THE POLITICS OF EVIDENCE-BASED MEDICINE IN THE UNITED KINGDOM

Stephen Harrison

English

Evidence-based medicine, the doctrine that professional clinical practice should be based on sound research evidence about the effectiveness of the procedures used, is now official policy for the National Health Service. Despite its obvious common-sense and political appeal, the policy seems to be based on a number of questionable assumptions about implementation, political popularity and scientific consensus, yet accords in general terms with contemporary developments in modes of controlling organisations.

Français

La médecine basée sur la preuve, c'est à dire la doctrine que la pratique professionelle clinicale doit être basée sur les résultats solides de recherche sur l'efficaceté des procédures adoptées, est à présent une politique officielle du Service National de la Santé. Malgré son évidente attraction politique et logique la politique semble être basée sur un nombre d'assomptions questionables sur l'implimentation, la politique populaire et le consensus scientifique, or elle suit en gros les développements contemporains dans les modèles de direction des organisations.

Español

La medicina basada en evidencia, la doctrina de que la práctica profesional clínica debe estar basada en investigación válida sobre la efectividad de los procedimientos usados, es actualmente la política oficial del Servicio Nacional de Salud. A pesar de su sentido común y su atractivo político, esta política parecería estar basada en un número cuestionable de suposiciones sobre implementación, popularidad política y consenso científico, y sin embargo coincide en términos generales con teorías contemporáneas sobre maneras de controlar organizaciones.

Introduction

Evidence-based medicine (EBM) is the doctrine that professional clinical practice ought to be based upon sound biomedical research evidence about the effectiveness of each diagnostic or therapeutic procedure ('intervention' hereafter). It is very much a common-sense aspiration for a healthcare system such as the UK National Health Service (NHS); after all, who wants to be the object of ineffective interventions? It has also, relatively recently, achieved the status of official policy in the NHS. The purposes of this article are threefold: each is the subject of a main section below. The first is to suggest why this

notion has achieved the status of 'an idea whose time has come': that it is rooted in an attempt at an elegant solution to the problem of healthcare rationing. The second is to describe the main elements of the policy itself and the politics which underpin it. The third is to argue that this ostensibly both rational and politically appealing policy has three serious naiveties: in ascending order of abstraction, one in respect of its implementation, another in respect of its political appeal, and the third in respect of its scientific basis. A concluding section briefly addresses the relationship of EBM to contemporary macrotheoretical social analyses.

Solving a problem? Supply, demand and rationing in healthcare

Like the majority of health systems in the world, the NHS is an example of a 'third party payment system', that is one in which the recipients of healthcare do not (or at least not for the most part) pay for it out of pocket at the time of access. Such third party payment systems may be tax-based (like the NHS), social insurance-based, or private insurance-based, but all represent an attempt to socialise the financial risks of ill-health by a pooling of risk and of financial provision. In theory and in practice such systems give rise to two kinds of problem related to demand: consumer moral hazard and producer moral hazard respectively (Donaldson and Gerard, 1993).

Consumer moral hazard may be thought of as an axiom which holds that where the cost to the user of some good is zero, demand for it will tend to exceed supply. Even in a third party payment system, the cost is, of course, never zero; I have to make an appointment to see my GP and perhaps take time off work; I might have to suffer the indignities of waiting in a crowded and chaotic hospital outpatient department; it will hurt when the doctor sticks the needle in me, and at worst I might die or be reduced to a vegetative state as a consequence of the side effect of a drug. So moral hazard is in practice more of a heuristic than a real theory, but it does seem to describe what happens in a third party payment system, many of which are now facing the consequences of demand inflation over time. Such arguments are sometimes countered with the assertion that consumers do not want healthcare for its own sake but only for the improvement that it will bring to health. A neat expression of this counter-argument has been put forward by a health economist:

Patients seek care in order to be relieved of some actual or perceived, present or potential, 'dis-ease'. The care itself is not directly of value; it is generally inconvenient, often painful or frightening. As a thought experiment, one could ask a representative patient (or oneself) whether he/she would prefer to have ... a condition perceived as requiring care plus the best conceivable care for that condition, completely free of

all ... costs, or would prefer simply not to have the condition ... [C] are is not a good in the usual sense, but a 'bad' or 'regrettable' made 'necessary' by the even more regrettable circumstances of 'dis-ease'. It follows that patients want to receive *effective* healthcare, ie, care [in respect of which] there is a reasonable expectation [of] a positive impact on their health! (Evans, 1990: 118–9, emphasis original)

This formulation is inadequate in two ways. First, it is a matter of fact that people sometimes do value care for its own sake, irrespective of its effectiveness. Any general practitioner (GP; primary care physician) has the story of a patient who demands a prescription for antibiotics despite being assured that it will do no good, and the public often value heroic but obviously vain rescue attempts, whether medical or at sea or on the mountains. Second, Evans' reasoning rests entirely on the ability of the relevant social actors to agree upon what constitutes a 'reasonable' expectation of a positive outcome from treatment. It is easy to see that, in fact, such agreement is not always forthcoming, as was graphically demonstrated in the much-publicised case of Jaymee Bowen ('Child B') who was denied a second bone marrow transplant by her local health authority; NHS haematologists and a private consultant differed over the probable effectiveness of such treatment whilst her family felt that any positive probability was acceptable.1

