HESG July 2000

SOME LAW AND ECONOMICS OF A **NICE** RATIONING PROBLEM

Diane Dawson
Centre for health Economics
University of York

I. Introduction

On 1 April 1999 the National Institute for Clinical Excellence (NICE) came into being. NICE is to evaluate new therapies (and later existing ones) in terms of cost-effectiveness, health gain (measured in terms of quality of life and , where relevant, life expectancy) and impact on NHS resources (NHS Executive 1999a). NICE is then to recommend whether the new therapy should be provided by the NHS in light of the Department of Health policy that scarce resources should be allocated in a way that maximises expected health gain or benefit for the available NHS budget[†]. The White Paper outlining the new institutions of the "New" NHS made it clear that a prime function of NICE would be to eliminate "postcode rationing". There was to be national consistency in access to treatment, availability of care would not depend on "where you live".

At the time the consultation document on NICE procedures was being drafted, there was a very public discussion of the approach taken by the Department of Health in deciding the extent to which Viagra would be provided by the NHS. The appearance of Viagra on the market drew attention (yet again) to the question of which mental and physical conditions should be treated by the NHS. This paper does not pursue that important issue. The present focus is on the evolving guidance as to how a new product for the treatment of a condition already treated on the NHS should be evaluated and integrated into the system for rationing NHS resources. How does this evaluation relate to the legal and institutional framework required if NICE is to ensure national uniformity in access to a new product? Post-code rationing occurs where availability is determined by local commissioners or purchasers in response to local budget constraints and priorities. What control mechanisms are required if the variety of local conditions is not to be reflected in differences in the rates at which a new product is made available to patients in different parts of the country?

The paper is focused on three interrelated issues: Section II sets out the elementary microeconomics of introducing a new product into a budget constrained system. This makes the relationship between two NICE criteria very clear—cost-effectiveness and impact on the NHS budget. Section III examines the critical importance of the budget constraint, incremental budgeting and withdrawal of treatments for existing patients. It

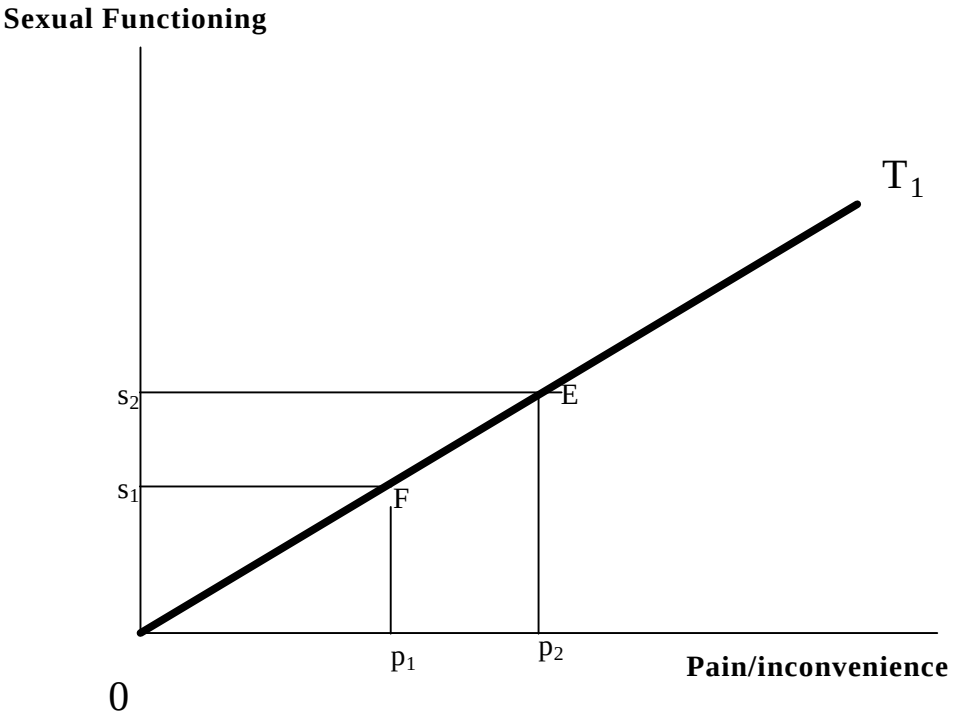
[†] The DH does not use the term "maximise". However a succession of White, Green and Discussion papers make clear the Government intends resources to be focused on improving health states. The basic economic logic of this position is that of maximising health gain for a given budget. The Government is currently stressing equity objectives so the economic problem is maximisation of equity weighted health gain for a given budget.

addresses the two key questions raised by the Secretary of State in his guidance on Viagra: (1) How should the appearance of a new therapy affect the "priority" of patients with a particular condition and (2) How should the total expected cost of a new treatment affect the likelihood of it being offered within a cash limited NHS. Section IV examines the legal response to the attempt of the Secretary of State to limit the availability of Viagra in a way that would avoid "post-code" rationing. How does the law affect the substance of rationing (who gets what) when regulation rather than voluntary compliance is used to restrict access? One set of "inequitable" outcomes may simply be replaced by another.

II. The Building blocks

Lancaster (Lancaster 1971) reformulated basic demand theory to ease the analysis of situations where new products are introduced into a market but consumer preferences remain unchanged. Preferences are defined over characteristics and products designed to provide similar services differ in the way they bundle these characteristics—e.g. different makes of car differ in the way each combines the characteristics of safety, reliability and acceleration.

Figure 1



To keep things simple, we assume that products designed to deal with erectile dysfunction (ED) have only two important characteristics: they provide improved sexual functioning and they involve pain / inconvenience. In Figure 1 we define a product in terms of these two characteristics and measure these characteristics along the two axes. An existing treatment, say injection, combines the two characteristics in proportions indicated by the ray T_1. Let point F correspond to one injection per

month. As a consequence of that level of treatment, the patient would be expected to experience improved sexual function of S_1 and pain/inconvenience of P_1. If two injections per month were given, the patient would expect to realise S_2 and P_2. Moving along the ray T_1 the number of treatments per month increases and we assume the proportion in which the two characteristics are delivered remains constant.

Patients have preferences defined over the two characteristics. For any given level of utility, an individual is willing to trade-off increased pain/inconvenience for improved sexual functioning. Obviously, for any given level of pain/inconvenience, the patient is better off the higher the level of sexual functioning. While these general characteristics are assumed to apply to preferences of all patients, patient preferences are not identical. One group of patients (group K) may trade-off improved sexual functioning against pain as indicated by the indifference curves in Figure 2(a). If injection (treatment T_1) is the only treatment on offer, these patients would seek out and accept treatment. The amount of treatment they would receive would depend on the rules of the health care system to which they belonged. If "patient preferences" counted in a system where treatment was free at point of use, individuals with type K preferences would ask for and be given treatment at point E. If rather than maximising patient utility the health care system allocated treatments to maximise something else, some measure of health gain (QALYs?), valued in terms of population (rather than patient preferences), the quantity of treatment offered may be at a different level, say point F. Even though point F is not seen by the patient as his welfare maximising position, he is better off seeking and accepting treatment at F than having no treatment at all. ${}^{k}I_2$ is preferred to ${}^{k}I_0$.

