Dr Lansley's Monster

Too soon to let it out of the lab

GETTY IMAGES

NEWS, p 247
FEATURES, pp 256, 257
OBSERVATIONS, p 260
DES SPENCE, p 286

Tony Delamothe deputy editor, *BMJ*
tdelamothe@bmj.com
Fiona Godlee editor in chief, *BMJ*, London WC1H 9JR, UK

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First impressions of the health bill

What do you call a government that embarks on the biggest upheaval of the NHS in its 63 year history, at breakneck speed, while simultaneously trying to make unprecedented financial savings? The politically correct answer has got to be: mad.

The scale of ambition should ring alarm bells. Sir David Nicholson, the NHS chief executive, has described the proposals as the biggest change management programme in the world—the only one so large "that you can actually see it from space." (More ominously, he added that one of the lessons of change management is that "most big change management systems fail."[1]) Of the annual 4% efficiency savings expected of the NHS over the next four years, the Commons health select committee said, "The scale of this is without precedent in NHS history; and there is no known example of such a feat being achieved by any other healthcare system in the world."[2] To pull off either of these challenges would therefore be breathtaking; to believe that you could manage both of them at once is deluded.

Like all the other structural reorganisations of the NHS, this one aims to improve health outcomes. What's lacking is any coherent account of how these particular reforms will produce the desired effects, a point only underlined by the prime minister's attempts to justify the reforms last week.[3]

This latest top down reorganisation has been whipped up in an awful hurry. It went unmentioned in the political manifestos of the coalition parties before the last general election, was specifically excluded in pledges given before and after the election, and didn't make it into the Coalition Agreement of 20 May 2010. Yet less than eight weeks later, its outline emerged in the white paper "*Equity and excellence: liberating the NHS*."[4]

The NHS was unsurprisingly absent from the 2010 election campaign because satisfaction levels with the NHS were at an all time high,[5] and for most of the electorate the NHS was a non-issue.[6] In the words of Simon Stevens, president of global health at UnitedHealth Group, a company that stands to benefit from the reforms, "The inconvenient truth is that on most indicators the English NHS is probably performing better than ever."[7]

The reforms put general practitioners in the driving seat. Out go strategic health authorities and 152 primary care trusts and in come several hundred general practitioner consortiums, responsible for commissioning £80bn (€95bn; $1.6bn) of NHS care from "any willing provider." As Kieran Walshe, professor of health policy and management, described in his *BMJ* editorial, it comes as but the latest in a bewildering array of forms and structures put in place to run primary care and commission secondary care.[8] Since the introduction of the internal market in 1991, there have been family practitioner committees, health authorities, GP fundholders, total purchasing consortiums, GP multifunds, primary care groups, primary care trusts, and external commissioning support agencies. Yet, crucially, wrote Walshe, "we have little evidence to suggest that any of these organisational structures for commissioning are better or worse than others, or that the proposed new consortiums will work any better than the current arrangements."

Informed opinion about GP commissioning, past and present, has been almost universally negative. The previous government's primary care tsar branded practice based commissioning "a corpse not for resuscitation." Last year's health select committee report on commissioning concluded that "if reliable figures for the costs of commissioning prove that it is uneconomic and if it does not begin to improve soon, after 20 years of costly failure, the purchaser/provider split may need to be abolished."[9] This year's health select committee report on commissioning doesn't suggest abolition, but neither does it endorse the proposed reconfiguration as the best way to deliver the government's objectives. It says that general practitioners should "be seen as generalists who draw on specialist knowledge when required, not as the ultimate arbiters of all commissioning decisions."[2]

What's lacking is any coherent account of how these particular reforms will produce the desired effects

No matter how many GP consortiums eventually emerge, their number will probably greatly exceed the 152 primary care trusts they are replacing, which brings a set of new challenges. Smaller populations increase the chances that a few very expensive patients will blow a hole in budgets. More consortiums mean that commissioning skills, already in short supply nationally, will be spread even more thinly. Denied economies of scale, smaller consortiums may be tempted to cut corners on high quality infrastructure and management, thereby endangering their survival. These points emerge clearly from an examination of 20 years of US experience of handing the equivalent of commissioning budgets to groups of doctors. Some groups had severely underestimated the importance of high quality professional management support in their early days and gone bankrupt as a result.[10]

If GP commissioning turns out to be simply primary care trust commissioning done by GPs, aren't there less disruptive routes to this destination?

