The Whittington Hospital
NHS Trust

R&D ANNUAL REPORT 2002/03

EXECUTIVE SUMMARY

Research Activity at the Whittington Hospital

The Whittington Hospital NHS Trust hosts on average 60 new research projects per year. These are a combination of local and multicentre research projects that are either led by the Whittington Hospital or by other NHS or academic organisations with which we are collaborating. Of these projects there is range of commercially sponsored trials, non-commercial externally funded studies and own-account studies (no external funding).

The number of clinical trials has significantly reduced over the past couple of years although plans to establish a joint Trust/UCL Clinical Trials Unit on the Archway Campus will lead to an increase in this type of activity. Over the past six months there has been a significant rise in the number of Cancer Trials at the Whittington, which is due to an increased capacity within the Oncology Department to co-ordinate and host cancer trials on site. The Oncology unit now has a full-time dedicated Clinical Research Associate funded by the North London Cancer Research Network who is taking this work forward.

There has been a recent decrease in "own-account" research at the Whittington, which is a direct result of the DH's new criteria for NHS R&D. Under the new funding system the Trust is no longer able to support "own-account" research and must promote research activity that is externally grant funded and/or forms part of a coherent programme of research. The R&D department closely scrutinises all new research proposals to determine what R&D activity the Trust is both able and prepared to host in light of this guidance.

	2001/02	2002/03
Local projects (LREC)	48	42
Multicentre projects (MREC)	9	16

	2001/02	2002/03
Commercially Sponsored Trials	3	6
Non-commercial externally funded studies	29	28
Own account research (no external funding)	25	24

Overview of NHS R&D Funding System

Over the last few years the Department of Health has significantly reformed the NHS R&D Funding System. The former system, known as R&D Levy 1 & 2 that was based on the Culyer report recommendations, has been replaced by two new funding streams:

- NHS Support for Science (SfS)
- NHS Priorities and Needs (PNF)

NHS Priorities and Needs R&D funding is intended to meet the costs of research and research capacity (such as supporting PhD students) through NHS Priorities and Needs R&D. NHS Support for Science is intended to provide funding to meet the NHS costs of supporting non-commercial research, including, in future, research with agreed NHS Priorities and Needs R&D Funding.

Data for the development of the NHS Support for Science system has been gathered by the DH over the past 2 years and information to support the ongoing development of these two funding streams now forms a major component of the Trust's R&D annual report to the DH.

In order to be eligible for SfS Funding NHS organisations must be engaged in external grant funded R&D. For NHS Priorities and Needs Funding, NHS organisations must demonstrate that their research activity is structured as a research programme. A research programme, as defined by the DH, is as follows:

A research programme must be collaborative (meaning it must involve a minimum of one NHS and one academic organisation, e.g. Whittington + UCL). It must involve 3 or more projects that are coherent and integrated. It requires a leading expert with a track record in the field. It must have an identified sponsor (as defined below) and adhere to Good Clinical Research Practice and Research Governance. The results of any research must be available in the public domain either through publication or presentation.

A positive aspect of the requirements of a research programme is that research is required to be 'capacity building', meaning that an identified researcher could be employed to undertake a studentship, PhD or MD.

A sponsor, as stipulated by the DH, is an organisation that has declared itself willing to act as a research sponsor. In doing so it accepts the responsibilities of sponsor, which essentially means that it agrees to ensure the necessary systems are in place for the research to be carried out safely and properly.

The Whittington Hospital's Research Programmes

Last year the Trust's R&D Department identified five areas where research activity at the Whittington was strongest and could be organised into research programmes according to DH criteria. These five programmes have

continued to develop and strengthen with some new projects and grants underway. This year a new Clinical Sciences Programme has been established. A summary of these programmes is outlined below.

1. Cardiology Department: Heart Failure Across Primary and Secondary Care

This programme of research is made up of a number of ongoing projects led by Dr Suzanna Hardman, Consultant Cardiologist at the Whittington Hospital, in collaboration with various academic institutions. Since last year the programme has changed to accommodate expansion and the title of the programme has been revised to reflect the broader programme. The following studies now make up this programme:

a) Accurate and early diagnosis of heart failure in the community: This research is investigating the use of B-type natriuretic peptide as a useful diagnostic tool in screening for heart failure and thus preventing the need for echocardiography.
b) The evaluation of nurse-led intervention to improve self-management of patients with heart failure: This study aims to show whether nurse-led intervention can lead to a reduction in admissions, morbidity and mortality.
c) A number of projects are underway to examine psycho-social and psychological intervention in determining outcome from coronary heart disease. These are being conducted in collaboration with the UCL Department of Psychiatry and Behavioural Sciences.
d) Participation in the NHS Modernisation Agency's Coronary Artery Disease Collaborative Heart Failure Initiative.
e) A study of the methods for ensuring best clinical practice.
f) A pilot study, in preparation for an application to the British Heart Foundation (BHF), of the pathophysiology of arrhythmias in heart failure.
g) A BHF funded study exploring the causes of the progression of left ventricular hypertrophy into left ventricular failure.
h) A grant proposal to the DH has been short-listed, "The DH/BHF Heart Failure Research Initiative".

