

CASE STUDY: PLANNING BEST PRACTICE IN UK HEADACHE SERVICES

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INTRODUCTION

The purpose of this study is to illustrate, using the UK as an example, how the case for improved health care for headache might be mounted in order to persuade policy-makers of the need and priority for improvement. To support the argument for change it is necessary to show two things: first, the extent of the burdens attributable to headache disorders; and, second but crucial, that these burdens are reducible through effective and cost-effective treatment which, for whatever reason, is not currently reaching those who would benefit.

The questions that arise are: what manner of reform of headache services will engender best practice, and how extensive should it be?

Two circumstances coming together gave origin to the ideas explored in the case. The first, that headache disorders in the UK – common, disabling and burdensome – are under-treated by health services that are poorly organised, applies to a greater or lesser extent everywhere in the world. The second – the political context – is more specific to the UK, where government reforms of the National Health Service (NHS) are pushing health care generally back into primary care, and supporting this shift by redistribution of resources.

In attempting to answer each of two questions, it is essential not only to acknowledge but also to respect the political context if the case for change is to be made successfully. This study shows how this might be done.

SECTION 1:

MAKING THE CASE: THE NEED AND OPPORTUNITY FOR CHANGE

Introduction

The United Kingdom's NHS is statutorily charged with providing comprehensive health care free at the point of delivery, paid for out of general taxation (the Beveridgian model). It has a particularly strong system of primary care (Dixon *et al*, 1998) in which general practitioners (GPs), the first contact for patients for all except emergency consultations, maintain personal lists (Badia, 1996). In theory this means that registered patients consult the same GP on all occasions and for all purposes, strongly promoting continuity of care which, it is argued, engenders trust and satisfaction (Mainous *et al*, 2001) and should be preserved (Pereira Gray *et al*, 2003). In practice, few GPs now practise alone; most work in health centres of up to 12 GP-partners and patients may choose to consult any of the partners. GPs perform a gate-keeper role to specialist services in secondary care (Ferris *et al*, 2001).

This first section begins with a basic account of headache disorders, their manifestation in populations and the burdens they impose. It continues with a description of current headache-related health-care utilisation in the UK under the NHS, arguing that the present system throws up barriers to access to care that result in socially significant deficiencies in health-care provision. As a result, there is need for reform. Finally, government intentions for NHS reorganisation, as set out in the *NHS Plan* (DoH, 2000a), are described as a *supportive* context for beneficial change in headache services based in primary care.

Headache

Headache is manifest in a number of primary disorders – most commonly tension-type headache and migraine – and it occurs secondarily to a considerable range of other conditions which, in an epidemiological if not personal sense, are of lesser consequence (Headache Classification Committee of IHS, 1988).

Burdensome to individuals and society

Taken together, as demonstrated by the evidence adduced above by Leonardi, headache disorders are extraordinarily common world-wide. Headache is obviously painful; but, depending on its intensity and other symptoms that may accompany it, headache disorders are also disabling (Leonardi, 2003). Migraine alone is the cause of more years lived with disability world-wide than epilepsy (WHO, 2001). In consequence, headache disorders impose recognisable burdens on sufferers that include sometimes substantial personal suffering, impaired quality of life and financial cost (Osterhaus *et al*, 1992; Kryst and Scherl, 1994; Rasmussen, 1994; Stewart *et al*, 1996; Schwartz *et al*, 1997).

But their impact also extends beyond those immediately affected (Steiner, 2000a). Employers, work colleagues, family and friends may be required to take on work and duties abandoned by headache sufferers. They may acquire carer roles for them, or lose the society of those with headache.

It should be unsurprising that the World Health Organization (WHO) recognises headache disorders as a high-priority public health concern (WHO, 2000), but they do so against a world-wide backdrop of low priority given to them by society in the queue for health care (AASH and IHS, 1998). This is paradoxical: estimates

of the financial cost of headache disorders to society, which relate principally to lost work-time and reduced productivity due to impaired working effectiveness, are massive. On any working day in the UK, over 100,000 people are absent from work or school because of migraine alone (Steiner *et al*, 2002a). Tension-type headache (less disabling but more prevalent) and chronic daily headache (less prevalent but more disabling) may each cause similar losses although the empirical basis for this assertion is less solid.

Health-care utilisation

As might be expected, large numbers of people with headache are seen by GPs and by neurologists in the UK (Hopkins *et al*, 1989; Wiles and Lindsay, 1996). In a general population sample, a high majority (86%) of those with migraine had seen a doctor for headache at some time in their lives, a quarter making more than 10 visits (Lipton *et al*, 2002b). Of patients aged 16-65 years registered in a large general practice, 17% had consulted because of headache at least once in 5 years; 9% of these were referred to secondary care (Laughey *et al*, 1999). A survey of neurologists found that up to a third of all their patients consulted because of headache, more than for any other single complaint (Hopkins, 1997). Furthermore, numbers were increasing.

Diagnosis and treatment gaps

The appearance from these figures of health-care needs being met by the health service is, however, quite false.

In fact the volume of headache referrals to neurologists is difficult to justify. The common headache disorders require no special investigation and are manageable with skills expected to be generally available in primary care (BASH, 2001; Steiner and Fontebasso, 2002). Yet, at the same time, there is good evidence that very large numbers of people disabled by headache do not receive effective health care. For example, face-to-face interviews of people with migraine drawn from a representative sample of the UK general population revealed that only half (49%) had seen a doctor for headache-related reasons in the last 12 months (Lipton *et al*, 2002b). Only 67% overall and 80% of those consulting within 12 months were correctly diagnosed. Most were solely reliant on over-the-counter (OTC) medications, without access to prescription drugs. In a UK general-population questionnaire survey, two-thirds of respondents were searching for better treatment than their current medication (Dowson and Jagger, 1999).

Crucially, disease- or treatment-related factors do not explain consultation patterns: in the general population sample only a minority gave "my headaches are not that bad" or "I already have found/been given a treatment that works" as reasons for never seeking or lapsing from medical care. Instead the reasons were largely negative: "it is too inconvenient to see a doctor" (53% of those who had never consulted); "there is nothing the doctor can do" (22% of those who had never consulted and 27% of those who had lapsed); or "the doctor has shown no interest in headache" (10% of those who had lapsed). On the other hand, most who had never sought (60%) or had lapsed from care (66%) showed high migraine-related disability, as did 64% of those with undiagnosed migraine and a large majority (72%) of people using only OTC medications.

Barriers to care

The evidence, therefore, is of substantial and perhaps growing demand for headache-related health care which, however, has limited reach. In the face of significant illness-related disability, problems of access together with low

expectation or poor actual experience of the outcome of a consultation are contributory factors to not seeking care, at least for migraine. A similar situation probably pertains to other headache disorders (since there is no reason to assume otherwise) although far less is known about the demand for health care related to these.

In other words, barriers to access to headache care appear not only to exist within the NHS but to be set rather high, a situation to a large extent reflected globally (AASH and IHS, 1998; WHO, 2000).

Ability to benefit

There is a final, crucial link in the chain of this argument. It is that the potential for benefit through the delivery of appropriate health care, and alleviation of the burdens attributable to headache disorders, translates burden into need.

