

Research update at University Hospitals of Morecambe Bay

The editor is grateful to Kay Gilbey, assistant director of nursing, for her assessment of the future of the trust's research and the role its research practitioners have to play.

Historically, University Hospitals of Morecambe Bay Trust (UHMBT) has received very little research funding; ten years ago funding from the Department of Health was £30,000. Despite this, we have developed pockets of excellence, for example the patient safety research of Professor Andrew Smith. However, the opportunity for our patients to participate in first class clinical trials has been limited.

'Operating Framework 2009-2010; High Quality Care for All'⁽¹⁾ made it clear that innovation has to be at the centre of the NHS if we are to increase the quality of care; health research is key to this. The framework states, 'providers of NHS care will need to increase their participation in research. The national ambition is to double the number of patients taking part in clinical trials and other well-designed research studies within five years.'

The development of the Comprehensive Local Research Networks (CLRN) has significantly changed the situation at UHMBT, as can be seen by the following article. The trust now has an annual research budget for national portfolio trials of over £400,000. Clinicians who were previously unable to participate in trials due to lack of funding for research practitioners (RPs) and support services are now able to do so.

This is an exciting time for research at UHMBT, with the opening of a research suite at both Furness General Hospital (FGH) and Royal Lancaster Infirmary (RLI), and the appointment of RPs. The evident enthusiasm and willingness of the RPs to take on new challenges and develop new skills will help the trust to achieve its mission statement: 'The needs of our patients will drive everything we do.'

INTRODUCTION

Over the last 12 months a thriving research culture has begun to evolve within UHMBT. In addition to an already well-established, experienced cancer research team an additional nine speciality RPs have taken up posts. Their role has been to further develop ongoing investigations and/or to instigate new areas of research within specialities along with the principle investigators (PIs) leading the clinical teams. You will see from the following reports from some of our RPs that, depending on a range of factors, it can be a very different experience for each of them and also varies as time goes by. Like all jobs, things are sometimes surprisingly successful and sometimes disappointingly slow.

With the Research and Development (R&D) department a supportive research environment has resulted. Some of the RP roles are in areas of medicine for which there are established topic-specific networks, whose staff give added support. This can be in the form of site visits, distance mentoring or regional meetings and conferences which offer additional help and sources of information and expertise.

As well as the seven topic-specific networks, we are part of the Cumbria CLRN. All of these are organised on a national scale, giving us access to a range of support including specialist training sessions and RP cover.

Across the country speciality and comprehensive research networks are in collaboration giving rise to large scale research, enabling environmental and geographical factors involved in disease to be explored also.

We must not forget that patients and the public are the focal point of research, which we hope will provide them with access to research suited to their disease/condition and offer them opportunities for advancing care and treatment.

RESEARCH UNDERTAKEN

Palliative Care Research Specialty Group goes from strength to strength

Study and development of end-of-life care continues to grow at St John's Hospice as the palliative care research team, led by Professor Mike Bennett, works closely with their network of research staff from Trinity Hospice in Blackpool and St Catherine's Hospice in Preston.

Recruitment on the Prognosis in Palliative Care Study (PiPS) closed in autumn 2009 with the successful recruitment of 51 patients from two sites (Lancaster and Blackpool). The key achievement of this study was the recruitment of non-competent patients.

Hospice recruitment onto the first industry-sponsored trial went well. SPRAY (a randomised controlled trial (RCT) with placebo arm of cannabis for poorly-controlled cancer pain) was adopted onto the National Institute for Health Research (NIHR) portfolio and the research team recruited two participants and were amongst the top four recruiters in the country. As a result plans are afoot for the St John's team to recruit on to further cannabis trials later in the year.

Since the New Year we have been setting up for three major projects:

- a feasibility study of a handheld fan for breathlessness
- KPS – an RCT of Ketamine in conjunction with best pain management in neuropathic pain in cancer
- Modafinil – a trial of Modafinil for fatigue in lung cancer

Thanks to the hard work of our pharmacy and hospice colleagues we have established a process for dispensing, storing and reconciling trial medication remotely from the hospice.

