tidal wave

NEW TECHNOLOGY, MEDICINE AND THE NHS

A report by John Hoare based on the proceedings of the Caversham Conference on health technology assessment

Sponsored by IHSM and MAS

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PREFACE

TOWARDS A KNOWLEDGE-BASED HEALTH SERVICE

Traditionally, it has been anticipated — even expected — that opinions and actions vary from one clinician to another, such differences being viewed as justifiable and usually beyond criticism. As a result there is often a range of approaches to practice even within individual institutions, which extend from minor variations around a common theme to more substantial departures from what might be regarded as good practice. Although failure to keep abreast of new developments and resistance to change goes some way to explaining why variation occurs, undoubtedly a lack of reliable data on the costs and benefits of many health practice methods has compounded the problem. To correct this deficiency there is a real need to move towards a knowledge-based health service in which decisions are based on scientifically-derived information.

The classical model of science inspired innovation in health care has led to remarkable advances. At the same time undervalued approaches and technologies of doubtful value have irrestistibly penetrated and persisted in the NHS. At a time of high productivity in basic research and in biotechnology, biomedical engineering and other areas of health research, including the social sciences, science-led development needs to be complemented by R&D targeted to NHS priorities. Hitherto there has been no coherent mechanism for assessing new practice methods, neither has there been a means of displacing obsolete technologies or a way of promoting the use of methods of proven value.

As part of the NHS R&D programme a national capability for assessing health practice will be built up recognising that technology assessment is neither simple nor inexpensive. Large multicentre trials are often very costly so that the questions being addressed need to be important as well as relevant, and the methodology used needs to be high quality and appropriate. The potential scope for health technology assessment is wide so that prioritisation is inevitable. Opportunities need to be taken for sharing the burden internationally and for ensuring that best use is made of the outcomes of studies conducted within the NHS programme or by other bodies and countries. Finally, of course, the costs and benefits of the investment in health technology assessment itself need to be kept under review.

These proceedings are the welcome outcome of a multidisciplinary meeting which provided an excellent forum for an interchange between managers, doctors, economists, consumers and others involved in health care. The involvement of health service managers is particularly crucial if the information derived from R&D is to be used to best effect as a management tool. The 'Tidal Wave' aptly describes the surge of activity in contemporary research and the wealth of new diagnostic methods and treatments being presented to the NHS. The image is perfectly illustrated by Hokusai's celebrated woodcut, the 'Great Wave'; as it hangs over the boats in Hokusai's picture the wave is a threat, while taken on the crest it would impart impetus and momentum. The challenge for the NHS is to take advantage of the wave while resisting its excesses.

Michael Peckham
Director of Research and Development
Department of Health

May 1992

INTRODUCTION

'The tidal wave of new developments coming our way is quite astonishing.'
(Michael Peckham)

NHS managers are embarked unaware on a great sea-change. The change has two, interwoven components:

- a surge in the development of health care technology; and
- an associated revolution in the way health care will be provided over the coming decade.

Managers have to learn more now about this sea-change. They will either influence it or find their services, business plans and management increasingly out of control.

Managers today experience confusion and a conflict of priorities in the introduction of new technologies and in the new approaches to health care which come with them. They must expect this year, next year and every year thereafter:

- increasing expenditure on new technology;
- technology-driven changes in local health care organisation;
- a continuing gap in information on the true value of technology;
- increasing pressure for the introduction of new technology (from clinicians, the public, the manufacturers);
- increasing reluctance by purchasers to invest in costly but unproven techniques:
- increasing public demand for information and action on safety, quality and value.

Have managers given enough attention to this potent brew?

This booklet focuses on the use of HTA as a tool for better health service management. The task under discussion is the *effective* use of technology in the NHS. The task includes both the introduction of new technology and the use of existing technology.

The impact of technology on the way we provide and organise health care in the future is also discussed, and that too demands early attention from managers.

EXHIBIT 1

SOME QUESTIONS FOR MANAGERS

- What are your service development priorities?
- What are your priorities for future technological investment?
- Do you have a record of the technologies now in use in your hospital or district, their purpose and capital and running costs?
- How has each technique affected the results of patients' treatment?
- What changes in the cost and organisation of care have resulted?
- What new technique, or techniques in combination, would bring real benefit to users?
- What difference in benefit will result and what is the real cost?
- Are we wasting money on some high-cost technologies which produce little benefit?
- Would that money elicit more benefit for more patients if invested in a simpler or different technology?

Health technology assessment (HTA) could give information to clinicians and to managers to answer some of those questions; and therefore, potentially, to improve profoundly the effectiveness and management of the NHS.

DEFINITIONS

What is health technology assessment (HTA)?

HTA is a process of *evaluation*. It measures the *effectiveness* of clinical procedures and of the tools (drugs, disposables, machines, systems) used to carry them out. HTA is also concerned with the *cost* and *acceptability* of those techniques.

