R&D IN THE NHS – 'THE TIMES THEY ARE A-CHANGING'

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INTRODUCTION

The last two years have witnessed many changes in the way that research and development (R&D) is managed within the health service. This article will briefly describe the key national developments and then explore how these have been translated to local management of research and development. It will outline what all of this means for would-be researchers within Morecambe Bay. Finally it will explore how research and development may evolve and progress within Morecambe Bay.

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Why is R&D important?
Research and development is vital to the NHS in order to improve health, improve the quality of the service, to support modernisation and to promote knowledge-based decisions – clinical, managerial and policy.

National developments
The impetus to introduce research governance undoubtedly came from events which loomed large in the nation's conscience – Bristol, Alder Hey and North Staffordshire were all important triggers for change.

Research governance
The Research Governance Framework for Health and Social Care (RGF) was introduced in March 2001. It delineated three central objectives:

- to ensure that the public can have confidence in and benefit from health and social care research
- to improve research quality across the board
- to prevent poor performance and research misconduct.

The document lays out principles of good governance and describes these within five domains which are outlined below:

Ethics
The need to safeguard patients by means of independent ethical review is a keystone of NHS research. RGF details the ethical responsibilities of all involved in research and its approval – the research ethics committees, the principal investigator, researchers, sponsors and the care organisation involved in the research.

The role and make-up of research ethics committees is currently under review. A new form, which will be downloadable from the Central Office of Research Ethics Committees (COREC) website (www.corec.org.uk), will ensure consistency in the way information is requested. The website is a useful reference tool giving guidance on all ethical aspects of research, including such topics as informed consent, confidentiality of patient data, and involvement of participants in design.

Science
Any research which is carried out within the NHS must be scientifically valid. This means that it has to add to the body of knowledge and must conform to applicable regulations eg the use of embryos and GM organisms.

Information
Research findings must be shared if they are to improve practice and lead to better quality care for patients.

Health, safety and employment
Within a research project the safety of participants and of staff is a priority. Issues around health and safety regulations must be addressed.

Finance and intellectual property
All research should be subject to financial probity. The potential issue of compensation must also be taken into account. RGF addresses the hitherto largely neglected area of intellectual property (IP) and the obligation of Trusts to identify and exploit their IP.

Responsibilities
The responsibilities of people and organisations involved in research are defined and a summary of these can be found in RGF (Table 1).

Research Governance Implementation Plan
The Research Governance Implementation Plan was published in October 2001 and details action required to ensure compliance with RGF. The implementation plan groups research governance issues into:

- legal requirements
- systems for urgent attention
- systems development
- systems development by March 2003
- capacity building by March 2004.

Principal Investigator and other researchers	• Developing proposals that are ethical and seeking research ethics committee approval • Conducting research to the agreed protocol and in accordance with legal requirements and guidance e.g. on consent • Feeding back results of research to participants
Research Ethics Committee	• Ensuring that the proposed research is ethical and respects the dignity, rights, safety and well-being of participants
Sponsor	• Assuring the scientific quality of proposed research • Ensuring research ethics committee approval obtained • Ensuring arrangements in place for the management and monitoring of research
Employing organisation	• Promoting a quality research culture • Ensuring researchers understand and discharge their responsibilities • Taking responsibility for ensuring the research is properly managed and monitored where agreed with sponsor
Care organisation/Responsible care professional	• Ensuring that research using their patients, users, carers or staff meets the standard set out in the research governance framework (drawing on the work of the research ethics committee and sponsor) • Ensuring research ethics committee approval obtained for all research • Retaining responsibility for research participant's care

Table 1 – Summary of key responsibilities of people and organisations accountable for the proper conduct of a study
Research Governance Framework for Health and Social Care

The legal requirements cover data protection, financial probity and health and safety. Systems for urgent attention include notification of research proposals, gaining ethical approval, and monitoring informed consent for research projects.

Eleven indicators have been identified which have to be complied with as of March 2003. These are:

i. Documented agreements with research partners to allocate responsibilities

ii. System to ensure all staff are aware of the research governance framework

iii. Links between research governance and clinical governance systems

iv. Arrangements for monitoring research projects

v. System to record adverse events

vi. Compliance with the research governance framework to be included in all employment contracts

vii. Arrangements to issue NHS honorary contracts to non-NHS researchers

viii. Systems to ensure all research has a nominated sponsor

ix. Systems to ensure all research is subject to independent expert review through accepted scientific and professional channels

x. Systems to have all research by students approved by the organisation

xi. Appropriate written agreements with research sponsors and other funders to cover all funded research.

