

Health Care Technology in the United Kingdom

by Jackie Spiby

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OVERVIEW OF THE UNITED KINGDOM

The United Kingdom, with a total population of 48.2 million in 1992, consists of four countries: England, Wales, Scotland, and Northern Ireland. Geographically, it consists of one large island and numerous smaller islands covering 94,500 square miles. Although physically small, its position at the northwest coast of Europe has meant that it has been able to maintain independence as an island and establish close relationships with Europe and with North America. The United Kingdom is essentially an industrial and trading nation; most of its working population is engaged in manufacturing and commerce.

Government and Political Structure

The United Kingdom has a constitutional monarchy, and one sovereign body governs all four countries. The central government takes its authority from the two-tiered Parliament (the House of Commons and the House of Lords). The Prime Minister is the leader of the party with the majority of Members in the House of Commons. Government departments and ministries are headed by Secretaries of State or Ministers, a subset of whom form the Cabinet. All departments and ministries are led by individuals from the majority party in Parliament, so there is no separation of the executive and legislative branches of government. The departments and ministries also have permanent secretaries and other executives who assist these Secretaries and Ministers.

Northern Ireland has regional independence but not a federal relationship. Wales and Scotland have a degree of administrative devolution that is of limited significance, although it has led to some differences in how health services are organized.



HEALTH STATUS OF THE POPULATION

Despite an increasing emphasis on prevention, the United Kingdom continues to compare poorly in health status to most of its European neighbors. Death rates for ischemic heart disease in England and Wales are just over 300 per 100,000 male population aged 45 to 64; in contrast, West Germany has a rate of approximately 250 and France, 100. The rates of Scotland and Northern Ireland are even higher than those of England at 450 and 400, respectively. This pattern is similar for breast cancer.

The main causes of death in the United Kingdom have remained stable, with the major burden resulting from coronary heart disease (CHD) and cancer. Stroke is also a major health problem, accounting for 6 percent of health service spending. The health of newborns has been continually improving; the infant mortality rate fell from over 10 per 1,000 live births in 1982 to 6.5 in 1992. Although the progress is encouraging, infant mortality is still higher than it is in several European countries, such as Sweden and Denmark.

Smoking remains the single most important cause of preventable disease and premature death in England, but some trends are improving. Adult smoking rates are falling; in men, this is reflected in a reduction in lung cancer. The epidemic in women (who have generally taken up smoking more recently) is still rising. Rates of smoking among children are not falling quickly enough, and efforts are being made to stop children from smoking.

Sexual health has also become a focus of national and public health policy, with two primary areas of concern. First is the rising level of conceptions, especially among young teenagers. Second is the increase in AIDS cases, mostly in and around London and mainly homosexual men. However, the highest proportional rise in AIDS cases is among heterosexuals.

Britain remains low in the level of expenditure on health services. In Europe it ranks only above Greece, Portugal, Spain, and Ireland in the level of expenditure per person.

National Targets for Improving Health

A white paper entitled "The Health of the Nation," published in 1992, set forth the government's strategy for improving health (18). It established the following targets for CHD and stroke:

- to reduce death rates for both CHD and stroke in people under 65 by at least 40 percent by the year 2000 (baseline 1990),
- to reduce the death rate for CHD in people aged 65 to 74 by at least 30 percent by the year 2000 (baseline 1990), and
- to reduce the death rate for stroke in people aged 65 to 74 by at least 40 percent by the year 2000 (baseline 1990).

For cancers:

- to reduce the death rate from breast cancer in the population,
- to reduce the incidence of invasive cervical cancer by at least 20 percent by the year 2000 (baseline 1990),
- to reduce the death rate for lung cancer in people under the age of 75 by at least 30 percent for men and by at least 15 percent for women by 2010 (baseline 1990), and
- to halve the annual increase in the incidence of skin cancer by 2005.

For mental illness:

- to improve significantly the health and social functioning of mentally ill people,
- to reduce the overall suicide rate by at least 15 percent by the year 2000 (baseline 1990), and
- to reduce the suicide rate of severely mentally ill people by at least 33 percent by the year 2000 (baseline 2000).

For HIV/AIDS and sexual health:

- to reduce the incidence of gonorrhea by at least 20 percent by 1995 (baseline 1990) as an indicator of HIV/AIDS trends, and
- to reduce by at least 50 percent the rate of conceptions among the under-16 population by the year 2000 (baseline 1989).

For accidents:

- to reduce the death rate for accidents among children under 15 by at least 33 percent by 2005 (baseline 1990),
- to reduce the death rate for accidents among young people aged 15 to 24 by at least 25 percent by 2005 (baseline 1990), and
- to reduce the death rate for accidents among people aged 65 and over by at least 33 percent by 2005 (baseline 1990).

The Patient's Charter

The Patient's Charter, published in 1991 by the Department of Health, articulates numerous rights and standards, many of which have existed since the establishment of the National Health Service (NHS) (15). The Patient's Charter provides a yardstick against which performance is based. It gives patients the right to:

- receive health care on the basis of clinical need, regardless of ability to pay;
- be registered with a general practitioner (GP);
- receive emergency medical care at any time through a GP or through the emergency ambulance service and hospital accident and emergency department;
- be referred to a consultant (acceptable to the patient), when a GP deems this necessary and to be referred for a second opinion if the patient and GP agree that this is desirable;
- be given a clear explanation of any treatment proposed, including any risks and alternatives;
- have access to health records and know that those working for the NHS have a legal duty to keep the contents confidential;
- choose whether to take part in medical research or medical student training;
- be given detailed information on local health services, including quality standards and maximum waiting times;

TABLE 8-1: Sources of Funding for the NHS, 1991/92

Source	% of total
National Exchequer (general taxation)	83
National Insurance Fund	14
Other sources (charges, land sales, etc.)	3

SOURCE C Ham, *The NHS—A Guide for Members and Directors of Health Authorities and Trusts* (Birmingham National Association of Health Authorities and Trusts, 1993)

- be guaranteed admission for treatment by a specific date no later than two years from the day when the patient is placed on a waiting list; and
- have any complaint about NHS services investigated and receive a full, prompt, written reply from the chief executive or general manager.

One of the most important elements of the drive to improve the quality of care has been the policy of reducing waiting times for treatment. No patients wait more than two years for treatment. In 1993 a guarantee was introduced that no one should wait more than 18 months for a hip or knee replacement or a cataract operation.

THE BRITISH HEALTH CARE SYSTEM

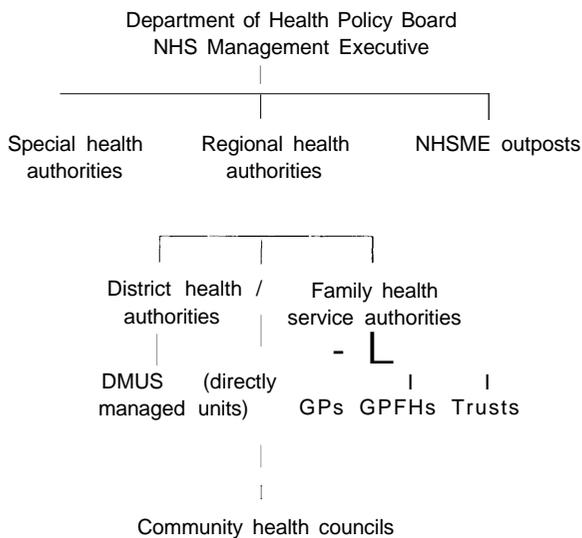
Introduced in 1948 by the Labor Party, the NHS is based on the principle that everyone is entitled to any kind of medical treatment for any condition, free of charge. The NHS is not insurance-based but is funded primarily from general revenues (see table 8-1 and figure 8-1).

There are nearly 980,000 staff employed in the delivery of health services. In the fiscal year April 1993 to March 1994, the total expenditure was set at 29.9 billion.¹

In England the Secretary of State for Health is responsible to Parliament for the provision of health services. In Scotland, Wales, and Northern Ireland, the respective secretaries of state assume the responsibility. The relationship between the

¹ Exchange rate in mid. 1994: \$US 1.4410 = 1.00.

FIGURE 8-1: General Structure of the NHS



SOURCE J Spiby, 1994

Department of Health and the NHS has its origin in a series of acts, starting with the National Health Services Act (1946) and consolidated in the National Health Service Act (1977) and the NHS and Community Care Act (1990) (13,14).

England

In England the secretary of state is assisted by the executive at the Department of Health. The Policy Board sets the NHS'S strategic direction. Chaired by the Secretary of State, it has these members:

- health ministers,
- the Chief Executive of the NHS Management Executive,
- the Permanent Secretary of the Department of Health,
- key individuals from outside the Department, including two regional chairpersons and top business people, and
- the Chief Medical Officer and Chief Nursing Officer.

The NHS Management Executive (NHSME) is responsible for achieving the strategic goals set by

the Policy Board. It is chaired by the Chief Executive of the NHS, and its members, drawn from NHS and business, lead various directorates. Both the Secretary of State and the Chief Executive are accountable for the prudent administration of funds to the Public Accounts Committee, which oversees public expenditures of Parliament.

The Department of Health is staffed by permanent civil servants (of whom the permanent secretary is the head) and many other staff drawn from within the ranks of health care professionals, particularly doctors and nurses (about 4,500 staff in all). The Department provides:

- advice to the Secretary of State and answers to questions of Members of Parliament on all aspects of the NHS, with a particular emphasis on political considerations, and
- a range of professional advice to the Secretary of State to guide policy development with reference to national and international issues and taking into account broad political considerations.

Department of Health officials and NHSME staff have both formal and informal arrangements to ensure complementary activities. Day-to-day activity is managed by a range of agencies on their behalf (as shown in figure 8-1).

Wales, Scotland, and Northern Ireland

Responsibility for health care in these three countries rests with the Welsh Office, Scottish Office, and Northern Ireland Office, respectively. In Wales the Secretary of State is assisted by the Health and Personal Social Services Policy Board and the Executive Committee. There are nine district health authorities and eight family health services authorities that increasingly work together.

In Scotland the Secretary of State operates through the Scottish Home and Health Department and a Chief Executive. There are 15 health boards responsible for family health services as well as hospital and community services. In Northern Ireland there are four health and social services boards covering social services as well as health care.

Health Policy

The Department of Health is concerned with both health and health care. Policies for improving the quality of health care are centered on the Patient Charter, which is part of a wider governmental initiative to raise the standards of public services. The Department is also responsible for social care and seeks to improve services through policies set forth in a 1990 white paper entitled "Caring for People" (12). Local authorities are the lead agencies for community care (often used as a synonym for social care) and are expected to work closely with NHS authorities to ensure that a comprehensive range of services is available. One of the aims of policy in this area is to shift the provision of services away from residential care to supporting people in their own homes.

The three key priorities for NHS in 1994 and 1995 include:

- implementing "The Health of the Nation,"
- developing the Patient's Charter at national and local levels, and
- ensuring high-quality social care.

A fourth priority is to achieve greater health care efficiency and effectiveness through sound use of resources and development of effective organizations.

