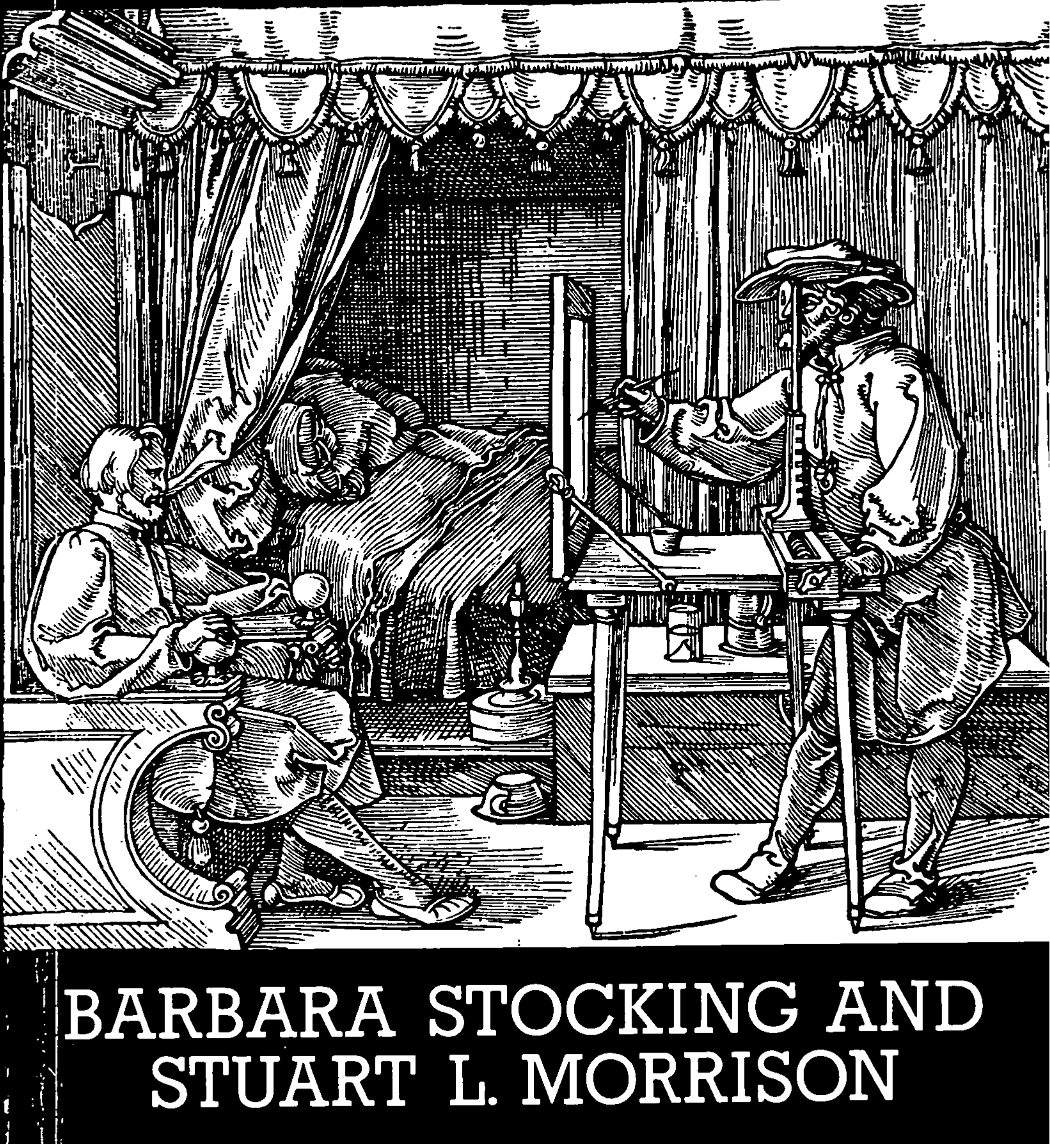
THE IMAGE AND THE REALITY

A case-study of the impacts of medical technology



BARBARA STOCKING AND
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Foreword

By SIR ANDREW WATT KAY, MD, ChM, DSc, FRSE
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The study described in this report throws light on the application of a startling new technological development. The introduction of the whole body scanner adds to the growing list of diagnostic weaponry and, at least for the present time, involves high capital and running costs. It is not difficult to foresee that some technologies in the future will be so costly in relation to benefits that society will be forced to renounce them. The present study is highly relevant to this issue in that it casts serious doubts on the adequacy of the present arrangement—if indeed planned arrangements exists—to correlate the costly interplay of the research, development, evaluation, and health care assessment prior to the general introduction of an expensive new technology into the NHS. In undertaking this analytical exercise *ex post facto* the authors have revealed the clear need for some rigorous oversight of the total arrangements required, starting from the conception of an idea and proceeding through the development and proving stages, if the application of new technologies into health care are to be efficient and effective. Complementary to this is the need to assess the implications of these innovations in terms of health service logistics.

Are the existing arrangements for services in Britain ever likely to allow for such exercises in the co-ordination of activities? If the answer is 'no', the time is ripe to consider the establishment of an independent focusing agency to oversee the evaluation and assessment of new developments by commissioning studies from appropriate research workers. In addition to providing the information and the drive to fuse all the elements for developing and testing technology in the Health Service, the agency would be expected on the one hand to anticipate new developments and, on the other, to monitor an innovation as it is grafted on to the health care system. It is evident that any agency brought into being, whatever its form, would require adequate resources to commission work on identified problems.

If analyses of the likely impacts of new technologies became a routine feature of an active health system, there would be a greater awareness of the technological needs in health care; there would be a sounder basis for the stimulation of research and development in particular areas through the universities or the research councils by providing the 'intelligence' to make industry conscious of needs to be met. To take the long strategic view, an integrated approach to innovation in health care would seem to be inevitable to replace the haphazard reactions to problems which suddenly present themselves. It should not be forgotten that one of the ancillary roles of the NHS to a manufacturing and exporting nation such as Britain, is to provide an efficient testing 'laboratory' for emerging technologies designed to improve care in all its aspects.

Research exercises such as this explore relevant issues and I have used this foreword to emphasize the necessity for action. The 1974 reorganization of the NHS has added urgency in so far as devolution of financial resources and of decision-making has increased the difficulty of formulating national policies. This may not be the appropriate medium for sketching the constitution of a focusing and overview agency, but at least it can be envisaged that to function effectively it would require the full support of the health departments and should work in close association with the research councils and the NRDC.

Acknowledgements

We would like to thank the Nuffield Provincial Hospitals Trust for a Research Fellowship for one of us, Barbara Stocking, which made this study possible. We are also pleased to acknowledge the support of the Trust's Secretary, Gordon McLachlan, particularly in the report's final stages. At the University of Sussex several members of the Science Policy Research Unit provided us with a great deal of encouragement and we would especially like to thank Jay Gershuny, Mick McLean, Ian Miles, and Roy Rothwell.

Many people were interviewed during the study and their information and ideas were invaluable. They cannot all be mentioned here but we are grateful to a number of staff at the DHSS, to several manufacturers, including EMI, Elscint, and Siemens, and to radiologists and staff in departments with whole body scanners in the United Kingdom. Finally we would like to thank the various people involved in the final manuscript preparation, in particular Gwen Bradfield and Teresa Humphreys.

1 Introduction[1]

With its strong desire to believe in miracles, whether provided by a new procedure or a new treatment, the public welcomes any new medical technology with open arms. It is also natural for doctors to feel morally obliged to try a new technology or treatment that shows any promise at all. For this reason new procedures and treatments are often adopted in practice without even a thorough examination of their effectiveness, let alone an assessment of their possible impacts on health services generally. Only for new drugs is there a formal mechanism which requires thorough clinical testing before the innovation is adopted for widespread use.

In recent years many new technologies have been developed for use in medical care, including renal dialysis machines, implantable cardiac pacemakers, and automatic analysers. All such innovations need to be thoroughly evaluated and, in addition, their possible impacts need to be assessed if the NHS is to make appropriate use of them. The purpose of the study described here is to initiate discussion about how a new technology should be assessed and to do so by taking one particular health care innovation as a case-study.

As a recent innovation and one which has received a great deal of publicity, computed tomographic (CT) scanning was chosen as the example. Except where unavoidable (as in the chapter on historical development) the discussion has been

1. Notes and references appear on p. 69.

restricted to whole body scanners and little attention given to brain scanning. Narrowing the area covered in this way made it more manageable, especially since whole body scanning raises a number of issues quite separate from brain scanning. It seemed preferable to discuss whole body scanners since they are not so well accepted as brain scanners at this time, and decisions about resource allocation are still in the process of being made. It is hoped that this study will provide some awareness of the general impacts whole body scanning might have as well as stimulate discussion of the whole process of technology assessment.

At the outset it should be made quite clear that a case is not being made that the NHS should not have this or any other technology. This is not to say that how much technology the NHS needs should not be questioned and discussion of this issue, along with others raised by modern technologies, is important. The aim in this report, however, is to discuss how the introduction of a new technology should be managed including future developments and implications.

In drawing together the information on CT scanning, important philosophical and ethical considerations arose. Although these issues will be discussed thoroughly in proper context, it is appropriate as an introduction to the study to highlight some of them here.

One major issue concerns resource allocation and the choice of priorities. It is assumed that, during the time-scale of the adoption of the whole body scanning, resources will be scarce in the NHS. If only a limited rate of growth is possible then the adoption of one technology may mean that another has to be foregone, or perhaps more importantly, investment in a new technology may mean that funds are not available for new buildings, more staff or an increased emphasis on health education and prevention. There is a broader question to be considered. Health expenditure in the UK rose from 4·1 per cent of the Gross National Product (GNP) in 1950 to 5·3 per cent in 1973 and it is possible that we, like other developed countries, may shortly be reaching a point where health services cannot continue to grow as a percentage of the GNP.[1] The demand for health services may be unlimited but sooner or later a point will be reached where it is no longer practicable to keep putting a greater proportion of resources into health. This makes it all the more imperative to consider what sort of health service is wanted, and to decide on the relative priorities for prevention, for acute care, for attempts at cure of chronic diseases, and for the care for chronic disorders.[2] New technologies are often expensive and it would be easy to spend an increasing proportion of a fixed budget on them, if such investment is not even questioned. The underlying question is: what sort of Health Service do we want, and what sort of technologies would be appropriate for it?

At first sight, decisions about allocating resources to a particular technology would seem to involve assembling the necessary data on cost-effectiveness and making a once and for all decision in the light of the evidence. Unfortunately, this does not take into account the confusion that can be caused by unforeseen developments in the future; CT scanning provides an obvious example. It is not enough to look at the effectiveness of CT scanning now and compare it with other techniques in their present state. The whole picture could be quite different in the future if, for example, CT scanning became cheaper, or alternatively if another cheaper imaging technique became more effective. Decisions affecting future options have to be made now, even though the future circumstances may be quite different from those of today. The decision maker has to take action in the face of such uncertainty and, although completely unforeseen developments cannot be ruled out, it is possible to make some forecasts about the future, based on the ideas and developments already in being. In looking at CT scanning some of the likely developments which will affect its place in medicine in the future have been suggested in this report. Based on these possibilities two future scenarios have been described and used as the framework in which to look at the impacts of whole body scanning. This is only an exploratory study. A very important point is, however, being made: when a technology is evaluated it is not enough to compare its usefulness with that of another technology or another form of health care now. Explicit recognition must be given to the effects of future developments and arrangements for continuing evaluation and assessment of the technology must be made as these developments take place.

Another issue, related to resource allocation, concerns the pressures put on the NHS associated with new technologies. These pressures may come from doctors who recognize the benefits from a new technology but who may not consider whether it will affect the outcome of treatment or how cost-effective it is in relation to other forms of health care. The adoption of the technology abroad may serve to strengthen the demands by doctors at home for its provision here. Especially for new technologies for which large, and sometimes unsubstantiated, claims are made, the general public may also be involved by demanding access to it in the NHS. CT scanners are a fascinating case history of how the system has responded to demands from doctors and to a more limited extent from the general public. Almost all the capital costs of the whole body scanners now in use or on order in the UK have been paid for from funds outside the NHS. When the NHS did not respond to the demands by doctors for scanners, it seems that the doctors found other routes to obtain this equipment. This development brings up some important questions about the role of philanthropy in the NHS and about its effects on planning and on the availability of a technology to patients.

Again related to resources, in times of economic constraint it is very hard for policymakers in the NHS to justify large expenditures on new technologies. This poses something of a dilemma for British industry and for the central government officers who wish to encourage industry. Exclusive concentration on the UK market would lead to only limited sales so that an innovation has to be taken overseas to achieve profits, yet this has to be done without the benefit of a firmly based home market. The difficulties inherent in such a situation may be a disincentive to industry to invest in research and development of new medical technologies.

Finally, as a separate aspect, the whole body scanner brings up the difficult medical question of the relationship between diagnosis and treatment. Whole body scanners provide an example of a situation where diagnostic sophistication has developed beyond effective therapy. The practical and ethical consequences are difficult to resolve and questions have to be asked about the degree of diagnostic precision needed.

