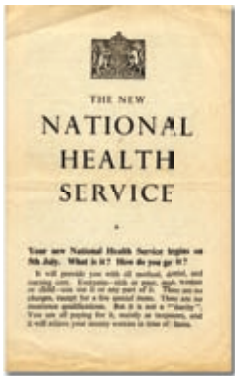


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## What does the future hold for the NHS at 60?

Flux and conflict constrained by consensus as in the past



**FEATURE, p 18, OBSERVATIONS, p 23, ANALYSIS, p 25, VIEWS & REVIEWS, pp 55, 56**

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When the NHS celebrated its 50th anniversary with much pomp, commemorative stamps, and a service in Westminster Abbey, a new Labour government was busy reversing many of the policies of its Conservative predecessor. The internal market was abolished, as was general practitioner fundholding. The NHS would indeed be modernised, but it would be on the basis of cooperation not competition.

Who then—in the euphoria of the celebrations when Frank Dobson, the secretary of state for health, could claim that “the NHS remains the envy of the world”<sup>1</sup>—would have anticipated that within a couple of years policy would go into reverse gear? Who then would have predicted the emergence of a new model for the NHS based on choice, competition, payment by results, and a plurality of providers, let alone the emergence of institutions like foundation trusts? To ask these questions is to underline the perils of prediction. It is easy to list the demographic, technological, and other challenges that will face the NHS as it moves towards its 70th anniversary, but quite another matter to be confident about likely policy responses.

But if the past carries a warning, it also provides some reassurance. From one perspective the history of the NHS is one of flux and conflict. Its 60 years have from the start been marked by conflicts between the medical profession and governments of both parties, while the political parties in turn take every opportunity to attack each other's policies.

Meanwhile, the structure of the NHS has been in a constant state of flux, as organisational maps and nomenclatures change to the accompaniment of talk of crisis and prophecies of impending collapse. Yet from another perspective, the NHS is a remarkable monument to institutional stability and political consensus. The old building has been massively remodelled, but the basic architecture remains intact. The principles of the founding fathers—as ministers remind us constantly—have been preserved: the NHS is a universal service, funded by taxes, which provides care on the basis of need, not the capacity to pay.<sup>2</sup>

Moreover, political parties now compete about which one is most committed to the NHS. The critics of 1948, like the BMA and even the Conservative Party, have become the NHS's advocates. And underpinning this consensus is the fact that the NHS remains the UK's most popular institution with iconic status. This suggests in turn that future pressures on, and tensions within, the NHS will be worked out within the existing framework. As in the past 60 years, calls will doubtlessly be made for radical change—such as the adoption of a social insurance

funding model—which will probably be ignored. As in the past, again, adaptive changes will occur in policy instruments rather than policy goals.

The main reason why flux and conflict have characterised the past 60 years and will probably continue to do so is that the tensions within the NHS (and in all healthcare systems) cannot be neatly resolved by heroic policy initiatives. For they involve balancing desirable goals and values that conflict with each other. The values of the NHS do not necessarily point in the same direction, and the weight attached to individual values may vary between different groups.<sup>3</sup>

The subject of whether patients should be able to top up treatment by buying drugs not available in the NHS is a case in point.<sup>4 5</sup> To permit this would clearly offend against the equity principle—that patients with equal need should receive equal treatment irrespective of their ability to pay. But to prohibit it would offend against the autonomy principle—that the decisions and preferences of patients should be respected. Or consider opposition to reconfiguration proposals. Many factors are involved, but the different weights attached to different policy goals by different groups is prominent among them. Clinical safety and excellence (the professional aspiration), efficient and economic use of resources (the managerial imperative), and local accessibility (the public preference) are all worthy goals, but they are not necessarily and invariably consistent with each other.

Many examples of complex problems that involve difficult trade offs are available. It is now conventional wisdom that the NHS has become excessively centralised and the time has come to devolve decision making to the periphery. Yet postcode rationing—different health economies making different decisions about their priorities—is also unacceptable. So are uniform national standards to be brought about without central direction?