The Health Care Purchaser-Provider Relationship

Since April 1991 and the introduction of the NHS and Community Care Act, there has been a philosophical and practical change in the way NHS is managed (14). Health authorities have been given specific responsibility for identifying their population's health needs and for using public money to buy services under a specific contract so as to meet those needs. Responsibility for providing services rests with hospitals, GPs, and other providers, such as community units. Providers can now obtain funds only by contracting with purchasers.

The purchaser-provider separation has accelerated changes that were already under way and has stimulated new changes, including:

- greater accountability for service provision, as the required service is more carefully specified;
- more emphasis on quality issues and on patients' rights, including the introduction of audit systems;
- more involvement of patients in specifying requirements; and
- a degree of competition between providers and the use of outside agencies to provide certain services, particularly in nonmedical areas.

■ The Purchasing Chain

The Regional Health Authority is a statutory body responsible for strategic planning and monitoring of the activity of purchasers as well as for allocating resources on the basis of an agreed-on formula. It also has a range of other enabling functions.

The District Health Authority (DHA) is a statutory body whose main function is to assess the health needs of the resident population and to purchase services to meet those needs. In England its key priorities for 1993/94 were as follows:

- to embrace a wider role as champions of health in the local community, to develop strong alliances with other agencies (e.g., social service departments, Family Health Service Authorities (FHSAs)), and to set an example as an employer by looking after the health of its staff.

Top priorities for action include implementing the "Health of the Nation," ensuring high-quality health and social care in partnership with local authorities, and developing the *Patient's Charter*.

FHSAs are statutory authorities that continue to plan and manage the development of services provided by GPs, family dentists, retail pharmacists, and opticians, all of whom are independent practitioners. In some places DHAs and FHSAs are forming health commissions for joint purchasing. A formal merger of the two organizations would require legislative change, which is expected in 1996.

GP Fundholders are larger GP practices—those with 7,000 or more patients. They may become purchasers for a limited range of services (11). They may purchase all investigative ser-

vices, community nursing and community psychiatric nursing, some outpatient and therapeutic services, and, most notably, a limited range of specified acute procedures (costing no more than 5,000).

DHAs and GP Fundholders place contracts with providers to deliver service, containing details on the volume and quality of service to be delivered for a price. DHAs and GP fundholders may place contracts where they choose. A contract may be with any trust, private or voluntary provider, or other directly managed units; however, these will take into consideration historic patterns of referral, access to services, and the wishes of GPs and patients. It is therefore the responsibility of purchasers to decide (within their financial allocation) what services patients will receive.

Trusts

Trusts are accountable to the Secretary of State and vary in the range of services they provide. Their performance is monitored (although not managed) by the NHSME via one of seven outposts. Most outposts span two regions and are separate from the regional function.

NHS trusts are self-governing units with their own boards of directors, and they are operationally independent of the district health authorities. They make decisions on how to deliver service to achieve the highest quality. The trusts are free to determine their own management structure, to employ their own staff, and to set their own terms and conditions of service. They are also free to acquire and sell their own assets, to retain surpluses, and to borrow money subject to annual limits.

Each trust is required to prepare an annual business plan articulating its proposals for service development and capital investment, and showing support from purchasers for the development. Each trust also prepares and publishes an annual report and accounts.

Contracts or Service Agreements

All providers now work on contract. As the trusts are completely financially independent, they can survive only if they undertake procedures for

which they have a contract. (As these are not legally binding, they are officially termed “service agreements,” but are commonly referred to as contracts.) If trusts undertake work for which they have no contract, they will not normally receive payment. This is of particular importance in non-emergency surgery, where the maximum number of operations is usually stipulated.

Most trusts obtain the majority of their work from the local DHA by which they were previously managed. However, there is no rule stipulating locales from which their patients should come, and DHAs are free to place contracts where they like. Certain historic patterns of patient referral are being broken down, particularly those involving referrals to inner London teaching hospitals for relatively routine conditions. Providers (if they have extra capacity) may try to persuade distant purchasers to buy their services, but cannot always generate extra business because purchasers tend to have little uncommitted money.

NHS Management Reforms Planned for 1994 to 1996

A series of changes in the NHS management in England were announced in October 1993 by the Secretary of State for Health. Subject to consultation, the new structure will be put into place by 1996; some preliminary changes were due for implementation by April 1994 (21).

Initially, mergers will reduce the number of RHAs from 14 to eight. Legislation will then be introduced to abolish the RHAs altogether, replacing them with eight corresponding regional offices of the NHS Management Executive. Another aim is to enable DHAs and FHSAs to merge, creating stronger local purchasers; this, too, requires legislation.

Provision of Funds

Public expenditures on the NHS are determined by the Public Expenditure Survey Committee, on which the NHS is represented by the Department of Health. The process begins each summer, and final figures for the next financial year are agreed on in the fall.

TABLE 8-2: NHS Expenditures on Hospital and Community Services (by Patient/Group or Type of Service), 1990/91

Patient group or service type	f million	% of total
Acute care hospital	6,717	45
Elderly	1,868	13
Other hospital	1,764	12
Mentally ill	1,133	8
Maternity	816	6
Other community	927	6
Administration	775	5
People with learning disabilities	746	5

SOURCE C Ham, *The NHS- A Guide for Members and Directors of Health Authorities and Trusts* (Birmingham National Association of Health Authorities and Trusts, 1993)

In 1993/94 spending on the NHS was set at 29.9 billion, or 12.25 percent of total government expenditures. Although this proportion has increased over the years, at 6 percent of the United Kingdom's gross domestic product, health care still accounts for a smaller part of the economy than it does in most developed countries. The primary source of NHS funding is general taxation.

Salaries are the biggest single budgetary item in a service with 980,000 staff members, including 500,000 nurses and midwives, 53,000 doctors and dentists, 160,000 administrative and clerical staff, and 145,000 ancillary workers (1992 figures). Workers in primary care who are self-employed, including 30,000 GPs and 15,000 dentists, are covered separately.

The NHS produces an annual report on expenditures. Table 8-2 shows the proportions of expenditures on hospital and community services by patient group in 1990/91, indicating the priority given to acute care and the importance of services for the elderly.

Distribution of Funds

Spending on health services in different parts of the country has historically been unequal. From the mid- 1970s until 1991 a formula was used to redistribute resources gradually. The main change

has been the movement of resources from the southeast, particularly London, toward the north and, in each region, away from the large teaching hospitals and conurbations.

Funding is now allocated on the basis of the resident population of a health authority and not, as before, on the catchment population (i.e., patients who come to be treated in the district hospitals). This is called resident/capitation-based funding. Health authorities are allocated resources on the basis of a formula that takes into account the size and structure of the population, the pattern of illness, the number of elderly people, and certain geographical considerations. Consideration is now being given to including so-called social deprivation factors, which will give some districts more money for growth and development.

Sources of Funds for Providers

Most of the funds for activities in a provider unit come from the Exchequer through contracts with DHAs and GP fundholders (11). Most capital funds are obtained as part of the business planning process and according to agreed-on external financing limits for each trust. Although trusts can in theory borrow money on the open market, the interest rates are always higher than those available from the central government. Partnerships with private companies are encouraged for some capital projects.

Private patients provide a small but important part of the income of units. For these patients, units are free to price services as they like. They are able to offer private patients treatment and facilities in any part of the hospital but are increasingly developing separate rooms and sometimes whole buildings for them. In 1992, private patients generated 12,771 million in revenue.

Almost all hospitals have some charitable trusts, usually accumulated over many years from donations. In long-established hospitals, particularly those with a famous name, these funds can be sizable, and special trustees are usually appointed to administer them. Such funds are a useful source of money for staff facilities, research, and equipment.

Public Organizations

Community health councils (CHCS) are charged with representing the local community's interest in the health service. They are an important source of public information and a channel for consultation, representation, and complaint. There is usually one CHC in each district, made up of 18 to 24 lay members, a chairperson, and a paid officer (or secretary).

The basic duty of each CHC is to review the operation of the health service in its district and make recommendations on such matters as the Council thinks fit. The CHC'S main functions are to consider complaints, visit NHS premises, serve as a forum for consultation on the planning of local health services, provide information on local services, and monitor the quality of services through surveys and other means.

Consumer interests are also represented by community health councils in Wales. They are represented by the local health councils in Scotland and by the health and social services councils in Northern Ireland.

Although not directly concerned with individual patients, two influential bodies outside the NHS carry out audits of its performance:

- The National Audit Office carries out studies, particularly ones concentrating on value for money, which are regularly used by the Public Accounts Committee when investigating the NHS'S performance.
- The Audit Commission, established in 1982, looks at local government activity. Its powers were extended in 1990 to cover the NHS, and its governing body includes ministers. The Commission appoints auditors to look at areas in which there is significant variation in performance. It attempts to spread good practice and has produced a number of influential reports.

■ Impact of the Reforms

One of the key changes that has resulted from the separation of purchaser and provider roles is that GPs have started to work much more closely with the DHAs. With GPs responsible for referring pa-

tients to hospitals and DHAs responsible for placing contracts, it is essential that there be a continuing dialogue between the DHAs and the physicians on which hospital and community health services should be purchased and where contracts should be placed.

As a result of this developing dialogue, service provision has shifted toward primary care. There has also been a change in the balance of power between GPs and hospital consultants, which has forced hospital doctors to pay greater attention to GPs and to be more responsive to their demands. Consultants in some districts now hold their outpatient clinics in GP offices rather than in hospitals.

Some of the most significant changes resulting from the reforms have been pioneered by GP fundholders. The first wave of fundholders included many of the best-organized GP practices, and these GPs have used their new powers to improve the services they deliver. The result has been a shift in favor of GPs and greater accountability of hospital doctors to purchasers.

The NHS trusts have also used their freedom to improve the quality of care, including steps to reduce waiting times, provide greater flexibility in clinic hours, and improve arrangements for patient appointments. Of particular importance has been the ability of trusts to run their own affairs and make decisions more quickly than in the past.

No national blueprint for reform has been set forth by the Department of Health and to a large extent implementation has been characterized by "learning by doing." In this sense the development of NHS as an organization depends on actual implementation experience and cannot be predicted in advance. This observation applies particularly to the evolution of the internal market. There was little competition in the first year of the reforms, as the main emphasis was on laying the basic building blocks of change. In 1992/93 purchasers were more active in switching to alternative providers, and such switches caused financial problems in a number of hospitals, especially in London. (The future of health services in London has been the subject of a special inquiry (45).)

It is not clear how ministers will respond to the emergence of losers in the internal market. The logic of the reforms is that competitive incentives should be used to reward providers who are efficient and to penalize those who are not. The difficulty with this approach is that the NHS'S founding principles, such as access and equity, may be undermined if people have to travel further for treatment as a result of the closure of hospitals that fail to compete successfully. Ensuring that people who have the poorest health receive the treatment they need remains a continuing challenge. For this reason the market must be managed to diminish the risk of gaps in service provision or unplanned interventions.