2. Cardiology Department: Electronic Health Records in Cardiovascular Disease

This is a clinical software development project. The aim is to create a secure electronic patient record that can be accessed through the NHS Net. Staff in secondary and primary care have access, as do patients. The records interact with an expert system that guides management decisions based on the data entered. An early prototype allows patients and pharmacists to supervise anticoagulant treatment using data from coagulometers of standard clotting studies. Modules adopting similar principles are being developed for heart failure and chest pain.

It is hoped that in time this system will be able to operate over an IPv6 Wireless Internet facility.

3. Department of Medicine: Incontinence Sciences Programme

The focus of this programme, led by Professor James Malone-Lee, is to study the clinical management of urinary incontinence including the pathophysiology, diagnosis, treatment and containment through the use of absorbents. The programme is made up of a number of external grant funded research projects, which are split across two main themes:

a) The development of absorbents and devices for the incontinent patient aims to produce products that function efficiently and ergonomically

b) Clinical incontinence studies – this work is designed to simplify the diagnosis and management of urinary incontinence with the intention of simplifying care and reducing laboratory service demands.

4. Haematology Department: Developments and Improvements in the Clinical Management of Thalassemia Major

The pioneering research that has been carried out by Dr Beatrix Wonke in the Whittington hospital over the past 40 years has significantly changed the clinical management of Beta Thalassemia major world-wide. As a consequence, the Whittington hospital has become a national and international referral centre for Thalassemia Major. The studies performed have led to the treatment of Hepatitis C, the use of bisphosphonates in osteoporosis, the use of oral iron chelating agents and the introduction of magnetic resonance imaging as an advanced tool for the quantification of tissue iron overload in Thalassemia.

This ongoing programme of research currently includes the following research themes:

a) The use of novel chelating agents in the treatment of iron overload in patients with Thalassemia Major.
b) The use of magnetic resonance imaging as an accurate assessment of cardiac and hepatic iron overloading.
c) The use of double dose red blood cells for transfusion in Thalassemia.

5. Women's Health: Improvements in Cervical Screening

The main focus of this programme of research, led currently by Professor Albert Singer, is concerned with the development of new technologies in order to improve existing methods of cervical screening. There are three main areas of research related to cervical screening:

a) The development and evaluation of a real time screening device. This is an ongoing clinical trial to compare its efficacy with conventional

cytology. This real time screening device provides immediate results and thus reduces the anxiety for women undergoing cervical screening.

b) Evaluation of a genetic transcription factor (Brn3a) in cervical smear material to identify high-risk patients.
c) A longitudinal study to evaluate the sensitivity and negative predictive value of human papilloma virus (HPV)-DNA as a primary screening strategy for cervical cancer.

6. General: Clinical Sciences Programme

This year the R&D department established a new Clinical Sciences Programme that draws for its method on good whole-body physiology, or an alternative discipline. The Trust wishes to encourage clinical research that addresses symptoms, thereby complimenting the basic mechanistic research provided by our host institution.

a) A clinical trial of intra-vesical atropine to treat detrusor hyperreflexia in patients with MS using intermittent catheterisation. This study is being led by Professor J Malone-Lee and involves collaborators from the Institute of Urology and Institute of Neurology at UCL.
b) The influence of glycation on the physical characteristics of keratin in diabetic foot callous and development of diabetic foot ulcers. This study is being led by Miss F Hashmi and Dr M Barnard and involves collaborators at the London Foot Hospital (UCL) and Birkbeck College, University of London.
c) The influence of gender in the aetiology of Hallux Valgus (Bunions). This study is being led by Professor J Malone-Lee and Miss J Ferrari and involves collaborators at the London Foot Hospital (UCL)
d) The Sentinel Node Project. This is designed to test the validity of sentinel nodes where they are used clinically - melanoma, breast and oesophageal cancer. This study is being led by Mr M Hashemi, Dr R Wakeel and Mr A Wilson and involves collaborators from UCL.
e) The use of laryngography in the diagnosis of swallowing dysfunction and aspiration. This study is being led by Mr M Hashemi and Miss J Stanbridge (MD Project) and involves collaborators from the Department of Phonetics & Linguistics, UCL
f) The efficacy of preoperative fluid optimisation in elderly patients: The effect on morbidity and hospital stay. This study is being led by Dr Nik Harper and Miss Angela Chamberlain (PhD project) and involves collaborators from UCL.
g) A study into the prevalence of pulmonary TB in disadvantaged populations including London Prisons. This study is being led by Dr N Johnson and Miss S Steel (PhD Project) and involves collaborators at the Public Health Laboratories Service, Prison Reform Trust, Home Office, Department of Health.

Over the past year the R&D department has been working with researchers to identify potential areas for development and, as a result, there are now a number of pilot projects underway, as development work towards future external grant funded support and/or programme activity.

Each year the R&D department puts out a Call for Proposals for Whittington employees for the sum of £30k to seed pilot work within the Trust. The research must demonstrate a commitment to meeting the Trust's five main research objectives and DH criteria for NHS R&D. This year the money was awarded to two applicants both requiring a part-time research nurse to assist in co-ordinating their research and seeking additional external grant funded support to continue the work forward after the initial pilot phase.