In addition Mandy Hughes (Clinical Trials Manager) and Gail Wiley (RP) presented a poster at the Help the Hospices Conference in November 2009 and also at the NIHR Research Network National Conference this January. Gail Wiley shared experiences and challenges of palliative care research at the CLRN Conference last October, at a recent education session of specialist registrars (SpRs) in Bolton Hospice and at the Palliative Care Link Nurses meeting at Crooklands in May. Gail is looking forward to sharing the new facilities at RLI, enabling her to link in with the growing RP community.

Work goes on in collaboration with the CLRN to develop standard operating procedures for clinical research that can be adopted by hospices, and our clinical trials manager continues to work to clarify issues of indemnity for research in hospices and overcome a number of other challenges related to ethics and research governance in non-NHS sites.

When trials are being set up progress can feel slow but a review of the last year's work shows success, good progress and lessons learnt.

Mandy Hughes, Gail Wiley

Oncology

There is much potential for developing oncology clinical trials work in Morecambe Bay. It is hoped that an increase in research staff will allow us to recruit to haematology and urology studies and to increase even further our recruitment to epidemiological studies. Currently the team is successfully recruiting to lung, breast, colorectal and upper GI studies.

Oncology clinical trials at Morecambe Bay are conducted at three hospital sites: FGH; RLI; and Westmorland General Hospital (WGH). There is an enthusiastic research team with Dr Gerry Skalles and Dr David Fyfe working at Barrow and Lancaster and Dr David Eaton at Lancaster. Claire Bartlett is the fulltime oncology RP at Furness. The oncology research team at RLI are RPs Clare Tibke and Samaher Swaitti and data manager Mary Robinson. There is invaluable support from our clinical trials pharmacy technicians Vickie Eddowes and Andrew Taylor.

We currently have 17 clinical trials open to recruitment and numerous patients on longterm follow-up. In order to start recruiting to a new trial a detailed feasibility study is completed, assessing the involvement and support needed from other departments. It can take six months or longer from first considering a trial to recruiting the first patient.

The oncologists are the PIs or co-investigators and have ultimate responsibility for the correct running of the studies in compliance with good clinical practice. The nurses are involved in identifying suitable patients and ensuring that they receive appropriate written and verbal information about the study. This is part of the informed consent process and is ongoing as

long as the patient remains in the trial. The oncologists are fundamental to this process and ensure the patient's full understanding before the consent form is signed. The nurses liaise with the patient and ensure that all the requirements of the various protocols are met. This includes initiating investigations and recording the data. The data manager is invaluable in managing the numerous clinical trial amendments and complicated site files, working closely with the trust's R&D department and clinical trials sponsors. Together the team develops strategies for the longterm follow-up of patients and managing the large amount of data generated.

Clare Tibke

Samaher Swaitti joined the oncology research team in January 2010. This is not her first experience as a research nurse, as before this appointment Samaher worked in Leeds for almost two years on renal oncology studies.

My aim in this role is to relieve some of the pressures of a demanding work load by supporting and working with the rest of the team, as well as to contribute to improving the organisational quality of the studies and increasing the accrual into oncology clinical trials.

Working as an RP is very exciting: I am never bored. This job allows me to combine my clinical expertise in nursing with an in-depth knowledge of the research projects. My role includes running the day-to-day research activities and assisting the clinical investigators. I also support the patients through each stage of the study. I use my skills to provide accurate data collection as well as to ensure that we are compliant with national and local research regulations. Interestingly, I am in a unique position of being an advocate for both the research subjects and the principal investigators.

This unique job has provided me with many education and training opportunities which have enhanced my understanding of the research environment and its challenges. I have been able to develop and improve my communication, organisational, and administrative skills. My confidence in dealing with complex and difficult situations has also developed significantly.

Being an RP has kept me motivated, even during challenging times. I have found myself and discovered my potential.