Figure 2(a)

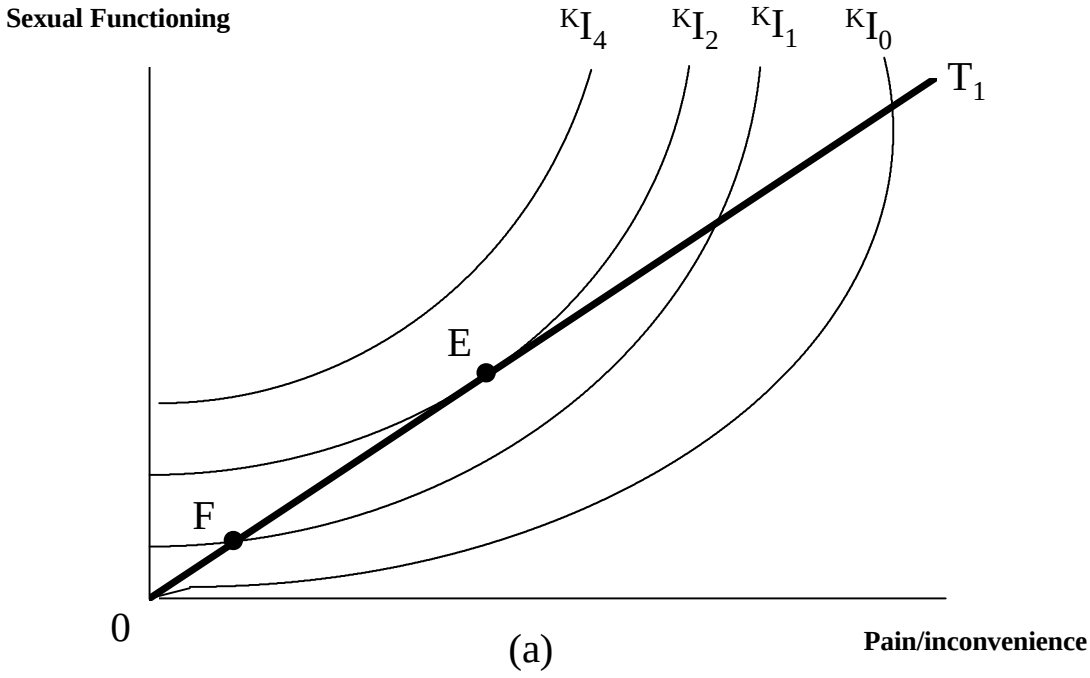
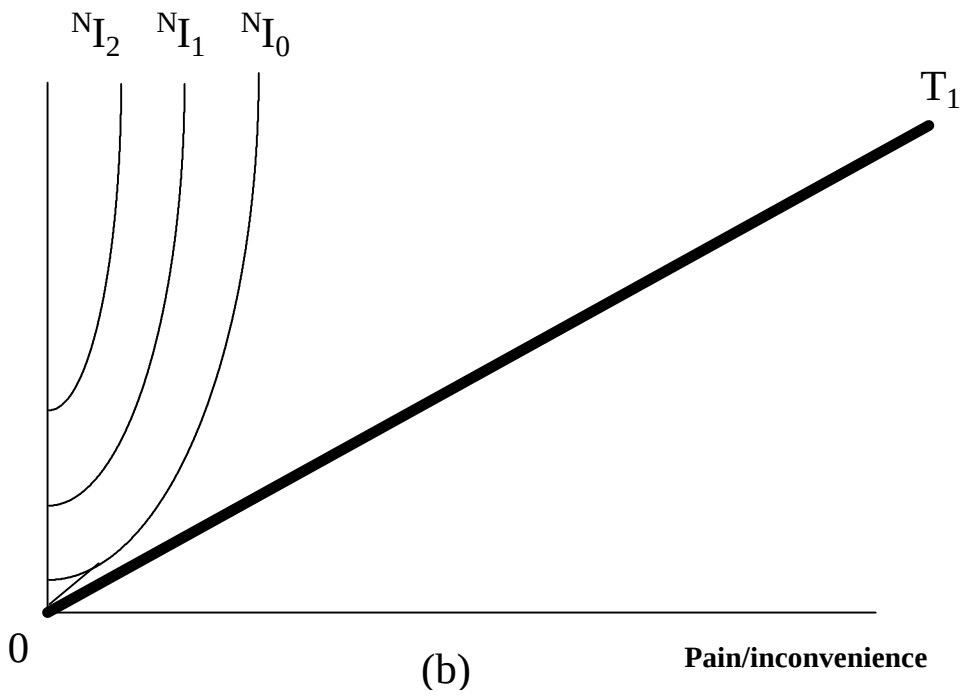


Figure 2(b) illustrates the case where the preferences of the patient are such that no treatment is preferred to the treatment on offer, T_1. Individuals in group N are willing to trade-off some pain/inconvenience for improved sexual functioning but not at the rate required by the existing treatment. Patients of type N do not present for treatment or, if they do seek medical care, decline the treatment offered. The patient is better off remaining at the origin (no treatment) on indifference curve ${}^{N}I_o$.

Figure 2 (b)



It has been argued that patient preferences are irrelevant to decisions by individuals to seek out and accept treatment since the patients have little knowledge of the treatments available or the characteristics of these treatments (effectiveness, pain etc). This has historically been true but it will be increasingly important to maintain a place for patient preferences in our models of health care if we are to understand how patterns of utilisation change over time. Information on drugs and treatment is becoming increasingly available to patients. Those who want information can increasingly access it on the internet. Support groups and pressure groups for patients collect and disseminate information to help patients argue their cases with clinicians. In the US some HMO's use video tapes to inform patients of the risks and benefits of procedures. The role of informed patient choice is likely to increase.

A more conventional view of the role of preferences in health care is that clinicians impose on patients the clinician's view of the acceptability of the trade-off between characteristics (effectiveness and pain) when considering whether to give a particular treatment. A clinician may offer no treatment to patients of type N because in the clinician's view the trade-off is unacceptable. When a new treatment becomes available with greater effectiveness and less pain the same clinician may decide to treat.

Preferences have not changed but the characteristics of the products available to treat the patient's condition have changed. The analysis of the remainder of this paper is unaffected by whether "preferences" are treated as those of the patient or a clinician's interpretation of patient preferences.

