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The Management of Medical Technology in the United Kingdom

Barbara Stocking
London School of Hygiene and Tropical Medicine
London, England

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THE UNITED KINGDOM: COUNTRY DESCRIPTION

The United Kingdom, with a total population of ***55.5*** million ***(23),*** consists of four countries: England, Scotland, Wales, and Northern Ireland. It has a constitutional monarchy with government by a two-tier Parliament (the House of Commons and the House of Lords). All four countries are directly governed by Parliament at Westminster, though Northern Ireland has, in the past, had its own Parliament. Despite direct rule, a certain amount of power has been devolved to the separate countries, producing some differences, for example, in how the health services are managed. In recent years, both Scottish and Welsh nationalism have increased and will almost certainly lead to further devolution of power. The idea of separate assemblies for these countries, however, was rejected in a recent referendum.

The two major political parties in the United Kingdom are Labour and Conservative, although a number of other parties (e.g., the Liberals, the Scottish Nationalist Party, etc.) are represented in Parliament. Members of the House of Commons are elected democratically, with each Member representing a particular constituency. The government is formed by the party with the majority of Members of Parliament in the House. The Prime Minister is the leader of that party, and he/she forms the Cabinet from the Members of that party in the Houses of Parliament. The various 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 House of Lords is composed of hereditary peers, as well as peers appointed for life. It is the privilege of the Prime Minister to select a certain number of individuals for life peerages each year; those selected tend to be individuals who have had distinguished careers in various walks of public life. The House of Lords is of less importance than the House of Commons, but does provide a useful check on parliamentary legislation and can initiate bills itself. There is agreement from both major parties, however, that some reform of this body is due.

The economy of the United Kingdom is mixed. A number of major services and industries are nationalized (e. g., British Rail, the British Steel Corp., etc.). In many cases, these industries are managed, not directly by Parliament, but by independent corporations whose leadership, composition, and powers are laid down by Parliament. The National Health Service (NHS) is an exception in that a Secretary of State for Social Services in Parliament does head the corresponding government department, i.e., the Department of Health and Social Security (DHSS). ' In recent years, particuiar]y under Labour governments, the number of na-

'The Ministry of Health was combined with the Ministry of Social Security in *1968,* when it became DHSS.

tionalized industries has increased. In addition, where industries have particular importance to the economy, the government has stepped in to support firms in the free enterprise sector (e. g., Rolls Royce, Chrysler).

Britain's relative lack of productivity, as compared to its European, American, and Japanese competitors, has been blamed on a number of factors. The management side of industry is blamed for not modernizing its equipment and for not being willing to risk involvement in new ventures. These problems are, in turn, blamed on the government, which is said to have produced a lack of incentives for investment or for entrepreneurial activity. On the workers' side, the unions are blamed for strikes, for enforcing rigid demarcation rules, and for overmanning. There would seem to be truth in the statements that each of these factors has contributed. Nevertheless, the sum of all of these factors, not any particular one, has caused Britain's decline relative to other countries.

The problems of British industry give some insight into the attitudes towards technology. New technology is often rejected by the unions, not for itself, but because it will lead to a reduction in jobs. Management may be fearful of a confrontation with the unions or may not be willing to invest in innovations. The result is a fairly conservative attitude towards technology in Britain, despite the very high quality of science and technology research carried out in British universities and research institutions.

In discussing British attitudes towards technology, a somewhat different point should also be made. Although science and academic research in Britain are of high status, technology has for a long time been considered somewhat second rate. This attitude, perhaps, can best be exemplified by the status of engineers. Engineers in the United Kingdom do not receive the same respect as other professionals; in comparison to the status of engineers in other countries, their status is low, The large gap between the development of inventions and innovations in research institutions and their actual implementation or production by industry very likely reflects the predominant attitude toward technology.

Recently, concern over Britain's declining economy has led to a slow recognition that industry, technology, and innovation must be given increased status and more incentives. In particular, the previous Labour government took steps to ensure that Britain would not get left behind in the microprocessor revolution. Whether these steps are adequate and whether more fundamental attitudes towards technology can be changed remains to be seen.

THE HEALTH CARE SYSTEM

A national insurance system that covered the health care of most of the working population was initiated early in the century, but it was not until 1948 that Britain established its NHS. World War II changed many public attitudes and fostered the belief that a postwar social order should be created that 'would include health care as a right for all. Although the Beveridge plan for NHS was drawn up during the war, legislation creating NHS was not passed until 1946, and the Service was not finally begun until 1948. Funds for NHS come from national insurance contributions and from general taxation. All health care is provided to patients free of charge (apart from small payments for drugs, spectacles, etc.).