It is difficult to avoid the conclusion that, just as beauty is proverbially in the eye of the beholder, 'goodness' in healthcare, as in other areas of economic activity, is in the eye of the demander. At a general level, it is easy to show that demand for healthcare in the UK is high; a time series of opinion poll answers to the question, 'What is your first priority for additional government expenditure?' shows health consistently at the top, and by a widening margin through the 1980s and 1990s (Jowell et al, 1991). It also seems clear that demand for healthcare expressed through public pressure groups is increasing; well-informed lobbies are able to articulate specific demands for intervention, such as the Multiple Sclerosis Society's demand for

Beta Interferon (see above) or the National Osteoporosis Society's demand for bone densitometry (National Osteoporosis Society, 1994), the measurement of bone density as an assumed predictor of osteoporosis and indicator for treatment with hormone replacement therapy (Effective Health Care, 1992a). The Internet, to which access is increasing, already carries a wide range of websites through which individuals and groups with a shared interest in a particular medical condition exchange information and opinion, a development which is likely to increase direct demand for particular technologies (Coiera, 1996). Finally, in the UK as elsewhere, health issues continue to be prominent in national and regional newspapers and reports of putative new technologies are a significant proportion of such copy.

Producer moral hazard (more usually 'supplier-induced demand') refers to the fact that a great deal of demand for healthcare, not just in third party payment systems, is mediated through the agency of a clinician, usually a doctor. In practice (though the examples of pressure groups cited above are exceptions), patient demand is often unspecific; we go to the GP and explain our symptoms or concerns, but it is the latter who translates our unspecific demands into specific demands for prescription drugs, for x-rays or blood tests, or for a visit to a specialist outpatient clinic at the local general hospital. When we get to the outpatient clinic, it is the consultant (specialist) (or their junior physician) who further translates our initial unspecific demand into more tests, more drugs, surgery or whatever. Supplier-induced demand is not unique to medicine, and is likely to occur wherever the supplier of some specialist good or service possesses a great deal more knowledge than the consumer; many of us are familiar with the proverbial 'sharp intake of breath' with which the mechanic prepares us for the news that our car 'needs' new shock absorbers or the builder announces that our house 'needs' rewiring. Although we cannot lead completely self-sufficient lives (and supplier-induced demand is therefore potentially ever-present), with medicine, as with car maintenance or building, there is the possibility of do-it-yourself, but in the case of medicine our enthusiasm may be somewhat tempered by the recognition that our life or long-term health may

be at stake. In short, we are prone to take the doctor's advice.

With the mechanic or builder, the economic incentives underlying supplier-induced demand are obvious. (This is why it is an example of moral hazard.) In a system in which doctors are paid fees on an item of service basis, the same incentives exist; do more to patients in order to increase your earnings, or perhaps to reduce the number of patients that you have to have in order to reach your target earnings (Hughes and Yule, 1991). In general, however, the NHS does not pay its doctors on this basis, so there must be some other factor(s) to drive supplier-induced demand. The critical one seems to be medical ethics; if, in a third party payment system, your doctor believes that an intervention would be good for you and does not have to worry about whether you can afford to pay for it, then the ethical action to take is to provide, or refer you for, the intervention. From this perspective, supplier-induced demand is moral, rather than morally hazardous, behaviour. The hazard is borne by the third party payer, in the UK the central government and the health authorities who are its agents.² Of course, supplier-induced demand may well also be driven by intellectual curiosity: to research, to see what happens with the treatment and so on.

Thus, in a third party payment system for healthcare demand will tend to inflate over time as a result of the interaction of the factors outlined above. This is not necessarily to assume that demand is literally infinite, but merely to observe from international comparisons that it is possible to expend a much larger proportion of a gross domestic product on healthcare than does the UK (World Health Organisation, 1996) without any obvious natural limit being discovered. Not all patients or potential patients can have all their demands met, so that some demands must be denied, or deterred or deflected or delayed, a process to which I refer as 'rationing' (Harrison and Hunter, 1994; Klein et al, 1996). For an institution such as the NHS which, as noted, is both extremely popular with the public and required by its founding legislation (the 1946 and 1977 National Health Service Acts) to provide a 'comprehensive' service, this necessity is something of an embarrassment, a factor which presumably leads the politicians who are in charge of it to resort to more anodyne language about, for instance, 'prioritisation'.

It has been observed that 'ration' can carry connotations of fairness and having needs met, as in wartime food rationing (Klein et al, 1996), and at the time of writing the King's Fund has launched a major project calling for the notion to be explicitly recognised and addressed (New, 1996). In fact, it is only this explicitness that is new to the context of NHS rationing. In the past, there have been three main rationing mechanisms in the NHS, though they are not always clearly distinguishable from each other. First, GPs have acted as 'gatekeepers' for secondary care; other than through the accident and emergency department and a few exceptional cases such as genito-urinary medicine, there has never been direct patient access to secondary care. Second, there have been waiting lists for hospital care. Third, the 'clinical freedom' accorded to consultants and GPs has allowed clinical judgements of 'need' to be adjustable in the light of available resources. As two American students of the NHS noted,

The British physician often seems to adjust his [sic] indications for treatment to bring into balance the demand for care and the resources available to provide it. (Aaron and Schwartz, 1984: 111)

Thus, there is evidence that, ceteris paribus, a GP's propensity to refer varies inversely with the length of waiting time in the relevant specialty at the relevant hospital (Henderson et al, 1989; 1993), a phenomenon which, incidentally, suggests that government policies aimed at reducing waiting times by speeding up hospital throughput are likely to be self-defeating. More dramatically,

