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who needs it and why?**

Michael Drummond

DISCUSSION PAPER 152

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ABSTRACT

Disease management is attracting considerable attention from the pharmaceutical industry, which sees this as a way of extending its activities beyond drug development to health care management and organisation. However, it is unclear whether disease management offers advantages to the NHS or society more generally.

This paper explores different interpretations of the term ‘disease management’ and assesses its likely advantages to the pharmaceutical industry and the NHS.

It is concluded that the main attributes of disease management activities are that they encourage consideration of the full costs of disease, the cost-effectiveness of alternative approaches to diagnosis and treatment, and the development of innovative approaches to the provision of care. However, the NHS needs to make a careful assessment of whether partnerships with the pharmaceutical industry or any other party are likely to lead to increased efficiency. For this reason any disease management strategy should include a thorough examination of the costs and effectiveness of alternative health care treatments and programmes.

INTRODUCTION

'Disease management' is the fastest growing job title in the pharmaceutical industry, having joined 'pharmacoeconomics' and 'outcomes assessment' as key areas of activity, where it is thought every company should be involved. The term originated in the USA, where pharmaceutical companies have been active in building partnerships with major managed care organizations (MCOs), such as health maintenance organizations (HMOs) and in making acquisitions of pharmacy benefit management (PBM) groups, that in principle will enable them to play a broader role in the management and delivery of health care.

Participation in disease management activities is rapidly being seen as essential for an industry that must develop or die. It is increasingly being recognized that drug discovery will become more difficult and more costly in the future. Therefore, many commentators argue that the industry needs to diversify into health care activities beyond those of drug discovery and manufacture if it is to survive. In short, 'disease management' is a new product that can be offered by pharmaceutical companies or other suppliers.

On the other hand, it is difficult to obtain a precise definition of 'disease management', even from those individuals with the term in their job title. It seems to encompass everything to do with the organization and delivery of health care, with the particular slant in a given company being determined by individuals' perceptions of initiatives the company has taken to date. Also, the potential for disease management activities in the United Kingdom is uncertain following the issue of executive letter EL(94)94, although more recently the NHS has become more interested in exploring a wide variety of links with pharmaceutical companies or others offering disease management expertise. However, concerns have been expressed (Burns, 1996).

Therefore, the objectives of this paper are:

- (i) To explore different interpretations of the term 'disease management'.
- (ii) To assess whether disease management offers any advantages to the pharmaceutical industry, to the NHS, or to society more generally.

Different notions of disease management are explored below and the arguments for and against each notion are presented.

DISEASE MANAGEMENT AS A WAY OF ANALYSING THE COSTS OF DISEASE

One of the central problems in analysing the cost of drug therapy is the tendency to concentrate on the drug acquisition cost itself. This is understandable as the cost of the medicine is readily identifiable. However, there are other costs in the preparation and administration of the medicines concerned. For example, Plumridge (1990) found that the rank order of hospital antibiotics in terms of acquisition cost was quite different from that based on the total cost of drug therapy, since some medicines required mixing and others required additional patient monitoring. More obviously, a medicine that can be delivered orally may have economic advantages over one that requires an intravenous infusion. On a very simple level, a disease management approach would recognize these factors when considering the relative cost-effectiveness of medications and could also help target them to patients who will benefit most.

More broadly, it is important to consider the costs of drug therapy in the context of the total costs of disease. For example, Davies and Drummond (1994) showed that drug costs only account for 3% of the total cost of managing schizophrenia in the United Kingdom. The

majority of the costs result from the hospital and institutional care for a minority of seriously ill people.

This information is useful in two ways. First, it suggests that it may be inappropriate to focus attention on cutting expenditure on the drugs budget if this is only a small proportion of the total. Secondly, it suggests that priority should be given to the development of interventions that could reduce hospitalization of the more seriously ill patients. These could be new drugs (Davies and Drummond, 1993), or improved community care services, that would enable more patients to be discharged. Of course, the problem still remains that the funding for hospital and community services comes from different budgets, but identifying the potential for improvements in efficiency is still useful.

