

# Health-care technology assessment: a clinical perspective

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Health technology assessment needs to relate to contemporary questions which concern public health-care systems: how to keep people healthy, how to focus on the needs of those with chronic disabilities and integrate care between the hospital and the community, how to encourage and audit effective teamwork, and how to establish a consensus about what is effective and affordable. Clinicians have an ethical responsibility to practice efficiently and economically, for profligacy in the care of one patient may mean that another is treated inadequately. For similar reasons, clinicians need to play a full role in the management of services. Advice from health technology assessment is vital and needs to be accurate, relevant, timely, clear, and accessible. As well as being concerned about what works, we need also to eliminate from practice what does not. Regular audit and appraisal of practice against the evidence base should be useful in this respect. Alternative approaches to management, such as the provision of care as opposed to aggressive treatments, need to be evaluated, and health technology assessment needs to consider how services are delivered, not just specific treatments.

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The rising costs of health care are a concern in all countries. New or substitution technology accounts for between 30 percent and 50 percent of these costs while pharmaceutical costs are noted to have risen by 12 percent per year over the past 10 years in Sweden and reached 15 percent of the total costs of the health-care system (4). In the United States, it has been estimated that pharmaceuticals will comprise 14 percent of the total spent on health care by 2010, whilst treatment and care for the elderly will consume 41 percent of total expenditure (21). The application of this new technology and improved medicines have enabled us to survive longer but with the diseases and disabilities which used to reduce life expectancy. Put simply, we are now living with diseases from which we used to die.

In my view, we need to pay attention to four issues. First, how can we encourage people to stay healthy for longer. This is, of course, an important issue for public health but it is also a question about how we organize care and support for those with disabilities, not least in an ageing population. The concept of retirement villages has recently been pioneered in the

United Kingdom by the charity Extra Care, and early experience suggests that improvements in health with a reduction in the need for social support can be achieved (23).

Second, we need to organize the delivery of health care around the needs of those with chronic disabilities, particularly in communities, perhaps changing the traditional model of separation between the acute hospital and community services, which is more suited for episodic interventions rather than continuing care (6). The emphasis will need to be on integrated care, delivered by service networks rather than by institutions (7).

Third, there is a need for a radical rethink in the roles and responsibilities of different health-care professionals with the development of effective teamwork (5). The country papers published in this volume emphasize the widening gap between what is possible and what is affordable in the delivery of health care even in wealthy countries. Staff costs account for approximately two thirds of health-care expenditure and efficiency and effectiveness in the use of scarce and expensive professional skills is paramount.

Fourth, we need to pay particular attention to what works and what does not work and reach a consensus on what should be provided and what cannot be afforded. This, of course, is why health technology assessment (HTA) is so important. The rise in the interest in this area and the research which is now available or being undertaken is of vital importance to those engaged in clinical practice.

## MEDICAL THINKING AND MANAGEMENT THINKING

It is apparent, perhaps all too readily, that doctors and indeed other clinicians think differently than politicians and managers. A British politician wrote "The politician is all the time concerned with the general consequences of individual decisions." One might add that this also applies to those with management responsibility. He continued "The doctor takes his characteristic professional decisions not only for individuals but as an individual, on his own single and ultimately unsharable responsibility" (19). In ethical terms, the politician and manager tend to take the utilitarian view, whilst for the doctor, his or her duty of care to the individual is paramount. This is why doctors tend to view managerial questions in light of what would be the effect on their own individual patients, drawing on their own experience. That this may not properly take into account the needs of other patients or the general working of the system for the delivery of health care is not their prime concern. It is almost as though politicians and managers view problems using different ends of the telescope to that used by doctors.

One cause for optimism is the extent to which this antithesis has been modified over the past 15 years. The increasing involvement of clinicians in the management of clinical services is exemplified in the United Kingdom by the rise in the membership of the British Association for Medical Managers and its increasing influence not only amongst doctors, but also in the determination of policies for the delivery of care. New curricula introduced into medical schools in the United Kingdom, following the publication of *Tomorrow's Doctors* by the General Medical Council (GMC) in 1993, have also meant that medical students and young doctors are more aware of their ethical responsibilities to be concerned with efficacy, effectiveness, efficiency, equity, and economy in the delivery of treatment and care. There is the realization that profligacy in the use of resources in the care of one's own patients may, when resources are necessarily constrained, lead to the denial of adequate care for other patients (5).

