings and this perspective is invaluable across various stages of the study lifecycle. There is a breadth of work – really too much for one person, which is why we'll soon be on a recruitment drive to increase consumer numbers."

The work that has been done includes:

- Review of protocols and patient information sheets developed by local Chief Investigators (CIs). All comments to date have been adopted by the CIs and have enhanced the patient information. Here are examples of what has been identified in patient information sheets:
  - Take out any non-essential scientific jargon and provide a glossary for any that is essential;
  - use plain English;

- make sure the information includes what will be important to someone, eg timelines for finding out diagnosis.
- Review and comment on patient and public materials about cancer research, for local booklets, websites etc.
- Review and comments adopted for the Northern Ireland Biobank patient information sheet.
- Placing consumer representatives on the NICTC coordinating committee, steering group and executive committee.
- Representing Northern Ireland on the National Cancer Research Institute consumer liaison group.
- Responding as a consumer to the UK consultation on the PPI strategy for Experimental Cancer Medicine Centres.
- Collaborating on the draft PPI strategy for cancer research in Northern Ireland and developing the Northern Ireland Cancer Research Consumer Forum, planned as part of the strategy.
- Producing a webcast on the consumer perspective for a lecture as part of clinical trials module at Queen's University Belfast.

You can read the HSC R&D strategy for PPI on the PHA website, [www.publichealth.hscni.net](http://www.publichealth.hscni.net)



## Medicines Management

The team at the Pharmacy and Medicines Management Centre at the Northern Health and Social Care Trust have been actively involved for many years in research and development to improve the delivery of clinical pharmacy services. A key focus of their work is medicines management: seeking to maximise health through the optimal use of medicines.

One recent innovative project undertaken by the team has resulted in the NHSCT receiving income of £50,000 from Hospital Metalcraft Ltd for their work to develop a new locker system for use at the patient's bedside. The keyless lockers facilitate safer storage and administration of medicines and in the future will permit self-administration of medicines by patients. The locker was developed as part of the national award winning Medicines Management Programme in Antrim Hospital

Hospital Metalcraft Ltd designers worked with both pharmacy and nursing staff within the NHSCT to ensure that the locker meets the needs of patients, nursing staff and the statutory storage requirements for medicines. The main advantages of use of the lockers are:

- reduced medication error rates compared to the traditional trolley system;
- elimination of multiple keys via digital lock;
- enhanced security via computerised monitoring of locker use;
- improved ability to effectively disinfect.

Professor Mike Scott, Head of Pharmacy and Medicines Management at the NHSCT, noted that this was one of several joint health service private sector initiatives being

undertaken by the team. The projects are all linked to aspects of medicines management and contribute to reengineering the pharmacy workforce and systems relating to medicines management.

Dr Des Rooney, NHSCT Director of R&D, said that this particular collaboration was representative of the Trust's commitment to the development of innovative ideas to improve healthcare working with industrial partners.

Mr Ian Farnfield of Hospital Metalcraft said: "The help of the Trust's employees in enabling us to evaluate our designs and to react to



Sean Donaghy, Chief Executive of the NHSCT, is pictured receiving a cheque for £50,000 from Ian Farnfield, Sales Director of Hospital Metalcraft Ltd, in recognition of the NHSCT's contribution to the development of a keyless locker system. The locker system facilitates storage and administration of medicines at the patient's bed-side, and includes self-administration ability.

# Success in research and development

## Medicines Management (continued)

practical medical input was very useful to us in this project. We have many decades of experience in designing and manufacturing hospital equipment but the practical advice given by your staff enabled us to achieve a very useful result in this project.”

Professor Bernie Hannigan, Director of HSC R&D for Northern Ireland, congratulated the NHSC and said: “It is excellent to see how knowledge and experience gained within the health sector can contribute to the province’s business development.”

For HSC Innovations, Dr Brownlee worked closely with Hospital Metalcraft Ltd in securing the agreement for this payment to the NHSC and he indicated that this was an excellent example of how the HSC sector can work with the private sector. Dr Brownlee encouraged HSC staff with innovative ideas to improve patient care to contact HSC Innovations for support in developing ideas into products that will ultimately lead to patient benefit.

The Centre for Pharmacy and Medicines Management is actively involved in research and development on all aspects of medicines management and is involved with industrial

partners in some of this work. The centre has won national awards for its work and has published widely in peer-reviewed journals as well as at conferences worldwide. The centre has links with Sweden, The Netherlands and Republic of Ireland in this regard.