2 *The development and diffusion of computed tomography*

In much of the literature, computed tomographic (CT) scanning is talked of as revolutionary, the most important development in radiology since the discovery of X-rays (see references to Appendix). This discussion must, then, start with what CT scanning is and what it can do. Because they have a common background, both brain and whole body scanning are included.

CT scanning combines radiological and computer techniques to produce cross-sectional pictures of the head or body. X-rays are passed through a cross-section of the body and detected using scintillation counters on the other side. As with conventional X-rays the difference in intensity between the X-rays emerging from the body and those entering it depends on the density of the tissue through which the rays pass. The change from longitudinal to cross-sectional images is not altogether new since conventional tomograms also take pictures in different planes. What is new, however, is the number of readings which are recorded by the very sensitive detectors. The measurements are then processed by a computer to produce a cross-sectional picture.

The technique can perhaps be more readily understood from a description of the process in one currently marketed machine. With EMI's whole body scanner a narrow beam of X-rays scans across the body and the intensity of the emerging X-rays are measured by a bank of sodium iodide detectors. The beam and detectors make a short linear movement with the body between the source and the detectors, and readings are taken during this movement. The whole mechanism is then rotated through 10°. The translation and rotation procedure is repeated eighteen times until a full 180° has been covered. During the total scan over 300,000 individual readings of X-ray intensity have been taken and these measurements are then used by the computer to produce the cross-sectional image.

In conventional X-ray pictures the internal structures are superimposed on each other. High-density structures like bone, therefore, mask underlying structures. In the skull, where bone covers all the internal structures, this was a particular problem. In conventional X-ray photographs, it is also difficult to distinguish between adjacent soft tissues of similar density and between normal and diseased tissue in an organ where they are of similar density. Because of the sensitivity of the detectors, as compared to photographic films, and because of the large number of readings which can be mathematically processed, CT scanning gives a much higher degree of resolution. Even with CT scanning there is still a problem differentiating between soft tissues of similar density but because of the sensitivity of the system this is much less than with conventional X-rays. The lack of other non-invasive techniques for diagnosing abnormalities in the skull and the fact that the information CT gives is in some instances unique, has meant that brain scanners have been a major advance. In the rest of the body where other acceptable techniques are available, the place of CT scanning in the diagnostic spectrum is not yet worked out. The state of the art in the clinical evaluation of whole body scanners will be discussed in a later chapter.

Initial development of CT scanning

By the late 1960s the field was clearly 'ripe' for the development of CT scanning with several investigators in different parts of the world arriving at the basic concept at more or less the same time. In a report[1] for the President's Biomedical Research

Panel, the Battelle Columbus Laboratories documented the major scientific advances necessary for the development of CT scanning. They concluded that the principal elements in the timing were developments in computer technology, mathematics, instrumentation, and radiology. Only because of the availability of on-line mini-computer installations did CT scanning become a viable economic undertaking. Advances in digital image processing and in the mathematical methods for image reconstruction were essential to CT development. Advances in scintillation counting were needed to give the precision in X-ray measurements at the high speeds required in CT scanning. Finally, advances in conventional tomography provided the radiological background for the new technology.

Although W. H. Oldendorf and A. M. Cormack in the United States both built crude scanning devices, their ideas were not taken up by Government agencies or by industry. It was G. N. Hounsfield at EMI's Central Research Laboratory in Britain who first developed a clinically useful CT scanner. Hounsfield had been working on pattern recognition studies at EMI and in 1967 produced pictures of inanimate objects using a crude scanning machine. Recognizing the implications of his work for radiology he tried to persuade EMI to develop a clinical device. EMI was unsure about this development and turned to the Department of Health and Social Security for advice. The DHSS set up a panel of experts and agreed to fund the development of a prototype brain scanner. This first prototype was installed at the Atkinson Morley's Hospital in 1971 to enable Dr J. Ambrose (one of the members of the DHSS panel on CT scanning) to carry out a clinical evaluation of the machine. Subsequently two other prototypes were funded by the DHSS. In all, five scanners were used for the clinical evaluation and the DHSS had an involvement in all of these in providing funds for the equipment, for staffing and other costs. The advantages of the brain scanner were quickly recognized. The competing technologies of cerebral angiography, pneumoencephalography, and isotope scanning are more invasive, have more risk associated with them and are much more uncomfortable for the patient. Apart from the discomfort involved with these other procedures the scanner provides a more accurate diagnosis and, for example, in one unit it was reported that angiography had been virtually eliminated in the investigation of head injuries.[2] As it became evident that the brain scanner was a clinically useful device, the DHSS formulated a policy that every region should have at least one brain scanner which should be located in a neuro-radiological centre. There are now (mid 1977) about thirty brain scanners in the UK and others are on order.

In the US the first brain scanner was installed in the Mayo Clinic in 1973 and this was EMI's first commercial scanner. Since then brain scanning has been widely accepted in the US and in many other countries. EMI has sold over 600 brain scanners and the combined sales of other manufacturers may bring the total to almost double that number worldwide.

Development of whole body scanners

While brain scanners were being evaluated, EMI and others in the field were going ahead with the development of whole body scanners. There were several problems to be overcome in adapting the technology from brain to whole body use. The major problem concerned scan time and body motion. If motion, such as breathing and intestinal movement, takes place during the scanning period, then artefacts are produced on the image. The brain scanner took five minutes to scan a single slice, which was not a drawback since no motion was involved with the brain. However, it was not until a machine with a much faster scan time was developed, a time during which patients could hold their breath, that whole body scanning really became feasible. In addition, the body is much larger than the head, there is a greater range of body size among patients than is the case with the head, and the body contains many different organs of different densities. All these elements had to be dealt with in adapting the technology.

In fact the first whole body scanner was produced not by EMI but by R. S. Ledley at the Georgetown University Medical Center in the US. This first body scanner had a 2½-minute scan time, which meant that the patient could not suspend respiration for the scanning period. This scanner, the ACTA body scanner, was marketed by Pfizer and now also has a faster scan time. Shortly after, EMI did produce a whole body scanner with an 18–20-second scanning time and the prototype was installed in Northwick Park Hospital in Britain.

The clinical evaluation of whole body scanning in the UK has taken quite a different path from that of the brain scanner. In the case of the brain scanner the DHSS had a high degree of control over the initial evaluation, the clinical role of the equipment became evident rapidly and additional machines were not bought until the DHSS was satisfied. With the body scanner, events overtook evaluation and the same orderly procedure was not followed.

It was recognized that evaluation of the body scanner poses quite different problems from evaluation of the brain scanner. It is much more complex because so many different organs are involved and other acceptable techniques (for example, ultrasound) are available for use in diagnosis. Unlike the brain scanner it is not so obvious that the body scanner has an effect on patient management or on the final outcome of the patient's disease. Not only does one technique have to be compared to another, but there is also the question of whether more precise diagnosis will be advantageous to the patient. Evaluation is made more difficult because the techniques with which the scanner is being compared are also in a state of rapid development. At the same time as this complexity was being recognized two other factors affected the course of the evaluation. First, the cutback in the DHSS budget made it impracticable to buy enough scanners for a thorough exploration. Secondly, a number of philanthropists had already donated body scanners to the NHS and private institutions. In the circumstances these donations were perhaps fortunate but, as will be discussed later, scanners purchased in this manner are not subject to the same control by the DHSS.

With this background the DHSS believed that the way to evaluate the scanner was to bring all the users together to discuss their studies. This mechanism appears to have become unwieldy and it has recently been superseded by a committee of experts. This committee will not only analyse all the available data from users in the UK and overseas in an attempt to determine the scanner's emerging place in medical care but will also encourage research efforts where gaps in evaluation are identified.

The widespread diffusion of whole body scanners is described below. This remarkable spread of the technology prior to thorough clinical evaluation is a cause for concern. In the final chapter this issue will be taken up again.

Diffusion of CT scanners

The diffusion of CT scanners has been exceptionally fast especially considering that brain and body scanners each cost of the order of a quarter of a million pounds. Since 1973 when the first commercial brain scanner was installed, EMI alone have sold over 600 brain scanners worldwide. By mid 1977 EMI had also installed 188 body scanners and had orders for at least 100 more. Although other firms have sold large numbers of brain scanners, with Ohio-Nuclear being the closest competitor, EMI is still very far ahead in sales of whole body scanners.

The way the markets have opened up is interesting itself. Britain, as the country of origin of the technology, had the first brain scanner in action but, as noted earlier, the first commercial scanner was installed in the US. By 1977 Britain had over 30 brain scanners in operation, while the US had probably ten to twenty times that number. The US has also accepted the body scanner very rapidly. At the time when 11 body scanners were installed or on order in Britain, over 760 scanners (either brain or body) were in operation or on order in the US[3] of which as many as 200 may be body scanners.

Recently the markets in other countries in the world have been opened up and there is now a major drive to sell scanners in Europe, the Middle East, Japan, and a number of other countries. An important focus of the sales drive is the mounting of exhibitions of the machines at radiological conferences around the world. EMI have gone one step further and loaded their body scanner on to a bus to tour major hospitals in several European countries and demonstrate the capabilities of the machines. The first countries to have scanners probably bought a brain scanner because at the time their first purchase was made body scanners were not commercially available. The countries who are buying scanners now are often purchasing whole body scanners with the intention of using them for both brain and body investigation. This trend is likely to continue although there will, no doubt, remain a large market for brain scanners in specialized centres.

As a postscript to this section it is interesting to look at the effects the diffusion of CT scanning has had in two particular countries: the UK and the US. In the UK only the implications of the diffusion of whole body scanners will be discussed; in the US both brain and whole body scanners form the basis of the discussion.

The diffusion of whole body scanners in the UK

In April 1977, eleven EMI whole body scanners were installed or on order in the UK. The prototype whole body scanner was provided by EMI and installed in Northwick Park Hospital. (This scanner has recently been replaced out of DHSS funds.) The second scanner was bought using regional health authority and some University funds and was installed in the University of Manchester. Of the remaining nine only one was bought with health service funds, and the others were donated by philanthropists and charities, or were bought by using endowment funds. The eleven scanners are by no means the end of the story. At this same time, discussions were taking place about buying scanners for at least six other hospitals and in some of these cases negotiations were already in progress with EMI. While EMI suggest that the number of individual philanthropists who might donate scanners to the NHS or to private institutions is fairly limited (and it should be mentioned that two of the first eleven scanners went into private institutions), new methods of raising money are being found. For example, some publicity has recently been focused on a fund-raising exercise to obtain a scanner for the Christie Hospital and Holt's Radium Institute, in Manchester. Similarly, in Stockton-on-Tees a local newspaper is involved in a campaign to obtain a scanner for the local hospital.

Although other large expensive pieces of equipment have been donated to the NHS by philanthropists or through fund-raising campaigns, the speed and extent of diffusion of this particular technology by this route is unusual. No doubt the pump was primed by the publicity which had been received by brain scanners. The prime movers for obtaining body scanners were, and probably still are, consultant radiologists who see great potential in the new body machines but the general public has also rapidly become involved. The manufacturers have played an important part in developing the level of awareness. They have certainly made major efforts to ensure that all radiologists are aware of the developments. In addition, it seems likely that where interest has been expressed they have provided advice on how funds might be raised and even, perhaps, which potential philanthropists might be approached.

The diffusion of this technology by this particular route has implications which need to be discussed. While the gift of a piece of expensive machinery to the NHS may be a great boon, unfortunately costs for this particular machine (and for many others) do not end there. Sometimes the donors have also provided funds for renovation of the space used to house the equipment; sometimes these funds have had to be found from elsewhere. Sometimes the donor has agreed to pay for the maintenance contract; sometimes this has had to be included in the running costs and found from elsewhere. None of the donors so far have provided funds for running costs, although in the case of the Christie Appeal, the target set includes funds to cover operating costs for the next ten years.

It is difficult in the NHS to determine exactly what the annual running costs are for this machine. It depends on how many staff are employed and some calculations have omitted the consultant radiologist's salary. The number of patients who receive scans has little effect on the costs (unless the hours of use are extended and extra radiographers have to be employed or overtime paid) because the fixed costs are so high. A rough estimate for running costs, including the maintenance contract, might be £50,000 a year.[4] Although this is a small figure compared to a total hospital budget it is clearly not trivial when it is considered that the cost of a renal dialysis machine is only about £3,500.

The importance of this figure in this discussion is not so much whether it is exactly right as where the money is to come from. Whether implicitly (through squeezing staff time paid for by the hospital budget) or explicitly (in receiving extra funds from regional health authorities) much of the running costs are being paid for by the NHS. The situation poses something of a dilemma for those controlling budgets. It would be very difficult to turn down the gift of a scanner yet accepting it has revenue consequences which health authorities might not wish to take on at a time where funds are very limited. A number of health authorities have done some serious heart-searching over this problem and it is interesting to find that community health councils (CHCs) are also facing up to the same dilemma. In fact, it was a CHC which brought this whole issue out into the open most clearly.[5] The Area Health Authority at Leeds was offered a whole body scanner by a group of businessmen and rather precipitately, in the local CHC's view, agreed to accept it. The CHC's complaint was not so much over the scanner itself as over the way in which the decision was made. Nevertheless, asking that more time should be given to decide whether the Area Health Authority should accept the scanner, suggests that the answer could possibly be 'No'. This is a somewhat unusual development in that public discussion about technology in the NHS more often focuses on why a technology was not available to a particular patient or population. Yet here the public (as far as they can be said to be represented by CHCs) are saying that they may not want the 'latest' technology because it means that they may not have money for some other resource. This is an important development in making the public aware that resources are not infinite, that choices do have to be made, and that they could play a greater role in making these choices.

