



SMF HEALTH PROJECT: BACKGROUND PAPER 3

Commissioning Healthcare

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Dr Niall Maclean, Lyndsay Mountford and Charitini Stavropoulou

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INTRODUCTION

This paper is the third of five papers which form the background to the ongoing work of the SMF Health Project. The papers have been prepared following an extensive literature review, as the basis for a research scoping exercise, which explores future policy challenges facing the NHS in England. Other papers consider the NHS in relation to high-level health systems issues (Background Paper 1), long-term financing pressures (Background Paper 2), the changing role and expectations of providers – including the changing nature of healthcare supply, the role of new technologies and the challenges of coordinating care in an increasingly diverse and specialised provider environment (Background Paper 4) – and issues and policies relating specifically to the role and expectations of patients (Background Paper 5). As they explore these topics in detail, these papers identify and propose a series of possible topics and questions for further research, which are brought together and summarised in a final Research Proposal.

This third paper looks in more detail at issues in commissioning. First, it considers the organisational aspects of commissioning in the NHS: the introduction of the purchaser/provider split in 1991, more recent reforms and current structures. Developing some of the themes in earlier papers, it then goes on to look in more detail at target-setting and the tensions between central control and local autonomy; the performance of commissioners and the ambiguous role of GPs, both as purchasers of health services through practice-based commissioning (PbC), gatekeepers and managers of demand, and as independent providers. The paper considers the moves to institutionalise standard setting in clinical practice, in the form of National Service Frameworks (NSFs) and the establishment of the National Institute for Clinical Excellence (NICE), and considers the financing mechanism within which commissioners have to establish contracts. In the course of this discussion, the paper provides a critique of current commissioning issues and problems, and considers what questions might be appropriate for the SMF Health Project to consider further.

2 COMMISSIONING AND TARGETS

COMMISSIONING STRUCTURES IN THE NHS: A BRIEF HISTORICAL PERSPECTIVE

Until 1991, management of the NHS was essentially about the direct management and organisation of health services. In the hospital sector, budgets were devolved to district health authorities in support of a range of provision for which those authorities were responsible. In the primary care sector, which incorporated GP services, pharmacy, ophthalmology and dentistry, supply and financing was essentially demand-led.

In the quasi-market reforms introduced into the NHS in 1991, a distinction was drawn between the purchasing of health services and the responsibility for providing them. The old district health authorities became purchasers, establishing contracts on behalf of geographically based patient populations with newly established, quasi-commercial NHS trusts under independent management. In the primary care sector, with the introduction of GP fundholding, GPs were given the option of becoming both purchasers and providers of healthcare, and for the first time since the inception of the NHS, primary care budgets were capped.

The split between functions of purchasing and providing healthcare, including the introduction of contracts, was not of itself a new concept in international health systems management: all insurance-based systems of third-party payment for healthcare incorporate such a split. Part of the novelty lay in the attempt to do this in a tax-funded national health service.

THE SCOPE AND IMPACT OF RECENT REFORMS

Since 1997 there have been further far-reaching, and often controversial, reforms to the structure of NHS commissioning, split into three broad phases. The first was the creation of primary care groups (PCGs) and strategic health authorities (SHAs). The second phase saw PCGs replaced by primary care trusts (PCTs), and a reduction in the number of SHAs. The third phase of reform involves the ongoing extension of practice-based commissioning, whereby individual GP practices take

on some of the commissioning functions of PCTs.

In this chapter, we will describe these reforms to NHS primary care in greater detail, and will suggest possible areas of further research for the SMF Health Project.

Phase one: primary care groups and strategic health authorities

In 1998, health authorities lost the majority of their commissioning functions to newly created PCGs. These covered groups of GP practices (typically around 50), organised into commissioning collectives. By 1999, there were 481 PCGs.

For their part, the remaining 96 NHS health authorities in England were consolidated by 2002 into 28 new SHAs. At the same time, the ten NHS regional offices were abolished, and their functions (e.g. public health monitoring) were transferred to the new SHAs. In 2006, Patricia Hewitt (then secretary of state for health) announced that the SHAs were to be further reorganised. Another wave of mergers led to the creation of ten new-generation SHAs as of 1 July 2006.

Phase two: primary care trusts

PCGs were, from the outset, supposed to evolve into primary care trusts after a probationary period in which they demonstrated their ability to manage budgets and services. The first wave of PCT creation began in 2000. The 481 PCGs in existence in 1999 were, as they merged in their transition to PCT status, to become 303 PCTs by early 2006. In May of that year, the government announced plans to reduce the number of PCTs still further. By October, 303 PCTs had been consolidated into 152. These new-generation PCTs cover populations in excess of 300,000. It is hoped that the larger groupings will make it easier for them to commission care more effectively and economically.

PCTs control their own budgets and set their own clinical care priorities, with reference to the overarching priorities set by SHAs and within the parameters of budgets set also by SHAs. PCTs fund GP services and cover prescription costs, and are responsible for commissioning acute care services from NHS hospital trusts or diagnostic and treatment centres.

The 1999 Health Act put in place a statutory framework for PCTs and the social services departments of local authorities to work more closely together in delivering integrated health and social care by pooling budgets and jointly commissioning certain services. Following the 2006 mergers, the boundaries of most new PCTs (more than 70% of them) mirrored those of local authorities,¹ precisely in order to make such joint operation easier. Although the Act allows for joint commissioning arrangements, in practice one body acts as the “lead commissioner.”

Phase three: practice-based commissioning

Practice-based commissioning involves PCTs in devolving the power to control budgets and to purchase services to individual GP practices. In this way, commissioning is expected to happen at the level at which most patients make choices regarding their healthcare. It accompanied the introduction of the patient choice agenda as a means of incentivising GPs to reduce inappropriate hospital referrals and encourage more services to be provided within primary care and community settings. PbC has been compared to the Conservative Party’s policy of GP fundholding.

PbC will not extend to every aspect of healthcare provision – highly complex and specialised services are likely still to be commissioned at PCT level. It is possible that in future practices will be offered the option of a real cash budget as an alternative to the indicative budgets currently set by PCTs. Other practices may merge their commissioning function with other GPs, or seek the support of private providers. The plurality of commissioners in the NHS is both a challenge and an opportunity, with the potential to create a dynamic marketplace in which innovation is encouraged and costs controlled. However, there are clear issues to overcome in negotiating the different roles of different agencies – will this be a barrier to effective working?

This repeated and ongoing reform of commissioning structures has been the subject of sometimes strident criticism. For example, Gwyn Bevan, writing in the *BMJ* in 2006 comments:

1 E-Health Primary Care, “Number of PCTs to be halved,” *E-Health-Media* (May 2006): www.ehiprimarycare.com/news/item.cfm?ID=1897.

The Department of Health has been reorganised three times: the regional structure and purchasing tier in the NHS have each been reorganised four times; there have been mergers of providers of acute services and reorganisation of mental health services; and inspectorates have been created, expanded, abolished and merged (with one lasting 17 days). The policy of a market driven by provider competition in which money followed the patient was introduced in 1991, abolished in 1997, and reintroduced from 2006, after a five year interregnum during which the NHS was subjected to annual star ratings, a Soviet-style regime of targets backed by sanctions and rewards.²

So, questions remain about the capacity of the new system to attain the goals set for it.

COMMISSIONING PRIORITIES AND THE GROWTH OF TARGET SETTING

The ending of the Labour Government's commitment to Conservative spending plans saw the introduction of a series of major expenditure promises for the NHS. The increase in spending accompanied publication in 2000 of *The NHS Plan*. In this document, the government announced that it would use "a limited number of ambitious but achievable national targets"³ as a tool to drive up local standards, the backdrop for which was the introduction by the Treasury in 1998 of public service agreements (PSAs), as part of a comprehensive spending review – in line with a new public management agenda. Taken collectively, these national targets have given rise to what has been referred to as a "target culture."

2 G. Bevan, 'A third way,' *British Medical Journal* 333 (2006), quoted in A. Dixon and A. Alvarez-Rosete, 'Governing the NHS: Alternatives to an independent board', *King's Fund Discussion Paper*.

3 Department of Health, *The NHS Plan: A Plan For Investment, A Plan For Reform* (London: HMSO, 2000), 62.

Public service agreements

The NHS Plan of 2000 set out a list of 'must-do' targets: a small core of targets that formed the Department of Health's PSA with the Treasury.

These targets were as follows:

- to reduce the maximum wait for an outpatient appointment to three months and the maximum wait for inpatient treatment to six months by the end of 2005;
- two-thirds of all outpatient appointments and inpatient elective admissions to be pre-booked by 2003/4 on the way to 100% pre-booking by 2005;
- to ensure guaranteed access to a primary care professional within 24 hours and to a primary care doctor within 48 hours by 2004;
- to achieve standards of cleanliness and food as measured by independently audited surveys;
- to reduce substantially the mortality rates from major killers by 2010: from heart disease by at least 40% in people under 75; from cancer by at least 20% in people under 75; and from suicide and undetermined injury by at least 20% (key to the delivery of this target will be implementing the National Service Frameworks for coronary heart disease and mental health, and the National Cancer Plan – see below);
- to develop specific national targets early in 2001 to narrow the health gap in childhood and throughout life within socio-economic groups and between the most deprived areas and the rest of the country;
- to make the cost of care commissioned from trusts which perform well against indicators of fair access, quality and responsiveness the benchmark for the NHS; everyone expected to reach the level of the best over the next five years, with agreed milestones for 2003/4.⁴

⁴ Ibid., 131.

The impact on process and quality of target-setting

Despite criticism of a target culture, there can be no doubt that the combination of top-down targets, investment and increased capacity has been successful in achieving the stated aims with regard to some key areas, particularly waiting times, as can be seen in figures 1 and 2.