Again, although everyone agrees that competition is a spur to efficiency, services need to be integrated. So how can these challenges be met? One suggested option is to allow patients to choose between integrated systems rather than between individual providers of one-off treatments.<sup>6</sup> In effect, primary care trusts would become redundant and be replaced by “health maintenance organisations.” But if they were to disappear, so would the NHS's capacity to plan for geographically defined populations. Once again, competing and desirable policy goals seem to be incompatible. Most importantly, perhaps, there is dissonance between the rhetoric of a consumer driven NHS and the reality of a model for allocating (and rationing) resources that is based on professional need: what would happen if consumer demands

were to trump judgments of professional need?

The list of such incompatibilities goes on, but the point has been made. And it has an implication not only for the future but also for the present. As far as the future is concerned, it means—as argued—that flux and conflict are inevitable. For the present, it suggests that flux and conflict can be reduced, but not eradicated, to the degree that the policy making process acknowledges the complexities involved. It underlines the danger of rushes of blood to the head of policy makers—the search for instant fixes.

The warning is perhaps all the more appropriate with the publication of the Darzi review of the NHS. The Department of Health is now dominated by former NHS managers who have brought with them a “can do” culture that has scant tolerance for the civil service tradition of putting policy proposals on the rack of analysis,

examining inconsistencies, and identifying possible perverse outcomes.<sup>7</sup> Analysis has too often been farmed out to management consultants who do not have to live with the consequences of their work. The civil service tradition was much derided by Margaret Thatcher and Tony Blair, who saw it as a recipe for delay and obstruction. But given the policy turmoil and fiascos of recent decades, the time may have come to revise it.

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## Drugs for cancer and copayments

Principles underpinning copayments must preserve equity, be transparent, and enhance knowledge on treatment outcomes

### VIEWS & REVIEWS, p 54

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The topic of how to pay for new and experimental drugs will not go away. The government of the United Kingdom has announced a review of whether patients should be able to remain NHS patients if they pay privately for such drugs. The current controversy exposes broader challenges, including how widely patients should make additional copayments for NHS services, and how an “episode of care” should be consistently defined.

The NHS has changed radically since its foundation in 1948. Major breakthroughs in therapeutic drugs and applied technologies have offered new hope of prolonging life and improving quality of life in people with serious disease. Although drugs for cancer have hit the headlines, others that may have wider indications and applications are just around the corner. So should the NHS simply allow copayments to deal with the problem?

In reality, other health systems signal problems with this. Copayments mean that—contrary to the founding principles of the NHS—access to treatment depends on ability to pay. In a recent study by the Commonwealth Fund, 40% of patients from the United States, which has a copayment system, reported that they had not sought medical attention when they needed it because of the costs involved. The UK proportion of 9% was the lowest recorded in the study.<sup>1</sup>

The National Institute for Health and Clinical Excellence (NICE) was created to determine the use of drugs and treatments within the NHS. It draws much evidence from clinical trials, which usually study patients aged 18-65 without significant comorbidity and, in the case of cancer, with a clear histological diagnosis. Yet the clinician must often advise individual patients on whether anticipated benefits outweigh risks and burdens in their particular, perhaps atypical, presentation. Moreover, how can a clinician explain that, although

there is new and emerging research evidence of benefit from a licensed drug, the drug is not available because it has yet to be appraised and funded, and if they access it they are excluded from NHS care?

Almost half of patients with cancer use a wide range of non-prescription complementary treatments,<sup>2</sup> yet no one suggests such self medication should be forbidden if they also access NHS care. Indeed, clinicians need to know what is being taken because drug interactions cause morbidity and mortality.

The number of patients wanting to pay for additional drugs is small in the scale of the NHS. Moreover, the drugs are mostly ones that have yet to be reviewed by NICE or for which insufficient evidence is available to show exactly which patients might benefit, at what stages of disease the drugs are most effective, and in what clinical and other circumstances they should be used.