In addition to running costs a second important implication results from the spread of technology by philanthropy: the NHS has no control over the distribution of the scanners. The majority of the first eleven scanners are in the south of England and in particular in the London area. This point is emphasized strongly in one of the fund-raising appeals. At a time when the NHS is attempting to rectify regional disparities (for example, through the recommendations of the Resource Allocation Working Party)[6] regional maldistributions imposed on the NHS from outside are of particular concern. Moreover, the scanner may not be going into the most appropriate site. At this stage the whole body scanner should be located in hospitals where a proper evaluation of its use can be conducted. The diffusion of the technology by philanthropy means that very little control can be exerted over the location of scanners.

Evaluation would still be a very complex undertaking, as pointed out earlier, but diffusion through philanthropic gestures has exacerbated the situation yet further. Although philanthropy can be of great benefit to the NHS, in this instance it has also had considerable drawbacks. Some further discussion will be given to the role of philanthropy in the NHS in the final chapter of this report.

The diffusion of CT scanners in the US

As can be imagined from the figures which have been given, it is in the US that CT scanning has had the most serious economic and political repercussions. Why has the technology been accepted more rapidly in the US than in other industrial countries?

The health care system in the US is run on a largely free enterprise basis and there are sound financial reasons for institutions to purchase scanners. Machine depreciation is included in the charges for a scan and with a high patient throughput the initial capital outlay can be recouped in about a year. Since a new machine is unlikely to be purchased in under five years, this leaves plenty of margin for profit. In addition, even aside from the prestige involved, there are other reasons for health care providers to feel pressure to own the most up-to-date equipment. First, if they do not have the latest equipment they may lose patients and perhaps more importantly, physicians to neighbouring institutions. Secondly, health care providers are being increasingly subject to malpractice suits and as a defence against such suits feel obliged to have all the latest equipment.

During the same period that scanners have been spreading through the country, there has been increasing concern about health care expenditures. Given that the average charge for a scan is $295 (including both technical and professional fees) and that 2,000–3,000 patients can be scanned on one scanner in a year, it is obvious that the costs associated with CT scanning are enormous.[7] Concern over escalating costs has led several agencies (particularly third-party payers—of which the Federal Government is a major one) to take a hard look at CT scanning and reports have been issued recently by three of them: the Office of Technology Assessment, the American Hospital Association, and the Institute of Medicine. The latest report, from the Institute of Medicine (IOM) made a number of recommendations on the control of CT scanning. To place these recommendations in context, some comments on health planning in the US must be made.

Resulting from Health Planning Acts passed by Congress in 1967 and 1974, States have been developing Certificate of Need (CON) Laws for major capital expenditure. An institution planning to buy expensive equipment, such as a scanner, must get permission from local, and ultimately State, agencies under these laws. Unfortunately the CON Laws may actually have exacerbated the situation with CT scanning because institutions rushed to buy scanners before the laws came into effect. In addition, it is possible to circumvent the laws by locating scanners in physicians' offices, which are not subject to the same control, a development which is unsatisfactory both in terms of the patient's well-being and in the full usage of the machine.

The IOM report recommended that third-party payers should only reimburse providers who purchased scanners under CON Laws. Secondly, they recommended that the 1974 Act be amended to include a review of 'large capital equipment expenditures in freestanding ambulatory care settings' (that is, physicians' offices should be included).

These recommendations by no means solve the whole problem since the basis on which need is determined still has to be resolved. In addition, even if an institution has approval for a scanner it is still not clear what the indications are for its use.

With so many scanners in the country and with the emphasis on giving patients every conceivable test in order to protect the institution from malpractice suits, there have undoubtedly been many patients scanned unnecessarily. Although CT scanning is much less risky than many other procedures it does involve a radiation dose to the patient and should not be used indiscriminately. The issues of need determination and indications for use are both difficult to resolve in the absence of thorough clinical evaluations. The IOM therefore recommended development of an evaluation programme with willingness to generate uniform data for that purpose being a condition for reimbursement of scans by third-party payers. Yet by this time over 700 scanners had already been purchased.

In the US, CT scanning has, then, highlighted the whole problem of cost containment in a largely free enterprise health care system. In European countries the health care systems are more centralized than in the US, making control over major capital expenditure more feasible. Nevertheless European countries are also concerned about escalating health care costs. It might be noted that one country, Belgium, has developed somewhat similar controls over scanners to those in the US. Criteria of need have been developed by their Health Ministry and permits will be needed to install scanners. Without these permits, health care providers will not be entitled to include machine depreciation in charges when claiming reimbursement for scans.

In general as more countries take up the CT scanning technology, it is certain that more questions will arise about the cost of this technique. As will be discussed later, adoption of the technique by other countries could have important effects on the price and on the way the technology develops.

3 *The clinical use of whole body scanners*

Computed tomographic scanning is a diagnostic technology and must therefore be compared with other diagnostic techniques in the information it gives, the risk for the patient, whether it improves management and treatment of the patient and ultimately whether it improves the patient's condition, that is, patient outcome. In a recent study by the Institute of Medicine[1] a useful hierarchy was provided for thinking about how efficacy should be assessed. This hierarchy is based on the work of Fineberg, Bauman, and Sosman.[2] Determination of efficacy at one level is a necessary but not sufficient condition for a finding of efficacy at the next level. The levels are:

1. Technical capability: accurate representation of the area scanned.
2. Diagnostic accuracy: provision of information that contributes to the formulation of a correct diagnosis.
3. Diagnostic impact: the extent to which CT scan information replaces other diagnostic procedures, including diagnostic imaging, surgical exploration, and biopsy.
4. Therapeutic impact: change in disease management that would not have taken place without the information from the scan.
5. Patient outcome: the effect of CT scan information on patient morbidity or mortality.

This hierarchy can be taken one step further to the assessment of the impact of CT scanning on health over-all. The efficacy of scanning needs to be put in an epidemiological perspective. That is, even if CT scanning affects patient outcome, how common are the conditions for which it is used? What are the ages of the patients with these conditions and what is the over-all contribution of the scanner to the reduction of death, disability, and discomfort in the population served?

How far has the evaluation of whole body CT scanning proceeded in terms of this hierarchy?

Levels 1–3. Evaluation of the whole body CT scanner as a diagnostic tool

The literature published so far from both the US and Britain on whole body scanning is mainly descriptive and (except for the most recent papers) gives little indication of whether the patient's diagnosis was already known or whether CT findings were confirmed subsequently at surgery or by histological examination. Very few comparisons are made with other techniques so that it is difficult to assess where CT fits into the diagnostic armamentarium. Some of the more recent publications are beginning to make these comparisons and several authors note that after their preliminary investigations they are going on to controlled trials. It is to be hoped that the enthusiasm for CT scanning will not mask the need for proper trials.

Although CT scanning is only now undergoing evaluation, it is possible to draw some conclusions about its potential clinical usefulness. These conclusions are based on the published literature (which is reviewed more thoroughly in the Appendix) and on discussions with radiologists who have experience with whole body scanning.

The indications are that CT scanning has much to offer in investigation of abdominal organs, particularly the liver, pancreas, and retroperitoneal space.[3] Its main use may be in patients with known or suspected malignancies both in identifying whether a tumour exists and also in describing the extent of the disease, including metastases. The clear images of lymph nodes in areas not readily seen on lymphography may be important both in Hodgkin's Disease and in lymph node involvement with other cancers. In regard to malignancy, CT scanning may be a very important tool for monitoring the effects of therapy and in fact, if combined with a treatment planning computer, it may provide directly the information needed for radiotherapy planning. (A treatment planning computer is used as an aid to plan the exact position and intensity of radiation given during radiotherapy treatment.) The use of whole body scanners in follow-up may be broader than radiotherapy alone since the effects of chemotherapy and surgery may also be monitored. Thus, although a number of techniques may be involved in the initial diagnosis, CT scanning may be the technique of choice for monitoring progress.

While this brief summary gives some idea of the type of condition for which CT scanning is particularly useful, it does not delineate at what point in the evaluation of a particular organ or condition CT scanning should be used in preference to other techniques. CT scanning is a non-invasive technique and therefore would be used in preference to other more invasive procedures, particularly exploratory surgery. Since CT scanning involves the use of X-radiation however, it is not entirely without risk and is inappropriate in some conditions. It is not likely to replace ultrasound during pregnancy, for example. Eventually it seems likely that CT scanning will become the technique of first choice in the investigation of some organs, especially if other technologies do not provide such good information or are highly invasive. For other organs, for example the kidney, where there are good alternative procedures, CT scanning may be used only as a last resort when other techniques have given equivocal results.[4] In general, although it may replace a particular procedure in certain diseases and conditions, the indications are that it is most unlikely to displace any other diagnostic tool completely.

As a final comment here it must be remembered that the comparison of diagnostic technologies has some complications. For example, the techniques are not equally operator dependent. Thus while CT scanning might not be preferable to ultrasound in a modern teaching hospital where the ultrasound operators are highly skilled, in a district general hospital the situation might be quite the reverse. In the next chapter mention will also be made of the rapid development of other diagnostic technologies: this means that the results of the comparisons of CT scanning with other techniques which are being made now may not be applicable in the future.

Levels 4 and 5. Therapeutic impact and patient outcome

Important considerations arise from the fact that currently CT scanning is mainly of use in diagnosing cancer and in delineating the extent of the disease. This raises the problem that diagnostic accuracy has gone far ahead of therapeutic effectiveness. It does not follow automatically that better treatment results from a better diagnosis, especially with malignancies. In some cases the amount of detail known may not affect the treatment given, in other cases there may be little effective treatment available. Earlier diagnosis may be possible with CT scanning but again the prognosis will only be improved if effective intervention is possible.

It can be argued that there is justification for accurate diagnosis in the absence of effective therapies on the grounds that understanding the extent of a disease may indicate that active treatment should be stopped and that palliative measures may be more appropriate. Knowing when to stop may save a good deal of unnecessary suffering and improve the quality of the last few months of a patient's life. Another possibility should be noted: finding that no disease is present can provide tremendous reassurance to the patient and may put an end to a whole series of diagnostic tests.

Unfortunately there has been very little mention in the literature about the effects of CT scanning on treatment or on the final outcome of the patient's condition. The most information presented so far was given in a paper by the group at the Mallinkrodt Institute who studied patients' charts (records) and concluded that CT scanning had affected patient treatment in three ways:[5]

1. It had made the definitive diagnosis when other non-operative methods had failed, leading to specific therapy.
2. It had brought a potentially lengthy evaluation to a halt, thereby expediting or obviating surgery.
3. It had resulted in a change in radiation therapy.

It should be noted that even if the immediate effects of CT scanning on therapy and on the patient's health are limited, the availability of scanners for research purposes could still be justified. The quality of the information produced is such that, in the right setting, scanners may make an important contribution to knowledge about disease processes. Ultimately this may lead to more effective treatment.

Finally at the epidemiological level, there is currently no information available. Until the indications for the use of the scanner are established and until its effects on treatment and on outcome are evaluated, there are no data on which to assess the scanner's over-all contribution to health.

Costs and general implications for the NHS

It should be evident by now that the evaluation of whole body CT scanning is far from complete. But even if evidence about clinical efficacy was available then another question has to be considered before widespread diffusion of the technology is accepted. That is, what are the costs to the NHS and are those costs justified if measured against the benefits lost by not being able to purchase other technologies or health care procedures? Explicit recognition must be given to this choice, by decision-makers, doctors, and the public.

At a £$\frac{1}{4}$ million the machine itself is expensive and the runnings costs are not negligible. Whether these costs are justified can also be assessed, like clinical efficacy, at different levels. At one level it can be asked whether the technology is cost-effective in terms of diagnostic efficacy. In reality, it is much more important to know if the scanner is cost-effective at another level, that is, in terms of its effects on patient management and ultimately on the outcome of the patient's condition. Of course, in the absence of data on the effects of therapy and outcome it is impossible to measure cost-effectiveness or cost benefits at this level. So far, then, the only work which has been carried out has been concerned with cost-effectiveness at the level of diagnostic accuracy. That is, what are the costs of diagnosis with and without the scanner? This measurement of cost-effectiveness has been made for brain scanners[6] and more recently EMI have stated that they are engaged in a similar study for whole body scanners.

Two major arguments are put forward by the manufacturers and by some users for cost-effectiveness in diagnosis and some comments need to be made about them. One argument is that CT scanning obviates the need for other diagnostic techniques. The first question then is whether CT scanning is a substitute or an 'add-on' technology. At present whole body CT scanning seems to be an add-on technology being used after other techniques have given equivocal results (although the situation may be somewhat different with brain scanning). In the US where the availability is much greater the situation may also be different. Even if it is used as the method of first choice in certain instances, however, this does not necessarily result in any cost saving. Because whole body scanners are unlikely to replace any technique *completely,* then the other equipment will have to be available and maintained even if not used so frequently.