The combination of knowledge of effectiveness and cost has profound implications for the value of the services we provide to our public and for the management of the NHS locally and nationally.

Exhibit 2 shows the definitions of 'technology' and 'assessment' provided by Barbara Stocking, and used at the Caversham Conference and throughout this booklet.

EXHIBIT 2

Based on the talk given by Barbara Stocking

DEFINITIONS

Health Care Technology

The drugs, equipment and procedures, used singly or in combination, and the health care support systems in which they operate.

Technology Assessment

Assessment of the full range of impacts of a technology. In health care this includes the technical and clinical evaluation of a technology, as well as its economic, social and ethical implications.

Note on the definitions

'Technology' embraces a very wide range of artefacts and practices, hi-tech and low-tech — from incontinence pads to implants, scalpels to lasers, aspirin to monoclonal antibodies.

HTA is carried out by researchers, and can embrace a range of research disciplines. Managers need to have an understanding of the work involved and of the significance of the results of an assessment, but will not themselves carry out HTA.

THE METHODS OF HTA

The term HTA embraces a range of research techniques. Perhaps the one most widely accepted as being a reliable judge of effectiveness is the randomised controlled trial (RCT). The RCT has been the staple technique for testing and evaluating the effect of new drugs and clinical procedures. The RCT carries conviction to clinicians and scientists, but there are difficulties in applying it to much of the innovation in equipment and systems now pouring into our hospitals.

Unlike drugs, the introduction of new equipment is not regulated and the diffusion of new machines and systems into routine practice can be fast and widespread. The generally slow pace of RCTs and the difficulty of establishing controls in a fast-moving development (such as computer-assisted imaging) have led researchers to variations on the RCT approach.

Other research techniques have proved useful for HTA, such as the systematic overview, economic analysis and quality of life surveys — often in combination with trials. The method has to be *appropriate* to the question posed. The Snapshots at the end of this report illustrate different approaches; they also show that the results of HTA are not always clear-cut.

The debate on appropriate methods for HTA intensifies. What methods will both carry conviction with clinicians and be timely enough to be useful to decision-makers?

MANAGERS AND HEALTH TECHNOLOGY ASSESSMENT

Few managers are yet aware of what HTA is, or have realised that it is a missing piece in the management jigsaw. The Caversham conference demonstrated that the questions around HTA are not just matters for debate among specialists — clinicians, scientists, technicians, consumer groups. Nor are they simply rarified problems for higher levels — the Government, the MRC, regions, 'someone up there'.

'Managers have a duty to consider whether what they are delivering is effective.' (Barbara Stocking)

Consider the following facts:

- The NHS is cash-limited, and the cost of health care is high: management is required to demonstrate value for money.
- The introduction of costly medical technology to the service is accelerating.
- Most current hospital and practice procedures have not been evaluated.
- There is little reliable information about the effectiveness of most current or new technology.
- Consumer awareness and insistence on information and choice are growing.
- Technology is changing local health care organisation.

Barbara Stocking summed up three costly sins in our record of dealing with new technology in the NHS:

- the sin of commission (eg lithotripters and asymptomatic stones)
- the sin of omission (eg corticosteroids for pre-term babies)
- the sin of happy ignorance.

CLINICIANS AND MANAGERS

The introduction of general management, and now the polarisation of purchasers and providers, have narrowed the gap between the objectives of clinicians and managers. There is a greater realisation that the success or health of a hospital, practice or purchasing authority depends on doctors and managers working together towards similar objectives. We're all in it. Managers as well as doctors need to be informed about what's coming up in medical technology, and what the real issues are, rather than be bulldozed or enthused into costly funding decisions with little knowledge of the consequences. Those consequences may prove to be enormous.

THE NEXT DECADE

New technologies relevant to health services will develop and proliferate over the next ten years. These technologies are even now urgently knocking at our door. At the same time, and in part related to technology, conventional ways of organising and providing health care will change.

TRENDS IN HEALTH CARE TECHNOLOGY

(Based on the talk given by David Banta)

The introduction of new technology into routine use for diagnosis and therapy will accelerate and intensify. Some of the technologies which are certain to develop intensively and to spread in the NHS over the next decade include:

Laser technology
Neurosciences
Genetic screening
Vaccines, antibodies
Pharmaceuticals
Computers
Minimally invasive surgery
Medical Imaging
Other diagnostic techniques
Transplants
Home care technology
Telecommunications

These developments cover virtually the whole field of medicine, and characteristically blur the dividing lines between specialties. Which of these will spread most rapidly, and which will bring the most benefit to the public? Managers need to know more to be able to prioritise, plan and control. We are ill-prepared.

Consider the power of just three practical applications of these technologies to transform the treatment and health of patients, and to change the way we organise health services:

1. Minimally invasive surgery (MIS)

The continuing development of fibreoptics, endoscopes and the laser (in combination with a battery of other technology) is already resulting in startling changes to surgery. In gastroenterology, gynaecology, ophthalmology, orthopaedics — indeed in most specialties — conventional surgery is giving way to new, minimally invasive techniques.