Moving to consortiums will incur the costs of transition in addition to their recurring costs. On the basis of past National Audit Office data, Kieran Walshe has put the cost of the NHS reorganisation at £2-3bn,[8] and the government's figure is at the lower end of this range.[11] The white paper's key financial pledge was to reduce the NHS's management costs by more than 45%: GP consortiums would replace primary care trusts with administrative costs of over a billion pounds a year (for a population of 51 million)—and practice based commissioners. Since then, potential consortiums have learnt that their running costs will be capped at between £25 and £35 per head of population,[12] not far off the primary care trust average management spend.

Slow down, you move too fast

The government's recent "bonfire of the quangos" provides an instructive example of how a rush job doesn't necessarily guarantee the best outcome. Earlier this month, the parliamentary select committee on public administration criticised the axing of 192 public bodies and the merging of 118 more as poorly managed. It also said that this move would not deliver significant cost savings or better accountability—two of the government's key aims. The committee's chairman said that, "The whole process was rushed and poorly handled and should have been thought through a lot more."[13]

Rationalising a few hundred arm's length bodies hardly compares with turning the NHS upside down, yet the proposed timescale for the health reforms is dizzying. The bill promises that all general practices will be part of consortiums by April 2012, yet it took six years for 56% of general practices to become fundholders after the introduction of the internal market. Nearly seven years after the first NHS trust was granted foundation status, there are still more than half to go—within two years. And there's more. The replacement for the 10 strategic health authorities—the NHS Commissioning Board—needs to be fully operational by next April. By then, GP consortiums should have developed relationships with local authorities, which will assume ultimate responsibility for public health via their new health and wellbeing boards, working alongside Public Health England, a completely new entity.

The health secretary has made much of these changes being evolutionary rather than revolutionary. People "woefully overestimate the scale of the change," he said. After all, practice based commissioning, choice of provider, an NHS price list, and foundation trusts already exist.[14] True, but a week later came the revelation that hospitals would be allowed to undercut the NHS tariff to increase their business.[12] Health economists queued up to say what a terrible idea this was, citing evidence that it would lead to a race to the bottom on price, which would threaten quality. Taken with the opening up of NHS contracts to European competition law, it was the last piece of evidence needed to convince critics that the government was unleashing a storm of creative destruction on to the NHS, with the imperative: compete or die.

Whatever the eventual outcome, such radical reorganisations adversely affect service performance. As Kieran Walshe wrote, they are "a huge distraction from the real mission of the NHS—to deliver and improve the quality of healthcare" that can absorb a massive amount of managerial and clinical time and effort.[8] Even the earliest days of the transition have proved disruptive, with employees of the doomed primary care trusts and strategic health authorities choosing to jump ship rather than to go down with it.

With an estimated one billion pounds of redundancy money in their pockets,[11] many of the survivors are likely to be employed by the new GP consortiums in much their same roles. It raises the question: if GP commissioning turns out to be simply primary care trust commissioning done by GPs, aren't there less disruptive routes to this destination?[15]

Meanwhile, the need to begin making efficiency savings hasn't gone away. Although the impact assessment of the new bill calculates that savings will have covered the costs of transition by 2012-13,[11] overall savings won't have contributed much to the £15-£20bn efficiency savings required from the NHS by 2014-15.