A detailed account of headache treatments would be inappropriate here but can be found in evidence-based management guidelines (BASH, 2001). Numerous studies demonstrate a range of effective migraine therapies, from analgesics and antiemetics to specific drugs (triptans) that act on tissues close to the origin of symptoms, relieving pain and associated symptoms and restoring ability to function. Treatments exist also for tension-type headache, and for most chronic daily headache. There is even some evidence that efficacious treatment gets people with headache back to work (Saper *et al*, 1999; Wells and Steiner, 2000). Burdens imposed by headache disorders *are* (at least in large part) remediable through effective health care (Steiner and Fontebasso, 2002).

The impetus for change

Given the high prevalence of headache disorders, and in view of the burdens they impose, it is surprising that those affected by them are not better heard. That said, the existence of treatable but untreated burden may demonstrate *need* but does not, of itself, establish a case for change.

A wide variety of demands are made of the NHS, many backed by underlying needs, in a climate of increasing public expectation and government commitment to provision of high-quality services. Any proposal for change requires two-fold justification: that change is capable of realising the potential for benefit, and also that there is a case for priority if, as is almost inevitable, change causes consumption of additional resources. The first of these ultimately requires empirical proof, although there is nothing unusual about that in the context of health-service innovation. As for the second, commitment of extra resources requires proof (also empirical) of cost-effectiveness; but pending that, arguments can be advanced that change will result in more efficient use of the share of resources already allocated to the management of headache disorders. They run as follows.

Headache disorders have been shown above to be the cause of substantial suffering, disability and impairment of quality of life. People affected by them *deserve* to be treated effectively, whilst good evidence shows that in many cases they are not although treatments exist. In fact none of the available evidence is able to demonstrate that the present NHS-expenditure on headache management has *any* effect in reducing overall costs or other burdens attributable to headache. That is the humanitarian argument to drive change, and it is a very important argument.

There is a societal argument, too, that some may perceive as having greater

force since it has economic merit. Because the indirect costs of headache disorders so greatly exceed direct treatment costs (Bosanquet and Zammit-Lucia, 1991) (remember the 100,000 absentees every working day referred to earlier [Steiner *et al*, 2002a]), better management should mitigate the total financial cost of headache. In other words, from a societal perspective good headache management may be cost-beneficial (Oliver *et al*, 2002).

Furthermore, there is considerable potential, which is in part realised, for *adding* to the burden of headache through mismanagement (Steiner, 1995; Steiner, 2000b), whilst consuming health-care resources. Thus poor management may be worse (from a health-service perspective as well as from individual and societal perspectives) than no management. Turning poor management into good management will arguably release health-care resources (Guterman and VanRooyan, 1998) to offset those that will be additionally consumed through the treatment of larger numbers.

The opportunity for change

The UK government has made a clear commitment to a more efficient, primary care-led NHS, reflecting a public perspective that increasingly recognises the importance of improved quality of life, not only prolonged life, as a central objective of health care. Under the *NHS Plan* (DoH, 2000a), primary-care services are undergoing radical reform.

Primary-care reorganisation: the source of opportunity

Beginning in 1999 Primary Care Groups (PCGs), later amalgamated into Primary Care Trusts (PCTs), brought neighbouring general practices together (DoH, 1998a). In meeting local health-care needs, PCGs were expected to make choices *based on cost-effectiveness* (DoH, 1997), thereby improving quality of care and access to care (DoH and RCGP, 2002). PCTs acquired a broader responsibility for securing the provision of a full range of services to the local population (DoH, 1997). A key innovation introduced by PCGs and extended by PCTs was joint working across practices.

These changes in primary care present an enormous opportunity to do things differently in pursuit of doing them better. In a new non-competitive climate enabling inter-practice referral, each practice is no longer expected to be the provider of primary-care services at all levels in all therapeutic areas to all of its population: where better care (or cost-savings) will result, some services can be provided by one (or a few) practices for the entire population of a PCT.

Shifting the balance

These organisational changes, however, are mere reflections of much more fundamental political reform. Whilst hospitals were once the NHS providers of virtually all specialist services in the UK, consecutive reforms began (NHS and Community Care Act, 1990; Jones *et al*, 1995) and are continuing (DoH, 2000a) a diversion of resources from the hospital sector towards primary care. The *NHS Plan* (DoH, 2000a) lays out significantly greater roles for GPs, and a power-shift (DoH, 2001) in which PCTs will become the lead NHS structures in assessing and providing for all the health needs of their local communities. This includes commissioning such services as are thought necessary from secondary providers such as acute hospitals. By 2004, 75% of NHS funds will flow directly to PCTs.

An important theme of the *NHS Plan* is fundamental and whole-service review of working practices. This includes care pathways from GP to hospital and *what*

might or should be done in primary care and what must be done in secondary care.

Thus the new "primary-care-led NHS" takes emphasis, and potentially money, away from the acute hospital sector and moves them to a more broadly defined primary care (Hossain, 1998) in which GPs will have considerably more influence and freedom in the use and allocation of resources. An explicitly intended consequence is integrated working in primary care, with greater involvement of multi-professional teams (DoH, 2000b). The likely result is the appearance of different models of integrated care, shared care schemes, specialist outreach services, intermediate hospital care and other forms of substitution for hospital care together with community services focused on prevention and education of the public on health-related issues.

GPs with special interests (GPSIs)

In this context the development of GPs with special interests – primary care physicians with enhanced expertise in areas that often have long waiting times to be seen by hospital specialists – is another intention (if not pillar) of the *NHS Plan*. GPSIs are not "cut-down specialists" but expert generalists providing services at an advanced level (Dhillon and Rout, 2002; Baker, 2002). They are expected to provide more complete care in a particular therapeutic field to patients outside hospital (DoH and RCGP, 2002; DoH, 2002). A blurring of the interface between primary and secondary care is a clearly intended result.

In fact, the *NHS Plan* sets a target of four million outpatient consultations moved into primary- and community-care settings by 2004.

The specific opportunity for headache

The opportunity for headache services – to establish the right structure with the optimum involvement of primary care – arises directly from these changes. Although the *NHS Plan* specifies ophthalmology, orthopaedics, dermatology and ear, nose and throat surgery as initial target areas for the development of GPSIs, later guidance makes clear that PCTs have freedom to take this approach, if identified as the best way forward, *in any area they wish* (DoH and RCGP, 2002).

This opens the way for the development of PCT-based headache centres, staffed by GPSIs along with nurses with special interests (and, perhaps, other appropriate professionals such as physiotherapists, psychologists and pharmacists). One or more such centres per PCT can offer headache-related health-care services at an intermediate level between primary and secondary care to all of that PCT's population.

Using the opportunity

This brief review of the performance of existing headache services in the NHS and of the reorganisation now afoot has established need, impetus and opportunity for change. In response, this case study assesses the level of provision of headache-related health care that would represent best practice whilst respecting political priorities.

Three objectives were identified: first, to know the headache-related health-care needs of the general population, where "needs" are defined in terms of capacity to benefit from health care; second, to understand what is wrong with current headache services within the NHS in terms of their failure to meet assessed need, and what are the remediable deficiencies given the opportunity for reform; and

third, to obtain a consensus view of desirable change.