These appear to achieve the desired result faster, more simply, with less morbidity, less pain, shorter hospital stay and quicker return of the patient to normal activity. They also have dramatic implications for the organisation of services. There seems to be good reason for much of this therapy to be undertaken away from the hospital, some of it perhaps even at home.

There are also major economic consequences of the use of MIS — most of them as yet unexplored. For example, in America the shift in surgical practice from conventional hysterectomy to an MIS technique is estimated to reduce expenditure on that treatment by $250m annually.

Exhibit 8 shows some applications of MIS, and judgments of their value.

David Banta predicts that within ten years conventional hospital surgery will be ended, with the exception of major trauma, major cancer and transplant surgery.

2. Computers

The rapid development of computer applications to health care continues without rest. Computer-assisted diagnosis, imaging, expert systems, information databases, microprocessors built in to most new technologies, hospital information systems, the computerised record, telecommunications — all are evolving rapidly. Possibly the most important change over the coming decade will be seen in the *networking* of systems, linking hospitals, practices, community services, and, eventually, the patient at home. There is great potential for improved monitoring and treatment of patients, and for speedier, cheaper and less inconvenient attendance regimes for the public. But despite this potential, there is at present very little evaluation of the benefits of computer applications to health care.

3. Rehabilitation and home care

The development of artefacts to ease disablement and hasten recovery at home includes products from the entire range of technology. Low-tech inventions are less exciting than high-tech devices but may ultimately influence health care more. The application of polymers to pads for incontinence, for example, is resulting in products which are more effective, more convenient and more comfortable, and which may be cheaper. At any one time there are 3 million incontinent people in the UK, of whom 200,000 are

being treated by the NHS at a cost of £60m annually.

4. Trends in health care delivery

Technology is altering the shape and structure of our health care institutions and the way we provide treatment and care for the public. This is sometimes difficult to perceive by those closest to it. The pace and extent of change will be dramatic.

We can predict with confidence at least three trends in the way we will provide and organise health care over the next ten years:

- a steady growth in the volume and proportion of care of the elderly;
- care services increasingly provided away from the hospital;
- the development of wide information networks among between hospital, practice and community.

Some of the consequences will be:

- hospitals will use fewer beds;
- increasing emphasis on the general hospital as a critical care hub;
- hospital services increasingly becoming highly specialised;
- growth in minimally invasive surgery; reduction of conventional surgery;
- increasing emphasis on primary and home care.

Based on the talk given by David Banta

EXHIBIT 3

JUDGEMENTS OF EFFECTIVENESS AND COST-EFFECTIVENESS OF SELECTED HEALTH CARE APPLICATION IN MIS

Treatment of condition/procedure	Promising	Established Clinical Experiment	Established RCT	Probably Cost Effective	Proven Cost Effective
Laser treatment of bladder tumors		X		X	
Extra-corporeal shock wave lithotripsy (ESWL)		X			X
Percutaneous nephrolithotripsy		X			X
Laparoscopic treatment of endometriosis	X			X	
Laparoscopic removal of ovarian cysts	X			X	
Laparoscopic cholecystectomy		X		X	
Laparoscopic appendectomy	X			X	
Catheter treatment of coronary artery disease		X		X	
Palliation of colon cancer by endoscopic intervention		X		X	
Treatment of upper Gastrointestinal bleeding (UGI) by endoscopic intervention		X		X	
Arthroscopic knee surgery		X		X	

EXHIBIT 4

TECHNOLOGIES THAT CAN AID AND ENCOURAGE DECENTRALISATION (OR LESS USE) OF HOSPITAL SERVICES DURING THE NEXT 10 YEARS

Diagnostic Kits
Dry Chemistries
Desk-Top Laboratory Analysers
Vaccines
Laparoscopes
Endoscopes
Vascular Catheters
Laser Microsurgery
Laser Vaporisation(eg of tumours)
Laser Angioplasty
Prostheses
Drug Delivery Systems (eg pumps)
Assistive Devices (for support at home)
Social and Psychological Technologies
Computers and Telecommunications

Based on the talk given by David Banta

A STITCH IN TIME

'Technology is the major cause behind elevated health care costs.'
(David Berkowitz)

Faced with this potential turmoil, NHS managers need to arm themselves. They need to move towards a position where they can look ahead, think through, anticipate and plan (as far as practical) both the technology and the service changes inherent in the predicted changes in the patterns of care.

There are opportunities for greatly improved results for our patients; and there is also the danger of wasting scarce resources on technology which makes little impact.

Potentially, HTA offers the best means of managing the introduction and diffusion of technology to the benefit of our public's health and purse. It is certainly not the only resource required for the related tasks of investing in technology and planning service change, but it is the key.