Samaher Swaitti

Critical care

I'm Jayne Craig and I am the critical care RP at RLI, which means I try to support the research efforts of the Emergency Department (ED), Intensive Care Unit (ICU) and anaesthetics/theatres. I came into post at the beginning of March and by the end of April we launched a research project studying acute severe asthma in ED. The clinical trial is called 3Mg and our PI is Dr Andy Webster. This is the first research project run in the ED here for quite some time and therefore you might be fooled into thinking that it would take a while to achieve a research-oriented culture in a busy clinical setting. The opposite has proven to be true: all the ED staff were immediately involved in surveillance, which was evident by the number of patients proposed as potential study candidates. In the first full week following the study launch we managed to recruit two patients, which is pretty good going considering we are only expected to see one potential candidate a month based on statistical averages.

This is just one testament to the excellent teamwork and high level of proactive patient care standards in our ED. It is also testament to the expertise, efficiency and speed with which the UMBHT R&D department works.

Clinical trials in both ICU and theatres are in the pipeline and I'm really looking forward to them starting. The FIRE study (Fungal Infection Risk Evaluation) is due to start in ICU in June with Dr David Highley as our PI. For anaesthetics/theatres, Dr Ian Parkinson is working towards laying the foundations for the ENIGMA II clinical trial to start later in the year.

The ENIGMA II trial is an international randomised control trial looking at whether nitrous oxide, a commonly used anaesthetic agent, is responsible for causing increased cardiac morbidity in those undergoing general anaesthesia for non-cardiac surgery.

It is interesting to note that none of this has seemed like hard work for me because the people involved are so enthusiastic; everything seems valued and that is truly infectious.

Jayne Craig

Dermatology

During more than 14 years of dermatology nursing experience my work has changed continuously, evolving from inpatient care to leading a nurse-led skin lesion treatment clinic. I've been lucky to have new challenges, including now taking on the role of RP for dermatology.

Part of my hours I work as a dermatology nurse and the rest for R&D. This suits me as I have the best of both worlds – keeping up to date with nursing practice and gaining an insight into research. I like the variability and am even able to continue to do the odd bank shift on the community, which is a complete change.

I've been in the research post for five months and have got my teeth into a study now. The study, British Association of Dermatologists Biologics Interventions Register (BADBIR), is very relevant to changes in practice and monitoring the safety of patients' treatments. The study compares the new biologic treatment with the more conventional systemics. It is a national study run from Hope Hospital in Manchester and information is needed from people with severe, chronic psoriasis from all over the UK, so we're making our contribution of data from the Morecambe Bay area. Some patients are quite keen to take part as the research has implications for the future treatments of people with chronic, disabling psoriasis. I'm looking forward to recruiting more patients and considering taking on another research project. I'm choosing the most appropriate project to undertake from the national portfolio of research studies. At the moment I'm looking at one concerning the elasticity of the skin in patients with eczema but there are many to choose from. Factors to think about are the relevance of the study and ease of recruitment... watch this space!

Jennifer Riley

Gastroenterology

I'm Jill Conder and I'm the gastroenterology RP for UHMBT. I'm responsible for recruiting to clinical trials specific to gastroenterology across the three sites. I have now been in post for 12 months and recruit to three studies: BOSS (Barrett's Oesophageal Surveillance Study); NSAID-Induced Peptic Ulcers; and PBC Study (a genetic study into PBC). I also provide follow-up care for another one – Aspect. The PI for all these trials is Dr Andy Higham. Recruitment to all three is going really well and for BOSS we received a Gold

Certificate for recruitment at the recent British Society of Gastroenterology conference in Liverpool. We're hoping to open further trials in the future when they present themselves.

I have recently moved into the new Ashton Suite at RLI and base myself there four days a week now. This has improved my working day greatly; I'm closer to my recruits, primarily in endoscopy and the outpatient department, but also to colleagues with whom I work closely. It has a recruiting room, which is fantastic. For the last 12 months I've been using rooms around the hospital at the discretion of other departments, which can get tiresome. So the new suite is very valuable to me.

I'm now looking forward to a further 12 months of research and recruitment and hopefully some new studies also.

Jill Conder

Diabetes

The diabetes team recruited their first participant to an epidemiological study in November 2009 called Diabetes Alliance for Research in England (DARE). Initially this study was set up in the southwest peninsula, creating a cohort of people with all types of diabetes willing and ready to embark on clinical research. DARE has since been adopted in networks across England, the aim being to recruit all willing people living with diabetes. Each participant is invited to donate blood for DNA analysis which is extracted at local university research centres and stored for further study. Questions for further investigation will be asked on knowledge gained from genetic analysis along with biomedical data collected at time of recruitment, giving rise to specific relevant study of an escalating disease of several new variants.