The basic tenets of the 1946 Act creating NHS still hold, although the Service, particularly its organization, has been modified by various laws passed since. The most major change came in 1974 with the reorganization of NHS. Until that time, hospitals had been managed by regional hospital boards responsible to DHSS and ultimately to the Secretary of State in Parliament; community care, including district nurses, school health services, etc., however, had been the responsibility of local government

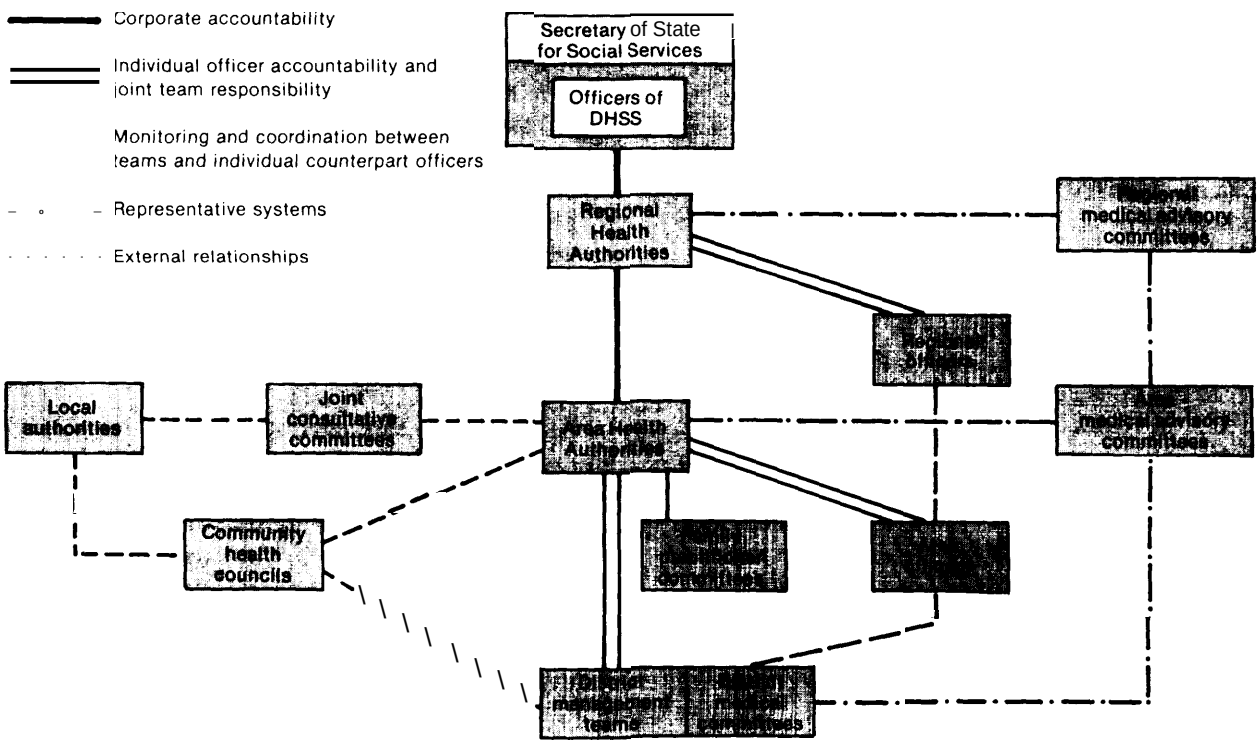
authorities. In 1974, the various facets of health care were unified under one authority.

Currently, the unified NHS in England is organized in a number of tiers. (See figure 1.) The bottom tier is the "district," serving perhaps a quarter of a million population. All hospital and community services are the responsibility of a district management team. The district is part of a larger "area" (although some areas contain only one district). The area has a team of officers who are actually employed by the Service but who are responsible to an Area Health Authority appointed by the Secretary of State for Social Services. The areas are overseen by "regions."[2] A regional team of officers carries out the day-to-day activities, but is responsible to a Regional Health Authority. Statutory authority for NHS is vested in the Area and Regional Health Authorities (all of whose members, apart from the chairmen, serve unpaid). In Scotland, although the organization of NHS is similar, there are three tiers.

One or two points need to be made about the structure of NHS. It is envisaged that actual management of health services should take place at the lower levels, with the upper levels providing a coordinating and policymaking function. There have been considerable difficulties in the Service about the role of each of the tiers, however, and there is some consensus

[2]There are 14 regions in England, The other three countries in the United Kingdom are comparable in size to an English region and are therefore organized slightly differently: Scotland has 15 Area Health Boards; Wales has 8 Area Health Authorities; Northern Ireland has 4 Health and Social Service Boards. Northern Ireland is different from the other countries in that health and social services are combined,

Figure 1.—Framework of the NHS Structure in England



SOURCE Office of Health Economics, The *Reorganised* NHS (London White Crescent Press. 1977) (19)

that there is probably one tier too many. Because much upheaval resulted from the 1974 reorganization of the Service, however, further disruption is not likely to be undertaken lightly.

Despite the position of DHSS at the top of the hierarchy, it is repeatedly pointed out that, subject to conforming with general policy, the regions and areas are free to manage NHS as they see fit, and in particular, to allocate resources according to their own judgment. Nevertheless, there is some confusion about how binding DHSS' advice is—confusion that is seen both in the purchase of medical equipment and in other activities. In one sense, DHSS is quite outside the Service in that it is the Regional and Area Health Authorities rather than the Department who actually employ NHS staff. Since DHSS holds the purse strings and distributes money to the regions, however, it obviously has considerable powers of persuasion.

