A purchaser experience of managing new expensive drugs: interferon beta

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Interferon beta is a new and expensive drug for treating multiple sclerosis. One published trial has shown that it reduces the exacerbation rate in patients who have relapsing-remitting disease without important disability. This paper describes the development of a strategy for purchasing the drug in one region of England before its licensing. Purchasers felt unable to decline funding for this marginally effective drug and thereby undertake explicit rationing. To ensure prescribing was within the guidelines, a vast communication network had to be sustained with managers, general practitioners, neurologists, the Multiple Sclerosis Society, and professional advisers in all the purchasing authorities. The workload involved was considerable. The dilemma of rationing in a public service with a high political profile is demonstrated.

Interferon beta represents a drug company's dream ticket—the first new product for a chronic incurable disease that is relatively common and has a variable course. This drug is one of the first of the new biotechnological treatments for multiple sclerosis, all of which are likely to be relatively expensive drugs. This paper describes the preparations undertaken by purchasing authorities in the North West region before the licensing of interferon beta. To our knowledge this is the first time such a major coordinated effort has been made by NHS purchasers to pre-empt the consequences of one drug.

Conclusions of published trial of drug

One published trial of interferon beta showed that it reduced the exacerbation rate in patients with relapsing-remitting disease.¹ The study population was aged 18–50 years and without important disability. The two year data demonstrated exacerbation rates of 1.27 per patient per year in the placebo group, 1.17 in the first treatment group (1.6 MIU dose), and 0.84 in the second treatment group (8 MIU). The difference between the placebo group and the second treatment group was significant, $P=0.0001$. Technically, the trial demonstrated clinical effectiveness but not an effect on disability, which is the outcome that matters to purchasers and patients.

Purchasers need to be able to answer several questions when making a judgment about this drug:

- Is the reported reduction in exacerbation rate clinically important?
- Is there a subgroup of patients who would gain greater benefit from the drug?
- If the results are clinically important how does the health gain demonstrated compare with other treatments competing for the NHS's limited resources?

Theory of purchasing

The theory is that any purchaser has a choice about the services it purchases, which is based on information

about the cost and effectiveness of these services. The cost of interferon beta is likely to be about £10 000 per patient per year and the benefits of treatment can be calculated from the published trial,¹ giving a cost of £21 276 per exacerbation prevented or £23 584 per hospital inpatient day prevented. Prevention of hospital admission may not be the most appropriate outcome measure for multiple sclerosis, but it is the only one which can be used to give a comparison between treatments from the published data.

Table 1 compares the costs of drugs used in potentially fatal chronic diseases that are currently competing for purchasers' resources and the costs of purchasing these drugs for all patients in North West region who would benefit. Compared with clozapine and dornase alfa, interferon beta does not seem to be a good buy. If purchasers were making real choices about investment, interferon beta would not be a priority as it would seriously impair their ability to purchase more cost effective treatments.

The reality of purchasing

A group of professional advisers from purchasers in North West region was convened in November 1994 after a notification from the regional drug information service. There was broad agreement that, in light of current evidence, the marginal benefit of the drug did not seem to justify the likely investment.

The working group agreed upon five options for purchasers:

- 1 Do not fund any prescribing at this stage
- 2 Limited prescribing through specialist neurology centres only
- 3 Prescribing by neurologists only within regionally agreed guidelines
- 4 Shared care with general practitioners—consultants initiate treatment, but general practitioners prescribe maintenance treatment and absorb costs in primary care prescribing budget
- 5 Prescribing initiated and maintained by general practitioners.

