RESEARCH AND THE NHS REFORMS

- *Researchers' Partnership with the NHS*
- *Why it is under strain*
- *What is being done.*

POST note 50 March 1994

POSTnotes are intended to give Members an overview of issues arising from science and technology. Members can obtain further details from the PARLIAMENTARY OFFICE OF SCIENCE AND TECHNOLOGY (extension 2840).

Parliamentary concern has been expressed for some time that separating the NHS into purchasers and providers could hinder research, and the Department of Health (DH) has just established a Task Force to look into this.

This briefing note examines the key role of the NHS in medical research and questions raised.

BACKGROUND

The NHS introduced the Service Increment for Teaching (SIFT) as long ago as 1976 to cover the 'excess service costs' of teaching in hospitals. When the Lords Science and Technology Committee reviewed 'Priorities in Medical Research' in 1988, it recommended that SIFT should also cover research and in 1991, the Government extended SIFT to cover **all** the excess service costs of teaching **and research**. Since then, however, many see the developing NHS internal market as making it increasingly difficult for purchasers to give adequate weight to the long-term benefits of research against the short-term pressures to obtain 'value for money'. On 15 October 1993, the President of the Royal Society wrote to the Prime Minister expressing the "serious concern felt by my scientific colleagues about prospective developments in the Health Service and their potential impact on medical research and education". On 23 November 1993, the Minister for Health announced that a Task Force would be set up chaired by Professor Culyer (University of York) to "review ways in which the NHS currently funds its own research and development (R&D) and supports that funded by others". The Task Force will report by April 30 1994.

RESEARCH AND THE INTERNAL MARKET

Over two billion pounds a year are spent on research which has some potential relevance to the NHS (**Table 1**). At the broadest level, much of the work carried out by the pharmaceutical industry, charities and the Medical Research Council (MRC) may have an impact on the NHS through the development of new medicines, equipment or treatments. In addition, much of the work necessary to demonstrate the safety and efficacy of new treatments in the UK necessarily involves access to patients in NHS facilities. The DH and NHS also commission research, which has since 1991 been the responsibility of the DH Director of R & D (DRD).

The strength of the NHS is that it has for many years offered a single organisational structure within which:-

a) Patients' disorders and diseases may be studied to open up avenues for research into new treatments.
b) Treatments developed in the laboratory can be evaluated through clinical trials.
c) The efficacy of different clinical approaches can be assessed in diagnosis, prevention or treatment.
d) Epidemiological investigations can be conducted into the possible causes of disease.

Box 1 illustrates the range of NHS resources which are linked with research, and the importance of access to patients, the NHS central data archives, support services and NHS staff. Research funders report that the internal market has led to problems in covering the additional costs of research, and that some clinical trials are experiencing difficulties as a result. Patterns of patient referral have also changed and are expected to change further as service rationalisation closes hospitals (particularly in London). Centres of excellence rely on adequate numbers of specialist (tertiary) referrals, and falls in patient numbers are said to be threatening specific projects and the viability of some centres.

Table 1 MEDICAL RESEARCH AND TEACHING IN THE UK (£M)

Organisation	1990/1	1991/2	1992/3	1993/4
Pharmaceutical Industry	1151	1262	1451	n.a.
Medical Research Council	203	228	253	~285
Medical Research Charities	193	211	269	~360
Health Departments and NHS	71.1	58.6	56.4	57
SIFTR (R component:-25%)	343(86)	366(92)	385(96)	397(99)
Higher Education Funding Cls	224	244	241	226

In that medical research benefits the NHS and is fully supported by Ministers, there is no dispute that the NHS should continue its indispensable role in this area. The issue is over how best to avoid aspects of the internal market inadvertently 'squeezing out' research.

CURRENT RESEARCH COST RECOVERY

There are three components to the proper support of clinical research in the NHS:-

- The extra service costs due to the need for additional staff, laboratory time, complexity of cases, longer hospital stays etc. (**Box 1**).
- Support of infrastructure within which research may be carried out.
- Costs of particular research projects.

