



From l; Clive Peedell, Monitor's David Bennett, RCGP's Clare Gerada, doctors from Keep our NHS Public outside the Department of Health in January

THE HEALTH AND SOCIAL CARE BILL

10 things for the Lords to consider

Although the NHS bill for England has passed the first hurdle, the House of Lords could still force further changes. **Edward Davies** highlights some of the remaining controversies

After a third reading and heated debate in the House of Commons, the Health and Social Care Bill was passed by 316 votes to 251 on 7 September. It received its first reading in the House of Lords, little more than a formality, the next day but will be subject to far more rigorous debate at its second reading in October. Despite more than 1000 amendments in its near 600 pages, many individuals, groups, and organisations still harbour grave concerns. Here we look at 10 of the outstanding questions that the Lords will want to consider.

1. Privatisation

“Privatisation” has become the central battle ground of the reforms. The bill is unashamedly supportive of markets and competition, with the government believing that this is the best way to improve the quality of NHS services. But the word “privatisation” has been interpreted and objected to in many ways.

Some health unions vociferously opposed the bill on the basis that it is the first step down a road to a fully private insurance system like that in the United States.¹ Others do not believe this will happen but are still forcefully arguing that the bill amounts to privatisation. Writing in the *BMJ*, Clive Peedell, co-chairman of the NHS Consultants' Association, claimed that “the World Health Organization has defined privatisation in healthcare as “a process in which non-governmental actors become increasingly involved in the financing and/or provision of healthcare services” and as such the bill was clearly a move in this direction.²

Although amendments to the bill have softened the language, much of the central drive remains

Passage of the bill

(<http://services.parliament.uk/bills/2010-11/healthandsocialcare.html>)

House of Commons

- First reading, 19 January 2011
- Second reading, 31 January 2011
- Committee debate, February-July 2011
- Report stage, 6 September 2011
- Third reading, 7 September 2011

House of Lords

- First reading, 8 September 2011
 - Second reading, 11 October 2011
 - Report stage, to be decided
 - Third reading, to be decided
- Consideration of amendments, to be decided
Royal assent, to be decided



the same. However, both Conservative and Liberal Democrat ministers have repeatedly denied that the NHS will be privatised. A statement on the Department of Health website declares: “Health ministers have said that they will never privatise the NHS. Providers are organisations that provide services direct to patients . . . they will be given more freedom to help them deliver the best possible care for patients, and it will be easier for new providers to offer services. NHS patients won't have to pay for their care but they will be able to choose from a range of providers.”³ It remains to be seen whether the Lords will agree.

2. Monitor

Within the debate about privatisation, the role of Monitor, the independent regulator of NHS foundation trusts, has come under particular

scrutiny. The original bill was heavily criticised for mandating that Monitor's main duty would be to “protect and promote the interests of people who use health services . . . by promoting competition.” The Future Forum, which the government charged with reviewing the bill, recommended in its final report that Monitor's primary duty to promote competition should be removed and replaced with a duty “to protect and promote the interests of the patient.”

As a result, parts of the bill concerning Monitor have been changed and the organisation's duty is now to promote competition only where it is “economic, efficient and effective, and maintains or improves the quality of the services.” The House of Lords will need to review these passages and ask whether the forum's recommendation has been sufficiently implemented.

3. EU competition law

The increasing role of competition has also led to questions around the application of European competition law. The Royal College of General Practitioners has been at the forefront of dissent over the legal implications of the bill. In a letter sent to the prime minister in May the college's chair, Clare Gerada, demanded “clarity as to the legal implications of EU competition law (particularly when, and in what circumstances, it is enforceable) and other contractual and regulatory details.”⁴

The Future Forum dismissed EU legal fears in its report, stating: “There have been visions of an economic regulator that imposes EU law indiscriminately, with no acceptance of the needs of healthcare . . . This is not a vision we recognise. We have been reassured that the Health and



From l: Guy Opperman MP, King's Fund's Anna Dixon, Norman Williams from the Royal College of Surgeons, how the BMJ has covered the health bill in 2011

Social Care Bill does not change the application of competition law in the NHS.”

Guy Opperman, the Conservative MP for Hexham, reinforced the forum's view during the third reading of the bill in the Commons. He told parliament that competition laws were well established in the NHS and that he had brought a case concerning operational management against a primary care trust while working as a barrister in 2005: “The UK health service is subject to competition law under the 2002 Act, the 1998 Act and European community laws on competition. This is therefore not a new thing. . . it was introduced by the previous Government and large parts of the Bill follow on from what was done previously.” However, legal opinion is divided on the implications.