Apart from complete substitution for another technique CT scanning may be cost-effective if exploratory surgery can be avoided and, of course, this is of particular benefit to the patient. This point also forms part of the second argument for cost saving and that is in the reduction of in-patient days. If exploratory surgery is avoided then the length of stay of the patient in hospital is likely to be reduced. It is also argued that as CT scanning can be performed on an out-patient basis this may also reduce in-patient costs. With body scanners it seems unlikely that much saving would result on this basis since the patients receiving scans are probably undergoing a battery of tests and treatments and are thus likely to be hospitalized anyway.

Documentation of the use of CT scanning and particularly its effects on the use of other technologies and procedures is badly needed. But definitive statements, even at this level of cost-effectiveness, cannot really be produced until clinical evaluation is reasonably complete and the indications for use of the whole body scanner are determined.

Finally there is a separate aspect of the costs to the NHS which needs to be considered to complete this section. This concerns whether the whole body CT scanner will increase or decrease service demands on the NHS in general, and what consequences this will have on costs. If scanning means that a disease can be detected earlier, for example, what effect will this have on demands for care? How many people will be affected and will earlier detection mean that the disease can be treated more cheaply or more effectively than at a later stage? If early detection only prolongs the length of treatment then this places a greater burden of care on the NHS. Of course, earlier detection could mean that patients' lives might be prolonged by continuing treatment and care. This, in itself, may increase costs and could also lead to demands for the use of scanning in screening. Only when effective intervention could *cure* at that earlier stage of disease might actual NHS costs decrease. Apart from an over-all increase or decrease in service demands the scanner could shift the balance from one service to another, for example from drug therapy into surgery. Though it is not possible at this stage to determine the direction of changes it seems certain that the scanner will have some impact on demands for health care.

It has been suggested, for example, that the throughput of patients in neuro-radiology has increased considerably as a result of CT brain scanning.[7] A similar development could occur with whole body scanning. Given the number and type of patients who are being scanned it seems unlikely that over-all service demands are being affected greatly at the present time. Of course, in the future, once the indications for use are determined the effects could be quite different.

This whole discussion of clinical efficacy and cost-effectiveness has in fact presupposed that CT scanning as it exists at present will provide the basis for determining its impacts on health care in the future. In fact, this is most unlikely. Developments in CT scanning and other imaging technologies are already altering the efficacy of CT scanning in comparison to these techniques. To form any judgements about the role of CT scanning in health care in the future these developments must be taken into account. The next chapter discusses some of the possible changes that may take place.

4 *The future*

With CT scanners there are indications that the future is not merely an extension of the present. The situation is far more complex than the arguments laid out so far would suggest. At least five important factors will determine the future of CT scanning:

1. Changes in price of the machines and their running costs.
2. New diagnostic capability of the machines by either (*a*) technological development of the machine or (*b*) new applications of current CT scanners.
3. The development of other competing diagnostic technologies, in particular the application of computer techniques to other diagnostic equipment.
4. Development of effective therapies, especially for cancer and other currently intractable diseases.
5. The influence of policymakers both in UK and overseas.

Costs and prices

The basic whole body scanning unit costs about £¼ million and running costs may be about £50,000 a year. These high costs are major drawbacks to the rapid diffusion of CT scanners, at least in the UK. If the price of the machines changed, many more machines might be bought and this in turn would have important effects on the strategy for use of the machines. For example, instead of using it sparingly as a last resort technique where other non-invasive techniques have been tried, it might be possible to use it much more commonly as a first choice technique and in a much broader range of situations. For example, at a much cheaper price it could be purchased in place of a conventional X-ray machine. The improved clarity of the scanner would provide satisfaction to radiologists even if a more precise diagnosis was not required. The possibilities of a change in price of the machines needs therefore to be considered.

The market

In April 1977, EMI had sold 11 body scanners in the UK, compared to about 300 overseas. No other firm had sold a scanner in the UK. In the US 760 whole body or brain scanners from various firms are in operation or on order in mid 1977, and with the possibility for many more orders, events in the US are the most important in influencing market strategy,[1] but strategies for the future might be quite different if aimed at the markets in other countries where the health care system is less pluralistic and where centralized decision-making plays a more important role. The markets in European and other developed countries are only just opening and these may take on greater importance if Certificate of Need Laws impose serious restraints on scanning purchase in the US.

The competition

At the most recent count nineteen different firms were committed to the production of brain or body scanners.[2] At present only EMI, Ohio Nuclear, and to a lesser extent Pfizer, have scanners that have been thoroughly tried out (if not evaluated) clinically. For this reason these firms have considerable advantages over their competitors, and are leading the market. As giant corporations, including General Electric, become established in this field it remains to be seen whether the first-comers can maintain their lead.

They may lose some of the edge in the market as manufacturers in various countries begin to produce scanners, if purchasers prefer to support a home-based industry.

Price

With CT scanners it is difficult to estimate how much hardware costs contribute to the price. A rough guess based on discussions with manufacturers suggests that hardware costs make up about half the current price. This estimate has important implications since price changes in components for computer hardware are expected in the near future, especially as the use of microprocessors becomes more widespread. However firms may decide to incorporate an extra refinement rather than decrease the price.

The effect of competition on price

There are a number of reasons for thinking that although competition is having a limited effect on price at this moment, competition is not likely to reduce price dramatically, and perhaps not affect it at all in the longer term. Firms would have to sell many more scanners to get back the costs of development but if price really is a factor inhibiting institutions from buying scanners then they could get access to a much larger market.

But would cheaper prices really open a wider market? It is not in the interests of the established firms to reduce prices since they are selling well at the higher price and a new entrant is in a difficult position since he has no evidence to point to on the use of his machine in clinical practice. Whilst US doctors (and they are the indirect purchasers even if the scanner is actually bought by an institution) seem likely to accept a clinically untested model if it is the latest, most advanced type with refinements over the earlier technology, they are not necessarily so eager to accept a new model which simply has cheapness to recommend it. But if Certificate of Need Laws cut back on the purchase of scanners at current prices but more are allowed if they cost less, this could be an incentive for firms to decrease prices. Otherwise, only if the major market switched to countries other than the US is it possible that policies set in these countries might influence firms to produce a cheaper scanner.

While it may not be a sound policy for a firm to enter the CT scanning field with a cheaper machine, the situation could be very different for a firm entering the market with a new ultrasound or isotope scanning equipment incorporating computer techniques. The market for these machines is open and it might be in their interests to sell their machines at a much lower price. This development could then have repercussions on the CT scanning market.

Eventually it may be that the market will break into at least two levels. Some scanners will be very high priced, advanced machines and limited in availability. Other less sophisticated machines may be sold at a cheaper price and will be much more widely distributed. It is clear, however, that even though the technology was a British development, the future will be much more strongly influenced by overseas events than by decisions and policies made in Britain.

Changes in the capabilities of whole body scanners

There is good reason to believe that the most competitive area in CT scanning is in technological development, particularly as it affects diagnostic capabilities or the number of patients scanned. Although whole body scanning has not yet been fully evaluated clinically and all the potential applications have not been investigated, it seems likely that any major developments in clinical application will require at least minor changes in the technology. For example, several radiologists have suggested that CT scanning may be useful in investigation of the spinal cord but to make this feasible much higher resolution of that particular area is needed. Several firms are now suggesting that with modification of their data processing they can obtain good pictures of the spinal cord. A similar situation applies to cardiac scanning. Because of the motion of the heart, unless very fast scans could be carried out (faster than a heart beat) or scanning synchronized with phases in the cardiac cycle, good pictures cannot be obtained. Various, perhaps all, of the firms in the market are therefore trying to develop technology to allow cardiac scanning.

Scanning time

The original brain scanners were slow, taking several minutes to scan the patient. To make body scanning possible, the technology had to be adapted to produce faster scan times (in the 18–20-second range). The EMI 18–20-second scanner device has been described briefly but other firms have already made changes in the technology to produce faster scans. Some of the other firms in the market are producing 5–6-second scanners in which the X-ray source and detectors rotate in a continuous movement around the body. EMI argue that this system requires the detectors to be very evenly matched if artefacts are to be avoided. The firms (for example, Siemens and Ohio-Nuclear) using the rotational system claim that the problem can be overcome by constant recalibration of the detectors and by correction during the data processing. Another way around this problem is to have a stationary circle of detectors all around the patient with only the X-ray source rotating. Such a system has been produced by American Science and Engineering but because many more detectors are required this is a much more expensive machine.

The main argument against a 5–6-second scan time is that this is no real improvement, because it does not eliminate artefacts caused by intestinal movement. However, to go to much shorter times requires that a much higher radiation dose be given to the patient for the same resolution. Dosage itself is under debate but EMI claim that for equivalent picture quality about six times the dose is given on Ohio-Nuclear's super-fast (2-second) scan than on EMI's 18–20-second scan. Because such a high dose would have to be given to obtain a good picture at a very fast scan (for example, less than 1 second) the development of the first cardiac scanner is likely to be a slower scanner synchronized with the cardiac cycle. This development would seem to be particularly feasible with the newer scanners which use a pulsed beam of X-rays which perhaps could be synchronized with the heart. Apart from dosage considerations very fast scanners are likely to be extremely expensive since the consensus is that they would require multiple X-ray sources and multiple arrays of detectors. Although cardiac scanners may give good pictures of the arteries and may be used to measure ventricular volumes, it is not expected that the valves will be visualized nor that they will provide dynamic information.

Scan time, reconstruction time, and patient throughput

Major factors in determining patient throughput have been the amount of time it takes to get the patient properly aligned for a scan at the correct anatomical location and also the time it takes to produce the image once the scan is completed.

Several firms including EMI and Elscint have designed systems where the patient can be placed on the couch and subsequently moved on to the machine. Siemens have devised a moving table which acts as a conveyor belt for the patient.

The other area where patient throughput has been improved has been in the length of time the computer takes to reconstruct the image before the next slice or the next series of slices can be taken. If the machine takes several minutes to process the image after a long time period to get the patient in place, the radiologist is unlikely to remain to follow the scan through, preferring to review the scan later. Siemens now claim an instant image with the processing being carried out while the scan is continuing. Immediate decisions can be made. The radiologist may decide one slice is enough, that the slices are not being taken in the correct place, or that a contrast medium is needed. The decisions made may not only improve the quality of the scans but may also speed up patient throughput.

The collection and the use of information

Unlike conventional X-rays, CT scanners are particularly good at collecting all the available information, and it is in the data processing that developments are taking place that could result in different uses for the machine. For a given radiation dose to the patient a certain amount of information is collected and this can be used to give high spatial or density resolution. Higher positional resolution can be achieved at the expense of higher density resolution and vice versa. On neither the spatial nor density resolution side has the possible uses of the information been fully explored.

Tissue density work is only now getting under way and one of the first areas of interest is in the mineralization of bone. By taking scans at intervals it is possible to investigate the extent of demineralization in oesteoporosis. Tissue density information may in future be taken much further; for instance, it is already possible to differentiate between fluid-filled cysts and solid cysts or tumours. Further research, based also on physiology and pathology, may make it possible to differentiate between cell types. Because different rates and types of cell metabolism will also alter the cell's absorption characteristics it may also be possible to use CT scanning to look at function in different groups of cells. There is also interest in using different parts of the X-ray spectrum to differentiate between tissues which have similar absorption values when the total spectrum is used.

There is, then, a great interest in developing the data processing and data manipulation side of CT scanning. This area is likely to lead to application of CT scanning to new areas and different diseases and probably to much more precise information about the type of abnormality.

Some conclusions about developments in CT scanning

At the moment EMI and Ohio-Nuclear are leading the world market mainly because their machines have been tested in clinical settings. It will not be long before other firms, although not necessarily the full nineteen in the field, become established as their machines are put into clinical use. EMI claims the best picture quality but some of the newer entrants may match them. It seems certain that the 5–6-second scans will be accepted in the market. Where does it all go from there?

There are several directions which seem likely for the next few years.

Firms will try to develop faster and faster scan times, a cardiac scanner will probably be produced and there may be a great deal of development on the data-processing side, especially involving tissue density determinations. Apart from present CT scanners being applied to other anatomical areas, these technological developments may also extend their range of usefulness; for example, if patient throughput is increased the use of CT scanning could be extended from situations where it is really the only satisfactory, non-invasive technique available, to situations where it gives slightly more information at slightly less risk. It is easy to visualize its use in place of exploratory surgery, but with greater patient throughput it might be possible to use it in situations where isotope imaging would be an alternative. Another way to increase the scanner's diffusion would be to develop a more flexible machine capable of taking conventional X-rays and tomograms.[3] In this case the machine could be bought in place of conventional X-ray equipment and CT scanning would be much more widely available, so bringing it to more patients and possibly extending the clinical application of the machines.