The first two categories are meant to be covered by SIFTR[1], while the third is for research funders (MRC, DH, charities, etc.) to provide via competitive grants.

1. The equivalent to SIFTR in Scotland is the 'Additional Cost of Teaching and Research' (ACTR) and STAR in North Ireland.

Box 1 EXAMPLES OF SERVICE SUPPORT INVOLVED IN RESEARCH AND THE NHS

Virtually all clinical research carried out in NHS Hospitals involves clinical staff on NHS contracts, NHS nurses, ancilliary staff, scientific staff and NHS patients; as well as NHS facilities and equipment. Such research can be grouped into 4 broad categories.

General Clinical Research

Understanding the mechanisms of disease and seeking better diagnosis, prevention or treatment necessarily involves patients in a treatment setting, together with the necessary back-up analytical and investigative facilities. The fact that patients are part of research may necessitate their staying longer in hospital and incurring additional tests. For instance, work on developing **gene therapy to treat cystic fibrosis** is now moving out of the laboratory and into clinical evaluation. Demands on NHS infrastructure include the need for bronchoscopies, support from consultant physicians and anaesthetists, nurses and other hospital facilities. Some of the treatment options under consideration include up to one month on isolation, placing additional demands on facilities.

Epidemiology

Many causes of diseases have been detected through a thorough analysis of patient conditions and records to find out possible reasons for their condition (e.g. smoking and lung cancer, diet and heart disease, factors affecting low birth weight). The NHS Central Registry at Southport is one of the most valuable resources available to epidemiology anywhere in the world. These records allow patients to be traced, contacted, questioned and tested. For instance, a current project on the effects on **diabetes risk of low birth weight** depends on tracing people born 50 years ago through the Register, contacting their GPs and using NHS facilities to store and analyse blood samples.

Clinical Trials

Clinical trials test the effectiveness of new drugs or therapies, as well as new applications of drugs. They rely on large numbers of patients participating in order to reveal treatment effectiveness, and may thus spread over many district health authorities and many hundred practices - even over several countries. Most clinical trials involve patients already undergoing treatment, and accounting for the extra cost of research thus requires comparison with what would be 'normal' treatment. For instance, one clinical trial is looking at **effects of genito-urinary infections on premature births,** and whether antibiotics would avoid this. Such a study must inevitably mesh with the normal NHS provision of maternity services and involve not only patients but also midwives, obstetricians, pharmacists and secretaries in administering antibiotics and placebos. Other clinical trials evaluate new procedures. For instance, can cancer chemotherapy be improved by reducing the associated side-effects, thus allowing higher doses more effective against cancer cells? Finding appropriate patients places exra work and costs on consultant oncologists and GPs, and both the pharmaceutical industry and MRC find that pressures to reduce unit costs can conflict with participation in research projects, due to the associated need for extensions in hospital stay.

Screening Studies

As National health policy increasingly focuses on prevention or early treatment, screening becomes important to detect the incidence of previously unknown or untreated conditions. For instance, the value of **colo-rectal cancer screening** is currently being assessed, based on faecal blood measurement. Running this trial involves GPs and hospital-based barium enemas for those with a positive test.

In short, MRC and other research funders may, on any given project, place demands on the following NHS resources:

Staff:	Extra nursing time; extra medical time; paramedic support (e.g. physiotherapy, counselling, occupational therapy)
Funds and Facilities:	Extra In-patient days; Extra Out-patient visits; extra drug/ treatment; additional Investigations/pathology/ scans, additional care services; post-mortems; data management and records; charges for cross-referrals; Library
Patients:	Tertiary referrals to specialist centres; adequate supply of patients with common conditions.