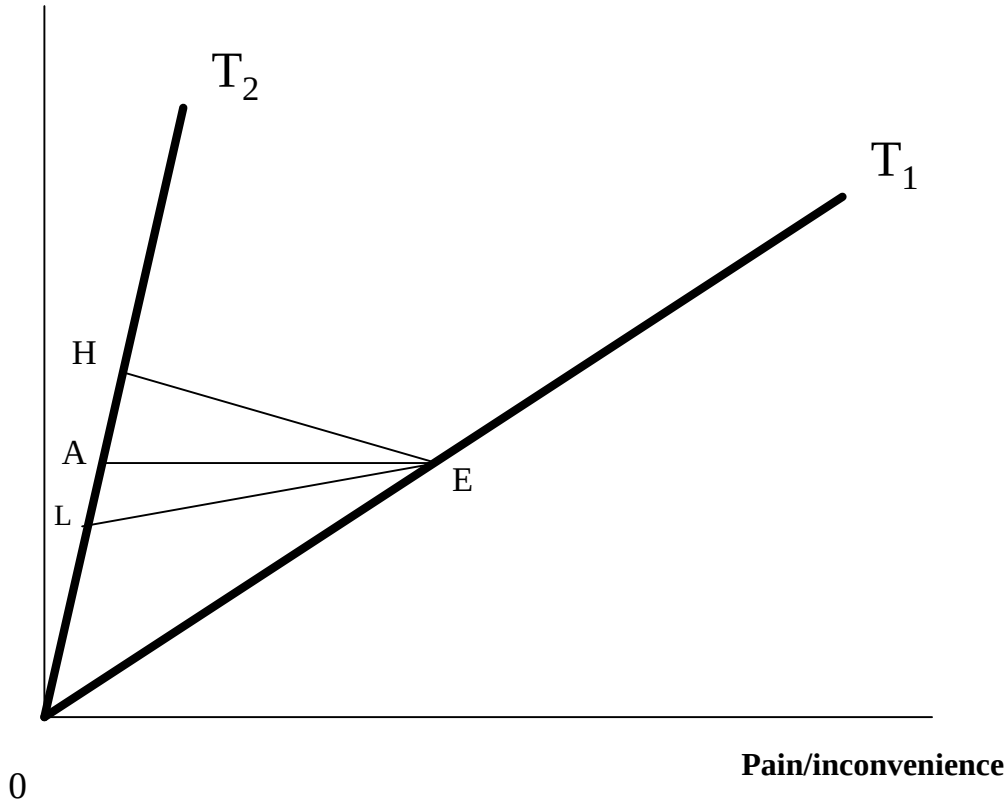
III. Introduction of a New Product: Cost-effectiveness and Cost-utility

Now assume a new treatment becomes available, a blue pill. The new treatment also has the two characteristics of improved sexual functioning and side-effects but in different proportions. In Figure 3 the ray T_2 shows that the new treatment has far less pain and discomfort at each level of improved sexual functioning than the old treatment.

Had this new product been referred to NICE, it would have been required to examine the cost-effectiveness of the new therapy. Given the cost of an injection and the number of injections at each point along the ray T_1 there is an implied total cost of treating a patient with the old therapy. Total cost varies with dose, hence the actual total cost depends on the particular point on T_1 chosen by the clinician. Similarly, given the price of a pill and the number of pills prescribed at each point on ray T_2, there is a corresponding total cost of treating a patient with the new therapy, the actual cost depending on the point chosen on T_2.

Figure 3

Sexual Functioning



Given the prices of the two products it is possible to construct isocost (or "isoexpenditure") lines showing the quantities of the two characteristics that could be purchased if a given budget is spent on each treatment. For example, in Figure 3, total expenditure is held constant as we move along E-H, but the quantities of the two characteristics that can be purchased with that budget change as we move from spending all the budget on T_1 at point E to spending the same amount on T_2 at point H or any combination of the two treatments along E-H. If for the moment we take the price of injection as fixed, the slope of an isocost line will depend on the pricing strategy adopted by the company introducing the new treatment. The slope of the isocost line E-H in Figure 3 assumes the company has priced the product to dominate the alternative treatment: for each level of total cost the benefits will be higher and the side-effects lower. Obviously the company could have followed a different pricing strategy and isocost line E-A illustrates one alternative. The pill could have been priced so that for any existing outlay on Treatment 1 (injection), the patient/NHS could achieve the same outcome in terms of sexual functioning at the same cost but with fewer unpleasant effects if they switched to Treatment 2 (the pill). With isocost line E-L we consider a third pricing strategy where the company takes advantage of the fact that its product has all of the benefits and few of the drawbacks of the existing treatment and can fetch a premium price - the NHS/patient will have to pay for reduced pain/inconvenience. Whether this last marketing strategy turns out to be profitable depends on whether the company's guess as to the rate at which individuals

or the NHS will trade-off reduced pain/inconvenience against higher cost turns out to be correct.

If the pricing of the new treatment results in the pattern of relative prices depicted in E-H or E-A of Figure 3, the treatment would clearly be deemed cost-effective: given a lower or the same cost per treatment, outcome is better or the same while pain/inconvenience is reduced. If the new treatment is priced to generate E-L, then the outcome of a cost-effectiveness study is less clear cut: the cost per treatment is higher but the adverse side effects are lower. Studies to date suggest the new treatment for ED is cost effective (Burls *et al* 1998; Health Affairs 2000). However, NICE is expected to move beyond cost-effectiveness and consider cost-utility . The Committee is to evaluate a new therapy in terms of:

- estimated impact on quality and (where appropriate) length of life
- estimated average health improvement per treatment expressed in terms of standard measures for combining life years and quality of life;
- net NHS costs associated with this health gain;

Where the new treatment is, by whatever measure used (SF36, EQ-5D, etc) expected to lead to a higher health related quality of life per £ spent than the existing treatment, the new treatment will appear higher up any ranking of treatments by health gain than the treatment currently on offer in the NHS[‡]. In the language of rationing by health gain, once a new treatment is shown to provide a larger increase in health gain per £ than the existing treatment, patients with the relevant condition will have "higher priority" in the set of all demands on NHS resources (see p ? below). The NHS presently lacks information to other than "guesstimate" the relative health gain that might be expected of treatments currently funded but part of the NICE remit is to produce the information that will permit a more evidence based, explicit ranking of treatments by expected health gain.