Therefore, from an individual pharmaceutical company's point of view, this approach to disease management is useful, in that it puts the cost of drugs into a broader context and indicates areas where potential improvements in resource allocation can be obtained. Furthermore, for companies planning clinical trials with an economic component, an analysis of the costs of disease may identify the important cost drivers, that should be carefully estimated in a prospective study.

From the health care system's viewpoint, this approach to disease management emphasises that strategies to improve the cost-effectiveness of health care delivery are multifactorial and that ad hoc cost cutting measures are likely to be limited in scope.

In general it is hard to argue against this notion of disease management. It is likely to provide information that will be useful to pharmaceutical companies and health care decision makers alike. Above all, it encourages a holistic view of the disease process, its management

and its cost. Furthermore, this notion of disease management is the closest to the approaches involved in the economic evaluation of medicines (often called 'pharmacoeconomics'). In economic evaluation the costs of alternative treatments or programmes are compared with their consequences (Drummond *et al*, 1987). The analysis of costs includes not only the costs of the medicines themselves, but also the costs of administration, the costs of treating side effects and the broader economic impact of any difference in efficacy between alternative therapies.

DISEASE MANAGEMENT AS A WAY OF BUNDLING PRODUCTS AND SERVICES

Some approaches to disease management involve the bundling of products and services. For example, a pharmaceutical company may offer a discount if a hospital or health care provider buys a range of the company's products. This can be used to support the notion that the company provides the full range of drugs required for those patients suffering from a given disease (e.g. diabetes).

Sometimes the cost of the drug is bundled with other, non-pharmacological, services. For example, when clozapine was introduced as a therapy for treatment-resistant schizophrenia, one problem was the incidence of a rare but serious side effect, agranulocytosis. In the USA the drug manufacturer argued that, as part of the therapy, a blood monitoring service must be purchased. This was clearly important for safety reasons, but there was considerable debate about whether the blood monitoring service could have been provided more efficiently by other agencies. In the UK the blood monitoring service was provided 'free' by the company and included in the price of the medicine. Essentially this embodied the same 'disease management' approach, but was relatively free of criticism.

There have been other attempts at bundling of services. For example, in the USA Stuart Pharmaceuticals (Zeneca) offered a range of additional services (under the name 'Wellspring') alongside its selective beta-blocker (Tenormin) and its ACE-inhibitor (Zestril) in the treatment of hypertension. The Wellspring package consisted of lifestyle and 'healthy' food information for patients and follow-up to check that repeat prescriptions had been filled. The clinical justification for this approach was that poor compliance is a central problem in the control of hypertension. However, there were also potential benefits to the company in brand loyalty resulting from the additional services, for which no charge was levied.

Two conditions need to be satisfied for this approach to disease management to be economically beneficial. First, the extra service must represent real added value. That is, in principle, it should offer something that customers would be willing-to-pay for. Secondly, its provision by the pharmaceutical company must be at lower cost than alternative suppliers. There may be cases where these conditions hold. For example, a company with a product in a given disease area may be in a good position to provide useful disease information at low cost. However, given the 'public good' characteristics of information, it is difficult to see how this could be sustained in the long run. Moreover, it would probably be inefficient for a pharmaceutical company to insist that essential additional services can only be bought from a single source, when other reliable suppliers exist. The patent on a drug cannot extend to a patent on understanding of the disease.

In general, this approach to disease management is hard to interpret. Probably the simplest approach would be to let the market determine whether particular initiatives have added value to consumers. The role of government would merely be to make sure that consumers were adequately informed and that no artificial barriers to market entry were being created by the bundling of products or services.

Nevertheless, a number of pharmaceutical companies feel that this approach to disease management offers considerable promise. In the USA, Zeneca has expanded its disease management activities through Stuart Disease Management Services, the philosophy being that the effectiveness of health care can be enhanced through improved patient management. Strategies to improve compliance are therefore of high priority, particularly for chronic diseases which have repeat prescriptions.