Figure 1: Outpatient waiting times: England, 1996–2005

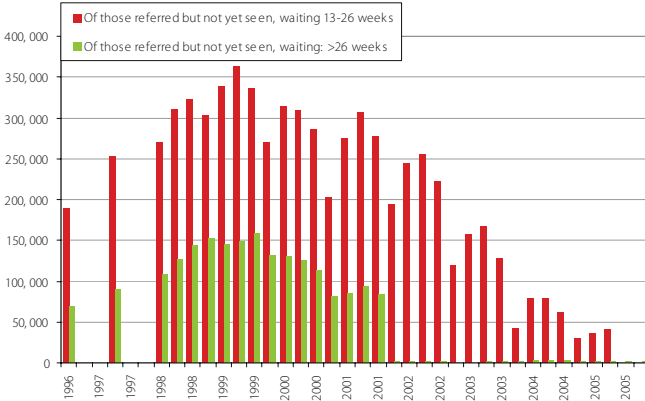
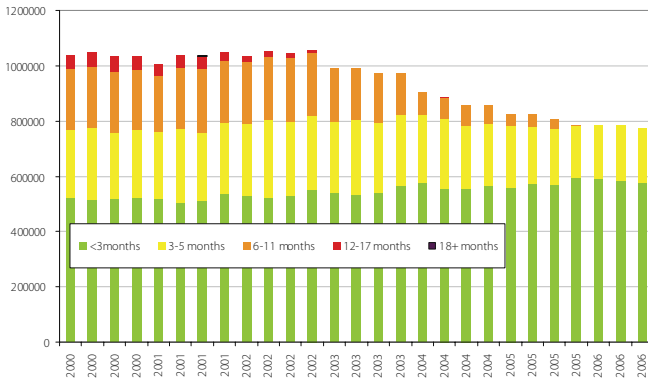


Figure 2: Inpatient waiting times: England, 2000–66



5 Ruth Thorlby and Jo Maybin, *Health and Ten Years of Labour Government: Achievements and Challenges* (London: King's Fund, 2007), 4.

6 *Ibid.*, 4.

Access to the NHS has certainly improved, with waiting times declining, although there has been some recent criticism about the ability of some patients, particularly of working age, to access GP services. However, this criticism should be balanced against the overall good record of the NHS in this area. Reductions in mortality from certain major diseases have been mostly steady, there is little evidence to suggest that health inequalities are narrowing.

Establishing universal clinical standards: national service frameworks

Along with national targets, national service frameworks (NSFs) were used to drive policy from the centre. NSFs contain national standards for the treatment of key conditions and diseases, such as cancer, coronary heart disease, mental health problems and older people's services. They are based on the best available evidence and are backed up with support from newly created "Tsars" (national directors appointed to implement the frameworks). Working alongside the National Institute for Clinical Excellence (NICE; see below), a rolling programme of NSFs has been used by the Department of Health since 1998⁷ to develop national protocols for specific care pathways. To some extent, this involves taking decisions regarding the level and type of treatment used for patients away from the GPs and health authority managers, who had controlled these issues before then, to create a more equitable, and strategically directed, national structure of care. Again, this refers to a centralising tendency, but it is in fact a positive example, as strategic planning in this area makes absolute sense. Part of the motivation for introducing these changes was the fact that the NHS was falling so far behind other countries in terms of outcomes.

Labour's policy approach to specifically identified areas of priority healthcare provision (particularly the "big killers" of heart disease and cancer, but also with mental health – a problem less in the public eye) was, first, to lay out a comprehensive set of prevention and treatment guidelines in the form of an NSF. Then, the Department of Health set out high-level national targets and appointed a national director (or "Tsar") to drive forward their implementation. Subsequently, the number of specialist physicians and/or surgeons in the appropriate field was increased (the number of cardiologists, for example, increased by 10%

7 Department of Health, "National Service Frameworks (NSFs)": www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/DH_4070951.

a year between 1999/2000 and 2004/5, in good part through bringing in expertise from abroad). Expenditure on certain key drugs was also ring-fenced and increased. At the same time, expert teams (such as outreach teams in mental healthcare) or specialist clinical networks (such as the cancer service “collaboratives”) were frequently created.

A question which the SMF Health Project might consider in more detail is:

How successful have NSFs been in raising overall standards of treatment for NHS patients? Was the introduction of NSFs (and NICE) a suitable response to concerns about a postcode lottery in NHS provision?

Other national and local targets

Despite its assertion that a small focused set of targets would be most effective, the *NHS Plan* did not stop with the PSA; in addition, the document also set out a raft of other national and local targets. These included increases in NHS facilities, such as extra beds in hospitals and intermediate care, new hospitals and new one-stop primary care centres. Targets for increases in NHS staff were also set out, including more consultants and GPs, nurses, therapists and medical school places. Alongside these were plans for new NHS buildings, new equipment, clean hospitals, better hospital food and the introduction of new IT systems.

In addition, the *Plan* outlined a number of further waiting-for-treatment targets to tackle – what it described as the “public’s top concern about the NHS.”⁸ These additional waiting-time targets included:

8 Department of Health, *The NHS Plan*, 101.

- GP appointments within 48 hours;
- an end to long trolley waits;
- accident and emergency waiting times cut;
- three-month maximum wait for outpatients by 2005;
- six-month maximum wait for an operation by 2005, falling to three months thereafter;
- treatment according to urgency and individual need within these new maximum waiting times.⁹

Along with the NSFs for cancer, coronary heart disease and mental health (see above) the *Plan* also introduced clinical priorities targets. These included:

- expansion in cancer screening programmes;
- rapid access to chest pain clinics across the country by 2003;
- shorter waits for heart operations.¹⁰

Core and developmental targets

In response to criticism that targets were becoming all consuming, in 2003/4 the government subsequently introduced a new framework of healthcare standards in an attempt to simplify the array of national targets that had evolved out of the *NHS Plan* and respond to some unintended consequences of the original target regime. The new framework emphasised the need to set local targets alongside a smaller number of national targets. The framework introduced a standards-based approach which requires healthcare organisations to take account of the quality and safety of all their services, not just those covered by a national target for improvement.

⁹ Ibid., 101.

¹⁰ Ibid., 113.



The aim of the framework was to move away from a system that is mainly driven by national targets to one in which:

- *standards* are the main driver for continuous improvements in quality;
- there are *fewer national targets*;
- there is greater scope for addressing *local priorities*;
- *incentives* are in place to support the system; and
- all organisations locally play their part in *service modernisation*.¹¹

Healthcare organisations are now expected to meet certain standards in terms of a number of areas: safety, clinical- and cost-effectiveness, governance, patient focus, accessible and responsive care, care environment and amenities, and public health.¹² In each of these areas the standards fall into two categories:

1. *Core standards*: which set out the minimum level of service patients and service users have a right to expect. Meeting the core standards is not optional. Healthcare organisations must comply with them.
2. *Developmental standards*: which signal the direction of travel expected of healthcare organisations. The Healthcare Commission assesses progress by healthcare organisations towards achieving the developmental standards.¹³

11 Department of Health, *National Standards, Local Action: Health and Social Care Standards and Planning Framework* (London: HMSO, 2004), 7.

12 *Ibid.*, 8.

13 *Ibid.*, 8.

New local target-setting

The reduction in the number of national targets has allowed PCTs more room to set local targets in response to local needs and priorities. The government has not set prescriptive guidance on these local targets, but has instead formulated a framework of principles within which PCTs should consider their local needs and priorities. Local targets are subject to assessment by the Healthcare Commission.

The government principles state that PCTs must ensure that their local plans:

- are in line with population needs;
- address local service gaps;
- deliver equity;
- are evidence-based;
- are developed in partnership with other NHS bodies and LAs; and offer value for money.¹⁴

TARGETS TODAY: THE NHS OPERATING FRAMEWORK FOR 2008/9

The most up-to-date NHS targets and priorities are set out in the NHS *Operating Framework for 2008/09*.¹⁵ David Nicholson, NHS chief executive, emphasises in the foreword to the *Operating Framework* that the government and the Department of Health are seeking to move away from national targets, instead allowing PCTs, in conjunction with their local communities, to “set more of their own ambitions rather than having them mainly set by Whitehall.”¹⁶

However, as explored in Background Paper 1, these developments haven’t done away with central requirements altogether. The *Framework* outlines new national priorities for 2008/9 which cover cleanli-

¹⁴ Ibid., 11.

¹⁵ Department of Health and NHS Finance Performance & Operations, *The NHS in England: The Operating Framework for 2008/09* (London: HMSO, 2007).

¹⁶ David Nicholson in *ibid.*, 3.

ness and healthcare-associated infections, improving access, cancer, stroke, children, maternity, staff satisfaction and engagement, public engagement and emergency preparedness.

In addition to these national priorities, the *Framework* also states that PCTs should set local improvement plans for areas of concern. The document argues that this “marks a radical shift in NHS planning and is designed to give more authority to local NHS organisations and their communities.”¹⁷ However, it goes on to highlight “issues requiring local attention”,¹⁸ in effect setting out priorities that are determined centrally, but set locally. These include equality, mixed-sex accommodation, learning disabilities, diabetic retinopathy, crisis resolution, improving access to psychological therapies, dementia, end-of-life care and disabled children.

The *Framework* also makes it clear that PCTs are expected to determine and set their own local priorities and targets. And finally, the document reminds PCTs that the 21 existing national targets to be achieved by April 2008 still apply.

REACTION TO THE TARGET CULTURE

Despite being effective in some areas, target-setting did not meet with universal approval, with many commentators criticising perverse and unintended negative consequences. An example was New Labour’s target of recruiting 20,000 additional nurses by 2004. This was achieved two years early, but mostly by recruiting overseas staff, and it was criticised on ethical grounds for diverting skills needed abroad.¹⁹ Furthermore, it has been argued that the target culture has antagonised health workers, who treated the top-down reforms with some scepticism.²⁰ This is in part a reflection of the difficulty of reconciling the interests of patients, staff and the public, who may all have different priorities for improving the health service.

It is understandable – and in many cases essential – that the

17 Ibid., 20.

18 Ibid., 20.

19 Christopher Deeming, “Policy targets and ethical tensions: UK nurse recruitment,” *Social Policy and Administration* 38, no. 7 (2004), 775–92.

20 Ian Greener and Jane Powell, “Health authorities, priority-setting and resource allocation: A study in decision-making in New Labour’s NHS,” *Social Policy and Administration* 37, no. 1 (2003), 35–48.

government sets national priorities and uses targets as a way, for example, to attack hospital infections and drive down waiting times, particularly since ministers find themselves answerable to the public through the ballot box for the performance of the NHS. Having said this, it is also encouraging that the Department of Health is beginning to understand that central targets are not a panacea: better care and services will not be achieved through central targets alone, but through better local commissioning led by PCTs.