4. Responsibilities of the secretary of state

Public campaign group 38 Degrees has sought legal opinion about several parts of the bill. One of the group's main concerns is that it would remove the secretary of state's responsibility for ensuring the provision of health services. They say: “This is the means by which parliament ensures the NHS delivers what the public want and expect. Furthermore, a ‘hands-off clause’ will severely curtail the secretary of state's ability to influence the delivery of NHS care to ensure everyone receives the best healthcare possible.”⁵

The Department of Health disagrees with this interpretation of the bill. It says, “Ministers are accountable for the NHS and will remain so. The Bill does not change the Secretary of State's overarching duty to promote a comprehensive health service, which has underpinned the NHS since it was founded. The Bill simply makes clear that it should not be the responsibility of Ministers to provide or commission services directly.”⁶

5. Removal of private treatment cap from foundation hospitals

The National Health Service Act of 2006 established many of the rules under which foundation trusts could function. Among the rules it stipulated restrictions on the provision of private services and a cap on all private income. Section

162 of the new bill removes these restrictions. Various groups, including the British Medical Association, think this will have a detrimental effect on a hospital's NHS provision.

In an interview with the *Guardian* newspaper, BMA chairman, Hamish Meldrum, said that as hospitals are hit by cuts to the NHS budget they will be forced to treat wealthy foreigners rather than poor patients in order to raise cash. He said the government was forcing all hospitals to become foundation trusts and that without a cap on private income the trusts would be gearing up to lure private patients from home and abroad.⁷

6. Commissioning: capability and conflicts

The principle of general practitioner commissioning has won broad support from most quarters, including those such as the BMA and the Royal College of General Practitioners that have been vehemently opposed to other parts of the bill. However concerns about GPs' capability and conflicts of interest persist. The government has sought to address the first of these by abandoning its original plan to shoehorn all GPs into commissioning groups to replace primary care trusts by 2013. Instead, commissioning groups, which will now include other health professionals, will be encouraged to form as and when they are ready to take on responsibility. Although many have welcomed the removal of the deadline, it has raised fears of a repeat of the two-tier system that existed under fundholding, when only some GPs took on the role.

With regard to conflicts of interest arising from GPs both commissioning and providing services, both Labour and Liberal Democrat MPs have been outspoken in their demands for safeguards.^{8, 9} The Future Forum also raised concerns and recommended that commissioning groups should have governance bodies with independent membership and that meet in public; should consult publicly on their commissioning plans; and should publish details of their contracts. The government has largely incorporated these into its amendments, but questions persist over whether private firms could conceal much of this information from the public by claiming it is financially sensitive.

7. Bureaucracy

One of the central aims of handing commissioning responsibility directly to GPs was to eliminate some of the complexity and layers of bureaucracy within the NHS. However, during the government's listening exercise various groups voiced fears about a lack of accountability and openness in the arrangements as well as too much burden falling on GPs. The result has been some additions, including the introduction of clinical senates and widening of commissioning groups to include other health professionals as well as GPs.

For some observers the changes mean that the original plan to decrease the layers of management has been lost. Anna Dixon, director of policy at the King's Fund, believes that “the complexity of the new arrangements and weakening of accountability risks [sic] creating confusion and additional bureaucracy.” However, Norman Williams, president of the Royal College of Surgeons, disagrees. “The new emphasis on how integration benefits patients, commitments to transparency in medical outcome and audit reporting, promotion of innovation, and the cutting of bureaucracy are all to be welcomed,” he said.

The true effect hinges on whether these new groups will come from existing organisations, such as professional executive committees within primary care trusts, or sit as completely new bodies in addition.¹⁰

8. National Commissioning Board

Among the new bureaucracies, by far the biggest chief is the NHS Commissioning Board. Its size has given rise to accusations that the bill gives too much power to one central body, and even the NHS chief executive, David Nicholson, described it as having the potential to become “the greatest quango in the sky.”¹¹

Amendments to the bill have given the board even greater powers over commissioning groups and place it as both regulator of commissioning groups and the failsafe for any groups falling short in their responsibilities. However, the Department of Health has defended the board's scope: “The Board is there to support [commis-



From l: BMA's Hamish Meldrum, Imperial College medical students protest over the bill, NHS chief executive David Nicholson, health secretary Andrew Lansley

PHOTOS: MARK THOMAS

sioning] groups to become ready, not to hold them back. Therefore, any group that is able to take on its functions will do so. However, where a group is not ready to take on some or all aspects of commissioning, the local arms of the NHS Commissioning Board will commission on its behalf while continuing to support the group through a wide-ranging development programme until it is ready to be authorised."