One way forward would be to accelerate the NICE process as much as possible and—recognising that NICE cannot always produce a quick or definitive response—find a way to ring fence some drugs as specific cases. Thus, a definitive list of drugs on which copayments were permitted could be compiled, with copayments sanctioned on the basis of four criteria. However, it is a fundamental and essential principle that all drugs and devices fully proved through appraisal should be available freely and equitably to all NHS patients regardless of their ability to pay.

The first criterion would be that the drug or device is listed as one for which copayment is allowed. Secondly, the patient should want the treatment and have discussed the risks and likelihood of failure as well as success with their clinician, so that hopes are not raised unrealistically. Thirdly, the clinician should have a reasonable belief—supported by peers—that the anticipated benefits for their patient of the unfunded drug outweigh

the benefits of other treatment. Fourthly, patients who are unable to participate in a clinical trial should be willing for their treatment and its outcomes to be recorded on a register and potentially available to research.

Such a register would enable copayments to be monitored and audited to ensure that the system is operating properly, and it would allow data on the outcomes of treatment to be used in subsequent reviews by NICE. The register would also allow monitoring of adverse incidents, support additional investigations, and provide mortality data.

Professor Michael Richards, the national cancer director, has been asked by the secretary of state to review whether patients should be allowed to pay for additional drugs and report in October 2008. It will

not be an easy task. The review will have to tackle, for example, whether payments should cover not just the cost of the drug but also the costs of administering it and of possible complications, because the NHS often picks up the cost of complications arising from private treatment. He will need to balance choice against the founding principle of the NHS—that treatment is determined by need not ability to pay. But while preserving the general principles of equity and fairness in the NHS, whatever emerges must deal with the current problem, which is grossly unfair to desperately sick people.

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## Affect and heart disease

Are linked, but the mechanisms are unclear



HENRIK SORENSEN/STONE/GETTY IMAGES

### RESEARCH, p 32

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Although connections between emotions and the health of the heart have been postulated for centuries,<sup>1</sup> population based empirical studies were not available until recently. Early interest in the 1970s centred on the type A behaviour pattern characterised by a tendency towards impatience, anger, competitiveness, and achievement. On the whole, however, findings on type A behaviour as a risk factor for coronary heart disease were inconsistent, leading to the notion that subcomponents such as anger may have a more definitive role.

More recently, studies on psychological risk factors have focused on anger, anxiety, and depression.<sup>1-3</sup> Although the topic is continually debated, many prospective studies suggest that anxiety and depression increase the risk for heart disease, especially incident heart disease.<sup>3</sup> Results for anger are more mixed.<sup>3</sup>

The linked study by Nabi and colleagues uses data from the Whitehall II study to examine the association between affect and the development of incident coronary heart disease over 12 years of follow-up.<sup>4</sup> Coronary heart disease was defined as the occurrence of fatal coronary heart disease, first non-fatal myocardial infarction, or first angina. This paper adds to the literature by considering negative affect, which may function as a higher order psychological construct or general disposition that underlies previously studied emotions such as anger, anxiety, and depression.<sup>3</sup>

Nabi and colleagues also looked at the independent influence of positive affect. High positive affect does not necessarily correspond with low negative affect, and most work has focused on the role of negative emotions rather than positive ones.<sup>5</sup> Nabi and colleagues conclude that there is a weak positive association between negative affect and coronary heart disease, but no association for positive affect or for the balance between positive affect and negative affect.

The lack of stronger findings may relate, in part, to the measure of affect and the time between assessing affect and outcomes. Affect was measured by the Bradburn

affect balance scale, which was designed to measure overall psychological wellbeing at a given point in time.<sup>6</sup> The scale consists of questions on feelings over the past few weeks and was explicitly designed to capture affect within a particular time period rather than longer term trends reflecting more enduring dispositions.<sup>6</sup>

Affect can be conceptualised as a state, reflecting a short term experience of emotions brought on by specific situations, or as a trait, reflecting a more stable and general disposition. Because traits are sustained over a longer period, they may have more effect than states on the development of chronic diseases, including coronary heart disease, which are the product of pathophysiological processes that evolve over time. In contrast, short term emotional states may be relevant as triggers for acute events that occur in close time proximity.