In addition, geographical and environmental factors can be explored across a wide range of socio-economic cultures. To add further dimension to the research process that derives from DARE, control subjects will be recruited living with or close to their relatives/friends with diabetes to support geographical and environmental findings. This is one example of how the research networks can work together with universities and NHS trusts. To date 60 patients have joined during clinic visits at RLI. What is needed now is extension of RP time to recruit, as numbers of people living with diabetes willing to be involved exceed current capacity to recruit.

Controversy over benefits of aspirin in primary prevention of cardiovascular disease in diabetes over recent years has resulted in ASCEND (A study of Cardiovascular events in Diabetes). This is the largest study conducted looking into benefits of aspirin and omega 3 in primary prevention versus risk factors associated with aspirin use. Three general practitioner surgeries within the area are also conducting ASCEND, which is coordinated from Oxford. A sample size of 10,000 patients was the aim across England, each taking part for five years, randomised to aspirin and omega 3 or placebo, a double-blind 2 x 2 factorial design. This study has taken off extremely well and 10,000 patients are now in the study and sample size has increased to 13,000 for now and may be extended to 15,000 enhancing the weight of the results.

Work continues into prevention and treatment of Type 1 diabetes. To support this After Diagnosis Diabetes Research Support System (ADDRESS) has been adopted at RLI. Whilst newly-diagnosed patients with Type 1 diabetes are inpatients they are introduced to the study. Once they have had time to

consider and are discharged home they are invited to join. This can be a difficult time for them with a new diagnosis of a lifelong condition, but, once again most are very receptive, pleased to have the opportunity to get involved with research and are recruited from their home if they wish.

ADDRESS is designed for children aged five years and above as well as adults, the only exclusion being any incapacity within the consent process for parents or adults. To date only adult patients are being invited as we get the study off the ground. Recruitment must be within six months of diagnosis. Like DARE this study is a cohort of people willing and ready to embark in research looking at therapies other than insulin in preservation of beta cell function or that affect beta cell regeneration in the early stages of the disease when there is only partial destruction of the beta cells. Therefore, recruitment must be soon after diagnosis increasing feasibility of early intervention trials.

Now that we are familiar with the research arena we are looking into interventional studies in the area of diabetes which could take us in many directions working with a multifaceted disease.

We are fortunate to have a new research facility at RLI. The Ashton Suite on the Bromley Corridor provides clinical space for patients and their research team, as well as IT equipment for the RPs to work with. Across the road in Pointer Court, within the new R&D department, are further offices for RPs now that the team has expanded. Here the R&D team are on hand to support research work within and around Morecambe Bay.

Diabetes could be described as the epidemic of the next millennium. Therefore, work put in now to extend our knowledge and offer prevention and cure is well worth the effort. 'Health research provides us with the means to tackle the increasing challenges that disease and ill health are placing on our society.'⁽²⁾

Janet Singleton

Stroke research

With Dr Pradeep Kumar as the PI, we have for the past 12 months been developing stroke research, in particular research in acute stroke, at RLI. This has been developed as part of the regional Northwest Stroke Research Network research portfolio.

We are currently undertaking the ENOS trial (Efficacy of Nitric Oxide in Stroke) looking at the efficacy of GTN in lowering BP in acute stroke. We recruited our first participant in June 2009, and are so far meeting our recruitment target of one participant a month. We have also started the SOS (Stroke Oxygen Study) in February, and are currently working on R&D approval for the CLOT3 trial, looking at the effectiveness of intermittent pneumatic compression to prevent post-stroke DVT, and also hope to be doing ICONS (a stroke rehab study looking in particular at continence management post-stroke) by this autumn.

In my capacity as the stroke RP, I also prioritise my 'outreach work', which involves visiting the ED and the Medical Admissions Unit on a daily basis. This is aimed at ensuring early patient identification and timely transfer of stroke patients to the stroke unit, both very important factors in maximising recruitment to our trials.

