Bury the bill

The proposed changes to the Health and Social Care Bill would leave it unfit for any purpose

FEATURE, p 20

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- This week's poll asks, "Should the Health and Social Care Bill now be withdrawn?" Cast your vote on bmj.com
- Read more about the NHS reforms on the *BMJ* NHS reforms microsite at bmj.com/nhsreforms

In January we judged it too early to let the Health and Social Care Bill out of the lab.[1] Its proposals had no clear rationale, lacked coherence, and looked like costing more than they would save. Since then, the bill's flaws have become only more obvious. Instead of further tinkering, it would be better for the NHS, the government, and the people of England to sweep the bill's mangled remains into an unmarked grave and move on.

Activity over the past five months has continued at the same frenetic pace set by the publication of the white paper *Equity and Excellence: Liberating the NHS*, two months after last year's general election. This activity has included the bill's second reading in the House of Commons, a two month committee stage, and (in response to growing criticism) an unusual stopping of the legislative clock for an eight week "listening exercise." The group set up to do the listening, the NHS Future Forum, formally reported on 13 June, and the next day the government accepted the bulk of its recommendations. Amendments to the bill will return to the Commons, and an amended bill is expected to clear the house before it rises for the summer recess on 19 July.

Dead man walking

Surprisingly, it was the mild mannered grandees of the UK Future Forum who administered the coup de grâce. Competition was the beating heart of the bill, and the forum ripped it out. The bill had originally envisaged turning Monitor, the regulator of foundation trusts, into an economic regulator for the entire health and social care sectors. Its main duty would have been to promote competition where appropriate and regulate where necessary. Substantial tracts of the bill were devoted to how the rejigged Monitor would work and how competition would be promoted.

The forum had other ideas and called for the promotion of competition to be dropped as Monitor's primary duty. Instead, "competition should be used as a tool for supporting choice, promoting integration and improving quality and must never be pursued as an end in itself." Private providers should not be allowed to cherry pick the most profitable patients, and the government should not seek to increase the role of the private sector as an end in itself.[2] The government accepted all this [3]—but with such alacrity and so little obvious soul searching that some have doubted the government's good faith.

Despite this fatal blow, the forum had come not to bury the bill but to address its weaknesses. Some of its recommendations were to leave well alone; others were to slow down the pace of reform. But, worryingly, the forum also recommended stripping in new layers of bureaucracy.

If the recommendations are implemented worst affected will be the new clinical commissioning groups (previously known as GP consortiums, the replacement for primary care trusts). The groups will now have to include a hospital doctor and nurse and to consult clinical senates, clinical networks, patients, and local health and wellbeing boards. Local authorities could still appeal against their decisions over major service changes, and a new citizen's panel would examine how choice and competition are working.[4] Taken with the forum's other recommendations, this will leave the NHS with a proportion of bureaucrats similar to that in the Austro-Hungarian empire on the eve of the first world war—and about as flat footed.

Just as no one believed the white paper's claim that 45% of NHS management costs would be saved while GP consortiums and a National Commissioning Board were swapped for primary care trusts and strategic health authorities, now no one can understand how the managerial costs in an NHS refashioned along the lines suggested by the Future Forum wouldn't exceed what they are now.[4 5]

And still the most urgent problem facing the NHS—the need to make £20bn (€23bn; $32bn) in efficiency savings over four years—goes unaddressed. Instead we have reforms that "look like a (highly complex) solution in search of a problem."[6] We are left asking the same question we did five months ago: what is the rationale for the changes proposed in the bill?

Looking forward and back

Dropping the bill doesn't mean that some of the good ideas that have emerged over the past year can't be implemented; the secretary of state for health has already acknowledged that much was possible without legislation. Primary care trusts could still be reformed to put the GPs in the driving seat, as was originally intended, thus obviating the need for vastly more disruptive, and costly, structural change. Choice of any qualified provider could still be limited to services covered by tariffs to ensure that competition is based on quality. Mr Lansley can still give free rein to his appetite for greater transparency and openness. Laws don't need amending to require that foundation trusts hold their board meetings in public or that details of their contracts with primary care trusts are published. The gradual evolution towards a mixed economy of providers, initiated by a previous Labour government, can continue without the bill.