Nabi and colleagues assess the influence of affect assessed at the start of the study and the subsequent development of coronary heart disease over 12 years. Although the affect balance scale does measure affect over weeks rather than days, its stability over time in the study sample is unclear. Correlations between affect scores assessed at phase 1 (1985-8) and phase 2 (1989-90) were in the range 0.52-0.55, which suggests only moderate consistency even during the initial part of the study. Further research is needed to explore the differential effects of emotional states versus traits and the disparate mechanisms by which they can influence cardiovascular and other health outcomes.

The study of affect and health can be considered in the broader context of research on social inequalities in health and may help to clarify the influence of social factors. If, for example, negative affect is associated with both low socioeconomic status and poor health, it may be one of many mediators in the formation of gradients of socioeconomic status in health. Such gradients are inadequately explained by adjustments for conventional risk factors and access to medical care.<sup>7 8</sup>

Furthermore, psychological factors could shed light on the contribution of upstream factors (social conditions) versus downstream factors (such as behavioural and biological risk factors) in studying health disparities.<sup>9</sup> Affect, for example, could influence cardiovascular outcomes through its effect on physiological inputs (such as activation of the hypothalamic-pituitary-adrenal axis) or behaviours (such as smoking, exercise, and seeking medical care). As such, emotions may, to some degree, function as an overarching, mid-level factor that organises or assembles a variety of downstream risk factors. Affect could also function as a moderator of specific risk factors. A positive affect, for example, could mitigate the effects of stress. Researchers could even consider interactions between affect and socioeconomic status itself—negative affect could exacerbate the consequences of disadvantage or positive affect could act as a buffer.

So, what are the implications of such research for clinical practice? Trying to change a person's affect might seem a nebulous and difficult proposition, and it is self evident that people should try to be happy. Firstly, negative affect may relate to conditions such as depression and anxiety, which have established methods for diagnosis and various therapeutic options. However, it is not clear whether treatment would reduce the incidence or progression of cardiovascular disease.<sup>10</sup> Nevertheless, strong, independent reasons exist for treating such conditions.

Secondly, one of the hypothesised links between affect and heart disease is through health behaviours such as exercise, which are also subject to modification. Moreover, affect can influence behaviours and behaviours could, in turn, influence affect. Thirdly, depending on the strength and consistency of findings from continued research, and our overall confidence in the causal nature of these relations, psychological factors could eventually attain the status of more conventional risk factors in systems of clinical risk stratification.

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## Endoscopic ablation for benign enlargement of the prostate

Newer techniques are no better than transurethral resection, but the evidence base is poor

### RESEARCH, p 36

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The prevalence of prostatic enlargement on rectal examination reaches 50% at age 70 and directly correlates with age.<sup>1</sup> The age dependent prevalence of bothersome lower urinary tract symptoms, usually attributed to prostatic enlargement, has been demonstrated in population based studies in many countries, with moderate to severe symptoms being present in 27-56% of men aged 70-79 years in Scotland, France, Japan, and New Zealand.<sup>2-5</sup>

Transurethral resection has been the procedure of choice for surgically treating prostatic enlargement since the 1950s. Its use peaked in the late 1980s and has declined with the introduction of medical treatment and alternative surgical techniques. Drivers of the development of alternative surgical methods include bleeding, electrolyte abnormalities, and prolonged hospital stay associated with transurethral resection. The linked systematic review by Lourenco and colleagues compares several alternative methods of creating an immediate opening in the prostatic urethral channel to the gold standard—transurethral resection of the prostate.<sup>6</sup> These techniques can be broadly categorised as enucleation,

resection, and laser ablation (collectively termed endoscopic ablation by Lourenco and colleagues).