Consequently there remains a feeling that the government has still not got the balance right between dictating national targets and allowing PCTs the freedom to set their own priorities. Niall Dickson, chief executive of the King's Fund, commented: "One area of concern is that while the Department appears to have reduced the number of national targets, many of them appear in the guise of 'national priorities for local delivery'. It's unclear how much autonomy PCTs will have to deliver local priorities given all the national requirements and priorities."²¹ John Appleby, chief economist at the King's Fund, points out that there are ten pages detailing "national priorities (with 29 instances of the phrase 'we expect') and only one paragraph on priorities determined locally."²² It is clear that while David Nicholson hopes to "shift even more autonomy over local target-setting towards PCTs"²³ over the coming years, the days of the nationally set target are far from over.

Questions which the SMF Health Project might consider further include:

- What is the right balance between identifying national priorities for targets and risking distorting activity? What role do such targets have in ensuring value for money?

21 Niall Dickson, cited in King's Fund, 'King's Fund statement on NHS Operating Framework 2008/09' (14 December 2007): www.kingsfund.org.uk/media/kings_fund_96.html.

22 John Appleby, 'New year priorities for NHS under the microscope.'

23 Nicholson in Department of Health and NHS Finance Performance & Operations, *The NHS in England*, 3.

- To achieve specific health outcomes, are targets an appropriate mechanism?
- Were some targets (or sets of targets) more successful than others, not just in achieving specific health outcomes, but also in minimising unintended consequences, and what are the implications for future policy-making?
- Has the government properly taken account of, and responded to, the unintended negative consequences that a programme of targets creates? What can future governments learn from the targets introduced after the NHS Plan?
- Has the list of NHS national targets remained “limited” and “achievable”, as was originally envisaged in the NHS Plan? Ought it to do so? Is there a case for more demanding “stretching targets” in the NHS?²⁴
- Has the “ring-fencing” of expenditure on certain drugs (such as statins for blood cholesterol) created successful health outcomes in those areas? Has it caused unintended negative consequences (e.g., financial shortages elsewhere)?
- Has the government solved the “crisis” in NHS waiting lists? Or is there still a case for reducing waiting times further? Is the government likely to succeed in its 2004 pledge to reduce waiting times to 18 weeks by 2008? Should the government be pursuing ever-more ambitious waiting-time targets at the expense of other objectives, or perhaps pursuing outcomes instead?

24 As was mooted in Targets Commission, *To the Point: A Blueprint for Good Targets* (London: Social Market Foundation, 2005), 62–3.

AN ASSESSMENT OF COMMISSIONING PERFORMANCE

The impact of the “permanent revolution” in the NHS since New Labour came to power in 1997 has been major upheaval for NHS organisations. With large-scale redeployments of staff and extensive redundancies, it is perhaps not surprising that there has been a growing body of evidence to suggest that PCTs are not commissioning as effectively as they might. This evidence was usefully summarised in the SMF Health Commission’s 2005 report, *Choice and Contestability in Primary Care*.²⁵ The commission identified nine potential obstacles to effective PCT commissioning:

1. A lack of appetite amongst the senior management of some PCTs to engage fully with the challenges and opportunities presented by commissioning.
2. Insufficient attempts by PCTs to engage with other stakeholders in the local health economy, e.g. providers and primary care contractors (such as dentists, pharmacists and optometrists).
3. Financial restrictions facing PCTs, such as those stemming from their coming into existence burdened with historic NHS debts.
4. Restrictions on the autonomy of PCTs by the imposition of swathes of centrally imposed targets and priorities.
5. A lack of frontline clinical involvement in the commissioning process – though this may be beginning to change as a result of practice-based commissioning.
6. A lack of suitable staff to provide the expertise to drive a rational, evidence-based commissioning process:

25 Social Market Foundation Health Commission, *Choice and Contestability in Primary Care* (London: Social Market Foundation, 2005).

7. A possible blunting of incentives in the economic relationship between PCTs and providers, by the expectation that they will also work in 'partnership' with one another.
8. A lack of high-quality evidence to allow PCTs to engage in empirically grounded commissioning.
9. A possible lack of commissioning power stemming from the fact that average PCT size is too small to pose a significant enough financial threat to providers.

Since the publication of the SMF report in 2005, some headway has been made with the last of these problems: the government has claimed that the main reason for the steady increase in the average PCT size is precisely to strengthen commissioning power. The House of Commons Health Committee strongly supported this idea, but has also stated its view that there is no "perfect size" for PCTs.²⁶ There is, in fact, a trade-off between larger PCTs, which may have greater bargaining power in the commissioning market, and smaller PCTs, which can better respond to local health needs. What is more, it may be possible for PCTs to capture some of the advantages of larger PCTs without actually increasing in size (by, for example, operating collaborative working arrangements). The committee concluded that the government should allow PCTs "to develop organically, and adopt a managed approach to sharing best practice in commissioning. This would avoid the hugely disruptive and costly impact of another root and branch reform of the NHS."²⁷

Several new problems with PCT commissioning have emerged in more recent research. The King's Fund report, *Windmill 2007*, is very critical of the ability of PCTs to manage their relationships with providers effectively.²⁸ The report identifies a number of reasons why this might be so – e.g., a paucity of analytical and planning skills, and limited experience in handling negotiations sensitively. Too often there is an adversarial approach to contracting, with an over-emphasis placed on tasks and money at the expense of innovation, outcomes and ensuring good ongoing relationships with providers.

26 House of Commons Health Committee, *Changes to Primary Care Trusts* (London: HMSO, 2006).

27 *Ibid.*, 5.

28 Sarah Harvey, Alasdair Liddell and Laurie McMahon, *Windmill 2007: The Future of Health Care Reforms in England* (London: King's Fund, 2007).

The process by which PCTs decide on commissioning priorities has also come in for some criticism in a recent Department of Health report: it argued that PCTs currently focus too much on commissioning for volume and price, at the expense of quality and overall health outcomes.²⁹ The setting of commissioning priorities inevitably involves striking a balance between the meeting of local needs and complying with centrally determined priorities, and this has generated worries about the growth of disparities and inequalities between different PCTs. A 2006 report by the King's Fund argued that local variations in PCT spending priorities could only be partially explained by the different needs of local populations, leaving unanswered questions about why PCTs reach different decisions about their spending priorities.³⁰

The NHS Confederation has recently argued that PCTs are still not using and sharing information in a way that will facilitate effective commissioning.³¹ The confederation states that the data collected for the Joint Strategic Needs Assessment should not only be robust but also transferable. Much of the data collected by local agencies cannot easily be accessed by other providers. The confederation has called for a "common language" for locally compiled data and information.

Finally, the Picker Institute published a report in 2007 revealing that PCTs are failing successfully to engage patients and the public in their commissioning plans. The report found that although the notion of patient and public involvement is well established, the majority of PCTs are not ready to integrate patient and public involvement into all aspects of their commissioning strategies. In general, PCTs lack the skills, experience and confidence to engage successfully with patients and the public. PCTs want better data on the needs and preferences of the local population, training or guidance in techniques of patient and public involvement, and more funds. If these are not forthcoming, and if commissioning does not begin to improve, then, according to the Picker Institute,

29 Department of Health, *Our health, Our Care, Our Say: A New Direction for Community Services* (London: HMSO, 2006).

30 King's Fund, *Local Variations in NHS Spending Priorities* (London: King's Fund, 2006).

31 NHS Confederation, "Response to commissioning framework" (2007): www.nhsconfed.org/issues/issues-2559.cfm.

there is a danger that the local market will create greater, not smaller, health inequalities.³²

Commissioning has been one of the most heavily reformed areas of the NHS since 1997. The House of Commons Health Committee suggests that there will not be any further “root and branch” changes to the sector in the near future. However, the tone of the 2007 interim Darzi Review indicates that there may be further upheaval over the next few years. Whatever occurs in the future, the current onus must be upon ensuring that the existing reforms work as effectively as possible. As we hope to have made clear, there are considerable challenges in securing this goal. Of key importance will be the maturing of the commissioning role of PCTs. These organisations currently control around 75% of the total NHS budget, and thus their scope to widen the range of treatment options, venues and modalities is enormous. Equally important will be the development of practice-based commissioning, and realising the prospect it might offer for the injection of localism and clinical leadership into the primary care commissioning process.

Based on the foregoing, there is a range of possible avenues of further research for the SMF Health Project:

- Is there any evidence that the increase in average PCT size is beginning to yield benefits in terms of more effective commissioning? Equally important, has the merger process also produced the kinds of negative externalities described by the NHS Alliance, e.g. a decrease in locally sensitive forms of commissioning and a return to old-style non-responsive bureaucratic health authorities?³³

32 Alison Chisholm et al., *Patient and Public Involvement in PCT Commissioning: A Survey of Primary Care Trusts* (Oxford: Picker Institute Europe, 2007).

33 Michael Dixon, *Bigger Isn't Better* (London: NHS Alliance, 2001).

- Have we now moved away from the previously described problems to do with lack of appetite, insufficient expertise and empirical data, towards a new situation where PCTs are marked by motivated, expert and empowered commissioning teams that actively embrace the difficulties and opportunities offered by commissioning? This might usefully be explored in the SMF Health Project's qualitative interviews with health professionals.
- Do those involved in PCT commissioning now understand how to strike the delicate balance between working in partnership with providers while maintaining a sufficiently businesslike arm's-length relationship whereby they feel empowered to shift contracts for services if they are not yielding the expected benefits? Again, this is perhaps the kind of issue best explored via the aforementioned qualitative interviews.
- How might PCTs become better users and sharers of information? Can we expect the NHS IT programme to aid with this task?
- What progress has been made to remove what we might call the "structural" obstacles to effective PCT commissioning – e.g. too many centrally imposed targets and priorities, and the continued existence of historic NHS debts? In particular, have problems concerning the latter been exacerbated by the funding slowdown across the NHS as a whole?
- Do those involved in commissioning in PCTs now feel that there is sufficient clinical involvement in the process? In particular, are the professional executive committees in PCTs living up to expectations? Or does PbC offer the best chance for significant clinical input into the commissioning process?
- What can be learned from international commissioning models? Researchers at the Manchester Business School have been collecting data on several such models.³⁴ Their results

34 Manchester Business School, "International comparisons: Effective commissioning," NHS Institute for Innovation and Improvement, 2007. www.executive.modern.nhs.uk/developmentportfolio/courses/pdf/NHS-Programme-64.pdf.



have yet to be published, but a member of the SMF Health Project team has made initial contact with a view to obtaining early access to these results.