9. Why reform now?

Perhaps the most fundamental question to ask is why this bill is happening at all, particularly at a time when the most pressing concern for most managers is the need to make £20bn savings over four years (the Nicholson challenge). In a survey of NHS Confederation members published in March, 63% of the 252 respondents thought that balancing finances and making cost savings would be one of their top three concerns in the coming year, with 31% saying this would be the most important area.¹² Only 32% included understanding the government's reforms, the transition, and reconfiguration in their top three, with 13% saying this would be the most important area.

The health secretary, Andrew Lansley, has stated that many of the changes he wishes to make could happen without primary legislation.¹³ The Lords may want to ask whether this bill is necessary given the current state of NHS finances.

10. Is resistance futile?

The government has been repeatedly charged with railroading its bill through the Commons,¹⁴ and given Mr Lansley's assertion that much of it is achievable without legislation, is the end result inevitable? On the ground, most GPs have already been herded into commissioning groups and the dismantling of PCTs is well under way. Some are arguing that the growth in market forces is an expansion of a Blairite status quo and that the changes are already too far gone to be repealed.

While some critics, such as Dr Meldrum, argue that opposition must be pragmatic, others, such as Keep Our NHS Public (which comprises both

professional and patient groups), think it should be total. Critics within the Lords will need to ask what can be achieved.

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NHS CHANGES AT A GLANCE

The *BMJ* NHS reforms website includes links to all the latest articles, blogs, podcasts, and doc2doc discussions about changes to the health service in England. You can access it at bmj.com/nhsreforms. Here is a list of some key stories:

SEPTEMBER 2011

● Health bill passes to the Lords with majority of 65 votes (*BMJ* 2011; 343:d5740)

JULY 2011

● Lansley denies plan to create "super quango" to control the NHS (*BMJ* 2011; 343:d4320)

JUNE 2011

● Future Forum was truly independent and not influenced by government, claims chairman (*BMJ* 2011; 342:d3833)

● NICE will retain drug approval role in government U turn (*BMJ* 2011;342:d3862)

● Cameron proposes radical changes to England's NHS reforms (*BMJ* 2011;342:d3624)

MAY 2011

● Lansley says he "can entertain any amount of change in the bill" (*BMJ* 2011; 342:d3169)

● Cameron pushes ahead with reforms but promises "substantive changes" (*BMJ* 2011; 342:d3067)

APRIL 2011

● Former chair of RCGP will head government's "listening" panel on NHS reforms (*BMJ* 2011;342:d2258)

● Health secretary will "pause" and listen to staff over reform bill (*BMJ* 2011;342:d2216)

MARCH 2011

● Doctors vote for English health bill to be withdrawn (*BMJ* 2011;342:d1701)

● MPs propose toning down aspects of health bill that increase competition in NHS (*BMJ* 2011;342:d1643)

● Lansley writes price competition out of the health bill (*BMJ* 2011;342:d1481)

FEBRUARY 2011

● MPs support NHS reform as health bill passes first parliament debate (*BMJ* 2011;342:d711)

DECEMBER 2010

● BMA chairman urges doctors to monitor "unnecessarily ambitious" reforms (*BMJ* 2010;341:c7465)

JULY 2010

● GPs are handed sweeping powers in major shake up of NHS (*BMJ* 2010;341:c3796)

bmj.com/podcasts Seth Berkley, chief executive of the GAVI Alliance, talks to Rebecca Coombes about the organisation's work

How should GAVI build on its success?

Vaccine programmes supported by GAVI have prevented more than five million deaths in a decade, but critics argue that the alliance could do even more. **Sophie Arie** reports

There are not many development organisations these days that can say they have raised the full amount of funding they need to meet their goals. But GAVI, the Global Alliance for Vaccines and Immunisation, is in that happy position only 10 years after it was created.

At GAVI's first pledging conference in June this year, public and private donors pledged \$4.3bn (£2.7bn; €3bn), bringing the alliance's funds for 2011-15 to a total of \$7.6bn. With that, the organisation says, it can achieve its aim of immunising more than 250 million of the world's poorest children against life threatening diseases, thus preventing more than four million premature deaths by 2015.¹

Geneva based GAVI, which brings together governments of developing and donor countries, UN agencies, the World Bank, major philanthropists, and the drug industry, has prevented more than five million deaths since it began work in 2000, according to its 2011 progress report.²

But can donors be sure that the money pledged will be spent in the best possible way? Could GAVI be vaccinating more children and saving even more lives if it did things differently?