Given their scale, securing these efficiency savings should take priority over the massive upheaval proposed in the new bill. For the time being, we agree with the King's Fund that those GPs who are successfully involved in practice based commissioning should be given real rather than indicative budgets for some services and their performance monitored closely.[16] All other proposals should be kept on hold, pending an evaluation of whether this iteration of GP commissioning can bear the responsibility that the new bill seeks to place on it. If it turns out that it can, then the full introduction of the government's ambitious health reforms will have been delayed a few years. If it can't, then the country—and its government—will have got off lightly.

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Vitamin D and bone health in children

Adequate vitamin D status is needed throughout childhood and adolescence

RESEARCH, p 267

Nick Shaw consultant paediatric endocrinologist, Department of Endocrinology, Birmingham Children's Hospital, Birmingham B4 6NH, UK
nick.shaw@bch.nhs.uk

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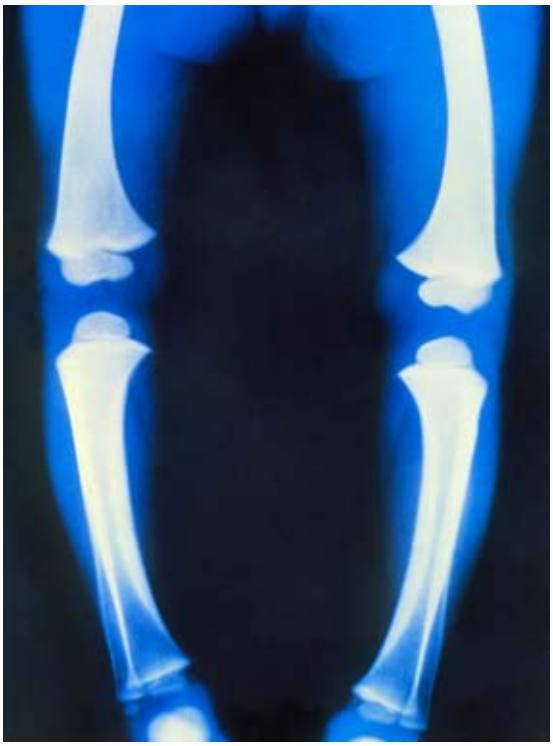
Osteoporotic fractures in adults are a substantial cause of morbidity and mortality, and they cost the health services about £2.3bn (€2.8bn; $3.6bn) a year in the United Kingdom and $30bn in the United States. Prevention, which includes manipulation of the development of bone mass during childhood and adolescence, is therefore important. Increasing peak bone mass in young adults might have a longstanding effect on the risk of osteoporosis in later years. Although genetic factors account for 50-85% of the variance in adult bone density, modification of environmental factors during childhood might have an effect on peak bone mass. One such factor is vitamin D.

In a linked systematic review and meta-analysis, Winzenberg and colleagues assess the impact of vitamin D supplementation on bone density in children.[1] They show that overall vitamin D supplementation had no significant effect on bone density in the whole body, hip, or forearm (with a trend to a small effect in the lumbar spine). However, in children with low serum vitamin D (defined as <35 nmol/L) supplements had a significant effect on whole body bone mineral content and borderline significance at the lumbar spine. The authors conclude that supplements are unlikely to be beneficial in children with normal vitamin D concentrations but could result in clinically useful improvements in children who are vitamin D deficient. The study complements previous research showing an association between vitamin D status and subsequent increments in bone density in peripubertal girls.[2]

What are the implications of this study for clinical practice and research given the high prevalence of vitamin D deficiency in children worldwide? Further research is important to clarify if such short term changes in bone density persist. The concept of peak bone mass influencing the risk of osteoporosis in adults has been a key influence on intervention studies in paediatric practice for many years but has recently been challenged.[3] A systematic review of studies of calcium supplements in children showed that short term improvements in bone density were not maintained in the longer term.[4] Most of the research to date has used dual energy x ray absorptiometry to assess bone density, and information about potential changes in bone geometry and estimated bone strength is limited. A recent randomised controlled trial in vitamin D deficient postmenarchal girls that used peripheral quantitative computed tomography in addition to dual energy x ray absorptiometry found that vitamin D supplements had no effect on bone density and geometry.[5] Although bone density has been shown to be related to the risk of fracture in healthy children, fractures should be studied as an independent outcome in the short term in children with vitamin D deficiency and in the long term as adults.