A further seven indicators have to be achieved by March 2004. These involve systems to detect and deal with fraud and misconduct, involving consumers in research, informing the public about ongoing research, systems for the costing and financial management of research, dissemination of research and the identification and exploitation of intellectual property.

Funding research and development

The government's policy on the purposes and principles of NHS R&D funding was set out in 'Research and Development for a First Class Service: R&D funding in the new NHS' (March 2000). Basically, funding will be organised into two systems – 'Support for Science' and 'Priorities and Needs'. The formulas for both these funding streams are still being finalised. It is, however, apparent that the DoH is defining the research that it will fund. The emphasis has turned to programmes of research which are collaborative and well-supported academically.

Local developments

The impact of national initiatives and policies have necessitated a lot of action at a local level.

R&D – What's been happening?	
1998	First SPREAD project in PCT funded
Feb 1999	R&D committee formed (MBHT)
Sept 2000	R&D manager appointed (MBHT)
Nov 2000	Lead clinican in R&D appointed (MBHT)
Dec 2000	First R&D newsletter circulated (MBHT – available quarterly)
2001	MBHT policies on financial management, intellectual property approved Second SPREAD project in PCT funded
Mar 2001	Research governance framework introduced
Oct 2001	Research governance implementation plan for health
May 2002	Scientific and Financial Committee (joint PCT and MBHT) formed
Nov 2002	First joint R&D committee (MBHT AND MBPCT)

Joint working

In May 2002 a new Scientific and Financial Research Committee had its first meeting. This committee is a collaborative venture between Morecambe Bay Hospitals NHS Trust (MBHT) and Morecambe Bay Primary Care Trust (MBPCT) and has three main functions:

1 To review all research proposals from within MBHT and MBPCT, or research which will involve patients, patient records, relatives/carers, staff employed by either trust and/or the facilities or resources of either trust

2 To grant or refuse approval on behalf of both trusts and to report all such decisions to the appropriate bodies and to the applicants

3 To protect all groups from potentially being 'over-researched'

The two Trusts have recognised the importance and usefulness of a joint approach to R&D and have also started (October 2002) holding joint R&D committee meetings which will address strategy and the wider research agenda. Both trusts have good communication links with the local research ethics committee and appropriate trust approval must be obtained before submission to the ethics committee (see Do's and Don'ts).

Do's and don'ts for research active staff

Do allow time to gain approval from both the trust and ethics committee

Do tell the R&D department about all research work, either current or proposed. We need to know

Intellectual property

This is an important area of law about which the NHS is becoming increasingly aware. IP can be a major asset to a NHS trust and needs to be protected and valued as such. IP can be divided into four main categories:

Copyright is the right to stop a person copying the words, drawings, photographs or plans created by another with his own effort and skill. Copyright also subsists in computer programs. *Registered Design* rights protect aspects of industrial designs which appeal to the eye while *Unregistered Design* rights give a more limited protection for purely functional industrial designs.

A patent is a monopoly, granted by the Crown for 20 years from the date of filing the application, in respect of a new invention capable of industrial application; novelty is an essential element of the invention although practicality is not.

A trademark or service mark is a distinctive mark (a word, made-up word, logo or signature) intended to identify and link goods with their source or manufacturer or to identify and link services with the provider of those services.

Know-how consists of inventions, processes, techniques, formulae, ideas and knowledge, some of which may be protected by copyright or a patent; its meaning is sometimes restricted to non-protected or non-registerable inventions.

Within MBHT an Intellectual Policy was introduced in 2001. Both trusts have also joined TrusTECH (www.trustech.org.uk) to help identify and exploit intellectual property from within the organisations.

Finance

Staff have to recognise that they work within the confines of trust finances and proposals need to be carefully costed to reflect this. Some research costs the trust money - this may be staff time, laboratory tests, consumables - and it is important that these costs are identified and recognised. In line with the trust's financial policy overheads should be added to commercial trials. MBHT approved a financial policy for research in 2001.

What does it all mean for researchers in Morecambe Bay?