Price concerns

Everyone agrees GAVI has made huge achievements and that vaccination is a highly efficient form of development aid. The knock on effects on the economies of recipient countries are huge in

terms of children being able to attend school and become productive adults and their parents being able to work rather than care for sick children.

The UK Department for International Development's assessment of multilateral development organisations showed that GAVI was the best value in 2011, and the UK is now the alliance's largest bilateral donor.

Most leading aid agencies are behind GAVI, whose small secretariat, based in the offices of Unicef, has boosted international support for vaccination, which was flagging in the 1990s. But many have serious concerns that it is not focusing—or spending its money—on the right things.

"GAVI could be a lot more effective," says Daniel Berman, deputy director of Médecins Sans Frontières' Access campaign. "Now that they have the money, they should be changing their strategy."

Dr Berman's main argument is that GAVI is too close to big Western drug companies. Although it has managed to negotiate major discounts on vaccines from multinationals, Médecins Sans Frontières and other leading non-governmental organisations say the prices GAVI is agreeing for supplies, which Unicef then buys from those companies, are still too high.

"The main thing GAVI should do is take advantage of a revolution that is happening in the vaccine industry and work with emerging market suppliers to ensure the best possible outcomes," says Dr Berman.

In recent years, manufacturers in India have developed the capacity to produce high quality vaccines for much less than the price offered by companies like GlaxoSmithKline (GSK), Pfizer, and Merck. India's Serum Institute now offers the best price for the pentavalent vaccine against five deadly diseases (diphtheria, tetanus, pertussis, hepatitis B, and haemophilus influenza b) at \$1.75 per dose.³ This compares with \$3.2 paid in 2010 by Unicef, which procures vaccines with GAVI funds, for a single dose vaccine from Crucell and \$2.95 for a two dose vaccine from GSK.⁴ China is about to enter the market following WHO's validation of its regulatory authority, and its manufacturers are likely to be equally competitive.

But GAVI says it still needs to buy most vaccines, particularly the newest ones, from the Western companies who have supplies immediately available on the scale needed.

"Our aim is to save as many children's lives as possible by getting vaccines to them as soon as possible," says Helen Evans, GAVI's deputy chief executive. "If we waited until the Serum Institute was ready [with a pneumococcal vaccine] we estimate that 600 000 children's lives would be lost because they wouldn't be immunised."

GAVI has created several innovative funding mechanisms to encourage big drug companies to slash prices on vaccines for developing countries. One of these so called "pull" mechanisms is the Advanced Market Commitment (AMC), a \$1.5bn fund to encourage companies to provide new vaccines at affordable prices for the long term.

So far, only GSK and Pfizer have qualified for this money with their pneumococcal vaccines (GSK has offered 300 million doses over 10 years at \$3.50 a dose, which is less than 10% of the cost in developed country markets. Under the AMC agreement they receive an additional \$3.50 a dose for the first six million shots).⁵

"The AMC provides us with the confidence to invest in manufacturing facilities," says Jon Pender, vice president of government affairs, access, and intellectual property for GSK, which sells 50-60% of the vaccines it produces to Unicef. "For other companies reviewing their plans for other vaccines, the promise of the AMC has meant that they can go ahead," he said.

Critics say this amounts to subsidising big drug companies and as such is an incomprehen-



Children receive balloons at a National Immunisation Day, Moradabad, India

sible use of aid money. But Ms Evans insists that the AMC is making it possible to start and plan long term vaccinations programmes as quickly as possible. England's international development secretary, Andrew Mitchell, is also convinced this works. "Because of the Advanced Market Commitment, a child born in Kibera, Freetown, or Addis Ababa will no longer have to wait 10 or 15 years to get access to the same vaccines that children in London get today. The AMC is already delivering lifesaving pneumococcal vaccines, tailored for developing countries, to some of the world's poorest children. And it is doing so at less than a tenth of the price charged to the richest countries, only a year after these vaccines were rolled out in the developed world," he says.

Members of the alliance, such as the Bill and Melinda Gates Foundation, are working on "push" mechanisms to help emerging market manufacturers produce their vaccines more quickly. If GAVI did more in that direction, the critics say, many more children's lives could be saved in only a few years' time. India's Serum Institute says it can make a pneumococcal vaccine for only \$2 a dose, but problems licensing the technology mean that its version has not yet qualified for use by GAVI.