- What can be done to ensure that PCTs successfully engage patients and the public in their commissioning plans?

The PbC initiative remains in its relative infancy, but there may nevertheless also be several possible avenues of research for the SMF Health Project here, including:

- What appetite currently exists amongst GP practices to participate in PbC? Is willingness to participate potentially weakened by the prospect of pooling any budgetary surpluses made by individual GP practices as a result of commissioning prudently?
- Are mechanisms in place to ensure that the two different kinds of commissioners within any given local health economy – the PCT, and individual GP practices participating in the PbC scheme – understand their respective roles, work together and do not replicate tasks?
- Even assuming that the preconditions can be put in place for an attractive and workable PbC model, how likely is it that PbC will produce the benefits anticipated by the current government? Are these benefits likely to outweigh the costs of the scheme?

3 FINANCING MECHANISMS

PAYMENT BY RESULTS

Under the payment by results scheme, hospitals and other service providers are paid a fixed price for each patient's completed stay in hospital or service received. The amount is based on the estimated cost of the procedure, averaged across all providers in England, and then adjusted by the market forces factor (MFF) – a mechanism for taking into account local staff, building and land costs – to arrive at a trust-specific tariff. The original aim was for the completion of a comprehensive national tariff for services by 2008, with full implementation of the new financing arrangements completed in the same year. By the accounting year 2006/7, PbR tariffs applied to around two-thirds of hospital activity.

In practice, PbR has been subject to a number of problems, which have led to some changes in direction. The budgetary problems of 2005/6, in which some trusts ran up significant deficits, showed – in view of one analysis – that government had introduced ‘rapid growth in funding before putting in place adequate levers to manage demand and to induce improvements in provider productivity.’³⁵ These budgetary problems were produced in part because PbR was causing historic imbalances and cross-subsidies to unravel in different parts of the NHS.

Questions remain about whether PbR can evolve into a system of appropriate financial incentives for providers to respond to patient demand. An Audit Commission report in early 2008 described PbR as ‘still bedding in’³⁶ and, while welcoming some positive contributions, questioned whether the policy has had a significant impact on activity and quality in the NHS. The commission pointed to significant changes in the tariff and problems with the underlying information systems infrastructure as key reasons why PbR has not

35 Keith Palmer, *NHS Reform: getting back on track*, (London: King's Fund, 2006) 16.

36 Audit Commission, *The Right Result? Payment by Results 2003–2007* (London: Audit Commission, 2008), 2.

had the impact it was intended to have. It recommended greater flexibility within the tariff, raising the possibility of having separate funding streams for capital and quality.

There are further potential policy challenges that require further investigation. Foremost among these is that PbR gives hospitals an incentive to drive up their levels of activity and thereby increase their revenue. However, the overall thrust of government policy is to try and avoid the need for hospital treatment, both by improving the health of the population and by delivering treatment in the community wherever possible. There are also questions about the efficacy of the tariff. Is it sensitive enough to take account of casemix variations that mean that some procedures cost far more than the tariff price? This is an important consideration – the international evidence shows that effective choice systems must prevent providers from “cream-skimming” the most straightforward cases in order to minimise their costs.³⁷

Summing up the above, possible areas of further research for the SMF Health Project might include:

- Is PbR capable of producing the kinds of incentives (both positive and negative) hoped for by the government?
- Is there evidence that the incentives inherent in PbR have caused an increase in levels of care activity, at the expense of judicious use of resources, and in tension with the government's desire to shift more care into community settings? Does it, for example, help to produce an unnecessarily high level of hospital admissions?
- Is the current PbR tariff sufficiently sensitive to stop providers cream-skimming the most ‘cost-effective’ patients, in a way that offends equity and undermines the practical and normative validity of the current choice mechanisms in the NHS?

37 Jonathan Williams and Ann Rossiter, *Choice: The Evidence* (London: Social Market Foundation, 2004)

4 DEMAND MANAGEMENT

One of the ongoing complexities of the NHS as set up in 1948 was the ambiguous position of GPs with respect to overall budgetary control. As Background Paper 1 has explored, the family practitioner services budget was demand-led until the 1991 reforms introduced GP fundholding. However, at the same time, GPs have maintained an important gatekeeping role vis-à-vis the much more resource-intensive sectors of the healthcare economy: those of hospital-based secondary and tertiary care; patients wishing to access secondary care services have first to obtain a referral from a GP.

Under the 1991 quasi-market reforms of the last Conservative Government, health authorities tended to maintain block contracts with NHS trusts. Rationing by queuing (waiting lists) was the main mechanism for balancing demand against available finance over the accounting year. However, as waiting-time targets have started to bite this is no longer an available option. Indeed, the greater emphasis on waiting-time targets implies increased activity in the acute sector.

Furthermore, as discussed above, PbR, a fee-for-service financing system which complements the choice agenda, also incentivises activity in the acute sector. Both policies are potentially inflationary in terms of activity and cost and, predictably, the number of referrals to secondary care is increasing, driving up costs for the NHS.³⁸ Consequently, the need for discrimination in demand management has become even more of an imperative.

38 Myfanwy Davies and Glyn Elwyn, "Referral management centres: promising innovations or Trojan horses?" *BMJ* 332 (2006), 844–6.

REFERRAL MANAGEMENT CENTRES

Referral management centres (RMCs) have been developed to help deal with this trend by monitoring, assessing and redirecting referrals. RMCs act as a middle man between GPs and hospitals, recommending where and when patients are treated.

The Commissioning Framework,³⁹ published as an annex to *Health Reform in England* in July 2006 by the Department of Health, stated that the job of RMCs is to accept GP referrals and provide advice on the most appropriate next steps for the treatment of patients. It is hoped that RMCs will improve referrals between primary and secondary care by providing a range of controls to manage NHS expenditure effectively and ensure that patients who need hospital care are seen quickly.

Advocates of RMCs argue that they will manage demand by encouraging referrals to services that are both underused and cost-effective. Davies and Elwyn, writing in the *BMJ*, state that referral management has three potential roles: to count and monitor referrals, to assess their nature (and perhaps their quality) and to redirect or bar requests for referral.⁴⁰ Each of these roles could bring significant gains to the NHS. First, by monitoring referrals, RMCs will collect data on referral patterns which will provide indications of disease prevalence and information about the quality of clinical practice. Second, assessing the nature and quality of referrals could help to ensure that patients are sent to the most appropriate service or specialist at the right time. Finally, RMCs have the potential to play an important role in redirecting patients. NHS services have become increasingly specialised and centralised, and, as a result, GPs may not be fully aware of the most appropriate specialists, diagnostic tests or treatments available for their patients.⁴¹ Referral management centres could potentially redirect referrals to the most relevant and cost-effective services.

39 Department of Health, *Health Reform in England: Update and Commissioning Framework: Annex – The Commissioning Framework* (London: HMSO, 2006).

40 Davies and Elwyn, "Referral management centres."

41 *Ibid.*

The Department of Health has outlined the principles that should guide RMCs:

- they must not lengthen the patient journey or create “hidden” waiting times;
- they must carry clinical support and abide by clear protocols that provide clinical benefits to patients;
- they should provide feedback to practices on referrals, thus enabling GPs to review appropriateness of their referrals;
- they should not preclude practices from the effective redesign of services under PbC where this might necessitate changes to the pathway(s) used by the RMC;
- they should not be imposed on practices without their agreement, or used as a device to avoid constructive challenge of poor or inappropriate referral behaviour.⁴²

It was hoped that, if RMCs were guided by these principles, then they would receive clinical support. However, despite these assurances, some health professionals feel that RMCs could have negative effects on the referral process. A press release by the BMA in January 2006 made it clear that they have concerns about the safety and confidentiality of RMCs.⁴³ The BMA also felt that RMCs may be used as an implicit means of rationing care and as a mechanism for delaying non-emergency operations.⁴⁴ This has been refuted by Gill Morgan, chief executive of the NHS Confederation, who disagreed with the assumption that RMCs are leading to delays and rationing. She argued that, if used correctly, RMCs would “ensure that the most urgent patients receive care faster, that all of the care options are evaluated and the most appropriate treatment is provided.”⁴⁵

A further worry is that the centres will impose a second tier of costly

42 18 Weeks Delivery Programme, “What is a Referral Management Centre?,” NHS, 2007 www.18weeks.nhs.uk/public/default.aspx?main=true&load=ArticleViewer&ArticleId=898.

43 BMA, “Referral management: frequently asked questions,” BMA, 2007 www.bma.org.uk/ap.nsf/Content/refmanfaqsjan06?OpenDocument&Login.

44 BBC News, “Doctors attack op referral change,” *BBC News*, 28 February 2008: <http://news.bbc.co.uk/1/hi/health/4759006.stm>.

45 Gill Morgan, cited in BBC News, “Doctors attack op referral change.”

administration, with little firm evidence that the benefits will outweigh the transaction costs.⁴⁶ The BMA has argued that this extra tier between primary and secondary care might mean that the relationship between a referring GP and a consultant will become more remote. This would make it less clear where the responsibility for a patient lies during the referral process – with the GP or with the consultant?⁴⁷ It is also unclear who will be accountable for any errors or delays that occur during assessment.

Along with ambiguities over responsibility are ambiguities over clinical and patient control. If referral centres have the power to decide whether a patient is to be referred and where they should be referred to, this has a potentially significant impact on clinical and patient autonomy. Doctors may feel that their clinical freedom is being eroded, while patients might feel that their choices are being curtailed.

Finally, if patients are being directed to services in the community, for instance, this could have financial implications for hospitals that are losing patients as a result.