It could be said that there are more hoops to jump through, more committees to satisfy and more paperwork to complete. All this is true. One could be justified in thinking that although we are trying to encourage research, all this might have the opposite effect. A number of points need to be made:

Firstly, doing research properly has never been easy and has always been time-consuming. If the new measures deter people from doing underpowered, poorly thought-out research that never reaches completion, presentation or publication then they will have been worthwhile. We want to encourage the right sort of research – by which we mean good-quality projects which are realistically scoped.

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Secondly, we would like to encourage would-be researchers to 'think big' and 'link up'. 'Think big' because it requires the same amount of work to steer a proposal through the Scientific and Financial Committee and Research Ethics Committee whether the project is a small-scale in-house investigation or a larger collaborative venture. 'Link up' because a larger bid which involves professional academics and interested clinical staff in other trusts is likely to be of better quality, more likely to achieve recruitment targets if these are important, and proper management arrangements can be costed in to ensure that the project is successfully guided to completion. Trust R&D staff can help by putting interested parties together, and clinicians usually have their own professional networks to draw on too.

Student Research

Student research must conform to the standards laid out in research governance. This means that projects should be approved by both trust and ethics committees. Obviously there are time implications to this and it is important that local education providers are aware of deadlines and so forth. Both trusts are working to facilitate this.

There are representatives from Lancaster University and St Martin's college on the Scientific and Financial Committee. There has been talk at the North West R&D Managers Forum as to the appropriateness of undergraduates carrying out primary research. Locally, discussions are taking place about establishing research projects which students could feed into.

The future

It is apparent that both trusts need to attract money to support research. This can come from a number of sources. The 'Support for Science' programme should allow us to claim for reimbursement of some research-related costs from the region. At present this is still being worked out. Secondly, we will continue submitting high-quality bids for moderate sums of research money from national sources. MBHT now charges overheads on salary costs in these bids (as university departments have been doing for many years) and we hope to establish a separate R&D fund.

It is envisaged that money accrued from various sources will be used to kick-start more research activity: for example, to pay for pre-protocol work (work done in preparation for a grant application), or worthwhile projects which meet local needs. In particular we are planning to set up mini-bursaries for nurses, AHPs and similar groups. The money would be used to pay short-term replacement salary costs to allow enthusiastic individuals to pursue ideas arising from their

clinical practice. Ideally these would improve patient care in some way whilst affording the opportunity to develop research skills. Spending decisions are likely to be made by the R&D Committee.

The longterm aim is to build research capability amongst all staff, both to encourage a critical attitude to day-to-day clinical work and to establish a cadre of people whose skills we could draw on for specific larger projects as the need arises. Both trusts have experience in delivering critically appraised research evidence workshops and it is envisaged that in collaboration with library staff these can be rolled out so that more staff have the opportunity to take part.

Research within the NHS is changing, the emphasis is very definitely on large-scale collaborative programmes rather than small projects led by individual clinicians. Research governance has encoded the responsibilities and accountability of all the people and organisations involved in research. The challenge for both trusts over the next few years is to ensure that all staff are aware of the changes, to develop robust governance systems whilst simultaneously encouraging research and providing people with the skills they need, and to attract funding to make all this possible.

Contacts

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Further Reading

All of these documents are published by the Department of Health and are downloadable from http://www.doh.gov.uk

Research and Development for a First Class Service – R&D Funding in the New NHS , 2000

Research Governance Framework For Health and Social Care, March 01

Research Governance Implementation Plan, October 01

The NHS as an Innovative Organisation – A Framework and Guidance on the Management of Intellectual Property in the NHS, Sept 02

MIRROR OF DENTISTRY

J. W. Davenport
1852

ON THE PROGRESS OF THE TEMPORARY TEETH, AND THEIR DEVELOPMENT

The time of the appearance of teeth varies from five to eight months from birth, and great care is requisite in the means used to allay the irritation consequent upon their development, for the gums are then in a high state of inflammation. This, however, depends in some measure on the state of the stomach, and often gives rise to convulsions and fever. In this stage the gums should be lanced, the bowels purged with some mild aperient (such, for instance, as small does of fluid magnesia or castor oil); and when there is a tendency to thrush, the admixture of borax, myrrh, and honey, will be found serviceable as an application.

To enter upon a history of the consequences which result from the irritation of teething, would be to treat generally of all diseases of infancy, for there is scarcely a disease to which this period of life is subject, that is not more or less produced by this cause. And all that art or skill can suggest to relieve the infant sufferer will prove useless, unless proper attention be observed in the first stages of dentition.