IV. Impact on NHS resources

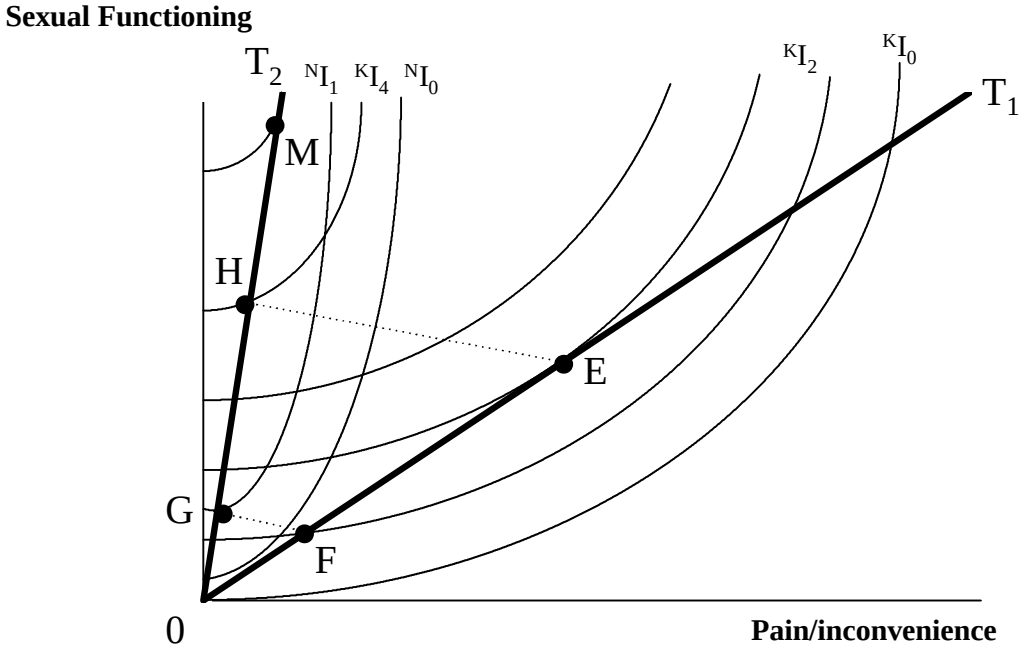
Having established that evidence suggests a new therapy is cost-effective and should be superior in cost-utility terms to existing treatments offered by the NHS, before deciding whether to recommend that the new therapy be offered by the NHS, the NICE committee must consider expected total impact on NHS resources.

In Figure 4 we consider what happens when treatment T_2 is introduced. Assume the pill is priced such that isocost line HE defines the relative prices of the two therapies. Individual K, at point E, will be better off if he is switched from treatment T_1 to T_2. Even though total cost to the NHS remains constant, at point H individual K is now on ${}^{k}I_4$. He would obviously be even better off if his preferences as to dose/frequency were taken into account and he was able to move to a point like M. If the level of treatment previously received had been restricted to point F, the patient could still be made better off, at no additional cost to the NHS by being switched to the new treatment at a level of G. Where the relevant measure of health gain uses population

[‡] This is a very well known result of any system that attempts to maximise health gain. See Williams (1985) or Birch and Gafni (1992).

preferences, the new mixture of characteristics would insure that health gain per £ would rise moving from F to G.

Figure 4



It is commonly expected that if a new treatment produces improved outcomes and or fewer adverse effects, there will be a change in the total number of patients treated. This is most likely due to the improved trade-off between benefit and side-effects leading more people to be willing to seek and/or accept treatment or to clinicians lowering the treatment threshold because they find expected outcomes more acceptable. Once the new treatment is on offer, patients with preferences of type N will present for treatment. Consider the case where the health care system uses criteria like maximising health gain valued by population (taxpayer) preferences (rather than patient preferences) and previously had offered treatment for this condition at point F in Figure 4. At the same total expenditure per patient, patients with type N preferences could be offered treatment 2 at level G. They would now be better off with treatment than without. ${}^{N}I_1$ is preferred to ${}^{N}I_0$. Patients, or clinicians acting on their behalf, will want treatment 2 to be made available to a set of patients who would not have been treated before. Clearly, even though the cost per patient treated may be constant or even fall, total expenditure by the NHS on this condition would rise as the proportion of the population treated increases. We have a cost-effective but expenditure increasing new treatment.

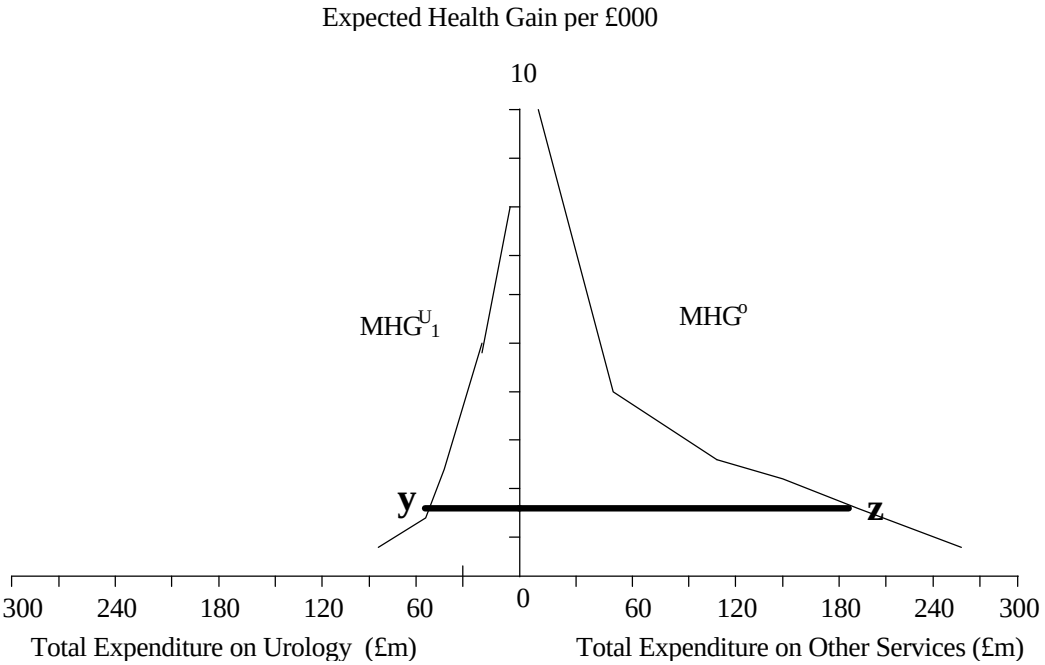
III The Budget Constraint and Introduction of a New Therapy

If agents in the NHS are expected to aim at maximising equity-weighted health gain, treatments offered must be ranked, in terms of expected health gain and provided until

the budget is exhausted (see Annex on the information NICE is expected to use and the basis for the figures of this section). Once treatments have been ranked, we can think of how the expected Marginal Health Gain (MHG) varies with the size of the budget. A new therapy , that is expected to provide improved outcomes per £ for patients and is expenditure increasing will not only push patients with the condition to be treated higher up the order of "priority", it will also, as long as the budget is fixed, displace patients with conditions that would previously have been treated. MHG, at any particular size of the budget will be higher and total expected health gain achievable with that budget will be larger. The MHG curve will shift outward.