What is the definition of vitamin D deficiency in clinical practice? This has been hotly debated given the current interest in the potential extraskeletal benefits of vitamin D. It has been recommended that serum concentrations of greater than 50 nmol/L or even 80 nmol/L should be regarded as vitamin D sufficiency.[6] Many laboratories have adjusted their reference ranges for vitamin D to reflect such recommendations, with a consequent increase in the prevalence of abnormal results.



BIOPHOTO ASSOCIATES/SPL

Rickets is the most common bone disease in children worldwide

However, a recent UK consensus vitamin D position statement indicates there is currently no standard definition of an optimal concentration of vitamin D, and that concentrations below 25 nmol/L should indicate deficiency.[7] Even at this value vitamin D deficiency is still prevalent in children worldwide. A study of adolescent girls in Beijing showed a 45% prevalence of vitamin D concentrations of less than 12.5 nmol/L during the winter.[8] The National Diet and Nutrition Survey of 2008-9 has not yet published the results of vitamin D analysis, but it is likely to be similar to previous data showing that 20-34% of 2 year old Asian children in the UK had values under 25 nmol/L.[9]

The most immediate problem of vitamin D and bone health is rickets, which is the most prevalent bone disease in children worldwide. A resurgence of this disease has occurred in many developed countries, and the prevalence remains high in Asia, Africa, and the Middle East. Many countries are trying to tackle this by ensuring that vitamin D supplements are provided to vulnerable groups. Healthcare professionals need to ensure that these are readily available and being taken. Experience suggests that vitamin D supplementation involves logistical hurdles, and that sustained input is needed for this approach to translate into a reduction in the prevalence of rickets.[10]

bmj.com/archive
- Fall prevention with supplemental and active forms of vitamin D (*BMJ* 2009;339:b3692)
- Association between pre-diagnostic circulating vitamin D concentration and risk of colorectal cancer in European populations (*BMJ* 2010;340:b5500)
- Patient level pooled analysis of 68 500 patients from seven major vitamin D fracture trials in US and Europe (*BMJ* 2010;340:b5463)
- Diagnosis and management of vitamin D deficiency (*BMJ* 2010;340:b5664)

The UK currently has no reference nutrient intake for vitamin D in children above the age of 4 years, in contrast to the rest of Europe and the US,[11] because it is assumed that exposure to sunlight results in adequate concentrations of vitamin D.[12] However, Winzenberg and colleagues' review suggests that adequate vitamin D status is needed throughout childhood and adolescence. This is unlikely to be achieved by vitamin D supplementation alone, and advice on sensible sun exposure and more extensive food fortification needs to be considered.

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Palliative care in people with chronic obstructive pulmonary disease

Passive acceptance of the illness has implications for end of life care and delivery of services

RESEARCH, p 268

Andrew Thorns consultant in palliative medicine
andrew_thorns@pilgrimshospice.org
Declan Cawley research fellow in palliative medicine, Pilgrims Hospices, East Kent NHS University Hospitals Foundation Trust, University of Kent, Canterbury CT9 4AD, UK

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The fact that chronic obstructive pulmonary disease (COPD) is a terminal illness comes as no surprise to clinicians on acute medical wards, especially as the winter takes hold. Why then are patients surprised when end of life issues are raised or referrals made to hospice services? In the linked study, Pinnock and colleagues postulate that patients passively accept their lot and see the increasing disability as part of normal ageing.[1] The researchers found that, unlike patients with other diseases (such as cancer and heart failure)—who can tell the story of how the illness occurred, events that have unfolded, and their current disease status[2]—patients with COPD seem to lack this narrative story. The realisation of illness, or "biographical disruption" to their life, is not a conscious thought for these patients. There is no clear point of diagnosis, especially one with a poor prognosis.

