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The *Health Bill (excluding Part 1)*

Bill 69 of 2005/06

This Paper covers the aspects of the *Health Bill* that are not covered in Part 1 on smokefree premises, places and vehicles. A separate Library Research Paper (05/79) is devoted to Part 1.

This paper covers the ten other topics contained in the Bill. These range from high profile ones, such as action to reduce health care associated infections, which was a General Election issue, to the relatively technical, such as the auditing arrangements for Special Health Authorities.

The extent of the different provisions in the Bill vary.

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Summary of main points

The Health Bill covers a diverse range of issues. The provisions relating to smokefree premises, places and vehicles are covered in a separate Library Paper (number 05/79). This Paper provides an overview of the other measures. Further details are in the Explanatory Notes on the Bill[1] and in the Partial Regulatory Impact Assessment[2] as well as in the documents referred to in this Paper.

The Bill would:

- provide for the Secretary of State to issue a code of practice to help prevent health care associated infections, including sanctions for non-observance
- reform the regulation of controlled drugs
- remove the requirement for retail pharmacists to be in personal control of pharmacy sales and introduce different safeguards
- introduce charges for applications from pharmacists to provide NHS services and change the criteria used for assessing the applications
- introduce a new contractual framework for ophthalmic services
- create a new organisation, with a wider remit, to replace the NHS Appointments Commission, to be called the Appointments Commission
- provide for auditing the accounts of special health authorities
- transfer responsibility for administering the Social Care Bursary Scheme to an NHS body
- widen the range of cases to be taken into account by the NHS when recovering the cost of treatment from those who have received compensation for injury
- enable the Secretary of State or the Welsh Assembly to transfer criminal liabilities of NHS bodies on their dissolution or abolition to other specified NHS bodies.

Julien Anseau wrote the appendix on MRSA statistics

Dr Kate Haire in the Science and Environment Section of the Library wrote section II on controlled drugs

Jo Roll in the social Policy Section wrote and collated the rest of the paper.

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1 The Health Bill Explanatory Notes [Bill 69-EN]
http://www.publications.parliament.uk/pa/cm200506/cmbills/069/en/06069x--.htm

2 The Health Bill Partial Regulatory Impact Assessment:
http://www.dh.gov.uk/PublicationsAndStatistics/Legislation/RegulatoryImpactAssessment/RegulatoryImpactAssessmentArticle/fs/en?CONTENT_ID=4121917&chk=sUauD/

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I Prevention and Control of Health Care Associated Infection (HCAI)

Part 2 of the Bill (clauses 13-15)

1. Introduction

Following years of government initiatives, newspaper headlines and official reports that the problem had not been solved, in 2005 health care associated infections became a General Election issue. Much of the attention focused on MRSA (Methicillin-Resistant Staphylococcus Aureus), which is often used as shorthand or proxy for health care associated infections in general. But as it is only one of many such infections, the focus on MRSA has also been criticised and measures in the Health Bill currently before Parliament refer to "healthcare associated infections" not just to MRSA.

A scientific issue reduced to headlines about "superbugs" and treated as a political football during a General Election did attract some derision. However, underlying the publicity was the essential issue that health care settings are places where people go to be treated or nursed, not to become infected or, at worst, to die from the infection. Where MRSA and certain other infections are concerned, there is the added issue that the bacteria are resistant to the antibiotic drugs most commonly used to treat them. This has resulted in a range of views about the best alternative approach or combination of approaches for dealing with the problem, such as cleaner hospital wards, ward practices such as hand-washing, lower bed occupancy rates or greater use of isolation facilities.

The Health Bill currently before Parliament makes provision for the publication and enforcement of a code of practice that will apply to relevant NHS bodies in England (and to cross-border Special Heath Authorities). This paper focuses on the development of these measures but also briefly refers to sources that provide a broader context, including some of the medical and scientific debates on the issue. Appendix 1 of this paper, by Julien Anseau in the Social and General Statistics Section of the Library, provides statistics on MRSA and answers some Frequently Asked Questions relating to the statistics, beginning with *What is MRSA*?

2. The General Election

Health care associated infections were not only a media issue during the General Election;[3] they were also included as a subject in the manifestos of all three major political parties.

The Conservative Party Manifesto, as part of its '*Are you thinking what I am thinking'* theme asked: "I mean, how difficult is it to keep a hospital clean?" and said:

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[3] See, for example, "Superbug stays under cover as politicians wage germ warfare", *Financial Times* 9 April 2005

> In response to local demand, hospitals will have the flexibility to increase the number of individual rooms and invest in infection control teams. We will bring back matron, who will have the power to close wards for cleaning. [4]

The Liberal Democrat Manifesto included the following:

> Labour cannot resist micro-managing how local hospitals and GP surgeries are run. The result? Money wasted, local needs left unmet. Targets get hit but the point is missed. MRSA and other superbugs are allowed to spread, and valuable scanners are allowed to stand idle when patients are trapped on hidden waiting lists for tests.[5]

The Labour Party Manifesto said:

> We will deal with the challenge of MRSA. Infections acquired in hospital are not new. The time to destroy MRSA was in the early 1990s – when only five per cent of the bacteria were resistant to antibiotics. At that time the Tory government did not even keep records about the incidence of MRSA and were forcing hospitals to contract out cleaning services. We were the first government to publish statistics on the problem. Now, thanks to the tough measures we have already taken, including the end to a two-tier workforce for contracted-out cleaning services, MRSA rates are on their way down. But there is still some way to go. We all want clean hospitals, free of infection. We have already reintroduced hospital matrons and given them unprecedented powers to deal with cleanliness and infections in their wards; we shall reinforce this by consulting on new laws to enforce higher hygiene standards. [6]

That the Parties were reflecting a genuine concern is suggested by a YouGov Omnibus poll commissioned by the British Medical Association that took place soon after the Election. Members of the public were asked to prioritise where Government NHS funding should be directed, 'cleaner hospitals' came top out of a list of 10 options. The BMA survey was conducted by between 17-20 June and 2009 people were questioned. A press release issued by the BMA gave the following details about the question and answer:

> *Below is a list of possible ways in which the government might spend money on improving the NHS. Please indicate for each one, how important it is to you personally. Please give each item a score from 0 to 10 where 0 is "wholly unimportant" and 10 is "very important".*
>
> The list of options provided to respondents and how they rated them is below:

Cleaner hospitals	9.23/10
Improved A&E	8.52/10
Shorter waits for out-patients app	8.42/10

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4 http://www.conservatives.com/pdf/manifesto-uk-2005.pdf

5 Liberal Democrat General Election 2005 Manifesto for Health http://www.libdems.org.uk/media/documents/policies/HealthManifestoWord.doc; see also http://www.libdems.org.uk/media/documents/policies/manifesto2005.pdf

6 Labour Party General Election Manifesto 2005, Britain, Forward not back: http://www.labour.org.uk/fileadmin/manifesto_13042005_a3/pdf/manifesto.pd

Research into new treatments	8.35/10
More funds for prevention	8.07/10
Better out of hours care	7.89/10
Expanded family doctor (GP) services	7.83/10
More time with doctor	7.26/10
Better hospital food	6.51/10
Choice of where to have an operation	6.43/10[7]

3. The Problem Persists Despite a Range of Measures

The problem of healthcare associated infections and the measures taken to deal with them have been described in many places. The Public Accounts Committee's report summarised below was based on a more detailed report published in 2004 by the Comptroller and Auditor General,[8] which was in turn charting progress since another report of the Comptroller and Auditor General published in 2000.[9]

In the last year alone a number of bodies have published overviews of the issue and the NHS National Electronic Library for Health has recently produced a list several pages long of relevant policy documents and commentaries on the problem.[10] Examples include: the Welcome Trust, which devoted one of its "Focus" documents to the subject of antibiotic resistance;[11] the Parliamentary Office of Science and Technology (POST) published a Postnote on infection control in health care settings;[12] the King's Fund, which produced a briefing on MRSA;[13] and the Health Protection Agency, which monitors levels of infection, has produced several information leaflets for patients in addition to its practical guidance.[14]

Most of the measures that already exist involve the provision of information, education materials and self regulation although there are some legislative requirements that are relevant. In particular, the health care standards that are issued under the *Health and*

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7 'Cleaner hospitals' – more important to patients than choice British Medical Association Press release, 26 June 2005: http://www.bma.org.uk/ap.nsf/Content/PressconfARM05?OpenDocument&Highlight=2,YouGov

8 National Audit Office, *Improving patient care by reducing the risk of hospital acquired infection: A Progress report,* Report by the Comptroller and Auditor General, HC 876 of 2003-4, July 2004:

9 National Audit Office, *The Management and Control of Hospital Acquired Infection in Acute NHS Trusts in England, Report by the Comptroller and Auditor General*, HC 230 Session 1999-00, 17 February 2000: http://www.nao.org.uk/publications/nao_reports/9900230.pdf

10 NHS Electronic Library: http://libraries.nelh.nhs.uk/healthManagement/viewResource.asp?categoryID=4031&dg=62&uri=http%3A//libraries.nelh.nhs.uk/common/resources/%3Fid%3D70098

11 Welcome Trust, *Antibiotic Resistance: an unwinnable war?* July 2005 http://www.wellcome.ac.uk/assets/wtx026231.pdf

12 Parliamentary Office of Science and Technology, *Infection control in healthcare settings*, POSTNOTE, July 2005: http://www.parliament.uk/documents/upload/postpn247.pdf

13 King's Fund Briefing, *MRSA,* April 2005: http://www.kingsfund.org.uk/news/briefings/mrsa.html

14 Health Protection Agency: http://www.hpa.org.uk/infections/topics_az/hai/menu.htm
Monitoring surgical wound for infection: http://www.hpa.org.uk/infections/topics_az/surgical_site_infection/patient_info.htm
MRSA (first edition) http://www.hpa.org.uk/infections/topics_az/staphylo/mrsa_leaflet.htm

Social Care (Community Health and Standards) Act 2003, which NHS bodies are required to meet do include action to prevent health care associated infection. The standards cover several domains. Health care associated infections feature under 'safety' and under 'environment'. In particular Core Standard C4(a), which relates to safety, requires that:

> Health care organisations keep patients, staff and visitors safe by having systems to ensure that the risk of HCAI to patients is reduced, with particular emphasis on high standards of hygiene and cleanliness, achieving year-on-year reductions in MRSA.[15]

Under the 2003 Act, health care standards are subject to inspection by the Healthcare Commission, a body set up under the Act as the Commission for Healthcare Improvement (CHAI) but generally referred to as the Healthcare Commission and to enforcement action by the Secretary of State (Monitor/the Regulator in the case of NHS Foundation Trusts). This includes the power to require specific actions to be taken within a specified timescale and could ultimately involve the removal or suspension of directors or boards.

A list of the specific measures already taken that were singled out by the Government in July is set out below. The document's message, however, was that despite some signs of improvement, more needed to be done:[16]

- A new national target to halve MRSA bacteraemias (blood infections) in acute trusts by March 2008.
- Ensuring that infection control remains a high priority for Trust Boards, e.g., all trusts should now have a Director of Infection Prevention and Control reporting directly to the Board. These directors will publish their first annual reports on infection control in their trust in summer 2005.
- A rapid review panel set up to assess new products with the potential to reduce HCAIs has reviewed over 100 products so far.
- An improvement package of key measures, to support local delivery and reduce the risk of infection, 'Saving Lives', was published on 16 June 2005 and is being disseminated to all NHS trusts.
- Three NHS trusts are setting up a trial of a new two hour test for MRSA screening. Early results will be available by the end of 2005 and will show if these methods can be used to improve patient care.[17]

The Public Accounts Committee report in June 2005 also concluded that existing measures to deal with the problem were inadequate. It particularly blamed the lack of evidence on the impact of different intervention strategies and, at Trust level, a conflict with other key targets and priorities. Its summary is reproduced below:

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15 Department of Health, *Standards for Better Health*, July 2004. This not only lists the standards but also explains the performance framework that applies to the NHS: http://www.dh.gov.uk/assetRoot/04/08/66/66/04086666.pdf

16 Department of Health, Action on Health Care Associated Infections in England, 15 July 2005, Foreword by the Patricia Hewitt, Secretary of State for Health: http://www.dh.gov.uk/assetRoot/04/11/53/06/04115306.pdf

17 Department of Health, Action on Health Care Associated Infections in England, 15 July 2005, paragraph 17: http://www.dh.gov.uk/assetRoot/04/11/53/06/04115306.pdf

The best available estimates suggest that each year in England there are at least 300,000 cases of hospital acquired infection, causing around 5,000 deaths and costing the NHS as much as £1 billion. In 2000, our predecessor Committee drew attention to the serious impact on patients of the NHS' lack of grip on the extent and cost of hospital acquired infection, such that it was difficult to see how the Department and NHS trusts could target activity and resources to best effect. They concluded that a root and branch shift towards prevention was needed at all levels of the NHS, requiring commitment from everyone involved and a philosophy that prevention is everybody's business, not just the specialists.

The Department told the Committee that it accepted that the incidence of hospital acquired infection could be reduced significantly with associated cost savings and that a wide range of action was already in hand to achieve this. Indeed they stated that tangible measurable progress was already being delivered. Given such a categorical assurance the Committee expects the Government to meet it.

On the basis of a follow-up Report by the Comptroller and Auditor General, the Committee examined the progress made by the Department of Health and NHS trusts in reducing the risks of hospital acquired infection. We found that progress in implementing many of our predecessor's recommendations had been patchy, and that there was a distinct lack of urgency on several key issues such as ward cleanliness and compliance with good hand hygiene; and limited progress in improving isolation facilities or reducing bed occupancy rates. Progress in preventing and reducing the number of such infections continues to be constrained by a lack of robust data, limited progress in implementing a national mandatory surveillance programme and a lack of evidence of the impact of different intervention strategies.

Rather than introduce mandatory national surveillance of all hospital acquired infections, as recommended by our predecessors, the Department focused on mandatory laboratory reporting of Methicillin resistant Staphylococcus Aureus (MRSA) bloodstream infections from April 2001. This surveillance, which covers less than 6% of infections, shows that the total number of reported Staphylococcus aureus bloodstream infections has increased by 5% over the last three years, and that the proportion of these infections that is MRSA, at 40%, is amongst the worst levels in Europe.