The government agreed with criticisms that more work was needed on its plans for education and training—and

will undertake further consultation before publishing more details later in the year. Similarly, the raft of public health reforms in the bill could be "parked," pending the outcome of the consultation that followed the publication of the public health white paper, *Healthy Lives, Healthy People*. If legislation is needed it can be introduced—in good time.

So what lessons can we salvage from this past sorry year? Firstly, "once in a generation" opportunities to reform the NHS are now seized on once every government. Secondly, dreaming up the reforms can't be entrusted to one person, no matter how long he or she has observed the NHS from the opposition benches. (The fact that the new bill was several times longer than the original bill setting up the NHS should have sounded warning bells.) Thirdly, reality testing, such as that provided by the Future Forum at the 11th hour, should have been scheduled much earlier in the process. And lastly, the breakneck speed that has characterised the legislative programme since the beginning has been both unnecessary and counterproductive.

Only a handful of companies in the world exceed the £100bn turnover of the English NHS; none would have embarked on change in this harebrained fashion. This is the take home message for the next government that spots a once in a generation opportunity to reform the NHS.

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Prevention of falls through podiatry care

Consider foot pain, footwear, and orthoses

JOSE OTO/SPL

RESEARCH, p 31

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In the linked randomised controlled trial, Spink and colleagues report a parallel group randomised controlled trial with 12 months of follow-up in 305 older people. The trial assessed the effectiveness of a multifaceted podiatry intervention for preventing falls.[1] The intervention included the use of foot orthoses, footwear advice supported by a voucher scheme, a foot and ankle exercise programme, falls prevention education, and routine podiatry care. The intervention significantly reduced the incidence of falls compared with routine care (incidence rate ratio 0.64, 95% confidence interval 0.45 to 0.91). No significant differences were seen between the groups in the proportion of fallers or multiple fallers.

Because the intervention reduced the incidence of falls in people with foot pain and should be inexpensive and simple to implement, the authors concluded that the programme could be used in routine podiatry practice and falls prevention clinics.

The causes of falls are multifactorial and include intrinsic and environmental risk factors.[2] Falls commonly occur in older people,[3] who often have problems with balance, walking, and mobility, and a third of older people also have foot pain.[4] The association between foot pathologies, decreased foot function, foot pain, and falls is established.[5-8]

Podiatrists treat people of all ages, but their work tends to focus on older people. Although older people have the same foot disorders as the general population, disorders are more common and cause more problems with advancing age and reduced mobility. Conditions that place the foot at greater risk, such as diabetes, are also more common in older people. Research into the effectiveness of podiatry interventions across all population groups has shown that they reduce pain in foot lesions[9]; that simple orthotic treatment also reduces foot pain[10]; and that screening, education, and podiatric interventions can prevent more serious disorders.[11]

Although foot pain is known to be related to falls in older people, Spink and colleagues show for the first time that standard podiatry interventions can reduce falls in older people with foot pain. The findings of the study could affect the assessment and referral of people with foot pain and provide the basis for evidence based guidelines, where none currently exists.

Despite the promising results, several considerations remain. The research looked at one form of orthoses only (prefabricated, full length, dual density orthoses with a firm density base and soft density top cover). A variety of orthoses are available, and the findings cannot necessarily be applied to other forms. The specific role of footwear in preventing falls is less clear and should be explored further. Similarly, the study looked at people with foot pain only, and many foot conditions are not painful but may still contribute to falls. A full economic evaluation is also needed to determine whether the authors' assertion about cost effectiveness is true.