### Sharing Responsibility

Doctors and other clinicians are now becoming more aware of their need to practice within a health service which is necessarily constrained and restricted by the availability of resources. Politicians must also be prepared to acknowledge restrictions, if not rationing, in what a publicly funded health-care system can provide. It is clear from the studies from

Sweden, Holland, and France as well as the United Kingdom that this position is now beginning to be implemented. In Holland, it is reflected by the "Dunning Funnel" and in the United Kingdom by the creation of the National Institute for Clinical Excellence (NICE). As a clinician, I welcome the creation of NICE with its requirement to both assess and appraise the evidence for the introduction of new technology. Inevitably, NICE's judgments are likely to be controversial, but they do provide a basis for the sharing of responsibility between clinicians and politicians, and making explicit what previously has been hidden. I welcome this because like many clinicians I have felt uncomfortable for many years with the moral dilemma posed by having to hide from patients that a treatment was not being provided because it was not being made available. Most clinicians are perfectly prepared to accept responsibility for the determination of clinical priorities, but they need to do so within a framework that is transparent and subject to political debate. As Berg et al. observe (1), priority setting is necessarily messy and difficult and is inescapably a political process. At last we have made a start in recognizing this, although there is much more that needs to be done.

We elect politicians to represent us. They have an important role in representing society's view in determining choices for the provision of treatment and care. There is a limit to how much an individual is prepared to spend toward health-care provision if other important needs such as education, housing etc. are to be met. It is not only desirable for politicians to articulate and determine what treatments and care should be available; it is necessary because that is what we elect them to do. It is their duty to explain and act.

### A Hierarchy For Making Decisions

We still have the dilemma posed by the different ethical responsibilities of politicians and managers on the one hand and clinicians on the other. Clinicians cannot escape their duty to do the very best they can for individuals with the resources available to them, nor would we, as patients, wish them to do so. I suggest that we need to consider different levels of decision-making. Government can set a broad framework for policy. In this respect, I welcome the commitment of the UK government to explicitly make funds available for implementing the recommendations made by NICE if they accept them; it is important that this actually happens (3), as there is a risk that the enforcement of NICE decisions, without additional resources, could squeeze out other effective treatments that have not been considered by HTA (22).

It is acknowledged by the UK government in their recent study on *Delivering the NHS Plan* that health care has to be organized and delivered on a locality basis. A recent discussion document from the Kings Fund concluded that decentralization of the responsibility for determining the provision of care and treatment is necessary to revitalize the British National Health Service (NHS) (11). A much larger degree of autonomy for local councils from central

government is a notable feature in Sweden (4), whilst insurers and patients have considerable influence in determining priorities in Holland and France (1;17).

Those responsible for the delivery of treatment and care at the local level need to develop their own priorities within the national framework (1). As Stevens and Milne point out, “all local commissioners will need to develop an appraisal function” (22). A good example of how this can be done was provided by Lambeth, Southwark, and Lewisham Health Authority in London, in reaching a decision over the provision of beta-interferon to people with multiple sclerosis (12). The health authority, as the commissioning body, consulted with patients with multiple sclerosis who were as concerned about the delivery of care, education, and support as they were about the use of interferon. An agreement was then reached about the total package of care to be funded, not just about the use of the drug.

The third level of the proposed hierarchy concerns the freedom of the individual clinician working with individual patients. It is my view that clinical teams must have some control and responsibility for the expenditure that they determine by the decisions that they reach. A devolved system of clinical budgeting, which was pioneered at Guy’s Hospital, London, in 1985, provided such a framework (5). Most patients have particular individual needs that are unique to them even if the diagnosis is the same as others’. Meeting these needs can at times require clinicians to make choices between treatment and care and to interpret clinical guidelines and the evidence base accordingly. I am not arguing for unrestricted clinical freedom but for flexibility. Under this proposed hierarchy, society’s views would be represented through the commissioning process at national and local level, whilst the individuals’ particular needs and wants would be met by clinical teams having sufficient flexibility to respond.