Following our predecessor Committee's 2000 Report, the Department issued guidance and initiatives which emphasised the priority to be given to infection control, but at trust level conflicts with other key targets and priorities have continued to stand in the way of improving prevention and control. Since publication of the Comptroller and Auditor General's 2004 follow-up report, however, Health Ministers have made it a top priority for NHS hospitals to improve cleanliness, and to lower both healthcare acquired infection and MRSA rates. In particular, they have introduced a target for all NHS trusts to reduce MRSA bloodstream infection rates by 50% by 2008; and established a "Towards Cleaner Hospitals and Lower Infection Rates Programme Board", chaired by the Chief Nursing Officer, with representatives from key stakeholders to drive through the much needed improvements.

Whilst these initiatives may also impact on infections other than MRSA, they do not target the broader issue of multi-drug resistant infections which have a wide range of risk factors and which require specific interventions other than improved

> cleanliness. It is also not yet clear how the 80% or so infections not covered by the Department's current mandatory surveillance programme will be measured and consequently managed.[18]

In the light of these apparent failings, there appears to be a good deal of uncertainty over the extent to which health care associated infections can in fact be avoided. A review of some of the literature is contained in the Partial Regulatory Impact Assessment (RIA) on the current Bill, which reports wide variations in the extent to which infection rates have been reduced by particular interventions. The RIA quotes the figure of 15% given in the National Audit Office Report (on which the Public Accounts Committee Report was based) but says that "currently experts consider the avoidable figure to be in the range 15-40%" and that a more determined approach in England could do more to reduce health care associated infections than current policies would:

> Although not conclusive there is good reason to believe from the literature and the field that where infection control is implemented and maintained in a determined manner, with effective leadership, corporate support and with clinical directorates taking responsibility and conducting appropriate audit, then significantly higher reductions in infection rates can be obtained than in the absence of such factors. This, in turn, strongly suggests that a statutory code will provide significantly higher infection rate reductions than relying on the current status quo arrangements.[19]

4. The Decision to Legislate for Hygiene

Suggestions that the Government might introduce legislation to tighten controls on health care associated infections predate the General Election. John Reid, who was Secretary of State for Health just before the Election, announced on 7 March 2005 that he was considering legislation on health hygiene in hospitals, nursing homes and care homes[20] and newspaper reports at the time suggested that the Chief Medical Officer, Sir Liam Donaldson, had advocated bringing in legislation to combat infection in hospitals several months before.[21]

Although based on a leaked report, the articles were in keeping with previous published reports of the Chief Medical Officer, which had been advocating "intensified control measures" for several years.[22] In particular, his *Winning Ways*, published by the

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18 HC Committee of Public Accounts, *Improving patient care by reducing the risk of hospital acquired infection: a progress report,* Twenty-fourth Report of Session 2004-5 HC 554 of 2204/5: http://www.publications.parliament.uk/pa/cm200405/cmselect/cmpubacc/554/554.pdf

19 Partial Overarching Regulatory Impact Assessment for the Health Bill, Annex 2 paragraphs 30 and 34: http://www.dh.gov.uk/assetRoot/04/12/19/32/04121932.pdf

20 "Reid considering legislation on health hygiene in hospitals, nursing homes and care homes" Department of Health Press Notice 7 March 2005, 2005/0097 http://www.dh.gov.uk/PublicationsAndStatistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4105564&chk=0HXdeS

21 "MRSA: they were warned last year and did nothing" Daily Telegraph, 8 March 2005; and "Health Secretary denies he ignored MRSA memo" Daily Telegraph, 9 March 2005

22 *Getting Ahead of the Curve*, Chief Medical Officer, Department of Health, 2002: http://www.dh.gov.uk/assetRoot/04/06/08/75/04060875.pdf

Department of Health in December 2003,[23] said that the Government had invested "substantial sums in improving the patient environment" but concluded that despite the extent of the guidance issued to the NHS, there had been little improvement. His list of the main aspects of the problem is reproduced below:

> - infection of patients during their care and treatment is common and in some cases lifethreatening;
> - whilst the problem is world-wide, the NHS in England does not perform as well as some other European countries;
> - evidence-based countermeasures of known effectiveness are not being implemented consistently or rigorously in the majority of hospitals;
> - escalating antibiotic resistance is making many infections very difficult to treat;
> - the emergence of strains of multi-resistant bacteria ('super-bugs') – three in particular: MRSA, ancomycin resistant enterococci, penicillin resistant Streptococcus pneumoniae – pose particularly high risks for some patients;
> - insufficient past emphasis on surveillance has meant that good information (the cornerstone of infection control) has not been available to clinical teams or patients.[24]

A press briefing from Prime Minister's Official Spokesman on MRSA on 8 March 2005 appeared to confirm the newspaper reports but said that the Government was not ignoring the Chief Medical Officer's recommendation; it would go further and include nursing and residential homes as well as hospitals. The briefing said:

> Asked why the Government had ignored the proposals of Liam Donaldson with regards to MRSA, the PMOS said that far from ignoring the recommendations, the Government was taking forward those proposals for a Hygiene act, one that went further than originally anticipated, covering Nursing Homes and other residences. John Reid held a meeting yesterday with the regulators to develop that further. Far from ignoring the issue the Government was taking it forward. It took time to implement the decision because of all the regulations involved and because the Government was widening the scope of the institutions it applied to. MRSA was not going to be beaten by one single measure, but it would be beaten by a range of measures. There was an impressive list of measures the Government had taken.[25]

Following the Election, the Queen's speech on 17 May 2005 confirmed that the Labour Government would bring in measures to deal with hospital hygiene. It said:

> Measures will be brought forward to introduce more choice and diversity in healthcare provision and to continue to improve the quality of health services and hospital hygiene.[26]

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23 http://www.dh.gov.uk/assetRoot/04/06/46/89/04064689.pdf

24 http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPAmpGBrowsableDocument/fs/en?CONTENT_ID=4095070&MULTIPAGE_ID=4879066&chk=xrcu82

25 http://www.number-10.gov.uk/output/Page7275.asp

26 http://www.publications.parliament.uk/pa/ld199900/ldhansrd/pdvn/lds05/text/50517-01.htm

In the debate on the address, Patricia Hewitt, the newly appointed Secretary of State for Health, referred to a health protection and improvement Bill to cut MRSA infection rates and to raise standards of hygiene in hospitals. After describing some of the measures already taken, she said:

> However, there is no doubt that we need to do more, so the new Bill will ensure that every hospital and care home pays proper attention to the need for the best possible hygiene and infection control. It will establish a statutory code of practice, improved inspection arrangements and, as a last resort, appropriate sanctions in both the NHS and the independent sector, including care homes.[27]

5. The Decision not to Introduce Criminal sanctions

In the months after the General Election and before publication of the consultation document on the code of practice that is the subject of the current Bill, media reports suggested that the Government was considering the introduction of new criminal penalties in order to enforce hygiene standards in hospitals. In May, Patricia Hewitt, the new Secretary of State for Health, was quoted as saying that the Government was "looking at'" holding hospital bosses criminally responsible for bugs such as MRSA,[28] and in June, Jane Kennedy, Minister at the Department of Health responsible for public health, was reported to have said that proposals due to go out for consultation later in the year might include the option of bringing criminal charges against hospital trusts where their failure to follow Government guidance led to deaths.[29]

When the consultation document on a statutory code of practice, *Action on Health Care Associated Infections in England*[30] was published in July, the accompanying press notice announced the Government's decision not to introduce criminal sanctions:

> The Government has considered introducing possible criminal sanctions for breaches of the new code but the powers of intervention that currently exist for the SofS and Monitor to take action in the NHS, including dismissal of Boards and individual members, are powerful enough to ensure improvement. The Govt has therefore decided to reject the option of introducing new criminal sanctions in the case of breaches of the code. The real driver for taking action will be the improvement orders issued by the Commission, It is only in truly exceptional circumstances that a case would require use of further sanctions.[31]

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27 HC Deb 24 May 2005 c574: http://www.publications.parliament.uk/pa/cm200506/cmhansrd/cm050524/debtext/50524-11.htm

28 "Hospitals could face MRSA charges" BBC News Online, 15 May 2005: http://news.bbc.co.uk/1/hi/uk/4549011.stm

29 "Hospitals face prosecution over MRSA" Times Online, 23 June 2005: http://www.timesonline.co.uk/article/0,,2-1665878,00.html

30 Department of Health, *Action on Health Care Associated Infections in England*, 15 July 2005: http://www.dh.gov.uk/assetRoot/04/11/53/06/04115306.pdf

31 "Government launches hygiene code of practice for consultation," Department of Health Press Notice 2005/0247, 15 July 2005: http://www.dh.gov.uk/PublicationsAndStatistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4115403&chk=0KoNlw

The decision not to create new criminal powers in the Health Bill was highlighted by the newspapers. For example, the Times began its report: "Hospital chiefs who fail to get a grip on MRSA and other hospital superbugs may be dismissed but they will not face criminal prosecution, the Government said yesterday"[32] and the Guardian began: "Ministers have backed off from a threat to prosecute hospital managers who fail to ensure that staff follow a legally binding code designed to stop the spread of superbugs.[33]

The Government's arguments against criminal sanctions were set out in the consultation document:

> The Government has also considered whether to introduce a new power for the HC to take criminal proceedings against those trusts which fail to give effect to the Code of Practice following an improvement notice. There are two apparent attractions to doing this. Firstly, it would introduce a similar approach to that currently applying to the independent health care and care home sectors. Secondly, the threat of criminal sanctions might help to encourage compliance.
>
> But introducing new criminal sanctions to apply to the NHS poses significant difficulties.
>
> First is the problem of false expectations of how and when criminal sanctions might be used. There is a real danger that they would be seen as representing a means to bring to book those whose actions or inactions could be responsible for fatalities and outbreaks. The existence of criminal penalties is bound to be associated with individual often tragic, and often well-publicised cases. In such circumstances there may well be an expectation that criminal sanctions must apply. However, any new offence would relate to the provisions of the Code and whether they were being implemented. There may therefore be no clear link between individual cases of infection and the scope for applying criminal sanctions. Not only would determining whether an organisation was in breach of the Code's provisions necessarily involve a long process, at the end of it there could be no certainty that criminal sanctions could be applied because either there was no initial breach or because, following the improvement order, matters had been put right.
>
> Secondly, while at face value it is attractive to introduce similar penalty structures for both the NHS and the independent sectors, this would require the establishment of a new offence, or range of offences, and the setting of a penalty or range of penalties for breaching the new requirements. If these were to be set at a level to act as a real disincentive for health care organisations, then the resulting large fines would have the effect of removing substantial resources from patient care.
>
> Thirdly, to give new prosecution powers to the HC would change the relationship between them and the NHS, which is in large part based on one where the Commission's role is to encourage improvement rather than to prosecute failure. Although the HC already has powers to recommend special measures where it

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32 "New regime to tackle superbugs" The Times 15 July 2005

33 "Ministers will not make dirty hospitals a crime" Guardian 15 July 2005

> sees fit, it does so sparingly. The Commission also relies heavily on self-assessment. There is a real risk that the possible use of criminal prosecutions would encourage failure to disclose and would result in a perverse incentive to drive safety underground. This would also run counter to the Government's patient safety policy, which encourages open reporting of errors and incidents so that lessons can be learned without fear of unjust persecution of individuals.
>
> We therefore believe that, while criminal sanctions are a means of ensuring compliance where no other means of directing action are available, the powers of intervention that currently exist for the NHS are a more powerful and more effective tool to ensure improvement in the quality of care for, and the safety of, individual patients. We have therefore decided to reject the option of introducing new criminal sanctions in the case of breaches of the Code.[34]

The decision not to introduce new criminal sanctions in the Health Bill does not necessarily mean that criminal sanctions in relation to health care associated infections might not be possible under existing laws, such as manslaughter or health and safety. Proposed legislation on corporate manslaughter might also be relevant. *NHS Employers* (which represents all NHS organisations in England in their roles as employers) has suggested that the standard of proof required by the current proposals would mean that it would be difficult, although not impossible, to conceive of cases where it might apply in the NHS.[35] The Home Office consultation document issued in March 2005 on a draft corporate manslaughter Bill said that NHS Trusts would be included in principle:

> The main driver for reform has been the difficulties identified in the prosecution of companies, particularly large corporations, under the current laws relating to gross negligence manslaughter. The new offence will follow the current law in applying to all corporate bodies. This includes companies incorporated under company law as well bodies, primarily in the public sector, that are incorporated under statute or Royal Charter. These include local authorities, NHS trusts and many Non-Departmental Public Bodies.[36]

6. The Bill (Clauses 13-15)

Following the four broad categories set out in the consultation document on the statutory code of practice,[37] the Bill contains four principle elements:

- A power for the Secretary of State to publish a new statutory Code of Practice;
- A duty on NHS bodies to comply with the Code of Practice, with a parallel duty on the part of the Healthcare Commission to assess compliance;

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34 Department of Health, *Action on Health Care Associated Infections in England*, 15 July 2005, paragraphs 34-39: http://www.dh.gov.uk/assetRoot/04/11/53/06/04115306.pdf

35 http://www.nhsemployers.org/docs/tmp/corporate_manslaughter.pdf

36 Home Office, Corporate Manslaughter: *The Government's Draft Bill for Reform, Cm 6497,* http://www.parliament.uk/documents/upload/DraftBillCorporateMan.pdf

37 Department of Health, Action on Health Care Associated Infections in England, 15 July 2005: http://www.dh.gov.uk/assetRoot/04/11/53/06/04115306.pdf

- Power for the Healthcare Commission to issue an improvement notice on non-compliant bodies;
- Enforcement action through use of the existing intervention powers of the Secretary of State and Monitor (for NHS Foundation Trusts).

These provisions relate to English NHS bodies other than Strategic Health Authorities (which are primarily overview bodies rather than direct providers of services) and to cross-border Special Health Authorities. (Special Health Authorities are health organisations that provide a health service to the whole of England not just to a local community; cross-border ones do not just cover England and may cover one or more additional UK country, for example, the NHS Blood and Transplant, which has a UK-wide remit). The Bill does not apply to NHS bodies that are exclusively in Wales, Scotland or Northern Irelands.