What do the results mean in practice? Although the interventions studied are routine to podiatrists, they have had little previous use in the context of falls. The study therefore confirms that podiatrists could potentially help reduce falls in older people, and that when assessing patients at risk of falling, primary care doctors should consider whether the patient has foot pain, foot and ankle weakness, and reduced range of motion. Balance and functional ability should also be taken into account, and whether the patient is already wearing orthoses and for what reason. The doctor should also look at whether the patient avoids walking barefoot and whether their footwear provides adequate stability, correct fit, an acceptably low heel height, a reasonable sole-ground contact area,

and slip resistance. If any of these risk factors is identified, referral to a podiatrist is warranted. Future research should focus on patients residing in alternative settings, such as residential homes and hospitals; those at risk of falling because of other risk factors not considered here, such as the presence of toe deformities; and those who have risk factors but no foot pain.

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What would happen to health inequalities if smoking were eliminated?

They would persist at a lower level because obesity would fill part of the gap

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RESEARCH, p 33

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Socioeconomic inequalities in mortality are a stubborn phenomenon. During the 20th century, despite increases in prosperity and various policies to take the sharper edges off social inequality, the gap in survival between those with a lower and a higher socioeconomic position has not disappeared. On the contrary, many countries in western Europe and North America have seen a widening of this gap during the past 40 years.[1]

In many of these countries, smoking now is one of the most important mediators of the effect of low socioeconomic position on mortality. Among men, and in some countries among women, smoking has been declining for several decades. Because this decline has been most prominent in more highly educated people and those with higher incomes, smoking has become relatively more common in lower socioeconomic groups.[2 3] The linked cohort study by Hart and colleagues is a welcome opportunity to see what could happen to health inequalities if smoking were eliminated.[4]

It is not unusual to find that smoking alone accounts for more than a quarter of inequalities in mortality, depending on the population studied and the methods used, especially in men.[5 6] Smoking has therefore become one of the main targets of policies to reduce health inequalities, particularly in the United Kingdom, where smoking is strongly socially patterned.[7]

But what would happen to health inequalities if smoking were eliminated and could no longer mediate the effect of a low socioeconomic position on mortality? Smoking is not the fundamental cause of health inequalities, and if underlying inequalities in access to material and immaterial resources remain unchanged, other risk factors may replace smoking as a mediator, so that the effect on health inequalities may in the end be small.[8]

Hart and colleagues studied the survival of 3613 women who, when this study in the west of Scotland started in 1972, had never smoked. They found that the death rate in women in lower social classes was a third higher than for those in higher social classes (social class IIIM, relative risk 1.35, 95% confidence interval 1.16 to 1.57; social class IV and V, 1.34, 1.17 to 1.55; both relative to social classes I and II) and that this was partly mediated by their higher body mass index.[4]

A previous study by the same authors found that although mortality in never smokers in this cohort is much lower than that in smokers, substantial inequalities in survival are present among never smokers and current smokers. Surprisingly, in this cohort inequalities in mortality are larger among never smokers. For example, in women who had never smoked, mean 28 year survival ranged from 56% in the lowest occupational classes to 65% in the highest (9% points difference). The corresponding figures for women who currently smoked were 41% and 35%, respectively (6% points difference).[9]

The current study quantifies the contribution of a risk factor that seems to have replaced smoking as a mediator in women who never smoked—overweight and obesity. As the authors note, their results show an interesting similarity with recent findings in southern European women. In this group the smoking epidemic is in its early stages, with smoking still being uncommon among middle aged and elderly women, and more prevalent in higher socioeconomic groups. Overweight is currently more prevalent in poorly educated southern European women in the age range in which most deaths occur.[10]

In women in the west of Scotland cohort who had never smoked, overweight and obesity explain about a quarter of the inequalities in mortality.[4] In the case of overweight and smoking, it could be argued that one can replace the other as a mediator of the effect of low socioeconomic status on mortality. Overweight is more common among never smokers, perhaps because of the effects of smoking on appetite and resting metabolic rate,[11] and the higher prevalence of overweight and smoking in lower socioeconomic groups may

partly result from higher exposure to psychosocial stressors.[12]