It is perhaps understandable that managers and politicians will, as Berg et al. point out (1), seek to erase subjective factors so that it becomes possible to manage on the basis of explicit knowledge laid down in rules, procedures, protocols, and manuals. Turning professional bureaucracies into machine bureaucracies (13) is an attractive proposition but fundamentally flawed because health care is about individuals and inevitably, therefore, about individual choice advised by professional judgment. Doctors and other clinicians have to make individual judgments and their professional expertise is vital in advising patients. It is also required in all aspects of HTA, and it is important that clinicians acknowledge and fulfill these responsibilities.

A system that depends on the sharing of responsibility, in this case between politicians, managers, and professionals, must also share a common set of values. In this respect, we are fortunate in Europe that there is a consensus regarding the importance of equity. Most would subscribe to the values set out by Berg et al. (1), namely that all people are of equal value, that the allocation of resources should be according to need and that resource utilization should be cost-effective.

But inevitably there are tradeoffs between values (15) and these need to be understood if not agreed. For example, further debate is required concerning conflicts between equity and efficiency (20).

## CLINICIANS AND HEALTH TECHNOLOGY ASSESSMENT

From the clinicians point of view, it is important that the advice which emanates from health technology assessment should be accurate, relevant, timely, clear, and accessible. Accuracy must always be dependent on available knowledge and, therefore, subject to constant re-assessment. In this respect, the publication of “Clinical Evidence” by the BMJ publishing group is welcome (2). This publication is now available online to NHS personnel through the National Electronic Library for Health, which itself is also a welcome development (14), and is updated at regular intervals.

Relevance is also important because, as Stevens and Milne discuss (22), there is a risk that the battle for the acceptance of systematic reviews as respectable research may have been won partly at the cost of diminished relevance.

Timeliness is important, if responsibility is to be shared. Clinicians cannot be left in a position of uncertainty when pressed to accept new expensive technologies which have been evaluated or recommended in other countries but not yet assessed in their own countries. A potential example is the treatment of patients with sepsis using activated protein C. Some time ago, clinicians in intensive care in the United Kingdom contacted NICE to ask what they should do if, as seemed likely, this new product was approved in the United States (this has now happened). NICE replied that currently they had no plans to review this product. NICE receives its remit from the Department of Health, and it is important that the processes that determine its priorities act quickly enough to ensure that it can issue guidance for clinicians in good time. At present, there is only one clinical trial supporting the use of activated protein C (10), but, as Padkin et al. point out, one advantage of high-quality clinical databases is that further information can be made available rapidly to support “action research” and supplement the data available from randomized trials (18).

Clarity in the advice provided is important if, as I have argued, responsibility is to be shared. Tension may exist between a remit to both assess and appraise, in other words to bring together systemic review elements and economic evaluation (22). Nonetheless, economic evaluation is important if opportunity costs are to be fully understood. Stevens and Milne (22) illustrate this dilemma clearly in relation to anti-rheumatoid arthritis drugs and the treatment of dementia, along with the potential of some costly new treatments to destabilize public health-care expenditure.

Accessibility is vital. One of my mentors, a distinguished professor of pediatrics now retired, used to keep a textbook

of pediatrics on his desk in his clinic. He had no hesitation in looking up the textbook in front of his patients to answer their questions. Even then, but much more so now, knowledge is about knowing where to get the information rather than trying to remember it. It used to be possible I suspect, to answer most of the questions he was asked from the textbook, but not now. Of course, it is possible when asked a question to which one does not know the answer in a consultation to reserve one's judgment, undertake research, and then re-address the question at the next consultation. But the time pressures on clinicians are considerable, and much more effort is needed to find new ways of dealing with this problem. The new publication, mentioned above, on *Clinical Evidence* (2) is, in my view, a major step forward. It contains not only an appraisal of the evidence but is organized around questions that are likely to arise during a consultation. Maybe this is a pointer to a way forward. In any clinical service, there are several questions which are asked frequently. Answers to these frequently asked questions could be developed in each clinical service, be it in the hospital, the community, or in general practice. The answers could be developed from the various databases modified as appropriate in relation to local circumstances. Clinicians then ought to be able to look up online through their local computer networks these questions, as appropriate, during the consultation. Not everyone can be an expert in everything. Experts need to make their expertise more widely available, and we need to trust their expertise without us being required to validate all their opinions by accessing original sources of information. The experts themselves should take the responsibility to update the users of their opinions as new information becomes available. The task is to make evidence-based medicine utilizable by those who have general responsibilities and little time.