In practice, there is not a single NHS budget constraint. The NHS budget is divided geographically (between Health Authorities or PCGs). Each budget holder will divide it between institutions (acute v. mental health contracts) and within institutions budgets are often allocated to groups of practitioners / clinical directorates (Urology, Orthopaedics, etc.). In Figures 5-7 this aspect of the problem is reflected in a situation where a budget holder (PCG or Trust) must allocate a fixed budget between Urology services and some basket of other services. If budget holders are intended to attempt to maximise expected health gain, then resources need to be allocated to different clinical directorates or hospitals in order to roughly equalise expected health gain for the last £ spent. This is illustrated in Figure 5 where we consider allocating a fixed budget between two groups of NHS services at a local (HA, PCG, Trust) level.

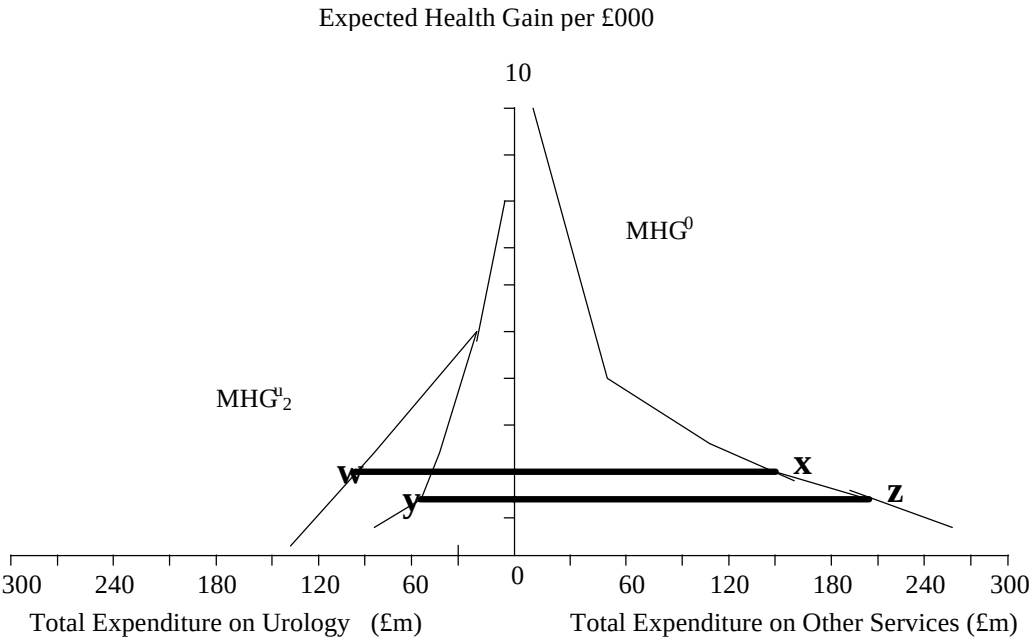
Figure 5: Allocation of a Fixed NHS Budget to Maximise Health Gain



The curve MHG^{u}_{1} gives the marginal health gain as the size of the budget spent on urology services for patients increases. The curve MHG^{o}_{1} gives the marginal health gain as the size of the budget spent on "other" services for patients increases. The Health Authority (or PCG) cannot afford to treat all patients for whom expected health gain is positive. It is necessary to introduce the budget constraint to determine which patients will not be treated. Let the fixed budget be £250m, the length of the budget constraint YZ in Figure 5. The budget constraint YZ means that some treatments with positive marginal health gain will not be offered in the NHS.

Now introduce a new treatment for men with ED. With this new treatment available, there is a new marginal benefit per pound spent curve for urology services indicated by MHG^{u}_{2} . Medical technology has increased potential health gain but the size of the budget remains constant. Applying the principle that the budget should be allocated to maximise health gain means the budget constraint of £250m shifts from YZ to WX (see Figure 6). To maximise health gain in the presence of this new therapy , part of the budget for "other services" should be reallocated to urology. Not only would fewer patients be treated for "other" conditions but some of the patients who previously would have received treatment in urology may not now receive treatment.

Figure 6: Allocation of a Fixed NHS Budget to Maximise Health Gain: Impact of Introducing a New Therapy

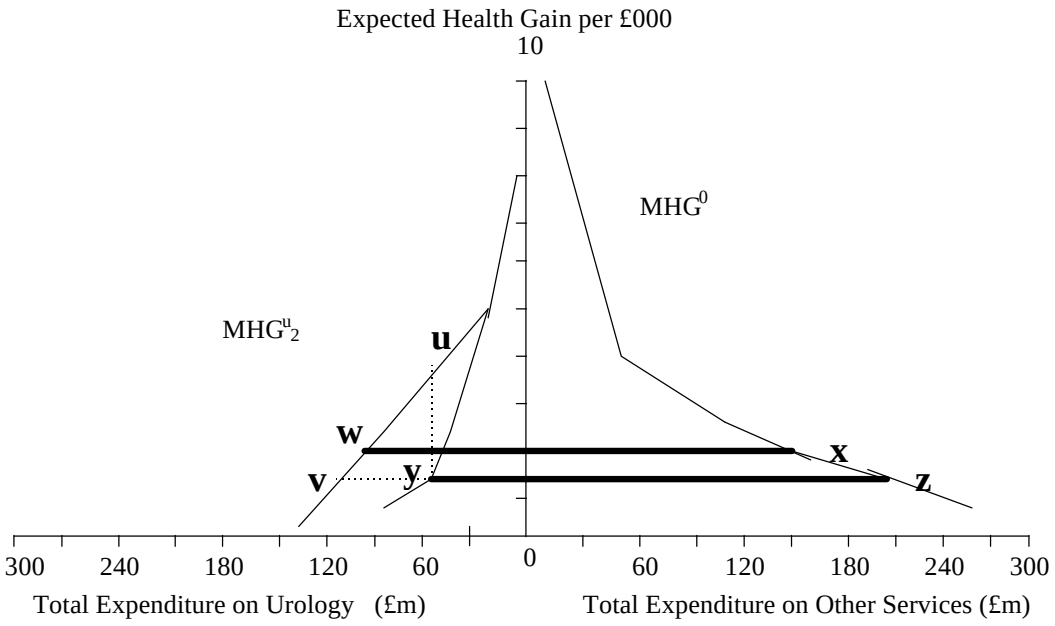


Two (at least!) issues are raised by this analysis of the impact of a new therapy. The first relates to information at the national v. the local level. NICE was marketed as a national institution that would seek uniform adjustment to use of a new product (no post-code rationing). This implies the NICE job should be to marshal or generate the information needed to identify when a new therapy is likely to provide more (less) health gain for existing resources than existing therapies and therefore to be (not to be) recommended for use in the NHS. If this approach is followed, expected total

expenditure on a new therapy would not be relevant to the question of whether the therapy should be included in those offered by a cash limited NHS. If the health gain generated by that expenditure was expected to be greater than the health gain generated by existing uses of those resources, then the new therapy should displace existing services. This is the relevant "impact on NHS resources" illustrated in Figure 6. If the problem is to identify which existing NHS patient treatments should be withdrawn to permit introduction of the new therapy, is that information more likely to available at the local or national (NICE) level? If NICE is unlikely to have the information required and if , for historical reasons, marginal expenditure will differ by area, then efficient adjustment to the new product will be at differential rates by budget holder and will appear as post-code rationing.