The precise additional costs caused by teaching and research in individual hospitals are difficult to quantify, so DH assesses the value of SIFTR by comparing the costs of the main teaching hospitals with district hospitals with no significant teaching or research commitment. The overall SIFTR budget is then paid to hospitals through the Regional Health Authority (RHA) in proportion to undergraduate student numbers. SIFTR payments were £342.8M for the first year (1990/1) in which research was included, and the 'R' proportion of SIFTR is generally assumed to be 25-30% (see Table 1 for other year's payments). Although small in relation to NHS total expenditure(~1%), the payments can represent up to 20% of funds available to teaching hospitals and 80/90% of the funds of some dental hospitals.

The Lords Science and Technology Committee and others have pointed out that undergraduate numbers are a poor measure of research activity in hospitals (see **Figure 1**) and argue that the 'R' component of SIFTR should reflect a medical school's contribution to research. In 1991, the Government retained the link with undergraduate numbers, but did expand the considerations which RHAs take into account to achieve "better targeted distribution of SIFTR" to individual hospitals[2]. Regions and Districts are also meant to allocate SIFTR through a contract which specifies what educational/research support should be provided by the hospital or hospital Trust, although SGUMDER[2] noted in 1993 that progress in this area was slow.

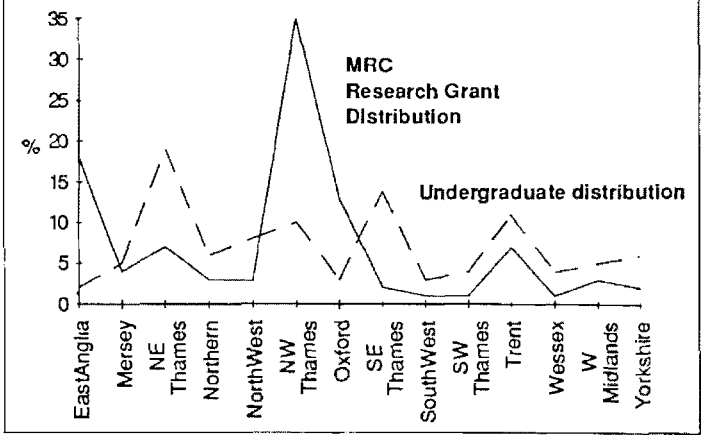
In 1991, there were at least 60 hospitals which did not receive SIFTR payments, yet conducted research funded by charity and MRC grants. The Government agreed that the hospitals most affected could receive a payment of 40p for every £1 of external clinical research grant provided eligible research grants exceed £100,000 and 1% of the unit's budget; £2 M is allocated annually.

CURRENT ISSUES

Although SIFTR is designed to 'level the playing field', so that teaching and research can take place without participating hospitals becoming uncompetitive in the NHS internal market, parliamentary and other com-

2. Following recommendations of the DH Steering Group on Undergraduate Medical and Dental Education and Research (SGUMDER), factors include a hospital's research activity, the extent of non-commercially funded research, costs of specialised facilities and complex cases.

FIGURE 1 EXPENDITURE ON CLINICAL RESEARCH AND UNDERGRADUATE NUMBERS (by region in 1989)



ments have questioned its effectiveness. In addition, the Government announced in 1993 its intention to abolish the 14 RHAs and replace them by 8 regional offices of the NHS Management Executive, raising questions over the arrangements necessary to take over the RHAs' role in encouraging teaching and research at the regional level. In London, changes are also underway in the funding of research in specialist hospitals which are currently Special Health Authorities (SHAs) - **Box 2**.

SIFTR payments are believed to be significantly below the actual costs of clinical research, so that research may be in conflict with a hospital's economic viability. Even if the overall sum reflected the true costs, MRC and the charities still see deficiencies in its application: *viz;*

- SIFTR calculation remains unrelated to the **actual** costs of teaching and research, which vary widely depending on the type of specialist facilities.
- SIFTR allocations bear little relationship to research activity (Figure 1).
- Research costs at many district hospitals involved in clinical trials are excluded, so that there is increasing unwillingness to participate.
- There is no provision for GPs' extra costs (e.g. from tertiary referrals or treating extra health problems revealed by research investigations), so that some GPs are unwilling to participate in research.
- Individual hospitals can see SIFTR as a non-specific subsidy rather than a compensation for research costs. At the same time, large multi-centre studies may require extensive negotiations with 10 or more health authorities over excess service costs. Administrative arrangements which remove rewards and introduce obstacles can be a significant disincentive to undertaking or taking part in trials.