SECTION 2. KNOWING NEEDS

Assessments of headache-related health-care needs of the general population are prerequisites for proposals for meeting them.

“Needs” were defined in terms of capacity to benefit from health care on the assumption that it was provided optimally.

Methods

Needs were assessed for a population of 280,000 people assumed to be representative of the general population of England (the “standard population”). This number was within the range of registered populations of inner-urban PCTs (LSLHA, 2001a). Because a number of assumptions were necessary, three approaches were adopted in an attempt at triangulation, using principles of practical health economics (Stevens and Gillam, 1998).

Epidemiological approach

Estimates were based on national prevalence and disability data for the common headache conditions, established by review of the relevant literature using standard search methods and borrowing from reviews already undertaken in previous studies (Lipton *et al*, 2000; Steiner, 2000a; Lipton *et al*, 2002a; Steiner *et al*, 2002a; Olesen *et al*, 2002). To convert data relating to burden into estimates of need and demand, *need* was taken to exist only in those able to benefit from headache-related health care, and *demand* only in the subset of those who expressed need by seeking health care.

Comparative approach

No area was known that might be said to provide “best-practice” headache services, and there were no quality measures for primary-care headache services that could be used comparatively. An estimate of “good” provision of front-line headache care by GPs, and referral rates to secondary care, was made from data published by a large practice where one partner had a known special interest in headache disorders (Laughey *et al*, 1999) (the “index practice”). These numbers were extrapolated to the standard population of 280,000 for comparison with those arrived at by the epidemiological approach.

Health-care provision for headache was compared with the provision for another condition causing widespread pain and disability in the population – low back pain – in expectation that this would be informative. It was done on the basis of the most-recently published or extrapolated estimates of the direct NHS costs of migraine (Blau and Drummond, 1991; Bosanquet and Zammit-Lucia, 1991) and low back pain (DoH, 1999). To complete the comparison, NHS expenditure on each was related to societal costs in lost work days attributable to the two conditions.

Determining service-provision requirement

Calculations were based on the above quantitative assessments of numbers in the standard population with need. The following assumptions were made:

- 1) *demand* was expressed within each year by only 50% of those in need;
- 2) 9% of patients complaining of headache required referral to specialist

care;

- 3) relatively so few patients with headache (<1%) *required* secondary-care management (Steiner and Fontebasso, 2002) that they could be ignored in calculating primary-care demand;
- 4) need arose in the child population at half the rate per head of the adult population;
- 5) medical needs required 1.25 hours of consultation time on average per adult patient per year, and 2.5 hours per child;
- 6) no wastage occurred through failures to attend.

To estimate medical-time requirements, the further assumption was made that two sessions per week of each medical whole-time equivalent (WTE) were needed for administration, audit and continuing professional development (CPD).

Sensitivity analysis was performed since it was likely that estimates would be highly sensitive to error in some of these assumptions. These assumptions were varied, and calculations re-made, as follows.

- 1) Demand within each year was taken as 75% of need. Whilst only 50% of patients with need might seek care initially, more could be expected to do so once they perceived better care to be available.
- 2) A referral rate of 20% was assumed. The assumption that 9% of patients seeking headache care needed referral to specialist care was based on records from the index practice where the established interest in headache disorders might result in a referral rate that did not apply widely. The majority of patients expected to have headache-related health-care needs would have migraine, for whom there was other evidence that 20% were referred to specialists (Lipton *et al*, 2002b).
- 3) Medical-time allocations of 2 hours per adult patient per year and 2.5 hours per child were assumed. The previous allocation of 1.25 hours of medical time per year per adult patient might be appropriate, as an average, for migraine, but patients with cluster headache and those with chronic daily headache arguably needed significantly more.

Corporate approach

In this third approach, principal stakeholders' opinions of what level of need should reasonably be provided for were ascertained. Unstructured interviews were conducted after circulation to respondents of the estimates above of service-provision requirement. They were first asked what level of need or demand should reasonably be met at primary-care and at specialist levels. When the response was that all demand should be met, whatever proportion it was of need and whatever the epidemiological and comparative assessments found it to be, there was concordance and the interview was terminated. When the response was that there should be some lesser provision, further questions sought reasons why under either or both of two possibilities: that the assessments were wrong, or that the case for priority in meeting this particular need was not met.

Amongst a range of specialities contributing to headache management, neurology is by far the most important (Hopkins *et al*, 1989). The number of neurologists per head of population and their median waiting time for routine appointments were ascertained, again from published data (Warlow and Venables, 2000), as

indicators of service quality relevant to corporate needs assessment. In evaluating service quality overall, including at primary-care level, the empirical data for migraine gathered from a general population survey (Lipton *et al*, 2002b) were recalled.

Reconciling estimates

It was anticipated, because of recognition that allocating resources to meet *all* headache-related health-care need would significantly diminish those available for other needs, that corporate assessment would be at odds with epidemiological accounts of “need”. In case that happened, the epidemiological assessment of need would be revisited in expectation of stakeholder resistance to it. If assessed need showed a requirement for increased rather than redistributed resources allocated to headache care (with opportunity cost), an argument based on cost-effectiveness (Oliver *et al*, 2002) would be mounted although proof of this would be empirical. It would consider the extent to which referrals to neurologists – a scarce resource – could be reduced by proposed change to headache services (opportunity gain).

Headache-related health-care needs

Epidemiological approach

Taken together, headache disorders afflict at least 75% of the UK population each year, but not all give rise to health-care need. For example, whilst the 1-year prevalence of tension-type headache has been estimated at 63% in males and 86% in females (Rasmussen *et al*, 1991; Rasmussen *et al*, 1992; Jensen, 1999), it is generally a mild-to-moderate self-limiting illness occurring occasionally which people often refer to as “normal” or “ordinary” headache. They treat it with OTC medications, mostly successfully (Murray, 1964; Peters *et al*, 1983; Langemark and Olesen, 1987; Moore *et al*, 1999; Martinez-Martin *et al*, 2001; MacEachern *et al*, 2001; Steiner *et al*, 2002b), and have no need to consult doctors. Migraine on the other hand, affecting 7.6% of males and 18.3% of females in England (Steiner *et al*, 2002a), is in many cases a lifelong and disabling condition (Lipton *et al*, 2002b). Almost 5% of the population have chronic daily headache (Scher *et al*, 1998; Castillo *et al*, 1999) with significant disability and a high probability of being chronically off work and of demanding health-care intervention: in at least half of these cases, medication misuse is a major (and remediable) factor in causation (Steiner, 2000b). These latter conditions account for virtually all assessable headache-related health-care need.

The calculations ran as follows. According to national statistics for England (ONS, 2002), in the standard population of 280,000 there would be 182,000 adults aged 16-65 years – the range in which headache disorders are most prevalent. Of these, 27,000 had migraine with 22,000 reporting significant consequential disability (Lipton *et al*, 2002b). An estimated 9,000 had chronic daily headache. Thus at least 31,000 adults (17% of the total adult population) were likely to benefit from headache care (therefore having *need*). Children under 16, who made up 20% of the general population (ONS, 2002), had needs also. Although few epidemiological data exist for children, their needs were expected to arise at a lower rate per head of population because the prevalence of all headache disorders rises from a low level in early childhood and remains below the mean of the adult range even in late teens.

