



## Priority Setting and Evidence Based Purchasing

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**Abstract.** The purpose of this paper is to consider the role that values play in priority setting through the use of EBP. It is important to be clear about the role of values at all levels of the decision making process. At one level, society as a whole has to make decisions about the kind of health provision that it wants. As is generally accepted, these priority setting questions cannot be answered by medical science alone but involve important judgements of value. However, as I hope to show values come into priority setting questions at another level, one not often explicitly recognised in much of the literature: that of the very definition of the effectiveness of treatments. This has important consequences for patient care. If we do not recognise that the effectiveness of a treatment involve subjective elements – a patient's own assessment of the value of the treatment – then this could lead to the belief that we can purchase *one* treatment that is the most effective for *all* patients. This might result in a detrimental reduction in the range of options that a patient is given with some patients not receiving the treatment that is most effective for them.

**Key words:** priority setting, evidence based purchasing, values, ethics, effectiveness

### Introduction

In recent years evidence based purchasing (EBP) has become the predominant means by which health priorities are decided. This paper considers its role in prioritising which treatments the health service should provide. The central theme is an examination of what role values play in a process which is sometimes couched in the language of science and objectivity. By values I mean both ethical considerations – what is right or wrong – and also values, in terms of personal and/or institutional preferences.

In discussions of EBP the medical literature does not often explicitly discuss the role values play. However, this lack of discussion does not mean that values themselves are absent from the decision making process. All the EBP literature sometimes contains explicit, but more often implicit, assumptions about the role that values play, or don't play, in the use of medical evidence. These assumptions can be usefully divided into three broad philosophical positions which I have called scientism, the mixed strategy, and the evaluative position.

In the first position, scientism, values have no role to play. The medical evidence is used to provide the basis for any purchasing decision – only those treatments that are effective will be purchased and effectiveness can be determined scientifically. In the second position, the mixed strategy, the research evidence provides scientific, objective evidence about which treatments are effective. The decision making process is seen to comprise two elements, the objective evidence of effectiveness and the values of those making the decision. This is often called evidence based decision making. In the third position, values come into the very definition of effectiveness itself. Clinical trials produce factual data and whether or not that data is judged to indicate effectiveness is a value judgment – an interpretation of the data. It is my contention that there can be a disjunction between the way the medical literature portrays the role of values in decision making and priority setting and the role they play in practice. It is the central aim of this paper to consider each of these philosophical positions to see which of them best reflects the role that values actually play in the everyday practice of EBP.

I shall first outline the policy initiatives which have led to the adoption of EBP by the health service as a means of setting priorities. I shall then examine the three philosophical positions in turn. I argue that scientism, a position often implicit in some of the policy statements about EBP, is untenable and does not reflect the role that values actually play in medical practice. I go on to consider the mixed strategy position. This reflects the way many practitioners and purchasers think about these issues, but although it is recognised that values play an important role, this position fails to recognise the role values play in the very definitions of effectiveness. Finally I examine the evaluative position, in which values come into the very definition of effectiveness, and argue that this most accurately reflects the role values play in the practice of EBP.

### **Health Care Practice and Policy Decisions**

In 1991 the NHS Executive began a research and development strategy for the NHS. The main aim of this policy is to approach the problem of scarce resources by seeking a rational basis for health care expenditure, ... “to create a knowledge-based health service in which clinical, managerial and policy decisions are based on sound information about research findings and scientific developments” (NHS Executive, 1998: 1.1). This knowledge base will be used to inform decisions and concentrate purchasing on effective and cost effective treatments. Thus, effective treatments will be prioritised and ineffective treatments eliminated from purchasing plans.

This process is, as yet, at a rudimentary stage: many health care interventions are untested and there are still time lags and entrenched difficulties in making sure that the most up to date research evidence is actually used in medical practice (Stocking, 1995). However, the rationale behind EBP is that, research evidence permitting, the most effective treatments can be identified and then used in practice.

The purchasing of grommets is a good example of how this policy has worked in practice. Grommets are a treatment for glue ear, a condition in which fluid builds up behind the ear drum sometimes severely affecting the patient's hearing. It was treated by inserting grommets, small tubes, into the eardrum to drain the fluid. The insertions were carried out under general anaesthetic and usually did not involve an overnight stay. Grommets were routinely used for treating glue ear until a document, *The Treatment of Persistent Glue Ear in Children* (Effective Health Care, 1992), reported that the evidence indicated that grommets were used too indiscriminately and too early, as half of cases clear up without treatment in three months and another quarter in six months. In light of this evidence grommets ceased to be a prioritised treatment for glue ear. The number of operations was significantly reduced, thus saving money which could then be redirected to other health care priorities.