The code itself is not in the Bill. There is a draft in the consultation document and also in the Partial Regulatory Impact Assessment, which says that the code is currently being revised in response to consultation suggestions.[38] The purpose of the code is to set out requirements by which NHS bodies should ensure that patients are cared for in clean, safe environments, whether the risk of Health Care Associated Infection is kept as low as possible, and where staff demonstrate good practice in infection control.[39]

As explained in the consultation document, the Bill does not cover independent health care organisations or care homes although the Government has expressed the intention of applying similar measures to cover such bodies, both of which are regulated under the *Care Standards Act 2000* (as amended). The consultation document said:

> Where appropriate it is proposed that the principles and procedures established in the Code should be introduced into regulations under the CSA [*Care Standards Act 2000]*. It is not possible to establish the full scope of the new regulations at present since the Code itself is subject to this consultation. However, there will be a full formal consultation on any changes to CSA Regulations introduced to effect the provisions of the Code of Practice.[40]

The Regulatory Impact Assessment identified six man categories of potential benefit from the proposed statutory code. These included greater certainty about action to be taken for tackling health care associated infections, particularly if the code rationalises and summarises existing guidance; raising the issue up the NHS agenda; providing reassurance to the public ; financial savings to NHS hospitals by reducing the level of health care associated infections; benefits to patients through reduced mortality and morbidity; reduced litigation costs through reduced premiums in the clinical negligence scheme for Trusts.

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38 Partial Overarching Regulatory Impact Assessment for the Health Bill, Annex 2: http://www.dh.gov.uk/assetRoot/04/12/19/32/04121932.pdf

39 As above, paragraph 15.

40 Department of Health, Action on Health Care Associated Infections in England, 15 July 2005, paragraph 42: http://www.dh.gov.uk/assetRoot/04/11/53/06/04115306.pdf

The Regulatory Impact Assessment examined three options: one to deregulate and halt inspection and monitoring; a second to rely purely one existing guidance and legislation and a third to introduce legislation of the kind contained in the Bill. Its resulting summary of the costs and benefits of the different options (in paragraph 95)is reproduced below:

Summary costs and benefits table		
Option	**Total benefit per annum: economic, environmental, social**	**Total cost per annum: - economic, environmental, social policy and administrative**
1 deregulate	• £90k saving for Healthcare Commission. • £25k saving for HPA. • Possible £1m saving on regulatory burden on NHS Trusts.	• Continuation of expenditure of £1bn by NHS Trusts to treat HCAIs. • Continuation of current patterns of deaths and morbidity.
2 status quo	• £200m savings to NHS Trusts from reducing HCAIs. • 7420 QALY benefit from reduced deaths and morbidity. • Possible £4m saving from reduced premium payments to CNST. • Limited public reassurance on patient safety.	• £100m annual investment in infection control. • Possible £2m on extra spending on Trust cleanliness.
3 statutory code	• £300m savings to NHS Trusts from reducing HCAIs. • 11,130 QALY benefit from reduced deaths and morbidity. • Possible £10m savings from reduced premium payments to CNST. • More pronounced public reassurance on patient safety.	• £150m annual investment in infection control. • Possible £4m on extra spending on Trust cleanliness. • £3.3m (high estimate) extra cost on the Healthcare Commission. • £34m (high estimate) extra cost of regulatory burden on NHS Trusts.

The clauses on *Prevention and Control of Health Care Associated Infection,* would all either add new sections to or amend the *NHS Community Health and Standards Act 2003*. Overall, they build on and use the existing regulatory framework rather than creating a new one. The Explanatory Notes to the Bill provide a detailed account of each clause. The account below is therefore simply a broad outline of the main provisions.

Clause 13 would add three new sections to the 2003 Act relating to the proposed code of practice:

One of these would give the Secretary of State power to issue the code of practice and contains related provisions, for example, that the code can cover staff and visitors as well as patients and that it can be revised. It would cover health care provided by or for English NHS bodies, other than Strategic Health Authorities, and cross-border Special Health Authorities.

Another new section would require the Secretary of State to consult "such person as he considers appropriate" when preparing a draft code and when issuing a revised code that results in a substantial change.

The third new section requires the relevant NHS bodies to observe the code in discharging their existing duty of quality, to "put and keep in place arrangements for the purpose of monitoring and improving the quality of health care that they provide". This says explicitly that failure to observe the code does not of itself make a person liable to criminal or civil proceedings but that it is admissible in evidence.

Clause 14 would amend existing provisions in the 2003 Act in order to place a duty on the Healthcare Commission to consider observance of the code when carrying out the various reviews and investigations that it makes as part of its existing functions, including its annual review. These are made under various sections of the 2003 Act, such as 50 (annual reviews), 51 (reviews), 52 (reviews and investigations). It would also be given the power to advise the Secretary of State about changes to the code.

Clause 15 would insert two new sections in the 2003 Act, one to give the Healthcare Commission power to issue a new *improvement notice* and one to deal with the consequences of issuing an *improvement notice*.

The power to issue an improvement notice would apply where the Healthcare Commission was of the opinion that the code was not being observed "in any material respect". "Material respect" is not defined but the Bill's Explanatory Notes suggest that this would include any failure to observe the code that, in the Healthcare Commission's view, could compromise the NHS organisation's ability to ensure health care associated infections are appropriately tackled.

The power to issue an *improvement notice* only applies where the Healthcare Commission is not required to make a report about failings to the Secretary of State or the Regulator under existing provisions (section 53 of the 2003 Act). These require the Healthcare Commission to produce a report where it is of the view that there are "significant failings" in the provision of health care, in the running of the organisation concerned or the practice of any individual providing health care in one of the relevant organisations. Such reports can recommend "special measures" to remedy the problem.

The Bill's Explanatory Notes describe how "significant" failings in relation to the proposed code could be the subject of reporting under the existing provisions. The 2003 Act does not define a "significant failing" but the Explanatory Notes describe some of the factors that might be involved. For example: "significant failings" could include (but are not limited to) a failure that endangers the lives of patients or the viability of the organisations concerned. Similarly the 2003 Act does not define "special measures" but the Explanatory Notes say that they may include practical assistance or organisational support. In addition a report about a failing under the 2003 Act could lead to intervention by the Secretary of State using powers of direction or intervention under the NHS Act 1977 or by the Regulator under the 2003 Act.

Under the terms of this clause of the Bill, if the Healthcare Commission did issue an *improvement notice*, it would have to inform the Secretary of State (or the Regulator in the case of NHS Foundation Trusts) and the relevant Strategic Health Authority (in the case of a Primary Care Trust or an MHS Trust). The Bill also makes various other related provisions, for example, about the contents of an *improvement notice*, which would

include setting a period of time by which the breach of the code would have to be remedied.

The new section on the consequences of an *improvement notice* would give the Healthcare Commission power to extend the time for remedying the breach specified in the notice if the organisation concerned requested it but only where it considered that there were exceptional circumstances. The Commission must carry out a review under existing powers in the 2003 Act (section 52) into whether the organisation has complied with the *improvement notice*. Following such a review, there would be two possible types of report and in both cases a copy of the report would have to be sent to the relevant Strategic Health Authority where the organisation concerned is a Primary Care Trust or NHS Trust.

Where Commission was of the view that the NHS organisation had not observed the relevant provision of the code in any "material respect" and that there were now "significant failings", then it would have to make a specific 'failings' report under section 53 of the 2003 Act to the Secretary of State or the Regulator, who, as mentioned above, already have various powers to take action, which could, for example, involve inviting in a Director from another Trust to act as a training advisor or, in more extreme circumstances, dismissing the directors. [41]

Where the Commission did not think that there were "significant failings", it would still have report to the Secretary of State or the Regulator under provisions in this clause explaining whether it was of the view that the relevant provisions of the code were being observed or not and give its reasons. Where its view was that the relevant provision were not being observed in any respect (material or otherwise) it would have to also explain why it did not think that a 'failings' report under section 53 was necessary and set out any action it proposed to take.

7. Other countries of the UK

Apart from the inclusion of cross-border Special Health Authorities, the provisions of the Bill on health care associated infections apply to England only. This section of the paper provides a very brief note on what is happening in other countries of the UK. Given the wide range of measures that have been introduced in England, the aim is not to provide a comprehensive comparison but to focus on a few developments that might help set the provisions on a code of practice in the Health Bill in context.

Northern Ireland: A recent Written Answer given by Sean Woodward, Minister for Northern Ireland, summarises the approach in Northern Ireland:

> Mr. Peter Robinson: To ask the Secretary of State for Northern Ireland what steps he is taking to raise awareness of MRSA in Northern Ireland. [22757]

[41] See also the section on 'The Problem continues Despite a Range of Measures' above.

Mr. Woodward: The Department of Health Social Services and Public Safety is taking steps to raise awareness of MRSA as follows:

- an MRSA patient information leaflet which provides relevant data on the origins, symptoms and treatment of the disease has recently been updated. The leaflet is available throughout the health service and is accessible on the DHSSPS website: www.dhsspsni.gov.uk/publichealth

- an antimicrobial resistance and hand hygiene TV advertising campaign was launched in 2004 and re-run in 2005.The aim of the campaign is to raise awareness of the need for good hand hygiene and also to emphasise the need to reduce the use of antibiotics.

In June the Department launched a consultation document, "A Strategy for Prevention and Control of Healthcare Associated Infections in Northern Ireland 2005–10". This document was issued to the HPSS, patient representatives and the general public. Responses to the consultation are being analysed at present and arising from this a detailed action plan will be launched at a major conference on the subject of infection control which the Department is hosting in Belfast in March 2006.[42]

Scotland:[43] In Scotland it is the responsibility of NHS Quality Improvement Scotland to set standards in order to improve the quality of treatment and care in NHS Scotland, and to monitor subsequent performance against them.

In relation to Healthcare Associated Infection (HAI), NHS QIS (then called the Clinical Standards Board for Scotland) issued 'Healthcare Associated Infection (HAI) Infection Control' standards in 2001. These were developed by the 'Healthcare Associated Infection Reference Group' established by NHS QIS.[44] The performance of NHS Boards against the standards has subsequently been reviewed with corresponding reports published [45]

However, in addition to NHS QIS, there is also the Ministerial Healthcare Associated Infection Taskforce. [46] According to the Scottish Executive the Taskforce does not have primacy over NHS QIS in tackling this issue, rather they work together closely in developing guidance and codes of practice.

In May 2004, the chief Medical Officer in Scotland published a code of practice for the local management of hygiene and health care associated infection. Although this is not

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42 HC Deb 1 November 2005 c1021W

43 Based on Information provided by Jude Payne and Kathleen Robson, Research and Information Group of the Scottish Parliament

44 available at: http://www.nhshealthquality.org/nhsqis/files/HAI%20Infection%20Control.pdf

45 For example see: http://www.nhshealthquality.org/nhsqis/files/HAI%20National%20Progress%20Report%20-%20Sep%202004.pdf .

46 http://www.scotland.gov.uk/News/Releases/2004/01/4952

a statutory code, in the foreword to the code, Malcolm Chisholm, Minister for Health and Community Care, said:

> While the Code of Practice did not develop from specific legislation, it may attract a legal effect through its definition of specific accepted professional practice in this sphere of healthcare provision. Any radical departure from such accepted practice without clear justification might be regarded as a controversial decision within a legal setting. [47]

In addition, Ministers have the power to intervene when there is service failure. Thus, if an NHS Board were to fail to address Health Care Associated Infections through the guidance and the code of practice, Ministers could intervene.

On 14 November 2005, the Scottish Executive announced a mandatory framework for monitoring cleaning across NHS Boards in Scotland together with several other measures aimed at improving standards of cleanliness in Scottish hospitals.[48]

Wales: The Care Standards Act 2003, which covers the functions of the Healthcare Commission, also provides for similar functions to be carried out by the Welsh Assembly and for health care standards to be issued. There is nothing called a code of practice but
in September 2004, Jane Hutt, Health Minister in the Welsh Assembly Government, launched a health care associated strategy for hospitals in Wales and there is an action plan. Developments as at July 2005 are contained in a Circular of the Chief Medical Officer in Wales. [49]

The website of the Chief Medical Officer within the Welsh Assembly Government's website provides an overview of policies to deal with health care associated infections in Wales. For example, it outlines the principal strands to the strategy:

- the organisation and infrastructure of infection control;
- training requirements and their delivery;
- the adoption and implementation of surveillance systems;
- interventions that demonstrably reduce infection.
- the organisation and infrastructure of infection control;
- training requirements and their delivery;
- the adoption and implementation of surveillance systems;
- interventions that demonstrably reduce infection.

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47 Scottish Executive. Health Department (2004) The NHS Scotland Code of Practice for the local management of hygiene and healthcare associated infection (HAI),with covering letter: http://www.scotland.gov.uk/Publications/2004/05/19315/36625

48 Scottish Executive Press Notice, "Action on Hospital Cleaning" 14 November 2005: http://www.scotland.gov.uk/News/Releases/2005/11/14090532

49 Welsh Health Circular, Healthcare Associated Infections: A strategy for hospitals in Wales: Feedback and guidance on action plans: http://www.cmo.wales.gov.uk/content/communications/welsh-health-circulars/54-05-strategy-feedback-guidance-e.pdf

The website also sets out the aims of the strategy:

- all staff will understand the impact of infection and infection control practices to enable them to carry out their personal responsibilities to patients, other staff and visitors and themselves;
- patients will be treated in environments that minimise the risk of infection;
- there are clear management accountability arrangements, with each directorate working with the trust infection control specialist to determine the priorities for action in their area of work;
- Trusts adopt comprehensive surveillance and audit programmes to monitor and direct their infection control programmes.

Further details are on the website.[50]

8. Responses

At the time of writing (November 22 2005), few organisations have published responses to the health care associated infections section of the Bill and responses to the Government's consultation held in the summer have not yet been published on the Department of Health's website.