Like the technology it addresses, HTA is complex and developing, and its application needs to be managed if it is to be useful. One manager summed up the feeling of urgency:

'Without the evaluation that HTA affords, inappropriate expenditure is likely to drive out appropriate expenditure on technology.'

PROBLEMS

If the need for HTA to be used widely and consistently in the NHS is manifest, why is it not yet a burning issue for most clinicians and managers?

Perhaps the biggest reason is that the NHS cash-limit and tight capital regulation have for years put a hard brake on investment in new technology. We are used to rationing, to technology coming a poor second in priority to building investment, and to arbitrary ways of cutting a small cake. One result is that the UK is seen to control overall technology costs tightly (compared with the runaway profusion in the US). But rationing is a blunt instrument.

Would a larger investment in technology yield a proportionately greater benefit to our users (if the selection was on the basis of considered evaluation)? Is the NHS depriving the public of true benefit readily obtainable elsewhere in the western world? What parts of our present practice would be displaced if we did invest more in technology, and what would be the net benefit or loss?

Barbara Stocking sees three difficulties in the way of making systematic use of HTA:

Getting information

Although there is a steady amount of HTA in progress round the country, there are large areas of medical technology for which we have no information about effectiveness. The pace of good evaluative information falls behind the pace of invention and marketing of new technology. The scale of this shortfall is such that a national strategy is needed, if it is to be reduced.

Informing users

What information we have needs to be sorted and got to clinicians, managers and public in an *appropriate*, user-friendly form.

The Caversham conference noted with envy the US monthly journal *Health Technology Trends* , which is published by ECRI (originally the Emergency Care Research Insititute) for health care managers. ECRI is an independent non-profit making trust and the journal is a sort of health care *Which?* At present, there is nothing comparable in the UK.

'Only about 15 per cent of practices in common use have been proven by good trials to be ameliorative.'
(Kerr White, quoted by David Banta)

'Health technology assessment is a complex subject.'
(Michael Peckham)

Consumer groups, patients, individual members of the public, are all 'users', whose voice is growing stronger and more articulate about the information they need.

Achieving change in practice

Of the three difficulties, this is the greatest. Good information alone is not enough to effect change. HTA information may indicate to a clinician that he or she should abandon or moderate an innovative professional choice. Or it might indicate that a procedure of long standing should be abandoned. Managers know from their own experience that rationality is seldom enough to convince anyone to change behaviour. Something more than information is needed. This difficulty is compunded by the noise of the sales bombardment targeted at clinicians by fiercely competitive manufacturers of technology.

The growing sense of corporate identity in provider units and in purchasers, together with the work of agreeing service contracts, may be one avenue to influence change. Perhaps positive financial incentives may be another. It is likely that the best route is for clinicians who are acknowledged by opinion-leaders in the profession (nationally or locally) to be convinced by researchers and thus influence their colleagues.

How are these difficulties to be tackled?

EXHIBIT 5

THE CONSUMER'S VOICE IN HTA

Based on the talk given by Leonie Somorjay

Involvement of the consumer in decisions on health service practice, management and in HTA has grown, but slowly. Consumers groups have had some input into a few studies (for example, the National Childbirth Trust had an input into recent trials of amniocentesis and CVS, and aspirin and pre-eclamptic toxaemia). There is an apprehension among consumers watching the progress of the current NHS reforms that the voice of the individual and of groups will dwindle in the new organisations, notwithstanding the Patients' Charter.

'We have a long, long way to go.'

Consumer groups wish for a voice in HTA, as well as in policy and management. Further, they are likely to press for collaboration rather than consultation, particularly in the following:

Priorities

Decisions about which conditions and technologies should be the subject of HTA studies. Consumers want to take part in *setting the agenda* for research, nationally and locally.

Other systems

Consumers are likely to remind decision-makers that health service processes other than clinical procedures are important (sometimes more important) to the user, and need to be assessed. For example, alternative appointment booking systems, styles of counselling, hospital environment.

Information

The best way to empower consumers (users, patients, individuals, the public) is to provide them with *good information*, on the basis of which they can make their own *informed choices*.

'Good information' is information which:

- describes a situation clearly;
- explains alternative treatments simply;
- lists possible risks and hoped-for benefits fairly; and
- gives the patient room for manoeuvre and the maximum possible freedom of choice.

'If only service providers and researchers could see us as partners — our perspectives and priorities may be different, but they are just as valid as yours.'

Collaboration

There is a growing pressure from groups for the participation of consumers at all stages of the HTA process

STRATEGY

The NHS needs a strategy now. The volume, the scale of significance and of cost of new inventions are so large that a national policy to co-ordinate evaluation, information and action is necessary.

To be successful, the strategy will require a strong and continuing contribution from general managers. Purchasers, providers, national and regional management all have parts to play.