Comparative approach

Front-line headache care throughout the UK is currently provided by GPs to their

own registered patients. They have the option of referring to specialists in secondary care when this is clinically appropriate. Published data from a large Yorkshire general practice show that 17% of registered patients aged 16-65 years consulted at least once in 5 years because of headache (Laughey *et al*, 1999). Extrapolation to the standard population of 280,000 of whom 65% are in this age range found that 31,000 adults aged 16-65 *demand* headache-related health care, a number identical to the epidemiological calculation of *need*.

The general practice data did not reveal annual consultation rates, so direct comparison was not possible. The epidemiological and comparative estimates are entirely compatible if, as is likely, need is expressed as demand in virtually all cases in a 5-year period. Evidence of health-care utilisation by those with migraine (Lipton *et al*, 2002b) gave support to this supposition: whilst only 50% reported medical consultations for headache in the previous year, almost 90% had done so at some time within their recall.

Some albeit imperfect data existed to allow comparison, on the basis of NHS spending, between health-care provision for headache and provision for another condition causing widespread pain and disability in the population: low back pain. Like headache, back pain is a leading cause of sickness absence from work. An estimated 11 million working days were lost in 1995 from musculoskeletal disorders including back pain (DoH, 1999). The extent of this problem prompted government initiatives such as "Back to Work" to identify and promote good practice within a framework that includes prevention, assessment, treatment and rehabilitation as well as raising awareness about the condition and its causes. Amongst headache disorders, migraine alone is estimated to account for more than double this: over 25 million wholly lost work- or schooldays each year (Steiner *et al*, 2002a).

Against this background of relative societal costs, direct NHS costs of migraine in 1991 were estimated at £23-30 million for all of the UK (Blau and Drummond, 1991; Bosanquet and Zammit-Lucia, 1991). Whilst these were the most recent published calculations, with the advent since then of new and relatively expensive drugs, costs today would be higher. With very few patients admitted to hospital for headache, GP- and specialist-consultations, investigations and drugs costs remained the major contributors. It was reasonable to assume that changes in consultation rates and requests for investigations were relatively small (certainly less than 2-fold) whilst drug costs, principally for triptans, could be re-estimated on published data (Williams *et al*, 2002) at some £60 million *per annum*. Whilst there is some uncertainty about this estimate, and the overall total of perhaps £100 million, the most recent calculation of annual NHS expenditure on back pain was very much higher at £481 million (DoH, 1999).

Estimating service-provision requirements

In the following tabulation, estimates of *demand* based on these calculations and the initial assumptions set out above (*Methods*) were conservative:

Registered population	Adults/children with headache-care needs	Estimated total demand	Estimated demand for specialist care
n	n	(hours of medical consultation per week)	
280,000	31,000/3,100	505 (17.5 WTE)	45 (1.6 WTE)

The patients of each GP (assuming a practice-size of 2,000) give rise to estimated demands of 0.125 WTE overall and 0.011 WTE of specialist care.

Sensitivity analysis

Errors in some of the underlying assumptions were likely, so the variations described above (*Methods*) were made. In the table below, in estimate 1, medical-time allocation was increased from 1.25 to 2 hours per adult and remained at 2.5 hours per child patient, with other assumptions unchanged; in estimate 2, demand was recalculated as 75% rather than 50% of need, with a specialist-referral rate of 20% rather than 9% and medical-time allocation to adults similarly increased.

	Registered population	Adults/children with headache-care needs	Estimated total demand	Estimated demand for specialist care
	n	n	(hours of medical consultation per week)	
Estimate 1	280,000	31,000/3,100	758 (26 WTE)	68 (2.4 WTE)
Estimate 2			1,137 (39 WTE)	227 (7.9 WTE)

The patients of each GP give rise under estimate 1 to demands of 0.19 WTE overall and 0.017 WTE of specialist care, and under estimate 2 to demands of 0.28 WTE overall and 0.056 WTE of specialist care.

Corporate approach

Representatives of principal stakeholders whose opinions were sought included two neurologists, two GPs, a health authority public health physician, an inner-London PCT clinical governance manager and members of a lay advocacy group.

Results were predictable. The lay group, already aware through their advocacy role of unmet need, not only recognised the levels of demand expressed above but also wished to see all need met through an expansion of service provision and facilitation of access to it. The provider-respondents were unconvinced that, even if unmet need existed on a considerable scale, all or any great part of it should be met.

Such evidence as could be adduced of current levels of provision did little to reduce the polarisation of opinions. The national figure for GP-recorded diagnoses of migraine was 4.7% of patients [Williams *et al*, 2002]). Regional variations

were marked: an inner-London borough general practice with a population of 4,204 (one of the few with fully computerised diagnostic records) listed 64 patients (1.5%) with a complaint of migraine. The predicted number was 450 [Steiner *et al*, 2002a]. Whereas the lay group were inclined to see this as clear proof of under-recognition and under-provision, the provider-respondents viewed it as evidence that demand was being greatly over-estimated.

Continuing interviews with the provider-respondents sought to elicit articulated reasons – whether (and why) it was felt that the assessments were wrong or that unmet need existed but should be tolerated. The following provocative but evidence-based observations on current service quality were put to them.

- The lay group's interpretation of the computerised diagnostic data from the inner-London practice could not be refuted, and these data were significantly at odds with published general-practice data (Laughey *et al*, 1999; Williams *et al*, 2002).
- GPs in the front line of headache services generally made little in the way of special provision for them. For example, amongst 56 sub-specialities for which dedicated clinics were being offered by over 400 GPs in one former inner-London Health Authority, migraine was listed once but headache did not otherwise feature (LSLHA, 2001c).
- GPs had access to secondary-care specialists as they judged appropriate and the only published data suggested that 9% of patients consulting for headache were referred to specialists (Laughey *et al*, 1999). Amongst a range of specialities contributing to headache management, neurology was by far the most important (and headache was the most common symptom to cause referral to neurologists [Hopkins *et al*, 1989]). The 340 neurologists in the UK (approximately one per 175,000 people) had a median waiting time for routine appointments of 28 weeks (Warlow and Venables, 2000). Perhaps 5% of these identified headache as a special (though not necessarily first) interest.
- As to how well these arrangements worked, the empirical data for migraine were that half of those affected in England were not currently seeing a doctor for headache, large numbers remained undiagnosed and most did not receive prescription drugs whilst many nonetheless had high disability (Lipton *et al*, 2002b).

Three themes emerged from this enquiry, none of which challenged the basis or outcome of either the epidemiological or the comparative assessments of need.