I shall now examine the three philosophical positions that I think can be found in the medical literature and consider whether I think they represent the role that values actually play in practice.

### **Scientism**

It could be argued that by using such a scientific methodology to make purchasing decisions values can be eradicated completely from the whole purchasing process. There is an implicit strand running through the literature that by using such tools in priority setting, decisions will be made on a more objective basis. Book titles such as *The Scientific Basis of the Health Service* conjure up images of a value-free utopia. It is easy to suppose that, as the evidence of effectiveness is improving and medical science is progressing, we are increasing our knowledge base and thus decreasing the need for values. Medicine in both clinical practice and research is concerned with establishing the facts of the matter and scientific method is often thought to be defined by impartiality and objectivity. "It is the objective nature by which the EBM paradigm approaches the question of 'what are we doing' and 'how can we do better' that causes health care providers and funding agencies to increasingly adopt this paradigm as a primary principle" (Cooper, 1996: 778). Thus, in the literature scientism is sometimes implicitly held. I shall first outline

this position and then argue that it is untenable and does not reflect medical practice.

The scientist position is based on two underlying assumptions. First, that there is rigorous evidence available on which to base treatment decisions. The evidence itself is held to be objective in the ontological sense, that is to say it exists independently of any perceptions people may have of it and hence is a more accurate picture of reality. Second, that by a clearly defined scientific process, that is non-subjective and not open to individual interpretation, it is possible to gain access to this objective evidence and hence use this evidence to make an objective clinical decision.

These assumptions are based on a realist view of the world, which is broadly the belief that reality exists independently of us and our perceptions of it and that if we employ the right methods we can have knowledge of this reality. Papineau says that realism can involve the conjunction of two theses, “(1) *an independence thesis*: our judgements answer for their truth to a world which exists independently of our awareness of it; (2) *a knowledge thesis*: by and large, we can know which of these judgements are true” (1996: 2).

Underlying the position of scientism is the embracing of both these facets of realism: the improvement in medical evidence gives us a more accurate picture of which treatments work and the use of systematic reviews can provide us with mechanisms that enable us to gain accurate knowledge of these findings. These findings are then implemented in clinical practice; because the findings are thought to be objective it is inferred the decision is objective too – values have no role to play. Given this understanding, by using high quality evidence purchasing decisions can be made on a ‘scientific’ basis and therefore are supposedly open to less interpretation. As Klein et al. note, this appears to allow decision makers, “the prospect of less pain, [and] less responsibility for taking difficult decisions” (1996: 104).

The position of scientism is untenable because it confuses two different things: the evidence of effectiveness and the decision. While a decision that is made on the basis of good evidence will be more scientific, it does not follow that it will be more objective, in the sense of being independent of value judgements. This is essentially a misunderstanding of the realist position. If it is accepted that clinical trials produce generally accepted factual data about the interaction of particular drugs or therapies, this will not automatically determine which course of treatment should be recommended or purchased. “The evidence itself will not automatically dictate patient care but will provide the factual basis on which decisions can be made” (Rosenberg and Donald, 1995: 1124). The evidence may be more objective and therefore we are clear about the facts at stake, the effectiveness of a treatment, but a fact cannot imply what we should do – you cannot deduce an *ought* from an

*is* – as Hume would say. The facts of the matter will provide good reasons for accepting some courses of action rather than others, i.e we could prescribe the more effective treatment, but it does not *imply* we should take that course of action. There may be other factors to take into account, such as the cost of the treatment or its availability. The decision will be made both on the basis of the factual evidence of effectiveness and the values, priorities and concerns of the decision maker, which cannot, as the scientist position assumes, be eliminated from the process. Thus, scientism plays no role in the actual practice of EBP as values cannot be removed from the decision making process. I shall now turn to the mixed strategy position which builds on the scientism position – in that effectiveness can be objectively determined – but recognises my criticism of scientism and claims that even once effectiveness has been established we still need value judgements to tell us what we should be doing.