According to DHSS, NHS spending for fiscal year 1979-80 (excluding central services) was 18.1 billion ($17.8 billion). ' The Office of Health Economics estimated that in calendar year *1978,* NHS expenditures were running at 5.7 percent of the gross national product (GNP).[4] Apart from government expenditure on health, an additional small but increasing amount of money is spent on private health services. There is also separate funding for biomedical research through the Medical Research Council (MRC).

How NHS funds should be distributed is a topic that has recently come in for considerable scrutiny. Concern about inequality in the provision of health services led to the setting up of the Resource Allocation Working Party (RAWP). RAWP recommended that resource allocation should not be based on existing facilities per se, since these tend to generate their own demand; instead, money should be allocated to regions on a population basis modified by various factors that might indicate the need for health care, such as standardized mortality ratios (11). The formula RAWP recommended is quite complex and has generated much controversy, not least because full implementation of the recommendations would lead to a decrease in funds for the Thames regions (which cover the whole of London) to provide for increases elsewhere. In fact, the previous Secretary of State for Social Services, in office until 1979, took more of a middle road, giving increases in funds to all regions but with the amount of growth proportional to each region's relative under- or over-provision. It remains to be seen how the present Conservative Secretary of State will handle this problem.

The resource allocation problem has highlighted the difficulties likely to be faced in the next few years. As in other developed countries, health care costs in the United Kingdom have risen (although here they have been comparatively well restrained, perhaps at the expense of the quality of the Service). Since it is clear that this situation of rising costs cannot go on indefinitely, NHS is in for a period of little or no growth. During that period, it will be hard to remove inequalities.

Finally, on NHS funding, it should be pointed out that the Health Authorities operate on a system of cash limits. Each year they must remain within these limits, though some allowance is made subsequently for inflation. Major salary increases negotiated at the national level and taking effect in the budget year in progress make it difficult for Authorities to plan their budgets to remain within these limits. In some cases, this difficulty has led Authorities to underspend during the year, and then at the end of the year to use their surplus funds for major purchases such as medical equipment.

To complete this section, a brief summary should be given of some of the other descriptors of NHS. Unfortunately, in government documents, some figures are given for England and Wales, some for Great Britain (which includes Scotland but not Northern Ireland), and some for the United Kingdom (including all four countries). This should be kept in mind when reading this section.[5] In 1976, there were

[3]For conversion of British pounds to U.S. dollars, the exchange rate used throughout this paper was £1 (British) = $2.20 (U.S.).

[4]Based on an estimated GNP of £1,286 billion ($3,049.2 billion).

[5]The information in this section is taken from two publications of DHSS, Annual *Report 1977 (4)* and *Health* and *Personal Social Services for England (s).*

479,359 hospital beds in Great Britain, of which about *300,000* were nonpsychiatric and the rest psychiatric beds.

The latest figures available on staff are for 1975, when a total work force of 914,068 was given for Great Britain, with something under half of this total being nursing and midwifery staff. For 1976, a full-time equivalent figure of 37,257 medical staff was given for hospital and community services. General practitioners (GPs), who provide the bulk of medical staff in the community, are not included in this figure, since they are not NHS employees but work on contract to the Service through family practitioner committees. (See figure 1.) Since GPs act as the front line for much of the Service and are responsible for referrals to hospitals, consultants, etc., they play a major role in Britain. There were 26,418 GPs in Great Britain in 1976.

To give some idea of the utilization of NHS, some figures for 1977 can be cited. In England, 5.3 million inpatients were treated in the country's approximately 376,000 hospital beds. The average length of stay was *20.9* days, but reduces to 9.2 days if pyschiatric, geriatric, and younger disabled units are excluded. The total attendancies of outpatients at consultant clinics was 33 million, not including accident and emergency departments, and there are also active day patient programs in psychiatric and geriatric units. On the average, a patient visits his or her GP three times a year.

MECHANISMS FOR MANAGING MEDICAL TECHNOLOGY

Research, Development, and Evaluation

In Britain, much technological innovation in medicine has stemmed from university and medical school research, particularly in bioengineering or medical physics departments. The pharmaceutical industries have always undertaken their own research, but the medical equipment industries have tended to develop inventions and ideas from academia. As more medical industries, particularly those in diagnostic equipment, are setting up their own research laboratories, however, this situation may be changing.

Funds for research in academia may come from a variety of sources—from university overheads, from government-funded research councils, and quite commonly in the medical field, from a number of trusts and foundations. At the development stage, a number of routes can be taken: The invention may be taken up by industry; the National Research and Development Corporation may provide funds for development work or may find a suitable firm to take up the idea; *or* DHSS, through its Scientific and Technical Branch, may provide "pump-priming" funds for inventions which it feels may be especially useful to NHS.

The processes for the evaluation of medical technology are generally more haphazard. For new drugs, however, a rigorous code of practice is followed. Trials of new drugs are usually sponsored by the drug manufacturer after animal trials have been completed and found acceptable by the Committee on Safety of Medicines. The clinical trials tend to take place in the NHS setting, although doctors are not paid for their involvement. Before a drug may be marketed, approval by the Committee on Safety of Medicines is required.