In enucleation, the adenoma is shelled out from the capsule of the prostate. Intuitively, enucleation should offer the best chance of improving symptoms and flow rate because the entire adenoma is removed. Historically, enucleation was done through an abdominal incision. Today, endoscopic holmium laser enucleation of the prostate offers a minimally invasive method of enucleation; however, it is time consuming and technically challenging. In resection procedures—such as transurethral vaporesction, bipolar transurethral resection, or the gold standard (monopolar) transurethral resection—the adenoma is excised piece by piece. These procedures should be equivalent to enucleation if resection is carried down to the capsule. Laser ablation opens the prostatic urethra by evaporating the adenoma. This was originally tedious and reserved for smaller prostates. With refinements in technology—including higher energy lasers—ablation has become more efficient; it is now the most commonly performed procedure for benign prostatic enlargement in the United States, at

least in part because it is associated with minimal blood loss and a shorter stay in hospital.<sup>7</sup>

The systematic review by Lourenco and colleagues identified 45 randomised controlled trials of different techniques for enucleation, resection, and ablation that met the inclusion criteria.<sup>6</sup> All studies were moderate to poor quality and had small sample sizes. Compared with transurethral resection, none of the newer technologies produced significantly different improvements in flow rate and symptoms at one year. Follow-up was too short and complications were too rare and inconsistently reported to draw meaningful conclusions about adverse effects.

The review did not cover “office based” technologies such as microwave treatment and radiofrequency ablation of the prostate. These differ from the surgical procedures described above in that they can be done in the general practitioner’s surgery under sedation and do not create an immediate opening in the prostatic urethra; rather they produce delayed necrosis and sloughing of tissue. A systematic review that compared microwave treatment with transurethral resection found that it was less efficacious, but the quality of the data was too poor to draw significant conclusions about long term complications.<sup>8</sup>

In the US, procedures performed for benign prostatic enlargement have increased by 44% in the past six years, whereas transurethral resections have decreased by 5% each year.<sup>7</sup> The newer procedures (primarily laser ablation and office based procedures) are replacing transurethral resection and expanding the number of patients seeking surgical treatment for benign prostatic enlargement. Yet are they, and are we, fully informed about the efficacy of such procedures relative to transurethral resection or medical treatment? Similarly, in the United Kingdom—where surgery is usually reserved for patients with urinary retention—are the indications for surgery expanding? If so, what are the health policy and economic consequences?

We should be careful about rapidly embracing new technology when it has not been properly compared with the gold standard. Although eager adoption of new technology fosters innovation in the biomedical industry, such innovation can progress so quickly that it outstrips our ability to measure the effectiveness of one treatment before the next is introduced. Furthermore, when so many generations of a single device are available—with each being only slightly different from the last (as in laser ablation technology and transurethral microwave thermotherapy)—how can we interpret the few studies that exist? This is why the systematic review by Lourenco and colleagues is so important—not only does it show what we do know but it also points out where evidence is lacking.<sup>6</sup> Better randomised controlled trials with follow-up of up to 10 years are needed to properly assess complications and efficacy. In addition to clinical trials, population based studies of “real world” effectiveness and economic impact are crucial.

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## Mental capacity and psychiatric admission

Many patients lack capacity to consent to treatment on admission, but not all qualify for treatment under the Mental Capacity Act

When the Mental Capacity Act 2005 and the Mental Health Act 2007 are fully implemented in England and Wales over the next year, both will be available to authorise a person’s psychiatric treatment without consent. The two acts are based, however, on different legal standards.<sup>1</sup> The Mental Capacity Act may be used only when a person lacks the capacity to consent. The Mental Health Act, in contrast, can be used regardless of a person’s capacity to consent, if the act’s different criteria of mental disorder, risk of harm, availability of treatment, and so on, apply. Nevertheless, a person can be covered by both acts at the same time, in which case clinicians would

have to choose which one to apply.<sup>2</sup>

In their linked study, Owen and colleagues throw some light on the frequency with which this choice between legal options will arise.<sup>3</sup> In a study of 350 consecutive admissions to psychiatric care in inner city London, they found that 86% of patients admitted under the Mental Health Act lacked capacity to consent to treatment on entry to hospital. This finding indicates that a considerable proportion of these patients would also meet the criteria for cover by the Mental Capacity Act. Thirty nine per cent of patients informally admitted also lacked capacity, as did 60% of those admitted overall.