CONTROLLING HEALTH CARE TECHNOLOGY

There is no overriding legislation to control the purchase and use of health care technology in the United Kingdom. The regions, districts, and FHSAS are allocated budgets annually. The regions maintain some control over major capital schemes or purchases, whereas the trusts and GPs control decisions at the local level—in collaboration, at varying levels, with the DHAs and FHSAS. The Department of Health is often involved in the development of new technologies at an early stage, but its involvement is variable, as is its level of control. Pharmaceuticals are the only area in which there is a clear process for controlling introduction; otherwise, the mechanisms of control vary considerably.

In recent years the need to control the introduction of new technologies has become more widely appreciated. This is due mainly to the fact that the health care budget is already under heavy pressure from the growing elderly population, and also to an increased awareness of the need to ensure that health care technology is effective and offers justifiable additional health gains and minimal side effects.

Development of a National Policy

In 1988 the House of Lords Select Committee on Science and Technology, in its "Priorities in Med-

ical Research," stated that coherent arrangements were lacking by which the NHS could articulate its research needs and ensure that the benefits of research were translated systematically and effectively into service. The Committee was particularly critical of the way in which public health research and operational research (i.e., research on the organization and management of health services) had been relatively neglected. It suggested a marked increase in funding for this area.

In response the government created a senior post of director of research and development to head the NHS Research and Development Division and to sit on the NHSME (16). A research and development strategy was launched in April 1991 as the first stage in creating an R&D program in the NHS. This R&D program emphasizes evaluation of the quality, effectiveness, and cost of health care methods and research into the delivery and content of health care. It also seeks to influence biomedical research not only by expecting NHS priorities to be taken into account when planning future programs but also by expecting the practical implications of major research discoveries to be anticipated early.

To ensure integration of R&D with NHS commissioning, the regions were given responsibility to commission and manage regional R&D programs and also to help ensure that 1) the results of good research are used to full effect, and 2) the regions promote a dialogue between the local research community and purchasers. During 1992 the regions developed their own R&D plans and appointed staff to oversee their programs. In the first round, the staff were mainly clinicians; therefore, some of the impact on NHS activity (as opposed to biomedical research) has been lost. However, to ensure that the strategy is close to NHS'S R&D needs, a Central Research and Development Committee (CRDC) was set up to review R&D of relevance to NHS'S work and to identify areas where further work would be of value. The committee brings together senior NHS managers, leading research workers from universities and elsewhere, lay members, and others with experience in industry. The work that it identifies as a priority will either be funded centrally or

by the regional health authorities and postgraduate hospitals.

The lack of real controls on medical technology and the role of technology assessment became apparent during the development of the R&D strategy. Early on, the Department of Health's director of R&D set up a health technology group to prepare a report on methods for assessing the effects of health technologies. Among the main points of the report are:

- the range of possible outcome measures by which health technology effects might be assessed should always be considered explicitly;
- existing evidence on the effects of health technologies should be reviewed systematically and the results disseminated in forms that a wide range of decisionmakers, including patients, can understand. If the evidence is strong, means should be used to ensure that it influences practice;
- there should be a systematic information system for disseminating the results of technology assessments;
- every effort should be made to assess the effects of new technologies before decisions are made on whether they should be used within the health service;
- multidisciplinary research centers, each focusing on a priority area, should be established to assess the effects of health technologies; and
- there should be training and a career structure for those who wish to specialize in technology assessment (17).

The report was considered by the CRDC, and in February 1993 a Standing Group on Health Technology was established. This Standing Group established six advisory panels to consider primary and community care; acute care; pharmaceuticals; diagnostic and imaging technology; population screening; and R&D methods. Following consultation with NHS and other interested bodies, each panel put together a list of its top 20 priorities, which was published in December 1993.

The Standing Group's key tasks are to:

- identify and rank technologies in need of assessment;
- identify and rank the need for R&D of technology assessment methods, especially in cases where diffusion of a technology must be controlled until more information becomes available; and
- identify emerging technologies likely to have major implications for the NHS.

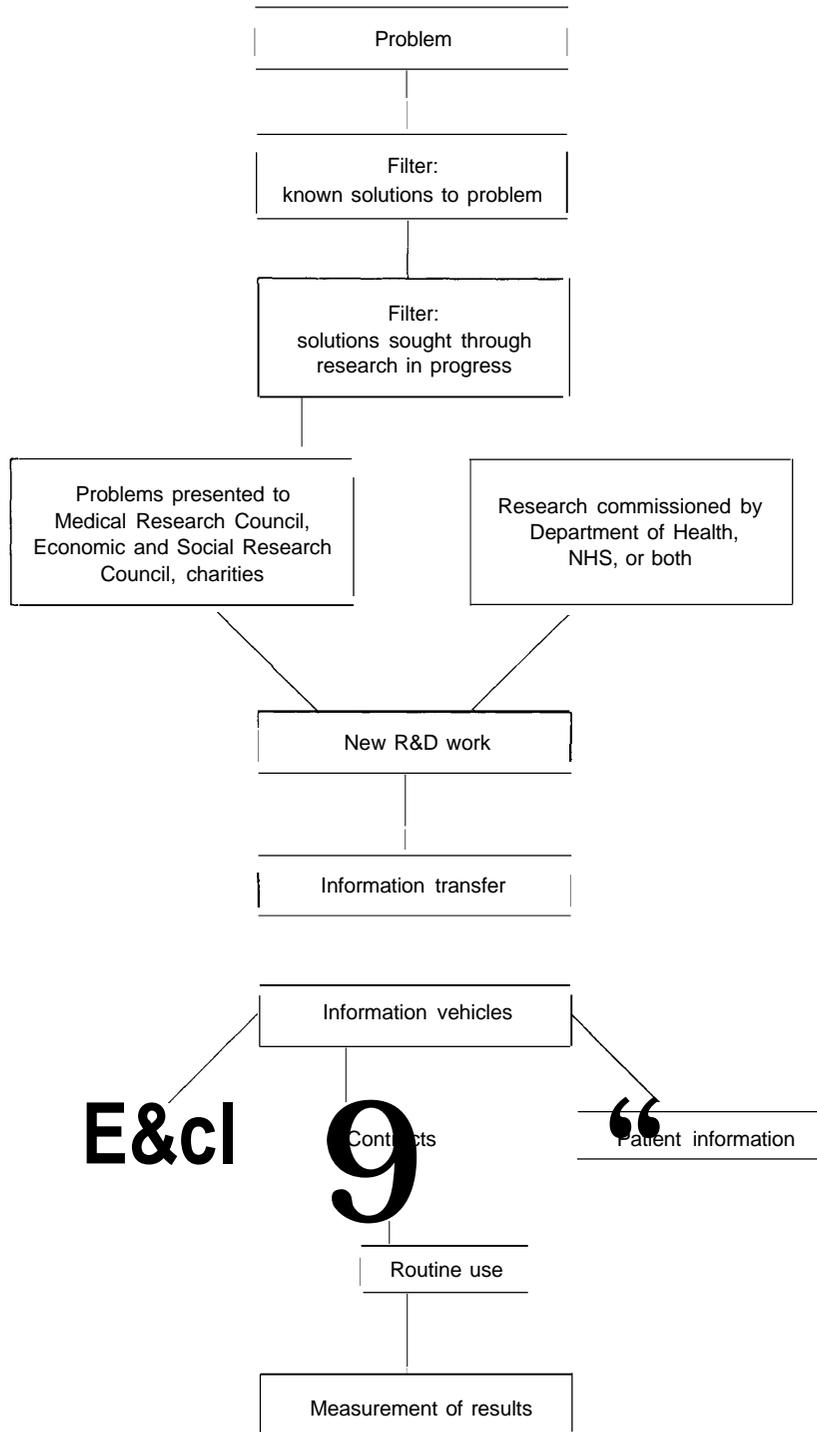
The R&D strategy, the Standing Group and associated infrastructures are major steps toward a rigorous national process. To date, however, technology assessment has been seen mainly as a source for R&D monies rather than a means of finding answers that will actually inform clinicians or managers. To address the ongoing need for practical information for short-term use, three units have been set up to handle existing research data. The Cochrane Centre was established in Oxford to undertake systematic analysis of clinical trials; a center in York will commission expert research reviews; and health care effectiveness bulletins, produced from Leeds, are already offering useful overviews of technology assessments (38). The York unit will also concentrate on the systematic transfer of this and other research information to users and will help develop skills for transferring research information to decisionmakers.

Figure 8-2 shows how a technology assessment problem is "managed" such that useful information is provided to NHS.

Regulation of Pharmaceuticals

The pharmaceutical industry, often depicted as a bastion of the free market, is in fact heavily regulated. A maze of rules has been created by separate, often isolated, government departments. The finance division pursues policies separate from those of its pharmaceutical price regulation scheme (PPRS) colleagues and often, it seems, with little liaison with officials of the Department of Trade and Industry, which pursues its own anti-trust and balance of trade goals.

FIGURE 8-2: Managing a Technology Assessment Process



SOURCE M Peckham, 1994, in R Smith, "Filling the Lacuna Between Research and Practice An Interview with Michael Peckham," Br. Med. J. 307:1403-1409, 1993

Safety and Efficacy

In the United Kingdom, voluntary regulations for pharmaceuticals emerged in the 1950s. Following the failure to prevent the teratogenic effects of thalidomide taken by pregnant women in the early 1960s, the 1968 Medicines Act created the Committee on the Safety of Medicine (CSM), which advises on the safety, quality, and efficacy of new medicines. This act also established the Committee on the Review of Medicines (CRM) to review the safety, quality, and efficacy of existing products. A licensing system was created to regulate clinical trials, marketing, the manufacture and distribution of products, and advertising and promotion.

The process of licensing a New Chemical Entity (NCE) has become long and expensive. Animal toxicity tests, if acceptable, are followed by clinical trials on human subjects. The company can then apply for a product license, without which the NCE cannot be marketed. This process may take 10 to 12 years from the time that the compound is patented.

If a new drug has potential breakthrough effects (e.g., for treating AIDS), a fast-track route can be found; however, this is rare.

Patent legislation rewards producers of innovative drugs by giving them monopoly power; without this incentive, R&D investment would probably be reduced. The legislation governing NCEs has eroded patent protection and reduced the duration of monopoly power (hence profits). In addition, the licensing rules raise costs, and together these factors may well diminish drug companies' R&D investments.

Regulating Prices and Profits

Since 1957 the prices and profits of the U.K. pharmaceutical industry have been regulated by the government and the PPRS. Each year, the Department of Health assesses firms' profitability in relation to targets set to ensure that costs, profits, and prices are reasonable—that is, in the range of 17 to 21 percent. If a firm's **return** exceeds this figure, it may be required to repay money to the Department. If returns are less, applications can be

made for a price increase. The Department also limits aggregate expenditures on sales promotion to 9 percent of total sales revenue.

PPRS is a voluntary agreement that the House of Commons Public Accounts Committee reviews irregularly and for which there is no other public review. The scheme is directly affected by cost containment mechanisms. If cost-reducing activities are successful within NHS, a firm may be allowed a price rise via PPRS.