Confronted by a person older than the prevailing unofficial age of cut-off for dialysis, the ... GP tells the victim of chronic renal failure or his [sic] family that nothing can be done except to make the patient as comfortable as possible in the time remaining. The ... nephrologist tells the family of a patient who is difficult to handle that dialysis would be painful and burdensome and that the patient would be more

comfortable without it. (Aaron and Schwartz, 1984: 101)

What is common to all three of these rationing mechanisms is that they are implicit so far as the patient is concerned; he or she simply perceives that they are being treated in accordance with needs 'objectively' identified by the doctor, and perhaps having to wait a little while for hospital attention. They therefore render the process of rationing as it were politically invisible, by fragmenting it across space and time into individualised and private transactions between doctors and individual patients. The result was that the NHS was able to maintain the fiction of meeting everyone's needs, an outcome which, given that rationing is inevitable, ought not simply to be written off as a kind of confidence trick, though such it is; there exist thoughtful defences of implicit rationing (Hoffenberg, 1987; 1992; Mechanic, 1992; Coast, 1997, and for more general discussions, see Calabresi and Bobbitt, 1978; Fishkin, 1979; Elster, 1992) partly based on the observation that the confrontation of such tragic choices is likely to be a brutalising experience for an unwilling public. Moreover, there is ample UK evidence that, when compelled to address the question, the public prefers rationing decisions to be made by doctors (Bowling et al, 1993; Heginbotham, 1993; Bowling, 1996).

But whatever the ethical, philosophical or political merits of implicit versus explicit rationing, the former has become difficult to sustain for a number of reasons. First, clinicians themselves are clearly less willing than before to play the game. One speculation about this, based on suggestive research findings about doctors' concepts of clinical freedom (Harrison et al, 1984) is that it results from their increasing pessimism about continued real growth in NHS resources. It is one thing to make difficult decisions in the belief that things will be better next year, another when the perceived prospects (which are what count in this sort of analysis) are for the worse. Second, challenges to medical autonomy have been a consistent feature of government policy for the management of the NHS since the early 1980s. Whilst academic analysts have tended to interpret the research evidence as showing that NHS management has not (or not yet) become what Alford (1975) terms the 'dominant interest', they do agree that the frontier of control between the two occupations has shifted somewhat in the direction of the latter (Flynn, 1992; Harrison and Pollitt, 1994). Third, aspects of the NHS reorganisation of 1991 along the lines of a 'purchaser-provider split' have gone some way towards institutionalising a body (the health authority) one of whose functions is to make explicit decisions (Harrison, 1991). Hence, there has been considerable discussion about whether or not in vitro fertilisation and cosmetic plastic surgery of various kinds should be available on the NHS (Harrison and Wistow, 1992) together with media saturation coverage of refusals to provide Interleukin 2, an experimental cancer drug (Freemantle and Harrison, 1993) and a second bone marrow transplant for Child B (see above and New, 1996).

The policy response: evidence-based medicine and its politics

Explicit rationing, whether or not described as such, implies that policy must provide answers to two questions. Who shall make rationing decisions? And what criteria will such decisions be based upon? It is evident from the preceding analysis that, from the point of view of politicians and other policymakers, there is considerable attraction in leaving the decisions to doctors; their legitimacy for such a role as perceived by the public, the controversy which has accompanied managerial attempts to fulfil the role, and the perception that a politician's involvement can only be a vote-loser are highly persuasive factors. Yet it remains necessary to persuade doctors to cooperate in circumstances where, as noted above, there has been increasing reluctance to do so. The recent conversion of the government to the notion of EBM has provided both a potential means for securing the involvement of doctors and an answer to the question of 'what criteria?'

At its simplest, the doctrine of EBM holds that the appropriate criterion for the provision of an intervention, either in the NHS generally or in the treatment of an individual patient, is its effectiveness (or efficacy; see Harrison and Long, 1989 for a discussion) as demonstrated by biomedical research evidence. This is now manifest in formal policy for the NHS; in 1993 health authorities were asked to begin to identify

interventions of which they would in future purchase more and less, on grounds of effectiveness and ineffectiveness respectively (NHS Management Executive, 1993). Some authorities chose the insertion of grommets (a treatment for children with otitis media – 'glue ear'), and dilatation and curettage ('D and C': a treatment for dysfunctional uterine bleeding) for women under the age of 40 as their candidates for the 'purchase less' category (see also Klein et al, 1996). Both procedures had been the subject of well-publicised academic reviews questioning their value (Effective Health Care, 1992b; 1995). Current official policy on EBM holds that,

The overall purpose of the NHS is to secure, through the resources available, the greatest possible improvement in the physical and mental health of the people ... In order to achieve this, we need to ensure that decisions about the provision and delivery of clinical services are driven increasingly by evidence of clinical and cost-effectiveness, coupled with the systematic assessment of actual health outcomes. (NHS Executive, 1996a: 6)

This line of policy has been supported, at some expense, by two types of related development in the NHS. First, there has existed since 1991 a national research and development (R and D) strategy for the NHS, involving the creation of national and regional directors of R and D, the establishment of national and local research budgets to be the object of competitive bidding, and reorganisation of the flow of research funds through NHS hospitals (Department of Health, 1991; Task Force on R and D Funding, 1994; for a general review, see Baker and Kirk, 1996). The central objective of this strategy was to disaggregate the large proportion of health interventions stated never to have been the subject of proper evaluation into two categories: the effective and the ineffective. Second, a range of specialist institutions has been funded as the means of reviewing, collating and disseminating the findings of effectiveness research to the NHS; these include the Cochrane Centre at the University of Oxford; Effective Health Care bulletins coordinated from the University of Leeds, the NHS Centre for Reviews and Dissemination at the University of York and the Outcomes Clearing House at the University of Leeds.³

Two key theories underlie this whole strategy. The first defines 'sound evidence', that is, that which may be relied upon to contribute to the classification of an intervention as effective or ineffective, as evidence derived from studies conducted in a certain way held to be 'scientific'. This approach is typified in the influential 'hierarchy of evidence' proposed by Canadian academics (and later modified in various ways) but widely cited as an authoritative definition of the soundness of scientific research purporting to demonstrate the effectiveness of medical and similar interventions. The hierarchy is displayed in Table 1.