For both faster scanners and for developments to make the machine more generally used, radiation dose is a factor to be considered. The quality of the picture depends on the dose and more flexible, or cheaper, scanners will only be acceptable if they do not require an increased dose to the patient. Similarly, dose constraints may put a limit on the speed of the scans and no doubt technological developments will be pursued to allow faster scans without increased dose.

Developments in other medical imaging technologies

The other techniques with which CT scanning can be compared are themselves developing. Predicting developments in these other technologies is as difficult as predicting where CT scanning itself is going.

Even though CT scanning technology itself is unlikely to revolutionize other imaging techniques the stimulus it has given to the whole field is important. As evidenced by the number of firms entering the field, CT scanner production is expected to be a very profitable undertaking. The widespread acceptance of this new technique also seems to have opened people's eyes to the profitability of other diagnostic technologies and some of the firms which entered diagnostic imaging with CT scanning are also now producing and developing other imaging equipment. EMI are the prime example of this. Having entered medical imaging with CT scanning they have recently taken over Nuclear Enterprises, a firm established in both ultrasonic and isotope imaging equipment. EMI are not likely to accept the level of technology in those areas and work solely on marketing. Without doubt they will develop their instruments further, again especially in association with computer techniques. CT scanning also has stimulated medical imaging; the very clear images produced on CT scanners make ultrasound and isotope images look outmoded. They may contain the same, better, or different information but there is no doubt that a clearer picture has much to commend it. Potential buyers now have to be shown that the ultrasound or isotope equipment can do things more effectively or more safely than a CT scanner. Again this encourages technological development in these other imaging fields.

Even the most sophisticated ultrasound and isotope imaging equipment is much cheaper than a CT scanner (almost all instruments being less than £80,000) and there is obviously the potential here to persuade cost-conscious doctors or institutions that an ultrasonic device, for example, would be more useful to them.

What then are the potential developments in these other imaging techniques?

Ultrasound

The basic principle in ultrasound is that high frequency acoustic energy (ultrasound) is reflected at organ and tissue boundaries providing an image of those organs and tissues. Although there is still some debate about possible *in vivo* effects,[4] the accepted view is that ultrasound is completely safe since it does not involve ionizing radiation and it is non-invasive. For these reasons it is the technique of choice for foetal investigation and this position is likely to remain unchallenged. Ultrasound is a good technique for soft tissue (for example, the liver) and has therefore been useful in abdominal investigation. It cannot be used for bony structures, since bone deflects the sound waves and it is not useful in the brain (except for measuring the displacement of the midline) because of the reverberations of the waves within the skull.

The commonly used B scan system is very operator dependent, requiring great skill in the manipulation of the probe; and the images produced require a great deal of skill in interpretation. Yet over the last ten years the market for ultrasound has grown enormously and associated with this has been a number of efforts to produce better equipment.

There are a number of ways that ultrasound equipment could improve and some of these have already been marketed, although none has yet really provided the complete answer to the difficulties involved in ultrasound. It is expected however that in several areas there will be breaksthrough in the next few years. The developments may result in more expensive machines. The prices have risen from £3,000 to £20,000 over the last ten years and one or two of the more sophisticated versions are now coming on to the market at prices as high as £150,000. It seems likely that most of the new models will be under £100,000 and ultrasound will therefore remain much cheaper than CT scanning. Part of the reason for this difference in price is that the amount of computing which could be associated with ultrasound is limited.

Some possible areas of development in ultrasound technology are:

1. The production of a fully automatic scanner that could be used by a radiographer. At present an ultrasound specialist is usually required to carry out the investigation, but one firm, Ausonics Pty Ltd, has produced an instrument which can be used by a radiographer. The price for this instrument is very high. It seems likely that other firms will take up this development.

2. Real time scanners, either mechanical or electronic. These instruments would give very fast pictures of organs (for example 30 or more images per second) so producing dynamic information. Real time scanning would be particularly attractive for cardiologists. Several firms have already produced real time scanners and as detector arrays, rather than single probes, begin to be used the quality of the images is improving.

Real time scanners are less operator dependent than the current B-scans.

3. There is also great interest in the association of data collection and manipulation techniques with B-scans. For example the recently announced[5] Sonicaid 3–D ultrasound scanner is a development of the B-scan in association with a more complex electronics system. There is also the possibility of using computerized axial tomographic techniques in association with ultrasound.

If instruments can be developed which are less operator dependent and which produce more easily interpreted images, then ultrasound will retain its position as the first choice technique in some situations.

It is very safe and will probably remain much cheaper than CT instruments. However CT and ultrasound are likely to remain complementary techniques each having advantages in particular situations.

Nuclear medicine

The techniques of nuclear medicine are based on the use of radio-isotopes injected into the body. The location of the isotopes is monitored through the radioactivity they emit, measured by isotope scanners or by gamma cameras. Certain radio-isotopes are taken up selectively by particular tissues and it is often possible to distinguish between normal and diseased tissue through differences in uptake. Radio-isotopes can also be injected into the bloodstream close to specific organs and the blood flow through those organs monitored. While the technique is often invasive because it involves injection of radioactive material it does have special advantages in that it can be used to provide knowledge about tissue function.

Radioactivity was originally detected using simple counters or isotopic scanners but the latter have now largely been superseded by gamma cameras. With recent developments in the electronics associated with these cameras much more precise information can be obtained and they are capable of taking real time pictures, for example of blood flow through the heart. Because of the particular application of gamma cameras in cardiology to measure ventricular volumes and to diagnose valve malfunction, mobile cameras have recently been developed. These can be taken into coronary care units so that the patient does not have to leave the specialized monitoring equipment in the unit.

A recent off-shoot of the isotope scanner has been a tomoscanner which combines isotope scanning with the computerized axial tomography techniques to give cross-sectional images. This instrument is very much simpler and very much cheaper (at £65,000) than a CT scanner. Although some form of tomoscanner will become one of the diagnostic systems available, developments in the gamma camera will probably still be preferred.

In general, although developments are expected in the field of nuclear medicine both in instrumentation and in application to particular sites, again the changes are not likely to be revolutionary. For most developments (the recently produced positron ring camera for the heart being an exception) the prices seem likely to remain low compared to CT scanners.

Other imaging techniques

The two established techniques of ultrasound and nuclear medicine have been discussed. Amongst other techniques which might be applicable to medical imaging, there is nuclear magnetic resonance but the application of the technique and commercial production are probably a number of years away. Generally speaking, none of the imaging technologies now, or as they seem to be developing, is likely to render another technique obsolete. The techniques are complementary and each will continue to have its use.

There are two sets of factors which make the techniques complementary. First of all there are the different properties and position of tissues which make one technology more useful for one organ than for another. For example, the bone covering of the skull has made CT scanning the technique of choice for most brain lesions. The desire not to expose the foetus to radiation during its development has made ultrasound the technique of choice in obstetrics. Secondly there is the type of information that the technique gives. Sometimes information about exact position is required (for example for radiotherapy planning); sometimes density information is useful (for example in differentiating between a cyst and a solid tumour); sometimes dynamic or functional information is useful (for example in the heart). Because different types of information are required under different circumstances and each of the techniques offers a different mix of these information types, it is likely that the techniques will remain complementary.

Therapy

In the earlier discussion it was emphasized that the major use of scanners at present is in the detection and monitoring of cancer. The lack of effective treatments, especially for solid tumour cancers, adds a difficult dimension to resource allocation decisions about scanners versus other health care expenditures. How far can investment in machines to give more precise diagnosis of diseases for which there is no effective therapy, be justified? Except where CT scanning has some effect on patient management and outcome it will be difficult to make a strong case for purchase. Not only with cancer, but with some other diseases, a real justification for wider CT scanning may have to await developments in therapy.

Policy

In an earlier section where the diffusion of CT scanning was discussed, it was noted that Certificate of Need Laws and reimbursement policies of health insurance agencies in the US are at present limiting the diffusion of whole body scanners. In most other countries the central government is more directly involved in the provision of health care resources and the decisions they make about the need for CT scanners may affect developments very markedly. Firms are in fact already adapting their body scanners to increase patient throughput in response to outside pressures.

If it were decided that CT scanners would be acceptable if they could be produced more cheaply, or if they could be used more flexibly, perhaps to carry out conventional radiography and tomography, then it might be possible to nudge the firms in that direction by making specific promises and policies. If such policies were adopted in the UK, many other governments might well be of the same mind since all of them are concerned with escalating health costs. The concern holds true in the US, but with the health care system being so pluralistic it may not be politically possible to develop such controls.

In the crystal ball

In this chapter some informed guesses about future developments involving or associated with CT scanning have been made. The five major factors which have been analysed are thoroughly entwined as can be seen from Table 1.

As a final comment here, a point made earlier needs reiterating. The future, and in particular technological developments, do not have a life of their own. Policies can and do affect the direction of technological development. For example, the demand for a higher patient throughput has already changed the focus of CT scanner development considerably. Technology, including the medical techniques described here, can be pushed in socially desirable directions which may not necessarily be the same as the route industry

TABLE 1
Cross impact matrix of future developments in CT scanning and related technologies

	Price	Use of current machines in other areas resulting in improved diagnosis
Price	—	If price keeps numbers very limited could delay extension of use to other areas. Seems unlikely as if new uses found to be important would be strong pressure to buy more scanners.
Use of current machines in other areas resulting in improved diagnosis	If new uses put enough pressure on decisionmakers to increase numbers purchased substantially, then price could be affected.	—
Development of new generations of CT scanners	Minor improvements likely to keep price up. Major changes may mean that new machines are very expensive—could bring down price of current generation of machines.	Might just make current scanners obsolete *or* might suggest new areas of application of current scanners.
Advances in therapy (especially cancer)	Could affect prices if advances meant that administrators were willing to buy more scanners.	Might stimulate investigation at other areas.
Major improvements in other medical imaging technologies	If firms came in with much cheaper forms of other technologies then competition could bring CT scanning price down. Alternatively, need to choose between various techniques could keep prices high to get returns on development costs.	Information from new technologies might suggest further areas of usefulness for CT scanners.
Policy	Certificate of Need Laws in US and elsewhere could (*a*) Bring price down to change CON need criteria; (*b*) Keep price high to maintain profits and investment returns with smaller number of sales. Possible that promises to buy many more in UK could induce EMI at least to reduce price.	If policy is to hold back on purchase of more scanners until more general use is found it could stimulate use of machines.

[This table should be read horizontally. To find the effects of policy on price, for example, the reader should read across the row labelled 'Policy' until reaching the vertical column headed 'Price'.]

Development of new generations of CT scanners	Advances in therapy (especially cancer)	Major improvements in other medical imaging technologies	Policy
If price keeps high, stimulates development of new models—easy to get returns on development. Price stimulates competition, stimulates new technological development.	None immediately obvious.	High prices in market (+ willingness of those particularly in US to buy up latest forms of technology) make it worthwhile for firms to invest in new technologies resulting in rapid advances.	Price is a major determinant of political decisions here and in US. Lower prices could change whole rationale for decision-making.
Might change direction of development if new areas show need for a particular form of technical improvement.	Possible effects through greater knowledge of disease processes.	Might reduce need for new innovations in other technologies. Unlikely to affect market for new technology strongly however.	Increased pressure from doctors and community to have more scanners available.
—	More knowledge of disease process could lead to advances in therapy—various diseases, not only cancer.	Innovations in CT technology could have spin-offs for other techniques. Sales from new generations of CT scanners could stimulate market for other technologies.	Pressure from doctors and community likely to be strong if new scanners can be used in other types of disease.
Could have important stimulus on way new machines develop, for example emphasis might develop on tissue density work rather than faster time scanners.	—	Could stimulate market for other technologies as well as CT scanners.	Effective treatment would lead to much pressure on decision-makers to purchase many more scanners.
Could delay new generations of CT machines if investment went into new technologies. Could stimulate it if CT scanning has to compete in new areas.	More knowledge of disease processes could speed up discovery of effective therapies. Indirectly could have negative effect if emphasis on diagnosis lessens interest in therapy.	—	Decision-making in UK becomes much more difficult. Have to choose between various technologies.
Restraints on spending could make it less worthwhile for firms to invest in new developments *or* might (for example in US) stimulate development in order to stimulate market for replacement machines.	Research policies unrelated to this matrix could affect breakthrough in therapies.	Policies of restraint could reduce interest in producing other new technologies. In particular an emphasis on prevention and primary care could reduce firms' interest in these technologies though others might become important.	—

would take if left to itself. But to achieve such movement, a better mechanism of interaction between the NHS and industry is needed and this is an issue which will be taken up again later.

5 *Impacts*

The aim of this study was to try to assess some of the impacts of whole body CT scanning and a number of important effects have been discussed already. In the UK, CT scanning has brought up questions about the role of philanthropy in the NHS. In the US, it has increased concern over health care expenditures and placed further emphasis on Certificate of Need Laws. In general, CT scanner sales have caused a number of companies to become involved in, or push ahead faster with, the development of other medical imaging techniques.