User Charges

Prescription charges were abolished in 1965 but reintroduced in 1968 (with extensive exemptions). Since then the charge per item has risen from 13 p per item in 1968 to 4.75 p in 1994. This is well over five times the general price level increase; however, the revenue obtained has decreased as a result of increasing numbers of people who are exempted from payment (52 percent were exempt in 1969, 85 percent in 1991).

Generic Prescribing

Prescribing of generic alternatives to brand-name drugs becomes possible when an NCE goes out of patent. Generic prescribing is strongly encouraged, and recently several campaigns and official reports have put pressure on GPs and FHSAs to increase the level of generic prescribing. In 1979, approximately 29 percent of prescriptions were generic; this had risen to 40 percent by 1990, and a target of at least 50 percent has been set in many regions. An educational program for the general public is under way to explain why the government promotes generic prescribing.

Limited List

In 1985 the range of drugs prescribable under NHS was limited by the Department of Health. No longer prescribable were medicines for which over-the-counter alternatives were widely available. The government claimed that in the first year, 275 million was saved by this mechanism. The aim of the limited list is to force consumers of all ages to pay for some medicines and to ensure that expensive drugs are not prescribed unneces-

sarily. The limited list was extended in 1994 to include drugs such as those for hay fever and duodenal ulcers.

Prescribing Analysis and Cost Data (PACT)

PACT and similar systems used in Scotland and Northern Ireland are an attempt by the Department of Health to disseminate information on prescribing behavior to GPs to increase their awareness of costs. The feedback system began in 1988; since then, there have been some changes in prescribing patterns, although it is difficult to know whether they are due to PACT. Capacity to use the data has been increasing; all FHSAS are directly on line to the Prescription Pricing Authority, which downloads PACT data monthly.

Indicative Prescribing Budgets

The indicative prescribing scheme, introduced in 1991, aims to build on the PACT system to improve prescribing and reduce drug expenditures (10). RHAs receive an annual block allocation to cover the cost of all prescriptions dispensed within their FHSAS. Initial allocations reflected historical spending patterns but are increasingly moving toward a weighted cavitation basis. FHSAS then set indicative prescribing amounts for each GP practice based on factors such as existing costs, number and age of patients, local social and epidemiological factors, morbidity, and special circumstances. If a GP overspends the indicative budget, the FHSAs medical and/or pharmaceutical adviser offers advice on how costs might be reduced. The budget is not a firm cap however, and FHSAs have no executive powers to penalize GPs. In the wake of a recent Audit Commission report, it is anticipated that the budgets soon will be cash limited.

Regulation of Medical Equipment

In comparison with pharmaceuticals, the control of medical equipment is minimal. In the Department of Health a fairly complex set of machinery supports and tracks new developments and advises scientific and supplies officers; this is not, however, the same as control. In certain extreme situations, a warning hazard note can be produced

by the Department, and particular equipment is removed. The scientific and technical division of the Department is mainly responsible for producing this information. Its work covers technical quality (i.e., whether the equipment does what the manufacturer says it will do), reliability, and mechanical and electrical safety for the patient and operator. This work rarely includes analysis of cost-effectiveness or an understanding of the impact of the equipment on organizations.

The Department of Health also regulates the introduction of equipment through its role in financing high-cost technology. These so-called pump-priming funds are used to support an industry introducing equipment that is deemed necessary by the NHS. Two or three items might be purchased to help the sales take off, especially if the Department has previously supported this development through its R&D program.

In the past there was a clear procedure for the purchase of new equipment: it was purchased with funds from a regional capital budget against which districts bid for their local hospitals. Many regions devolved a portion of this budget to districts in order to purchase smaller pieces of equipment.

Eighty percent of this equipment budget is usually required for replacement purposes, and only the remainder is available for new developments. The key decisionmakers in both the district and the region are managers and clinical advisory committees. The system tends to be somewhat arbitrary and is frequently based on a "he who shouts loudest" principle rather than a systematic analysis of need.

With the introduction of the split between purchasers and providers, the relationship for capital development is purely a matter to be worked out between the provider and region or NSME outpost. The use of non-NHS monies for capital is expected to extend as the trusts become more familiar with the use of private financing mechanisms.

At present, trusts make bids to the region or outposts in their annual business plans for specific capital development. The control of large pieces of equipment and the implications of developing

new technology have become more apparent to providers as these costs are included in their full costs and called “capital charges.” These charges are passed on to the purchasers; institutions with excessive building capital or equipment thus have higher costs within their contracts.

NHS Supplies Authority

In 1991 the Department of Health reversed its previous policy of devolving the purchase of medical supplies (ranging from catering to expensive scientific equipment) and established a central NHS Supplies Authority. This change resulted from a report by the National Audit Office that was critical of NHS buying. It stated that the considerable bulk buying power of the NHS was not being fully utilized because of lack of coordination and that many opportunities for more cost-effective purchasing were being missed. The main focus of the report was more cost-effective buying.

The Supplies Authority provides a central, coordinated policy for buying supplies. It has six divisions, with the national headquarters concentrating on key commodities such as food contracts, medical and surgical items, and x-ray equipment. The Authority also undertakes research into market requirements and has a small R&D program. This new development is rather at odds, however, with the establishment of trusts and the independence of providers. At present, it is expected that the trusts will be encouraged, but not required, to use the purchasing power of the Authority.

Control of Provider Locations

In the past the Department of Health and the RHAs had strong control over the placement of providers through a regional planning tier or specific, centrally promulgated regulations, concerning where GP practices could be sited. With the introduction of the internal market, it was anticipated that this regulatory planning function would be removed, and placement of providers would be subject to market forces.

It has become clear, however, that at present the government is uncomfortable with allowing trust hospitals to close merely because of market forces. The mode of control or “market management” is still under discussion. Theoretically, if purchasers do not place a sufficient number of contracts with a provider to ensure its continued existence that provider should close. In reality, while some are closing or unifying with adjacent units, no major hospital has yet closed.

In central London the government has determined that it is unhappy letting the market control the siting of providers. It has chosen to set up a central review body (the Tomlinson Review) that has clearly identified where teaching hospitals should be merged or where specific providers should close. These decisions have been much debated, and considerable lobbying has been undertaken. Some, though not all decisions have been overturned by the Secretary of State.

Regulating the Placement of Services

The role of districts in purchasing health care based on assessed needs provides a major impetus for technology assessment. For the first time, managers and public health physicians are working together to assess the literature on effectiveness of health care procedures, including cost-effectiveness.

The Department of Health has responded by commissioning a series of bulletins on the effectiveness of health service interventions for decisionmakers; the first editions were published in January 1992. These bulletins are specifically oriented toward health authorities rather than clinicians.

The need to purchase effective health care packages is also promoting interest in service evaluation, and research on local health services is increasing rapidly. At present the main effect of districts as purchasers is to reduce support for expensive technologies with little proven effectiveness. This potential conflict between teaching hospitals and their clinicians and the purchasers has not been resolved, nor have explicit mechanisms of control been established.

Districts are increasingly including GPs in this process as part of the advisory mechanism for purchasing services. This is a new role for **GPs**; **some** relish it, but others find it unacceptable either because they do not consider it is a good use of their time or because they have qualms about taking on even greater responsibility for what they consider **to be** management.

The role of the DHAs in determining where resources are allocated has become increasingly explicit, as they have lost their direct management role. This explicitness, inevitable with the NHS reforms, is proving difficult politically; previously, the long waiting list dealt implicitly with excess demand. Consumer expectations have also risen, and the conflicts between resource availability and patient need and demand are making the role of the DHA purchasers increasingly difficult.

Control of Use

Within the new purchaser/provider system, use is determined through the contract between the DHAs and their providers. The level of refinement of this contract is very limited at present, and utilization is measured by numbers of consultant episodes, which means that the emphasis is on inpatient activity and events rather than on individual patients. This is obviously not adequate, and better information systems are being developed (though not quickly enough for current requirements).

On the whole, most districts are signing contracts with providers which aim to reduce the level of activity in acute hospitals, either because of limited funds or because of policies that aim to shift activity from hospitals to the community. Demand is continuing to rise, and hospitals are seeing an annual increase of 2 to 5 percent in activity. This conflict between increased patient demand and reduction of activity levels in purchaser contracts can be seen clearly in districts in the south of England, where budgets on the whole are being decreased. In some hospitals, only urgent work is done near the end of the financial year to ensure that activity is kept within the agreed con-

tract and that budgets are not exceeded. Such restrictions are not acceptable **to the** government, however, and providers are being required **to pace** their activities throughout the year.

Utilization and Quality Control

The contracts **set** with providers by DHAs cover not only activity and finance but **also** aim to identify key quality measures. At present, the main emphasis in contracting is on activity and money. (This is due **to the** newness of the system rather than **to a** policy decision.) The level of detail and type of quality measures to be identified by the districts still are being developed. Clearly, the emphasis should be on outcome measures and expectations for the health of the population. As these are frequently difficult **to** identify and measure, process and structural measures probably will be used.

The Role of the Private Sector and Consumers

The private sector accounts for a small percentage of health care spending in the United Kingdom, most of which is funded through health insurance companies. There are clear rules **as to** which technologies are paid for under which policies; for example, cosmetic plastic surgery is not reimbursable. There is no published information on how these guidelines are determined. With increasing medical care costs, insurance companies are introducing cheaper policies that limit what can be provided.

A major part of the NHS reforms was a commitment **to the role of the** consumer in decision-making. The 1991 Patient's Charter **sets out** clearly, for the first time, the public's right **to** health care and to national and local charter standards, which the government intends **to see** achieved. This greater emphasis on the role of the consumer will no doubt increase actual patient questioning of medical practice, as well as interest in consumers' **views by** policy makers and others. The growing role of the consumer in technology assessment can be glimpsed in the inclusion of consumers in the planning of a few major random-

ized controlled trials (e.g., trial of chorionic villus sampling).

HEALTH CARE TECHNOLOGY ASSESSMENT

The United Kingdom has along history in some of the methods of technology assessment, such as randomized controlled trials and the development of health economics, but this has not been in a coordinated policy context. Interest in technology assessment has been slowly increasing because of pressures resulting from the costs of new technologies, increasing recognition of the potential dangers of new developments, and perceptions of more organized activity abroad. Originally, the main pressure for technology assessment came from those parts of the research community undertaking this work, including the King's Fund (a charitable health policy organization), health economists, the media, and some parts of the medical profession. More recently, however, pressure has come from NHS managers (including doctors), public health medicine, and purchasing authorities.