Charlotte Culmsee

Cardiology

My name is Peter Wilson. I was successful with my application for a part-time secondment to the temporary position of RP for cardiology for UHMBT and came in to post on 1 March 2010.

I will be based in the R&D department at RLI, in either the new offices at Pointer Court or in the new Ashton Suite within the main hospital complex, whichever is the more practical at the time. I am hopeful that the position will also allow me to travel to FGH, to work in the new Walney Suite, and possibly WGH as we progress with our participation in research studies.

Up to now the process of applying for and being accepted on to research studies has been frustratingly slow. My post is funded by the Cumbria and Lancashire CLRN, based at Preston, and as such I should be involved with studies which are posted on the NIHR portfolio website. Unfortunately the website is sometimes a little out of date and the information on there can be erroneous, which leads to more delays.

I've been strongly supported in my new role by Janet Myerscough, (research governance facilitator), and my peers. Although a research module was part of my degree course it doesn't prepare you for a role like this, so the ongoing help and guidance has been welcome and much appreciated.

With the help of the staff on the Critical Care Unit at RLI we have just started to work on a study, led by Linda Harrison (clinical scientist), looking for the presence of staphylococcal toxins in the body at the time of a suspected heart attack. We will also be starting to work on a study run by Professor Munir Pirmohamed from Liverpool University very shortly. For this study Dr Adrian Brodison is our PI. We will be looking at the 'Pharmacogenetics of Acute Coronary Syndrome'. We will start this project at RLI and then, with Dr Ayaz Mohammad acting as our local collaborator, we will start to recruit patients from FGH as well.

We are looking at the suitability of the CRONOS study; this is a 'Cross Sectional Survey on the Initiation of Drugs with Antiarrhythmic Properties in the United Kingdom'. This will be based around the introduction of the drug dronedarone. Dr Mohammad is hoping our application to join the TRILOGY study continues successfully; this study is 'A comparison of Prasugrel and Clopidogrel in Acute Coronary Syndrome (ACS) subjects with unstable angina/Non-ST-Elevation Myocardial Infarction (UA/NSTEMI) who are medically managed – the TRILOGY ACS study'. We are also on the lookout for more studies relating to the implantation of bi-ventricular pacemakers for Dr Brodison.

After a very slow start I'm hoping that we will now begin to progress and expand the cardiology research activity within UHMBT.

Peter Wilson

Rheumatology

I commenced a one-year secondment to the post of rheumatology RP in February 2010, having worked as a rheumatology specialist nurse for three years.

My PI, Dr Marwan Bukhari, has always been very keen to involve our department in current research projects, and this

secondment has given me an opportunity to commit time to research and commence additional studies and trials. I am very grateful to the whole rheumatology team, and especially my rheumatology line managers, Anne Craig and Lee Doyle, for their support and encouragement in allowing me to take this secondment.

Our current studies and trials include:

- BRAGGS – To evaluate the role of genetic variation in determining response to treatment with biologic therapy, for patients with rheumatoid arthritis (RA)
- TRACE RA – To assess the hypothesis that atorvastatin is more effective than placebo in the primary prevention of cardiovascular events in patients with RA
- TRACE RA Biobank sub study – All patients participating in TRACE RA will be invited to donate blood samples to the TRACE RA Biobank, which will identify DNA, serum and plasma variations
- TACIT – To assess if patients with active RA who meet NICE criteria for TNF inhibitors will gain equivalent benefits from intensive conventional drugs at less expense without more toxicity
- BSRBR – British Society for Rheumatology Biologic Register
- BSRBR control register – For RA patients not on biologic therapy
- GO-MORE – Open-label, multinational, multicentre, prospective trial of Golimumab in biologic-naïve RA patients
- Rituximab study – Observational study in RA patients who are switching to second biologic therapy
- Ankylosing spondylitis genetic study – To investigate the genetic factors predisposing certain individuals to develop ankylosing spondylitis
- Psoriatic arthritis genetic study – To investigate the clinical, serological and genetic factors predisposing certain individuals to the development of psoriatic arthritis.
- ERAN – Early Rheumatoid Arthritis Network

Bronwen Evans

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