DISEASE MANAGEMENT AS A WAY OF DETERMINING CAPITATED ARRANGEMENTS, OR RISK-SHARING AGREEMENTS

Under this approach to disease management, the pharmaceutical company agrees to cover the total cost of care for individuals suffering from a given condition, or enters into risk-sharing agreements with health care providers. For example, in the province of Saskatchewan in Canada, Merck Frosst Canada Inc., the manufacturer of finasteride, a drug for benign prostatic hyperplasia (BPH), agreed that it would cover the cost of finasteride for people experiencing progression of BPH after one year on the drug requiring surgical intervention (e.g. prostatectomy). This includes the cost of finasteride incurred during the treatment period.

The advantage of this approach to the pharmaceutical company is that it may overcome resistance on the part of decision makers to adopt new technologies. In the case cited above, prostatectomy is a common treatment for BPH. Therefore, a purchaser may be reassured that, if the drug failed to avert the need for surgery, expenditure on the drug would be partly recompensed. It also provides a signal to purchasers of the company's belief in its own product. That is, it constitutes a kind of 'money-back' guarantee.

However, closer examination of this approach to disease management reveals a number of problems. The main problem is that of uncertainty. Namely, is enough known about the epidemiology of disease? Which categories of patients will require a prostatectomy and when? What will happen to surgical and other technologies for BPH in the medium term? Will other innovations mean that the cost of treating BPH will rise or fall?

Under this approach to disease management, the pharmaceutical company is essentially behaving like an insurer. The success of insurance companies is critically dependent on their ability to estimate the financial consequences of different levels of risk. In many areas of medicine, neither the epidemiology of disease nor the anticipated developments in health technology are clear. Therefore, it is difficult to determine who will be the winners or losers under this approach to disease management. The first pharmaceutical company to strike a capitated deal for Alzheimer's disease will therefore either be incredibly successful or be totally bankrupt, or somewhere in between!

Another worrying feature of this approach to disease management is the impact it may have on the incentives facing prescribers and other health care decision makers. For example, if it were known that a particular drug company was covering the cost of prostatectomies of patients given its drug, would this affect the criteria for surgical intervention? More fundamentally, would the financial arrangements change the clinical criteria for prescribing the drug in the first place? Of course, cost-effectiveness studies can reduce the range of uncertainty. A recent study of finasteride in Canada estimated the payback in financial terms from giving the drug to different categories of patients over different time periods (Baladi et al, 1995).

Perhaps the most positive aspect of this approach to disease management is the potential to develop partnerships between industry and health care providers. That is, both parties have a shared interest in understanding disease processes, how technological development can impact on cost, and in searching for cost-effective solutions. Furthermore, capitation deals need not be in the 'all or nothing' category. They could incorporate guidelines for the cost-effective management of patients, which would outline the appropriate use of drugs regardless of who eventually pays for the care. In this way the pharmaceutical company and the health care provider can have a shared interest in making sure that care is provided efficiently.

DISEASE MANAGEMENT AS A WAY OF BUILDING RELATIONSHIPS WITH CUSTOMERS

It was mentioned above that disease management activities could help explore the shared interests between the pharmaceutical industry and those purchasing or providing health care. From the industry standpoint, the attraction of this approach to disease management is that many of the current dealings with health care providers are either confrontational or clouded in suspicion. Thus, disease management offers the potential for a fresh start.

There are clearly areas where investments in disease management activities can benefit all parties. The obvious examples are: (i) studies of the cost of treatment, where both the pharmaceutical company and the health care system can learn from more investments in data collection; (ii) implementation of guidelines for the cost-effective delivery of care, where the health care provider has the potential to save resources and the pharmaceutical company has the reassurance that its own product is included in the guidelines. However, a successful partnership needs to be based on mutual trust and NHS providers may not be happy if they

perceive that the development of guidelines is merely being used as a marketing tool for a particular product.

The success or failure of particular partnerships will depend on whether there is real shared interest at the end of the day. This is an empirical matter. In some instances a partnership approach to disease management will make sense, in others it will not. From a pharmaceutical industry point of view, the benefits are likely to depend on whether guidelines for an efficient use of its products would imply more drug utilization (e.g. ACE inhibitors for chronic heart failure in the UK), or whether it would imply less (e.g. ACE inhibitors for hypertension).