There are no formal procedures for the evaluation of medical devices. Two agencies, however, do exert some oversight: 1) the Scientific and Technical Branch of DHSS, and 2) MRC. MRC is responsible for most of the clinical trials of new procedures in the United Kingdom (apart from trials sponsored by pharmaceutical manufacturers). MRC has a well-earned reputation for the quality of its clinical trials, but does not evaluate all new procedures and treatments. Evaluation of a particular procedure or piece of equipment may be suggested by the committees, units, *or* council of MRC, may be suggested independently by a particular researcher in a grant application, or may be requested by DHSS. How many of these triaIs actually take

place depends on their importance in comparison to other uses of MRC funds; there is no fixed budget for clinical trials. Britain is in a very favorable position for carrying out clinical trials, however, because the costs of patient care (including salaries of staff, etc.) are already being borne by NHS. The actual costs of a clinical trial, then, are low, "particularly in comparison to the costs of trials in the United States. MRC tends to emphasize randomized trials of new or existing treatments rather than the evaluation of diagnostic or other procedures, or on medical equipment more generally.

The Scientific and Technical Branch of DHSS exerts a more general overview of the field than MRC. The evaluation activities of this branch tend to focus on the safety of equipment and its performance and reliability in clinical settings. Although the branch may provide funds for purchase of machines to be tested in the clinical environment, it is not involved in randomized clinical trials. It may suggest to MRC, however, that such trials are needed.

Thus, clinical performance, and to some extent clinical trials, of medical technology are the major facets of evaluation in Britain. There is virtually no emphasis on evaluating the more general social and economic impacts of innovations. Any such work that does take place probably arises independently in universities around the country, although it may be supported by DHSS-controlled research funds or perhaps by the Social Science Research Council.

The Purchase of Equipment[6]

The structure of NHS was discussed earlier, but it perhaps needs to be reiterated here that it is Regional and Area Health Authorities who decide how money should be spent, and it is up to them to decide what equipment is needed and which make should be purchased.[7] Thus, although there is a nationalized health service in Britain, there is much more scope for variability than one might at first suspect. Consequently, too, the introduction and diffusion of medical technology are not so well managed as might be thought.

The main reason that Britain has not had the pressures for more control which are in evidence in the United States is not so much that technologies are well managed as that NHS budgets are very tight and there are many competing claims on a Health Authority's funds. Through the NHS budgetary system, Britain has had some protection from the cost explosion of new technologies seen in other countries.

The controls over medical equipment purchasing are quite variable in NHS. Some equipment (e. g., X-ray apparatus, renal dialysis machines, and automated laboratory equipment) is purchased under central contracting arrangements. DHSS—again Scientific and Technical Branch or its counterpart in Wales, Scotland, or Northern Ireland—negotiates contracts with the supplying firms, and this equipment is produced to DHSS specifications and evaluated. Since DHSS does not directly place orders for equipment, however, there is no guarantee to a manufacturer that its equipment will be purchased by Health Authorities. Purchase will depend on whether an Authority decides it needs new equipment, and even if an Authority decides that it does, it may buy from another manufacturer (although the fact that the equipment has been built to certain standards and specifications is an incentive to use the firm with the DHSS contract).

Even within the central contracting arrangements, there is some variability according to the type of equipment. Orders for X-ray and radiotherapy equipment are placed through DHSS. With other equipment, such as automatic analyzers, the central contracting is for a base price, and individual Authorities negotiate with and purchase equipment from the firms directly. There have been complaints about the central contracting arrangements both from manufacturers, who have no guarantee of a number of sales and yet are selling at prices favorable to NHS, and from Health Authorities, who would like more freedom to negotiate with firms.

[6] "Much of the information in this section was taken from "Medical and Scientific Equipment in the NHS, " *Brit, Meal, J. 1(6120):* 1160, *1978 (16).*

[7] This is apart from the small amount of equipment purchased directly by DHSS for evaluation.

Apart from the central contracting arrangements, supplies, including medical equipment, are in the hands of the Health Authorities themselves. The cheaper equipment (under 15,000 ($11,000)) comes out of revenue expenditure and is handled through hospital budgets. If it costs more than 5,000, equipment is considered a capital expenditure and may be handled in a variety of ways depending on the area or regional policy. In some regions, a budget is set aside for equipment and there are committees set up at the regional level to decide on equipment (e.g., for radiology, for pathology, etc.). This system may have advantages in that the supply of equipment is rationalized throughout the region and the actual purchase decided on by specialists who understand the highly complex machinery.

In other regions, there may be no special budget for equipment; instead, areas may be allowed to decide how much of their minor capital allowance to spend on it. Devolving the decision downwards in this way has the advantage that money is not automatically spent on equipment, i.e., without comparison of that need to other needs for capital. On the other hand, the region may lose out on discounts for bulk buying and there may be other problems such as duplication of equipment. It should be pointed out that requests for equipment in these various systems tend to originate with clinicians; whether requests are successful will depend to some extent on clinicians' ability to argue their case in the face of other competing claims on resources.

Clearly, there is great variability in how NHS handles the purchase of medical technology. The general question of supplies for NHS, of which medical equipment is one facet, has been under examination recently by the Salmon Working Party. There is agreement that all is not well with the current mechanisms, and the working party recommended setting up a Supply Council to set policy, including policy for the evaluation of medical equipment (6). How far the working party's recommendations are implemented and how they will affect NHS await to be seen under the new government.