The NHS Confederation (which represents all types of NHS organisation in the UK) said in its submission on the consultation that it was broadly content with the proposals and agreed that more work needed to be done in order to "beat MRSA". Its main concern was about the proposal that:

> The Healthcare Commission be given powers similar to the H&S Executive to serve improvement notices where Trusts are not compliant with the Code of Conduct. Our concern is that this will be a burden applied to NHS organizations but not the private/independent sector. We would welcome the opportunity to discuss this further to see how we could move towards a "level playing field" particularly given media interest in control of infection issues; any censure applied will be highly detrimental to Trust business.[51]

The Patients Association, which has been campaigning for tougher infection control measures,[52] has said:

> We are particularly pleased to see the four Key Components relating to Health Care Associated Infections. We entirely echo the Health Secretary's view that patients deserve to be treated in a safe environment. We have every faith in the healthcare Commission and feel sure that they will diligently use the powers

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50 http://www.cmo.wales.gov.uk/content/work/communicable-disease/healthcare-associated-infections-e.htm

51 NHS Confederation, September 2005, *Response to Consultation on Action on Health Care Associated Infections in England,* September 2005.

52 See the Patients Association website: http://www.patients-association.org.uk/

> granted to them to ensure that the Codes are properly observed and sanctions imposed if necessary.[53]

The Royal Pharmaceutical Society of Great Britain has said:

> The Society is broadly supportive of the Government's proposals to set out a Ministerial code of practice setting out measures to combat health care associated infections. In 2003, £12 million was allocated to hospitals to recruit pharmacists to ensure the safe and effective use of antimicrobials, an initiative being overseen by the specialist advisory committee on antimicrobial resistance (SACAR).
>
> The Society is keen to ensure that Government recognises the significant investment made on this project and ensures that SACAR's findings are incorporated into any code of practice drawn up by the Secretary of State. The Society is concerned that the funding of this initiative is about to come to an end and says that this runs the risk of undoing the significant work that has been undertaken by pharmacists to manage the use of antimicrobials.[54]

STOP PRESS The responses to the consultation on the code of practice were placed on the Department of Health's website on 24 November 2004:
http://www.dh.gov.uk/Consultations/ResponsesToConsultations/ResponsesToConsultationsDocumentSummary/fs/en?CONTENT_ID=4123671&chk=uxz/Z7

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[53] Patients Association, 7 November 2005, communication to the Library.
[54] Royal Pharmaceutical Society of Great Britain News Release 9 November 2005

II Supervision of management and use of controlled drugs

Part 3, chapter 1 (clauses 16-23)

by Dr Kate Haire, Science and Environment Section

1. Controlled drugs

The *Misuse of Drugs Act 1971* makes provisions for the control of dangerous or otherwise harmful drugs. Section 2 of the Act defines a controlled drug:

> 2(1) In this Act—
>
> (a) the expression "controlled drug" means any substance or product for the time being specified in Part I, II, or III of Schedule 2 to this Act; and
>
> (b) the expressions "Class A drug", "Class B drug" and "Class C drug" mean any of the substances and products for the time being specified respectively in Part I, Part II and Part III of that Schedule;

The Act divides controlled substances into 3 classes A, B, and C. Class A drugs are the most dangerous and include heroin, and cocaine, whilst Class C drugs are considered the least harmful. Schedule 2 of the Act provides a list of the controlled drugs contained in each class.

The legitimate use of controlled drugs is regulated by the Misuse of Drugs Regulations, most recently revised in 2001. The Regulations divide controlled drugs into five schedules of varying degrees of control. Drugs in Schedule 1 have no therapeutic use and are not used in clinical practice. Drugs in Schedules 2 to 5 are all used therapeutically but are subject to differing levels of control according to their perceived addiction potential.

2. The Shipman Inquiry:

In January 2000, Harold Shipman, a GP from Hyde in Greater Manchester, was convicted of the murder of fifteen patients. Subsequently the Shipman Inquiry, conducted by Dame Janet Smith, concluded that he had killed 215 of his patients with doubts being raised over the deaths of a further 45 patients.

In September 2000, the Secretary of State for Health announced that an Inquiry would be held in public under the terms of the Tribunals of Inquiry (Evidence) Act 1921, to investigate the extent of Harold Shipman's unlawful activities. Dame Janet Smith, a High Court judge, was appointed Chair of The Shipman Inquiry. The independent public inquiry began in February 2001, with the public hearings starting in June 2001. The remit of the Inquiry included:

- Investigating the extent of Harold Shipman's crimes

- Enquiring into the performance of the actions and the performance of the statutory bodies, authorities, other organisations and individuals who have the responsibility for monitoring primary care provision and the use of controlled drugs.

- Making recommendations on the necessary provisions to protect patients in the future.

The Inquiry's First Report was published on 19 July 2002 and its Final Report, the Fifth Report on 27 January 2005. In July 2004, the Fourth Report, *The Regulation of Controlled Drugs in the Community*, was published.

3. Shipman Inquiry, Fourth Report

The Inquiry's Fourth Report, The Regulation of Controlled Drugs in the Community, investigated how Harold Shipman was able to obtain such large quantities of controlled drugs and how the system had failed to detect his inappropriate usage.

a. Current regulation

The summary of the Fourth Report included details of the current regulatory system for controlled drugs.

> The principles of regulation have not changed since 1973 when the MDA 1971 [*Misuse of Drugs Act 1971*] and the first set of Regulations made under it came into force. The basic principle is that it is unlawful to possess a controlled drug or to deal with one in any way without authority. Authority is provided by the issue of a licence by the Home Office or is conferred on certain classes of person by statute. For present purposes, the important classes of person who possess such authority are medical practitioners, pharmacists and patients. Medical practitioners, acting as such, are authorised to possess, prescribe, supply and administer any controlled drug for the treatment of organic disease. They may also prescribe some controlled drugs, such as methadone, for the treatment of addiction, although only specially authorised doctors are allowed to prescribe diamorphine, cocaine and dipipanone for the treatment of addiction. Medical practitioners who keep a stock of certain types of controlled drug must keep them in a lockable receptacle and maintain a controlled drugs register (CDR), which is a chronological record of all purchases and supplies of the drugs in question. Pharmacists are authorised to deal with controlled drugs in the course of business, subject to compliance with the Regulations. These impose a duty to maintain a CDR and to keep some types of controlled drugs in a locked safe, cabinet or room. Patients are authorised to possess controlled drugs prescribed for them but cannot lawfully supply them to anyone who is not authorised to possess them.[55]

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[55] Shipman Inquiry, Fourth Report: The Regulation of Controlled Drugs in the Community, Summary: The Legislative Framework, Cm 6249, 15 July 2004

b. Report recommendations

Dame Janet Smith identified serious weakness in the system of regulation of controlled drugs and highlighted the need to introduce a number of changes to strength the system, whilst accepting that no system could be totally immune to fraud.

The recommendations of the Fourth Report were intended to strengthen the statutory requirements relating to controlled drugs and to improve the systems of inspection and monitoring.

The report recommends strengthening current arrangements in four main areas:

- a new integrated, multiprofessional inspectorate to inspect the management of controlled drugs in NHS primary care to replace the existing uncoordinated arrangements for inspection;
- restrictions on the right of GPs to prescribe controlled drugs in certain circumstances, e.g. prescribing for oneself or one's immediate family or prescribing beyond the requirements of one's normal clinical practice;
- strengthened arrangements for auditing the prescribing of controlled drugs in primary care and the movement of supplies of controlled drugs in the community; and
- better information to patients on the special legal status of the controlled drugs which are prescribed for them.[56]

4. Government response to the Fourth Report

In December 2004, the Government published their response to the Fourth Report of the Shipman Inquiry. The Government broadly agreed with the recommendations made in the report but was careful to emphasise that any system of regulation should not be so burdensome that it adversely affected the care of patients who were prescribed controlled drugs. The Government stated that it believed that it would be possible to ensure that all the intended objectives could be met, although the means of implementing the recommendations may be different from those detailed in the Fourth Report.

Key Government proposals included:

> 8. The Government therefore intends to place on each healthcare organisation, both in the NHS and in the private sector, a statutory responsibility to nominate a "Proper Officer" of appropriate seniority, with responsibility for ensuring that the organisation has adequate arrangements for ensuring the appropriate management and use of controlled drugs.

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[56] Safer management of controlled drugs: The Government's response to the Fourth report of the Shipman Inquiry, Department of Health, Home Office, Cm 6434, 9 December 2004

> 9. The Government will also place a corresponding duty of collaboration on other local and national agencies, including professional regulatory bodies, police forces, the National Patient Safety Agency, the Healthcare Commission and the Commission for Social Care Inspection. Essentially, the Proper Officer will act as the central point of a local intelligence network which will detect early signs of poor handling or deliberate misuse of controlled drugs and will agree on appropriate remedial action.
>
> 10. The Government will require the Healthcare Commission to assess the performance of NHS organisations in relation to these responsibilities and to ensure that local networks are working as intended.
> […]
> 13. The Department of Health will work with the healthcare regulatory organisations in this context [the prescribing of controlled drugs] principally the General Medical Council, General Dental Council, Royal Pharmaceutical Society of Great Britain and Nursing and Midwifery Council) to ensure that they have clear and explicit guidance in this area and that there are effective means of enforcing it.[57]

However, the Government decided not to adopt one of the key recommendations in the Fourth Report which recommended the creation of an integrated, multiprofessional inspectorate to inspect the management of controlled drugs. The Government argued that whilst stricter regulation of controlled drugs was necessary this objective could be met in a manner more in line with general government policy on improving quality in the NHS.

> 2.5 However, the Government is not persuaded that setting up a new controlled drug inspectorate, divorced from the other systems which have recently been introduced into the NHS and private healthcare sector, would be the right way forward. As the previous chapter argued, any new arrangements for improving the management of controlled drugs in the healthcare sector should work with the grain of the new initiatives for improving clinical standards more generally. More pragmatically, the chances of detecting a future Shipman will be maximised if information on unusual or poor practice in the prescribing of controlled drugs is combined with information on other aspects of poor clinical practice.
>
> 2.6 As the Inquiry recognised, there are already substantial resources devoted to the inspection of healthcare organisations including in many cases their use of controlled drugs. These include:
>
> - regular inspections of pharmacies by CIOs and inspectors of the RPSGB;
> - inspections of NHS and private hospitals by the Healthcare Commission;
> - inspections of private care homes by CSCI; and
> - routine visits by prescribing advisors to discuss prescribing patterns as well as a range of less formal monitoring and developmental activities both by professional organisations and by NHS management.

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[57] Safer management of controlled drugs: The Government's response to the Fourth report of the Shipman Inquiry, Department of Health, Home Office, Cm 6434, 9 December 2004

But this activity is not systematically coordinated and the available resources are not used to their fullest potential.

2.7 The Government therefore proposes, subject to consultation on the legislative changes needed, to strengthen current arrangements for the monitoring and inspection of the management of controlled drugs as follows:

- at local level, a new statutory responsibility should be placed on each PCT and NHS Trust, Foundation Trust and private healthcare organisation to nominate a specific individual of appropriate seniority – a Proper Officer – who would monitor the use of controlled drugs within the Trust's sphere of responsibility;

- this would be complemented by a duty of collaboration on other local agencies, including the local police force, social services authorities, the National Patient Safety Agency (NPSA) and relevant inspectorates, to share information and intelligence relevant to the assessment of healthcare professionals working for the PCT or Trust

- new audit tools (described in more detail in Chapter 4) would be made available to help PCTs and Trusts discharge these responsibilities;

- for organisations and individuals working purely in the private and voluntary sectors, the Healthcare Commission and CSCI would continue (as now) to be responsible for assessing the management of controlled drugs as part of their regular inspections and for taking appropriate action over any concerns, including de-registration where necessary;

- at national level, an explicit responsibility would be placed on a named individual in the Healthcare Commission for the external review of these arrangements. He/she would be responsible for ensuring that all NHS organisations had satisfactory arrangements in place for assuring the safe use of controlled drugs, for ensuring the satisfactory operation of the local networks, and for alerting Government to any failure by other partners to collaborate fully or to devote adequate resources to controlled drug issues.

This combination of clear local responsibility for action, and national inspection of performance against the required standards, is in line with current arrangements for improving the quality of clinical care in the NHS more generally. It allows for local flexibility to determine the most appropriate arrangements locally with accountability to a national body. The Government believes that this combination will give the best assurance possible against a future Shipman.[58]

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[58] Safer management of controlled drugs: The Government's response to the Fourth report of the Shipman Inquiry, p.16, Department of Health, Home Office, Cm 6434, 9 December 2004

5. The Bill

Part 3 of the Bill details provisions which would strengthen the regulation of controlled drugs and improve the systems of inspection and monitoring. [59]

The intention of the provisions contained in part 3 of the Bill is to provide statutory implementation of proposals contained in the Government's response to the Fourth report of the Shipman Inquiry, *Safer management of controlled drugs*..[60]

a. Accountable officers

Clause 16 relates to the appointment of an accountable officer and provides details of their responsibilities. This new senior executive post was proposed in the Government Response in the Fourth Report of the Shipman Inquiry, although the Report uses the term 'Proper Officer' rather than the term 'accountable officer'.

> To reinforce this principle, the Government proposes to place a statutory responsibility (subject to consultation and Parliamentary approval of the legislative changes needed) on each healthcare organisation to nominate a specific individual – the Proper Officer – to undertake these functions on behalf of the organisation. The Proper Officer would be a senior executive officer of the organisation with appropriate professional standing, normally reporting either directly to the Chief Executive or to another executive director of the organisation; this might be for instance the Director of Public Health (for PCTs) or the Medical Director (for NHS or Foundation Trusts).[61]

The accountable officer would have overall responsibility for management and use of controlled drugs within an organisation. Responsibilities would include arrangements for the management and use of controlled drugs, audit, inspection, the training of staff who work with controlled drugs, and ensuring patient safety. The types of organisation would include NHS Hospital Trusts, Primary Care Trusts and independent hospitals.

b. Co-operation between health bodies

Clause 17 would require health bodies to share information and co-ordinate action in order to ensure safe management of controlled drugs and improved patient safety

c. Powers to enter and inspect

Section 23 of the *Misuse of Drugs Act 1971* contains provisions on law enforcement and the punishment of offences in relation to controlled drugs.[62] It allows the police or other authorised individuals to enter the premises of a person who is a producer or supplier of

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59 For greater detail see *Health Bill*, Explanatory Notes, [Bill 69-EN]

60 Safer management of controlled drugs: The Government's response to the Fourth report of the Shipman Inquiry, Department of Health, Home Office, Cm 6434, 9 December 2004

61 Safer management of controlled drugs: The Government's response to the Fourth report of the Shipman Inquiry, Department of Health, Home Office, Cm 6434, 9 December 2004

62 *Misuse of Drugs Act 1971*, Chapter 38, section 23, Law enforcement and punishment of offences

controlled drugs and to demand access to any books or documents relating to dealings in controlled drugs. It also allows for the inspection of stocks of controlled drugs.