DISEASE MANAGEMENT AS A WAY OF ENCOURAGING INNOVATION

A particularly fruitful outcome of a partnership is that objectives can be achieved that otherwise would not be possible. A frequent complaint of health service managers is that, although they would like to bring about change, various organizational or financial constraints, mean that this is not possible (Drummond *et al*, 1996). It is well known that, in the NHS, strict limits on budgets or staff establishments mean that some developments cannot take place. One possible contribution of disease management would be to facilitate change.

For example, imagine that a pharmaceutical company had developed a drug, for a particular form of cancer, that could be delivered by injection in the patient's own home. Suppose that the current regimen requires the patient to be hospitalized for two to three days for each of five cycles of chemotherapy.

In this case there could be an economic advantage to the health care provider to free up hospital beds by adopting the new drug, notwithstanding the advantages to patients. However, it may not be possible to adopt the new therapy because no trained nurses are available in the community to administer the injections. In this case it may be appropriate for the pharmaceutical company to provide funding for the nurses as part of the cost of the drug therapy.

Nurses have been funded by the manufacturer of the first beta-interferon therapy for multiple sclerosis in the United Kingdom. As with some of the other approaches to disease management mentioned above, the problem is one of determining which innovations are cost-effective overall and which are not. Therefore, it would be necessary to undertake an economic evaluation of the options being proposed. If this suggests that a change would be efficient, it is then a matter of negotiation between the company and health care providers to determine the exact financial arrangements. It is not in the health care provider's interest to accept arrangements that are not cost-effective overall. In such cases it would make sense for the pharmaceutical company to reduce the price of its drug rather than to offer meaningless 'add-ons' to care.

DISEASE MANAGEMENT AS A WAY OF CUTTING SALES AND PROMOTIONAL EXPENDITURE

From a pharmaceutical company viewpoint the main reason for engaging in disease management activities is to maximize profits from sales of its products. Considerable resources are currently devoted to the promotion of medicines. However, the increased interest in disease management is a symptom of the fact that the customers for drugs are changing.

In the past the major promotional effort by companies has been in detailing individual prescribers. The company's hope is that, after a visit by a sales representative, the prescribing decision may be influenced. The major cost of this approach to promotion is in the time commitments of the sales force. In addition there is minor expenditure on pens, 'post-it' notes, desk ornaments and free meals.

There is a recognition within the industry that promotional activities need to change, in that the future 'customer' may not be the individual prescriber, but the person who advises a group of prescribers or develops treatment guidelines. Such persons are rather fewer in number and a disease management approach would target these individuals, perhaps with more sophisticated data, rather than attempting to reach every single prescriber.

Therefore, a disease management approach might be consistent with cutting expenditure on sales forces and negotiating a smaller number of deals with a few key customers. Whether this will reduce sales and promotion costs overall is unclear. However, it is likely to result in a more cost-effective way of communicating information than one involving multiple sales representatives, from rival companies, giving potentially conflicting messages, to more than 40000 individual prescribers.

An extension of this approach would be for the pharmaceutical company and the customer to negotiate a price reduction in return for increased market share. This is quite common in other industries where there is one major purchaser. It probably also happens in the hospital sector in the UK and in major managed care organizations in the USA. However, in the primary care sector in the UK, where the majority of medicines are used, there are not yet major buying groups that could negotiate with the pharmaceutical companies. Most general

practitioners value their independence and may resist the health commission entering into contracts on their behalf.

The other question is whether this approach to disease management could be linked with some of the other approaches mentioned above, in particular those of determining capitated arrangements and encouraging innovation. Currently there is not enough evidence to assess whether or not new sales approaches, focusing on disease management, deliver additional benefits and to whom.

DISEASE MANAGEMENT AS A WAY OF FINDING A NEW ROLE FOR THE PHARMACEUTICAL INDUSTRY

The most fundamental view of disease management is that it represents the best chance of continued profits for the pharmaceutical industry in the future. Some commentators liken the position of today's drug industry to that of shipping lines when air travel was invented. The choice is simple: change with the times or die. So far most of the evidence for this view comes from the USA. The question is whether the same gains, for society at large and the industry in particular, could be obtained in the UK and other European countries.