Planning

To complete this section on medical technology management, something must be said about the NHS planning system. Since the *1974* reorganization of NHS, a highly complex planning system has been initiated. Under this planning system, the lowest tier (i.e., the district) prepares a 3-year operational plan which is passed up to the higher tiers and incorporated (with appropriate discussion and modification) into the higher tiers' larger operational plan. In addition, areas prepare 10-year strategic plans which are incorporated into regional strategic plans. These strategic plans are revised every 4 years. In theory, by a process of passing down information about policy from the top and receiving these plans upwards from the bottom, it is hoped that a region, and ultimately DHSS and the Secretary of State for Social Services, can guide NHS in appropriate directions. Although this planning system is in its early stages and is having teething troubles, it is necessary to mention it, particularly in the context of capital expenditure. Since capital will form an important part of a regional strategy for modifying its service provision, it should be through these plans that modifications of capital stock are approved.

Capital budgets are allocated to regions in a way similar to that described for resource allocation of revenue costs (i. e., the RAWP formula discussed above) (11). Although regions— and also areas, if decisionmaking is devolved downwards—are free to decide on how capital funds should be spent, it is likely that major capital developments (e.g., new hospitals) will have been thoroughly discussed with DHSS and approved by the Secretary of State. As an interesting aside, it is noteworthy that hospital bed closures cannot be made without the approval of community health councils, the community "watchdogs" of NHS. When these councils and a Health Authority disagree, the final decision is made by the Secretary of State.

SPECIFIC TECHNOLOGIES

CT Scanners[9]

In 1967, G. N. Hounsfield, working on pattern recognition studies at British manufacturer EMI's central research laboratory, built a crude scanning device which produced pictures of inanimate objects. Although similar devices had been produced by others, particularly, W. H. Oldendorf and A. M. Cormack in the United States, their ideas had not been taken up by industry. It was Hounsfield's success in persuading EMI of the medical importance of his invention which led to the manufacture of the first computed tomographic (CT) scanner.

DHSS was involved from a very early stage. EMI approached DHSS about the usefulness of Hounsfield's idea, and as a result, DHSS provided funds for the first prototype brain scanner. The Department also arranged in 1971 for this scanner's clinical evaluation at Atkinson Morley's Hospital in London (1). During *1973,* two additional first-production machines were purchased out of the Department's R&D funds and sited in well-known hospitals. Subsequently, DHSS purchased three more machines for further evaluation.

Early on, it became obvious that CT brain scanning was a remarkable breakthrough. The results of evaluation studies furnished to DHSS in *1976* by the six institutions with scanners led to the Department's recommendation that each region purchase at least one brain scanner. By August 1978, 33 brain scanners had been installed or were on order in England and Wales. The number did not increase greatly thereafter, because of Authorities' tendency to buy body scanners for both brain and body purposes. By January 1, 1979, there were 39 head scanners, and 1 more was added during 1979.

Meanwhile, EMI had succeeded in decreasing the scan time from 5 minutes to about *20 seconds,* thereby making body scanning a possibility. DHSS was much less involved with the development of body scanners, and EMI provided its own funds for the first prototype. This machine was installed in Northwick Park Hospital in 1975. Although DHSS did not take part in the evaluation of the machine, it did advise Health Authorities to be cautious about purchasing scanners until the evaluation was further advanced.

In fact, events overtook the evaluation. With resistance to purchase of body scanners in official channels, other sources of funds for such scanners were apparently sought. In a number of areas, various philanthropists donated scanners to NHS; in other areas, appeals were set up to raise the necessary funds. Table 1 shows the

Table 1.—CT Body Scanners Installed or on Order in the United Kingdom (October 1979)a

Location	Source of funds for machine
England and Wales	
Northwick Park	DHSS
Brighton	Donor
Manchester (Medical School)	University and NHSb
Birmingham	Donor
Bristol	Donor agency
Royal Marsden, Sutton	Cancer research campaign and additional sources
London (St. Thomas')	Endowment funds
London (University College)	Donor
London (St. Bartholomew's)	Endowment funds
London (Middlesex)	Endowment funds
Leeds	Appeal
Conventry	Appeal
London (National Hospital)	DHSS, donors, and additional sources
London (Great Ormond St.)	Appeal
London (Charing Cross)	Donor
Manchester (Christie)	Appeal
Guild ford	DHSS and NHS
Scotland	
Edinburgh	NHS
Glasgow	NHS
Northern Ireland	
Belfast	NHS
Outside NHS	
BUPA	Donor
Midhurst	Donor

[a]This table first appeared in *New Scientist,* London, the weekly review of science and technology.
[b]Source of funds may be through Health Authority or Board of Governors.
SOURCE: B. Stocking, "X-Rays Highlight the Doctor's Dilemma," *New Scientist* 81(1137): 84, 1979 (21).

[a]Much of the information for these case studies was derived from particular individuals. These sources are given, but the individuals concerned are not responsible for any mistakes or misinterpretations.

[9]A fuller discussion of CT scanning in Britain is given in B. M. Stocking and S. L. Morrison, The Image *and* the *Reality: A Case Study* of *Medical Technology, 1978 (22).*

sources of funds for the capital costs of all body scanners installed or on order in October 1978. Eighteen body scanners were operational by January 1, 1979, and another five became operational during 1979.