Raised within the context of the national R&D strategy, research dissemination and organizational issues (e.g., linkages between research and clinical practice) have become very significant. The report of the Standing Group also outlined the need for a career structure to encourage individuals in technology assessment. Problems in recruiting and retaining personnel had been a particular problem in health service research. The report argued for health technology assessment to be funded from public monies and coordinated by the national R&D strategy; to this end the funding mechanism itself was said to need clarification. The report also identified problems in organizing multicenter studies of major diseases. Finally, the report identified problems in undertaking proper randomized assessments resulting from litigation with regard to informed consent, corporate indemnity, and costs of treatment. These obstacles, stated the report, must be acknowledged more explicitly and overcome. The full impact of the Standing Group has yet to be fully felt, but it is

clear that the importance and relevance of technology assessment to the NHS has been firmly established. Outside the research community, this is not yet the case.

Technology Assessment Entities

The Medical Research Council (MRC) and the Standing Medical Advisory Committees

The Medical Research Council plays a key role in British medical research activities. It has been dominated by biomedical research and has been less interested in health services research or in the wider issues related to medical technology. After the publication of the House of Lords report, the appointment of a Director of Research and Development at the Department of Health, and a new Secretary at the MRC, change has accelerated. There appears to be a more positive attitude toward health services research and applied clinical research, as evidenced by the new board structure, which includes a fourth board for health services research, public health, and epidemiology.

Relations between the MRC and the Department are governed by a concordat that acknowledges the strong role of the latter in health services research. A report is also being considered by the MRC board that proposes that the MRC take a more active role in evaluating procedures (including consideration of economic, quality-of-life, and psycho-social issues).

Questions on such developments as neural tube defect screening or heart transplants are likely to arise in discussions between the Chief Medical Officer (CMO) and the medical profession. The CMO may then seek advice from the Standing Medical Advisory Committee (SMAC). For major issues a specialist SMAC subcommittee may be set up on an ad hoc basis to study the subject. Once the subcommittee has prepared a report and its recommendations are accepted by SMAC, a Health Circular on the subject may be sent out to NHS management. Such circulars provide advice on whether, to what degree, and how a service should be provided. In the final analysis, however, decisions are made by regions and districts. In

some circumstances, such as heart transplants, some central funds may be provided, but this occurs only for quite exceptional developments.

The Audit Commission

The Audit Commission is an independent body that audits the public sector. It has recently developed its work in health matters and has reviewed services such as those for day surgery, AIDS prevention, and bed utilization. Because it has access to all health authorities, it could potentially have a considerable impact on the use of medical technology.

King's Fund

One of the main proponents of technology assessment in Great Britain during the 1980s was the King's Fund, both behind the scenes and in the development of the U.K. Consensus Development Programme. The latter has now ceased, but as districts and RHAs authorities have come to recognize their need for assessment data, the method has been adapted to local circumstances.

Clinical Standards Advisory Group

The Clinical Standards Advisory Group (CSAG) was established in 1991 as part of the NHS Act to advise the health ministers or health care bodies on standards of clinical care, and access and availability of services to NHS patients. Most of the members are nominated by the Royal Colleges and faculties relating to medicine, nursing and dentistry, although the CSAG is funded by the Department of Health. Its initial work has covered the following:

- access to and availability of selected NHS specialist services,
- clinical standards for women in normal labor, standards of clinical care for patients admitted to hospital urgently or as emergencies. and standards of care for people with diabetes.

This body represents anew venture in developing and assessing clinical standards, and its success is still not assured-especially as it is advisory rather than mandatory. It produced a series of reports in March 1993 covering neonatal intensive care, cystic fibrosis, childhood leukemia, coronary artery bypass grafting, and angioplasty. There was no consistency in the methods or use of objective data in these reports. Their effects are difficult to assess but generally appear limited (4,5,6,7).

Medical Audit

A key part of the NHS reforms is encouraging all doctors to undertake medical audit, which includes the "systematic, critical analysis of quality of medical care and treatment, the use of resources, and the resulting outcome and quality of life for the patient." New monies have been released by the Department of Health for the development of medical audit, and in the fourth year of this initiative, a large number of clinicians are involved at some level. Much of the activity is focused on collecting data, but in some centers clinicians are now looking more critically at their work and judging it against agreed-on standards. This initiative, along with management changes that are encouraging doctors to be more involved in management issues, is forcing the professions to consider evidence on the costs and effectiveness of clinical procedures.

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE

Coronary artery bypass grafting (CABG) was developed in the United States in the late 1960s but was not introduced in the United Kingdom until the mid-1970s, probably because of financial constraints. Percutaneous transluminal coronary angioplasty (PTCA) was introduced in the early 1980s.

Because CABG requires relatively expensive equipment, it developed at the teaching institutions where capital monies were more accessible and medical staff sought to be at the forefront of medical expertise. The most well-endowed regions tended to be those in the London area; they had the greatest number of teaching and postgraduate institutions.

By 1982 the CABG rate was 107 per million population. This overall rate disguised a 12-fold variation among regions, from 21 to 263 per million. The rate of CABG rose steadily to 212 per million in 1986 and 278 per million in 1990. The extent of inter-regional difference fell, but there remained a fivefold difference: 97 to 466 per million in 1990. The most active regions were consistently in the southeast and in areas with a concentration of teaching hospitals. This increase in surgery was accompanied by a slow increase in cardiothoracic surgeons.

The differences among regions are mirrored by variation in utilization rates among districts within regions, most marked at the earlier stages of diffusion. Not surprisingly, uptake has been higher in districts with hospitals that provide the service, or where a local cardiologist is associated with a surgical unit, and not necessarily those with the greatest need. As this variance became well documented, attempts were made to redress the balance. However, change was limited until the NHS

reforms in 1990 when districts were funded according to their population size and characteristics rather than the facilities available in them. More recently, a further inequality has been reported: women have been shown to be less likely to receive surgery than men (32). Lower rates of surgery in the United Kingdom compared with the United States reflect a higher threshold for surgical intervention and greater dependence on medical treatments (based on a review of a region in the Midlands). This difference in threshold also serves to reduce demand in regions where levels of service provision are lower.

Funding Mechanisms and Changes in Control

Before the 1991 NHS reforms, CABG and PTCA were designated “regional specialities” and were funded by means of top-sliced allocations from regions. Now that districts have become responsible for purchasing these services, those districts with high levels of activity are beginning to question their spending levels and the relative efficiency of the service. Although the purchasing function is still relatively new, providers are beginning to see the impact of the reforms and to perceive the market as a form of regulation. It is unlikely that there will be a strong increase in CABG and PTCA activity unless it is achieved through an increase in efficiency. More emphasis will be put, however, on developing protocols and agreeing on criteria to establish appropriate use of these procedures. This process began with a report in a series of epidemiologically based needs assessments commissioned by the Department that stated:

. the use of CABG for disabling angina not responding to medical treatment is based on evidence derived from sound RCTS,

- the use of CABG for other indications and angioplasty for disabling angina not responding to medical treatment is based on fair evidence based on the opinions of experts and indirect evidence, and
- the use of CABG or angioplasty for other indications is based on poor evidence derived from opinions and indirect evidence (26).

Services in London

The Department of Health's "Report of an Independent Review of Specialist Services in London" (19) is part of a fundamental review of health care in London. The report suggests that the "ideal model of tertiary cardiac services consists of three equally important and interrelated parts," high quality clinical, diagnostic, treatment, and rehabilitation services; R&D to improve cardiac services and their delivery; and staff teaching to ensure current knowledge.

It was felt that none of the 14 London centers providing adult tertiary cardiac services met these criteria in all respects. There was a clear case for rationalization to create fewer, larger and stronger centers. The report proposed that nine units are required in London, with additional units elsewhere in the southeast and further afield.

The changes proposed are being hotly debated by each center and are unlikely to happen without political commitment. If they do, the likely outcome will be a more equitable distribution of services rather than any major increase in overall activity.

Department of Health Targets

In 1984 the King's Fund held its first consensus conference in London on CABG. It concluded that in the United Kingdom a realistic target for CABG should be 300 operations per million people. Despite various criticisms of the process, this target was endorsed in 1986 during a ministerial announcement at a Tory-sponsored conference by the government; it later found its way into central planning guidelines. The setting of such a clear guideline is unusual and reflects the influence of

the consensus conference and the evidence published by a health economist from York University who showed that CABG is a cost-effective procedure when analyzed according to the concept of quality-adjusted life years (QUALYS) (47). Although this methodology has since been severely criticized, it still plays a strong role in priority setting. This conference also established the credibility of CABG as an effective procedure.

The Department of Health monitors the level of CABG procedures but has not enforced a limit on them. Uptake of CABG and PTCA initially reflected the willingness of teaching hospitals and regions to invest in capital and staff to support them. Suggested appropriate levels of CABG and PTCA have had only a limited impact on activity. The Department is currently reviewing whether numerical targets are the best way to improve quality and quantity. Consideration is also being given to setting up a comprehensive, randomized study to identify which patients are most appropriate for CABG, PCTA, or medical treatment.

Clinical Standards Advisory Group

A review was conducted in 1993 by a working party of CSAG which concluded that "regional utilization rates are associated with the availability of consultant and nonconsultant staff in regional centres," and are also affected by varying patient expectations. In contrast, district utilization rates "are associated with the availability of a local cardiologist and the proximity of a regional center, and inversely associated with the mortality from coronary heart disease" (4).

The review expressed concern about long waiting times (particularly for CABG) resulting from lack of funds. CSAG'S report recommended that every district conform to national targets and aim to achieve a minimum level of 300 CABG procedures per million population within the next three years, with a review of the target possibly by another consensus conference. The report also proposed that a target for PTCA be set. To date, these recommendations have not been followed.

PTCA Update

By 1985, 15 hospitals had performed about 1,600 PTCA procedures, a rate of 29 per million population. At that point there was some questioning of the clinical effectiveness of the procedure, but as clinicians became more experienced, its routine use became established. The use of the procedure spread rapidly during the late 1980s so that by 1991, 53 (44 NHS and 9 private) centers had treated 9,933 patients (a rate of 174 per million population). This rapid rise has been enabled by the relatively low capital outlay required for PTCA equipment. In some regions debate has been heated as to whether angioplasty should be undertaken in hospitals without backup cardiothoracic surgery facilities because of the risk of perforated blood vessels during angioplasty. The increase in rates also reflects a 43 percent increase in the number of consultant cardiovascular physicians, from 223 in 1980 to 323 in 1990—again with a preponderance in the southeast. A greater proportion of these physicians are able to perform PTCA as younger staff trained in the new technologies become consultants. A recent report of the Royal Colleges of Physicians and Surgeons has recommended a level of 300 angioplasties per million population.

MEDICAL IMAGING (CT AND MRI)

Computed Tomography (CT)

The first clinically useful CT scanner was developed at EMI's Central Research Laboratory in Britain in the late 1960s, with funding from the Department of Health. The advantages of this brain scanner were quickly recognized; the competing technologies of cerebral angiography, pneumo-encephalography, and isotope scanning were more invasive, riskier, and more uncomfortable for the patient. Early evaluations were mainly clinically based. During the mid-1970s, the Department of Health formulated a policy that every region should have a least one brain scanner located in a neuroradiology center. By mid-1977 there were 30 brain scanners in the United Kingdom, and others were on order (41). Here, clearly,

at least in the initial phase, the Department controlled the introduction of the technology.