The second issue relates to mechanisms for removing resources from one group of patients and directing these resources to treatment of a different group of patients. In practice, there are very few. Where it is difficult to remove resources from existing users, change in resource allocation is ordinarily brought about by directing any real increment in the annual budget toward the area of preferred expansion. The existing budget is not reallocated, future budgets are reallocated, slowly over time as annual increments allow. This however, will lead to post-code rationing. Some purchasers receive larger annual budget increments than other purchasers. Resource releasing events (e.g. early retirement of a consultant) are not uniform across areas. The speed with which each budget holder can move toward the efficient allocation (as defined after arrival of the new product) will differ. Some possibilities are illustrated in Figure 7. In the absence of an overall increase in the budget we might observe some purchasers moving to a point like **U** in Figure 7 where the new therapy is offered but at the expense of a very restricted set of services (patients). Other purchasers may fail to cut sufficient other services and therefore , given the budget, refuse to offer the new therapy, so remain at point **Y**. Other authorities may be successful in cutting existing services and are able to move quickly to the efficient point **W**. Some budget holders may have sufficiently large annual budget increments that they are spared the need to cut existing treatments and can offer the new therapy, moving to point **V.** This is post-code rationing.

Figure 7 : Alternative Resource Reallocations after Introduction of a New Therapy



IV The Legal Solution to Post-code Rationing

To invoke the law as a mechanism to achieve the political objective of national uniformity in rationing appears draconian but if no "post-code" rationing is a serious objective, there may be no alternative. Simply providing information and advice on best practice as with the NHS Centre for Reviews and Dissemination (CRD) Effectiveness Bulletins, or issuing DH guidance in the form of a Circular will not result in uniform access or clinical practice. A very good example is the DH guidance on Beta-Interferon issued in November 1995 (NHS Executive 1995). The intention was to manage the introduction of an expensive new drug in a way that would "minimise inconsistencies in approach to prescribing, both within and across health authority boundaries…"(para11). It failed in this objective.

There are significant variations in the availability of this drug and one case reached the courts. A multiple sclerosis patient challenged the decision of North Derbyshire Health Authority to refuse to fund his treatment with beta interferon. The Health Authority lost the case on the grounds that it had not given proper consideration to the issues raised in the DH circular but the key point for the present debate is that Mr. Justice Dyson said the circular "both in substance and form was advisory and not mandatory" (The Times Law Reports 1997). That is still the case and will continue to be the case even now that NICE is fully functioning (see below) and the Commission for Health Improvement (CHI) is in action. In June 1999, four years after the Beta-Interferon guidance was issued, the director of public health in Oxfordshire was able to say that Oxfordshire Health Authority was guilty of 'post-code prescribing' in its use of beta interferon for people with multiple sclerosis. She reported that local clinicians and the

MS society opted for improved services rather than more drug spending when consulted in 1997 about how £200,000 available should be spent. “So we have gone ahead with our local decisions and criteria for rationing, since we can’t afford to give all patients with the disease the drug…”(Health Service Journal 1999).

Use of the law is not an easy solution to the problem of achieving uniformity of access. The Secretary of State wanted a mechanism that would keep NHS expenditure on ED at the level it had been before Viagra arrived **and** that would insure no post-code rationing. That meant restricting access to a sufficiently low level that purchasers could afford it in the absence of new resources and without withdrawing treatment for non-ED patients. Pfizer challenged the initial DH guidance that told GPs not to prescribe Viagra. The Court ruled in favour of Pfizer and in the course of the judgement laid down markers for future actions to limit availability of treatments to NHS patients. Three of the more important points arising in the judgement handed down by Mr Justice Collins are worth noting. (All references are to the written judgement Regina v Secretary of State for Health ex parte Pfizer Ltd.)

1. *Department of Health Circulars and guidance are not binding on clinicians:*

“Suffice it to say that there is no specific power in the Secretary of State to issue directions the effect of which is to prevent a drug from being prescribed either wholly or partially.”(p.6 lines18-20) As a body created by the Secretary of State, the interim guidance for NICE also stresses the non-mandatory nature of the decisions they will reach and the guidance they will issue. If the Secretary of State wishes to limit availability of a drug it will be necessary to obtain parliamentary approval. The National Health Service (General Medical Services) Regulations 1992, Schedule 2, sets out the terms of service of GPs contracted to the NHS (the GP contract). Schedule 10 of the Regulations lists drugs that the NHS will not reimburse. Schedule 11 lists drugs that the NHS will pay for only if prescribed for a more restricted range of conditions than the conditions for which the drug has been licensed. Until Viagra, and other drugs used in the treatment of ED were added, there had only been eight drugs on Schedule 11.

Justice Collins clearly thinks that the existence of parliamentary procedures to challenge amendments to Regulations in some sense guards against potential arbitrariness of a decision the Secretary of State may take on rationing: “...the circular was intended to and had the same effect as if Viagra were placed in Schedule 11 and none of the safeguards or procedural requirements have been followed.”(p.8 lines 46-48). However, as he pointed out earlier in his judgement, there are no criteria in the Regulations to establish the basis for “black listing” a drug. The Secretary of State can choose the criteria to suit the circumstances. The only procedural safeguard associated with requiring a rationing decision to be clearly set out in Schedule 11 is that MPs have the opportunity to challenge the amending order after it has been placed before parliament. Statutory Instruments are not scrutinised and debated the way a Bill might be but an MP can put down a motion (known as a *prayer*) to nullify a Statutory Instrument (Walker 1998). This happened in the case of Viagra. It is not surprising that the Government had no difficulty securing its desired amendment to Schedule 11; it is surprising that Private Eye did not run an article on MPs praying for less restricted availability of Viagra.

2. *European Union Competition Law*

The court found that in issuing Circular 1998/158, advising GPs not to prescribe Viagra, the Secretary of State was in breach of Directive 89/105/EEC, one of the "transparency" Directives[§]. The Directive in question deals with situations where the competent authorities of a member state are empowered to adopt decisions to exclude individual or categories of medicinal products from the coverage of its national health system. Article 7(1) requires that "Any decision to exclude a category of medicinal products from the coverage of the national health insurance system shall contain a statement of reasons based upon objective and verifiable criteria and be published in an appropriate publication." (OJ 1989). The Judge found that there had been no publication of objective and verifiable criteria nor had the criteria been communicated to the Commission or to Pfizer. The Directive is intended to ensure there is no distortion or hindrance of intra-community trade. Viagra clearly fell into this category as the raw materials are produced in Ireland, the pills manufactured in France and then exported to the UK. Circular 1998/158 advised GPs not to prescribe Viagra but placed no limitations on their ability to prescribe any other medication for patients being treated for ED.