Early on, DHSS had set up a committee to monitor the body scanner's evaluation, but it was not until August 1978, when a large number of body scanners were already in use, that DHSS issued a paper saying that whole-body scanning did have a place in diagnostic radiology (7). This letter went on to say: "In a few centres it is likely that general purpose scanners will need to be provided primarily for the body role. "

Whole-body CT scanning has raised a number of important questions in the United Kingdom. The central issue concerns how new technologies should be evaluated. A number of diagnostic techniques have been tried out in clinical settings before large-scale diffusion; CT scanning is unique in that questions have been raised about the usefulness of this as compared to other techniques and the need for randomized clinical trials of diagnostic equipment has been recognized.

The important issue of the role of philanthropy in NHS has also been raised. In a number of cases, Health Authorities have been put into an embarrassing position. Scanners have been offered to them, but individual Area Health Authorities have had to provide the operating costs (and probably eventually the funds for replacement machines). Operating costs are estimated at 50,000 ***($110,000)*** per annum, and given current tight budgets, these Authorities might prefer to use their funds for other purposes.

There are also other consequences of philanthropic gestures. Because local consultants have usually been the stimulus behind appeals and the local community itself has raised the funds, the local community expects to benefit by having the scanner in its own hospital. This may or may not be the best location for it. It is certain that some of the early scanners donated by philanthropists did not go into the most appropriate locations for a proper clinical evaluation. Even now, DHSS recommends that priority for body scanners should be given "to those centres prepared to undertake further clinical evaluation" (11). The hospitals that are getting scanners as a result of appeals, though, are not necessarily the most capable of evaluating them. Thus, although it is accepted that philanthropy can provide a very useful source of funds for NHS, in the case of CT scanners, philanthropy has produced a number of difficulties.

Renal Dialysis[10]

For patients with chronic renal failure, treatment by dialysis or the receipt of a transplant may be alternatives or may be complementary. Thus, in the following discussion, figures are given for both dialysis and transplant services.

Britain became involved in the provision of renal dialysis for chronic renal failure in the mid-1960's. The British Government, through the then Ministry of Health, became directly involved in establishing dialysis units and in evaluating the technique. By the end of the decade, the current network of dialysis centers was established, and Britain was leading the way in Europe in the provision of this service. (Britain no longer holds this lead.)

The Ministry of Health was also involved in setting up the network of transplantation units alongside the dialysis units after a working party on the subject had reported in the early *1960's.* Finally, central funds were used to setup the National Organ Matching and Distribution Service and the National Tissue Typing Reference Laboratory (referred to jointly as "UK Transplant").

After these early initiatives, the Ministry of Health handed over the responsibility for financing the now 49 dialysis and transplant units in England and Wales to the Regional Authorities. Particularly since reorganization of NHS in 1974, DHSS has emphasized that resource allocation decisions are in the hands of the Regional and Area Health Authorities.

[10]Much of the information for this case study was taken from a *1978* publication of the Office of Health Economics, Renal Failure: *A Priority in Health? (18)* and from discussion with author William Laing (15).

Despite this devolution of responsibility, renal dialysis has reached sufficient prominence in public debate for the British Government to become involved again. In particular, in late 1977, funds were provided through the special medical development (SMD) earmarking system for extra dialysis machines for children. The SMD money is for the initial stages of new programs. The conditions set are that the object of expenditure should be just emerging from the experimental stage and that the period of direct financial support should be short term. No provision was made for recurring revenue costs with the pediatric dialysis machines. Thus, Regional Authorities already battling with very tight budgets were not enthusiastic about the offer of machines. In fact, in some cases, the machines were not accepted.

More recently, in the 1978 budget, the British Government again entered the scene, this time quite outside its stated policy of minimal intervention in resource allocation. In the budget, 3.5 s million ($7.7 million) was allocated to cover the costs of treating ***400*** extra patients, with provision for the running costs for at least 2 years. It is unclear whether these machines were ever purchased, and if so, whether they are in fact in use.

The British Government has always been involved in the transplant service, because this service is a nationally based system. In particular, DHSS has taken initiatives to increase the numbers of cadaver kidneys available for transplant through the use of kidney donor cards. In current law, in the absence of any clear statement of the potential donor's wishes, the person lawfully in possession of the body must make reasonable inquiry to ascertain whether the deceased, the spouse, or any surviving relative objects to the organ donation (with all the attendant problems of securing their approval). Kidney donor cards signed by the potential donor, if carried by a large number of the population, would therefore be expected to increase the number of kidneys for transplantation. In 1978, DHSS intensified its campaign to bring the existing donor card system to the public's attention, hoping to increase the number of cards carried.

There has, then, been considerable British Government intervention in renal dialysis and transplant services. To understand why the British Government has felt obliged to take specific action, it is necessary to look at the figures for the service provision with estimates of need. In the late 1960's, three major surveys were undertaken in the United Kingdom to estimate the levels of chronic renal failure in the population. From these surveys resulted the often quoted figure that 40 new patients per 1 million population aged 5 to 60 years would need treatment per year. Even this must be considered an underestimate, since it is now accepted that people who were excluded from the treatable category because of associated conditions (e.g., diabetes) could now be treated. Also, there are obviously many individuals over the age of 60 who need treatment, and it is a matter of priorities about whether and at what age treatment should no longer be offered.