Many of these shortcomings are being examined in SGUMDER's latest review of SIFTR. However, simple solutions have not yet emerged and improved means of calculating and distributing SIFTR may just not be possible in view of the complexities of hospital funding and the imperfect knowledge of NHS costs. The Culyer Committee report will be an important input to the debate over the future of SIFTR.

Box 2 RESEARCH AND SPECIAL HEALTH AUTHORITIES

Eight of London's hospitals most involved in postgraduate teaching and research (e.g. the Hospitals for Sick Children, Moorfields Eye Hospital, the Royal Marsden) are currently funded centrally as Special Health Authorities (SHAs) outside the competition of the internal market. The hospitals concerned claim that this has contributed to their ability to establish strong centres of research and have argued for the retention of central support (£270M in 1993). The 'Tomlinson' Report on London's Health Service, Medical Education and Research, however, recommended that the SHAs move to operate within the internal market and that their research functions receive support as in other areas of the country - via a reformed SIFTR; this would enable all hospitals to compete on a level playing field for both service contracts and for support of research and teaching overheads. The Government, in its paper 'Making London Better' felt that central funding can insulate hospitals from the pressures to increase efficiency and effectiveness and thay they should join the NHS internal market from 1995. Central support of R&D will be progressiveiy focused on the "core patient workload needed to sustain high quality, relevant R&D programmes", and the Secretary of State for Health announced on 10 February a new interim central funding mechanism to support research at the SHAs from 1 April 1994 until 1995.

There are two broad options for future policy. The first would retain the current system structure but find ways of improving SIFTR - e.g.:-

- Research costs could be calculated and distributed separately from teaching costs.
- A better distribution formula could be used - e.g. based on numbers of postgraduate students, peer-reviewed research grants, or the honorary contracts which the NHS awards to clinical researchers.
- SIFTR could seek to identify both the infrastructure costs of a major research hospitals as well as the service costs of specific research programmes.
- Research costs could be clearly identified at all stages from the centre to regions, to hospitals and to projects, so that costs and benefits are transparent.
- All hospitals could be covered, and provision also made for primary care to participate.

However, many see current difficulties as requiring a complete rethink about the way research should be conducted in the NHS. The priority of purchasers to maximise the quality and quantity of health care while minimising present costs, does not encourage them to support R&D; moreover, developing well-coordinated high-quality research requires purchasers to become skilled at research commissioning and liaison, which would be impracticable and wasteful, given the number of purchasing authorities. Some thus suggest that R&D should be separated from the internal market altogether, and funded at a higher organisational level to enable a R&D market to be created in parallel to that for patient care.

If this were done, a means would have to be found of redistributing SIFTR funds. One option would be to apply the equivalent of the 'dual funding' system in

Box 3 RECIPROCAL ARRANGEMENTS IN THE NHS

The close relationship between clinical research education and treatment means that each helps the other in a 'two-way street':

- MRC and the DH have a concordat which allows DH to influence MRC strategy, while undertaking that the NHS should provide adequate clinical facilities and service support for clinical research and trials.
- RHAs support professorships at medical schools while clinical academic staff contribute to clinical service and care.
- MRC and the charities fund over 470 consultants, senior registrars and registrars within the NHS, all of whom undertake work for the NHS in addition to their research duties: other staff include training fellows, nurses, audiologists, pathologists and other specialist professionals. In the past, no attempt has been made to quantify let alone charge for such contributions.
- Some external funders of research, such as the Imperial Cancer Research Fund support special units in which treatment as well as research takes place. The ICRF calculates that for every 'clinical pound' it spends, 40% is used for patient care, the province of the NHS. Analogous situations exist with other charities.

university research, whereby central funds would support infrastructure at research institutions on the basis of a central formula or research quality assessment exercise. Such an exercise was recently carried out by the DRD on London's research hospitals and could provide a model for a national scheme by DH.

