Inequality in the availability of expensive treatments

A J Thompson

Limited resources for health care and ever increasing competing demands make essential some form of guidance in the use of expensive treatments. Without such guidance, marked inequality in the availability of these interventions has occurred. Beta interferon is a much publicised example of this phenomenon and serves to illustrate the complexity of the issues involved. Since the licensing of the first immunosuppressive treatment for relapsing remitting multiple sclerosis (MS), interferon beta–1b (which was greeted with some enthusiasm[1]), two similar agents have been licensed also for this subgroup. More recently, interferon beta–1b has been licensed for the larger and more disabled secondary progressive group. How has this translated into availability of the drug?

The first point to make is that the percentage of patients with MS in the UK receiving interferon beta–1b is less than in any other country within the European Union (1–2% vs 12–13% in Germany, France and Italy). This is mainly due to a combination of:

- different perceptions of its partial efficacy
- the cost of the drug (approximately £10,000 per patient per year)
- strict clinical guidelines which advise its use only for mobile patients with active disease, estimated to make up 5–10% of the MS population[2].

A more divisive and distressing issue for patients, their families and physicians alike has been the inequality of drug availability throughout the UK, ranging from a complete lack of the drug in some regions to provision to over 15% of patients with MS in others. Three major questions relate to this unhappy situation:

1 How has this situation come about?
2 What has been its impact?
3 How can it be prevented from occurring again?

In practical terms, this inequality has been a direct result of the transfer of decision making from central to local level in the form of the health authorities – implying, in turn, that issues relating to funding and interpretation of efficacy are also decided locally. The interpretation of the limited effect of the drug is a particular issue on which there have been wide-ranging views[3,4]. The production by the Association of British Neurologists of clinical guidelines for the use of beta interferon in relapsing remitting MS[5], subsequently endorsed by the NHS Executive[6], has done little to influence this situation.

In addition to the issue of efficacy, there is the more complex issue of cost effectiveness[7]. This has been addressed by several studies[8], all of which find that the drug is not cost effective. However, none of them has attempted to capture the entire impact of the disease, particularly in relation to the indirect costs which are much greater than the direct costs[9,10].

Despite these difficulties, a number of health authorities have attempted to manage the introduction of beta interferon in a way that balances benefit for the resources invested without disrupting the total drug expenditure[11]. A good example is given by the purchasers in the North West. They convened the North West Purchasing MS Treatment and Implementation Group, which guided the introduction of the drug, while at the same time encouraging improved facilities for the wider management of MS[12]. In contrast, the prescribing forum established by the South Devon Health Authority decided there was insufficient evidence to justify the use of beta interferon outside a clinical trial[13].

The impact of the inequality of availability is all too obvious, at least in terms of the anxiety and distress it causes patients in one area who feel they are being discriminated against in comparison with other areas. The impact is all the more devastating because it is not based on consistent interpretation of the evidence. However, even within this inequality, it is unclear which patients are actually getting the drug: whether it is those who are most appropriate or more articulate, or whether its administration is simply managed on a first come, first served basis. This question could easily be answered by detailed analysis of the outcome of the current prescribing policy.

Could this state of affairs have been prevented, and can anything be done to ensure that it does not continue indefinitely? It seems clear that one of the key factors is the need for 'central' involvement, both in terms of evaluating the results and in providing guidance in such difficult areas as the use of an expensive, partially effective drug in a devastating, incurable disease (as advocated by Walley in 1994[14]). However, this role can only be as effective as the quality of the data available for analysis. More effort needs to be put into trial design, selecting scientifically sound and clinically relevant outcome measures that evaluate both clinical efficacy and cost effectiveness, and ensuring independent data analysis.

The achievement of these ends will require closer co-operation between industry, clinicians, patient bodies and

Alan J Thompson MD FRCP FRCPI, *Garfield Weston Professor, Clinical Neurology and Neurorehabilitation, Institute of Neurology, London*

J R Coll Physicians Lond 1999;**33**:448–9

the Department of Health. In theory at least, the recent development of the National Institute for Clinical Excellence (NICE), which is likely to carry out an appraisal of beta interferon in MS, will go some way towards achieving those ends[15]. Much will depend on how well NICE achieves its objectives, particularly in relation to wide, as distinct from selective, consultation and transparent decision making, such that it reassures commentators that it does not simply become the National Institute for Clinical Rationing[16]. Finally, it will require access to trial data of new drugs well in advance of their launch if the current unhappy situation, whereby a drug is licensed for a new indication but no guidelines or funding mechanisms exist, is to be avoided.

References

1 McDonald WI. New treatments for multiple sclerosis (editorial). *Br Med J* 1995;**310**:345–6.
2 Andersen O, Runmarker B. What proportion of the total MS population comply with activity criteria actually utilised as indications for beta-interferon therapy? *J Neurol* 1997;**244**(Suppl 3):S66.
3 Mumford CJ. Beta interferon and multiple sclerosis: why the fuss? *Q J Med* 1996;**89**:1–3.
4 Anon. Interferon beta 1B – hope or hype? *Drug Therapeut Bull* 1996; **34**:9–11.
5 McDonald WI for the Association of British Neurologists UK. *New treatments for multiple sclerosis*. London: Association of British Neurologists, 1994.
6 Winyard G. NHS Executive issued advice to help NHS plan for introduction of the treatment. *Br Med J* 1997;**314**:601–2.
7 Richards RG. Interferon beta in multiple sclerosis: clinical cost effectiveness falls at the first hurdle. *Br Med J* 1996;**313**:1159.
8 Parkin D, McNamee P, Jacoby A, Miller P, *et al.* A cost-utility analysis of interferon beta for multiple sclerosis. *Health Technol Assess* 1998; **2**:1–58.
9 Holmes J. Avoidance of the need for social care should also be taken into account. *Br Med J* 1997;**314**:601.
10 Carton H, Loos R, Pacolet J, Versieck K, Vlietinck R. Utilisation and cost of the professional care and assistance according to disability of patients with multiple sclerosis in Flanders (Belgium). *J Neurol Neurosurg Psychiatry* 1998;**64**:444–50.
11 Walley T, Barton S. A purchaser perspective of managing new drugs: interferon beta as a case study. *Br Med J* 1995;**311**:796–9.
12 Young C. Improving health care for multiple sclerosis patients – a clinical neurology based service. Measured steps. Meeting of the MS Society, 1998.
13 Zajicek J. Personal communication.
14 Walley T, Edwards RT. Is there a need for an independent centre for pharmaco-economics in the UK? *Pharmacoeconomics* 1994;**5**:93-100.
15 Rawlins M. In pursuit of quality: the National Institute for Clinical Excellence. *Lancet* 1999;**353**:1079-80.
16 Horton R. NICE: a step forward in the quality of NHS care. *Lancet* 1999;**353**:1028–9.

Address for correspondence: Professor A J Thompson, Garfield Weston Professor, Clinical Neurology and Neurorehabilitation, Institute of Neurology, Queen Square, London WC1N 3BG.
E-mail: A.Thompson@ion.ucl.ac.uk