Despite these concerns it seems likely that, as referrals to secondary care continue to rise, the status quo will become less and less sustainable. Therefore, mechanisms such as RMCs, which aim to manage referrals and introduce quality controls, will become increasingly important. In addition, those who support RMCs see them not as blocking patient choice but as facilitating it by supporting Choose and Book, which routes e-referrals to the appropriate services, provides a central contact point for patients to enquire about a referral and offers patients choice for outpatient appointments. In addition, the Department of Health states that staff within RMCs will work with patient care advisers to ensure that patient choice initiatives are implemented.

46 Davies and Elwyn, "Referral management centres."

47 BMA, "Referral management standards and ethics." BMA (September 2007): www.bma.org.uk/ap.nsf/Content/Referralmanagementethics.

From this, it can be seen that there are a number of further questions that the SMF Health project could examine in relation to RMCs:

- Will RMCs increase or decrease risk and efficiency?
- Will RMCs prevent patient choice, or can they be used to help patients make informed choices and navigate through the system, thus reducing the likelihood of an exacerbation in inequalities in uptake of choice?
- Are the concerns about the safety and confidentiality of RMCs valid?
- Are the concerns about increased bureaucracy and confusion over clinical responsibility and control valid?
- Are RMCs a means of rationing care, or will the Department of Health principles ensure that RMCs will not be used in this way?



5 SETTING CLINICAL STANDARDS

THE NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

The National Institute for Clinical Excellence was established as a special health authority of the NHS in April 1999, with the overall aim of helping the NHS achieve the highest attainable standards of care.⁴⁸ On 1 April 2005, the institute amalgamated with the Health Development Agency to form the National Institute for Health and Clinical Excellence (NICE) to produce a broader range of health guidance “on the promotion of good health and the prevention and treatment of ill health.”⁴⁹ The institute’s mandate includes setting standards for the use of new technologies and procedures within the NHS as well as producing clinical and public health guidance. As such, NICE sits “at the controversial intersection of quality, innovation, access, and cost.”⁵⁰

Why was NICE established?

The origins of NICE lie in the 1997 White Paper, *The New NHS*.⁵¹ There it was argued that such a body would drive up clinical standards in the NHS by offering positive guidance regarding the use of products and technologies that were proven to be clinically and cost-effective. This marked an explicit move towards the practice of “evidence-based medicine” in England and Wales.

Prior to the existence of NICE, the Department of Health felt that new technologies were being adopted without adequate evidence of their clinical- and cost-effectiveness, while at the same time the uptake of such technologies that were effective and offered good value for money was slow and variable.⁵² This was partly because many practitioners did not have the time or expertise to make considered judgments about the clinical value of new medical technologies and also because there was a lack of adequate guidance to help inform them. Professor Sir Michael Rawlins, chair of NICE, argued at the time

48 Michael Rawlins, “In pursuit of quality: The National Institute of Clinical Excellence,” *The Lancet* 353, no. 9158 (1999), 1079–82.

49 National Institute for Health and Clinical Excellence, “About NICE,” www.nice.org.uk/aboutNICE.

50 Steven D. Pearson and Michael D. Rawlings, “Quality, innovation, and value for money: NICE and the British health service,” *American Medical Association* 294, (23/30 November 2005), 2618–22.

51 Department of Health, *The New NHS: Modern, Dependable* (London: HMSO, 1997).

52 Rawlins, “In pursuit of quality.”

that guidelines for new technologies were often of indeterminate quality, indigestible and inaccessible.⁵³ The existence of a plurality of guidelines also made it difficult to determine which offered the most credible advice.

The formation of NICE was an attempt to address these problems. Prior to the launch of the institute, Frank Dobson, then secretary of state for health, claimed that "NICE guidance will produce a common currency of effectiveness for the NHS, to inform and assist decision-making about treatment and healthcare at all levels."⁵⁴

NICE was also formed to help ensure the financial sustainability of the NHS. The government and academics agreed that the unchecked adoption of new technologies would put severe pressure on an already stretched NHS budget.⁵⁵ NICE was established to introduce some restraint and to help the health service allocate its resources more effectively.

Finally, NICE was created to address the inequalities in healthcare provision caused by the "postcode lottery" that existed in England and Wales, whereby the availability of treatments depended upon the NHS trust area in which a patient lived. From January 2005, the NHS in England and Wales has been legally obliged to provide funding for medicines and treatments recommended by NICE's technology appraisal board.

53 Ibid.

54 House of Commons Health Committee, *National Institute for Clinical Excellence: Second Report of 2001–02* (London: HMSO, 2002), 1.

55 Royal College of Physicians, *Setting Priorities in the NHS: A Framework for Decision Making* (London: Royal College of Physicians, 1995), 379–80; Rudolf Klein, "Puzzling out priorities," *BMJ* 317 (1998), 959–60.

How does NICE work?

NICE has four separate programmes that produce different types of guidance:

- technology appraisal guidance;
- clinical guidance;
- interventional procedures guidance;
- public health guidance (a new programme that began in April 2005).⁵⁶

In addition, NICE produces audit advice along with each of the technology appraisals and health guidelines that it publishes.

Technology appraisal

Technology appraisal, resulting in guidance on the use of health technologies, has been NICE's most visible contribution to the NHS. NICE aims to evaluate at least 30 technologies a year. The Department of Health decides when guidance is required for a particular health technology. In addition, the Department is informed about new technologies that might require evaluation by the National Horizon Scanning Centre, which provides an early warning about emerging healthcare technologies.⁵⁷

Once a health technology has been referred by the Department of Health, NICE undertakes a process of appraisal which lasts approximately 12 months. "Consultee" organisations – such as patient groups, organisations representing healthcare professionals, and the manufacturers of the product undergoing appraisal – may all submit evidence and comment on the appraisal documents. "Commentator" organisations, including the manufacturers of rival products, can comment on documents that have been drawn up, but usually do not submit information themselves.

56 National Institute for Health and Clinical Excellence, *A Guide to NICE* (London: NICE, 2005).

57 Nursing Times, "What is the National Horizon Scanning Centre (NHSC)?" *Nursing Times*, 18–24 August 1999.

NICE's technology appraisal is supported by the health technology assessment (HTA) programme, which ensures that the NICE appraisal committee has the knowledge and evidence it requires to produce appropriate advice. The HTA programme commissions an independent team of UK academics to analyse all the published information on the technology under appraisal. The consultees and commentators then comment on this analysis, in an evaluation report. This report is then amended by the NICE appraisal committee in light of oral evidence from clinical experts, patient groups and carers, in an appraisal consultation document (ACD). After further oral comments on this document, a final appraisal determination (FAD) is produced. Once this has been approved by the NICE board, final guidance is issued to the NHS. This is subject to appeal by stakeholders before finally being released.⁵⁸

Clinical guidance

NICE clinical guidance consists of recommendations on the appropriate treatment and care of people with specific diseases and conditions. An independent clinical guidelines committee is responsible for assessing the quality and content of these guidelines. Consultation on the content of the guidelines also takes place between NICE and interested parties such as healthcare professionals, patients and the healthcare industry. The final guidance is submitted to NICE, which formally approves the guidelines and subsequently issues them to the NHS.

Interventional procedures

The third type of guidance produced by NICE consists of recommendations about the safety and effectiveness of interventional procedures used for diagnosis or treatment.⁵⁹ The aim of these guidelines is to promote patient safety and to support the rational introduction of new procedures into the NHS.

58 Rawlins, 'In pursuit of quality.'

59 NICE defines interventional procedures as those used for diagnosis or treatment that involve entering the body in some way, or using technological means (e.g. electromagnetic radiation) to treat specific medical problems (National Institute for Health and Clinical Excellence, 'Interventional procedures,' NHS <http://guidance.nice.org.uk/IPG>).

Public health guidance

NICE's public health guidance is produced in two formats: first, public health intervention guidance, which makes recommendations on specific activities designed to promote healthy living, and, second, public health programme guidance, which deals with broader advice on how to prevent ill health. This latter guidance tends to focus on specific causes of ill health.⁶⁰

AN ASSESSMENT OF NICE

The objectives of NICE when it was established were extremely ambitious: not only did it aim to drive up clinical standards while, at the same time, improving cost-effectiveness; it was also assigned the task of putting an end to postcode prescribing. These goals were described by the House of Commons Health Committee as amounting to a "revolution" within the NHS.⁶¹

Such a broad remit and ambitious goals have meant that NICE has been open to criticism on a number of fronts. We review the available literature on the success of NICE under seven broad headings:

- securing cost-effectiveness within the NHS;
- improving clinical excellence;
- engaging stakeholders in the decision-making process;
- guaranteeing a universal and uniform standard of care;
- the speed at which NICE appraisals are undertaken;
- the methodological rigour of NICE appraisals;
- the scope of NICE appraisals.

60 National Institute for Health and Clinical Excellence, "About public health guidance," www.nice.org.uk/page.aspx?o=295876.

61 House of Commons Health Committee, *National Institute for Clinical Excellence: Second Report of 2001–02*.

Cost-effectiveness

Making tough decisions on the cost-effectiveness of medical treatments will always attract interest and controversy; product manufacturers, patient groups and sections of the media have all at various times expressed dismay at NICE decisions to withhold approval from treatments on the basis of their cost-effectiveness.⁶² Some writers have expressed fears that NICE might be vulnerable to these external pressures.⁶³

Nevertheless, the prevailing consensus seems to be that NICE has managed to deliver carefully reasoned decisions on the cost-effectiveness of treatments sent for appraisal. The World Health Organisation (WHO) has commended the NICE technology appraisal process as representing “an important model for technology appraisals internationally.”⁶⁴ This approval is echoed in a recent Office of Fair Trading (OFT) report, which declares that, as a body carrying out health technology assessments, NICE is “among the most respected in the world.”⁶⁵ Greater clarity about the boundaries of NHS provision is a very worthwhile goal, and NICE is making considerable progress towards its realisation.⁶⁶

It ought to be borne in mind, however, that NICE has operated during a period of unprecedented growth in the overall NHS budget. This growth will not continue, of course, and there is a belief that when the NHS funding slowdown begins to bite, NICE will not be able to keep recommending as many treatments as it currently does.⁶⁷ This will bring its decision-making processes under renewed scrutiny. The crucial issue of how NICE decides whether a treatment is “sufficiently” cost-effective will become ever more salient. The aforementioned WHO report, while generally highly complimentary about the NICE technology appraisal process, did remark that it was unclear why the institute was reluctant to approve treatments costing more than

62 Francois Schubert, “Health technology assessment: The pharmaceutical industry perspective,” *International Journal of Technological Assessment in Healthcare* 18 (2002), 184–91.