But it is important not to forget that smoking is a much stronger risk factor for mortality than most other risk factors, including obesity. In this cohort study, current cigarette smoking doubled the risk of (all cause) mortality, whereas moderate obesity increased the risk of mortality by only a third.[4 9] Exchanging smoking for obesity is a good bargain, but inequalities in mortality will not necessarily become smaller. Inequalities in mortality persist among those who have never smoked, partly because obesity takes over the role of smoking, but they persist at a much lower level, and that is good news for whoever wants to reduce health inequalities.

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Why do some ex-armed forces personnel end up in prison?

New report emphasises the role of alcohol, social exclusion, and financial problems

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On 23 June the well respected Howard League for Penal Reform published their report on ex-serving armed forces personnel in prison.[1] The league's remit was to find out why so many of these people become involved in the criminal justice system, to explore the problems facing them on transition back into civilian life, and to look at the reasons underlying their offending behaviour. It is hoped that the report can provide information on how these individuals' needs can best be met both in prison and in the community.

Concerns about how service personnel will reintegrate into society after war are nothing new. After the second world war, returning veterans were often seen less as heroes and more as potential social problems with violence and offending high on the list of concerns.[2] Since 2001, more than 160 000 UK regular and reserve forces have been deployed in Iraq, Afghanistan, or both counties. There have been many accounts in the media of the challenges these individuals face in their transition back to civilian life, including problems related to housing, mental health, employment, relationship breakdown, and substance misuse,[3] but also aggression, violent offending, and incarceration.[4]

Research examining the effects of war on psychological functioning has focused mainly on clinical outcomes, such as post-traumatic stress disorder, anxiety, and depression,[5 6] but a growing body of research from the United States shows a link between combat exposure and subsequent increased self reported aggression, antisocial behaviour, and criminal behaviour.[7 8] The National Association of Probation Officers, using unverified self reports of military service by prison inmates, estimated that 9.1% of English and Welsh prisoners have served in the armed forces.[9] The Defence Analytical Services Agency of the Ministry of Defence estimated a figure of 3.5% using a more robust method of record linkage between prison census data and Ministry of Defence personnel records.[10] Their analyses showed that although ex-serving personnel are less likely than the general population to offend, they are more likely to be in prison for violent and sexual offences, and they make up the largest single occupational group in prison.

However, such one dimensional statistics do not explain why these individuals end up in prison. The general acceptance that it is related to their experiences during military service[9] overlooks the fact that the armed forces recruit from areas of social deprivation and higher crime,[11] all of which are associated with subsequent offending, irrespective of any impact of military service. Research also shows that most service leavers do well after discharge.[12]

The report from the Howard League for Penal Reform drew on the opinions of politicians, military leaders, academics, and service charity practitioners. The report also includes interviews with 29 non-randomly selected ex-serving inmates, who were mainly convicted of serious violent offences.[1] Three main, although overlapping, groups of vulnerable people emerged: those from severely disadvantaged backgrounds who were involved in crime before they joined the forces; those who experienced difficulty in the forces, such as mental health problems or physical injury, which led to early discharge; and those who had successful armed forces careers but had difficulty adjusting to civilian life.

Not surprisingly, the report's conclusions emphasise the role of alcohol, social exclusion, and financial problems in offending. Perhaps more surprisingly, given the general themes of media coverage, they found less evidence that homelessness was a major problem, or that post-traumatic stress disorder or other occupational psychiatric injuries that service personnel are

exposed to played a major part. This is in keeping with the evidence from the King's Centre for Military Health Research (KCMHR) cohort that although post-traumatic stress disorder is a problem for some people who have served (2-7%, depending on combat role and regular or reserve status), alcohol is a larger problem during and after service.[5] The Howard League also drew attention to the relatively long time periods between leaving the forces and offending in the admittedly small sample, which again raises questions of a causal link between service and serious offending.