Areas for Development

Other areas that have been highlighted for future development and will eventually form part of a research programme include:

1. **Haematology: Sickle Cell Disease**

   The Whittington Hospital serves a large and growing sickle cell population and is therefore well placed to develop a programme of research in this area. This will be led by Dr Bernard Davis in the Haematology Department whose interests are nutrition and the use of antioxidant drugs in sickle cell disease. The work would be carried out in collaboration with the paediatric department in the Whittington and external academic collaborators from UCL. Dr Davis was awarded Whittington NHS R&D funding to appoint a research nurse to assist him with this research "A study into nutrition and anti-oxidant status in sickle cell disease".

2. **Department of Medicine/Care of the Elderly: Falls in the Elderly**

   The problem of falling in the elderly is well recognised. Much of the current published work has focused on cardio-vascular function. We feel that this needs to diversify. There are a number of scientific groups at UCL who have interests in the neuro-muscular mechanisms that govern postural stability. Their work indicates that there are lesions of these mechanisms that could contribute to falling and some therapeutic avenues might help the problem. Professor Malone-Lee is collaborating, therefore, with a number of these scientists and with the Clinical Research Network in order to start up a programme of clinical experiments that will test these options. In order to feed this programme the Trust has established a falls clinic, which is now collecting a steady flow of patients.

3. **Nurse Led Research: Various**

   The recent research assessment exercise (RAE) demonstrated just how important it is to develop opportunities for nursing research that is of a competitive standard. The experience and research interests of nurses tend to be diverse. However, it has been demonstrated that successful nursing research has been achieved by the exclusive focus on a research topic e.g. urinary incontinence in the Department of Medicine. We shall be taking advantage of specific interests and capabilities of this Trust to initiate new nurse led research programmes, which will be used to achieve

PhDs for the researchers and simultaneously provide the foundations for continued research activity in the future. Identified areas of research are:

a) A study into the prevalence of pulmonary TB in disadvantaged populations in our local community in particular HM prisons. This research is being led by Senga Steel, Lead Research Nurse, Dr Norman Johnson, Consultant in Respiratory Medicine and Professor Malone-Lee, Professor of Medicine. Substantial external funding is required for this research and grant applications have been submitted to the Wellcome Trust, MRC and BUPA Foundation.

b) Studies into the efficacy of interventions that reduce post-operative complications, morbidity and length of stay in hospital. This research is being led by Dr Nik Harper, Consultant Anaesthetist and Angela Chamberlain, Lead Health Care Researcher and academic collaborators from UCL. Pilot work is underway and external funding is being sought.

4) Other

1) The Sentinel Node Project. This is designed to test the validity of sentinel nodes where they are used clinically - melanoma, breast and oesophageal cancer. This research is being led by Mr M Hashemi, Dr R Wakeel and Mr A Wilson and involves collaborators from UCL.

2) The use of laryngography in the diagnosis of swallowing dysfunction and aspiration. Professor Fournis, Department of Phonetics and Linguistics at UCL, has invented a sensitive method of measuring chord dysfunction by using the electrical conductance across the chords. This project investigates the clinical applications. This research is being led by Mr M Hashemi and Miss J Stanbridge and involves collaborators from UCL.

3) The effect of metformin on plasma homocysteine levels in Indian Asians with type 2 diabetes. Vitamin B12 deficiency occurs in Indian Asians for nutritional reasons. Even subtle degrees of vitamin B12 deficiency has been associated with raised plasma homocysteine. Treatment with metformin has the ability to lower vitamin B12 levels even further. This may result in significantly raised plasma homocysteine levels, which may explain part of the increased risk for CHD among Indian Asians compared with Europeans. This research is being led by Dr Bakri Saeed and involves external collaborators. Dr Saeed was awarded Whittington NHS R&D funding to appoint a research nurse to assist him with this research.

The Whittington Hospital's Research Objectives

The R&D department is developing a Trust R&D strategy that will encompass the following five main strategic research objectives:

1) To concentrate the research effort into those areas which reflect our strengths and optimise our links with other academic institutions. In doing this we shall cull all other research activity which is unlikely to feed significantly the public good, and all research which, through subject or standard, is at variance with the NHS goals

2) To ensure the very best quality in our protocols, by using a panel of experienced researchers, drawn from collaborating groups, to provide mentors and supervision for all individuals who participate in research in the Trust

3) To ensure that all research activity is integrated into a strategic plan that is aimed at achieving long-term, external grant funded support. This will require a critical eye to where it is appropriate for us to compete as well as standards comparable to those achieved by other successful institutions

4) To concentrate on clinical research backed by basic scientific support drawn from our university partnerships. This is a busy district general hospital that can best serve the NHS R&D effort through work that is conducted on patient samples. To this end, our R&D is being backed by an effectively pragmatic in-house IT initiative

5) To promote approaches to research that encourage the informed participation of a wide body of staff who may be working according to very different patterns. This can be achieved on the back of the strong sense of organisational identity and cohesion that exists in our workforce

Melanie Hiles
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