This lack of biographical disruption stops patients from identifying COPD as a serious illness. Current strategies aimed at identifying patients in their last six to 12 months of life may fail because of this lack of a clear start to the illness as well as the difficulties of making an accurate prognosis.

DENNIS HALLINAN/ALAMY

The delivery of palliative care has moved from end of life care centred on people with cancer to a more proactive and earlier intervention that includes people with diseases other than cancer. Current initiatives on services for patients with chronic lung disease have called for better assessment of patients' and carers' needs and involvement of palliative care services.[3 4] An accurate holistic assessment of need can guide the delivery of care more effectively than projected longevity, so that those with the greatest need receive the specialist palliative care that they require. This would bypass the problem that clinicians face of knowing when to move to a palliative approach.[5]

Pinnock's concept of passive acceptance of the increasing dyspnoea and disability can be considered either as a weary resignation or a more helpful, comfortable adaptation by patients. The challenge for clinicians when seeing a gradual decline over many years is not to accept this as part of smoking related, accelerated ageing. Instead, they should consider when, or if, the patient is approaching the end of their life and how their care should be adapted. Awareness of this passive acceptance will help professionals to tailor care accordingly.

Transition points are opportunities to prompt professionals to open up discussions about the nature of COPD and the outlook for the future. The authors suggest potential examples, such as the point of diagnosis, the time of retirement for medical reasons, the point at which domiciliary oxygen is needed, or during hospital admissions. For these transition points to be effective clinicians should

communicate and explain the current clinical situation and the available management approaches. This will require courage to change the current mindset of health professionals in particular and embrace some of the difficult conversations needed with life limiting illnesses.

Neither an acute care approach nor a palliative care approach can meet all the needs of this group of patients. A gradual integration of services allows time to adjust.[6] Evidence from patients with cancer suggests that early involvement of palliative care is better for patients' quality of life and has no adverse impact on mortality.[7] Similar research in people with COPD would be helpful.

The challenge will be to integrate a model that traverses acute and palliative care settings, is sensitive to the requirement for active hospital care, deals with the life limiting nature of the condition, and does not overwhelm the limited specialist palliative care services currently available. For example, how should clinicians recognise when a palliative approach is more appropriate than an acute medical one? And, if this is the case, whether they, and the other services involved, have the skills to manage an acutely breathless patient at home when the patient does not want to be admitted to hospital? This is where experience from palliative care services could be most useful.

Several research questions remain. How will patients perceive coming from a mindset of passive acceptance of their medical problem to accepting that they have a life limiting illness? What will be their response to discussions about end of life care with an uncertain prognosis? How and when should clinicians tackle such discussions and manage their own emotions, especially if they have been treating the patient for several years? Questions around service provision and symptom control, especially of dyspnoea, remain. How can traditional palliative interventions developed mainly for cancer be applied to COPD?

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One nudge forward, two steps back

Why nudging might make for muddled public health and wasted resources

ANALYSIS, p 263

Chris Bonell senior lecturer in social science and epidemiology, chris.bonell@lshtm.ac.uk
Martin McKee professor of European public health
Adam Fletcher lecturer in sociology and social policy
Paul Wilkinson reader in environmental epidemiology
Andy Haines professor of public health and primary care, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine, London WC1H 9SH, UK

In the linked article, Marteau and colleagues offer a timely note of caution about "nudging"—an approach to behaviour change described in *Nudge: Improving Decisions about Health, Wealth and Happiness*, a book by the US academics Richard Thaler and Cass Sunstein—which is the coalition government's preferred strategy for promoting public health.[1]