Clause 18 would extend these powers to allow the police or other authorised persons to enter the premises of healthcare providers to inspect the arrangements for the storage, management and use of controlled drugs. Clause 19 creates a new offence for obstructing the individual making the inspection or concealing relevant evidence.

6. Responses

Royal Pharmaceutical Society of Great Britain issued a briefing on the *Health Bill 2005*, which included comment on the provisions contained in Part 3 of the Bill.

> PART 3, CHAPTER 1
> *Supervision of management and use of controlled drugs*
> The RPSGB has actively been involved in work to address many of the issues raised by Dame Janet Smith in Part Four of the Shipman Inquiry. This section of the Bill relates to the need for legislation based on that inquiry.
>
> Following Dame Janet's report, the RPSGB was made to understand that, from April 2006, the routine monitoring and inspection of controlled drugs in community pharmacies was likely to become a role undertaken by the pharmacy inspectorate of the RPSGB. The key advantage that Dame Janet and the Government had identified about moving the RPSGB's inspectorate into this role was that this field-force largely comprises pharmacists with up-to-date knowledge on the legislation, ethics and good practice guidance that govern the profession of pharmacy.
>
> The RPSGB is therefore surprised to see, in Clause 18 of the Health Bill, reference to "a constable or authorised person" being able to enter premises. Given the preparations for the transfer of this role to the RPSGB inspectorate, the RPSGB is keen to receive urgent clarification on this issue.[63]

The British Medical Association's comment is that:

> These clauses contain provisions intended to strengthen the arrangements for the safe management of controlled drugs in healthcare settings, resulting from recommendations contained in the Fourth Report of the Shipman Inquiry (published 15 July 2004).
>
> The clauses place a duty on all NHS and larger private healthcare organisations to appoint an accountable officer to ensure that the organisation has robust arrangements for the safe and effective handling of controlled drugs. In NHS primary care, primary care trusts will exercise this responsibility on behalf of GP practices and other contractors.
>
> The BMA believes there should be a specific requirement to ensure the input of pharmacists to the accountable officers' activities, particular in relation to primary care trusts.

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[63] Royal Pharmaceutical Society of Great Britain, The Health Bill 2005, A pharmacy briefing, online at:: http://www.rpsgb.org.uk/pdfs/TheHealthBill2005brief.pdf

The clauses also place a duty on those organisations concerned with controlled drugs issues in the health sector to share information about controlled drug use by health and social care professionals, and to agree joint action as needed. Police officers, accountable officers and their staff will have a right of entry and inspection into NHS hospitals, GP practices, community pharmacies and other organisations contracted to provide services to the NHS.

Consideration must be given to the confidentiality of patients' personal health information. Information that is being shared must be on a 'need to know' basis. The Regulations must be explicit that the involvement of the police in information sharing does not necessarily imply that criminal proceedings are being contemplated.

The BMA has been calling for the improved monitoring and audit of prescription drugs for many years and broadly welcomes proposals to change the management and regulation of controlled drugs. Much of the detail on how the system will operate and the responsibilities and duties of the accountable officers will be set out in secondary legislation.

The BMA is seeking a commitment from the Department of Health that they will involve the BMA's GP Committee closely in the development of the Regulations and guidance to ensure that the system is workable in practice. [64]

[64] BMA Briefing on the Bill

III Control and Supervision by Pharmacists

Part 3, chapter 2 (clauses 24-30)

1. Background

At the moment retail sale and supply of medicines at every pharmacy must be under the "personal control" of a pharmacist. In addition there is requirement that medicines that are not on the general sales list (GSL)[65] may only be supplied under the "supervision" of a pharmacist. The law covering this is contained in the *Medicines Act 1968* Part 4. It applies to an individual or to a corporate body conducting a retail pharmacy business and to each pharmacy premise from which the business is conducted. There are also related provisions in the *NHS Act 1977*, which apply to England and Wales, and in the *NHS (Scotland) Act 1978*.

The Regulatory Impact Assessment on the Bill provides a description of what the provisions mean:

> The intended effect of the first provision is unclear but has been taken to mean that a pharmacist may only be briefly absent from a pharmacy if the pharmacy is to remain open for business and continue to sell or supply medicines to the public. Debate has cast doubt on this interpretation. In addition, this provision includes the sale of GSL medicines from pharmacies although the sale of these medicines in other retail outlets does not require a pharmacist to be in "personal control" of the premises to maintain public safety. Over the past 40 years, the number and range of medicines on the GSL list has increased without a review of the legal requirement on pharmacies.
>
> The second provision requires a pharmacist to be aware of individual transactions involving the preparation, sale and supply of medicines from the pharmacy. However, again, the law is somewhat unclear as to the precise degree of involvement that a pharmacist needs to have with each individual dispensing transaction in order to supervise it. The courts have suggested – as long ago as 1943 – that given the right technology, a pharmacist's supervision responsibilities could be discharged without the pharmacist being physically present in the pharmacy.

In December 2004, the four UK Health Departments published a consultation document seeking views on possible changes in the law relating to pharmacist personal control and pharmacist supervision.[66] The aim was "to enable all those working in a pharmacy setting - pharmacists, pharmacy technicians, dispensing assistants, counter assistants, and others - to contribute as fully and effectively as possible to patient care". The consultation

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[65] These are the medicines that can be sold safely without the supervision of a pharmacist.

[66] Making the best use of the pharmacy workforce - A consultation paper, Department of Health, December 2004: http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4107811&chk=4EGPO1

closed on 11 March 2005 and the Government's analysis of the responses is available on the Department of health's website.[67]

Although the consultation was about relaxing the control and supervision that pharmacists currently have to exercise, the paper emphasised that proposals for changes rested on the following principles:

- The pharmacist should retain overall responsibility for ensuring that proper procedures are in place in each pharmacy for the dispensing and sale of medicines and that there is adherence to these procedures
- These procedures should include arrangements for checking the appropriateness for the prescription and for providing advice to patients or carers at the time of dispensing or sale of medicines.[68]

The consultation document set out various reasons why the Government considered it necessary to introduce greater flexibility into the current legal framework:

> For a number of reasons, there is a need to take stock of ways in which pharmacists and pharmacy staff can extend and enhance their roles in a modernised, integrated, NHS. These include
>
> - the time it will take to achieve the significant growth in the pharmacist workforce which will result from increases in the number of pharmacy school places and the number of pharmacists in training
> - shortages in the number of qualified pharmacists, placing continuing reliance on locum pharmacists and on pharmacists older than the normal retirement age; and a continuing trend towards flexible and part-time working
> - the development of extended roles for pharmacists in hospitals and in the community, drawing on their professional experience and expertise in areas such as medicines management, prescribing and public health
> - the development of an enhanced role for pharmacy technicians and other pharmacy staff in supporting pharmacists in the delivery of a wider range of pharmacy services in the community and as part of modern hospital services
> - hospital staff skill mix has developed at a pace not matched in the community
> - changes in the dispensing process – for example, advances in technology (such as robotics) and the proposals, announced in England in *A Vision for Pharmacy in the New NHS*, to look at rounding and prescribing in full patient packs.[69]

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67 Department of Health, Summary of Response to Public Consultation on Pharmacy Skill Mix http://www.dh.gov.uk/assetRoot/04/11/46/67/04114667.pdf

68 See Department of Health website: http://www.dh.gov.uk/Consultations/ResponsesToConsultations/ResponsesToConsultationsDocumentSummary/fs/en?CONTENT_ID=4114666&chk=8AFCOJ

69 See above, chapter 1 paragraph 2

The Regulatory Impact Assessment also gives the thinking behind the Government's proposed changes:[70]

> Community pharmacies have the potential to provide a much wider range of NHS services. Pharmacists are an underused resource in releasing that potential. They can support the delivery of more clinical care within the community and increase patient access to the professional advice available in high street pharmacies. In England and Wales, the new contractual framework for community pharmacy, implemented from April 2005, supports community pharmacy in taking on a much wider role as an integral part of the NHS. It is expected that similar changes will be introduced in Scotland and Northern Ireland. [71]

2. The Bill

Provisions in the Bill are UK-wide, as is the *Medicines Act 1968* that it amends, although most of health policy is devolved to the different parts of the UK and further development of the provisions is therefore likely to be at country level.[72] Detailed notes on the clauses are contained in the Bill's Explanatory Notes and further background information and explanation of the changes is provided in the Bill's Partial Regulatory Impact Assessment. This section provides an overview of the changes.

The Bill would remove the current requirements in the *Medicines Act 1968* relating to "personal control" by a pharmacist and substitute new requirements under which there would have to be a "responsible pharmacist", who would have a statutory responsibility for the safe and effective running of the pharmacy business. Some of the new requirements are set out in the Bill and there is provision for Health Ministers to make further provisions in regulations in relation to the responsible pharmacist.

The Government has also said that in addition to the Bill, it proposes to make orders under the existing powers of the *Medicines Act* so as to enable registered and suitably trained staff working in a pharmacy to supervise the preparation, dispensing, sale and supply of medicines, without direct supervision by a pharmacist. The policy intention is that:

> …the pharmacist can use his clinical skills and training to offer a wider range of services, including away from the pharmacy (for example, in health centres and clinics.[73]

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70 Health Bill - partial regulatory impact assessment, 27 October 2005, Annex 4: Pharmacist personal control and pharmacist supervision of the preparation, sale and supply of medicines: http://www.dh.gov.uk/assetRoot/04/12/23/00/04122300.pdf

71 Health Bill - partial regulatory impact assessment, 27 October 2005, Annex 4: Pharmacist personal control and pharmacist supervision of the preparation, sale and supply of medicines: http://www.dh.gov.uk/assetRoot/04/12/23/00/04122300.pdf

72 See the consultation document and the regulatory Impact Assessment Annex 4.

73 Health EN, Bill 69-EN page 23: http://www.publications.parliament.uk/pa/cm200506/cmbills/069/en/06069x--.htm

The Bill would also amend the *Medicines Act* provision relating to supervision by a pharmacist to enable Ministers to prescribe conditions under which an activity would be considered to have been carried out under the supervision of a pharmacist. The Bill's Explanatory Notes say that the policy intention is to clarify the pharmacist's obligation to supervise.

(There is also a consequential change relating to who may dispense medicines change in clause 33, which is in part 4 of the Bill.)

It will be a criminal offence for any person to contravene the new requirements.

The proposed changes are not expected to impose additional costs (beyond the need to keep a record of the responsible pharmacist rather than making an annual return to the Royal Pharmaceutical Society of Great Britain).[74]

3. Responses

The Royal Pharmaceutical Society of Great Britain:

> The RPSGB has long campaigned for changes in working practices in community pharmacies to allow pharmacists to make best use of their skills and expertise for the benefit of the public. The RPSGB welcomes the fact that the Bill addresses many of the issues of concern relating to requirements about supervision and responsibility in a pharmacy.
>
> The Medicines Act currently requires the pharmacist to be in "personal control" of key
> pharmacy functions. This effectively prevents the pharmacist from leaving the pharmacy, even for a short period, during the opening hours of the pharmacy. It also deters appropriate delegation and acts as a barrier to modern working practices. The Bill replaces this requirement with a provision for a 'responsible pharmacist' who will have professional accountability for all processes in the pharmacy. This allows the pharmacist to be temporarily absent from the pharmacy in order to carry out professional duties such as visiting housebound patients, meeting with local GPs, etc. Another provision is for the supervision of certain activities to be delegated to appropriately trained registered pharmacy technicians. Allowing suitably trained and registered staff working in a pharmacy to supervise the preparation, dispensing, sale and supply of medicines, without direct supervision of a pharmacist will help ensure that pharmacists can use their skills and training to offer a wider range of services.
>
> The Bill allows for much of the detail of these changes to be written into Regulations. These detailed Regulations will need careful consideration if they are to deliver benefits while maintaining patient safety. While the RPSGB would prefer to see the new measures set down on the face of the Bill, it will be seeking to be actively involved in the process of drawing up the regulations through which

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[74] Partial Regulatory Impact Assessment Annex 4: http://www.dh.gov.uk/assetRoot/04/12/23/00/04122300.pdf

the obligations of the pharmacist and the framework for responsibility are clarified.

The RPSGB takes the view that the legislation should clearly define those activities that can only be undertaken when the responsible pharmacist is present and should include:

- Clear lines of accountability;
- Provisions for the responsible pharmacists to be contactable when absent and in a position to return without undue delay;
- Provisions for the responsible pharmacist to have to justify any absence from the pharmacy.

The RPSGB has a number of concerns about the wording of this part of the legislation as it stands and will be seeking, at Committee stage, to clarify and amend where necessary. Patient safety is the RPSGB's primary concern and some tightening of the legislation will be required to ensure that proper safeguards are in place.

For example, the RPSGB believes that, under clause 25 on the control of pharmacy premises, it is vital that the responsible pharmacist is responsible for no more than one pharmacy in other than very exceptional cases, such as in an emergency. There could be significant financial incentives that could mean that a loosely-worded or -policed exception could become the rule.

In addition, the RPSGB notes the provisions to allow the responsible pharmacist to remotely supervise in another pharmacy. Again, the RPSGB believes that this level of supervision should only apply in very exceptional circumstances as there is a risk that patient care could be compromised if pharmacists were trying to supervise both the activities in the pharmacy in which they were present and a remote pharmacy.[75]

[75] Royal Pharmaceutical Society , the Health Bill 2005: a pharmacy briefing: http://www.rpsgb.org.uk/pdfs/TheHealthBill2005brief.pdf

IV NHS Pharmaceutical Services

Part 4, chapter 1 (clauses 31-33)

1. Background

Provisions on pharmacy contracts in the current Bill represent the tail end of the reforms that have followed an OFT report on pharmacies published in 2003, which recommended removing some of the restrictions on applications for contracts to dispense NHS prescriptions.[76] The report applied to the UK but as most of NHS policy is devolved, the response has varied in the different countries of the UK. The particular provisions in the Bill relate to England and Wales although Wales has not followed the same path as England in relation to the other changes that have taken place.