What might such a national strategy look like? Exhibit 6 is an independent sketch offered by David Berkowitz, an American HTA professional with no direct knowledge of the NHS. Interestingly, it can be seen that it coincides in its leading features with the agenda now emerging from the NHS Central Research Committee.

TOWARDS AN HTA STRATEGY FOR THE NHS

A Central Research Committee for the NHS has been set up by Michael Peckham, Director of Research and Development at the Department of Health and a member of the NHS Management Executive. It is at work now (1992) on a national strategy and an advisory committee on HTA has now reported.

Rationale

The rationale of the NHS research and development programme and of HTA (which will be a major part of that programme) is:

1. Above all, to improve the quality and outcome of care by optimising the use of resources;
2. to encourage biomedical research relevant to the health service;
3. to facilitate the uptake of new methods of proven value;
4. to provide a basis for preventing the use of inappropriate practice methods and technology;
5. to place the NHS in the mainstream of medical research practice, so that health priorities are taken into account.

Infrastructure

The infrastructure of the national Research and Development initiative is:

1. Deliberately wide membership of the central committee, to include a voice from each of the following:

   clinicians, public health medicine, academic medicine, general practice, nursing, dentistry, general management, financial management, health economics, health services research, industry, the consumer (public/patient).

2. The aim is to balance a central strategic plan with dispersed regional research programmes. Regional research plans are likely to include at least one project of national priority, and some others of national importance as well as projects immediately relevant to the region.

3. It is planned to increase research and development The target is 1.5 per cent of the NHS budget by 1996.

THE NATIONAL STRATEGIC TASK

The Central Committee will develop a clear strategy for HTA. It will enable the NHS to get significantly closer to the ideal represented in Exhibit 7, and will reduce the'bypass' by which so many unevaluated procedures come into practice at present.

In forming the strategy, the main task of the committee will be to think through the priorities to be set nationally for HTA. It will also consider:

- fields of new or old practice to target
- HTA methodology
- education and training
- how to bring medical audit and HTA closer together.

When it is ready, the strategy will offer an answer to the difficult question, 'how best to *facilitate* the appropriate use of cost-effective practice?'

It is this last question which should most directly involve managers. The promised national strategy will initiate a chain of activity which will reach eventually to all parts of the service. Researchers and clinicians will be in the forefront of that work (see Exhibit 8).

But what can *managers* do in the meantime?

Based on the talk given by David Berkowitz

EXHIBIT 6

SUGGESTION FOR A NATIONAL STRATEGY

At national level

1. Convene purchasers, providers, clinicians, scientists and the public to maintain a dialogue and set priorities.
2. Form a national clearinghouse for HTA information and disseminate as appropriate, in a proper format.
3. Use a national research and development programme to provide timely, high quality, responsive technology assessments, presented in a clear manner for: clinicians, providers, purchasers, the public and the media.
4. After technology assessment is performed, have a process for: implementation and diffusion, training, practice guidelines, managing older technology, and audit.

At regional and local levels

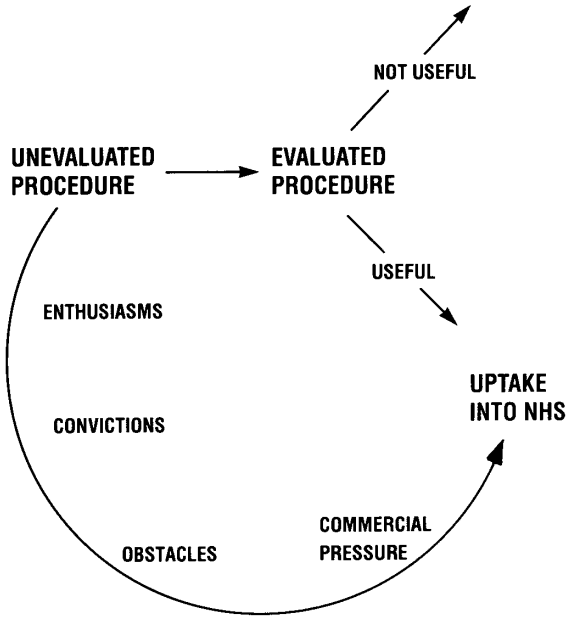
1. Regionalise HTA to allow for measured diffusion.
2. Develop technology priority-setting processess at individual hospitals.
3. During training of managers and clinicians include information on HTA.

EXHIBIT 7

THE EVALUATION BYPASS

The upper part of the diagram shows the process we are aiming towards.

The lower part of the diagram shows the 'bypass' mostly in use today, and the pressures which create it.



Based on the talk given by Michael Peckham

Based on the talk given by Sheila Adam and others

EXHIBIT 8

AN AGENDA FOR THE RESEARCH COMMUNITY

How may HTA be increased, advanced, improved, and be more effective? Some suggestions made to and by researchers at the Caversham conference follow.