Table 1: The hierarchy of evidence

Level of validity of findings	Type of research
	Strong evidence from at least one systematic review of multiple well-designed randomised controlled trials
	Strong evidence from at least one properly designed randomised controlled trial of appropriate size
111	Evidence from well-designed non- randomised trials, single group pre-post, cohort, time series or matched case- controlled studies
IV	Evidence from well-designed non- experimental studies from more than one centre or research group
V	Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees

Source: Canadian Task Force, 1979

The principle which underpins this hierarchy is validity, that is the elimination from research findings of bias arising from any differences between patients treated by means of the intervention being researched and patients not so treated (that is, treated with other interventions or simply not treated). The pinnacle of the hierarchy is occupied by the randomised controlled

trial (RCT) in which patients are conscientiously allocated randomly (and with the patient's informed consent) between the group which will receive the intervention under investigation and whatever group(s) with which they will be compared: 'control' groups receiving perhaps placebos, or no treatment, and/or existing conventional treatment, as the case may be. Ideally, it is held, RCTs should be 'double blind', that is neither the treating clinician nor the patient should know which intervention they are receiving. This ideal cannot of course always be met; for instance it is hardly possible to conceal whether or not surgery is occurring or ethically to perform a dummy operation.4 Special methods, described as 'meta-analysis', have been developed in order to aggregate the results of several RCTs (Mulrow, 1994). Other research methods are ranked lower in the hierarchy, with other types of controlled study second to the RCT and uncontrolled methods a poor third; in practice, advocates of RCTs tend to regard uncontrolled methods as suitable only for hypothesis-building with a view to an eventual controlled study.

The second key theory upon which EBM is based is that the most useful, though not necessarily exclusive, method for disseminating sound research evidence as defined above to practising clinicians is the 'clinical guideline' (NHS Executive, 1996b); clinicians can clearly not be expected to read every research study relevant to their practice as it is published. The logic of guidelines is essentially algorithmic, that is, it guides its user to courses of (diagnostic or therapeutic) action, dependent upon stated prior conditions: 'if ... then' logic. The logic is also normative, that is it tells the clinician what ought to be done. In general, guidelines do not claim to determine clinical action completely, and degrees of discretion are left.

The doctrine of EBM is of course by no means new and indeed the attempted popularisation in the UK of the notion that randomisation between comparison groups is a crucial means of avoiding bias in biomedical outcomes research dates from Professor A.L. Cochrane's seminal Rock Carling Lecture of 1971, published the following year as Effectiveness and efficiency: random reflections on health services (Cochrane, 1972). As is often the case with ideas, Cochrane's central

insight took a long time to become officially, or widely, accepted. As also is often the case, it was probably changes in social and political context which were more important in allowing the widespread acceptance of the idea than any intrinsic 'rightness' (Kingdon, 1984). It seems unlikely that in the early 1970s, a time when NHS resources underwent rapid growth in real terms (Klein, 1983: 67-8), Cochrane had any concern to provide the tools to solve a policy problem of rationing. Indeed his main concerns were for what he saw as the genuine progress of science towards truth and for the avoidance of subjecting patients to ineffective (and therefore in his analysis, unnecessary) interventions. He was fiercely critical of the NHS in this second respect:

I once asked a worker at a crematorium, who had a curiously contented look on his face, what he found so satisfying about his work. He replied that what fascinated him was the way in which so much went in and so little came out. I thought of advising him to get a job in the NHS, it might have increased his job satisfaction ... (Cochrane, 1972: 12)

Cochrane's ideas, 20 years on, serve both to provide criteria for health services rationing and to legitimate those criteria. Of this process we can ask the traditional question of political analysis, cui bono? Who benefits?

First, as is clear from what has been said above, EBM offers a solution to the particularly difficult political question of how to manage supply and demand for healthcare. The state (or the government, depending on one's theoretical presuppositions) is therefore a potential beneficiary. Although it is logically possible, as advocates of EBM regularly point out, that EBM might reveal the effectiveness of interventions and thereby increase demand, policymakers do not in practice seem to believe this to be likely; the retiring national NHS Director of R and D has been quoted as claiming that the implementation of research findings in clinical practice might save £1 billion per annum (Timmins, 1996). Not only does EBM offer a solution, but a solution which diffuses the responsibility for potentially unpopular decisions (Klein, 1983:

140) by their delegation to doctors. This is important for the political acceptability of rationing; in line with the general occupational status of doctors and the high public esteem in which they are held (for opinion poll data on these matters, see Harrison, 1988: 88-9; MORI, 1993), it was noted above that several studies have shown that the medical profession is seen by the public as by far the most legitimate actor in making rationing decisions. It is also the case that the NHS R and D strategy is in part a response to a report by a parliamentary Select Committee which saw medical research as an important component of the UK economy (House of Lords Select Committee on Science and Technology, 1988); there is therefore an implied economic benefit in EBM.