### **The Mixed Strategy**

I would argue that accounts of EBP in the medical literature, while sometimes slipping into scientism, most commonly express the ideas outlined in what I have termed the mixed strategy position. This approach, like scientism, builds on realist foundations: the evidence of effectiveness is seen to be objective, clinical trials produce factual information on the effects of treatments, and systematic reviews provide a means of gaining access to this information. However, it is not supposed that it can eradicate any form of value judgement, that the evidence will indicate incontrovertibly what course of action should follow. This is the crucial difference between scientism and the mixed strategy position. Scientism sees the evidence as driving decision making, whereas, in the mixed strategy position, the distinction between an *is* and an *ought* is maintained. The evidence of effectiveness may form the basis of a very good reason for pursuing a particular course of action, but value judgements are needed to tell us whether we *should* take that course of action. This is a recognition that no matter how good our evidence is, it can never eradicate value judgments. Hence, the evidence will be combined with the values that the decision makers want to promote. Our decisions will be better, more scientific because they are based on better evidence but they will not be value free. As Muir Gray says in *Evidence Based Health Care*, “Decisions about groups of patients or populations are made by combining three factors: 1. evidence; 2. values; 3. resources” (1997: 1). The mixed strategy position reflects how the role that values are thought to play in the use of evidence is frequently portrayed in the medical literature. So, does it accurately reflect the role values play in actual practice?

The mixed strategy position recognises that even if effectiveness could be objectively established it would not dictate what we should do, as the position of scientism holds. When setting health care priorities in practice, by using EBP, there are two main areas where value judgments have to be made before the evidence of effectiveness can be applied. First, the choice between purchasing different areas of medical interventions and second the choice between purchasing for the good of the individual or the good of the collective. Both in the medical literature and practice these are recognised as important areas for deliberation. Thus, the mixed strategy position reflects practice in one way in that these value judgements have to be debated when making purchasing decisions. However, the adoption of the view that effectiveness itself is objective can be questioned and a point that will be examined in the next section on the evaluative position. I shall now consider these value judgments.

### *Choice of Treatment Areas*

One of the hardest decisions purchasers have to make is which general areas of medical treatments should be given priority. Perhaps the most well known example where these debates have taken place is the Oregon plan, which became law in 1989. This was an attempt to draw up a list of conditions and their respective treatments that would be funded by Medicaid, the US public health insurance scheme. A list of treatments was developed in order of priority and then a line drawn below which treatments would not be funded. This list was drawn up by canvassing community views as to what conditions should be prioritized. This approach of community ranking produced many counter-intuitive results. For instance, cosmetic breast surgery was preferred over open thigh fracture and tooth capping to appendectomy (see Beauchamp and Childress, 1994). However, the plan is still operational and is continually revised and updated. In 1998, for example, there was a new round of community consultation, “to clarify the values the public think are important in the future funding of health care in the state” (HSMC, 1998: 2). The Oregon Plan is one way of setting priorities by explicitly recognising the need for rationing and involving the public in such decisions. It is clear that such a plan acknowledges that priority setting is essentially an exercise in making value judgments about what a community wants and considering the community itself as the best source of this information. When these value judgments have been made the scientific evidence can be used to determine what are the best means of achieving these priorities. For example, if hip replacements are chosen as a priority then the medical evidence is searched to find the best way of managing the condition. The Oregon Plan is thus an

example of the mixed strategy – values and evidence (and of course recourse constraints) are combined to reach a decision.

In the UK priority setting has not been carried out in such an explicit and public fashion. Rather, Health Authorities have set priorities behind closed doors. Nevertheless, in deciding between different treatment areas the Health Authorities base their decision on value judgments as to what the NHS should be providing. To illustrate this I shall consider the example of the infertility treatment in vitro fertilization (IVF). IVF is a relatively expensive treatment: around £15 000 per birth with about a 12% success rate of a live birth per cycle, women have an average of four cycles per birth. The arguments used for not providing IVF are underpinned by a belief that those requesting IVF are not actually ill and the NHS is therefore not responsible for caring for them. Infertility is not seen as a life threatening condition or even one that endangers ill health. It has been argued that being childless is more of a social problem, bound up with peoples' sense of self-worth and hence not within the remit of the health service. What is at issue here is not the substance of these arguments. Rather, that the kind of arguments used to justify not purchasing IVF are value judgments as to what we see as the appropriate role for a publicly funded health service, what is the appropriate role for medicine to play in procreation and how important we view the condition of infertility. These are not scientific but value-laden questions and ones that have to be addressed before medical evidence can be brought into the decision making process.

#### *The Individual or the Collective?*

I shall now consider the second area where value judgments come into purchasing decisions. In deciding priorities there is a fundamental clash of values: do we promote the interests of the individual patients as paramount and focus on the effectiveness of the treatment? Or should this individual ethic make way for concerns over the collective good, a population based ethic and focus on the cost effectiveness of the treatment? I think this is one of the key value judgments that has to be made by all health care systems and it is not a dilemma that can be solved by appealing to scientific evidence, it is a dilemma that can only be solved by deciding what kind of values we wish to see drive health care.