Centre for Pharmacy and Medicines Management,  
1st Floor,  
Beech House,  
Antrim Area Hospital Site,  
45 Bush Road, Antrim  
BT41 2RL.  
Tel: +44 (0) 2894 42 4945

HSC Innovations provides an innovation management service for Health and Social Care employees throughout Northern Ireland, ensuring that ideas that have the potential to improve patient care or offer benefits to healthcare providers are developed.  
[www.hscinnovations.org](http://www.hscinnovations.org)



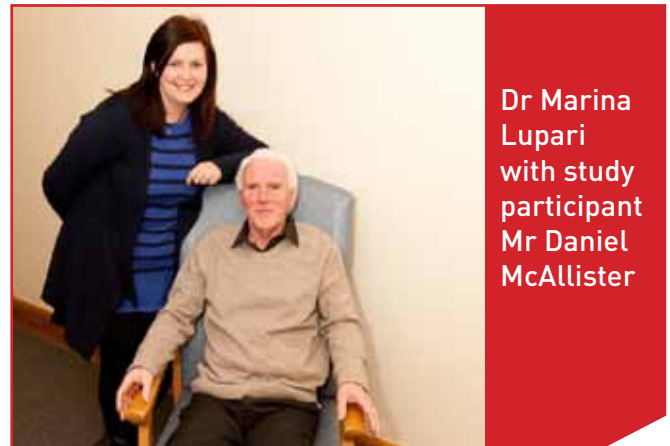
## HSC R&D Fellowship leads to RCN innovation award and £400,000 savings for the HSC

Earlier this year it was widely reported that Marina Lupari of the Northern Health and Social Care Trust had won the inaugural Royal College of Nursing (RCN) Frontline First Innovation Award through the research she undertook as part of her HSC R&D Doctoral Fellowship. This article provides some more information on Marina's work that was recognised by this award.

Marina's Doctoral project was *An evaluation of the effectiveness and cost-effectiveness of a case management approach for chronic conditions in a community healthcare setting*. This study confirmed that if care is provided to the right patient, at the right time, using the right professional intervention, the most effective and cost-effective outcomes will be achieved.

The research focused on the evaluation and promotion of a nurse-led community service that has greatly reduced unplanned hospital admissions among older people with long-term health conditions, with significant financial savings for the HSC. Marina undertook a non-randomised comparative study in which 50% of service users received routine care while the other half received a chronic illness case management service (CICM) intervention. Sixteen full-time nurses were recruited to deliver the specialist care for patients with serious respiratory problems, heart failure and diabetic conditions. Nurses were provided with additional education and support in working with high-risk older people in their own homes in order to manage their multiple chronic conditions.

The outcome was that hospital bed days were reduced by 59% in the CICM group. These patients also reported feeling better and said that support from the CICM allowed them to function more effectively. The difference in average cost



Dr Marina Lupari with study participant Mr Daniel McAllister

per patient was also £1,493 lower for those who received the CICM service, representing a total saving of more than £400,000 across the nine month follow-up period.

For this work, Marina came first out of 300 nominations from across the UK for the RCN Frontline First Innovation Award. The award was presented at a ceremony in London in January and comprises a commemorative award and funding to assist in further developing the project within the Northern Trust.

Marina said: "I am delighted to win this prestigious award. The main principle behind this innovation is proactively to manage the patient's identified risk factors, which prevents deterioration and therefore avoids unplanned hospitalisation. It's about working out when patients are showing the early signs of being sick and then giving them the tools to help rectify the problems."

Marina carried out this University of Ulster doctoral project under the supervision of Professor Vivien Coates, Institute of Nursing Research, and Professor Gary Adamson, Psychology Research Institute. She has now successfully achieved her PhD.

# Noticeable achievements

## Bamford implementation - rapid review

Lead applicant	Review topic
Professor Brendan Bunting	Personality disorders

## Adding value - Knowledge Transfer Awards

Lead applicant	Project title
Dr John Winder	Breast cancer reconstruction: communication and information using novel digital technologies

## HSC R&D Doctoral Fellowships 2011

Lead applicant	Project title
Dr Michael Moran	Differences in gene methylation due to human papillomavirus infection in oropharyngeal squamous cell carcinoma
Dr Gareth Irwin	Molecular characterisation of poor prognosis triple negative breast cancers

Clinical

Lead applicant	Project title
Mrs Geraldine Conlon	An investigation into the effect of an antibiotic cycling policy, based on retrospective time series analysis data, on the incidence of hospital acquired MRSA and CDAD
Ms Una St Ledger	Moral distress in end of life care in the intensive care unit

Health and social care

### GPARTS Award 2011

Successful applicant

Dr Michael Aicken

### Cochrane Fellowships

Lead applicant	Review topic
Dr Jacqueline Casey	Wheeled mobility for children (0-11 years) with physical impairment
Dr Cherith Semple	The effectiveness of psychosocial interventions for patients with head and neck cancer

### Cochrane systematic review - Family Nurse Partnership workstrand

Lead applicant	Review topic
Professor Geraldine Macdonald	Intensive home visiting programmes for socially disadvantaged mothers

### Ireland - Northern Ireland NCI Cancer Consortium Award

Successful applicant

Mrs Eileen Dillon



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and Public Safety**

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**For further information please contact:**

HSC Research & Development Division  
Public Health Agency  
12-22 Linenhall Street  
Belfast  
BT2 8BS

Tel: 028 9055 3617. Fax: 028 9055 3674. [www.publichealth.hscni.net](http://www.publichealth.hscni.net)

Produced by the **Public Health Agency**, Ormeau Avenue Unit, 18 Ormeau Avenue, Belfast BT2 8HS

Tel: 028 9031 1611. Textphone/Text Relay: 18001 028 9031 1611

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