Multiple factors therefore contribute to ex-serving personnel ending up in the criminal justice system. But data are needed on the relative contributions of pre-service adversity, military experiences, and post-service life. Such data are crucial—firstly, because any interventions need to be based on an understanding of the risk factors and critical pathways operating, and secondly, as a matter of policy. The current debate around the Military Covenant, likely to be adopted into law via the latest Armed Forces Bill, is built around two relevant themes. Firstly, that society has a duty to compensate for any injuries or disadvantages that have occurred as a result of military service (but not those that result from factors whose impact began before service), and, secondly, that there should be rewards for the specific nature of military service—that is, that higher duty is owed to those who have been prepared to sacrifice their lives in their country's service.

To this end, a large scale study linking the KCMHR cohort data on more than 13 000 UK military personnel to all conviction records,[5] both before and after military service, is looking at the relative contributions of pre-military factors, deployment and combat, and finally post-deployment mental health and substance misuse to any conviction and self reported violent behaviour. Individuals in prison make up only a small proportion of those who offend, and the issues around offending behaviour in ex-service personnel are not restricted to criminal convictions and incarceration, although that is the focus of the Howard League's report, but also violent and antisocial behaviour that does not result in conviction.

The Howard League's report concludes that "for the majority, service in the forces significantly improves life opportunities." But some veterans do end up in prison, and it is reasonable for us to consider whether our society is doing everything possible to reduce that number.

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Axillary dissection in women with sentinel node metastasis

Can be avoided in selected subgroups

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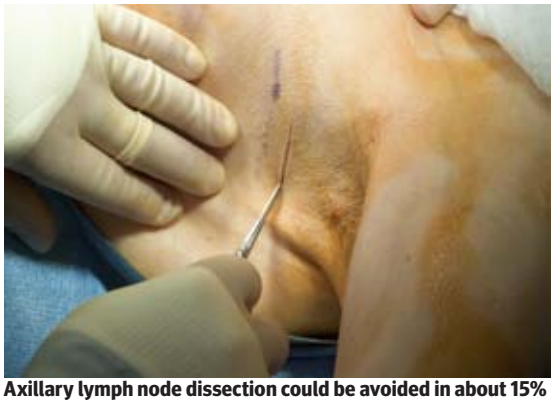
Randomised trials published over 15 years ago established local excision, level I and II axillary lymph node dissection (ALND), and whole breast radiotherapy as appropriate locoregional treatment for women with early stage breast cancer. The recent publication of the American College of Surgeons Oncology Group (ACOSOG) Z0011 trial will reduce the use of ALND in women with positive sentinel lymph node biopsy (SLNB).[1] The ACOSOG Z0011 trial compared ALND or no ALND in women with clinically negative axilla, no more than two sentinel lymph nodes affected (with no gross extracapsular extension), and primary tumour less than 5 cm who received lumpectomy, postoperative whole breast radiation, and appropriate systemic treatment.[1] The trial was timely because about a third of women with a positive SLNB in the United States during the time of enrolment (1999-2005) did not undergo completion ALND after SLNB despite guidelines recommending it.[2] As a non-inferiority trial, 1900 patients were needed to show with 90% confidence that the hazard ratio for overall survival did not include 1.3 in the patients who had no ALND, with final analysis after 500 deaths. Because the mortality rate in both arms was lower than expected, an independent data and safety monitoring committee recommendation resulted in only 891 patients being enrolled. Only 94 deaths occurred over a median follow-up of 6.3 years, which is a testament to the effectiveness of modern systemic treatments and radiotherapy, even in the absence of ALND. Factors such as patient withdrawal (35 patients), failure to receive the assigned treatment (43 patients), poor follow-up (166 patients), and poor study design or implementation will tend to negate the outcome of a superiority trial but



DR BARRY SLAVEN/VISUALS UNLIMITED/SPL

Axillary lymph node dissection could be avoided in about 15% of women with invasive breast cancer

artificially support a trial designed to show non-inferiority, so additional scrutiny of such trials is warranted.