Firstly, whilst calculations in proposals for reform might assume that patients remained within primary care who would otherwise go to secondary care, only the lay group unreservedly welcomed this as a beneficial development bringing improved access. The PCT representative saw potential cost advantages in such a shift, but wished for empirical demonstration of them. It was not evident to the other provider-stakeholders that this assumed shift would necessarily occur: the numbers presented in the need assessments pointed only to a requirement for significantly greater resource allocation. Notwithstanding the evidence of unmet need, there was great concern that allocating resources to meet *all* headache-related health-care need (or even demand) would significantly diminish those available for other needs. An allocation of 1.6 WTE of specialist time per 280,000 people – the conservative estimate – proved especially challenging. If this were provided by neurologists in secondary care, it would require a 75-100%

expansion in the current provision for all neurological complaints (interestingly, the Association of British Neurologists [1997] had argued that an increase of this order was necessary). But GPs were in no position to add to their work loads: if it were provided by GP-specialists, a 1.14% increase in primary-care service provision would be needed.

Secondly, and related, the argument that headache should have priority in any claims for additional resources, whilst resting on the size (and inequity) of the untreated headache burden, depended also on the ability of reformed headache services to reduce this burden (clinical effectiveness). This had yet to be shown. Cost-effectiveness was at issue as well, so, thirdly, although there was some evidence that efficacious treatment got patients back to work (Gross *et al*, 1996; Wells and Steiner, 2000), even if this was widely generalisable such returns did not accrue to health-care budgets.

Discussion

Assessments deliberately distinguished between need and demand (Wright *et al*, 1998), assuming the latter to be that part of the former that is expressed. This is not quite true: demand can occur in the absence of medical need for a number of reasons. No formal assessment of the extent of this is possible whilst clinical experience (for example, at The Princess Margaret Migraine Clinic, Charing Cross Hospital, London) suggests such demand exists but is relatively small and may be ignored.

Two quantitative assessments – one derived epidemiologically and the other by a comparative approach – provided reassuringly similar estimates of numbers within a standard population. Based on these, calculations of levels of service provision required to meet demand were high, even when made conservatively, and induced quite stubborn resistance amongst the health-care professionals consulted as representatives of provider-stakeholders.

Alongside this finding, estimates of health-service spending on headache disorders were substantially below those for low back pain although the latter, according to evidence adduced, was of lower cost to society. If this suggests that headache attracts unduly low health-care investment, it reflects a world-wide context of mismatch between high need arising from headache disorders (WHO, 2000) and low priority given to them in the queue for health care (AASH and IHS, 1998).

Prioritisation

Prioritisation is the key issue. The central principle that needs always exceed supply underlies health needs assessment undertaken to guide the provision of health-care services. A typical framework for prioritisation was set out by a former inner-London Health Authority in its Health Improvement Programme (HImP) (LSLHA, 2001b). With the purpose of “improving the health and well-being of individuals and communities [and] to reduce health inequalities”, the HImP *inter alia*:

“embraces health in its widest sense;

builds on ... knowledge of the local population and their health needs ... and evidence of effectiveness and agreed good practice;

represents the most appropriate means of addressing ... local health needs, accepting that [it] can only initially tackle a limited number of priorities;

is based on the values of Health and Local Authorities and their partners, including effective and equitable resource allocation.”

Thus stated, this HImP embraced a set of values and priorities that would be well served by an initiative seeking to improve access to health care for the large numbers of residents of the Health Authority whose health and well-being were currently damaged by headache. Such an initiative would contribute directly to the stated broad objectives of the HImP, which included [my emphases throughout]:

“make *the best use of available resources* for promoting health ... and delivering the highest standards of health care;

increase life expectancy *and reduce disease and disability; adding years to life and life to years* of local residents;

improve access to healthcare and other services that can improve health”.

This might be seen as a call for best practice.

The toleration of unmet need

Assuming the above is not entirely rhetoric, why are provider-stakeholders willing to reject the concordant conclusions that follow from epidemiological and comparative accounts of need? It is clearly a toleration of evident unmet need.

Their concern is the opportunity cost: both accounts of need show a requirement for substantial increases in resource allocation to headache care which, if made, would have significant negative impact on resources available for other needs. There is a response to this, based on cost-effectiveness. Two perspectives are possible (Oliver *et al*, 2002). From the societal perspective, there is solid evidence of lost work-days attributable to headache (over 25 million per year from migraine alone [Steiner *et al*, 2002a]), rather more tenuous evidence that treatment gets people back to work (Gross *et al*, 1996; Wells and Steiner, 2000), and a well-supported argument that current mistreatment can make headache disorders worse, incurring health-service expenditure whilst *increasing* the illness-burden (Steiner, 1995; Steiner, 2000b). From the health-service perspective, it remains a key question whether referrals to neurologists – a very scarce resource in the NHS – can be reduced by reform of headache-services (opportunity gain).

SECTION 3. ASSESSING THE *STATUS QUO* AND DESIRABLE CHANGE

In this section there is movement from the largely objective evaluation of headache services currently provided by the NHS (the *status quo*) to the more subjective process of identifying the remediable deficiencies. Judgement of achievable change is based on evaluations not only of need for change but also of the opportunity for reform in the context of the political priorities of the *NHS Plan* (DoH, 2000a).

Methods

Section one of this case study set out an evaluation of headache services currently provided by the NHS (the *status quo*). It was derived from a review of the relevant literature using standard search methods and borrowing from past reviews (Steiner *et al*, 2002a; Lipton *et al*, 2002b).

Identifying the remediable deficiencies in the *status quo* and the setting of priorities for change towards best practice were then partly a matter of objective measurement of failure (unmet need) and partly one of subjective judgement of achievable change (realism rather than idealism) based on an evaluation of the opportunity for reform. These would be the cornerstones of the proposals to be formulated for reorganising health-care services for headache in a manner and to an extent that were appropriate to assessed need whilst respecting the political priorities of the *NHS Plan*.

Consensus development panel

These cornerstones were set in place through use of a consensus development panel (Bowling, 1997) bringing together an expert/lay mix of the essential stakeholders: three specialists and four GPs, representing the two main levels of service provider, and three lay members having formed views as service users and/or on behalf of relevant advocacy groups. The lay members were important since there was evidence that the wants of headache sufferers are not exactly as health-care providers tended to perceive them to be (Packard, 1979; Blau and MacGregor, 1995), and they were therefore selected purposively to have credibility within the group.

The methods employed in the panel discussions were adapted from those recommended by Jones and Hunter (1995) for expert panels somewhat towards those associated with consensus development conferences (US NIH, 2002), without public input. Materials brought to the panel were the needs assessment and the literature review of current performance (the *status quo*), supplemented only by *ad hoc* presentations by the panel members. Whole-day facilitated discussions were guided by a pre-set agenda of main topics and subsidiary issues (*table 1*).

Discussions moved from a largely quantitative base to one that was essentially qualitative. Use was made of the group dynamic to explore possibilities and their implications as broadly as possible, and to bring in any outliers. Observational notes were taken in preference to video- or audio-recording to encourage uninhibited discussions. These notes also permitted review of content by the panel (feedback) in an iterative process (Jones and Hunter, 1995) towards consensus. The output was agreed basic proposals for reform (*ie*, a consensus view of desirable change) that had sensible regard to perceived political and other constraints (*ie*, acknowledging feasibility).