63 R E Turner and Sarah McDowell, *How NICE Might Be Outflanked* BMJ 332 (2006) 1268–1271.

64 World Health Organisation, *The Health Technology Appraisal Programme* (Geneva: World Health Organisation, 2003).

65 Office of Fair Trading, *Pharmaceutical Price Regulation Scheme* (London: HMSO, 2007).

66 Among the considerable spin-off benefits from this goal is the opportunity for non-NHS providers to plan ahead and offer targeted additions to the range of NHS treatments.

67 Simon Stevens, “Reform strategies for the English NHS,” *Health Affairs* 23 (2004), 37–44.

£25–35,000 per Quality Adjusted Life Year (QALY). NICE might not operate an absolutely rigid threshold, but why is it that, if the cost of a treatment falls above this *particular* price range, the institute needs to see “special reasons” before it grants approval to a treatment?

These issues are difficult to divorce from the question of what the NHS is able to afford. As we have discussed, NICE has not so far explicitly concerned itself with affordability. Rawlins has stated that NICE should stick to this position, arguing that affordability questions are “for the Government when deciding the annual budget for the NHS.”⁶⁸ This stance is supported by the Health Select Committee which, in its 2002 report on NICE, argued that decisions about the affordability of NICE’s recommendations must “be seen to be made entirely separately from NICE’s decisions about clinical- and cost-effectiveness.” The report concluded that the widespread perception of a link between questions of affordability and NICE decisions about cost-effectiveness ought to be “dispelled.” Furthermore, the committee recommended that the government “should take steps to clarify its own role in taking decisions about whether or not individual pieces of NICE guidance will be funded.”⁶⁹

There is some merit in the argument that questions of affordability ought to be made by elected politicians. What the NHS can afford is directly linked to its funding, and this comes from the tax-payer. Therefore, there must be a direct link to the electorate when considering questions of affordability. Nevertheless, some commentators argue that NICE ought to take on a greater role in considering questions of affordability. Barrett et al. examined NICE’s positive recommendation of the drug Herceptin and revealed that Norfolk and North University Hospital Trust will have to find £1.9m each year in drug costs alone to make Herceptin available to the 75 patients who may be eligible. They argue that “the real cost lies in the services that will be cut to provide this money. This is an important element currently missing from the debate.” They conclude that NICE should be given responsibility “to decide what should be cut to fund newly recommended technologies or the ability to allocate extra funds for implementation, or both.”⁷⁰

68 Michael Rawlins and Anthony Culyer, “National Institute for Clinical Excellence and its Value Judgments,” *BMJ* 329 (2004).

69 House of Commons Health Committee, *National Institute for Clinical Excellence: Second Report of Session 2001–02*, 33.

70 Ann Barrett et al., “How much will Herceptin really cost?,” *BMJ* 333 (2006), 1118–20.

Maynard et al. argue that NICE could play a useful role in deciding on affordability by adopting one of two strategies. First, NICE could be given an annual notional budget to fund its recommendations. It would have to cost its proposals and stay within that budget or recommend services suitable to withdraw in order free up resources. Alternatively, NICE could be given an annual, top-sliced, real budget which it would allocate to NHS trusts to enable them to fund its recommendations. Maynard et al. argue that the second option would be the more effective. It would allow NICE to “examine the effect of their decisions on the whole NHS, and also provide incentives to balance cost enhancing against cost reducing recommendations.”⁷¹

In sum, the issue of how NICE decides which treatments are “sufficiently” cost-effective, and the associated question of whether or not NICE should become involved in questions of affordability, are fruitful areas of further research for the SMF Health Project. For instance, it might consider whether questions of affordability ought *solely* to be the preserve of elected politicians. The importance of democratic input into these questions does not straightforwardly license the conclusion that they ought to be made only by politicians. It is certainly important to feed the views of citizens into the making of these decisions, but might more direct methods be more appropriate? Might it be possible, for example, to expand the role of NICE’s Citizens Council to consider difficult questions about affordability? And should more widespread measures be considered, such as a national programme of citizens’ juries tasked with considering these questions?⁷²

71 Alan Maynard, Karen Bloor and Nick Freemantle, “Challenges for the National Institute for Clinical Excellence,” *BMJ* 329 (2004), 227–9.

72 Asking about the willingness of citizens to pay for new health technologies from their own resources (either their actual resources, or some hypothetical set of resources based on, for example, average income) might be an interesting way into considering issues of affordability. Something like this methodology has been suggested by the American political philosopher Ronald Dworkin. See Ronald Dworkin, *Sovereign Virtue* (Cambridge, MA: Harvard University Press, 2000).

In addition, the SMF Health Project could assess the merit of suggestions such as those put forward by Maynard et al., whereby NICE is either given a notional budget within which it must cost its proposals, or a real budget which it allocates to NHS trusts to fund NICE-approved treatments. Both methods must, however, incorporate the views of citizens, for the reasons already adduced.

Improving clinical excellence

In its drive to ensure clinical excellence through its technology appraisals as well as its clinical, public health and interventional guidance, NICE has received a good deal of praise, but also some criticism. In the House of Commons Health Select Committee's September 2002 report on NICE, some contributors of evidence criticised NICE's appraisal of Relenza. This drug was initially refused approval in 1999, but NICE reversed its decision in 2002 on the basis of new evidence from the manufacturers. Some contributors of evidence felt this gave the impression that external pressure had caused NICE's change of view. The Select Committee also expressed concern over what it saw as a failure by NICE to communicate effectively with specialist-prescribing organisations such as the Drug and Therapeutics Bulletin (DTB) and the British National Formulary (BNF).⁷³

It must be remembered, however, that this report was published in 2002, a mere three years after the establishment of NICE. At that time, the committee stressed that its confidence in NICE was strengthened by the fact that the institute was already taking steps to improve. NICE has subsequently entered into a formal relationship with the BNF, which now has the opportunity to comment on all draft appraisals of pharmaceutical technologies. In addition, NICE has met with the editor and other staff of the DTB "to consider how to work effectively together."⁷⁴ This indicates willingness on the part of NICE to accept recommendations for change and to act upon them.

73 House of Commons Health Committee, *National Institute for Clinical Excellence: Second Report of 2001–02*.

74 National Institute for Clinical and Health Excellence, *NICE Response to the Report of the Health Select Committee Following the Committee's Short Inquiry: March 2003 Update* (London: NICE, 2003).

The SMF Health Project could conduct research into how successful NICE has been in improving the way in which it works with stakeholders such as the DTB and the BNF, and whether any improvements that have resulted from these working relationships have led to gains in the quality of NICE guidance. This stream of work might usefully be conducted by way of interviews with relevant senior figures in these organisations.

Engaging stakeholders

The House of Commons Health Select Committee also praised the attempts made by NICE to include stakeholders in its appraisal process, but claimed that NICE could improve further in this area. In particular, the committee argued that NICE could do more to engage frontline NHS staff, who felt excluded from the process of drawing up technology appraisals. NICE has now ensured that stakeholders can be nominated and can self-nominate at any point in the appraisal process up to the appraisal consultation document stage. In addition, the institute now publishes its appraisal consultation documents on its website and enables anyone, be they a health professional, a manufacturer, a patient or a member of the public, to enter comments.⁷⁵

The 2002 Health Select Committee report also assessed the transparency of NICE's decision-making process, and recommended that all information used by NICE in arriving at its decisions should be easily available for public scrutiny. NICE responded to this recommendation by improving the transparency and clarity of its decision-making and audit trails, including posting the minutes of appraisal committee meetings on its website. In addition, Sir Michael Rawlins announced that the deliberations of NICE's five standing advisory bodies would be open to public scrutiny. He told MPs that the action was an attempt to improve transparency, and that although NICE deliberations are made public in written form, it had been a matter of "regret" that its committees had previously met in private.⁷⁶

⁷⁵ Ibid.

⁷⁶ Cited by Andrew Jack, "Move to Boost Openness on NHS Drugs," *Financial Times*, 18 May 18 2007.

Some patient groups feel their views are not adequately incorporated into the NICE appraisal process.⁷⁷ NICE denies these accusations, stating that patient groups are central to the appraisal process, and “comments from them are vital to ensuring that NICE understands the impact a technology has on the patients for which it is intended.”⁷⁸ In addition, and as described above, NICE set up a Citizens Council to feed social value judgements into its wider methodologies. An in-depth independent evaluation of the council over its first two years of operation reveals that it has achieved mixed success. The report states that for the individuals selected to sit on the council, the process was positive: council members were stimulated and stretched by the experience and, as a result, ended up feeling more informed about NICE, the NHS and healthcare more generally. The authors of the report also praised NICE for remaining open to new ideas on how to organise the council, and for taking pains to ensure that diverse social groups were represented.⁷⁹

However, the authors also highlight a number of fundamental problems. Council members frequently did not understand the question they were discussing and “there was little that could be counted as deliberation.” Although NICE has sought to learn from these difficulties, and more recent meetings have been more effective, the quality of deliberation at the meetings remains “patchy.”

In addition, NICE was over-cautious in ensuring that it did not influence the council too much. While this is a legitimate concern, it meant that council members found it hard at first to “enter imaginatively into the work of NICE”, and were thus unsure as to where their contribution would fit and what impact it would have.

77 HSC News International, “The National Institute for Health and Clinical Excellence,” *HSC News International* 35 (2007), 49; Jesme Fox, “Evidence Submitted by the Roy Castle Lung Cancer Foundation (NICE 24),” Select Committee on Health, www.parliament.the-stationery-office.com/pa/cm200607/cmselect/cmhealth/503/503we23.htm.

78 Lucy Betterton, Associate Director of Communications, NICE, quoted in HSC News International, “The National Institute for Health and Clinical Excellence.”

79 C. Davies et al., *Opening the Box: Evaluating the Citizens Council of NICE* (Milton Keynes: The Open University, 2005).