In order to achieve his objective of limiting total NHS expenditure on Viagra and at the same time not run foul of discriminating against a particular product, the Secretary of State was forced to adopt a solution that limited the number of men who could be treated for ED by the NHS (defined by a list of 12 predisposing causes) and to restrict availability on the NHS of the other main medications that have been used to treat impotence (HMSO 1999). Three more drugs were added to Schedule 11 not because they were being used inappropriately or were very expensive but to legitimise the restriction on the use of Viagra.

3. *Limitations on the exercise of clinical judgement*

"The doctor must give such treatment as he, exercising the professional judgement to be expected from an average GP, considers necessary and appropriate". This is a contractual obligation of a GP in the NHS. The problem with the circular was that advice was given "in a manner which meant that GPs would inevitably regard it as overriding their professional judgement.." (p.10, lines 15-17). Justice Collins wrote: "In my judgement, the evidence confirms that this was and was intended to be acted upon by GPs independently of whether in their professional judgement a patient needed treatment for ED and so should have the better such treatment available, namely Viagra. Thus I am satisfied that the circular was and is unlawful in terms of domestic law." (p.10, lines 24-26).

It is important to distinguish legal limitations on the exercise of clinical judgement and non-availability of a treatment on the NHS. A drug may be placed on Schedules 10 or

[§] The original "Transparency Directive" passed in 1980 was considered necessary because of the difficulty of determining whether competition is being distorted in sectors of the economy directly controlled by the government of a member state. The solution adopted was to require relevant information be made available and the transactions "transparent". See Whish (1993) .

11 and therefore not be available on the NHS but the GP who considers it to be a necessary and appropriate treatment for his patient can simply write a private prescription. Schedules 10 and 11 do not prevent a clinician from exercising his clinical judgement though we know there are cases where physicians who believe a patient may not be able to afford to fill a private (or even an NHS) prescription, may not offer a prescription.

There seems to be some confusion over when a GP can offer an NHS patient a private prescription and this confusion is reflected in the Pfizer judgement. In commenting on the effectiveness of the Circular in limiting the prescribing of Viagra, Justice Collins said "...and its effect was exacerbated because, since Viagra was not "blacklisted" in Schedule 11, it could not be prescribed privately to their patients by NHS GPs..."(p.9, lines12-13). It is not clear on what basis the Judge arrived at this conclusion[**]. On 4 May 1994 the NHS Executive issued a letter clarifying the GPs terms of service in respect of the issue of private prescriptions(NHS Executive 1994). After pointing out that Paragraph 44 of the 1992 Regulations clearly permits the issue of a private prescription for a drug listed in Schedule 10 or 11, it goes on to say "The Department's legal advisers have also given the opinion that a general practitioner may issue a private prescription at the request of or with the consent of the patient, provided that in such circumstances the doctor takes account of whether the patient is exempt from NHS prescription charges."(p.1) The letter implies there is no limitation on the right of a GP to write a private prescription for any licensed drug, private prescriptions are not limited to drugs on Schedules 10 and 11.

The lawyers of the BMA disagree with the lawyers of the DoH on this point and Justice Collins apparently agrees with the BMA. In guidance issued to General Practitioners (GMSC 1996) the BMA advises that if a GP considers that a patient needs a drug, s/he must prescribe it on the NHS unless the substance has been placed on Schedules 10 or 11. The procedure advocated by the Secretary of State in his original guidance, that GPs should not prescribe Viagra on the NHS but should feel free to offer a private prescription to any NHS patient willing to pay, was of disputed legal validity. Now that Viagra is on Schedule 11, private prescriptions are clearly lawful.

If to reduce post-code rationing in future, greater use is made of Schedule 11, patients excluded from NHS treatment will be able to request private prescriptions. The tighter eligibility is defined in Schedule 11, the greater will be the importance of willingness to pay in access to new treatments.

The reasoning of Justice Collins in the Pfizer case was clearly reflected in the first NICE guidance on Relenza published on 8 October 1999. The Guardian headline that day read "Dobson rejects flu drug despite threats" and the text included "GPs will be told they cannot prescribe the drug on the NHS." The NICE guidance on Relenza in fact contained the following statements:

- Relenza is accordingly now available for prescribing on the NHS.

[**] In his judgement Justice Collins cited Paragraphs 40 and 42 of Schedule 2 to the 1992 Regulations but these paragraphs only limit the ability of a GP to charge for writing a private prescription, they do not prohibit the writing of a private prescription.

- Individual health professionals have a responsibility to exercise their clinical judgement in determining what treatments are appropriate and necessary for patients with influenza-like symptoms.

- This guidance does not override that individual responsibility.

- On the basis of its findings and conclusions, the Institute advises that health professionals should not prescribe zanamivir (Relenza) during the 1999/2000 influenza season.

The Department of Health had learned from the legal challenge on Viagra that unless they were willing to use Schedules 10 or 11, the Department can not restrict, only advice.

V Conclusions

Whenever a new cost-effective but potentially cost increasing treatment becomes available, purchasers are confronted with a dilemma. If they were to adjust the allocation of their available resources to attempt to maximise health gain, they would need to withdraw resources from existing patients and treatments and direct these resources to the new therapy with its higher expected health gain. However, powers of direction in the NHS are limited and withdrawal of resources from one group of clinicians or patients to finance expansion elsewhere tends to be a slow and long-drawn out process. In practice change is brought about by using any real increment to the annual budget rather than reallocating the existing budget. Any "new" uncommitted resources can be directed toward the therapy promising extra health gain and over time the share of the budget that would be indicated by an objective of maximising health gain may emerge. Some purchasers may receive larger increments to their budgets than others and can move faster than others toward provision of the new therapy. Other purchasers may find non-budgetary events permit them to redeploy resources at a more rapid rate than annual budget increments would allow.

If this diversity is politically unacceptable and the new therapy is to be available on a uniform basis from the very beginning, there are two ways to achieve this given the differences between purchasers in available resources. First, The Secretary of State can decide to restrict availability to a level so low that it can be accommodated within the margin of available resources by the authority with the tightest budget constraint. Purchasers whose greater budget flexibility would have permitted them to provide more of this therapy must be prevented from doing so. In effect these purchasers are instructed to direct their marginal funds into therapies with lower expected health gain. This could be seen as a kind of equity-efficiency trade-off if uniform access is treated as an issue of equity and maximisation of health gain our notion of efficiency.