A theoretical alternative would be to require research funders to cover the full costs of research, as do pharmaceutical companies. This would however pose formidable problems. Firstly it would be difficult to separate the costs of patient care from the extra costs caused by research needs in each particular case. Secondly, there is a web of reciprocal arrangements (**Box 3**) whereby the additional costs for the NHS when patients are part of a research programme, are offset when teaching and research staff funded by the MRC, universities or the charities carry out treatment. If the NHS and the charities started cross-charging for all the current reciprocal arrangements, this would represent a complete breakdown of the current 'knock-for-knock' system, with implications also for ownership of intellectual property and other matters. Finally, research funders would expect the 'R' component of SIFTR to be reassigned to compensate for the increased costs. MRC could be compensated via a PES transfer of funds from DH, but this would not be possible for the charities.

Turning to the RHAs, these have traditionally developed strong links with local universities and ensured an adequate local base for research and teaching. Under the new arrangements, NHSME Regional Offices are meant to work closely with the universities and ensure that medical research and education are properly supported by the NHS. The Committee of Vice Chancellors and Principals (CVCP) however, sees a need for joint planning and liaison mechanisms at all levels if the SGUMDER recommendations and its 'Ten Principles'[3] are to be fulfilled in the new management arrangements. Thus universities could be represented on the NHS Policy Board, regional joint planning committees could be set up for education and research, and universities represented on the unified purchasing authorities, as they are already on the Boards of NHS teaching Trusts.

Box 4 DATA PRIVACY AND MEDICAL RESEARCH

The European Commission's Draft Directive on personal data protection could affect research in the following ways:

Work Affected	Reason
Work involving old records (e.g. identifying role of earlier workplace exposure on occupational disease; effects of nutritional status of mother on subsequent development in children.	**Art 6(1)e** states that data identifying the individual should be kept no longer than required for the original purpose. **Art 7a** specifies that personal data may only be used subject to the specific consent conditions.
Work relating medical conditions to genetic, environmental and life-style factors (e.g. examining records of women taking the pill to see if later side effects (e.g. cancer) develop.	**Art 8(1)** prohibits use of data revealing racial or ethnic origin or concerning health and sexual life. **Art 6 (1)b** requires explicit consent for every use made of patient information.

Finding a new approach may not be easy: the previous system had evolved over many years and reflected the fact that research, teaching and treatment were inextricably linked. The complex interlinking is now being unravelled at the level of accounting, and many are concerned that this is also leading to an unravelling of symbiotic relationships within the NHS. The Culyer Committee faces the task of finding a means of ensuring that the short-term imperatives of the internal market do not undermine the longer term benefits of research on improved services and treatment.

There are also other issues concerning medical research. It is important to ensure that **NHS records** of patients involved in research **are maintained** for the 15 years recommended and not destroyed prematurely to save storage costs. While unrelated to the NHS reforms, current proposals for a **Directive on personal data protection** are also causing concern, since restrictions proposed could either rule out or make impractical many types of medical research, particularly epidemiological studies (**Box 4**). The DH and Home Office argue that medical records should be excluded or the directive shelved on the grounds of subsidiarity; this is still under discussion in Brussels. Finally, concern has been expressed over the variable performance of **research ethics committees** which are meant to safeguard the interests of patients participating in research projects. Guidelines were issued by the DH in 1991, but issues of implementation, membership and training remain.

3. The Ten Key Principles were produced in SGUMDER's second report to define the shared goals of the Universities and RHAs and to govern the organisational arrangements set up between them.