Alan Maynard, Professor of health economics at York, argues (Maynard, 1997) that EBM and its application to EBP focuses on finding out which treatments are most effective and is therefore grounded in the individual ethic. EBM is concerned with finding out what is the most effective treatment for a particular patient. However, the treatment that might be the most effective might not be the most cost effective. A physician who adopted the population

based ethic would be more concerned with recommending a treatment that was cost effective and in the interests of society as a whole rather than just the interests of the individual patient. Maynard illustrates this tension between the individual and population-health ethic with an example:

A purchaser is choosing between two treatments, A and B. Therapy A produces 5 health years (HY) and therapy B produces 10 HY, leaving aside the problem of how to define health years, we can say treatment B is the more effective treatment and should be purchased. This would be purchasing according to the individual ethic, to do the best for the individual patient and provide the most effective treatment.

However, therapy A produces a HY for £300 and therapy B produces a HY for £700, given a fixed budget of £70 000 therapy A will produce over 130 more HY than therapy B. So, if one adopted the population ethic and was concerned with maximising the number of health years gained with a specific budget, then therapy A should be purchased. Hence, when making purchasing decisions a value judgment has to be made as to whether the relevant evidence is that of effectiveness or that of cost effectiveness. As Maynard's example indicates depending on one's choice different treatments might be purchased.

A practical example of the tension between individual welfare and the welfare of the collective is the case of Child B. Child B, who was suffering from leukaemia, was refused a second transplant operation by Cambridge Health Authority. Her father challenged the decision in the High Court, it then went to the Appeal Court where the Health Authority's decision was upheld.

The interesting aspects of this case are that the health authority was arguably using the population based ethic and considered the cost effectiveness of the treatment. The father was concerned with the individual ethic of finding the most effective treatment. The authority told the Appeal Court that it had refused treatment on the grounds that, in its view, it would not be a cost effective use of resources. The treatment cost of £75 000 was not justified by the predicted success rate, which was very low. Whereas, if money was spent on other treatments they would benefit a greater number of patients – in Maynard's terms increasing the number of health years of the population. Assuming, for the sake of the argument, that the treatment was in Child B's best interests, it is possible to see how the two ethics, the individual and population-based ethic could come into conflict. Sound evidence in terms of the effectiveness of the treatment for the individual or in terms of cost effectiveness for the population, does not in itself eliminate the need for value judgments.

While the mixed strategy position sees value judgments coming into the priority setting and purchasing process in the two areas that have just been

discussed, it fails to take account of a deeper level where it could be argued that values play a role: in the very definition of effectiveness. The evaluative position would, like the mixed strategy position, see value judgments coming into decisions about what areas of medical treatment to purchase and whether to adopt the individual or the population-based ethic. However, the evaluative position would take issue with the scientist and mixed strategy claim that effectiveness can be determined objectively and would argue that the definition of effectiveness incorporates value judgments. It is to this criticism of both the scientist and the mixed strategy position that I shall now turn.

### **The Evaluative Position**

In this section I first outline the arguments in support of the evaluative position; I then consider certain important counter-arguments and finally examine the consequences of this approach for purchasing decisions.

From the evaluative position values are seen to come into the decision making process in the very definition of effectiveness. While the evaluative position does not dispute the realist claim that we can have objective knowledge of a world that exists independently of us – and therefore accepts that clinical trials produce objective data on the effects of particular treatments – it does question the objectivity of definitions of effectiveness which are seen as being opinions about the scientific data. This clearly differs fundamentally from both scientism and the mixed strategy which both see effectiveness as being objectively determined.

Viewed from an evaluative position, clinical trials are designed to discover certain effects of a drug, for example the lowering of plasma cholesterol levels, effects that are capable of being measured by a piece of laboratory equipment. The findings that this equipment produces will be independent of the experimenters' perceptions and hence can be said to be objective. The researcher will then evaluate that effect and decide what significance it has: whether that effect is to be termed a good outcome or not and hence whether the treatment is effective. Effectiveness, good outcomes, a 'better' treatment are not pre-existing facts waiting to be discovered by medical science: they are value-laden assessments of the weight given to a particular effect of the treatment. Thus, to say a treatment is effective is summing up one's opinion on the data. It is in this way that values enter the EBP process at a much deeper level than is allowed for by the mixed strategy position.

It could be argued, however, that if effectiveness is defined as the ability of a treatment to achieve certain, commonly specified outcomes then the ability of a treatment to do this could be measured objectively. Hence, it is not important that the results produced by clinical trials incorporate a partic-

ular view of what defines a good outcome. If we can formulate a general consensus over what constitutes a good outcome then this can provide an adequate foundation for non-subjective agreement.