### RESEARCH, p 40

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The 60% prevalence of incapacity found in the group overall is higher than that usually seen in samples of general psychiatric inpatients—22-45% is more common.<sup>4</sup> This might be because Owen and colleagues assessed patients' capacity close to the time of admission, when rates of incapacity are likely to be high. They also found particularly high rates of incapacity in patients with schizophrenia and mania, and much lower rates in those with depression or personality disorder. Many patients with these last two diagnoses, who retained their capacity, would not be eligible for treatment under the Mental Capacity Act.

Two recent reviews of the characteristics of patients who lack capacity help us put these findings into context.<sup>4-5</sup> As might be expected, incapacity to consent is often associated with psychosis,<sup>4-7</sup> severity of symptoms,<sup>4-5</sup> lack of insight,<sup>6</sup> involuntary status,<sup>4-5</sup> treatment refusal,<sup>4-5</sup> and older age.<sup>7</sup> Specific risk factors include a diagnosis of schizophrenia,<sup>7-8</sup> mania,<sup>6</sup> Alzheimer's disease or other dementias,<sup>7</sup> the presence of delusions,<sup>6</sup> and other measures of neuropsychological or cognitive dysfunction.<sup>9-10</sup> No consistent association has been found with educational level or social class, or with sex or ethnicity once other variables are controlled.<sup>4</sup>

A considerable proportion of informally admitted psychiatric inpatients lack capacity,<sup>4-5</sup> as is true of patients in general medical wards,<sup>7</sup> particularly very old patients and those with acute conditions.<sup>7</sup> In one London study, 40% of general medical inpatients lacked capacity, a similar proportion to that found among informal psychiatric admissions in Owen and colleagues' study.<sup>7</sup>

The reliability of the process of assessing capacity can be substantially improved by training clinicians,<sup>5-11-12</sup> and by using standardised instruments like the MacArthur competency assessment tools.<sup>5-12</sup> Repeated communication of information can improve patients' understanding, which promotes their capacity,<sup>5</sup> and many swiftly recover their capacity after treatment.<sup>5</sup>

The important finding of Owen and colleagues' study—that a high proportion of patients admitted

under the Mental Health Act lacked the capacity to consent to treatment at the time of admission—does not tell us precisely how many might have been lawfully treated under the Mental Capacity Act, however. This is because, for the Mental Capacity Act to apply, further legal criteria—beyond the capacity test—must also be met. Notably, the patient must not be refusing treatment, and the care proposed must be in the patient's best interests.<sup>1</sup> Many patients admitted under the Mental Health Act would be refusing treatment, and others might not be admitted primarily in their own interests but to protect others. The Mental Capacity Act would then not apply. Only by measuring patients against all the criteria for cover established by the Mental Capacity Act could we accurately assess the proportion of patients who would be eligible for treatment under that act.

Owen and colleagues focused on patients' capacity at the time of admission to hospital. They did not assess whether patients lacked capacity later in the process—a month later, for instance, when they might be discharged to supervised treatment in the community. Many sectioned patients will recover their capacity after their initial treatment, or their capacity might fluctuate. If incapacity principles were strictly applied, such patients would have to be swiftly released from involuntary treatment whenever they regained their capacity, an outcome that might preclude the provision of sustained treatment.

So, even though some patients will meet the legal criteria for treatment under both acts at the time of admission to hospital, practitioners dealing with patients with fluctuating mental conditions might prefer to rely on the authority of the Mental Health Act when convinced that the patient needs a sustained programme of care.



BSIP/LAURENT/SPL

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