Cue the subconscious

Based on an explicitly self contradictory concept termed "libertarian paternalism,"[2] nudging recognises that our everyday decisions are often not conscious and rational. Much of our behaviour is automatic or follows perceived norms, and it relies on poor information about consequences or overinterpretation of misleading information. Consequently, nudging is based on the principle that it is legitimate to influence people's behaviour to make their lives healthier (paternalism), but that such influence should be unobtrusive and not entail compulsion (libertarian). Nudges might involve subconscious cues (such as painting targets in urinals to improve accuracy) or correcting misapprehensions about social norms (like telling us that most people do not drink excessively). They can alter the profile of different choices (such as the prominence of healthy food in canteens) or change which options are the default (such as having to opt out of rather than into organ donor schemes). Nudges can also create incentives for some choices or impose minor economic or cognitive costs on other options (such as people who quit smoking banking money they would have spent on their habit but only being able to withdraw it when they test as nicotine free).

As Marteau and colleagues note, despite the fanfares with which nudging has been presented in the recent public health white paper *Healthy Lives, Healthy People*, these ideas are far from new. Supermarkets have spent enormous sums on research into how to direct our choices in ways that serve what they define as our interests (in other words, their own), most obviously by lining check-out queues with sweets placed at children's eye level.[3] Meanwhile, concepts such as social norms and incentivisation are rooted in longstanding theories of health behaviour. Marteau and colleagues rightly point out the vagueness with which the term nudge has been used, its limited evidence base, and its potential for harm. They call for new primary research and systematic reviews to examine the effectiveness of public health nudges.

However, we shouldn't rush into investigating the evidence base of nudging unless it offers something that existing approaches do not. Defined negatively, nudges seem to be anything other than just giving people basic factual

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information to enable them to make more rational, conscious decisions, or compelling them to change behaviour. It isn't clear how nudges are distinctive in any other way. Public health is rarely coercive (other than to prevent harm to third parties), generally goes beyond information giving, and already seeks to influence how choices are presented. For example, social marketing engages with emotional decision making using techniques borrowed from advertising.[4] Motivational interviewing draws on people's need for cognitive consistency, and it helps people to identify disparities between their goals and current behaviours, with the aim of changing any disparate behaviours.[5] Peer education harnesses the power of social norms by enabling people to spread health messages through their social networks.[6] Structural interventions modify the physical, organisational, or social environment to change behaviour.[7]

Unlike nudging, all of these existing approaches are informed by theories that help define which interventions qualify as examples and identify the causal pathways along which they aim to operate. More research is certainly needed, but it should be focused on approaches with a clear theoretical basis and a coherent causal pathway linking the intervention to the desired outcome.

Furthermore, many of Thaler and Sunstein's examples of nudges don't fit with their own definition. They cite legislation mandating cigarette packets to present information on the risks of smoking, an example of using basic factual information to promote behaviour change in a way that nudging is supposed to transcend. They also cite a programme paying a "dollar a day" to teenage mothers contingent on their having no further pregnancies; this would exert a considerable financial pressure on young women in poverty, contradicting the definition of nudges as not exerting such pressures.

Nudge is an interesting book, but for its politics not its science. In describing nudging as libertarian paternalism, it makes a strong case for state action in the context of contemporary America, where large numbers of citizens have been influenced by a media shaped by corporate interests to vote against governmental measures that would benefit them.[8] Thaler and Sunstein argue for the legitimacy of state intervention to benefit citizens as long as it neither hectors nor coerces (but they acknowledge in their conclusions that there are no hard and fast cut-off points). Although persuasive, their argument rests on attacking a straw man. As argued above, most public health is not coercive (and goes beyond information giving); this is also surely true of most other social policies, aside from the compulsion to attend school and pay taxes.

In terms of public health science, the notion of nudging adds nothing to existing approaches. Public health policies should be based on the best available evidence, but the government has shown a worrying tendency to undermine the collection of such evidence—for example, by stopping the National Institute for Health and Clinical Excellence from undertaking appraisals of several strategies to improve public health.[9] *Nudge* contains some eye catching ideas, but little progress will be made if public health policy is made largely on the basis of ideology and ill defined notions that fail to deal with the range of barriers to healthy living.

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