1. Ensure the high quality of research methods and work. In trials seek important questions, large numbers, simplicity, and speed. Funds in excess of the current level will be needed.
2. Methodologies of HTA need to be kept under review. RCTs are not always necessary for studies to be effective and credible. The method should be *appropriate* to the specific question under review.
3. HTA can be as valuable when applied to low-tech as to high-tech procedures, to cheap as to expensive systems.
4. More systematic attention needs to be given to *priorities* for research, and the selection of procedures to be studied. The emerging NHS research and development strategy should provide a national and local foundation for this.
5. Recognise the politics of HTA (not just scientific and clinical politics, but also the strong interests of NHS management, the consumer, industry and commerce). New ways have to be found, nationally and locally, for collaborative working, from inception to application of HTA.
6. Researchers (and others) need to place more emphasis on practical questions of applying the results of research to routine practice. They have to convince opinion leaders in the medical profession if HTA is to be the precursor of adoption of new technology. Consensus conferences and multidisciplinary meetings may be one way into this.

'Use their preferred language.' (David Banta)

ACTION: WHAT CAN MANAGERS DO NOW?

Managers will not themselves carry out HTA, which is a task for specialists. Nor are they likely to encourage a programme of assessments to be done independently within their patch, because this is one activity for which a large framework (regional, national or international) is best.

Managers who have considered HTA are impressed by its potential for:

improving the quality of health service treatment;

controlling costs;

directing expenditure to where it will be most effective.

As good managers they want to do something to introduce the application and effects of HTA into their patch. The view of those at the Caversham conference was that managers should now:

1. Learn about HTA and its potential, and spread that awareness through their managerial network.
2. Keep themselves informed of the evolving national strategy.
3. Initiate informed and continuing dialogue locally between clinicians and managers, and start to involve the public.
4. Acquire and communicate *appropriate* (selected) information (about evaluation, trends in technology, etc) to advance that dialogue.
5. Start to apply the fruits of consensus from that dialogue to the policies, programmes and daily work of the unit or health authority.

In this activity, managers who are purchasers will have, of course, different roles from those who are providers; but they share a common interest and aim in advancing the use of HTA. Exhibit 9 sets out the agenda proposed by Sheila Adam for action by managers in both camps. This agenda attracted support and enthusiasm.

In discussion, further suggestions to take this agenda forward were made by managers, clinicians and researchers. Among the suggestions were:

- the holding of 'consensus conferences' locally;
- the possibility of insisting on protocols in service specifications;
- the importance of including GPs in the development of local networks;
- support for the creation at national level of a *Which* style, user-friendly monthly guide on the effectiveness of new technology.

Is it perhaps too soon for managers to enter the arena of technology and its implications for service change, and of HTA?

'It's always too early until, unfortunately, it's suddenly too late.'
(Buxton's Law — Martin Buxton)

EXHIBIT 9

HTA: AN AGENDA FOR MANAGERS

Based on the talk given by Sheila Adam

A *prerequisite* is that managers (in hospitals or in health authorities) *strengthen the clinician/manager dialogue and involve the local population.*

What *purchasers* might do now

1. Develop better ways to access and use HTA **information.**
2. Explore new **levers** held by purchasers to ensure managed diffusion of technology and appropriate training.
3. Develop **collaboration** between the purchaser and: provider (clinicians and managers jointly); other purchasers; local community (in order to legitimate purchasing strategy).
4. Explore the possibility of **regulating** the diffusion of new technology. (Whose responsibility? Quantity as well as quality to be regulated?)

What *providers* might do now

1. Initiate **dialogue** between clinicians and managers to: agree ground rules in whole field of technology; identify developments; manage new technologies; provide training; ensure commercial competition.
2. **Communicate** this approach to all users, the local community, and purchasers.
3. Encourage, **motivate** and support clinicians in the development of audit, education, participation in research.
4. **Extend** the role of the ethics committee: to be proactive as well as reactive; to include 'consumer' participation.
5. **Develop** the ethos of the 'healthy hospital', a corporate responsibility of clinicians and managers.
6. **Aim** to make participation in a clinical trial a condition of introducing new technology.

SNAPSHOT

1

based on the talk given by Martin Buxton

EVALUATION OF HEART TRANSPLANTATION

1. Background

This was a comparative study of heart transplantation completed in 1984 at the two embryonic British centres, Papworth and Harefield. It was made against a background of uncertainty about the effect of the procedure on survival, quality of life and costs, and about any difference between the two hospitals in those effects. Should the programmes continue? How would costs be met? Should the DHSS fund either, both, or neither of them? In the method of the study there was no scope for randomisation and there was weak evidence on the effect of 'no transplant'. The study made pioneering use of generic 'quality of life' assessment.

2. Findings: Benefits

Good, and improving, survival rates; dramatic improvement in quality of life; no obvious difference in the effectiveness of the two programmes.