Table 1. Outline agenda set before the consensus development panel

Main topics	Subsidiary issues
1. <i>The status quo</i>	<ul style="list-style-type: none"> • The burden of headache in the community for which a requirement exists for headache services • The current situation of headache services in primary and secondary care
2. <i>Impetus for change</i>	<ul style="list-style-type: none"> • The need for change • The context of change: how primary care is being re-organised • The opportunity for reorganisation of headache services • The evidence for what users of headache services would want • Objectives of reform
3. <i>Persuading others</i>	<ul style="list-style-type: none"> • Promoting awareness of economic aspects of headache and cost/utility analysis • The need to redirect research effort into primary care
4. <i>Guidelines</i>	<ul style="list-style-type: none"> • Existing guidelines for headache management, and their suitability or adaptability for use in primary care
5. <i>Limits of management in primary care</i>	<ul style="list-style-type: none"> • Agreeing limits • Appropriate relationships between primary and secondary care in meeting the need for headache services
6. <i>Getting real</i>	<ul style="list-style-type: none"> • Alternative models for organisation of headache services • The role of nurses • Cost, and other issues of constraint • Proposing a model • Implementation within a Health Improvement Programme
7. <i>Maintenance of standards</i>	<ul style="list-style-type: none"> • Education and its provision • Audit

Deliberations of the consensus development panel

In the following account of proceedings within the panel, where consensus was reached and expressed in agreed terms, these are mostly reported *verbatim*.

Aims and objectives

Not precisely following the pre-set agenda, the panel first came to agreement on what it was trying to achieve, and set this out as two principal aims:

- *to promote initiatives that improve the quality of diagnosis and management of headache disorders generally, and in primary care specifically to the extent that this best serves patients;*
- *thereby to contribute towards patients' greater satisfaction with headache services that mitigate the burdens of headache and*

enhance the quality of life of those affected by headache.

To achieve these aims the panel would:

- *evaluate the need for headache services and the extent to which it was currently unmet;*
- *achieve consensus on the appropriate role of primary care in the management of headache disorders;*
- *propose the right level of provision of services and develop recommendations for reform;*
- *justify the proposals as making optimal use of resources for the management of headache disorders in the community.*

These became the stated objectives.

Need for headache services

The panel endorsed the evidence that headache disorders were common and associated with recognisable and substantial burdens that included personal suffering, disability, impaired quality of life and economic cost (Osterhaus *et al*, 1992; Kryst and Scherl, 1994; Rasmussen, 1994; Stewart *et al*, 1996; Schwartz *et al*, 1997; Steiner *et al*, 2002a). They agreed that the impact of headache disorders extended beyond those immediately affected (Steiner, 2000a).

On the current provision of services in response to this evidence of need, the panel concluded that barriers to access were high but there was no direct and little indirect evidence of the clinical quality of headache services actually provided in primary care or of whether such services were provided cost-effectively. They observed:

- *Headache services are provided in response to demand from headache sufferers who, characteristically, present a mix of unrealistically high and pessimistically low expectation. Levels of satisfaction with services are dependent on what was initially expected of them; they are not, therefore, a good or reliable measure of quality of care received.*

The panel saw discordance in the comparison for NHS expenditure between headache (Bosanquet and Zammit-Lucia, 1991) and low back pain (DoH, 1999) as a consequence of misplaced priority (AASH and IHS, 1998) given that effective treatments existed (BASH, 2001). They drew particular attention to the fact that, whilst large numbers of people with headache self-treated with OTC medication (Lipton *et al*, 2002b), no data were available on the cost-effectiveness of this. At the same time, an estimated 1-4% of the entire population had a chronic daily headache disorder attributable to medication overuse, much of it OTC (Diener and Dahlöf, 2000; Steiner, 2000b).

On these issues, the panel concluded as follows:

- *Present headache services in primary care are neither adequate nor cost-effective for the following reasons.*
 - a) *No national or local targets are imposed by the NHS for headache management.*

- b) *Little research is undertaken in primary care to establish what are the health needs of the general population, or what should be the priorities for health care.*
- c) *Evidence indicates that access to headache care is restricted. GPs complain of difficulties in timely access to neurologists and other specialists.*
- d) *Only a very small minority of GPs demonstrate a professional interest in management of headache disorders. Undergraduate medical training provides little if any teaching in this field. Postgraduate headache education, even that recognised for continuing professional development (CPD) credits, is driven by the pharmaceutical industry and strongly biased towards new anti-migraine drugs.*
- e) *Few nurses, and even fewer physiotherapists and psychologists, are employed to provide headache services in primary care.*
- f) *The burdens imposed by headache disorders remain high. Headache disorders are shown to be the cause of substantial suffering and impairment of quality of life.*
- g) *Because indirect costs of headache disorders so greatly exceed direct treatment costs, better management should mitigate the reducible burden and lessen the total financial cost of headache.*

The role of primary care

Whilst government-driven reorganisation of primary care and government commitment to the provision of high-quality services created a highly fertile context for change, the panel acknowledged a wide variety of demands being made of primary care in a climate of increasing public expectation. Any proposal for change, therefore, required justification: in particular the panel agreed that commitment of extra resources would require proof of cost-effectiveness. The panel nonetheless saw opportunity for change for two reasons.

- *Opportunity for change is created by the possibility of more cost-effective use of the share of existing resources already utilised in the management of headache disorders.*
- *Patient-centred care is a government priority, and there is growing interest amongst people with health concerns in understanding their medical management (Illman, 2000). In addition, the public perspective increasingly recognises the importance of improved quality of life, not only prolonged life, as a central objective of health care.*

As a starting point to finding consensus on the role of primary care, the following were noted as service features rated by patients as highly important (MAA, 2002):

- *timely access to services nearby, in primary care rather than hospital-based;*
- *interested staff (whether doctor or nurse) who take them seriously;*

- *sufficient information and explanation, and opportunity to express their needs and preferences;*
- *follow-up when needed.*

These could be summarised as: time, interest and local provision. The panel set out its consensus in three arguments and a final conclusion.

- *We consider self-evident that interested and knowledgeable doctors provide an effective service; and that it is better for patients to be treated by interested staff, and more will be satisfied per consultation.*
- *We believe that the number of patients with headache disorders referred to secondary care is inappropriately high and can be reduced, with benefit to patients, if there are better organised services in primary care.*
- *Primary-care management of headache requires readily available support from specialist centres. Secondary-care headache centres might be based in regional neurological centres. However, we took note of the following:*
 - a) *in view of the numbers of patients likely to be referred, more than one secondary centre per region would be required even if these centres offered a peripatetic service to community outposts;*
 - b) *we estimate that 1 in every 10 neurologists would need to be interested in headache disorders if secondary-care centres alone were to provide this level of back-up.*
- *We conclude that the role of primary care in the management of headache disorders should be expanded.*

Proposals for reform

By the conclusion of the third meeting, the panel had reached consensus on its recommendations for change.