Much has been written about inefficiencies in US health care and the changes brought about by the managed care movement. Essentially, there is no history of management in the US health care system, beyond that within institutions like hospitals, and it is not surprising that: (i) any management could bring about improvements and that; (ii) the pharmaceutical industry could play its part. Therefore, in the USA it could well be the case that bigger pharmaceutical company profits are to be made from better health care management than drug discovery. After all, the health care industry is a large sector of the US economy,

accounting for 14% of gross domestic product. Therefore, it could make commercial sense to set up companies selling disease management services rather than pharmaceuticals.

Conversely, in the UK and many countries of Northern Europe, the health care systems are characterised by intensive management, either through centralized systems or through managed competition. (The NHS in the UK has moved from one approach to the other, but in no sense has management activity been reduced. In fact the NHS already operates like a large HMO.)

Therefore, what contribution could disease management activities from the pharmaceutical industry, or other parties, make in this context? Is there any sense in which the current system is being badly managed? Could the industry offer skills that are completely absent in the current NHS management hierarchy? Would it be acceptable for a major supplier, the industry, to play a major role in shaping the health care system of the future?

The answer to all these questions is a qualified 'no'. It is clear that the pharmaceutical industry has managerial skills that could assist the NHS, but these do not represent a quantum leap from what is currently available. Evidence on this point is difficult to adduce, but there is no clear evidence that managers imported from private industry following the 1983 Griffiths Report performed any better or worse on average than their public sector counterparts. The prevailing view is that management in public and private sectors involves different objectives and constraints.

However, the pharmaceutical industry does have considerable resources at its disposal, which could be directed to improve or support NHS management. It already invests large amounts of resources in postgraduate medical education, much more than the NHS itself would be

able to do if such expenditure were appraised alongside competing demands on resources. In general, expenditure by private companies is less subject to public scrutiny. The only concern is that of shareholders, who expect a good return on their capital. Therefore, industry money might be made available for management activities that the NHS would find it difficult to undertake by using its own funds.

If the industry could offer support to management in the NHS, are there any problems from increased industry involvement? Since the implementation of the internal market the management of NHS has been split between purchasers and providers. Under this model there would appear to be no problem in the industry forming partnerships with providers. On the other hand, partnerships with purchasers could raise concerns because it may compromise their ability to serve the health needs of their population (which is their main mission). Disease management activities involving fundholding GPs may raise similar concerns, since these act as both purchasers and providers.

Although the NHS owes it to society to embrace good ideas from whomever they originate, including the industry, advances by the pharmaceutical industry into NHS management are likely to be judged on their merits and are probably going to be limited. The most likely response from the NHS to pharmaceutical companies wanting to be involved in health care management will be to argue that they should stick to what they know best, the development of innovative drugs which benefit society. On the other hand, if pharmaceutical companies set up separate companies selling disease management services, these will be judged on their merits, alongside other management consultancy services.

CONCLUSIONS

This paper has explored several notions of 'disease management' and assessed their usefulness to the pharmaceutical industry, the NHS, and society more generally. The main attributes of disease management activities are that they encourage consideration of the full costs of disease, the cost-effectiveness of alternative approaches to diagnosis and treatment, and the development of innovative approaches to the provision of care.

However, they do not provide a prima facie case for the pharmaceutical industry to be more involved in the management of patient care, nor a lifeline to an industry struggling with its historic role, of drug discovery. From the industry viewpoint, the ultimate judgement on disease management will be relatively straightforward: does it increase profits? From the viewpoint of the NHS the judgement will be more difficult to make (Burns, 1996). Partnerships with the pharmaceutical industry or any other party are not worthwhile in their own right. They are only worthwhile if they lead to more efficiency. This should be the guiding principle for the NHS when it is considering deals offered under the general guise of 'disease management'. Therefore, an essential component of any disease management strategy should be a thorough examination of the costs and effectiveness of alternative health care treatments and programmes.

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