This chapter looks more broadly at the possible future effects of CT scanning on various groups in or associated with the NHS. Obviously there are no correct answers but it is hoped that the discussion here will stimulate others to consider the possible consequences of the technology. The current impacts have already been discussed in context and will not be repeated again here, but the reader may wish to use Table 2 to review them. Table 2 also lays out some possible future impacts, based on developments discussed in the previous chapter. Since the future will result from a complex mix of these developments, for the sake of clarity two possible contrasting scenarios are discussed in the text as a framework for analysing impacts in more detail.

The first considers the impacts if scanners are purchased on a limited basis perhaps resulting in one or two whole body scanners in each of the regions. The second suggests the impacts if whole body scanning becomes very widespread with each district general hospital having a scanner and with more

TABLE 2

Impact on:	Current impacts	Impacts if price decreases and it becomes possible to purchase many scanners
Patient: Diagnosis	Improved diagnosis in some areas: liver, pancreas, retroperitoneal area. May be very beneficial if obviates need for laparotomy.	Ability to use machines more freely might lead to discovery of new uses. Might decrease use of other more invasive or more uncomfortable procedures.
Patient: Management	1. May improve radiotherapy. 2. May show situations where therapy no use at all. 3. May provide negative diagnosis and obviate need for further exploration or treatment.	New uses might lead to improved management.
Patient: Outcome	No data but probably fairly limited since majority of patients scanned have known or suspected cancers for which there is no effective treatment.	Unknown.
Shape of NHS and demand for care	Increases emphasis on high technology medicine and on diagnosis. Little effect on demand for care. Most patients scanned would be receiving much care.	If many more people scanned might increase demand for care—perhaps earlier diagnosis. Might substitute for conventional X-ray equipment.
Staff associated with radiology	Number limited, therefore effect limited. Radiographers need extra training. Radiologists need to learn to interpret cross-sectional scans. May produce diagnostic imaging specialty.	Availability of scanners might improve morale of radiologists, less inducement to emigrate.
Decision-makers in NHS	Pressure on DHSS to give more encouragement to buy scanners. Difficult resource allocation decisions at regional and area level even if scanner donated.	If more scanners available less pressure from public. Machines still have to be bought, still resource allocation choices less severe.
Industry	Increased emphasis on developing all medical imaging technologies. Problems in sales (for EMI) when few bought in UK. Must look overseas but few in NHS may discourage buyers.	If many more bought would be more satisfactory for British industry.

Impacts if diagnostic capability changes	Impacts if effective therapies developed especially for cancer	Impacts if other medical imaging technologies improve greatly
Improved diagnosis.	Exact diagnosis by scanner could become very important.	Indications for use of scanner would have to be revised. Might make scanning appear less necessary for diagnosis.
Depending on what can be diagnosed could improve management significantly.	Scanner could alter management.	Unknown.
Could improve outcome.	Scanner could have effect on outcome as a result of correct diagnosis and management.	Unknown.
Could have major effect on demand for care.	Could have major effect on demand for care. Scanner effects will depend on complexity and cost of therapy.	Places increasing emphasis on technology. If new machine improves diagnosis could affect demand for care.
If more areas covered but still few machines available could increase radiologists' discontent with NHS.	If resulted in decision-makers buying more scanners might improve satisfaction. If not would increase dissatisfaction.	Could affect development of specialties like radiology. Either: force out into separate branches. Or: might stimulate development of diagnostic specialty.
More pressure on decision makers to buy them. Resource decision becomes more difficult.	Might ease situation by making it worthwhile to buy more scanners.	Increased pressure from public and doctors to have latest technologies. Increasing difficulties in resource allocation.
Becomes increasingly unsatisfactory for British industry if technology improved but NHS still not buying scanners.	Would put industry in much better position to argue need for scanners.	Might cause disillusionment in industry if new developments not taken up by NHS.

sophisticated machines available at regional centres. In each possible development the impacts on the same groups will be discussed. As well as the uncertainty as to whether either of these possibilities will come about, the rate at which they unfold will clearly be important in deciding on the effects they produce. The analysis is made as a basis for discussion and should not be taken as prediction. In fact in looking at potential impacts it may be that responsible bodies may wish to take steps to make sure the impacts suggested do *not* come about.

The future—a limited use

One future which seems quite plausible is that the NHS will begin to purchase whole body scanners but that their price and range of usefulness will mean that the number bought is limited. This scenario may result from a series of *ad-hoc* events or it might be a centrally defined policy. For example, it could be that the DHSS would reach the conclusion that whole body scanning is useful but will never replace conventional radiography, and if at the same time other imaging technologies are developing, then each region might decide for itself to limit the number of scanners purchased. Alternatively, the DHSS might recommend that each region should have one scanner.

Patients

A limited number of scanners in the future would mean that the number of patients scanned would be small and the technique would be reserved for complex cases. If, however, scanning were applied to one or more areas where there were possibilities for successful treatment then it could have an effect on patient management and outcome. Because the number of patients would be limited, the over-all effect on the health of the population would not be measurable. If new treatments were discovered for the diseases for which scanning is already used, for example, cancer, then the effect could be more marked. But then, no doubt, there would be a considerable drive to obtain more scanners for the NHS.

Major new applications for scanning are unlikely to result from use in this limited scenario, but scanners can also be used for medical research. Even with only a few scanners medical knowledge would be advanced. This could result in important improvements in medical care.

Demand for care and the shape of the NHS

A limited use of scanners is unlikely to have measurable effects on the over-all demand for care in the NHS, because of the types of disease for which they would be used and the relatively few patients involved. Even a limited use of scanners will however have some effect on the technology orientation of the NHS. Because funds are spent on this sophisticated technology which cannot then be spent on other forms of health care, this is a small step in the further 'technologization' of the NHS. To discourage purchase of any scanners would, however, run the risk of producing a backward health service in Britain.

It was noted earlier that the donation of scanners has resulted in some of them being placed in less than optimal hospital settings and has also resulted in an accumulation of scanners in the south of England. To encourage a limited spread of scanners with at least one per region would alleviate this maldistribution to some extent. There is still the problem of the difference between the 'centre of excellence' and the 'ordinary' district general hospital. A limited distribution of scanners is likely to accentuate the difference further since the scanners would almost certainly be located in the 'centre of excellence'. Some further comment on the effects of this on staff is given below.

Staff associated with radiology

CT scanning could affect three major staff groupings associated with radiology: radiologists, radiographers, and engineers/technicians. A limited diffusion is, however, unlikely to affect the last of two of these groups very strongly. Engineers have one more piece of equipment to maintain but otherwise are not greatly affected. The role of the radiographer *vis-à-vis* the radiologist is also unlikely to be affected in this scenario.

A limited availability of scanners may, however, have more major effects on radiologists. Because scanning is so new, not all radiologists are aware of what it can do and even if they are, not all of them are convinced of its usefulness. If, however, scanning becomes accepted then its limited availability is likely to cause frustration and, as pointed out earlier, it accentuates the differences between the 'centre of excellence' and the 'ordinary' district general hospital. Already there are shortages of radiologists and the emigration rate has been high for this specialty. A lack of availability of the latest equipment could make this situation worse particularly when CT scanners become a commonplace tool overseas. The frustration of staff who are aware of new technologies but who do not have them is a serious problem, and new developments in other imaging fields may make them feel more and more cut off from the forefront of knowledge.

One consultant radiologist who was in the process of installing a whole body scanner in his department had an interesting suggestion which could partially alleviate this problem. He was intending to encourage other radiologists from the surrounding area to come in and use the machine. The patients scanned would be selected according to a research protocol, not by the other radiologists, but these radiologists would run sessions on the scanner. This suggestion seems to be very useful for a number of reasons. First, it gives many more people access to the latest technology. Using the machine also helps radiologists to understand its capabilities and limitations and they can then make better judgements about which of their own patients would benefit from scans. Finally it alleviates some of the tension between the 'haves' and the 'have-nots'. Many more people would feel they are associated with the latest developments and this in itself would help to improve morale.

Partly because of the impetus CT scanning has given to the whole medical imaging field there has been much talk recently about setting up diagnostic imaging departments which would include X-ray, CT scanning, ultrasound, and nuclear medicine. To some extent this development has already begun to take place and even a limited distribution of scanners could encourage it. There has also been discussion of the radiologist's role being replaced by one in which he is much more of a diagnostician, using all these imaging technologies. If CT scanners are limited to 'centres of excellence' it seems more likely that there will remain a consultant in each of the imaging specialties, including CT scanning.

Decision-makers in the NHS

In this limited distribution scenario, decision-makers are in an unenviable position. The publicity which scanning has received has developed public awareness considerably. The public might accept regional access only; alternatively, questions may arise about why this technology is not more generally available. The CHCs could play an important part in educating the public about the choices being made.

Decision-makers are also in the difficult position of wanting to support a home-based industry (EMI) but this has to be balanced against the use of resources for other purposes. The problem could be exacerbated under several different circumstances. First, if ultrasound and nuclear medicine take strides forward, and especially if the newer models of these technologies are easier to use, there will be a great demand for these machines. Decision-makers will be faced with more difficulty in deciding where to invest limited resources. The public demand for more and better technologies would also increase if new therapies were developed, making accurate diagnosis increasingly necessary. In this latter case, however, it would become much easier to justify purchase of scanners and their use would become much more widespread.

Industry

A limited purchase of scanners is likely to leave industry in much the same situation as today. It obviously does not give British industry much incentive to develop new technologies but it is possible that it might provide an incentive to produce cheaper, perhaps less sophisticated, equipment which could be bought on a wider scale. Much depends on the markets overseas.

In this scenario anomalies exist for both the DHSS and EMI, very similar to those of today. The DHSS through its Supply Division is instructed to help in Britain's medical equipment exports. Yet, it would have to encourage overseas buyers at the same time as limiting purchase in the NHS. Similarly EMI would be faced with the problem of encouraging overseas buyers while at the same time having to admit that sales at home were limited.

The future—widespread diffusion of CT scanners

Widespread purchase of whole body scanners may come about as a result of various changes. Perhaps the most important development would be if CT scanners became a substitute for conventional X-ray machines. If the price of CT scanners dropped considerably, buying a scanner rather than a new X-ray machine might be feasible. Alternatively, the machines themselves might change. It has been suggested that CT scanners could be made more flexible to allow CT scans, conventional tomograms, and conventional radiographs to be carried out on the same machine. Such flexibility might encourage purchase of a scanner in place of an X-ray machine even at the current prices.

Patients

If scanners were more widely available, the result would be to change the whole strategy for use. At present it is reserved for special cases or as a last resort when other diagnostic techniques have proved inadequate. Widespread distribution would mean that it could be used more commonly as a first choice technique. A flexible machine like the one described above might mean it would be used for single slices at particular anatomical levels after conventional X-ray. In general, the number of patients scanned would be increased and the conditions for which they are scanned would cover a wide range. It is possible that such use could lead to a number of important spin-offs from observations or chance findings. The effects of widespread use of CT scanners on patient management and outcome will depend partly on how accurate a diagnosis is required to give appropriate treatment and partly on whether effective therapies are available for the conditions diagnosed.

With widespread diffusion of these machines there will need to be more thought given to the possible isolation and alienation of the patients. It is easy for patients to feel overawed and frightened by these large complex machines, and unless special care is taken, patients may come to feel they are being 'processed'.

Demand for care and the shape of the NHS

The more widespread use of the scanner could have important effects on the demand for care. If many more patients were scanned for many different reasons it is quite possible that some diseases will be detected earlier and will require treatment. This alone does not necessarily increase demand for care; it is equally possible that early detection could mean effective early treatment and obviate the need for much more extensive investigation or expensive maintenance care at a later stage in the disease. But early detection could mean only a longer course of treatment which in the end is not very effective. A widespread diffusion of scanners will almost certainly lead to increased demand for screening, making it all the more imperative that the effects of early detection on outcome are evaluated.

Early detection might also change the treatment even if overall demand for care is not affected. For example, at an early stage in the disease drug therapy may be more appropriate, while at a later stage surgery might be required. Thus, CT scanning might have repercussions on staffing in services besides radiology.

A widespread diffusion of scanners is likely to affect the type of medicine practised in the NHS. First of all it increases the emphasis on sophisticated technology. Even if the whole body scanner is found to be an essential tool, the extent to which it is desirable to increase the technological emphasis of modern medicine is a general question worth serious debate. More specifically, CT scanners are a very precise diagnostic tool and encourage the idea that great precision is needed in order to treat a patient.

The availability of scanners might lead to demands for open access to them for GPs because they feel they need to make an exact diagnosis. In general, CT scanning may become one more test which doctors feel the patient must have. It is reasonable to suppose that such exact diagnosis is not always necessary. While diagnosis is at the core of clinical medicine, more tests or more accurate information do not necessarily affect patient management. Data on changes in patient management as a result of more exact diagnosis are required to substantiate or refute this point.

Staff associated with radiology

In the first scenario radiologists were the staff group expected to be affected by CT scanning. In this second scenario radiographers may be considerably affected too. Some radiographers using scanners already feel they are acting too much like computer technicians and not using their special skills sufficiently. A widespread distribution of scanners would certainly exacerbate this problem, but one radiographer did suggest that some of the repetitiveness of the work could be alleviated by a rota system through the department which would include a period using conventional radiography. Despite this difficulty the radiographer's role seems unlikely to change greatly since there will still be a need for their skills in positioning patients and in general patient handling.