GAVI acknowledges that it needs to do more to get prices down further. "One of the aims of GAVI was to bring prices down. And that's an area where there's some disappointment," says Ms Evans.

GAVI's current strategy for 2011-15 includes a focus on shaping markets. But it does not talk about making specific efforts to increase competition, the surest way to bring prices down. The organisation is currently reviewing its supply and procurement strategy and acknowledges the need to do more to support emerging market manufacturers.

It helps that this year Unicef has begun publishing prices for the drugs and vaccines it buys after years of resistance from big drug companies. The data showed that in some cases, firms are making up to 180% profit on products, according to Dr Bernman's calculations.

Help for the poorest

Other questions have been raised about the way GAVI works. Experts argue that there is a fundamental flaw in GAVI's strategy if its goal is to help the world's poorest people and make basic medicine available to them. Under GAVI's co-financing policy, countries must contribute a sum (proportionate to their gross national income per capita) towards immunisation programmes with a view, eventually, to being able to fund them



GAVI FOUNDATION/GAVI

GAVI alliance member Bill Gates visits Nigeria, one of the last places with a major polio problem

entirely themselves. And countries must already have at least 70% coverage for DTP3 vaccine against diphtheria, typhoid, and pertussis.⁶ But this means the poorest countries cannot afford to launch a programme. GAVI has attempted to help countries like the Democratic Republic of Congo to kickstart their health system, channelling funds to the health ministry, but so far it has not worked.

"If we are to get to millennium development goals by 2015 that's not a realistic system to be working with," says Samson Agbo, head of health at Merlin, the UK's leading international health charity. "Fragile states will never get access to high impact vaccines."

It is estimated that 8.8 million children under 5 years old die annually from preventable diseases and 20% of those deaths (1.7 million a year) can be avoided by immunisation with standard vaccines.⁷ Half of the deaths occur in the bottom fifth of the world's poorest countries, Dr Agbo points out. "We need to put the money where the problem

is. We need to be looking at the most vulnerable of the vulnerable," he says.

GAVI has until now said it wants to focus on Nigeria and India, which because of their size together account for 50% of all unimmunised children.

Both countries are wealthy enough to participate in its programmes.

Dr Agbo is worried that this means the very poorest countries are missing out and that GAVI is focusing on new vaccines before it has made sure enough children get the DTP3 vaccine.

GAVI says that with average coverage levels over 70%, it can now focus on rolling out vaccines against the two biggest killers, pneumonia and diarrhoea, which together cause nearly 40% of all childhood deaths. Over 50 countries have applied to start vaccination programmes against these diseases.

Many believe GAVI needs to look at the model of the Global Fund to Fight AIDS, Tuberculosis, and Malaria, which has worked with non-governmental organisations in fragile states to

get treatment to people in countries where health ministries are too weak to do so.

Dr Agbo believes that grants for those countries could, perhaps over three years, help them to boost their health systems and stretch basic vaccine coverage to close to 70% (it is under 40%, on average, in the bottom quintile of poor countries).

Donors, including the UK, are keen to see more progress with vaccine programmes for fragile states. "We want to see GAVI strengthening health delivery systems so that vaccines can help the poorest and hardest to reach people," Mr Mitchell said.

Ms Evans acknowledges "one size doesn't necessarily fit all"—GAVI's model for eligibility for its programmes has not worked for fragile states. Alliance members began looking at developing a specific fragile states policy in July, she says, and should have finalised a new strategy for this by June 2012.

But GAVI sees its role in helping countries strengthen their health systems as limited. Other organisations exist to do that, says Ms Evans. GAVI's cash based programmes—to help countries boost their health systems—will always be limited to a maximum of 20% of its funds, Ms Evans says. "We absolutely need to put resources where they're needed to overcome bottlenecks, but our primary mission is not health system strengthening."

With the funds it has, GAVI can make huge progress and save lives more quickly in countries like India and Nigeria because fragile states are very expensive to help. The more messed up the country, the higher the costs in terms of administration and management of programmes and the greater the logistical difficulties in terms of storing and delivering vaccinations.

Future expansion

GAVI's main goal is to roll out pneumococcal and rotavirus vaccines in as many countries as possible between 2011 and 2015 with the new funds it has secured. And in the near future to bring vaccines against human papillomavirus and even malaria to the developing world.

It has just announced a new pneumococcal programme in three African countries and has received applications from over 50 countries hoping to start programmes. By doing so, it expects it can save four million lives by 2015.

Most people agree that GAVI has been enormously successful so far and is moving in the right direction. Which is perhaps why there are such hopes that it can achieve even more.

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