The figures reported for the United Kingdom for 1978 (2) show that 2,946 patients were alive on dialysis machines (about two-thirds of whom were on home dialysis). For the same year, ***820*** live or cadaver transplants were reported. The transplant rate of 15.3 per 1 million population per year compares well with the 4.7 per 1 million population average for Europe as a whole. The overall rate for all patients being treated by dialysis or with a functioning transplant in the United Kingdom in 1978 was 92.3 per 1 million population. The number of new patients accepted for either form of treatment in 1978 was 19 per 1 million population. If this figure of 19 patients per 1 million population is compared to the survey figures of an estimated 40 new patients per 1 million population per year, a serious shortfall in the number of patients who are receiving treatment compared to the estimated number of patients who could benefit is apparent. These figures, linked to the publicity there has been on the subject, are clearly reasons why the British Government has felt obliged to step in.

The questions raised by by the situation regarding the treatment of patients with kidney failure are quite unusual, because it is one of the few instances in which a directly lifesaving pro-

cedure is not being provided to individuals whose lives are threatened. Whether an increase in the number of dialysis machines would solve the problem, however, is another question. It appears that it is not so much a shortage of machines as an inability to recruit enough nurses, coupled with a lack of money to pay them, which results in machines' not being used as fully as possible (15). Even this, it is suggested, is not the whole story, since most dialysis units could in fact take more patients. It seems that patients are probably being turned away at an earlier stage, perhaps when they are seeing general medical consultants before even reaching dialysis units.

Although no new renal dialysis units are planned, a number of them are undergoing expansion; that is, the number of beds, including machines and the necessary staff, are being increased. If the numbers of patients on dialysis are to increase substantially, however, it would seem that these units would have to make it clear to doctors in their referral areas that treatment is in fact available.

Given the improving life expectancy of patients on dialysis, the constant input of new patients, and the easing of criteria for patient acceptance for treatment, then, it is certain that treatment of all patients by dialysis will never be feasible. The government's attempts to increase the number of kidneys for transplant, therefore, can be seen as an important means to resolve the current dilemma.

Coronary Bypass Surgery[11]

Coronary bypass surgery began to be carried out in various centers in Britain in 1969. Since a number of centers were equipped for open-heart surgery, no new technology as such was required. At the time, however, these centers were dealing with a backlog of valve operations. This backlog, coupled with the fairly conservative attitude of GPs in referring patients with angina to cardiac specialists for possible surgery, resulted in fairly slow growth in the number of operations performed.

[11]Dr. Celia Oakley, Hammersmith Hospital, London, provided much of the information for this case study (17).

With more widespread acceptance of the apparent benefits of the procedure for relieving angina symptomatically, pressure to increase facilities grew. Health Authority budgets were becoming increasingly constrained, however, and according to central policy, acute services were to be given lower priority.[12] From 1972, the European Coronary Bypass Study was underway to look at the effects of coronary bypass surgery on mortality, and this provided a suitable reason for saying that increased facilities would not be made available until more was known about the effectiveness of the procedure. In 1977, there were 2,532 bypass operations in NHS hospitals in England and Wales (operations in private hospitals are not included) (13).

The number of centers involved is based on the number able to perform open-heart surgery. As in the United States, guidelines have been proposed for how many operations should be carried out in each center. The Cardiology Committee of the Royal College of Physicians suggested that each center should do a minimum of 300 operations per year, with each surgeon performing at least 200 operations per year.

Cobalt Therapy[13]

Radiation therapy had been used to treat cancer for some time, but it was only after World War II that cobalt isotopes, producing the high energy radiation suitable for treatment of deep tumors, became available. The first commercial cobalt machines were produced in the 1950's, and the first cobalt machine in Britain was purchased with NHS regional hospital board funds from Atomic Energy of Canada (AEC) and placed in the Mount Vernon Hospital. Subsequently, three British firms, AEC, Hunslett, and

[12]This policy was explicitly stated in two documents issued by DHSS, *Priorities for Health and Social Services in England* (9) and *The Way Forward* (12). The increased priority to be given to long-term care of the elderly, mentally ill, handicapped, etc., and decreased priority for acute care services obviously has implications for all the technologies described here. It has never been clear, however, the extent to which Health Authorities should be constrained by this stated policy. Certainly, it was not intended to be an overnight change, but with tight budgets and alterations in resource allocation policy, Health Authorities have found it extremely difficult to make any change in the relative priorities of acute and "cinderella" services.

[13]Much of the information on cobalt therapy was obtained from D. Kidney, DHSS (14).

Nuclear Energy (now incorporated in TEM Instruments) sold machines in Britain, and these machines, too, were purchased with NHS regional hospital board funds, although the then Ministry of Health was involved in central contracting arrangements. Central R&D funds were not used to develop equipment and purchase early machines for clinical evaluation. 1[4]

At the time, there were *50* radiotherapy centers in England and Wales—a number of them in the London teaching hospitals, others in major cities around the country. Each of these centers purchased a cobalt therapy machine; some, depending on their patient load, purchased more than one. The decision to purchase machines was in the hands of the hospitals designated as radiotherapy centers, and there seems to have been little call from other hospitals for these machines.