## IMPACT

It is apparent that an enormous amount has been achieved over the past decade in the field of HTA and evidence-based practice. There is now a huge amount of carefully appraised information available throughout a variety of bodies to clinicians and patients. Persuading professionals to change their practice, however, is not so easy, but if we do not always know what does work to change practice, there is now information on what does not (16). To me, the key is in accuracy, relevance, timeliness, clarity, and, above all, accessibility.

Most clinicians want to do the very best they can for their patients, and the professional conscience of the individual clinician is the most important guarantee that a patient can have for the quality of the health care that they receive. However, regular audit of both an individual's practice and the performance of clinical teams is important. New legislation in the United Kingdom will require all doctors to obtain a renewal of their license to practice from the GMC at 5 yearly intervals. Such renewals will depend on the demonstration of an adequate standard of practice through regular appraisal.

One aspect of such appraisals needs to be related to knowledge of HTA and its application to the service provided.

I would suggest that we need to concentrate on what matters rather than marginal issues. Bertolt Brecht wrote in his play *Gallileo*, "The chief cause of poverty in science is imaginary wealth. The chief aim of science is not to open a door to infinite wisdom but to set a limit to infinite error." HTA and evidence-based medicine need to concentrate on making sure that each practitioner knows what does not work and then to eliminate it from practice.

What we must not do is attempt to insist on following guidelines without regard to the individual patient's particular problems or believe that all, or indeed most, patients' symptoms are diagnosable within the cannon of evidence-based medicine. There has been increasing concern about defensive medicine, occasioned by fear of litigation, and we need to be careful that fear of clinical governance procedures and defensive management does not compound this problem. The risk is that clinicians increasingly will be reluctant to do quite ordinary procedures to help patients because of existing guidelines. Recently, I was told that a trained nurse was not allowed to cut a patient's finger nails if the patient was diabetic and that a speech therapist was required to assess whether a patient who was thought to have had a minor cerebral vascular accident could have a drink.

## NEXT STEPS

It is increasingly important that health care is delivered as a partnership between doctors and patients (7). Care is often as important as treatment (12). Patients and the public need to influence HTA and the determination of priorities, not just professionals. Finding new and successful ways of doing this is important for those engaged in HTA.

HTA needs to embrace how services are delivered, not just assess the effectiveness and efficiency of treatments. A health service that is increasingly concerned with the treatment and care of people with chronic disabilities needs to be organized to meet their needs, and we need to know the effectiveness, efficiency, and cost-utility (economy) of the services that are provided. Knowledge of patients' views using qualitative methodology will be needed (8).

Finally, there is the vexed question of cost-utility or economic appraisal. Necessarily, such appraisals are based on averages. A treatment may be shown statistically to provide benefit, but not all who receive it will improve; the "number needed to treat" to obtain benefit for one person is a useful concept. Those who do not will have had to undergo treatment for no benefit and greater or lesser risk, depending on the nature of the therapy, for few treatments are without risk and iatrogenic disease from side effects is common. Some new chemotherapeutic drugs for terminal cancer are of marginal benefit and very expensive (9). Much health-care expenditure is incurred in the last weeks of life. Clinicians deal with individuals, and they need more information concerning patients'

experiences of alternative approaches to management, for example, care and palliation versus active intervention. Again, this will require a qualitative approach and appraisal of the evidence by society at large, not just professionals. HTA needs to increase its scope and ask not only does a treatment work, but which patients will benefit and by how much as well as at what cost. Are there alternatives to treatment, and are they preferable? How are we going to make these alternatives available, and what will they cost? How can we provide patients as well as professionals with the information they need, because finally, it must be their decision, within an overall policy framework.

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