Second, the medical profession also benefits in that it retains a monopoly of clinical decision making, thus helping to protect itself from the managerial challenges referred to above. (As will be seen in more detail below, it does however entail a shift of influence between different sections of the profession: away from the clinical practitioner and towards the academic/epidemiologist/health services researcher; see also Harrison, 1997.) It is also clear that the pursuit of EBM is defensible in the terms of traditional medical ethics; only a minority of clinicians seem to claim that they regularly undertake every healthcare intervention that might benefit the patient (Harrison et al, 1984). Moreover, although some commentators (see below and, for instance, Williams, 1985) have sought to extend its scope into the cost-effectiveness of healthcare interventions, its most prominent advocates insist that it is only concerned with effectiveness (see for instance, Sackett et al, 1996). There is a sense therefore in which EBM offers an accommodation between Alford's (1975) most powerful 'structural interests': the 'professional monopolists' and the 'corporate rationalisers'. The rationalisation is delegated to the monopolists, a tendency which may perhaps be read as the beginnings of a restructuring of the health policy field into new divisions.

Third, EBM can be made to appeal to the public and to potential patients. The approach draws on 'science' and all its modernist trappings of truth, progress and so on; it can therefore be presented as rational and politically neutral. Moreover, and despite the science, the rather neat

thought experiment on this proposed by Evans shows that it can also be presented as common sense: what is the point of ineffective healthcare?

Overall, EBM and the interpretive flexibility which it offers provide an elegant resolution of the problem of matching demand for healthcare technologies to the level of resources available. Like clinical autonomy (Harrison, 1997), the main actors can all see something in it (albeit different things) for themselves.

Some current issues for evidencebased medicine

However, any policy has problems of its own and this section reviews three that are central to EBM: the weakness of the assumptions which underpin the use of guidelines as the main mode of implementing EBM; the existence and advocacy of various criteria for rationing which rival effectiveness; and the existence of epistemologies (theories of knowledge) which rival the one upon which RCTs are based.

Implementing evidence-based medicine

The choice of clinical guidelines as the main vehicle for implementing EBM is, at one level, a logical one; it is obviously unrealistic to expect the average busy clinician to read and understand all research papers relevant to their own sub-specialty, discriminate between acceptable and inadequate research methods, interpolate findings with existing knowledge, and modify routine clinical practice accordingly. At another level, however, it is an assumption which is extraordinarily naive; it is hard to imagine another policy arena in which what amount to a set of bureaucratic rules (the phrase is used in a technical, not pejorative sense) would be thought to be self-implementing. Yet this is effectively the approach which has been taken in most research to date on this topic: essentially as an issue of communication with studies mainly focused upon dissemination strategies.

There are substantial, and highly consonant, research findings available (for reviews, see Mugford et al, 1991; Haines and Feder, 1992; Russell and Grimshaw, 1992; Greco and Eisenberg, 1993; Grimshaw and Russell, 1993; Effective Health Care, 1994). In summary, these conclude that most effective in changing behaviour is likely to be the patient-specific reminder

aimed at the specific clinician (perhaps through casenote markers or on-line prompts) at the time of treatment. Less, though still positively, effective is patient-specific feedback (perhaps through audit, continuing education, or 'preceptorship') from an educationally influential person or 'product champion'. The less clinician-specific and patient-specific the communication, the less effective it is likely to be in changing behaviour; general mailings and academic papers fall into this category.

Communication is, of course, a necessary condition for implementation of a policy such as EBM, but it is not a sufficient condition. Drawing on the logical approaches to the administration and implementation of public policy proposed by Hood (1976) and Gunn (1978), it is possible to outline a number of other necessary, though individually insufficient, conditions. These are as follows. (For a fuller account, see Harrison, 1994.)

Adequate resources: implementation clearly depends on the clinician's access to the material resources required for conformity to the guideline: drugs, equipment and so on. But non-material resources are essential too. Critical examples are skill and time and I shall give just one example to cover both. In the surgical treatment of rectal cancer, there is substantial evidence (MacFarlane et al, 1993) that the success of curative (as opposed to palliative) operations, measured in terms of non-recurrence locally, is heavily dependent on surgical technique. 'Total mesorectal excision', that is the precise sharp dissection of a specific plane of tissue, requires both particular surgical skills and substantially more theatre time than the standard operation. More generally, time requires trade-offs against other activities and it is not surprising that there is some evidence that clinicians consider time involved in audit activity to be less effective than seeing more patients (Black and Thompson, 1993). Even more generally, there is a recurrent theme in the sociology of the caring professions which explains 'corner cutting' behaviour, such as hasty diagnosis or the 'labelling' of clients, as an inherent and inevitable response to scarcity of time (Lipsky, 1980).

Incentives: it is clear that one cannot simply assume that communication of a guideline provides sufficient incentive for a clinician to

comply with it. Intrinsic incentives might include the source of the guideline's being seen as authoritative; there is some evidence that locally-determined guidelines are more likely to be seen as such (Brook, 1989; Russell and Grimshaw, 1992), even though it might be expected that nationally-determined ones would be the most technically expert. Otherwise, little seems to be known about intrinsic incentives, though there are, at the time of writing, a number of ongoing studies into the role of 'opinion leaders' and into the possible impact of 'academic detailing' (that is, marketing preferred clinical practice to individual doctors in much the same way that drug companies market their products by face-to-face contact). Extrinsic incentives such as economic rewards can also be considered. UK experience with target payments for general practitioners (GPs) suggests that payment does affect behaviour, though Hughes and Yule's (1991) study of GPs' work/wage relationship suggests caution in assuming that doctors will do more in response to monetary incentives; indeed there is some evidence of a 'target income' phenomenon and hence a backward-sloping supply curve.