As the use of brain scanners increased throughout the NHS, EMI and others in the field were proceeding with the development of whole body scanners. Interestingly, the clinical evaluation of whole body scanning took a different path from that of the brain scanner. In the case of the latter, the Department maintained a high degree of control over the initial evaluation, and additional machines were not bought until the Department was satisfied (although as the clinical advantage was quickly recognized this process was not particularly delaying). With the body scanner, evaluation was much more complex because so many different organs were involved, other acceptable techniques were available for use in diagnosis, and the effect on patient management and on the final outcome was not obvious. Even more difficult was the ever-developing state of other technologies against which whole body scanners would need to be compared.

A reduction in the Department budget made it impracticable to buy enough scanners for a thorough exploration. Very early on, various philanthropists and private institutions had purchased body scanners for the NHS or for use in private hospitals, and these were not subject to the Department's control (41).

The Department decided to evaluate the scanner by bringing together all the users to discuss their studies. This mechanism proved unwieldy and was soon superseded by a committee of experts that aimed to analyze all the available data from users in Great Britain and abroad in an attempt to 1) determine the scanner's emerging place in medical care and 2) encourage research where there were gaps in evaluation. No major, randomized controlled trials were initiated, however. In retrospect, the committee's impact was limited (42).

The Role of Charitable Funds and Clinicians

The diffusion of CT scanners occurred exceptionally quickly, especially considering the initial

high cost of each machine. Although Britain was the country of origin of the technology and had the first brain scanner in action, the first commercial scanner was installed in the United States. By April 1977, 11 EMI whole body scanners were installed or on order in the United Kingdom (41), only 3 of which were bought with NHS funds. The others were donated by rich individuals, charities, or endowment funds.

Early on, fundraising events for scanners became common. The prime movers were consultant radiologists, but they rapidly involved the public, encouraging support for this "high-tech magic machine." The manufacturers also played their part in ensuring that radiologists were aware of the developments. The collaboration of interested clinicians and the public proved to be a powerful agent for diffusion.

When diffusion results from non-NHS funding without central controls, machines are sited according to resources, not clinical need or capacity. And non-NHS funding also means that ongoing maintenance of the equipment may not be funded through private donations. Today, institutions are wary of such gifts. In the 1970s, however, hospitals had yet to experience decades of reducing budgets. The first time this problem was discussed publicly was in Leeds, where the CHC questioned the Area Health Authority for accepting a body scanner from a group of businessmen. As with most other technologies, most early scanners were placed in the south of England, particularly in the London area.

Utilization

CT scanners are now available in almost all radiological departments. As they are relatively inexpensive (no more costly than other major pieces of equipment) and funding is through the hospital major capital budget, acquiring them is relatively easy. They are also considered by most managers to be an essential part of any hospital diagnostic capacity. Numerous evaluations of their use for particular conditions have been done, but in general use is widespread among all specialties with little consideration of appropriateness or cost ef-

fectiveness. One area of particular debate has been the use of brain scans for patients with stroke. The 1988 King's Fund Consensus Statement suggested that CT be used for limited indications; more widespread use would have considerable resource implications.

In 1985, a review of the use of CT in the management of cancer concluded that despite a paucity of information "reported studies [of CT in patient management in oncology] indicate that CT directly alters clinical decisions in 14-30% of patients" (24). There has been no coordinated national evaluation or technology assessment following the Department's initial control of—and involvement in the evaluation of—brain scanners.

The University of York Centre for Health Economics (one of the major health economics departments in the country) produced a user-guide for individuals and groups concerned with planning for, and management of a CT scanner in a District General Hospital in 1987 (25). It raises key questions such as, "Will CT replace existing forms of examination?" and "What impact will CT have on the demand for other related services in the hospital?" However, as it is not a standard DH document but emerges from a research organization, its impact and subsequent use has been limited.

Magnetic Resonance Imaging (MRI)

The dissemination of MRI, like CT, depended primarily on the availability of resources. The initial seven units were supported by the Department of Health and MRC. Trials were set up to evaluate MRI's clinical applications and the Department of Health/MRC Coordinating Committee on Clinical Application of NMR Imaging commissioned a cost-benefit study that also included collection of data on costs and throughput at other centers in an attempt to forecast likely implications of the adoption of MRI for the NHS. This part of the work proved to be of limited success; several units declined to be involved, which was inevitable in an environment where management research is considered to be a hindrance.

Published in January 1990 (48), the committee's report held that for the applications studied, "MRI is no more cost-effective than existing diagnostic techniques." It also stated that the perceived diagnostic and therapeutic impact of MRI does not necessarily imply a positive effect on the final outcomes for patients:

Direct cost of MRI is much greater than that of CT. This is partly due to higher initial capital cost, but mainly due to lower throughput of patients in MRI. MRI is more cost effective if used as the first investigation of choice. However where CT is the only scanning modality there is no strong case for investing in MRI.

At the same time, a significant study was being undertaken within the West Midlands Regional Health Authority, funded by its Health Services Research Committee (43). As the service was already up and running, it was not possible to do a randomized controlled study. The report published in December 1990 determined that MRI did confer additional benefits in terms of diagnostic impact, mainly by turning a provisional diagnosis into a "diagnosis unknown." MRI also proved to be excellent at improving the accuracy of the site or location of an already diagnosed condition. In terms of value or benefit to the patient, however, the results were less obvious. This report further concluded that MRI was an additional cost to each patient and that it tended to be used as an additional means of investigation rather than to replace existing modes. When introducing such expensive services, clinical audit should be established to ensure maximum cost-effectiveness.

Neither of these reports was adopted by the Department of Health, and both were published by research units rather than by the Department or any organization with authority; thus, they have had little effect on controlling diffusion. The West Midlands work does not appear to have had any impact on policy (44). MRI adoption has been limited, mainly due to resource constraints rather than determination of need, especially as the NHS reforms have introduced capital changes that mean that the cost of expensive equipment is to be included in providers' prices to purchasers. A more recent review of clinical uses of MRI com-

pletely ignores the two earlier studies and is generally positive about MRI's success for a range of clinical conditions (1).

A report produced by the Royal College of Radiologists in 1992 identified 90 MRI units (37). This report advised that MRI be available to all teaching and district general hospitals with approximately four MRI units per million population, or 225 units in total. This considerable increase is unlikely to occur on grounds of cost rather than appropriateness.

LAPAROSCOPIC SURGERY

Because of the range of technologies encompassed in this category, the introduction of laparoscopic surgery provides different examples of the factors that help and hinder the diffusion of new technologies. The development of laparoscopic techniques in the United Kingdom is generally unstoppable; it is occurring across most medical specialties. Laparoscopic surgery has blurred the differences between surgeons, physicians, and radiologists; has supported reductions in lengths of hospital stay and requirements for hospital beds; and has made surgical treatment for many patients a short-term and relatively pain- and scar-free experience.

Early Diffusion

The early introduction of laparoscopic surgery occurred because of a few product champions that, like their first wave of followers, were sited in general hospitals, not only in teaching or academic centers. This is because most of the techniques did not require particularly expensive capital outlay, and in surgery, innovation occurs equally in nonteaching and teaching centers.

Laparoscopic cholecystectomy has diffused quickly throughout many surgical units within the last three years (box 8-1). Uptake has depended on local factors, and without any centralized planning there is wide variation in availability.

The private sector has been more easily able than the public sector to respond to the potential savings of laparoscopic surgery through shorter lengths of stay and increased patient satisfaction.

BOX 8-1: The Status of Laparoscopic Surgery in the United Kingdom, 1994

Laparoscopic treatment of endometriosis and removal of ovarian cysts

- Used and developing, evidence on cost-effectiveness and outcomes insufficient.
- Diffusion via a small number of enthusiasts.
- No central support, attractive to consumers.
- Not in position to replace conventional treatments.

Laparoscopic appendectomy

Not routine; routinely used by only one surgeon.

Laparoscopic cholecystectomy

Since 1991, actively supported by surgeons and patients.

- Extends operation time and queries as to outcomes, especially among inexperienced practitioners.
- Diffusion well en route.

Arthroscopic knee surgery

- Accepted practice but therapeutic application unevenly spread.
- No national policy, but national conferences have played key role in diffusion.
- Underfunding of orthopedics has led to shortage of equipment and facilities.
- Value of arthroscopy as diagnostic procedure accepted, but use as treatment resisted, especially by older surgeons (33).

SOURCE J Spiby, 1994

More recently, however, several private insurance companies have become concerned about the outcomes of certain procedures (e.g., laparoscopic uterine removal, laparoscopic cholecystectomy) and have banned activity until the results of longer term studies are available. Within the NHS this has not happened, as currently there are very limited mechanisms (except for peer pressure) to prevent surgeons from undertaking different techniques.

Cost Pressures and Policy

One of the main forces for the development of laparoscopic procedures has been increasing pressure on health care spending. Reduced lengths of stay in surgery has been seen as essential. There has also been considerable political impetus to reduce waiting lists, which has led NHS managers

to concentrate on supporting initiatives that appear to reduce the need for costly overnight stays.

The assumption that laparoscopic surgery will achieve cost reductions is not, however, well supported by research evidence; in general, the costs and benefits have been poorly studied. Early results of studies of long-term outcomes of some laparoscopic procedures show, in some cases, that laparoscopic procedures delay rather than avert open surgery, and some have higher levels of complications. Some procedures takes two or three times longer to perform than conventional surgery (2).

The Department of Health has been noticeable for its lag in developing policy on laparoscopic surgery (33). The Department appears to have considered developments within the NHS to be well ahead of central thinking and policy.

However, concern about the lack of evidence on efficacy and cost-effectiveness have led to support for several RCTS funded through the national R&D strategy. The results of these trials may or may not be timely enough to influence the diffusion of the more popular technologies.

Continued Diffusion

Patient preference has played a strong part in the development of laparoscopic surgery, as patients are able to return to normal life so much more quickly and suffer considerably less pain (33). More recently, however, concerns have been expressed by GPs about the relentless push to discharge patients early after surgery and the lack of backup for complications. This problem will need to be addressed if laparoscopic surgery becomes the norm.

In general, the product champions and early innovators have been younger surgeons at the beginning of their careers and possess the necessary skills for laparoscopic surgery. For the next stage of innovation, older surgeons and those who are less innovative will have to develop the necessary skills. This problem has not been addressed until recently, and most hospitals have had to rely on retirement to achieve change. Some older surgeons were willing to consider the new techniques, but they have found it difficult to obtain training, and they are unlikely to acquire the skills from junior colleagues.

In November 1992 the Department's Management Executive announced that in collaboration with the Wolfson Foundation, it was funding three minimally invasive surgical procedures units. Centers in Scotland, Leeds, and London have been designated as training centers, and surgeons will start to undergo "retraining" shortly. This is a unique initiative, as the need for acquiring new skills to cope with new technologies has been frequently discussed but never positively addressed before.