In April 1979, there were ***105*** cobalt machines in Great Britain, almost all of them of British manufacture. This figure probably represents a peak. Even though patient loads may increase, and in addition replacement machines will have to be purchased, there is a tendency to replace cobalt machines with linear accelerators. The advantages of linear accelerators are that: 1) patient throughput is faster, and 2) these machines are easier to use, because the size of the source is smaller and can be more readily pinpointed to reach a tumor.

It is unlikely that linear accelerators will replace all cobalt machines. Cobalt therapy may be more suitable for some treatments, and cobalt machines are less complex to maintain and also considerably cheaper than linear accelerators. At present, a cobalt machine costs about 4100,000 *($220,000),* a linear accelerator about double that price. Cobalt machines do require purchase of new cobalt sources about every 4 to 5 years, however, and these cost about *15,000* **($33,000).**

Both types of machines are bought through central contracting arrangements, but there is no policy on whether accelerators or cobalt machines should be purchased. The current policy guidelines (8) state only that each designated radiotherapy center should have a minimum of two megavoltage machines. In fact, the centers are quite variable. Four of the five Scottish centers, for example, have chosen accelerators, whereas the fifth has decided to use only cobalt machines.

Clinical Laboratory Testing: Laboratory Automation [5]

The first single-channel automated laboratory analyzers became available at a time when there was much concern about the increasing workloads in pathology laboratories in the United Kingdom. The then Ministry of Health's response to the first commercially available machine, the Technicon system, was to ask hospitals not to buy these analyzers. Because of the pressure of the workloads, a number of teaching hospitals and regional hospital boards did go ahead and buy machines in the early 1960's, despite the Ministry's request. Meanwhile, by providing funds for development and offering guarantees of purchase as an inducement, the Ministry of Health attempted to encourage British manufacturers. The one machine that resulted from this encouragement was not very successful.

By the mid-1960's, two-channel and then multichannel machines were becoming available, and it was at this time that the Ministry of Health began working with Vickers to produce a multichannel analyzer. It was already being suggested that laboratory services should be centralized, and it was with this aim in mind that the Vickers development was supported. Vickers did produce a satisfactory machine. The Ministry of Health purchased 22 Vickers machines for NHS, and Health Authorities then paid their running costs. Health Authorities subsequently purchased additional Vickers machines, as well as analyzers produced by other manufacturers. The figures on exactly how many single-channel and multichannel analyz-

[14] with DHS now commonly involved in the development of equipment and purchase of early machines for clinical evaluation, current practice represents a departure from this.

[15] The information on laboratory testing was obtained from Dr. C. Riley, Royal Sussex County Hospital, Brighton (20) and Dr. C. Connally, Regional Scientific Officer, South-East Thames Regional Health Authority, Croydon, England (3).

ers are in NHS are probably not known. A reasonable estimate is that there are about 19 to 20 multichannel machines in each English region, making a total of perhaps 280 for England alone.

DHSS is still involved in automated analyzers in that it negotiates central contracts with manufacturers. As described earlier, however, this negotiation does not guarantee any sales; it merely sets a base price. Health Authorities are then able to negotiate directly with manufacturers for a particular machine and purchase it directly.

One major policy that has affected the number of machines purchased is the centralization of laboratories, a policy set out in a health circular in 1970. The aim is that each district (the lowest tier in NHS, serving about a quarter of a million population) should **have** only one laboratory for clinical chemistry. Again, because of the potential for automation, hematology is also centralized. Histology and microbiology have been centralized to some extent, but since they are much less machine-oriented, there has been less pressure on these branches of NHS.

Some concerns have been raised about the implications of the increased volumes of data produced by automatic analyzers, and DHSS funded a study to investigate the question. [16] This study indicated that the increased information was marginally beneficial, but the issue is still frequently raised.

Another question concerns the reliability and safety of machines and the accuracy and reproducibility of the data they produce. DHSS-funded evaluations of new automated equipment address these questions, as well as the total costs of purchasing, operating, maintaining, and manning the machines in relation to laboratory workload (10).

[16]The results of the study can be found in T. P. Whitehead and I. D. P. Wootton, "Biochemical Profiles for Hospital Patients," *Lancet* 2:1439, 1974 (24).

CONCLUDING REMARKS

Britain's fairly conservative attitude towards technology has been noted; notwithstanding this attitude, in the health sector, calls for the latest equipment are common from the public and doctors alike. In fact, a certain amount of dissatisfaction is felt by health workers because they do not have the latest technologies available to them. The reasons for the lack of availability throughout the country of the newest generation of each technology have already been described: NHS operates on a budget set by Parliament, and choices between one technology and another or between equipment and other uses of the funds must be made in the context of this overall budget. Because these choices are rarely stated explicitly, however, there is a sense in some quarters that technology gets priority funding over some of the less glamorous NHS activities, particularly, the so-called "Cinderella" services such as care of the elderly, the handicapped, etc. The relatively slow growth of NHS in the next few years is likely to sharpen the whole debate on technology and its role in British health care.

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