The radiographers' role *vis-à-vis* radiologists might be more seriously affected. On initial consideration, it seemed possible that the clear images produced by CT scanning might allow radiographers to carry out much of the interpretation. It is argued, however, that although some of the more obvious pathological changes can be seen clearly on a scan, when previously considerable skill on the part of the radiologist would have been required to interpret the same lesion on a conventional radiograph, the interpretation can now be taken a step further. Smaller lesions can be detected than would have been possible with conventional X-rays and the type of pathology can be better assessed. The radiologist's skill, it is contended, is needed as much as before, despite these clearer images. If, however, CT scanners are in future used in situations where the diagnosis is not difficult to make and the technique is not just a last resort, the argument does not hold so well. In such circumstances, radiographers may seek a much greater role in interpretation.

Both this pressure from radiographers and the developments in all the imaging technologies may force the medical specialty to change its focus from radiology to general diagnosis. The consultant would piece together all the information from the tests carried out rather than just considering the radiological evidence. It will be interesting to see whether the Royal College of Radiologists will foster such a development or not.

Decision-makers in the NHS

If scanners become much cheaper or flexible enough to substitute for X-ray machines, then the decision-making burden is eased somewhat. Again, if more general uses were found for the machine and clinical application could be developed into areas where patient management would be affected, this would make purchase more easily justified. There will always remain some problems for decision-makers, however. Once a large number of machines are bought then they also have to be replaced. New generations of machines make the older models obsolete and decision-makers are faced with requests to update the equipment. The continuing development of CT scanning and other imaging technologies will make resource allocation difficult as long as resources remain limited.

Industry

The purchase of many CT scanners by the NHS would provide an important boost to British medical equipment industries and might also encourage overseas exports. It is also possible that a bigger market at home might encourage firms to develop their machines more towards British requirements.

The two possible developments described here provide a contrasting view of the future. What may be more likely is that the first will lead gradually into the second as a result of various developments. Table 2 provides some analysis of the impacts of some specific developments which may take place along the path from the first scenario to the second. The reader may find it useful to refer back to this table to try to envisage an emerging future for CT scanning and the possible impacts along the way.

While the impacts described here can only be speculative, it is hoped that this discussion will cause various individuals and bodies to consider the possible effects of CT scanning and of medical technology in general. Identification of the groups affected is important in itself since it is only through an awareness of these groups and an understanding of the ramifications of a decision on them that rational choices can be made. By thinking about futures it also becomes possible to decide what sort of future is desirable. Steps can then be taken to increase the likelihood that it will come about.

6 *Discussion*

It is fascinating to see how widespread the effects of one technological innovation can be. In this final discussion the many issues which whole body CT scanning has raised will not be repeated. Instead, the discussion will focus on three topics which have emerged as quite central in the study: the need for mechanisms for evaluating and assessing new technologies; the role of philanthropy in the NHS especially in regard to innovation in medical care; and finally, the interaction between industry and the NHS in developing and modifying health care technologies.

Evaluation and assessment

By investigating one particular health care innovation, whole body CT scanning, it has been possible to identify more clearly what is required if the NHS is to make use of new technologies appropriately. Because an increasing number of technical innovations are being developed for health care it has become imperative that the NHS develop mechanisms to cope with their introduction and use. These new ways of diagnosing and treating disease and disability are often expensive and need to be evaluated before being purchased widely. As the CT scanner has shown, however, the evaluation needs to be an ongoing process taking into account future developments and being modified accordingly. Because technologies can have important impacts on the whole Service it is also essential that assessments be made of these potential impacts. How then are these evaluations and assessments to be made, and who is to be responsible? The events concerning the whole body scanner have provided some important lessons and helped to indicate the direction to be taken if these tasks are to be accomplished.

With the brain scanner a certain amount of evaluation took place before its widespread diffusion. It might also be argued that the brain scanner is an example of a technique which is such a dramatic improvement over the other available techniques that randomized controlled trials are not necessary to prove its usefulness. Without a full analysis of the uses and effects of brain scanning it is not possible to comment definitively on this point. With most technologies, however, once some of the initial exploratory work has been done to indicate potential usefulness, it becomes essential to conduct properly controlled trials. In the case of the whole body scanners, controlled comparisons with other diagnostic techniques in the level of information provided and in the accuracy of diagnosis (preferably confirmed by histological examinations or by surgery) are needed first. The comparative costs need also to be established. Even this is not enough. What really needs to be known is what effect the technique has on patient management and outcome, for this, randomized controlled trials are required. The remarkable diffusion of this expensive technology prior to proper clinical evaluation is unsatisfactory. This view is shared by others in overseas countries. For example, one of the major recommendations of a recent report from the Institute of Medicine in the US was the following:[1] 'The federal government, perhaps in co-operation with national professional and third party organizations, should develop and implement a comprehensive research protocol to provide definitive evaluation of CT scanning.'

Although randomized controlled trials are common in the evaluations of drugs and other therapies the technique can and should also be used to evaluate diagnostic techniques. Recently, such a trial was reported.[2] In this study the effects on patient outcome resulting from either endoscopic or radiologic investigation were compared in patients admitted to hospital for acute upper gastro-intestinal tract bleeding. No difference in patient management or outcome was found between the two techniques: the newer and more sophisticated technique did not, in fact, improve outcome. This type of approach needs to be applied to a great many accepted techniques and certainly to all new innovations before they become widespread. Appropriate resource allocation decisions about investment in one technology rather than another or in the provision of one form of health care versus another cannot be made in the absence of this type of data.

The case for randomized controlled trials in the evaluation of medical techniques has been made by many others.[3] The additional point which needs to be made here is that technological innovations are not once and for all phenomena. Technologies are modified and developed by manufacturers and others and evaluation of a technology at the time of its introduction, though necessary, is not sufficient. It is essential to look into the future and make some predictions about how the place of this technology in the medical scene might change as a result of new developments. That is, the data from current clinical evaluations provide information for one aspect only of the over-all policy considerations. Future developments need to be taken into account and it is equally important that clinical evaluations continue as these new developments take place. In other words, an evolving technology in an evolving system requires continuing evaluation and continual reassessment of policy.

Some comment should be made on the funding required for the evaluation of new technologies and on the bodies which should be involved. The DHSS is rightly given credit for the foresight it showed in encouraging and providing some funds for the development of the first brain scanner by EMI. This involvement is not enough, there must be provision of a sufficient number of machines in the early stages to ensure that a thorough clinical evaluation is carried out. This is necessary both to ensure health service funds are not wasted later but, equally importantly, so that the technology is placed where the expertise is available for proper clinical trials. Although several brain scanners were purchased for clinical evaluation, the same procedure was not followed with the whole body scanner.

No one centre could carry out the whole evaluation of a technique like whole body scanning but in the UK we are in an ideal position to carry out multi-centre trials because of the nationalized health system. The Medical Research Council (MRC) also has a great deal of experience in setting up and co-ordinating large scale multi-centre trials and this expertise could be put to use in the evaluation of new technologies. It was surprising to learn how little involvement the MRC had in the evaluation of either the brain or body scanners. Where there has been MRC involvement in the evaluation of new techniques it has often resulted in considerable savings for the NHS. Two examples have been given elsewhere[4] of instances where enthusiasm for a new technology was shown by MRC trials to be unfounded. The purchase and appropriate installation of a handful of machines for gastric freezing showed this technique to be ineffective in treating peptic ulcers. Considering the US had already purchased over 2,000 such machines the savings to the NHS are obvious. Similarly when hyperbaric oxygen treatment was being advocated for a variety of conditions, MRC trials showed that its effectiveness was very limited; again expenditure on a large number of hyperbaric units in the NHS was saved. Even if technologies are proved to be desirable, as may be the case with whole body scanners, controlled trials are needed to define their place in health care. It would seem appropriate that the MRC should play a much more central role in the clinical evaluation of CT scanning and other medical technologies.

Looking at the impact of a technology now and in the future provides a second type of information which is needed for planning. A technology must be assessed not only for its clinical efficacy but also for its effects on the system in which it operates. Too often the system is expected to adapt to changes after they have taken place, and there is no doubt that this causes a good deal of disruption and dissatisfaction. The study described here has attempted to provide an example of what can be done in looking into the future and this type of approach should be refined and implemented in assessing all new technologies.[5] The assessment would provide information for policy decisions now and guidance for clinical evaluation as it continues into the future. It would also suggest possibilities for influencing technological modifications along particular lines and enable the NHS to prepare for the likely impacts of a technology. Such an approach is quite lacking at the moment.

Some organization should be given the responsibility and resources to carry out such assessments. It could draw on the experience of the Medical, Science, and Social Services Research Councils, the DHSS, industry, and users of health technology. A Medical Technology Assessment Group of this nature could oversee the whole process of evaluation and assessment. Investment in such assessment should be well rewarded by the improved management of technological innovations that results.

Philanthropy and the NHS

Resources for health care are limited and philanthropy, in its broadest sense, including donations by groups and fund-raising appeals, can help the NHS to continue to move forward. In particular, even the limited number of machines required for evaluation of an innovation can be expensive (though much less costly than the indiscriminate purchase of many machines which then turn out to be ineffective). Philanthropy can provide the mechanism for introducing innovations into the NHS to get such experiments done. If it is to have such a role, however, philanthropy must be integrated into the over-all policies and needs of the NHS. The difficulty lies not with the gesture itself but in the lack of control exerted currently. Control is needed both over the gifts which will be accepted and over the appropriate location for these gifts.

The situation with whole body scanners has been very unsatisfactory. Health authorities have been presented with a *fait accompli* and have had little choice but to accept these gifts. In the case of appeals it also seems that the public has not always been presented with the full story. It is not necessary to deny that the whole body scanner is an impressive technological innovation in order to say that the public should be presented with the other aspects of the case: that there are expensive installation and running costs associated with the machine, that clinical evaluation is not yet complete, that there are other technologies which might be equally useful, and that the evidence about the scanner's effect on the outcome of the patient's condition is as yet very limited and hardly overwhelming.

Perhaps one solution to the problem of which gifts are needed by the NHS would be for regional health authorities to prepare lists of gifts which they would welcome. Alternatively, if philanthropy is truly to provide a means to test innovations, it would be preferable if technologies and appropriate locations were identified centrally, with the DHSS reviewing the field and making these identifications. The events associated with the whole body scanner have highlighted a general lack of policy about the role of philanthropy. Discussion is needed of how it can be used to greatest advantage, and how local interests and initiatives to enhance health facilities can be integrated into over-all policies for the NHS.

Industrial innovation and the NHS

From the investigation of CT scanning several questions about the interaction between industry and the health system have emerged. There are no easy answers to these questions but they are discussed here in the hope that some rethinking of the issues may lead to fresh approaches.

The most obvious concern caused by CT scanners is in the anomaly of having the major market for a British invention overseas. How can British industry be encouraged when sales at home are likely to be very limited especially in medical technology where priorities and resources mean that widespread diffusion of an innovation in the NHS may be quite inappropriate?

Perhaps a more fundamental question is how industry can learn about the technologies needed for health care. There is a whole spectrum in the types of innovation conceivably of use in medicine ranging from simple biomedical engineering modifications to existing equipment, to the most complex technology required to produce an artificial heart. To some extent where doctors present specific requirements these can often be satisfied by hospital engineering and medical physics staff or by university departments. Often, however, these are unique requirements and the innovations are unlikely to be of widespread use. For economic reasons it can only be where widespread sales are possible that industry can become involved. How then can industry be informed about the general gaps in medical technology?

The CT scanner provides an interesting example here. In this case it was not that a deficiency was identified and the challenge taken up by industry to meet it. Instead it was the lateral thinking of an inventor who saw how his work could be applied in the health context. However brilliant the innovation, it does not seem that this is the most efficient mechanism for the development of medical technologies. A mechanism is required to identify the major gaps in health care technology so that industry can respond. The interaction works both ways, health technology users, current and potential, are generally unaware of the possibilities open to industry in solving the problems they might pose. It would seem that the entrepreneurial basis of industry is not necessarily a sound way to produce the most desirable medical technologies. A *laissez-faire* approach to industry tends to result in the production of very sophisticated machines, often very costly, which may not meet the most important technological needs of the NHS. Some thought needs to be given to how industry and health care users able to identify general deficiencies can be brought together. Perhaps this should be integrated with the 'technology assessment' of health care innovations suggested earlier. After all, the lessons learned in the assessment of one technology are quite likely to indicate other gaps in the health care system. Certainly the same bodies (the MRC, SRC, DHSS, industry, and so on) will need to be involved in both.

Apart from the initial idea, a close interaction is needed between manufacturers and the NHS during development and even subsequently as new generations of machines are produced. Technology does not have an autonomous life of its own, modifications in design can be made and it may be that intervention during development may persuade manufacturers to produce a simpler, cheaper machine of general use rather than the sophisticated, and often costly, developments which are currently in favour. Although firms are interested, though not always successful, in ensuring their equipment is usable in the clinical setting there could be much more intervention by users to produce more 'appropriate technology'. T. S. Eliot wrote: 'Between the idea, and the reality . . . falls the shadow.' Here the shadow should be the guiding hand of those for whom the innovation is to become a reality.