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Despite the fact that it is a relatively uncommon condition, ESRD and its different forms of treatment were extensively (and often emotionally) discussed in the United Kingdom during the 1980s and early 1990s. This attention results from the fact that untreated patients die and treatment costs are high, particularly as patients need treatment for the rest of their lives. Patient survival for all age groups has improved consistently over the last 15 years, as have levels of service.

International Comparisons

The United Kingdom has long been regarded as a laggard in its level of treatment of ESRD, even when compared with countries with similar per capita health expenditures; however, far more patients are being treated than 10 years ago. Nonetheless, compared with Europe and the United States, relatively fewer elderly patients are accepted, reflecting the lower priority accorded to ESRD in the Britain.

Pattern of Diffusion

The United Kingdom has one of the lowest nephrologist to population ratios in developed countries (20). This is also reflected in the number of hospital centers for renal replacement therapy (RRT). Many of the existing centers were setup through a system of central planning in the 1960s (3). In the 1970s NHS established a few new centers at a time when facilities were mushrooming in other parts of Europe. British centers tend to be centralized in teaching hospitals.

Between 1980 and 1987 the number of UK RRT patients doubled from 128.6 per million population to 267.6, but the gap between the United Kingdom and other countries narrowed only slightly (see table 8-3). This low level of provision reflects the low level of spending generally on health care and the tight constraints that central control have placed on capital spending on new units and ongoing expenditures for a high-cost

TABLE 8-3: New Patients Accepted for Renal Replacement Therapy United Kingdom, Germany, France, Italy, 1980-1987 (per million population)

Year	United Kingdom	Germany (FRG)	France	Italy
1980	24.9	46.7	41.6	37.7
1983	33.4	55.8	44.3	45.5
1985	43.1	59.4	42.9	46.8
1987	50.8	84.9	58.1	48.8

SOURCE N B Mays, *Management and Resource Allocation in End Stage Failure Units, A Review of Current Issues* (London King's Fund, 1990)

treatment. Spending has been low despite the relatively high level of public discussion and relatively well-organized lobbies both of patients and professionals.

Selection of Patients

A result of the low level of service available is the careful selection of patients for ESRD treatment. In general, rationing is achieved by preferentially treating younger, fitter patients with dependent children. Diabetic patients are also less likely to receive treatment because of the reduced success in their outcomes. This selection appears to be due to some level of gatekeeping by GPs. In a 1984 study, GPs were more likely than hospital physicians and nephrologists to assume that treatment was not appropriate for the elderly and other higher risk patients and did not refer such patients, instead treating them conservatively (3). The reduction in referrals to treatment is also related to the low level of nephrologists, who are sited mainly in the renal units rather than in district general hospitals.

Despite increases in the numbers of patients receiving ESRD in the 1980s, a survey in 1990 concluded that there was still under-referral of patients suitable for treatment (20). The authors of the survey estimated that the incidence of ESRD is 78 per million population, and that only 55 per million were being treated.

Variations in Treatment Rates

Within the United Kingdom there is a marked variation in ESRD treatment rates between regions (see table 8-4), due primarily to the availability of facilities. This variation can also be seen

within regions where the uptake is higher by the populations living closest to the units (8). In the North West Thames region a new peripheral unit was established to provide a local service for people not close to a teaching hospital. Even then, within a few years the population closest to the unit was more likely to receive care than those further away.

Regional differences can also be seen among the different treatment modalities favored by units. East Anglia's renal replacement therapy program has long been dominated by renal transplantation at Cambridge, and continuous ambulatory percutaneous dialysis (CAPD) has been little needed. However, in the Oxford region, transplantation has grown more slowly, and home hemodialysis has played a major role, heading other methods of dialysis. These differences reflect a number of interacting factors: the preexisting pattern of dialysis provision, treatment, and selection policies of individual units and consultants; policy decisions of the RHAs; the degree of population dispersal; and the availability of different types of resources, including the domestic circumstances of patients (which affect their ability to cope with different modalities).

Cost-Effectiveness of Different Treatments

Care of ESRD is significantly more expensive per patient than many other diseases. Dialysis is expensive primarily because it is needed for a long period of time. The most cost-effective option is a successful transplant, but the costs of a graft that fails in the first year are considerable and comparable to the costs of hospital hemodialysis.

TABLE 8-4: Regional Acceptance Rates for New Renal Replacement Therapy Patients (per million population), 1984 and 1988

Region	1984	1988
Northern	40.6	58.5
Yorkshire	34.2	44.2
Trent	40.4	49.1
East Anglia	40.5	65.0
NW. Thames	30.6	49.7
NE. Thames	30.3	61.1
S.E. Thames	47.5	76.1
SW. Thames	25.3	23.3
Wessex	27.9	44.8
Oxford	37.5	50.4
South Western	32.6	51.2
West Midlands	26.3	52.0
Mersey	31.3	34.6
North Western	31.5	83.8
Wales	34.3	66.4
Scotland	38.2	62.8
Northern Ireland	20.1	42.5
Isle of Man	33.3	40.0
United Kingdom (total)	33.8	55.0

SOURCE N B Mays *Management and Resource Allocation in End Stage Failure Units, A Review of Current Issues* (London: King's Fund, 1990)

In 1990 the Department of Health estimated that the first year of hospital hemodialysis costs the NHS 16,500; home dialysis, 13,000; and CAPD, &14,000. In general the United Kingdom has a pattern of modalities that reflects a policy to invest its limited resources for ESRD (approximately 0.6 percent of the annual budget of a typical RHA) by giving greater priority to home dialysis and, recently, to CAPD than do many other countries. This was not necessarily a planned strategy was compelled by the strict control exercised in the NHS over the opening of new renal units. Heavy emphasis has also been placed on achieving a high level of transplantation, not only because it is a low-cost option but because it so dramatically achieves a better quality of life. Much work has been done to increase the harvesting of cadaver kidneys by developing increased awareness in medical staff of the need to request the use of organs, and by appointing regional

nurses who are responsible for ensuring that hospitals are prepared to maximize the availability of organs.

During the 1980s, in the absence of major capital schemes for renal services in many regions, units responded in a variety of ways to increased demands. These include:

- development of minimal care dialysis with shorter treatment times and more shifts;
- setting up satellite units, managed by a parent unit;
- growth of CAPD, generally considered a cheaper form of treatment, with the advantage that patients can quickly and easily be trained to treat themselves at home; and
- an increase in transplant rates, which has greatly helped reduce the required increase of dialysis programs.

CAPD has released units from the existing physical space constraints in the hospital and has allowed revenue to be converted directly into additional patient acceptances. With respect to transplants, minimal care and satellite units were often set up because of physical space constraints as well as the desire to improve geographical accessibility for distant patients. The service is primarily concentrated in regional centers; however, despite the fact that satellite units have proved to be a cost-effective means of providing dialysis, they have not developed as quickly as might have been expected.

Erythropoietin (EPO)

Erythropoietin for renal patients arrived at a time when the increase in demand and the lack of additional resources for ESRD services were posing major problems. EPO'S efficacy has been generally accepted, but what has been challenged is the level of effectiveness for the considerable cost. Health economists have led the debate, questioning the widespread use of the drug. Units limited in their resources have had to ration its use to those most at risk of anemia due to contraindications to transfusion. More recently, units have found a funding loophole and have asked GPs to prescribe

the drug, as well as other dialysis-associated drugs and consumables, from the budget for primary care drugs, which is separate from hospital budgets and at present is not cash limited. Many GPs have felt unhappy about taking clinical responsibility for a drug with which they are unfamiliar, but faced with a patient who will not receive treatment if they do not prescribe, most have reluctantly agreed to do so. However, it is expected that the funding mechanism will be changed in 1994 and such off-loading will not be possible, thereby increasing the pressure on renal units budgets.

Role of the Private Sector

The development of renal services has been assisted by the private sector since the mid- 1980s. Commercial companies moved from supplying dialysis units and, in some cases, helping units with financial information and stock management to directly providing dialysis treatment. The first private dialysis units were set up in Wales in 1985 as part of a program to increase the supply of dialysis services. Main renal units remain solely on NHS, but subsidiary care centers were contracted to the private sector. The experience has been successful, but surprisingly (considering the general changes in NHS), subsidiary care units have not developed to any major degree elsewhere.

NEONATAL INTENSIVE CARE

Services for neonatal care received their first official support in the United Kingdom in 1961, when the Joint Subcommittee and Standing Maternity and Midwifery Advisory Committee recommended the creation of a comprehensive program for the care of neonates. In the same year the Central Health Services Council argued that special care facilities would reduce neonatal mortality. Before 1961, services had developed mainly where there were enthusiasts in teaching hospitals. The development of the service was promoted by professionals, and there was little scientific evidence for their claims that neonatal mortality would be reduced or that reductions seen at that time were related to special care facilities.

In 1971 the Sheldon report advocated a two-tier system of service provision, with 1) special care units in each district for low-birthweight babies and those with illnesses unique to the newborn, and 2) neonatal intensive care units (NICUs) that would provide higher level care at specialist teaching hospitals (39). As well as centralizing expert care, the latter were regarded as a prerequisite for training doctors and nurses in the special care required by the sickest neonates. There was at the time some suggestion that such centralization would increase the risk of infection or the possibility of over-aggressive treatment, but this was not investigated in any serious manner—probably because those doing research in the area were mainly proponents of the service. The consensus was that each region should have one to three NICUs: these should be sited where the high-risk obstetric service was sited and where specific expertise in neonatal intensive care existed.

Three reports of the Social Services Committee during the 1980s (5) recommended the addition of a third tier to neonatal services, such that all districts would provide short-term care backed up by subregional facilities at larger maternity units and a regional specialist perinatal center. The service by then was well established, although in most regions the actual distribution of services and level of expertise available depended on local circumstance rather than careful planning. Two explanations for this can be put forward: first, the lack of hard evidence on the service; and second (and more likely), the establishment by younger pediatricians of one or two cots in smaller hospitals in order to create a local service and provide an extra professional challenge for themselves and other staff. Several regions produced planning guidelines that they backed up with resources, but subsequent reviews found that small local services with one or two cots were being set up by clinicians despite these guidelines (29).

Policies and Diffusion

During the 1980s the main policy thrust was toward improvement in neonatal services. These services were singled out by the Royal College of

Physicians in 1988 and the National Audit Office in 1990 as an area for improvement, and the NHS'S Chief Executive made it a priority in 1990 for regions and districts to review their maternity and neonatal services with a view to further reductions in mortality (31,36).

In England between 1980 and 1986, the number of cots for neonatal intensive care more than doubled, and birthweight-specific perinatal and neonatal mortality fell in all categories of birthweight. There were, however, a few skeptics who had reservations about the rapid growth in neonatal services, doubting that neonatal intensive care was a determinant in the reduction in neonatal mortality. Concern was also expressed about the high cost of these services and the long-term health outcomes. By this time it was deemed unethical to undertake a randomized trial, and advocates of NICUs cited experience abroad and expert opinion rather than data. Typically, the discussion centered on the lack of services and problems in obtaining a cot for all the babies who required this level of care.