Applications to dispense NHS prescriptions (to be on the pharmaceutical list) have to be made under what are known as the 'control of entry regulations'.[77] Under the regulations, applications have to be made to the relevant local body – currently the Primary Care Trust in England and the local Health Board in Wales – which has to decide whether it is "necessary or desirable" that the application be granted.[78] These 'control of entry' requirements are separate from the requirements for registration with the Royal Pharmaceutical Society, with whom all qualified pharmacists have to be registered in order to be able to dispense medicines at all.

Although registered pharmacists can dispense medicines, they cannot dispense NHS prescriptions without an NHS contract and, in practice, according to the OFT Report, most pharmacies are not viable without such a contract. The report said that only around 130 of them (just over one percent) dispensed prescriptions without an NHS contract and that NHS dispensing accounted for a round 80% of a typical pharmacist's revenue.

The report recommended that the 'control of entry' restrictions should be lifted so that any registered pharmacy with qualified staff would be able to dispense NHS prescriptions. The recommendation received a hostile reception from many community pharmacists but appeared to be supported by one or two of the big supermarket chains who had reportedly been lobbying for deregulation.[79] The House of Commons Health Select Committee published a report on the issue, generally opposing deregulation.[80]

The Government gave an initial reaction in March, and announced its full response in July, 2003.[81] It held a consultation on the proposals in autumn 2003,[82] the results of

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76 The Office of Fair Trading (OFT), *The control of entry regulations and retail pharmacy services in the UK* January 2003, http://www.oft.gov.uk/business/market+studies/pharmacies.htm

77 In 2003 these were the "control of entry regulations" for England and Wales were the *National Health Service (Pharmaceutical Services) Regulations SI 1992/662*, which have now largely been replaced in England by the *National Health Service (Pharmaceutical Services) Regulations SI2005/641*

78 The requirement for the "necessary or desirable" test is also contained in the health Act 1977 section 42.

79 See, for example, Polly Toynbee, "Find a new prescription," *The Guardian*, 24 January 2003

80 The Control of Entry Regulations and Retail Pharmacy Services in the UK, Health Select Committee 5th report of 2002/3, HC 571 of 2002/3 http://www.publications.parliament.uk/pa/cm200203/cmselect/cmhealth/571/571.pdf

81 Final Government response to the OFT published July 2003

which were published in August 2004,[83] and new 'control of entry' regulations came into force as part of a wider set of pharmacy reforms in April 2005, which contain various new provisions including an exemption from the "necessary or desirable" test. In summary, these are basically those in large shopping areas; those opening for more than 100 hours a week; those in one stop primary care centres; and distance sellers (internet and mail order pharmacies). [84] These exemptions were not introduced in Wales.

Charges for applications and the role that sales of over-the-counter (i.e. non NHS) medicines should play in the assessment of applications were included in the consultation although the original proposals were slightly different from the measures that have ended up in the Bill. Both were considered to require changes to primary legislation within the *NHS Act 1977* so could not be included in the 2005 regulations. The consultation asked whether to allow:

- charges for pharmacy applications and any appeals arising from PCT decisions on such applications to be introduced; and

- NHS primary care trusts to consider in their assessment of applications what improvements they bring to the provision of, or access to, over-the-counter medicines and other healthcare products.

According to the Bill's Regulatory Impact Assessment,[85] the two questions received fewer responses than most of the other proposals in the consultation. The first proposal received broad support (60 in favour 25 against). PCTs supported the second proposal by a bare majority (16:14) but contractors, their representative bodies and Local Pharmaceutical Committees opposed them by a clearer margin.

The Government also set up an expert advisory group to advise how best to implement the proposals. The group reported in January 2004.[86] The group supported charges for applications but was more equivocal about charges for appeals and the Bill does not include charges for appeals. According to the Regulatory Impact Assessment the Government made that decision so that "there can be no doubt as to financial interests influencing appellate procedure and outcomes. The groups supported the second proposals, that is to include access to over-the-counter medicines within the assessment of applications. However, the proposal has now been modified so that it would apply to competing chemist applications only.

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http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4050949&chk=MhgvsP

82 Proposals to reform and modernise the NHS (Pharmaceutical Services) Regulations consultation document, August 2003
http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4050930&chk=AOGVQW

83 Proposals to reform and modernise the NHS (Pharmaceutical Services) Regulations 2005 summary of responses, http://www.dh.gov.uk/assetRoot/04/08/79/01/04087901.pdf

84 The *National Health Service (Pharmaceutical Services) Regulations SI2005/641*

85 Partial Regulatory Impact Assessment and Competition Assessment; Annex 5 on Implementation of the Government Response to the Office of Fair Trading (OFT) Report on Pharmacy Services
http://www.dh.gov.uk/assetRoot/04/12/19/35/04121935.pdf

86 Advisory Group on the reform of the NHS (Pharmaceutical Services) Regulations 1992 report, January 2004
http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4106288&chk=0Spdsj

The Government held a further consultation in summer 2005 on these proposals:

- to enable reasonable charges, but not full cost recovery, to be introduced for applications concerning a chemist's inclusion on a NHS Primary Care Trust list; and
- to allow NHS Primary Care Trusts to take into account, when assessing applications, the improvements they would bring to the provision of, or access to, over-the-counter medicines and other healthcare products[87]

A summary of the results of the consultation is available on the Department of Health's website.[88] According to the Regulatory Impact Assessment, no changes have resulted from the consultation.[89]

2. The Bill

The Bill provides for two changes. Clause 31 provides for charges to be levied in respect of a chemists' application to a pharmaceutical list and clause 32 provides for regulations to be made authorising a Primary Care Trust (in England) or a Local Health Board (in Wales) to take account of any proposals contained in applications relating to the sale or supply of over the counter medicines and other healthcare products but only where there is more than one application. (Clause 33 would make changes consequential on those in Part 3 Chapter 2 of the Bill, which are discussed in the previous section of this paper.)

The Partial RIA's summary of the costs and benefits of the changes is reproduced below:

	Total cost per annum	Total benefit per annum
Charges	Estimated annual cost to business of up to £450,000 transferred from NHS.	Defrays NHS costs and reduces impact of any increase in costs arising from more applications due to liberalising measures introduced in April 2005. Charging would help deter speculative or "blocking" applications
New criteria for determining applications	Some marginal but unquantifiable risk to smaller businesses. Businesses may conclude they now need to provide a wider range of over-the-counter products and at lower prices they previously were considering not providing.	Applicants able to offer improvements to access and provision of over-the-counter products and advice. NHS able to take these into account where there are competing applications in relation to their plans for local health economy. Resulting benefits to patients and consumers from better quality of services and prices from more competition.

87 Proposals to reform and modernise pharmaceutical services legislation in England consultation document, July 2005 http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4119462&chk=BdXQYA

88 Summary of responses to the above: http://www.dh.gov.uk/assetRoot/04/12/27/64/04122764.pdf

89 Partial Regulatory Impact Assessment and Competition Assessment; Annex 5 http://www.dh.gov.uk/assetRoot/04/12/19/35/04121935.pdf

3. Responses

At the time of writing no responses on these provisions have been received in the Library but the summary of the responses to the consultation carried out in summer 2005 published on 9 November 2005, which in addition to the extracts reproduced below also separates out the views of Primary Care Trusts from those of contractor representatives and contractor bodies:[90]

Charges for application

> The majority of those who responded (17) were in favour of charging for applications as long as the fees were for a contribution towards PCT costs in processing applications rather than full cost recovery. One pharmacy business felt that charges should be refunded if the PCT did not adhere to the normal timetable for dealing with applications. Some contractor organizations felt a refund should be payable for applications which were subsequently successful. Another commentator considered that a flat fee should be charged with an extra fee where an applicant was successful. Others commented that would be fairer if dispensing doctors who applied to provide pharmaceutical services also paid a fee. Two responses advocated charging for appeals – the Government had decided not to pursue this option prior to this consultation.
>
> Those against the proposal felt that the costs for contractors of making and application was high enough already. The majority of those who responded (16) were against having different fees depending on the size of the company on the grounds that this would be discriminatory.
>
> A majority (11 out of 15) who responded considered the fee levels suggested (ranging from £150 - £500 depending on the type of application) were reasonable. Some commentators considered a fee should only apply to applications which involved local consultation prior to the PCT's decision.

Over the counter medicines as a criterion in applications

> Overall, a majority of those who responded (18) were against the introduction of new criteria concerning over-the counter (OTC) medicines to the "control of entry" test. The contractors and contractor organisations who responded were unanimously against this proposal. However, the majority of PCTs who responded were in favour of the proposal. Those who opposed the measure felt that such medicines were outside the scope of NHS pharmaceutical provision and were also sold in other places (such as supermarkets, corner shops etc). Many felt that the reforms already introduced in April 2005 had had an effect on OTC medicine prices and that OTC prices were already competitive. Those who

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[90] Summary of responses to consultation document Proposals to reform and modernise pharmaceutical services legislation in England, Department of Health November 2005 http://www.dh.gov.uk/assetRoot/04/12/27/64/04122764.pdf

were in favour of the proposal felt that it would improve access to OTC medicines, particularly in areas of social deprivation.

The majority of those who commented on monitoring these new criteria felt it would be difficult. Some felt that applicants would promise lower prices, but then would put them up once they had been granted a right to provide NHS services. It would be difficult for PCTs then to take corrective action. One contractor organisation felt that any action on OTC pricing would most likely be challenged by competition legislation. One organisation felt there would need to be a mechanism for determining whether a contractor has failed in its obligation and, if so, to deal with shortcomings. This might be achieved via the new fitness to practise requirements or through monitoring of the new contractual arrangements.

V Ophthalmic Services

Part 4, chapter 2 (clauses 34-40 and schedule 8)

1. Background

At the moment NHS general ophthalmic Services (GOS) are provided by optometrists and ophthalmic medical practitioners who work as independent contractors from High Street opticians. [91] Although the GOS is administered by Primary Care Trusts as part of the Family Health Service, optical contractors are engaged under a uniform national contract. Funding is provided from the national demand led or non-discretionary budget, and is not subject to local resource limits and does not form part of a PCT's HCHS discretionary allocation.[92]

The GOS offers priority groups of patients free NHS sight tests or vouchers to help with the purchase of glasses. NHS sight tests are mainly available to children, people aged 60 or over, adults on low income, or people suffering from or predisposed to eye disease. NHS optical vouchers are mainly available for children, adults on low incomes, and those who need certain complex lenses.

Only optometrists, ophthalmic medical practitioners and corporate bodies registered with the General Optical Council as being in business as opticians may contract with Primary Care Trusts to provide general ophthalmic services. [93]

On 29 August 2005, Rosie Winterton, Minister at the Department of Health, announced that there would be a review of General Ophthalmic Services. The press notice that made the announcement referred to a range of issues that the review would consider, including, among other things, the respective roles of primary and secondary care; the planned extension of prescribing responsibilities to optometrists; allowing Primary Care Trusts to contract optical services from a wider range of providers; and the position of dispensing opticians[94] in relation to the NHS. It also said that the review should report to Minister early in 2006. [95] Its terms of reference would be:

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[91] There are three kinds of opticians that provide eye services to the general public: *Ophthalmic medical practitioners* are qualified doctors who specialise in diseases and abnormalities of the eyes. They will test your sight, examine the health of your eyes, and give a prescription for spectacles, although they do not dispense them. *Optometrists (also known as ophthalmic opticians)* are the opticians you are most likely to visit for sight tests and spectacles. They are also trained to recognise abnormalities and diseases that are revealed in the eye, such as diabetes and glaucoma. *Dispensing opticians* are qualified to fit and supply spectacles to a prescription provided by an optometrist or ophthalmic medical practitioner. Source:
Department of Health NHS website: http://www.nhs.uk/England/AboutTheNhs/Default.cmsx

[92] Department of Health Departmental Report 2004

[93] As above

[94] See footnote 1 above.

[95] Department of Health Press Notice, 'Review of General Ophthalmic Services, 29 August 2005: http://www.dh.gov.uk/PublicationsAndStatistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4118493&chk=66ZQro

> To review the scope, structure and organisation of General Ophthalmic Services, their fit with a modernised NHS, in light of the planned move to performers list arrangements, and to make recommendations, if necessary, for reform.

The press notice explained that the proposed 'performers list arrangements' referred to the planned replacement of the present ophthalmic listing arrangements. The planned arrangements would allow a wider range of businesses to contract with the NHS to provide general ophthalmic services subject to the clinical work being undertaken by properly qualified performers who would be listed with PCTs, i.e. on the "performers list".

The press notice also listed topics that would be excluded from the review, that is: issues about the level of funding for ophthalmic services, including remuneration for sight tests, and eligibility criteria for entitlement to NHS sight tests and optical vouchers.

The review has not yet been published and no consultation has been announced but on 2 November the Royal College of Ophthalmologists wrote to Rosie Winterton saying that it was willing to assist the review team and asked to be informed of the arrangements for detailed submissions and the necessary deadlines.[96]

2. The Bill

Overall the provisions in the Bill are intended to introduce a new "contract system" for the provision of ophthalmic services in place of the present system, on the model of what already been done for primary medical services and primary dental services. In those cases the policy is to give Primary Care Trusts greater responsibility including responsibility for the funding of the services although there are national regulations, set out in secondary legislation, that provided detailed framework for the contracts that Primary Care Trusts have with General Practices and similar regulations are being introduced for dentists.

Provisions in the Bill amend the *Health Act 1977* to set out the responsibilities of Primary Care Trusts in relation to ophthalmic services. Currently the role of PCTs in relation to ophthalmic services is governed by Part 2 of the *Health Act* but, as has already happened with doctors and dentists, the new provisions will be in Part 1 of the Act, to which different funding provisions apply.