I would respond to this argument by raising two points. In the first place, it is often very hard to gain consensus over what constitutes a good outcome. Chronic diseases and the effects of ageing, that cause purchasers vexing funding problems, are not areas in which outcome measurements can be precisely quantified. Hopkins and Soloman make this point arguing that while outcome measures may be useful for surgical procedures or acute illnesses, the care of the elderly and the chronically ill is largely based on support, reassurance and explanation, “for which the technical interventions available do not influence outcome very much. . . . The implicit contract here is not based on process and outcome measures but on mutual trust between doctors and patients that the doctors will provide the best care they can within budgetary constraints” (1996: 476).

Secondly, even if a consensus can be reached, it is still important to recognise that this is a particular view of a good outcome and it is possible that in different times (or places) a different view of a good outcome could prevail. Patrick Suppes, for example, has argued that it is possible to gain agreement over what should be considered good outcomes of treatments, “the direct medical consequences and the direct financial cost of a given method of treatment are the most important consequences, and these can be evaluated by summing across the patients and ignoring more individual features” (1979: 151). Suppes is right in one respect. It may be possible to construct broad generalisations about patients’ preferences for certain medical consequences and purchasers’ preferences for cost effective treatments. However, these would have to remain at a very broad level as many of the individual factors affecting these consequences are ignored. For example, financial cost may not be an issue for someone who is very wealthy, whereas for others even the cost of a simple prescription could be prohibitive. Others may value their life only in so far as they are able to look after their children. Although it might be possible to ascertain the types of consequences that are, on the whole, most important, it is impossible to predetermine their respective value objectively.

I shall now consider an example which I think clearly demonstrates how values come into the process of EBP. In purchasing decisions for breast cancer treatments there is an implicit use of value judgements in defining exactly what is said to be an effective treatment. The purchaser wants to purchase the most effective treatment for breast cancer and conducts a literature search, then a systematic review, after which it is found that mastectomy and breast conserving therapy lumpectomy followed by breast radiation have equal rates

of local recurrence and overall survival for early stage breast cancer (see Sawka et al., 1998).

If effectiveness is defined as the ability to produce a desired outcome, then individual patients will have different conceptions of what is, in their view, a good outcome. Professor Brazier cites an example that illustrates this point, “A woman is told that radical mastectomy will maximise her prospects of recovery from breast cancer. She knows that if she loses a breast her husband will leave her and she knows that psychologically she is unable to cope with the necessary mutilation” (1992: 88). Hence she opts for the option of lumpectomy. She is concerned both with the success rate and the consequences for her life and relationships – the side-effects. Here this woman’s assessment of which treatment is most effective could be different from another patient’s assessment. A different woman may choose a mastectomy as she is less concerned about losing a breast and does not want to go through radiation therapy. This illustrates that effectiveness is a relative concept, relative to the individual who receives the treatment.

Thus, to suppose that a purchaser can search the literature and find evidence on effectiveness that will mean that the treatment will be effective or appropriate for every patient is not possible. Patients need to be offered the treatment that is effective for them and as patients are not a homogenous group these treatments will vary. In practice, with breast cancer, there is a recognition that the patient should be given a choice over which treatment to have, as only they can decide which is the most effective treatment for them (Sawka, 1998). This is an implicit recognition of the role values play in the definition of effectiveness.

I have argued that the evaluative position most accurately reflects the role values play in the EBP process. First, in the way that value judgments need to be made to decide what areas and general aims should be prioritised. This is recognised by both the evaluative and the mixed strategy positions, and second, that values play a role in the very definition of effectiveness, a factor only taken into account by the evaluative position.

## **Conclusion**

The purpose of this discussion has been to consider the role that values play in priority setting through the use of EBP. It is important to be clear about the role of values at all levels of the decision making process. At one level, society as a whole has to make decisions about the kind of health provision that it wants, the areas of provision it seeks, and the weight of importance it gives to the individual and the collective. As is generally accepted, such priority setting questions cannot be answered by medical science alone but

involve important judgements of value. However, as I hope to have shown, values come into priority setting questions at another level, one not often explicitly recognised in much of the literature: in the very definition of the effectiveness of treatments. This has important consequences for patient care. If we do not recognise that the effectiveness of a treatment involves subjective elements – a patient’s own assessment of the value of the treatment – then this could lead to the belief that we can purchase *one* treatment that is the most effective for *all* patients. This might result in a detrimental reduction in the range of options that a patient is given, with some patients not receiving the treatment that is most effective for them. If, when involved in priority setting decisions, we continually keep in mind that the effectiveness of a treatment also involves an important subjective element then we can help ensure, as far as is practically possible, that patients receive the treatment that is most effective for them as individuals.

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