3. Findings: Costs

Costs were less than expected, and falling; cost of lifelong immuno-suppression was an important part of the full cost; considerable cost differences between the two centres (indicating ways of further reducing the total cost at each); the cumulative cost of the growing 'stock' of transplanted patients was significant.

4. Practical impact of the evaluation on:

- **National policy setting:** Interim funding supra-regional policy
- **Local policy implementation:** Budget-setting programme planning
- **'Coal-face' policy operation:** Programme monitoring, cost reduction
- **Research:** Influence internationally on heart transplant research; and nationally on research into other technologies.

OVERVIEW OF CARDIOLOGY TECHNOLOGIES (USA)

SNAPSHOT

2

based on the talk given by David Berkowitz

Of the many technologies introduced, and diffused widely in the USA over the past twenty years at great cost, very little is yet known about their true value. The devices do wonderful things, but are diffused without study.

1. Non-invasive diagnostic technologies

From the early physiological monitoring to the recently introduced positron emission tomography (PET), the stream of devices has included cardiac ultrasound, cine computed tomography (CT), magnetic resonance imaging, gamma camera. It has been usual to claim that each new invention would supplant older techniques, but in practice it is usual for it to be *added* to the range already in use. In critical care units, dustbins are full of continuous stationery and data from machines such as ANIBP (automatic noninvasive blood pressure monitoring). How much use is made of the mass of monitoring information and with what benefit?

'When you have a hammer, everything you see starts to look like a nail.'

2. Invasive diagnostic technologies

One million cardiac catheterisations are performed annually in the USA. With what benefit to outcomes? How many cardiac laboratories does the country need? We do not have data to make judgements about the utility of this procedure or of other invasive techniques. What will continuous cardiac output monitoring do for us? Will it improve outcomes or care?

3. Invasive therapeutic technologies

From pacemakers to arterial stents, these technologies have driven up the cost of health care, and cause ever-increasing problems to fundholders faced with the bill. It had been thought that balloon angioplasty would reduce the need for open-heart surgery, but the latter continues to thrive, even with the rapid diffusion of angioplasty.

4. Discussion

Some of the problems inherent in this very costly, uncontrolled and ignorant expansion follow:

- Unlike the control of drugs, the introduction of new devices to routine practice is not regulated (in the USA or the UK).
- The pace of invention and 'improvement' of devices is rapid. How is technology to be kept still long enough to make a sensible trial? Alternatively, is it possible to devise credible assessments which are speedy and make use of small numbers?
- Litigation and, in its wake, defensive medicine, add to the commercial pressures on clinicians to employ the latest additions to the technological armoury.

SNAPSHOT

3

based on the talk given by Ala Szczepura

MAGNETIC RESONANCE IMAGING

In mid-1988, the West Midlands region opened its first MRI service installation, in Coventry. A technology assessment was commissioned from the Health Services Research Unit of Warwick Business School. The aim was to measure the impact of MRI on diagnosis, patient management, patient care costs, and short-term patient outcome — in other words its cost-effectiveness in a services setting. Does MRI displace other imaging techniques, does it contribute to improved diagnosis and patient management, and what is the resulting patient outcome?

A controlled observational study design was chosen. This required clinicians to specify a differential diagnosis and therapeutic plan *before* as well as after each scan. The 'control' was provided internally by comparing planned patient management before scan results are known with that recorded after MRI. All 782 neuroscience quota patients scanned during the first year of service were entered into the technology assessment. In addition, a detailed cost study was made, and information on patient outcome (using QALY measures) was collected before and after the scan.

Results

- The annual cost (1989) of the Coventry or similar UK MRI service installation was calculated as £464,000 (or £206 per patient at a throughput of 2250).
- Abandoned radiographic and surgical procedures produced an average saving of £80, reducing the marginal cost of providing the service from £464,000 to £282,000 annually.
- A change in patient management was reported in 27 per cent of MRI referrals.
- Changes in diagnosis were recorded in 20 per cent of cases. 'Diagnosis unknown' cases increased from 5.5 per cent to 7.5 per cent.
- There were no indications from the audit of large changes in health status following MRI (quality of life score before MRI was 0.904; 6 months after MRI, 0.845).

Although the HTA recorded a high level of diagnostic and patient management effects, MRI increased neuroscience patient costs substantially overall.

The cumulative costs of *other* radiographic procedures pre-MRI for these patients was an average £463 per person. MRI is likely to enter clinical practice as an 'add-on' test.

The high neuroscience patient costs may mean that the possibility of limiting radiographic procedures in the run-up to imaging is a legitimate area for managers to encourage clinicians to explore.

HORMONE REPLACEMENT THERAPY (HRT)

SNAPSHOT

4

based on the talk given by Maria Goddard

HRT is a drug therapy which has great potential benefit for women between the ages of 50 and 64 but which has been shown to have risks. The cumulative evidence of many studies over the years has (so far) failed to establish to the satisfaction of many clinicians or scientists the extent of that benefit or the degree of risk.