Two specific changes that the Bill makes provision for are highlighted in the Explanatory Notes and in the Partial Regulatory Impact Assessment. These are that:

> The measures will allow PCTs to contract with anybody they consider appropriate for the provision of ophthalmic services, subject to certain safeguards and to their employing properly qualified clinicians to undertake the clinical work. They will also give PCTs powers to stop making payments for optical vouchers to people and companies where they have reason for concern about redemption.

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[96] Letter from Nick Astbury, President of the Royal college of Ophthalmologists, 2 November 2005: http://www.rcophth.ac.uk/docs/college/GOSReviewLetter.pdf

> Allowing PCTs to contract directly with practices owned by dispensing opticians and lay people would allow for direct payments to be made to these businesses and simplify their entry into provision of NHS ophthalmic services and their administration. There will no longer be a need for dispensing opticians and lay practice owners to have legal agreements with an optometrist or ophthalmic medical practitioner who then contracts with a PCT, removing the risk that practice owners cannot find a practitioner prepared to enter into such an agreement. This will in turn provide protection to service provision.
>
> Giving PCTs the power to prevent people from redeeming vouchers who had been doing so inappropriately will strengthen efforts to reduce fraud.[97]

The Government's rationale for making some of the specific changes that are in the Bill is that:

> The optical business has developed and a number of companies owned by either dispensing opticians or lay people have to negotiate these restrictions to enter the market. Allowing direct contracts between Primary Care Trusts and a wider range of providers, subject to standards and safeguards, would recognise business reality and facilitate market entry. Arrangements were introduced temporarily to manage this situation but they are cumbersome and artificial and the proposed measures provide a lasting solution by allowing for contracts with dispensing opticians and lay practice owners for the provision of general ophthalmic services.
>
> At present Primary Care Trusts are unable to disqualify persons or companies who have fraudulently redeemed vouchers from doing so. Continuing without this power would leave a weakness in the regulatory framework and maintain a potential vulnerability to fraud.[98]

These clauses of the Bill relate to Primary Care Trusts and therefore to England only.

3. Responses

Measures in the Bill appear to cover some of the same ground as the review announced at the end of August, about which some organisations feel that they have not been consulted. On the issue of consultation, the Bill's Partial Regulatory Impact Assessment says:

> There has been limited consultation on the policy intention with specific stakeholders, including representatives of providers, patient and consumer interests (letters to twelve organisations of whom eight responded). More detailed consultation will take place on regulations which would have to be made under powers created by the Bill to give effect to the proposed changes.

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97 Partial Overarching Regulatory Impact Assessment for the Health Bill: http://www.dh.gov.uk/assetRoot/04/12/19/30/04121930.pdf

98 Partial Regulatory Impact Assessment Annex 6, Modernisation of Ophthalmic Services http://www.dh.gov.uk/assetRoot/04/12/19/36/04121936.pdf

> The representatives of providers have not objected to the introduction of provider/performer arrangements as such, or to the proposals on optical vouchers, but they have raised concerns about regulations that might be made under the powers granted by the Bill. The Department has assured the representative bodies that there will be early involvement of stakeholders in discussions on regulations.[99]

The Association of British Dispensing Opticians, the Association of Optometrists and the Federation of Ophthalmic and Dispensing Opticians have been lobbying Parliaments with their concerns about the changes but some of the lobbying date from before the Bill was published and therefore may not all be relevant to the provisions in the Bill. A joint briefinf from all three organisations about how to lobby MPs says:

> Without consultation, the Department of Health is taking powers to re-write the GOS
> contract for England. We all know how inadequate our terms of service under GOS are, but unbelievably the Department seems to want to make them worse. In a letter received in late June we were advised of changes that imply or state a number of things we need to resist:
>
> - ·A locally held GOS budget that would inevitably be cash limited
> - The removal of the current right of every optometrist to a GOS contract (if listing criteria are met)
> - Proposals that could allow a PCT to negotiate "sweetheart deals" with some optical outlets to the exclusion of others
>
> These impositions would severely limit patient choice. Even if the Department of Health were to offer several years of protection for all existing practices that would only hold good for existing locations and for the existing level of sight test fees.
>
> The Department will probably claim that this is just tidying up, that the details will be agreed when they consult us, and anyway they have no plans to make these changes in the near future. The Civil Servant concerned has already rehearsed that line.
>
> We have to assume that if the Department secures these changes and obtains the enabling powers then they will use them. We also cannot take their word that they would subsequently consult. Over the last two years they have only consulted us when backed into a corner and, on ophthalmic lists and the new domiciliary regulations, did not do so in any meaningful way until threatened with legal action.[100]

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99 Partial Regulatory Impact Assessment Annex 6, Modernisation of Ophthalmic Services http://www.dh.gov.uk/assetRoot/04/12/19/36/04121936.pdf

100 http://www.aop.org.uk/uploaded_files/local_lobbying_brief.pdf

VI Other measures in the Bill

Other measures in the Bill not so far covered in this paper cover:

- NHS counter-fraud and security management;
- Audit of special health authorities
- Widening the role of the NHS Appointments Commission
- Administration of the Social Care Bursary Scheme
- Injury cost recovery in the NHS
- Transfer of criminal liability in the NHS

This section provides a very brief note about each one of these. (Research Paper 05/79 covers the first Part of the Bill, which is on smoking in public places.)

NHS Counter-Fraud and Security Management
Part 4 chapter 3 (clauses 41-52)

These clauses would enable the appropriate national authority dealing with NHS fraud or security to require the production of documents, records and data. This would give NHS counter fraud organisations the same powers as other regulators and auditing organisations.s[101] A consultation document on the issues was published in October 2004[102] and a report on the responses was published in May 2005.[103]

At the moment the Secretary of State can and does issue Directions to require NHS health bodies to provide information and data. The Government's rationale for the change is given in the Partial Regulatory Impact Assessment on the Bill, which says that the NHS Counter Fraud and Security Management Service (or any replacement body) is likely to face problems obtaining such information because of the increasing use of public/private partnerships, to which Directions cannot apply. The legislation would ensure that all such work could be investigated in the same way as the rest of the NHS.[104]

These provisions apply to England and Wales except that the powers for security management purposes are limited to the Secretary of State and are not provided for the National Assembly for Wales.

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[101] Health Bill Explanatory Notes [Bill 69-EN]: http://www.publications.parliament.uk/pa/cm200506/cmbills/069/en/06069x--.htm

[102] Access to Relevant Documents, Records & Data to Counter NHS Fraud- Consultation Document- (Oct 2004) http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4101901&chk=M12vqW#

[103] Access to Relevant Documents, Records & Data to Counter NHS Fraud- Report on Consultation- (May 2005) http://www.dh.gov.uk/Consultations/ResponsesToConsultations/ResponsesToConsultationsDocumentSummary/fs/en?CONTENT_ID=4112148&chk=T68WA5

[104] Health Bill Partial Regulatory Impact Assessment Annex 8 on NHS Fraud: Power to Require Production of Documents: http://www.dh.gov.uk/assetRoot/04/12/22/41/04122241.pdf

Audit of special health authorities
Part 4 chapter 4
(clauses 53 and schedule 3)

Clause 53 and schedule 3 insert a new schedule into the *NHS Act 1977* to make provision relating to the auditing of the accounts of special health authorities NHS bodies in England and Wales.

Some background information is contained in the report on the Government's review of arm's length bodies.[105]

Widening the role of the NHS Appointments Commission
Part 5 (Clauses 54-68 and schedules 4-7)

The Bill would replace the NHS Appointments Commission with a new organisation called the Appointments Commission. This would be sin line with the Government's Response to the Public Administration Select Committee published in June 2003.[106] This indicated that some Departments could benefit from using the services of the NHS Appointments Commission to support their sponsor teams in making appointments but that statutory authority would be needed.

The Bill would establish the Appointments Commission as a Non-Departmental Public Body and give it powers to exercise, if directed to do so, the appointment functions of the Secretary of State for Health and the Privy Council in relation to the appointment of chairmen and non executive members to NHS and other health and social care bodies and health professional regulatory bodies and certain appointment powers of the National Assembly for Wales. The Appointments Commission would also be able to assist, if requested to do so, the Boards of NHS Foundation Trusts with their similar powers of appointment and also assist, if requested to do so English ministers with their similar powers of appointment to other public bodies.

These provisions would apply to the UK.

Administration of the Social Care Bursary Scheme
Part 6 (clause 69)

Clause 69, which applies to England only, would extend the powers of the Secretary of State to direct a Special Health Authority to enable it to carry out a function that relates to the training of social workers. A commentary in the journal *Community Care* is reproduced below:

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[105] "Reconfiguring the Department of Health's Arm's Length Bodies" (July 2004) http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4086081&chk=y4UIfP

[106] Government Response to the Public Administration Select Committee's Fourth Report of Session 2002-2003 "Government by Appointment: Opening Up the Patronage State" (HC165): http://www.publications.parliament.uk/pa/cm200203/cmselect/cmpubadm/165/16502.htm

> The body that administers grants for NHS students is to take over the running of the social care student bursary scheme from the General Social Care Council.
>
> The Department of Health's student grants unit is likely to be given the powers under provisions in the Health Bill published last week. The move follows more than a year of talks between the DH and the GSCC. Chief Executive of the GSCC Lynne Berry said it was better for the organisation to focus on its "overriding objective" of regulating the quality of the social care workforce.
>
> The GSCC has so far distributed almost £100 million in grants.[107]

Injury Cost Recovery in the NHS
Part 6 (clause 70)

Clause 70 would amend the *Health and Social Care (Community Health and Standards) Act 2003* to allow for contributory negligence to be taken into account in a wider range of cases when the NHS recovers hospital treatment and/or ambulance costs where people receive compensation for injuries. This is an expansion of the current scheme for road traffic accident cases as set out in the Road Traffic (NHS charges) Act 1999.

The intention is that when the scheme comes into effect in October 2006, it will replace the existing Road Traffic Act (RTA) scheme, which already operates in relation to road traffic accident victims. The Partial Regulatory Impact Assessment explains the background and rationale for the change:

> The Government conducted a public consultation on draft regulations to underpin the expanded ICR scheme during the autumn of 2004. One of the outcomes of the consultation was that the mechanisms for taking account of contributory negligence are too restrictive and are likely to result in some claim purely in order to get a ruling on contributory negligence that is acceptable for the purposes of the ICR scheme. This is a particular risk in severe injury cases where the ICR charges may reach the maximum for a single claim – currently £35,500 in the RTA scheme – so that a contributory negligence reduction could represent a significant saving to the compensator.
>
> Equally significantly, however, it became clear that the existing provisions in the 2003 Act have inadvertently created a situation where the ICR scheme would be running contrary to the long-standing policy of Government to try to simplify and speed up civil claims, minimising the need for formal litigation. Unless the approach is changed there is a serious risk of undermining initiatives that the Department for Constitutional Affairs have been developing over recent years through revision of the Civil Procedure Rules and pilot studies encouraging use of alternative dispute resolution mechanisms rather than going to court.
>
> The proposed solution is to widen the circumstances in which contributory negligence can be taken into consideration, rather than relying on the court processes or mediation. However, at present the 2003 Act gives no scope for it. A

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[107] "Bursary Scheme Set For Move To NHS" *Community Care*, 3 November 2005

> simple amendment to the 2003 Act will resolve this, removing the regulatory powers in respect of mediation cases, and replacing them with a wider-ranging power to make regulations concerning non-court based contributory negligence agreements which can be taken into account for ICR purposes. This will keep the provisions in place regarding the court-linked mechanisms, but will allow a much wider range of non-court based situations to be covered in regulations, and make it easier to respond to future changes in claims management practice as well. It will remove the perceived incentive to use court-based processes purely for ICR scheme purposes, and work in tandem with the DCA's work to minimise the number of claims going to court.[108]

According to the Explanatory Notes, this clause would apply to England and Wales.

Transfer of Criminal Liability in the NHS
Part 6 (clause 71)

Clause 71 would amend previous legislation to give the Secretary of State for Health, or in the case of Wales, the National Assembly of Wales, the power to transfer criminal liabilities of NHS bodies on their dissolution or abolition to other specified NHS bodies. the Government's rationale for this measure is set out in the Explanatory Notes to the Bill:

> The purpose of clause 71 is to address a lacuna which arose from the case of R v The Pennine Acute Hospitals NHS Trust formerly Rochdale Health Care NHS Trust 2003. In that case, the Court of Appeal held that the general power in paragraph 30 of Schedule 2 to the NHS and Community Care Act 1990 to transfer property, rights and liabilities on the dissolution of an NHS trust did not include the power to transfer criminal liabilities. The policy of the Department is that there should be a power to transfer the criminal liabilities of NHS bodies on their dissolution or abolition to other NHS bodies so that accountability for criminal offences committed by any such bodies can be retained within the NHS and will not wither away. Clause 71, therefore, gives the Secretary of State for Health the power to transfer the criminal liabilities of any English NHS body on its abolition or dissolution to another specified English NHS body and the National Assembly for Wales the power to transfer the criminal liabilities of a Welsh Special Health Authority, a Local Health Board and a Welsh NHS Trust on its abolition or dissolution to another specified Welsh NHS body.[109]

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[108] Partial Regulatory Impact Assessment Annex 7: NHS Injury Cost Recovery: http://www.dh.gov.uk/assetRoot/04/12/22/40/04122240.pdf

[109] Health Bill Explanatory Notes Bill paragraph 265: http://www.publications.parliament.uk/pa/cm200506/cmbills/069/en/06069x-d.htm

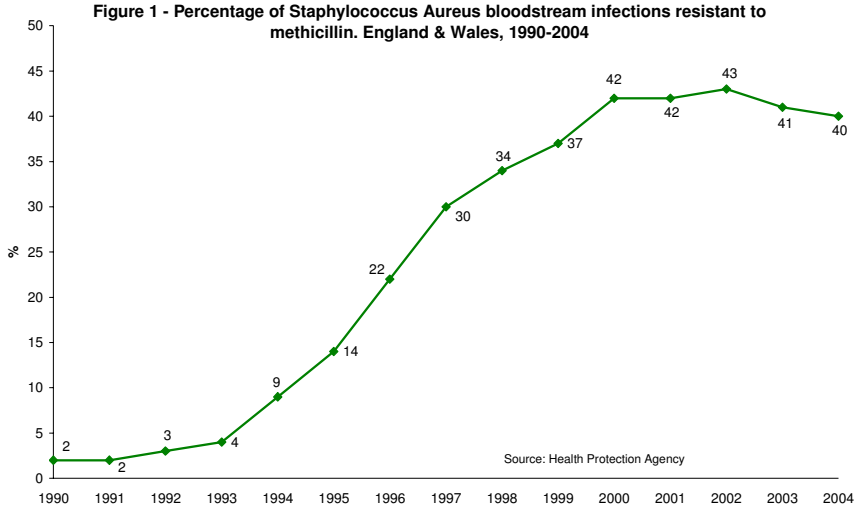
VII Appendix MRSA statistics FAQ

by Julien Anseau, Social and General Statistics Section

What is MRSA?