The report concludes that “more experimentation is required, as government and other institutions continue the search for new modes of public participation to renew and revive interpretations of democracy”.⁸⁰

Ensuring a universal standard of care

High-quality guidance from NICE will not, in itself, drive up clinical standards in the NHS; this will only be achieved if health professionals across England and Wales actually *implement* the guidance they receive. There is some debate about the extent to which implementation is occurring. Some have argued that there is a significant amount of non-compliance with NICE guidance, especially within the primary care sector. This may be due in part to the fact that NICE guidance is not always reflected in incentives set out in the general medical services (GMS) contract.

A national study of the implementation of NICE guidance carried out by Sheldon et al. found only “mixed” evidence that it “has made a difference either to the quality of care or to variations in practice.” The authors of the study praised the establishment of NICE as a “unique initiative”, but argued that the institute is not sufficient to ensure “rapid and universal implementation of evidence based healthcare.”⁸¹ This is partly because the NHS is going through a significant period of change, with new structures, funding deficits and staff shortages, all diverting attention away from the implementation of NICE guidance.⁸²

Sheldon et al.’s findings are supported by those of Rishi Mannan and Melvyn Jones from the Royal Free and University College Medical School, who examined how NICE guidance altered prescription rates of glitazones for type 2 diabetes mellitus. They found that there were “no notable changes in prescribing rates as a result of NICE guidance.”⁸³

Sheldon et al. also highlight a number of factors that they believe would make the adoption of NICE guidance more likely. These include

80 Ibid., 15.

81 T. A. Sheldon et al., “What’s the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients’ notes, and interviews,” *BMJ* 329 (2004), 999.

82 Ibid.

83 Rishi Mannan and Melvyn Jones, “What’s the evidence that NICE Guidance has been implemented? Maybe NICE needs to do more to ensure implementation of guidelines,” *BMJ* 330 (2005), 1085.

strong professional support, a stable and convincing evidence base and no increased or unfunded costs. Guidance is also more likely to be put into practice in organisations that have “established good systems for tracking guidance implementation and where the professionals involved are not isolated.” Guidance also needs to be clear and to reflect the clinical context.⁸⁴ The authors conclude that the active promotion of guidance by NICE is likely to increase its adoption, but the impact will probably not be proportionate to the effort invested. They argue that it would be far more effective if opinion leaders such as the professional bodies and associations were to promote the guidance.

Nick Freemantle from the University of York argues that the results of the Sheldon study should make us sceptical as to whether “there is any real return from the substantial efforts and resources that go into producing NICE guidance.”⁸⁵ He argues that unless the guidance leads to real change it would be better to spend the resources used to fund NICE on care for patients. However, Freemantle points out that other regulatory structures, such as the pharmaceutical benefits scheme in Australia, have managed to achieve change. Therefore, rather than give up on NICE, he urges careful thought on how the institute can be made more effective.

It must be stated that Sir Michael Rawlins and Andrew Dillon (NICE’s chairman and chief executive, respectively) have robustly defended NICE’s implementation strategy.⁸⁶ They admit that it was probably a mistake not to give NICE explicit responsibility at the outset for monitoring the implementation of its guidance, but they point to NICE’s implementation support strategy, launched in June 2004 as evidence that the institute takes implementation seriously. Rawlins and Dillon emphasise the fact that the study by Sheldon et al. covers the period *before* January 2005. After this date, trusts were legally obliged to fund treatments approved by NICE

84 Ibid.

85 Nick Freemantle, “Is NICE delivering the goods?” *BMJ* 329 (2004), 1003–4.

86 Michael Rawlins and Andrew Dillon, “What’s the evidence that NICE guidance has been implemented? More recent data on NICE implementation show different picture”, *BMJ* 330 (2005), 1086.

technology appraisals, and as a result implementation rates should have improved.

Rawlins and Dillon also state that more recent studies give a different picture of NICE implementation rates, the most extensive of which was undertaken by Abacus International. The Abacus study covered 28 appraisals, including appraisals published after January 2005. It concluded that "NICE guidance is driving change but at different rates for different disease areas." Of the 28 topics that the study reviewed, 12 were "reasonably implemented" within the expectations of guidance, 12 were classified as "under implemented" and four were over-implemented, exceeding NICE's expectations of levels of treatment.⁸⁷

This certainly suggests that NICE guidance is having more of an impact than the Sheldon study suggests. However, Freemantle has counter-argued that the Abacus study is a simple audit of NHS activity and "lacks the methodological rigour that characterises the paper by Sheldon et al. and fails completely to use appropriate methods to examine the important issue of causation."⁸⁸

Whatever the exact levels, it is plain that implementation is extremely important for maintaining high clinical standards, cost-effectiveness, and uniformity of provision. As part of its ongoing research, the SMF Health Project could investigate how the implementation rate of NICE guidance could be improved. For example, might financial incentives, such as changes to the general medical services contract, help encourage the implementation of guidance? NICE could conceivably play an important role in ironing out significant and unwanted variations in the provision of medical services. Such unevenness has been recognised as having negative impacts on both clinical- and cost-effectiveness.⁸⁹ The Department of Health has taken this on board and is attempting to address the problem.

The chief medical officer has recently identified several measures to eliminate unjustified variation in the supply of health interventions.

87 Simon Howard and Linda Harrison, *NICE Guidance Implementation Tracking Data Sources, Methodology & Results* (London: Abacus International, 2005), 37.

88 Nick Freemantle, "What's the evidence that NICE guidance has been implemented? Author's reply," *BMJ* 330 (2005), 1086.

89 John E. Wennberg, "Education and debate: Unwarranted variations in healthcare delivery: Implications for academic medical centres," *BMJ* 325 (2002), 961–4.

Groups and programmes have been established with the aims of identifying barriers to effective provision, removing ineffective treatments, varying tariff payment in the NHS, so that less effective treatments result in less money going to hospitals that provide them, and improving the dissemination of medical knowledge (via national knowledge days, a national knowledge board, and chief knowledge officers in NHS trusts).⁹⁰ In addition, the NHS “Better Care, Better Value Indicators”, primarily targeted at PCTs and acute hospital providers, aims to improve efficiency by determining where there is variation in performance between NHS organisations and considering what changes will lead to improved performance.⁹¹

Speed of appraisals

Related to the question of implementation and ensuring an even standard of care is the issue of how quickly NICE can complete technology appraisals. The institute has received some criticism for being “too slow” in this regard.⁹² One cause of delays is the fact that a treatment is only appraised when the Department of Health requests it, which tends to be only after a new treatment has been licensed. In addition, a NICE technology appraisal is a complex process involving many interested parties, and will always be time-consuming – although this of course begs the question as to whether the process ought to consume quite as much time as it currently does. It has been pointed out that the Scottish Medicines Consortium (SMC), which provides advice to NHS Scotland about the status of all newly licensed medicines, has not suffered from the same delays as NICE. The SMC aims to issue advice on all newly licensed medicines within 12 weeks of products being made available.⁹³

In response to these criticisms, NICE has developed the single technology appraisal (STA), which has been modelled on the SMC. The STA is a revised process for the appraisal of an individual product with a single indication, where most of the evidence lies with one

90 Department of Health, *On the State of Public Health: Annual Report of the Chief Medical Officer 2006* (London: Department of Health, 2006).

91 Institute for Innovation and Improvement, ‘NHS better care, better value indicators,’ www.productivity.nhs.uk/.

92 Bengt Jonsson and Nils Wilking, ‘A global comparison regarding patient access to cancer drugs,’ *Oxford Journals: Annals of Oncology* 18, supplement 3 (2007).

93 Scottish Medicines Consortium, ‘About us,’ NHS Scotland www.scottishmedicines.org.uk/smc/smc_displayLeftNav.jsp?pContentID=24&p_applic=CCC&p_service=Content.show&.

manufacturer.⁹⁴ Work on an STA can begin before regulatory approval has been granted for the treatment in question. The whole process can now be completed in around 40 weeks, so that the appraisal can be made available within a few months of the drug being licensed.⁹⁵ However, so far the STA has produced only a relatively small number of outputs, and it is difficult to tell whether it will have enough of an impact to speed up the delivery of NICE appraisals.

Bearing in mind the foregoing, possible avenues of further research for the SMF Health Project are as follows:

- Exactly how much quicker can we reasonably expect the NICE appraisal process to become, without losing its reputation for rigour and accuracy? The goals of rigour and speed are naturally in tension with one another, and there will come a point at which we cannot speed up the process any further without losing what we might consider to be an unjustifiable amount of rigour: but how far away are we from hitting that point? At a more fundamental level, what would a justifiable trade-off between these goods look like?
- Is the Department of Health the correct body to determine which treatments should be appraised? Ought this decision to be left to NICE itself? Or to another body? Ought we be happy to cede this decision to any body that can satisfy the aims of independence and democratic accountability?

94 National Institute for Health and Clinical Excellence, *Guide to the Single Technology Appraisal (STA) Process* (London: NICE, 2006).

95 Turner and McDowell, *How NICE Might Be Outflanked*.

- How much impact will the STA have? Can the streamlined STA process justifiably be extended to other treatments that don't meet the STA criteria? For example, could all technology appraisals begin before the treatment has been granted regulatory approval? Or would this be wasteful (since at least some treatments will ultimately fail to secure this approval)?

Are there further lessons that can be learned from the SMC regarding the ways in which the NICE appraisal process can meet the twin aims of rigour and speed?

Methodological issues

The methodology that NICE employs includes an attempt to value differing states of health. This has been subject to criticism. Professor Paul Dolan has argued that the use of preference-based methods such as the Time Trade-Off is flawed and leads to a misallocation of resources.⁹⁶ This is because, according to Dolan, the general public tends to overestimate the severity of certain hypothetical health states. The reason for this is that preference-based questions focus the respondent's attention on the immediate experience of, for example, losing a limb (which is very traumatic), but consideration is not given to the fact that people usually adapt very well to many physical impairments. Also, attention is focused on the health domain to the exclusion of others, such as personal relationships, which may be unaffected by the changed health status. Both of these factors lead respondents to overestimate the impact of their hypothetical loss. As a result, Dolan argues that resources should be reallocated so that more money is put into mental health, as it is generally more difficult to adapt to a mental health problem.