- *Most patients with headache disorders are in the category of long-term sufferers with recurrent acute primary headache needing advice now or from time to time. Their management is mainly routine but occasionally problematic. A minority have recent-onset headache and require ready access to their own GP. Most present no diagnostic difficulty or management problem, but some do. A very few require urgent intervention.*
- *We recommend reorganisation on three levels.*

Since most do not require specialist management or investigation, people with headache are best served if they can see their own GP locally in the first instance. We recommend that each general practice should provide first-line headache services for their patients ("Level 1"), working according to accepted guidelines that include criteria for referral to specialist care.

We recommend the establishment within each PCT of one or

more primary-care headache speciality centres ("Level 2") staffed by GPSIs, adopting a multidisciplinary approach incorporating the unique skills of each of the members of the primary care team (Wagner, 2000). These centres, working together and according to accepted guidelines that include criteria for referral to secondary care, should be responsible for all but a very few patients with headache referred for specialist care by GPs within the PCT.

We recommend that specialist secondary-care centres be formally established ("Level 3"), probably in association with regional neurological centres, providing telephone advice, emergency, urgent and routine referral services as needed and education to GPs and GPSIs at levels 1 or 2.

On implementation, the panel said this:

- *We recommend incremental change implemented in response to local need, testing innovation in three to six PCTs.*

The panel went on to consider the educational implications of these recommendations.

- *Since headache disorders are common and potentially disabling, and a few are medically serious, it is incumbent on all GPs to be better educated in headache diagnosis and management than they generally are at present.*

Finally the panel recommended audit at all levels, with suggestions for methods of audit that might be appropriate at each. The delivery of headache care to the population within a PCT could be audited according to published proposals (BASH, 2001).

Justification: resource implications

The panel carefully considered the argument that proposals whereby people with headache are seen and treated by GPs with an interest rather than by GPs with none required only resource redistribution (without increased allocation). They rejected it.

- *We believe there will be resource implications of these recommendations, which will need to be assessed.*

The crucial factor was the allocation of time which, in Section 2, gave rise to high demand in terms of medical staffing and clearly indicated that additional resources must be allocated to meet more of the estimated demand. As more people with headache sought care in response to improved quality of primary care for headache, additional costs to the NHS must be anticipated. However, there were mitigating factors.

- *Proposals involving the employment of additional staff (nurses, physiotherapists, psychologists) accord with other planning strategies within primary care. They will incur added costs initially but should reduce demands on medical time eventually.*
- *At the same time, savings to the NHS should accrue from reduction in iatrogenic illness and disability due to mismanagement, and from*

fewer referrals to secondary care.

- *Substantial economic costs of untreated or inadequately treated headache disorders have been identified. Significant savings in the workplace are expected if absence or shortfalls in output due to sickness are mitigated.*
- *The net effect is uncertain, but likely to be increased costs to the NHS with improved patient outcomes and savings to the economy. Overall, the result should be cost-effective.*

Discussion

The consensus development panel reached clear conclusions on the need for change and on the form it should take. Interestingly, these were not fundamentally influenced by the formal assessments of need: reform was necessary because there was persuasive evidence that optimal care was clinically effective but there were barriers preventing access to it by many. By this approach, the panel did not squarely confront the resource issue: their proposals related to *how* health care should be provided for headache, not *how much*.

Bias is a recognised problem in consensus methods of research (Jones and Hunter, 1995) and the origin of possible bias is not hard to see here: the consensus reflected the views of those with an agenda that already included the improvement of headache care. Some stakeholders whose views might be highly relevant were not represented on the panel. There was no public input. So, for example, amongst absent stakeholders were those unaffected by headache disorders whose interests might compete in that they would like to see health-care resources allocated elsewhere.

The panel did express an expectation of expanding demand leading to increased NHS costs, and theorised that the proposed change would be cost-effective from the societal perspective. However, they did not base this on any quantitative cost analysis. If they failed, therefore, in their attempt at justification of their proposals, which was opinion- rather than evidence-based, this was undoubtedly because of the absence of evidence. This is an important point, highly relevant to the panel's key recommendation that headache services should be returned to primary care.

The problem of no evidence

In fact it is surprisingly difficult to find evidence of cost-effectiveness in the very basis of the *NHS Plan* and its central philosophy that services should be shifted from secondary to primary care (Pederson and Leese, 1997). In a WHO publication, Tarino and Webster (1995) wrote the following.

"Primary care has become a favourite of politicians, who regard it as a mechanism for containing technology-driven demand for medical care, for balancing the costs and consequences of care, and for fostering self-reliance in individuals. It is seen as the way to provide medical care to everyone in the community, irrespective of income or social class."

Van Weel (1996) cited evidence of better outcomes – in relation to costs – where there was greater orientation of care towards primary care (Starfield, 1994), and of economic benefits from the gate-keeper role and personal lists of primary care (Badia, 1996). Gate-keeping (Ferris *et al*, 2001) ostensibly guides patients

efficiently and in their best interests through the medical-care system (Picker Institute, 1996), according to their needs rather than their demands. But it has an ambiguous purpose. In the US, gate-keeping developed in the 1980s as a means by which managed care organisations controlled costs and the inappropriate utilisation of resources (Lawrence, 2001). And, whatever its original purpose in the UK, gate-keeping by GPs is believed to have contributed to maintaining low levels of expenditure on the NHS in comparison with health-care systems abroad. Today the gate-keeping role of primary care is regarded as essential for cost-containment, in part because of evidence that suggests that unrestricted access to specialists induces a demand for costly and sometimes unnecessary services.

In this analysis, primary care holds down costs by denial of access to what is behind the gate. It is not clear what will happen when specialist services are brought to lie *in front of* the gate.

So, whilst countries undertaking health-service reform are generally shifting away from secondary and towards primary care (Coulter, 1995), if the main driver is cost-effectiveness there are remarkably few evidence-based studies which give, at best, equivocal support to it (Naji, 1994; Grampian Asthma Study of Integrated Care, 1994; Carey *et al*, 1995). Furthermore, there is little evidence that developments in primary care reduce demands for secondary-care services. For example, availability of minor surgery in primary care only encouraged demand for it, and did nothing to reduce hospital-based minor surgery (Lowy *et al*, 1993).

The need for empirical proof

Shifts to primary care, therefore, are only theoretically justified on the basis that they will prove cost-effective. Empirical evidence that this is so has yet to be adduced.

Certainly it can be argued that primary care has generally lower overheads. GPs may well be cheaper than consultant neurologists, but more GPs are needed if headache services are relocated to primary care whilst it is highly unlikely that anyone will argue for the *quid pro quo* of fewer neurologists. Nurses are cheaper still, and can take over some aspects of headache care, but again more will be needed. What seems inescapable is that, if services are improved or merely moved to where patients are, more patients will seek care. Demand will rise, as will costs if any of this new demand is met. Neurologists may be freed of work, but will not stand idle; they will see other patients. Paradoxically, as a result of this opportunity gain, benefits accruing from shifting headache services to primary care may be seen in better secondary-care management of epilepsy, multiple sclerosis and Parkinson's disease!

Ultimately, proposals for reform will have to demonstrate empirically both clinical effectiveness and cost-effectiveness of change. To do this will necessitate the setting up of local demonstrational projects in which change is based on the theoretical model proposed, then evaluated and modified accordingly in an iterative process to arrive at best practice for local need. National roll-out will follow if *politically* agreed targets are achieved.