MRSA stands for methicillin-resistant Staphylococcus aureus. It is one of many strains of Staphylococcus aureus (SA), bacteria that can cause infections. MRSA is resistant to antibiotic drugs most commonly used to treat these infections. MRSA was first isolated in 1961, the same year that methicillin reached the market. After some early spread, numbers of MRSA reported cases declined to almost zero in the late 1970s and 1980s. The proportion of MRSA among all SA blood-stream infections remained under 3 percent until 1992. Over the next ten years or so, the UK saw an increase in MRSA prevalence, with 40 percent of all SA blood-stream infections being methicillin-resistant in 2004.

Figure 1 - Percentage of Staphylococcus Aureus bloodstream infections resistant to methicillin. England & Wales, 1990-2004



What does MRSA do?

SA is commonly found on human skin and mucosa (lining of mouth, nose, etc) and is carried harmlessly by about 30% of normal healthy people. This is known as colonisation or carriage. SA can cause actual infection and disease if bacteria enter the body, for example through burns, accidental wounds and grazes, surgical wounds, or the entry point for catheters or intravenous drips. MRSA and SA can cause boils and abscesses, the skin infection impetigo, septic wounds, heart-valve infections, food poisoning, pneumonia and toxic shock syndrome.

Who is at risk of MRSA infection?

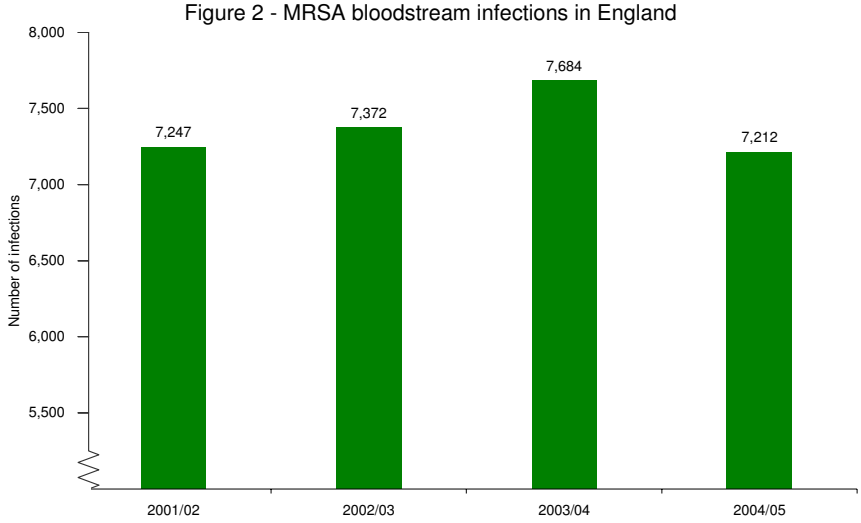
MRSA infections are more likely to occur in hospital environments and in particular to vulnerable or debilitated patients, such as patients in intensive care units, those who are immune-deficient, and on surgical wards. Some nursing homes have also experienced problems with MRSA. MRSA is mainly passed on via the hands of healthcare workers,

from surfaces to patients or between patients. Generally, healthy people are at a low risk of MRSA infection.

How is MRSA monitored?

The surveillance of MRSA in England is a mandatory scheme run by the Department of Health and measures the number of blood-stream infections reported by Acute NHS Trusts. The number of MRSA bacteraemias (blood-stream infections) in the first three complete years of the mandatory recording system rose from 7,247 in 2001/02 to 7,372 in 2002/03 and 7,684 in 2003/04. The figure for the fourth year (2004/5) showed a reduction to 7,212.

Figure 2 - MRSA bloodstream infections in England



The Department of Health mandatory MRSA bacteraemia surveillance scheme also provides rates[110] of MRSA bacteraemia by NHS Trust in six-monthly periods. In order to allow some comparison of similar institutions acute NHS Trusts are categorised into:

- 'single specialty' Trusts (for example, Trusts only undertaking orthopaedics or cancer or children's health services);
- 'specialist' Trusts (Trusts with specialist services which receive patients referred from other Trusts for these services);
- 'general acute' Trusts (Trusts providing general acute healthcare services).

Results show that MRSA rates tend to be highest in specialist Trusts and lowest in single specialty Trusts. This is not surprising as MRSA bacteraemia rates will be higher in Trusts that have more vulnerable patients and that undertake more invasive and high-risk specialist care. This does not mean that these Trusts are poor performers in either infection control or other performance measures. In other Trusts the MRSA bacteraemia rate may be low because they have less vulnerable patient groups. In addition the MRSA may not have been acquired in the reporting Trust, or may have been acquired in the

[110] MRSA rates measured as number of patients with MRSA isolated from blood specimens per 1,000 bed days

community. The individual Trust figures reflect the burden of serious infections associated with MRSA blood-stream infections and not all MRSA infection or carriage. Full results from the Department of Health mandatory MRSA bacteraemia surveillance scheme by NHS Trust are available at:

Summary results http://www.hpa.org.uk/infections/topics_az/staphylo/MRSA_four_year.pdf
Annual data 2001-2005 http://www.dh.gov.uk/assetRoot/04/11/40/15/04114015.pdf
Data for each 6 months 2001-2005 http://www.dh.gov.uk/assetRoot/04/11/40/14/04114014.pdf
MRSA is also monitored through laboratory services. The Laboratory of HealthCare Associated Infection (LHCAI) analyses isolated cases from Public Health, National Health and commercial laboratories. http://www.hpa.org.uk/srmd/div_nsi_lhcai/
The Antibiotic Resistance Monitoring & Reference Laboratory (ARMRL) is the national reference laboratory responsible for the detection and investigation of antibiotic resistance. Again, it tests isolated cases. http://www.hpa.org.uk/srmd/div_nsi_armrl/index.htm

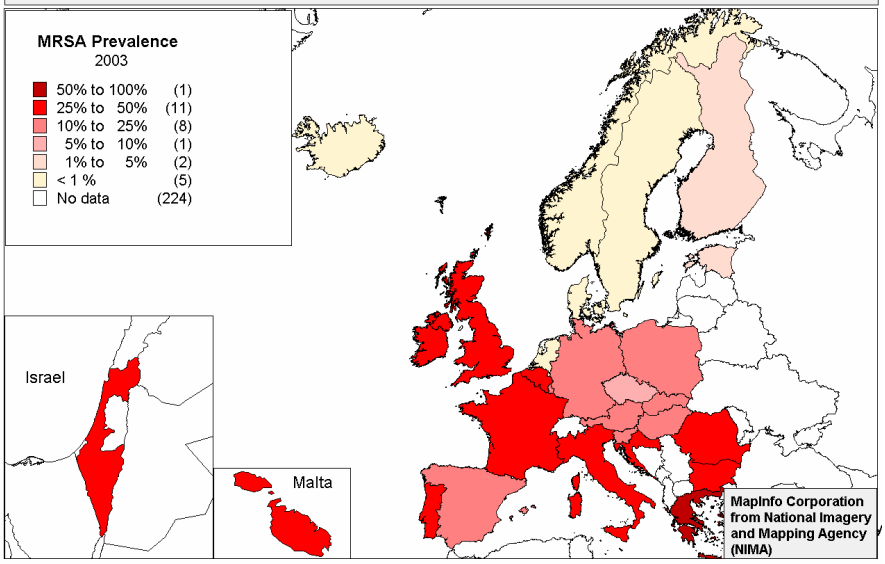
How do MRSA rates in the United Kingdom compare to those in other countries?

Data from the European Antimicrobial Resistance Surveillance System[111] for the proportion of *Staphylococcus aureus* bloodstream infections that are resistant to methicillin (MRSA) in EARSS countries in 2003 are shown in Figure 3.

There are wide geographical variations of MRSA prevalence in Europe. The data show a north-south gradient, with the lowest MRSA prevalence in northern Europe and highest in southern Europe and Israel, but also in the United Kingdom and Ireland. Denmark, Iceland, Sweden, Norway and the Netherlands have the lowest rates in Europe. MRSA proportions vary almost 100-fold, with the lowest proportion in Iceland (<1%) and the highest proportion in Greece (51%). The trends are consistent with previous years. Rates in the United Kingdom are among the highest in Europe. Yet the proportion of MRSA reported per year seems to have stabilised in the UK, which might be the result of increased efforts to contain the MRSA epidemic, or a saturation effect as a result of fitness thresholds that limit the spread of typically hospital-acquired MRSA outside hospitals.

[111] The European Antimicrobial Resistance Surveillance System performs ongoing surveillance of antimicrobial susceptibility in invasive infections caused by *Staphylococcus aureus*. EARSS was established in 1999 and is co-ordinated by the National Institute of Public Health and the Environment (RIVM) of the Netherlands. EARSS collects data from selected laboratories (a total of 731) that serve approximately 1,300 hospitals covering an estimated population of 100 million inhabitants in 28 countries. EARSS covers a proportion of the population in each country, and the proportion covered differs from country to country.

Figure 3 - MRSA Prevalence in Europe, 2003



How many patients die of MRSA each year in England?

The Office for National Statistics (ONS) reports that MRSA was a contributory factor in 955 deaths in 2003, compared with 51 ten years earlier in 1993. The death rate involving MRSA is greater at older ages. MRSA is involved in 0.07 percent of all deaths (0.12 percent of deaths in NHS General Hospitals). The National Audit Office (NAO) estimates that approximately 5,000 deaths a year are attributable to hospital-acquired infections.[112]

Table 1 - Number of death certificates with *Staphlyococcus aureus* and MRSA mentioned and as the underlying cause, England and Wales 1993-2003

England and Wales	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Mentions											
All *Staphylococcus aureus*	432	447	612	746	785	872	964	1150	1211	1221	1403
MRSA	51	92	199	301	389	412	487	669	734	800	955
Percentage of *S. aureus* mentions that were MRSA	12	21	33	40	50	47	51	58	61	66	68
Underlying cause											
All *Staphylococcus aureus*[1]	156	150	192	233	241	262	268	344	436	410	493
MRSA[1]	15	19	69	79	102	118	126	195	254	248	321

Source: ONS
Note: [1] excludes neonatal deaths

The ONS states that some of the increase in the number of deaths relating to MRSA may be due to better reporting.[113]

[112] National Audit Office, Improving patient care by reducing the risk of hospital acquired infection: a progress report. HC 876 Session 2003-04: 14 July 2004).
[113] ONS, Letters to the Press. Sunday Express 8 May 2005

> Some of the increase in mentions of MRSA on death certificates may be due to improved levels of reporting, possibly brought about by the increased public profile of the disease.

Note that patients who die with MRSA are often already seriously ill with another medical condition. It is therefore difficult to say whether a patient would or would not recover from their underlying illness had they not acquired MRSA infection. Routine mortality statistics based on death certificates alone therefore cannot measure the contribution that MRSA makes to overall mortality. To do so would require epidemiological research comparing the outcome in patients who are otherwise equally ill and receive similar treatment, but who do or do not contract MRSA. The Department of Health plans to establish a national audit of deaths from healthcare associated infection and investigate a proportion of the deaths that occur to identify avoidable factors and lessons to be learned from them.

How much does MRSA cost the NHS?

There are no reliable figures for MRSA, but it is estimated that each year in England there are at least 300,000 cases of hospital-acquired infection, causing around 5,000 deaths and costing the NHS as much as £1 billion. Patients with one or more infections incur costs greater than uninfected patients, mainly because they remain in hospital on average 11 extra days.[114]

Further information and useful links

Contact Julien Anseau (x4310).

A Simple Guide to MRSA (Department of Health)
http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/HealthcareAcquiredInfection/HealthcareAcquiredGeneralInformation/HealthcareAcquiredGeneralArticle/fs/en?CONTENT_ID=4093113&chk=7/XgcQ

General information on MRSA is also available at:
http://www.hpa.org.uk/infections/topics_az/staphylo/menu.htm

Summary results from the Department of Health mandatory MRSA bacteraemia surveillance scheme by NHS Trust are available at:
http://www.hpa.org.uk/infections/topics_az/staphylo/MRSA_four_year.pdf
Results for individual Trusts are available at:
http://www.dh.gov.uk/assetRoot/04/11/40/15/04114015.pdf (annual data 2001-2005) and at: http://www.dh.gov.uk/assetRoot/04/11/40/14/04114014.pdf (data for each 6 months 2001-2005).

The Laboratory of HealthCare Associated Infection (LHCAI)
http://www.hpa.org.uk/srmd/div_nsi_lhcai/
The Antibiotic Resistance Monitoring & Reference Laboratory (ARMRL)
http://www.hpa.org.uk/srmd/div_nsi_armrl/index.htm

[114] House of Commons Committee of Public Accounts, *Improving patient care by reducing the risk of hospital acquired infection: a progress report*. Twenty-fourth Report of session 2004-05

MRSA information for Wales http://www.cmo.wales.gov.uk/content/work/communicable-disease/healthcare-associated-infections-e.htm

Surveillance data for Wales
http://www.wales.nhs.uk/sites/page.cfm?orgid=379&pid=5362

MRSA information for Scotland
http://www.show.scot.nhs.uk/scieh/

Surveillance data for Scotland
http://www.show.scot.nhs.uk/scieh/

Deaths relating to MRSA in Northern Ireland
http://www.nisra.gov.uk/Uploads/publications/mrsa.pdf