Option 1, although rational in view of above data about cost effectiveness, was not considered to be politically sustainable after discussions with key groups such as the Multiple Sclerosis Society, general practitioners, and colleagues from the regional health authority and the Department of Health. Option 2 was not considered to be the ideal option because of a concurrent review of neurology services in the region, and the advisory group had no desire to promote any particular service configuration. The advantages and disadvantages of options 3–5 have been discussed by Walley and Barton.⁶ Option 3—keeping prescribing within hospitals—had the advantage of making it easier to target the drug appropriately and maintain a universal audit system among all prescribers. Options 4 and 5 were excluded because it was considered that general

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Table 1—Comparative costs for three drugs

Drug	Cost per hospital inpatient day prevented (£)	Estimated annual cost in North West region (£m)
Interferon beta ¹	23 584	30
Clozapine ^{2,3}	33	9.9
Domase alfa ^{4,5}	2 857	6.1

practitioner prescribing could lead to patients who did not meet the entry criteria of the trial¹ receiving the drug.

However, assessment of patients for the drug would further stretch neurology services, which already had substantial waiting times. An investment in neurology services was needed to avoid general practitioners being pressured to prescribe. Preliminary estimates of the drug's annual costs for the region varied from £30m (45% of patients with multiple sclerosis receiving the drug) to £0.67m (1% receiving the drug). Option 3 was finally recommended to purchaser chief executives, and a commitment to invest in neurology services was made.

The drug company's marketing strategy involved offering "free" nurses as part of a support package of care. Although current nursing support was felt to be inadequate, there were reservations about accepting product specific nurses as, firstly, they could encourage consultants to prescribe the drug in order to gain nursing support and, secondly, there were other products in the pipeline to be considered. Consequently, each hospital was asked to draw up its own profile of service costs that included nursing.

VIEWS OF NEUROLOGISTS

Neurologists in the region varied in their opinion of the value of the drug. A preliminary paper from Professor McDonald of the National Hospital for Neurology and Neurosurgery suggested that widespread prescribing of the drug could not yet be justified.⁷ Some local neurologists did not wish to prescribe the drug on the basis of current evidence and thought that any additional resources should be directed to better supportive care for patients with multiple sclerosis. Others thought that patients should be able to try any new product that had shown some benefit.

A meeting was arranged with Professor McDonald, who was preparing guidelines for the Association of British Neurologists, to give neurologists in North West region the opportunity to influence these national

guidelines and assist in developing some local consensus. Neurologists thought that the assessment of patients should, ideally, be undertaken by neurologists, who were in short supply, although some felt that elements of the assessment could be delegated to other health professionals. If patients with multiple sclerosis were not seen quickly they might pressure their general practitioner to prescribe the drug, and this was not thought to be clinically appropriate. However, there was a danger that this drug could distort clinical priorities. A policy of giving priority to patients with multiple sclerosis over patients with other diagnoses was not acceptable to most doctors.

COMMUNICATIONS

Consultation and communication with all the key players was an essential part of the strategy. In view of the high profile of this drug the NHS Executive was consulted at key stages to ensure our local actions did not conflict with national policy. Communicating progress to general practitioners, professional advisers, and managers was time consuming. Communicating with the general public was more difficult—for example, an attempt to provide journalists with unbiased information to avoid sensationalist stories at the time of the drug's launch was abandoned as journalists were reluctant to spend time on a story that could not be published immediately.

Conclusions

Purchasers were unable to decline funding for a marginally effective drug and thereby undertake explicit rationing. To ensure prescribing was within the guidelines, a vast communication network had to be sustained with managers, general practitioners, neurologists, the Multiple Sclerosis Society, and professional advisers in all the purchasing authorities. The workload involved was considerable.

The impact of this drug on the NHS will be apparent over the next few years. Purchasers fear that if the guidelines are not tight enough to limit prescribing within available resources or neurologists find themselves unable to stick to them because of patient pressure, then resources will be sucked from elsewhere in the NHS to fund this drug. Neurologists fear that if uptake is greater than predicted then implicit rationing beyond the criteria in the guidelines may be needed, even though purchasers state that they are committed to fund prescribing within the guidelines.

We particularly thank all the neurologists in the North West region, who steadfastly refused to cancel any clinical commitments to talk to us but devoted many evenings and lunchtimes to open and thoughtful discussions without which progress would not have occurred.

How much choice do purchasers really have about what they buy?

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