Potential biases in enrolment could have been introduced during randomisation, because most patients were selected after final pathology results were available. Academic centres were less likely to enrol patients and 115 institutions participated, so many surgeons enrolled a small number of patients.[3] It is therefore surprising that these patients' clinical characteristics including age, T stage, oestrogen and progesterone receptor status, and tumour histology were not significantly different from those who had lumpectomy in the general US population (J Rescigno, unpublished; based on Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov) Limited-Use Data (1973–2004), National Cancer Institute, DCCPS, Surveillance Research Program, Cancer Statistics Branch, released April 2007). However, the proportion of patients with grade 3 cancers enrolled in the trial was lower than in the general population (29% *v* 39%). Furthermore, non-significant imbalances in prognostic factors between arms—such as T1 stage, progesterone receptor positivity, low grade, and absence of lymphovascular space invasion—were consistently in favour of the SLNB alone arm. Tumour grade and lymphovascular space invasion were unknown in about a quarter of patients. Those in the SLNB arm were also more likely to have no lymph node involvement (7% *v* 1.2%), and it is unclear why such patients were randomised.

Although non-inferiority was not proved on the basis of initial statistical assumptions, the fact that these assumptions were incorrect does not negate the results. Only 3% of patients experienced locoregional recurrence. More than 75% of locoregional recurrences are expected to occur by five years, and such recurrences influence overall survival at 15 years when the difference is greater than 10% in absolute terms.[4] Therefore, survival will not differ between the treatment arms at long term follow-up.

It is counterintuitive that disease left in the axilla in potentially more than 25% of the patients who received SLNB alone did not result in higher recurrence rates. Preoperative chemotherapy trials suggest that chemotherapy can eradicate disease in the lymph nodes in a third of node positive patients.[5] Antioestrogen drugs are associated with low locoregional relapse in selected patients who do not undergo radiotherapy or ALND.[6] Also, traditional tangential radiation to the whole breast treats a large portion of the axilla, and minor changes to tangential radiotherapy can allow full therapeutic dose to levels I and II.[7 8]

What does this all mean in practice? A two stage procedure of initial local excision and SLNB, followed by further discussion of ALND if the SLNB is positive is appropriate for most patients. Preoperative consent for ALND is no longer universally necessary, and neither is intraoperative assessment of the SLNB specimen. ALND remains necessary for women who have tumours larger than 5 cm, those who require mastectomy, or when partial breast radiation is planned. Completion ALND should be considered in women who on the basis of available nomograms are at particularly high risk of residual nodal disease, as well as those with high grade tumours, lymphovascular invasion, or extracapsular extension. Women who wish to avoid chemotherapy and those with comorbidities may also benefit from ALND, so that the absolute benefit of chemotherapy can be more accurately assessed on the basis of the number of axillary lymph nodes affected. Also, further research is needed to know if patients whose tumours respond well to preoperative chemotherapy can be spared ALND. Lastly, more than a fifth of women in the trial who underwent ALND had three or more axillary lymph nodes affected, in which case infraclavicular and supraclavicular radiotherapy would have been considered, but was prohibited in this trial. Given the excellent locoregional control demonstrated, it is reasonable to avoid infraclavicular and supraclavicular radiation in such patients. However, in the absence of specific information on radiotherapy field design, it is prudent to modify tangential breast fields to encompass levels I and II in node positive patients who undergo SLNB alone.

There is a now a new option for selected women with positive sentinel lymph node biopsy to avoid the morbidity of ALND. About 15% of all women diagnosed with invasive breast cancer are eligible for this new approach.

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