The second way to secure uniform availability in the face of differences in available resources is through earmarked funding. Each purchaser could be given a specific

grant, funding only to be used for the purchase of the new treatment[††]. In this way the Secretary of State could choose any level of provision he thought appropriate and distribute the funds by any criteria he thought appropriate. However, such grants have income effects and those purchasers who would want to spend more on the new treatment must be prevented from doing so. A specific grant may allow the new treatment to be introduced on a more generous scale than the policy of the previous paragraph but it still requires an enforceable restriction on the right of purchasers to provide more than the stipulated amount of the treatment if post-code rationing is to be prevented. There is no straight forward way of doing this. Schedule 11 can be used to limit GP prescribing but there appears to be no equivalent legal mechanism to limit the prescribing of hospital consultants. The usual method would be for the Health Authority, or in future the PCG, to refuse to reimburse a hospital for use of a drug or treatment outside of a restricted list of patients or conditions. Patients excluded by the restricted list, if they can afford it, may seek private prescriptions.

The way in which economic evaluations of new products are commonly presented disguises the nature of this rationing problem. Use of a "cut-off" or "threshold" cost-effectiveness or cost per QALY value gives the impression of a soft budget constraint. If a new therapy can be expected to generate health gain per £ equal to that of treatments already provided, the message appears to be that the new treatment "should" be provided. If, instead of a soft budget constraint, we have a hard budget constraint, the rationing problem is that of identifying what existing treatments should be displaced when a new product is introduced. This requires information on health gain and costs of existing treatments as well as information on new products. Without the information on existing treatments, it is not possible for a central body to identify the activities to be displaced by the new product. This rationing principle (obviously) also requires mechanisms for shifting resources from one group of patients (clinicians) to another. The NHS lacks both the information and the mechanisms necessary to implement nationally uniform rationing when new, expensive, products become available.

What we might call the "Viagra model", gives priority to achieving national uniformity in introduction a new drug over attempting to maximise any measure of health gain or health benefit. It avoids the problem of identifying what services are to be displaced by the new therapy by the straight forward means of restricting availability of the new treatment to a level that can be financed from the existing level of expenditure on the condition. It therefore side steps the problem of inadequate information on the cost effectiveness of existing treatments. To implement the "Viagra model" requires choosing for NHS treatment a sub-set of all patients for whom the new therapy is cost-effective and preventing NHS funded treatment of the remaining patients for whom it is also cost effective.

There must be a mechanism to enforce this restriction on treatment. Historically the NHS has relied on two mechanisms. The first, and until now, least important, was

[††] This is in effect the recent recommendation of the Royal College of Physicians (2000) but the ear-marked funding would only last for one year.

Schedule 11 of the 1992 NHS (General Medical Services) Regulations. The schedule lists drugs which GPs are only allowed to prescribe on the NHS for a limited set of patients. The fact that only four drugs had been added to the list since 1992 (until Viagra on 1 July 1999) is an indication of how rarely this legal mechanism was used to enforce a national policy. More common have been DH circulars and advice suggesting that GPs might want to defer to consultants decisions on prescribing expensive new drugs. The effectiveness of this mechanism ultimately rested on voluntary compliance with DH advice by consultants, GPs and Health Authorities. Post-code rationing was a consequence.

Developments in information technology will make it increasingly easy for patients and their families to obtain information on potentially useful drugs. When a new product promises some improvement on existing treatments, patients will seek access. Where a policy of uniform availability, constrained by marginal resources and no displacement results in a very restricted availability of the new drug on the NHS, the system will need a safety valve. The availability of private prescriptions from NHS clinicians provides the safety valve. It will be ironic if the first serious attempt to prevent geographical (post-code) rationing in the NHS bequeaths to the nation a system for increasing the extent of rationing by income.

REFERENCES

Birch, S. and Donaldson, C. Cost effectiveness/utility analyses: Do current decision rules lead us to where we want to be? *Journal of Health Economics*, 1992, 11:279-296.

British Medical Association, General Practitioners Committee (1996) Prescription Charges Guidance for GPs

Briggs A. Handling uncertainty in economic evaluation. *British Medical Journal*, 1999, 319:120.

Burls A, Clark W, Gold L, Simpson S. Sildenafil: an oral drug for the treatment of male erectile dysfunction: a West Midlands Development and Evaluation Committee (DEC) Report, 1998, Birmingham: University of Birmingham.

Department of Health Press Release. Treatment for Impotence, 21 January 1999a.

Department of Health Press Release. No Place in the NHS for Inequalities of Care. August 1999b.

Health Service Journal, 17 June 1999 p.11.

HMSO, Statutory Instrument 1999 No. 1627, The National Health Service (General Medical Services) Amendment (No.2) Regulations 1999.

Keith, A. (2000) The Economics of Viagra, Health Affairs, pp.147-157.

Lancaster, K. Consumer Demand: A new approach. 1971, Columbia University Press, New York.

McIntosh. Arousing Debate, *Health Services Journal*, 4 February 1999.

NHS Executive. Health Service Circular HSC 1999/115 Treatment for Impotence, 7 May 1999.

NHS Executive. EL(95)97 New Drugs for Multiple Sclerosis.

NHS Executive. FHSL (94) 26, General Practitioners Terms of Service: Private Prescriptions, 4 May 1994.

NHS Executive. "Faster Access to Modern Treatment": how NICE will work. January 1999a.

NICE. Appraisal of New and Existing Technologies: Interim Guidance for Manufacturers and Sponsors, 1999b.

NICE. Memorandum of understanding on appraisal of health interventions, 1999c.

OJ No L 40, 11.2. 1989, p11.

Regina v North Derbyshire Health Authority, Ex parte Fisher. The Times Law Reports 2 September 1997.

Regina v. Secretary of State for health ex parte Pfizer Ltd, Case No: C)/4934/98, 26 May 1999.

Royal College of Physicians (2000) The Prescribing of Costly Medicines, RCP, London.

Walker, (1998) Statutory Instruments and Deregulation Orders, House of Commons Information Office , HMSO.

Williams A. Coronary artery bypass grafting: an economic appraisal. *British Medical Journal*, 1985, 291:326-329, 735-737.

Whish (1993) Competition Law. Buterworths. London

ANNEX

Figures 5-7 in the text reflect a way of organising the data NICE is expected to collect in a way that highlights the effect of introducing a new treatment in a budget constrained system. The interim guidance on NICE procedures only requires the information in columns (a), (b), (c), (e) and (f). However, if we have estimates of (b) and (c), we can calculate (d), information necessary to identify which of several alternative use of resources is likely to produce the highest health benefit. If we rank treatments by expected health benefit per £ and we have estimated total cost of each treatment, we can see the impact on total expenditure of providing additional treatments (g). The figures in the text make clear the relationship between the core data to be collected and analysed by NICE and the well known concept of a "QALY league table". There are many important economic issues/problems with use of such information (e.g. Briggs 1999) but they do not affect the central point of this section—how does the arrival of a new product affect the ranking of treatments.

Procedure/ patient character-istics (a)	Expected health gain (QALYs or other measure) (b)	Expected cost per patient episode (£000) (c)	Expected health gain per £000 (d)	Expected number of patients to be treated (e)	Expected total cost (£m) (f)	Cumulative total expenditure (£m) (g)
A						
B						
C						
D						
E						
F						