Broadening the scope of NICE

Finally, there have been calls for NICE to broaden its remit so that it makes more decisions regarding the cost-effectiveness of existing NHS treatments.⁹⁷ NICE would require a significant increase in resources in order to undertake the extra assessments, but the potential benefits

96 Paul Dolan and Daniel Kahneman, *Interpretations of Utility and Their Implications for the Valuation of Health* (London: Tanaka Business School, Imperial College, 2006); Paul Dolan, *Finding a NICEr Way to Value Health: From Hypothetical Preferences to Real Experiences* (London: Social Market Foundation, 2007).

97 Social Market Foundation Health Commission, 'Defining a Core Package for the NHS: Report 2c.' (London: SMF, 2003).



could be significant. Derek Wanless argued that if NICE were routinely to examine older technologies and practices as well as new ones, it could root out treatments that are no longer cost-effective, which might result in significant savings.⁹⁸

This is a suggestion that the SMF Health Project could investigate further. Of particular interest will be the question:

- Would it be cost-effective to put more resources into NICE in order to root out treatments that are themselves no longer presenting good value for money.

98 Derek Wanless, *Securing our Future Health: Taking a Long-Term View* (London: HMSO, 2002).

CONCLUSIONS

As the body that decides whether treatments will or will not be funded by the NHS, NICE will always attract controversy. However, it must be pointed out that since its inception NICE has managed to win political support across the mainstream parties and has been granted a substantial increase in its funding. It has also taken on a wider range of responsibilities. NICE has become a seemingly permanent feature in the English healthcare system, and commands respect across the world.

Nevertheless, NICE continually faces new challenges and has had to adapt to keep pace. The Select Committee on Health has announced that it is to update its 2002 review by producing another inquiry into aspects of the work of NICE. The Committee will be focusing on some of the areas discussed above, including: "NICE's evaluation process, and whether any particular groups are disadvantaged by the process; the speed of publishing guidance; the appeal system; comparison with the work of the Scottish Intercollegiate Guidelines Network (SIGN); and the implementation of NICE guidance, both technology appraisals and clinical guidelines."⁹⁹ This report will give a further insight into where NICE is succeeding and where reform is needed, and the SMF Health Project awaits its findings with interest. In the interim, we believe we can usefully contribute to the debate concerning the future direction of healthcare rationing in the UK in general, and of NICE in particular, by investigating some or all of the issues highlighted above.

99 House of Commons Health Committee, "Health Committee Press Notice No 11: National Institute for Health and Clinical Excellence (NICE)," House of Commons Health Committee 2 February 2007 www.parliament.uk/parliamentary_committees/health_committee/hcpn070202.cfm.



ANNEX A

TARGETS: EXISTING COMMITMENTS TO BE ACHIEVED BY APRIL 2008

- four-hour maximum wait in A&E from arrival to admission, transfer or discharge;
- guaranteed access to a primary care professional within 24 hours and to a primary care doctor within 48 hours;
- a maximum wait of 13 weeks for an outpatient appointment;
- a maximum wait of 26 weeks for an inpatient appointment;
- a three-month maximum wait for revascularisation;
- a maximum two-week wait standard for rapid access chest pain clinics
- thrombolysis "call to needle" of at least 68% within 60 minutes, where thrombolysis is the preferred local treatment for heart attack;
- guaranteed access to a genito-urinary medicine clinic within 48 hours of contacting a service;
- all patients who have operations cancelled for non-clinical reasons to be offered another binding date within 28 days, or the patient's treatment to be funded at the time and hospital of the patient's choice;
- delayed transfers of care to be maintained at a minimal level;
- all ambulance trusts to respond to 75% of Category A calls within 8 minutes;
- all ambulance trusts to respond to 95% of Category A calls within 19 minutes;

- all ambulance trusts to respond to 95% of Category B calls within 19 minutes;
- a two-week maximum wait from urgent GP referral to first outpatient appointment for all urgent suspected cancer referrals;
- a maximum waiting time of one month from diagnosis to treatment for all cancers;
- 100% of people with diabetes to be offered screening for the early detection (and treatment if needed) of diabetic retinopathy;
- delivery of 7,500 new cases of psychosis served by early intervention teams per year;
- all patients who need them to have access to crisis services, with delivery of 100,000 new crisis resolution home treatment episodes each year;
- all patients who need it to have access to a comprehensive child and adolescent mental health service, including 24-hour cover/appropriate services for 16- and 17-year-olds and appropriate services for children and young people with learning disabilities;
- chlamydia screening programme to be rolled out nationally.

ANNEX B

NICE and the Technology Appraisal Methodology in Detail

INCREMENTAL COST-EFFECTIVENESS RATIO

In a typical scenario, NICE is confronted with a treatment that has been proved to be more clinically effective than the alternatives, but which costs more. As such, NICE must determine what increase in effectiveness, over and above that achieved by the alternative treatment options, is likely to accrue from the increase in expenditure. This is known as the incremental cost-effectiveness ratio (ICER) and is a

measurement of the ratio of change in cost to change in effect. ICERs can be expressed in a number of ways, but the measure favoured by NICE is the cost per quality-adjusted life year (QALY).

QUALITY-ADJUSTED LIFE YEARS

QALYs measure the benefit of medical interventions. They are calculated by working out the increase in quality of life that a treatment may bring about and the number of years over which this quality of life may be enjoyed. Each year in perfect health is assigned the value of 1.0. Years of less than perfect health are scored all the way down to zero for death, and even less than zero for health states considered worse than death (such as permanent unconsciousness).

QALY scores are combined with the monetary cost of providing the intervention to calculate the ICER. It is then possible to make comparisons between interventions that are relatively inexpensive (low cost per QALY) and those that are relatively expensive (high cost per QALY).¹⁰⁰

HOW HEALTH STATES ARE VALUED

NICE uses preference-based methods to value different health states. The most common method is the time trade-off (TTO), which determines the value of a health state by asking respondents to choose between remaining in a certain hypothetical state of ill health for a period of time, or being restored to perfect health but having a shorter life expectancy.¹⁰¹

100 Ceri Phillips and Guy Thompson, *What is a QALY?* (Newmarket: Hayward Medical Communications, 2003).

101 Paul Dolan, 'Modelling valuations for EuroQol health states,' *Medical Care* 11 (1997), 1095–108. Other preference-based methods employed by NICE include the standard gamble (SG), in which respondents choose between remaining in a state of ill health for a period of time or undergoing a medical intervention which has a chance of either restoring them to perfect health or killing them, and the visual analogue scale (VAS) in which respondents rate a state of ill health on a scale from 0 to 100 (with 0 representing death and 100 representing perfect health).

HOW NICE SETS LIMITS

NICE has not set an absolute monetary value threshold for determining the funding of new medical technologies. The main reasons for this are laid out by Rawlins and Culyer in their article “National Institute for Clinical Excellence and its value judgments.” They present four reasons for not setting such a threshold: first, there is no empirical basis for deciding where the threshold should be set; second, imposing a threshold prevents flexibility in decision-making; third, to set a threshold would mean that cost and efficiency have priority over other objectives such as fairness; and, fourth, a threshold would discourage price competition between medical technology manufacturers.¹⁰² Andrea Sutcliffe, Deputy Chief Executive of NICE, expanded on Rawlins and Culyer’s first two points by arguing that “health economics is an art not a science” that involves the use of factors other than costs and benefits. Given this, Sutcliffe concluded that NICE must make its decisions on a case-by-case basis rather than by applying an absolute threshold.¹⁰³

However, despite seeming to reject an absolute threshold, NICE and its advisory bodies have also stated that “NICE would be unlikely to reject a technology with a ratio in the range of £5,000–£15,000 per QALY solely on the grounds of cost ineffectiveness” and, conversely, “would need special reasons for accepting technologies with ratios over £25,000–£35,000 per QALY.”¹⁰⁴ When attempting to make a judgment about cost-effectiveness for ratios of £25,000–£35,000 per QALY, NICE considers factors such as: “The degree of uncertainty surrounding the estimate; the particular features of the condition and population using the technology; the innovative nature of the technology; when appropriate, the wider societal costs and benefits; when appropriate, reference to previous appraisals.”¹⁰⁵

It is important to stress that NICE does not take into account the

102 Rawlins and Culyer, “National Institute for Clinical Excellence and its Value Judgments,” 224-227.

103 Andrea Sutcliffe, NICE Deputy Chief Executive, speaking to the authors at a private meeting on 22 March 2007. Other commentators have stressed how, despite this de facto threshold, there is considerable variation both above and below the threshold, and it is often difficult to ascertain exactly how the balance between costs and benefits has been struck in individual cases (James Raftery, “NICE: faster access on modern treatments? Analysis of guidance on health technologies,” *BMJ* 323 (2001), 1300–3).

104 Rawlins and Culyer, “National Institute for Clinical Excellence and its Value Judgments.”

105 *Ibid.*

impact of recommending a new treatment on NHS expenditure as a whole. If a new drug has a favourable cost-effectiveness ratio of (for example) £20,000 per QALY, then NICE would recommend the drug regardless of the fact that if very large number of patients were eligible for treatment, the overall impact on individual PCTs or the entire NHS budget might be quite substantial. It is the government that takes responsibility for macro-level questions of affordability.

SOCIAL VALUE JUDGEMENTS AND THE CITIZENS COUNCIL

NICE does not make its decisions solely on the basis of clinical- and cost-effectiveness: it also seeks to include social value judgements into the decision-making process.¹⁰⁶ To try and achieve this goal, NICE has set up a Citizens Council, which aims to garner a representative sample of social value judgements bearing on the particular issue in question.¹⁰⁷ At each meeting, council members hear presentations from expert witnesses, and are also able to cross-examine them. The council's conclusions are written up in a report that is presented to the NICE board.

As an example, in 2004 the Citizens Council produced a report on age in which it concluded that health should not be valued more highly in some age groups than in others, and that individuals' social roles at different ages should not influence considerations of cost-effectiveness. However, the council also concluded that it is appropriate to take age into account where it is an indicator of health benefit or risk.¹⁰⁸

106 Ibid.

107 National Institute for Health and Clinical Excellence, *NICE Citizens Council Report of the First Meeting: Determining Clinical Need* (London: NICE, 2003).

108 National Institute for Health and Clinical Excellence, *NICE Citizens Council Report on Age* (London: NICE, 2004).

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