In an attempt to address these criticisms, one region, Trent, undertook a prospective study examining the short-term outcome (survival to discharge) of all infants who required admission to a baby care unit. They showed that infants of 28 weeks' gestation or less who received all their perinatal care in one of five large centers (each providing more than 600 ventilator-days per year) had significantly better survival than infants treated throughout their entire course at one of 12 smaller units (22). These differences occurred despite the elective transfer of many of the sickest infants from smaller to larger units. Differences in survival between more mature infants were not significant.

The National Perinatal Epidemiology Unit in Oxford, which has been central in developing an understanding of technology assessment and the relative validity of different types of clinical trials, raised questions regarding the interpretation of the results and implications for policy (30). It suggested that biases may have affected the results, and that the differences in mortality might have been in part the result of differences in unmea-

sured risk factors; moreover, a decision to transfer all babies might not reduce mortality but instead increase the mortality rate for admissions to the referral units as they take in higher risk babies. The outcome was that the case for regional NICUS was not made, but policy continued to support them.

Throughout the development of neonatal intensive care, the argument for it has been that it reduces neonatal mortality. Little or no reference has been made to its impact on morbidity. Concern has been expressed about the possibility of an increased level of severely mentally and physically handicapped children, but little epidemiological evidence has been forthcoming. Recent work indicates that increasing numbers of preterm infants survive without (major) handicaps but with more subtle long-term problems, such as learning difficulties and lower school grades. The chief implication of such information is the need to press for better obstetric care so as to avoid the necessity of neonatal intensive care.

Financing NICUS and the NHS Reforms

Until the 1990 NHS reforms, the responsibility for financing and developing neonatal intensive care had belonged primarily to RHAs. The NHS reforms aimed to devolve responsibility to the districts for such services so that their relative importance would be assessed against the total needs of the population. This change created major concern among those involved in the service, who feared that centralization would be eroded (34). It was felt that the reforms might encourage the establishment of small, less well-equipped NICUS, with few if any effective constraints or controls over those providing neonatal care. This concern was reiterated in a House of Commons Health Committee report in 1992, which stated that "we are not persuaded that the establishment of contracts for regional services for perinatal and neonatal intensive care can be left to market forces and audit."

The service became one of the first to be reviewed by the Clinical Advisory Group set up by the Secretary of State. Its report on neonatal intensive care concentrated primarily on access, as had

so many of the previous official reports on this service. Overall, it was felt that contracting had not significantly affected the service. There was still considerable variation across the country in the service provided, and in some regions the service was under considerable pressure. However, it appeared that purchasers were intending to move an increased proportion of intensive care to local units (probably for financial rather than clinical reasons), and this might have a deleterious effect on the viability of the larger training institutions and on quality of care. The report noted that few consistent measures of quality existed and that a population-based audit of outcome in terms of mortality and disability was required.

Extracorporeal Membrane Oxygenation (ECMO)

The well-controlled introduction of ECMO to the United Kingdom is due largely to the influence of the perinatal research unit in Oxford. ECMO was introduced unevaluated in Leicester in 1991. Before any other units were installed, planning by researchers at Oxford University began for a randomized controlled trial to cover the entire United Kingdom. Recruitment started in January 1993: to date, more than 80 babies have been included, making it by far the biggest controlled trial of ECMO in the world. Results are expected in 1996.

SCREENING FOR BREAST CANCER

Interest in screening for breast cancer developed slowly in the 1970s mainly in the form of specially funded projects or adjuncts to symptomatic mammography services. During the early 1980s, a considerable lobby developed; it consisted of surgeons who specialized in breast cancer treatment and women's groups. In 1985 the health minister announced that a committee would be set up to:

- consider the information now available on breast cancer screening by mammography;
- the extent to which the literature suggests necessary changes in policy on the provision of

mammographic facilities and the screening of symptomless women;

- suggest a range of policy options and assess the benefits and costs associated with them; and
- identify the service, planning, labor, financial, and other implications of implementing such options.

Forrest Report

The committee reported in November 1986 in a document known as the Forrest report (9). On the basis of evidence from randomized trials in New York and Sweden and two studies in the Netherlands, the committee concluded that "screening can reduce mortality from breast cancer, although the reduction varies with the age of the women screened." Despite the existence of a large, seven-year, multicenter, population-based trial that was being conducted and was due to report in 1988, the committee recommended the introduction of a national breast screening service for women between the ages of 50 and 64, with the expectation of reducing deaths from breast cancer by a third or more. The key screening test was to be one-view, high-quality, medio-lateral oblique-view mammography. The program was to include a personal invitation to all eligible women, arrangements to ensure that positive results were followed up, a specialist team to assess detected abnormalities, a call-and-recall system, quality control, and a designated person responsible for managing local screening services.

This report was fully implemented because the government, on announcing its acceptance of the recommendations, also agreed to finance the screening program in full. Over £50 million nationally was invested of new funds to the NHS provided by the Treasury. By 1991 there was 77 screening programs covering the 190 health authorities.

On a more practical level, the Forrest report clearly acknowledged that "the development of any national programme will require careful planning not only of the basic screening services but also to ensure the availability of the necessary as-

assessment, diagnostic and treatment services for screen-detected abnormalities.”

Results of the U.K. Trials

In 1990 the Scottish arm of the U.K. Trial for the Early Detection of Breast Cancer reported a non-significant reduction in mortality after seven years with an initial attendance rate of 61 percent (35). The net result of the trial was to emphasize that a high level of reduction in mortality could be achieved only with high participation rate in screening (46). The service was set up with a well-structured call-and-recall system, but it became clear that although uptakes of 80 to 90 percent were possible in areas of high socioeconomic status, such rates were not achievable in inner-city areas and among those populations that traditionally do not use preventive services (28).

During this period the results of the U.K. trial led to criticism of the Forrest report. It was suggested that the expectation of a 30 percent reduction in mortality was too ambitious; that the disadvantages of screening had not been adequately measured, especially in view of the number of false positives; and that the group had been biased and should have considered selective screening to ensure proper use of resources.

The National Screening Program

Following the Forrest report, major new evidence was reviewed by Forrest and a group of experts. This evidence consisted of the U.K. trial, further evidence from Malmo (Sweden) and New York, and the Edinburgh randomized trial. This review concluded that “the original evidence that screening for breast cancer can reduce breast cancer mortality is supported by additional results from recent evidence. The expected impact after about 10 years was that roughly 1,250 deaths attributable to breast cancer would be prevented each year in the United Kingdom.

Concerns about translating trial results into national experience have focused on three main issues: population coverage, skills development, and proper introduction of the program. Adequate population coverage is clearly challenging in some parts of the country. The Forrest review acknowledged this and identified difficulties with the population denominator register used for contacting women about attending their screening. Certain sectors of the population are unlikely to attend even if contacted, however—a problem that is being addressed locally with a range of initiatives.

It was reported that the development of skills through training centers had been sufficient to train the required staff in three years. In fact, the training program had initially lagged but eventually came to play an ongoing role in supporting continuing education.

The U.K. Cancer Coordinating Committee Breast Screening Sub-Committee set up three trials looking at the interval between screening episodes, the number of views, and the effect of screening women under the age of 50. The Sub-Committee also coordinates research on acceptability and economics. This high level of central control reflects the program’s unusual commitment to centralization and uniformity.

Impact of the NHS Reforms

The NHS reforms at present have not affected the screening service in any major way. At present, the funding for breast screening and the centralized style of service provision have been protected, but this will not necessarily continue to be the case.

Breast screening has been given additional impetus by virtue of its inclusion in the national health strategy. The proposed target is to reduce the death rate for breast cancer in the population invited for screening by at least 25 percent.



CHAPTER SUMMARY

The picture painted above shows a varied pattern of influences on the introduction of health care technologies in the United Kingdom and little evidence of a coherent policy for technology development until very recently.

In the past, the constant requirement to limit the availability of care has been met primarily by general practitioners who act as gatekeepers and by the acceptance of waiting lists for nonemergency care. This system of priorities has become politically unacceptable over the last decade, however, as shown by the Department of Health's waiting list initiative. Patients have been encouraged by the Patients' Charter to demand their "rights." Consequently, without any major increase in resources, different mechanisms for the control of spending have had to be developed.

To date, limiting development by constraining resources has resulted in a haphazard control of technological development based on cost considerations rather than on effectiveness. Those who have found it easiest to obtain new resources (primarily the main teaching hospitals) have been the most successful in introducing new technologies and those who live closest to such facilities are more likely to receive care.

Looking at the way in which different technologies have developed in the United Kingdom, it is clear that the government has had little control of technological development except in the case of breast cancer screening, where specific funding was provided to fund a new national program. With other technologies, the government has tried to influence development by more indirect routes, such as identifying expected service levels or planning norms. Yet without any real method of enforcement, such means appear to have had little influence.

The most important factor in technology diffusion has been product champions: individual clinicians or members of key regional or district management teams who have found appropriate

ways of obtaining resources (public, private, or charitable), and ushering in the introduction of new developments. Such champions have been found mainly in teaching institutions, where the environment is more encouraging (both in terms of availability of resources and tolerance of more maverick personalities). That this is not always true is illustrated by the development of local renal dialysis units, minimally invasive surgery, and neonatal units.

Over the past decade, awareness of the concepts of appropriateness, effectiveness, and cost-benefit analysis have moved to center stage on the agenda of purchasers and the NHS Management Executive. Ten years ago, few managers or politicians were aware of the level of inappropriate use of technology or of new developments that were about to occur—and of how to assess their usefulness. Clinicians continued to battle for resources for their particular specialities but were rarely challenged on the effectiveness of their activities.

The main challenge today is finding ways of using the NHS reforms to implement technology assessment results so as to ensure the most cost-effective use of resources. The creation and appointment of a national Director of Research and Development and the commitment of this entire structure to technology assessment is a major step forward. At present, however, there appears to be more discussion and publication of strategies than funding of useful research or use of previous work to effect change. Little new money is available, and at regional levels, R&D directors are finding it difficult to obtain realistic budgets.

Some regions have also had difficulties finding appropriately qualified candidates. Most senior clinicians with a research background who are acceptable to the medical fraternity are knowledgeable only about their own specialties; they do not have an overview of the whole of health care, nor are they experienced in working within health service management. It is hoped that these problems will be resolved and that the real power of the post-

holders will be felt. Unfortunately, this will inevitably be delayed by the structural reorganization of the regional health authorities and potential dislocation of this function.

Possibly more effective in achieving change will be the purchasing authorities. In theory, they play a powerful role in identifying what they wish to purchase and ensuring through contracts that desired patterns of health care are provided. In reality, however, difficulties arise in identifying exactly what is required and in using the contract process effectively.

In summary, although the United Kingdom did not become systematically involved in technology assessment until recently, the field has recently been much publicized and discussed. It is ironic that the randomized clinical trials and cost-effectiveness studies undertaken in British research units have had relatively little impact on health care and its management up to now. The increasing necessity for making choices, along with the increasing availability of research from health care technology assessment, makes this problem unlikely to persist.

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