The most obvious benefit has been the relief of menopausal symptoms. There are other longer term but less certain benefits: notably, protection against osteoporosis and subsequent bone fractures, and protection against cardiovascular disease (CVD). There is an increased risk of endometrial cancer, and possibly, of breast cancer; but there is seriously conflicting evidence from different trials about the scale and significance of either of these risks. This may be because trials have been on too small a scale.

The method of assessment of HRT has been the construction of a model which simulates the effects of HRT in a hypothetical population, part of which has been treated with HRT and part untreated. The model traces the relevant events (cancers, fractures, CVD, etc), their risks, effect on quality of life, and costs. The results are expressed in terms of: net cost per woman treated: cost per life year gained by treatment; and cost per quality-adjusted life year gained by treatment. The technique has become sophisticated. Necessarily, a number of assumptions and hypotheses have to be made, and these are open to challenge.

In this assessment, there is a continuing struggle, so far unsuccessful, to calculate and agree the scale of risk and cost of known potential benefits.

Two examples of the problems

First, how does one calculate and cost the benefit to the individual and to society of the relief of menopausal symptoms? The number of potential candidates in the UK for HRT will be about 5 million by the year 2010. With what confidence can one predict the savings in other treatments, the improvement in the quality of life, and the effect on the economy?

Secondly, the benefit of greatly reduced risk of hip or vertebral fractures cannot be realised until about 25 years after initial treatment at about age 50. An inherent complication in this is that the protection thus afforded appears to decline when the patient ceases HRT. Costing these and other consequences of the treatment is a complex and uncertain business. There is as yet no really good medical evidence about the long-term effects of past HRT use.

Greater sophistication in the method used for the assessment of HRT does not compensate for the uncertainty surrounding many of the results to date. Indeed, the process of 'expertisation' may succeed in confusing, not clarifying, the issues for decision makers.

SNAPSHOT

5

based on the talk given by Rory Collins

LARGE TRIALS

(Extracted from a discussion of the ISIS trials)

- The criteria for a good trial are similar in many serious diseases. First, ask an *important* question and, secondly, answer it *reliably*.
- Studies should address important questions about the effect of widely practicable treatment for a common disease; *they should be simple, recruit large numbers and have clear outcomes*

ISIS (International Study of Infarct Survival) is a large and simple trial. It is a randomised, controlled study of the effects of early intravenous beta-blockade on mortality. More than 16,000 patients were eventually enrolled in the study. The results of the study have increased steadily in value with time. The trial provides uniquely reliable evidence about the average effects on mortality of the widespread use of beta-blockers.

Many randomised trials are too small to be of much independent value. Trials of the effects of widely practicable treatments on major endpoints (such as mortality) in common conditions *can* be ultra-simple, and hence large. It is probable that a number of important medical questions will in the next few years be answered reliably only if some ultra-simple, ultra-large, strictly randomised trials can be mounted. The evolution of collaborative groups that will result in significant questions being addressed by such trials at a practical cost is one of the major challenges facing clinical research.

The rationale of the large study is:

1. The identification of effective treatment is likely to be more 'important' if the disease to be studied is *common* and if the treatment is *widely practicable*.
2. The study of the effects of treatment on *major endpoints* (for example death) is likely to be more important than on minor endpoints. Assessment of major endpoints *can* often be simple.
3. *Entry protocols* can also be simple because the reliability of the main treatment comparison is improved little by adjustment for any initial imbalance in prognostic features.
4. For a question to be important it must not yet have been answered reliably. If a widely practicable treatment had a large effect on an important endpoint in a common disease this would probably already be known, so the true effect is likely to be, at most, moderate.

The *moderateness* of what can plausibly be hoped for from such a study has profound implications. A small trial may suffice to detect a large treatment effect, but it may well fail to detect a moderate (yet worthwhile) effect. On a national or international scale, such a 'moderate' gain (decreasing the risk of death from myocardial infarction by, say, 20 per cent) could have substantial public health implications; and many middle-aged patients would benefit from a reasonable expectation of enjoyable life. These 'moderate' gains are substantial.

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tidal wave

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NEW TECHNOLOGY, MEDICINE AND THE NHS

A report by John Hoare based on the proceedings of the Caversham Conference on health technology assessment

As yet few people working in the health service are aware of the scale of the tidal wave of new medical technology now breaking over the NHS.

While these technologies offer startling improvements in medical information and therapeutic technique, they are also costly. What they accomplish for the patient in terms of *effective* treatment is as yet largely untested and unknown.

Tidal Wave addresses the key questions which managers, as well as clinicians, need to be considering as a matter of urgency:

- how can decision makers control investment in health technology to the benefit of the patient, and get value for money?
- why is health technology assessment the key to this difficult question?
- have managers realised the great impact that technology will make on the organisation of health care services locally?

Tidal Wave explores these issues and proposes a common agenda for clinicians and health service managers.