Notes and references

1. Introduction

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4. The future

1. This figure was taken from the Institute of Medicine *Policy Statement* op. cit.

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3. This suggestion has been made by Professor B. R. Pullan, University of Manchester.

4. See, for example, *Lancet* (1977), **i,** 999.

5. It is interesting that this development has received so much publicity, again possibly due to an awareness of medical imaging resulting from CT scanners. See for example, *Observer,* 10 July 1977; *The Economist,* 25 June 1977; *Health and Social Services Journal,* 1 July 1977.

6. Discussion

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APPENDIX

Clinical evaluation[1]

The use of computed tomography (CT) in examination of the brain is now well established (4) and has had considerable effects on the use of other diagnostic procedures, for example, pneumoencephalography, radionuclide brain scanning, and cerebral arteriography (6). Whole body CT scanners can be used for brain scanning and, now that a water bath is no longer required, can also be used for examination of the base of the skull. There is, however, still dispute about whether whole body scanners produce as good images of the brain as brain scanners. The use of computed tomography in whole body scanning is not yet established. Unlike brain scanning a variety of other acceptable non-invasive techniques are available for areas covered by the whole body scanner. Reports evaluating the use of whole body scanners have only recently begun to emerge. To date only whole body scanners from three companies have been clinically evaluated: EMI, ACTA, and Delta (Ohio-Nuclear).

One problem with the early reports is that at the same time the evaluations were being carried out, the machines themselves were changing. The evaluations of the ACTA scanner, for example, are based on a 2½-minute scanning time while the newer generation of scanners have 18–20-second scan times. Thus reports of accuracy may not be applicable to the newer machines. Since respiratory and peristaltic motion cause imaging artefacts the probability is, however, that the newer machines are capable of much greater accuracy than the very early reports would suggest.

1. A list of references is provided at the end of this Appendix.

A second difficulty in assessing the role of the whole body scanner *vis-à-vis* other diagnostic techniques from the early reports (2, 3, 15) is that very few comparisons are given. The early reports tended to be descriptive and give little indication of whether the patient's diagnosis was already known or whether CT interpretations were subsequently confirmed. The more recent reports tend to be more rigorous. CT scanning results are now being compared with subsequent findings at surgery or histological examination. Reports giving comparisons with other techniques are also being published and several authors suggest that, after their preliminary explorations in CT scanning use, they are going on to controlled trials.

Evidence concerning the effects of scanning on the patient's therapy or outcome is very limited, but what anecdotal evidence there is, is included below. Again several authors note that they are now involved in studies of the effects of scanning on therapy and outcome.

Each of the organs and anatomical areas evaluated so far (that is, reported in the literature by December 1976) will now be considered. It must be pointed out that by no means all possible uses of CT scanning have been tried out and even when some work has been done there may not be agreement among radiologists at this early stage in its evaluation.

Thorax

The groups who have published CT scanner evaluations suggest that the use of scanning in the thorax may be limited mainly because it does not give more or better information than chest radiographs or conventional tomograms. There are exceptions to this view when particular applications are considered, however. Kreel (11) investigated 13 patients who had been exposed to asbestos for varying lengths of time (ranging from 1 to 40 years). He was able to detect many abnormalities not shown on standard chest films including pleural thickening and calcification and parenchymal abnormalities. No comment was made in this paper on whether treatment was initiated or altered as a result of CT scanning.

Kreel (13) also has used the scanner to investigate lymph node enlargement. He points out that there are some regions particularly in the thorax (although also some in the abdomen) inaccessible to lymphangiography. CT scanning was used to evaluate thirty-three patients with malignant disease, mainly lymphomas or testicular tumours. He found the scanner useful in investigating areas inaccessible to lymphography but also found that in several lymphoma cases only a small proportion of enlarged nodes took up contrast medium. Thus CT scanning was more useful in assessing the total lymph node involvement. In addition, other metastases (pulmonary, liver, and bone) could be seen. He notes that the scanner also proved useful in monitoring the effect of therapy.

Cardiac imaging is not feasible at present because of motion artefacts. There is however great interest in two approaches which may make it possible:

1. Physiological synchronization so that scanning takes place at the same time during the cardiac cycle even though long scan times are used.
2. Development of very fast (i.e. a fraction of a second) scanning machines which may make cardiac imaging practicable. Some work (18) has already been done using animals and these authors feel that CT is a promising technique, others (8) suggest that ultrasound will remain the primary non-invasive cardiac imaging technique.

Abdomen

It seems likely that CT scanning is of most potential use in certain abdominal areas where other non-invasive techniques are not so successful. For example, the pancreas has been a particularly difficult organ to investigate and CT scanning may have a major impact there. In contrast, the kidney may be investigated well by other techniques and CT scanning may be used there only perhaps when other techniques have left the problem unresolved. Because of motion artefacts it seems unlikely that CT scanning will be of great use in investigating intestinal disorders, although very short time scans may make this a possibility. Another limitation in the use of CT scanning in the abdominal region occurs in very thin patients. In the absence of fat planes it is very difficult to visualize the various organs as separate entities.

Each of the major organs and areas evaluated so far in the abdomen will now be discussed.

Liver

All the groups involved in evaluation have used whole body scanners to investigate the liver. Two groups in particular have presented data comparing CT scanning with other techniques and comparing subsequent diagnostic confirmation either surgically or histologically. Alfidi (1) reported that of 20 patients with normal livers both CT scanning and nuclear medicine scans gave three false positive results. Of 26 cases with mass lesions of the liver, 20 were correctly identified both by CT scanning and by nuclear medicine. CT scanning was less successful than nuclear medicine scans in diagnosing cirrhosis (8 out of 11 cases identified, compared to 10 of 11). It should be noted that Alfidi's group were using a scanner with a 2½-minute scan time. This group also used CT scanning to differentiate between obstructive and non-obstructive jaundice.

Stanley (17) reported correct interpretation of CT scans of the liver in 46 of 84 cases, only two were incorrect and the rest were unconfirmed (see Table 3). Many of the unconfirmed cases were thought to be correct in that the scanner results were normal and based on their clinical course many patients were presumed to have normal livers. This group did compare some of their results with radionuclide scans and noted that while there was a high correlation in the results, particularly for space-occupying lesions, CT scanning has an advantage in that it can differentiate among the various types of lesions. In addition, CT scanning can distinguish dilated bile ducts from other diseases which produce inhomogeneous radionuclide scans.

TABLE 3

Accuracy of interpretation of CT scans (from Stanley et al. *[17])*

Anatomic area	*No. of cases*	*Correct*	*Incorrect*	*Unconfirmed*
Liver	84	46	2	36
Pancreas	75	31	6	38
Kidney	36	17	1	18
Pelvis	21	13	0	8
Extraperitoneal space	24	14	0	10

Pancreas

The same two groups have produced much of the evidence on accuracy of scanning in the pancreas. As shown in Table 3, the lowest accuracy obtained by Stanley's group was in the pancreas but they feel that the information was in fact present on the scan and that with more experience in scan interpretation the accuracy will improve.

Alfidi's group (9) also had some difficulty in early interpretations, identifying five patients as false positive and missing two patients (one with a pseudocyst and one with an inflammatory mass) with pancreatic disease. On comparison with angiography, CT scanning was more accurate in that three normal patients gave false positive angiograms, two with adenocarcinoma gave false negative angiograms, and two with lymphomas gave false negative angiograms. CT scanning correctly diagnosed these patients.

In comparison with ultrasound eight patients with known pancreatic tumour were correctly diagnosed by either method but CT scanning showed the extent of spread of the disease into the retroperitoneum better. Haaga (9) comments that although CT scanning is a very useful tool in the pancreas it is not possible to differentiate between inflammatory and neoplastic masses based on CT evidence alone.

Kidney

Although CT scanning can be used with great accuracy in the kidney, other non-invasive, accurate techniques are available. Stanley (17) does note however that CT scanning may have a useful role in resolving indeterminate or technically unsatisfactory ultrasound scans and so obviate the need for arteriography.

Retroperitoneal space

This area is again one where CT scanning may have particular usefulness as it is difficult to evaluate with routine radiographic techniques (12). In discussing the thorax, lymph node evaluation was mentioned and CT scanning is important for lymph node enlargement in the retroperitoneum. In addition tumour masses have been identified and some authors note (16) that a normal retroperitoneal space may be an equally important finding for patients with back pain.

Peritoneal cavity

Both Kreel (12) and Sagel (14) have identified ascitic fluid even when clinically undetectable.

Pelvis, genito-urinary tract

Work on this area appears to be limited so far, although several authors have suggested that it may take on more importance in future, particularly in the assessment of genital cancers.

Other sites

Various reports are in the literature concerning CT scanning in many other sites. Apart from the organs in the thorax and abdomen given above, bone, aorta, and spinal cord seem to be more thoroughly evaluated.

Bone

Kreel (12) reports visualization of sclerotic deposits in bone as well as areas of bone destruction. He has suggested that CT scanning may be useful in tissue density measurement in osteoporosis.

Aorta

Axelbaum (5) reports using the ACTA scanner to evaluate thirty patients with abdominal or thoracic aortic aneurysms. The majority of these patients were known from physical examination, X-rays or ultrasound to have aneurysms. For some of the later patients, CT scanning was used as a primary diagnostic aid. They were not able to get internal detail (for example, plaques or mural thrombi) but anticipate that improved machines should be able to do this. The authors do point out however that CT scanning does have one limitation as compared to ultrasound in that it only gives a limited view of the aorta. Sonograms or plain X-ray give a longitudinal picture which covers much more of the area.

Spinal cord

De Chiro (7) reports using the scanner on eighteen patients to detect syringomyelia. He notes that the currently accepted myelography methods are invasive and have a small but definite number of complications associated with them. Although CT scanning will need to be used in conjunction with myelography, for accuracy, he concludes that CT scanning may be appropriate for screening and for follow up because it is desirable to limit the number of myelograms. Kreel (12) is also investigating CT scanning of the spinal cord and has suggested that it may be possible to identify intervertebral disc protrusion. If so, this would be a great advance in the diagnosis of patients with backache.

Other uses of CT scanning

To this point the emphasis has been on the comparison of CT scanning with other diagnostic tools and on the confirmation of CT diagnostic findings. Several authors report other related uses for CT scanning and a major emphasis here is on CT scanning for radiotherapy planning and follow-up. Jelden (10) has reported using CT scanning in association with a treatment planning computer. Although the investigations are only just beginning and there are no reports in the literature, it is known that at least two scanners in Britain will be used in association with treatment planning computers. Both Jelden and Kreel (12) emphasize the important use of CT scanning in more generally monitoring the effects of treatment (particularly radio- and chemotherapy) in cancer patients.

Another use that has been suggested for CT scanning is for positioning instruments accurately both for biopsy and for aspiration of cysts and abscesses. Alfidi (1) reports successfully treating one patient with an intrahepatic abscess primarily by CT guided puncture and drainage so obviating the need for surgery. The same group have used CT guided needles for biopsy of both liver and pancreas (1, 9). Again, where biopsy is necessary the use of CT guided needles may avoid the need for a laparotomy.

Finally, although strictly not a different application of CT scanners, the use of contrast agents in scanning should be mentioned. There appears to be no clear viewpoint on whether contrast agents are of any advantage in whole body scans. The most complete assessment at this time is presented in a paper by Stanley (17) (see Table 4).

TABLE 4
Value of intravenous contrast medium

Anatomic area	*Diagnostic*	*Improved definition*	*No improvement*	*Hindered*
Liver	0	10	5	3
Pancreas	0	3	7	0
Kidney	1	4	4	0
Retroperitoneum	0	3	0	0
Spleen	0	1	1	0
Aorta	0	0	1	0
Inferior vena cava	0	1	0	0
	1	22	18	3

Thus in some areas contrast agents may improve definition. In the liver although contrast agents may improve definition in some patients it may hinder it in others. This same finding was observed by Alfidi (1).

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The following is the main evaluation literature, published on whole body scanning up until December 1976. It includes reports from all groups who published literature on CT whole body scanning evaluation by December 1976 but does not necessarily include *all* their papers.

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The Image and the Reality

A case-study of the impacts of medical technology

BARBARA STOCKING AND STUART L. MORRISON

The study described in this report throws light on the application of a startling new technological development. The introduction of the whole body scanner adds to the growing list of diagnostic aids but it also involves both high capital and running costs. In these days when decisions on priorities are being forced on society, the question is fast becoming whether in future technological development will itself have to be scrutinised closely for its total implications and for comparisons by sophisticated cost/benefit techniques.

As the Chief Scientist of Scotland's Health Department comments, a clear case is revealed for some rigorous oversight of the total arrangements required for the effective and efficient application of new technologies in health care. Complementary to this is the need to assess the total implications of these expensive innovations in terms of health service logistics. It is doubtful whether the existing arrangements allow for such co-ordination as is necessary. The time is surely ripe to consider the establishment of an independent focusing agency to oversee the orderly development of such innovations, as well as the range of research needed for the evaluation and assessment of the actual developments.

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