In the final section of this case study, although not strictly part of it, the difficult issue of evaluation is discussed.

SECTION 4. THE PROBLEM OF EVALUATION

Although not part of this case study, an important question has been raised by it. If it can only be known empirically what best practice is in headache-related health-care provision, what measurement(s) can reveal whether or not it has been achieved?

The question is not readily answerable by controlled evaluation of change: *eg*, comparing a PCT with change and a neighbouring socioeconomically similar PCT without. There are ethical difficulties in seeking to make such comparisons when patients in one PCT, not receiving the service, become a control group without the opportunity to consent to being observed. Concerns exist, too, about the equity of randomising at practice/GP/patient level within a PCT so that one part of the population is offered the service and another is not. But two other arguments are ultimately persuasive. Firstly, the existence of a new service, and observation, will change practice even where the service is not directly available (Hawthorne effect [Roethlisberger and Dickson, 1939]). Secondly, there is no agreement on objective measures of outcome that may be applied to headache service development (Olesen *et al*, 2002) on which power calculations can be based.

There are six domains in which evaluation of change might be carried out. They are discussed in relation to the specific proposals above.

1. **Practical or technical success (does the innovation work?)**

The NCC SDO (2001) national listening exercise showed "a contradiction between the level of service provision stakeholders want to see as service users and their recognition that there is a lack of resources to meet these expectations." Service perfection is not a reasonable ambition, but technical efficiency is. I suggest that technical success is marked by the following:

- the level-2 service is established, with functioning supportive links to level 3 and a specified percentage of local level-1 general practices integrated with it;
- waiting times for routine first appointments and did-not-attend (DNA) rates are below prescribed limits;
- clinical governance procedures are in place;
- staff in post express job-satisfaction.

These are not objective standards, nor are all of them objectively measurable.

2. **Uptake (is the service being used?)**

Measures of uptake include the percentage of local GPs referring to level 2 and numbers of patients seen there (absolute, and as percentages of numbers seen at level 1 complaining of headache and of predicted total demand/need). Referral "norms" need to be established to discover whether any GP's referral practice is out of line.

Consultations for headache in secondary care (level 3) should show concomitant falls over time. Relevant data may be collected without requiring access to details of individual patients.

3. **Clinical effectiveness (have headache services improved?)**

It is not sufficient to assess outcomes only in those with known headache. This will not measure success or failure in identifying and diagnosing those not complaining of or already receiving treatment for headache (unrecognised need), who are likely to be numerous and in whom burden may nevertheless be significant (Lipton *et al*, 2002b). Evaluation should aim to measure *population* headache burden over time, before and during intervention.

Methods do exist for this. Within a PCT-population, burden may be assessed periodically in random samples of, say, 1,000 adults, reselected at each evaluation. MIDAS (Sawyer *et al*, 1998), a self-administered questionnaire which can be mailed, measures time loss over the preceding 1-3 months, from work and other activities, attributable to any headache disorder and regardless of whether any headache condition has been diagnosed (BASH, 2001). Whilst mailed questionnaires typically produce response rates of under 50%, those who are significantly affected by headache are more likely to complete the assessment; those who do not can to a large extent be discounted.

There are difficulties. This method and all alternative methods of longitudinal evaluation assume a certain stability of the local population. Highly-fluid populations have limited opportunity to benefit from interventions over time, and then are not available for measuring outcome. Especially in inner-metropolitan areas (annual turnover in one inner-London PCT, for example, exceeds 20%), it may be that these measures can be applied only to the stable segment.

4. **Patient-satisfaction (do patients agree?)**

An increasingly consumerist approach to the NHS exists within a context of expanding demand for services. A high "satisfied patients per patient-encounter" ratio is presumably, therefore, one hallmark of a good service, though not to be used alone. The NCC SDO (2001) puts "organising the NHS around the needs of the patient" first amongst ten themes that R&D programmes should take on board. General aspects of this include more flexible opening hours, appointments at convenient times for the patient, and a choice of treatment settings. Specifically in headache management, the following are rated by patients as highly important (MAA, 2002):

- 1) timely access to services, in primary care rather than hospital-based;
- 2) interested staff who take them seriously;
- 3) sufficient information and explanation, and opportunity to express their needs and preferences;
- 4) follow-up when needed.

Exit surveys can measure short-term satisfaction, and include objective indices such as waiting times but also seek subjective perceptions in the five major domains of service quality (Zeithaml *et al*, 1990):

- a) *tangibles*: the fabric, furnishings and condition of the centre;
- b) *responsiveness*: how well and promptly the service reacts to *me* (including (2) above);
- c) *empathy*: how the service is tailored to *me* as a person (including (3) above);
- d) *assurance*: how the service-provider(s) instils confidence in *me*

(including (4) above);

- e) *reliability*: dependability and error-avoidance.

5. **Success in tackling inequality (is the service equitable?)**

There is evidence that the more socially-deprived experience greater difficulty in accessing health-care services and obtain less good care with poorer outcomes (Shaw and Smith, 2001). The Acheson (1998) report clearly set out that equitable access to effective care in relation to need should be a governing principle of all NHS policies, applied to all new initiatives.

Evaluation needs, therefore, to monitor the factors likely to affect access (*eg*, patient characteristics such as socioeconomic status and ethnicity) in order to be aware of, and endeavour to remedy, special problems that may apply to certain groups.

6. **Cost-effectiveness (is the service innovation affordable?)**

Though left until last, this is the domain that will matter politically, and it will be the most challenging to demonstrate.

The new level 2 requires additional GP-time. The increase in resource allocation will be sustainable only if it is shown to be cost-effective in the long term. Evaluation should measure direct treatment costs (*ie*, the costs to the health-care system) – overall and *per capita* – of providing care: these are the costs of consultations at levels 1 and 2, investigations, referrals to secondary care and prescriptions. But an important issue is that assessable costs are not limited to these but widened to include the much larger non-health-care costs (Osterhaus *et al*, 1992; Kryst and Scherl, 1994; Rasmussen, 1994; Stewart *et al*, 1996; Schwartz *et al*, 1997; Steiner, 2000a), where savings are more likely to accrue.

Economic analysis requires an estimate of the *net* costs of the initiative. Some of the added costs of enhancing headache services in primary care will be offset by savings both within this setting and elsewhere: *eg*, costs should be recovered to primary-care budgets by cut-backs on wastage through mismanagement and inappropriate prescribing, and to commissioning budgets through avoided referrals to secondary care. To determine what has been avoided or saved, changes from base-line resource-use need to be measured. Where neurologists' workloads are reduced, analysis must include how they utilise released time (opportunity gain).

Formal *cost-effectiveness analysis* (CEA) will be unnecessary if change is shown to improve outcomes whilst reducing total costs to the health-care system. However, it is likely that health-care costs will rise as additional demand emerges. CEA must then relate the costs (derived above) to indicators of success in reducing headache burden in the population (*eg*, X per cent of the estimated headache population are under primary-care management, Y percent of whom are successfully managed as judged by the clinical effectiveness and satisfaction indices). The problem remains of the absence of agreed indices (Olesen *et al*, 2002).

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