Disincentives: whatever incentives exist for compliance with guidelines may, of course, be wholly or partly offset by disincentives. Again there is little systematic knowledge, though it seems that covert organisational imperatives can often subvert ostensible policy (for an example from industry, see Brewster et al, 1981). Thus one UK study found that clinicians were prepared to manipulate audit results by modifying casenote entries to maintain the appearance of reaching targets, as well as a pervasive view that audit would have adverse consequences for the practice of medicine by routinising it and destroying both initiative and the ability to think through the logic of treatment (Black and Thompson, 1993). Melia's (1987) well-known study of nurses' work on the wards showed that they might actually be punished for practising what they had been taught in the school of nursing!

Coordination: a good deal of the literature about clinical guidelines makes the implicit assumption that what matters is the diagnostic and therapeutic behaviour of individual clinicians. Given the intellectual origins of much guidelines work in the puzzle of medical practice variations

(Andersen and Mooney, 1990), this not surprising. Yet it may be misleading; in practice the success of healthcare can depend on whole teams or chains of health workers performing the correct tasks correctly. This is particularly true in nursing care, where the 24-hour commitment multiplies the scope for error and omission, and community care, where multi-agency, multi-professional working has the same effect. The formal mathematics are gloomy; on the relatively optimistic assumptions that a chain of 10 health workers is involved in flowing a guideline for a particular patient, and that there is 0.95 probability that each will fully comply, the total probability of the patient getting precisely the care specified is 0.95 to the power 10, or little better than evens! This calculation, however, departs from what occurs in the real world in that it assumes that the compliance probabilities for each individual worker are independent. This is unlikely to be the case; people's behaviour is usually affected by the social (in this case, workplace) context in which they find themselves. Expressed differently, an important factor in guideline compliance is likely to be organisational or workplace 'culture', a concept which has been widely analysed in general (see, for instance, Allaire and Firsirotu, 1984; Meek, 1988) but not so far applied to the particular question under discussion.

Overall, the attention which has so far been paid to the problem of implementing EBM has been partial. It is clearly not sufficient to treat it as solely a matter of communication.

Rival criteria for rationing

The attractions of effectiveness as a criterion for rationing are obvious. First, we can refer once more to Evans' formulation cited above; it can seem (or be made to seem) ludicrous to suggest that anyone might want ineffective care, even though we have seen that it is not uncommon to find disputes about what is the probability of an intervention's being effective, and about who is authorised to determine it (Freemantle and Harrison, 1993; New, 1996). A policy of effectiveness implemented through EBM promises authoritative answers to both kinds of dispute. Second, it allows the rationing process to be defended as the authority of 'science'. Third, it leaves the decisions in the hands of doctors

which, as noted above, concords with public preferences. (As the next main section notes, however, it is with a different group of doctors from before: academics, epidemiologists and health services researchers.) But there remain other rationing criteria which have their attractions too. Without any claim to be exhaustive this section describes four (Harrison and Hunter, 1994): the 'rescue principle'; entitlement; costutility; and equity.

The rescue principle: this term was coined by the American philosopher Ronald Dworkin to refer to the belief that the moral imperative of medicine is to attempt to help those who are acutely ill or whose lives are threatened (Dworkin, 1994; see also Boyd, 1979). The moral content of such action is in the process (hence 'attempt') rather than in the outcome. Although the application of such a principle clearly implies potentially significant opportunity costs (since others may suffer whilst resources are expended on hopeless cases) it is one which seems to receive wide support in public policy generally, underpinning as it does such services as air/sea rescue and mountain rescue. I have a cartoon in which a coastguard is answering a distress call with the words, 'Stay with your boat Sir, whilst the Secretary of State decides how important you are.' It is far from obvious that such an outrageous suggestion would become any less outrageous by the substitution of, 'Stay with your boat Madam, whilst the coastguard calculates whether the probability of getting to you in time is high enough to make it worth bothering.' Whatever its internal incoherences or unsought consequences, the rescue principle is one to which people subscribe. It is also the ostensible moral basis of medicine; as the British Medical Association's Handbook of medical ethics puts it:

Within the [NHS] resources are finite and this may restrict the freedom of the doctor to advise his [sic] patient ... [and thus] infringes the *ordinary* relationship between patient and doctor ... The doctor has a general duty to advise on equitable allocation and efficient utilisation [but this] is subordinate to his professional duty to the individual who seeks his clinical advice. (British Medical Association, 1980: 35, emphasis added)

Entitlement: strictly speaking (and in contrast to the detailed statutory provision for social security) UK citizens have no rights to publicly-financed healthcare. Rather, the legalities are accomplished via the Secretary of State's statutory duty to provide a comprehensive health service. As a consequence, litigation in pursuit of treatment typically takes the form of an action against the Secretary of State (or their agents, the health authorities) for breach of statutory duty. Courts have been generally unsympathetic to plaintiffs in such cases (Dimond, 1993), but this does not mean that people do not see themselves as having rights to treatment irrespective of calculations of effectiveness. Denied arterial surgery on the ground that his continued smoking increased the risks of treatment and reduced the probability of benefit, a 62-year-old Wakefield man was quoted as saying:

I have worked since I was 14 up until recently and paid a hell of a lot in taxes to the government both in income taxes and on the 40 cigarettes a day I smoked. Surely it is not too much for me to ask to have an operation that might ease my pain in my old age and make me live a little longer. (Yorkshire Evening Post, 26 August 1993: 1)

Cost-utility: unlike effectiveness, which provides no formal basis for making comparisons between different interventions for different diseases, cost-utility analysis both provides a lowest common denominator concept in terms of which the outcome of any intervention may be assessed and provides for the calculation of the unit costs of producing such outcomes. The best-known operationalisation of this outcome measure is perhaps the Quality-Adjusted Life Year (QALY, for a straightforward account of the basic calculation of which see Gudex, 1986), but the World Bank used the Disability-Adjusted Life Year (DALY) in its recent review of world health (World Bank, 1993) and there is at present increasing interest in the EUROQOL which aims to support cross-national measurement of quality of life (EUROQOL Group, 1990).

Despite a number of technical problems (see, for instance, Mooney et al, 1992; Drummond et al, 1993; Gerard and Mooney, 1993) this

approach possesses a good deal of technical appeal due to its culmination in a 'league table' of healthcare interventions, from which policymakers can in theory maximise the health outcomes from any given level of expenditure. Indeed it was this approach that formed the core of the well-known 'Oregon formula' applied to the determination of Medicaid priorities in the eponymous US state (Kitzhaber, 1993).

Equity: may be defined as equal treatment for persons with equal need. There is a sense in which increasing the degree of equity with which healthcare is distributed in a society forms the rationale for any system of third party payment, whether tax-based, social insurance or private insurance. In other words, such systems pool resources and spread risks so that (to a varying extent in different systems) people can receive healthcare when needed without immediate outof-pocket payment of the full cost. In practice, equity can be extremely difficult to operationalise according to a single definition, since there are options about whether it is the distribution of resources, healthcare interventions or health outcomes that are taken to be important, as well as options about the social dimensions of inequity (race, class, gender, locality) which are held to be policy priorities (Harrison and Hunter, 1994).

It is not necessary to go into great detail about these rival criteria or their strengths and weaknesses (see Harrison and Hunter, 1994 for a review); rather, the thrust of the present argument is that these criteria exist and have their supporters so that it cannot simply be taken that the criterion of effectiveness which underpins EBM commands predominant support. Moreover, the different criteria are in many cases mutually incompatible. Thus there may well be a trade-off between cost-utility (which is concerned with maximising total health gain) and equity (which is concerned with distribution). Some of the criteria (effectiveness, cost-utility and some interpretations of equity) are instrumental, that is treat healthcare as a means to an end, whereas others (the rescue principle, entitlement, and other interpretations of equity) treat it as at least partly an end in itself.

Rival epistemologies

The epistemological underpinnings of randomised controlled trials and meta-analyses

which, as we have seen above, form the basis of the EBM movement are in fact not necessarily identical with the way working clinicians think about evidence of effectiveness. This has recently been examined in a small-scale, but important American study of clinicians (Tanenbaum, 1994). In her study, Tanenbaum contrasts the traditional biomedical model of research, which is based in laboratory methods, with that entailed by RCTs. This contrast is summarised in Table 2.

Table 2: Alternative epistemologies in medicine and research

Traditional biomedical/ laboratory research	
Reveals cause—effect mechanisms (via aetiology, pathology etc)	Demonstrates statistical relationships from past experience
Provides knowledge of what ought to be effective,	Provides knowledge of what is likely to work, irrespective of why and why
Based on deterministic models	Based on probabilistic models
Underpinned by realist/ naturalist epistemology	Underpinned by empiricist/ positivist epistemology
Espoused by working clinicians	Espoused by epidemiologists and health services researchers

Source: Adapted from Tanenbaum, 1994

For the sake of contrast Table 2 presents the two epistemologies as ideal types, though in the real world it seems unlikely that many clinicians are not influenced by elements of both. The point, however, is that in the last analysis it is the traditional model that predominates in medical decision making. (In contrast, as Table 1 above makes clear, the health services research model places clinical observations at the bottom of the hierarchy of evidence.) The traditional model, taught to and espoused by clinicians, relies on the discovery of cause-effect mechanisms by the observation of the way in which disease processes develop over time and impact upon normal physiological processes. Treatment is therefore very much a logical process of intervening in the aetiology (natural history) of a disease so as to arrest, reverse or retard it. Expressed in more philosophical/technical terms, the model is deterministic (that is, it assumes that clinical events necessarily have causes which can be identified and, in principle, modified) and realist or naturalist (that is, it entails a belief in a world of objectively real entities whose nature can be observed).

The outcomes/RCT model is the foundation of epidemiology and the relatively new discipline of health services research. It consists primarily of the *inference* of cause-effect relationships from past statistical relationships between treatment and outcomes. It is therefore less concerned with disease processes than with establishing what interventions are *likely to be effective*, *irrespective of why*. In technical philosophical language, the model is therefore *probabilistic* (that is, one where the cause-effect relationships are inherently uncertain) and *empiricist* (that is, one where knowledge can only justifiably be derived from past experience).⁵

A very practical consequence of these apparently rather abstruse observations is that clinical doctors are more likely to be influenced in their practice by their own (and close colleagues') experience with similar types of patient, and by their own reasoning about treatment logic, than by the publication of meta-analyses of large numbers of cases. This, of course, is highly consonant with the individualistic ethic of the practice of medicine and the habit of doctors of being influenced by their own experience of single cases, a habit that is reflected by the occasional column in the *British Medical Journal* entitled 'A memorable patient'.

Concluding remarks: meso- and macro-level perspectives

The above analysis has been mainly concerned with the meso-level of politics, with occasional references to the micro. It might be summarised as having identified three main areas of naivety built into current policy for EBM. First, the attention so far paid to the problem of implementing EBM has been partial; it is clearly not sufficient to treat it as solely a matter of communication. Second, it is not uncommon to find disputes about what is the probability of an intervention's being effective, and about who is authorised to determine it; EBM is as much a social and political artefact as a scientific or technical one. Third, alternative criteria for rationing

exist and have their supporters; it cannot simply be taken that the criterion of effectiveness which underpins EBM commands predominant support. Moreover, the different criteria are in many cases mutually incompatible. Thus there may well be a trade-off between cost-utility (which is concerned with maximising total health gain) and equity (which is concerned with distribution). Finally, it is not the outcomes/RCT model of knowledge, but rather the biomedical/laboratory one which is consonant with the individualistic ethic of the practice of medicine and the habit of doctors of being influenced by their own experience of single cases. The outcome of the policy of EBM remains to be discovered empirically. From a meso perspective, its chances look slim; all the above naiveties amount to the assumption of a consensus where there is none. From a more macro perspective, there is a sense in which EBM looks like a project which runs against the tide of the times: a late flowering of Fordism in a post-Fordist world, a blossoming of rationalism in a postmodern world. To address whether this is the case requires separate consideration of these two view points.

First, post-Fordism: it has been argued elsewhere (Harrison, 1988: 110-1) that, whilst elements of the welfare state such as the NHS are important legitimators of the capitalist state, one should not assume a linear relationship between expenditure and the degree of legitimacy which it provides. Thus, 'cutting out waste' by means of the managerialist solutions applied to the NHS during the 1980s (Harrison et al, 1992) can be seen as one method for sustaining its legitimation function whilst controlling expenditure: a Fordist labour process applied, as it were, to the production of legitimacy and hence constituting a Fordist mode of regulation (Lipietz, 1992). Whether seen as labour process or mode of regulation (Jessop, 1992), post-Fordism does not however seem to entail the complete abandonment of Fordist methods; Hoggett (1990: 4) cites the familiar example of McDonalds, and Harrison et al (1992: 14-5) have noted the strong Fordist elements in the Griffiths general management reforms of the NHS which began in the mid-1980s, and have argued that they may well be a necessary condition for the more obviously post-Fordist developments of the purchaser-provider split. Rather, as Hoggett also notes, the core of post-Fordism is its rejection of the notion that there is a single 'best way' of production: mass production by an integrated organisation. In its place is "the progressive decentralisation of production under conditions of rising flexibility and centralised strategic control" (Hoggett, 1990: 5; see also Hirst and Zeitlin, 1992). Given that the production of personal medical/health services is necessarily decentralised to individual clinicians (and, as noted above, that flexibility has already been enhanced by the creation of the purchaser-provider split), it might be expected that post-Fordist change in the NHS would entail the assertion of greater strategic control over medical production. Indeed, as the NHS becomes more flexible, with production increasingly delegated to general practice and similar settings (the so-called "primary care-led NHS"; NHS Executive, 1995), such control may be seen as even more inevitable. Moreover, in principle at least, the algorithmic guidelines which, as has been seen, form a core element of EBM are capable of computerisation, a key strategy of post-Fordist control. Without assuming that it represents the only possible dimension of such strategic control, it is nevertheless clear that EBM is comprehensible as an element of the post-Fordist mode of regulation, and is in this sense not out of its time.

Whilst post-Fordism and postmodernism have a number of insights and observations in common (flexibility and the rejection of single 'best ways' are key examples) they imply fundamentally different epistemologies, a factor which makes the postmodern perspective much more inimical to EBM than is post-Fordism. Postmodernism's strong element of constructivism or epistemological relativism (Fox, 1993) is radically different from the philosophical realism which underpins both the naturalist and the positivist epistemologies outlined above. Postmodernism implies rejection of the unique truth claims of EBM. Indeed, it is often seen as a threat to medicine as a whole (see, for instance, Hodgkin, 1996), or more broadly to science as a whole. The proponents of the latter, unsurprisingly, have begun to defend their enterprise against this threat, for example, by the proliferation of academic posts in the 'public understanding of science' (Levinson and Thomas, 1997). EBM therefore has the prospect of

becoming an additional component in this defence of science, thereby adding a further dimension of dissensus to an ostensibly commonsense policy.

Notes

- 1. For details of this case, see New, 1996.
- 2. Health authorities are the official bodies responsible for identifying and prioritising the healthcare needs of a geographically-defined local population and for purchasing services accordingly; for a brief account of this 'purchaser-provider split' in UK healthcare, see Harrison, 1991.
- 3. For a full list, see NHS Executive, 1996a.
- 4. For a detailed account of this method, see Elwood, 1988: 96–101.
- 5. For brief accounts of all these terms, see Bullock et al, 1988; for a more substantial discussion, see Hammersley and Atkinson, 1995; for a basic health services research approach to causal analysis in medicine, see Elwood, 1988.)

Acknowledgements

The author is indebted to two anonymous referees for helpful comments and to Messrs KPMG for financial support.

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Stephen Harrison Reader in Health Policy and Politics, Nuffield Institute for Health, University of Leeds, UK