

Partial Regulatory Impact Assessment

Trust, assurance and safety –
*the regulation of health professionals
in the 21st century*

and

Safeguarding patients –
*the Government's response to the
recommendations of the Shipman
Inquiry's 5th report and to the
recommendations of the Ayling,
Neale and Kerr/Haslam Inquiries*

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Partial Regulatory Impact Assessment

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PART ONE - Trust, Assurance & Safety

Introduction & overview

1. This partial regulatory impact assessment provides in Part I, the Government's assessment of the likely regulatory impact of the proposals made in the White Paper *Trust, Assurance and Safety - The regulation of health Professionals in the 21st Century*; and in Part II, to the Government's overall response to the Shipman Inquiry *Learning from tragedy, keeping patients safe : overview of the Government's action programme in response to the recommendations of the Shipman Inquiry*; and to the recommendations in the Shipman Inquiry "Fifth report" and the reports of the Ayling, Neale and Kerr/Haslam inquiries *Safeguarding patients: the Government's response to the recommendations of the Shipman Inquiry's Fifth Report and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries*.
2. The costs set out in this document are preliminary estimates and will need to be refined as we move into the implementation stage for our proposals. In some cases the costings have been done on a United Kingdom basis (where the matter is about statutory regulation of the professions) and on an England only basis (where the proposal is for action in England only).
3. *Good doctors, safer patients* was a comprehensive report examining medical regulation in its broadest sense. In it, the Chief Medical Officer for England made 44 recommendations. The *Regulation of the non-medical healthcare professions* was published at the same time and made a further 25 recommendations. The "Fifth report" made 109 recommendations. The reports of the Ayling, Neale and Kerr/Haslam inquiry made a further 119 recommendations.
4. The White Paper sets out a programme of reform to the United Kingdom's system for the regulation of health professionals, taking into account the results of the consultation on the two reviews of professional regulation published in July 2006. It is complemented by the Government's response to the Shipman and three other Inquiries¹, which set out a range of measures to improve and enhance clinical governance in the NHS.
5. In the three documents now being published we have brought together the overall implementation strategy for the Government's response. All these

¹ **Smith J.** *The Shipman Inquiry*. Chairman: Dame Janet Smith. (www.the-shipman-inquiry.org.uk) *Fifth Report; Safeguarding patients: lessons from the past - proposals for the future*. Cmnd 6394. The Stationery Office, London, 2004.

Pauffley A. *Independent investigation into how the NHS handled allegations about the conduct of Clifford Ayling*. Chairman: Dame Anna Pauffley. Cmnd 6298. The Stationery Office, London, 2004.

Matthews S. *To investigate how the NHS handled allegations about the performance and conduct of Richard Neale*. Chairman: Her Honour Judge Matthews. Cmnd 6315. The Stationery Office, London, 2004.

Pleming N. *The Kerr/Haslam Inquiry: full report*. Chairman: Nigel Pleming QC. Cmnd 6640. Crown, London, 2005.

reports have made it clear that there are important lessons to be learned and a substantial amount of work needs to be done to retain the public trust in the healthcare system and the regulation of the health professions within it.

6. The White Paper is based on five key principles:

- first, the overriding interest of professional regulation must be the safety and quality of the care that patients receive from health professionals;
- second, professional regulation needs to sustain the confidence of both the public and the professions through demonstrable impartiality. Regulators need to be independent of Government, the professions themselves, employers, educators and all the other interest groups that impact on healthcare;
- third, professional regulation should be as much about sustaining, improving and assuring the professional standards of the overwhelming majority of health professionals as it is about identifying and addressing poor practice or bad behaviour;
- fourth, professional regulation should not create unnecessary burdens, but proportionate to the risk it addresses the benefit it brings; and
- finally, we need a system that ensures the strength and integrity of the health professions within the United Kingdom, but is sufficiently flexible to work effectively for the different health needs and healthcare approaches within and out with the NHS in England, Scotland, Wales and Northern Ireland and to adapt to future changes.

7. The changes to professional regulation are one part of a comprehensive strategy by Government to improve the quality of care that patients and the public can expect from their health services, including: substantial investment; radical changes to the national organisations that regulate the health and social care system; the extension of patient choice; the enhancement of clinical governance; a new approach on patient safety; and, greater devolution of responsibility to clinicians working at the front line. This drive in England is complemented by similar approaches in Scotland, Wales and Northern Ireland.

8. The White Paper addresses the regulation of all health professionals, not just doctors. While in some areas, additional safeguards and support mechanisms are proposed for the medical profession, the intention throughout the White Paper is to ensure that there are no weak links in the chain of care and that there are effective and more consistent measures across all professional groups to ensure that patients receive the highest quality care from every professional that they encounter.

The Case for Change

9. Significant changes to the system of regulation of health professionals are necessary for a number of reasons:

- a. first, it is important that the lessons learned from the Inquiries into the conduct of Harold Shipman, Richard Neale, Clifford Ayling, Michael Haslam and William Kerr are put into practice. The documents to which this RIA relates set out the Government's response to those inquiries.
- b. Second, society has changed rapidly over the past four decades and professional regulation needs to keep pace with public expectations. Whereas in the past, people were more willing to take the expertise and professionalism of those who cared for them as a matter of trust, today a better informed and more questioning society requires that trust to be underpinned by objective evidence.
- c. Third, the increasing complexity and technical capability of medicine is placing growing pressures on multi-disciplinary teams and the regulatory system needs to adapt to that, distinguishing better between honest human error and lapses in professionalism as well as providing more effective support and rehabilitation to well intentioned health professionals who have got themselves into difficulties.

The full case for change is set out in the Chief Medical Officer's introduction to the White Paper.

Intended effect

10. The recommendations contained within *Good doctors, safer patients* had a sole and unifying aim – to improve the quality and safety of medical care in the United Kingdom. In the White Paper and associated documents we have endorsed these aims. Important underlying objectives include:

- promoting and assuring good practice, whilst also protecting patients from bad practice;
- increasing public and professional confidence in the General Medical Council and its procedures;
- narrowing the regulatory gap between the General Medical Council, as statutory regulator, and those who employ or contract with doctors.

Rationale for Government Intervention

11. The National Health Service, financed by the State, delivers the majority of medical care in the United Kingdom. Likewise, the majority of doctors practising in the United Kingdom are trained through publicly funded medical schools in the universities.

12. The medical profession has a duty to identify and remedy poor practice that compromises patient safety. The Government shares this responsibility to protect its citizens and to ensure that the National Health Service delivers quality and value for money.

13. The four major public inquiries published in 2004 and 2005 have identified major weaknesses in those NHS systems that were in place to protect the safety of patients. In particular, the Shipman Inquiry made a number of fundamental criticisms of the UK system of medical regulation and clinical governance. Dame Janet Smith, the Inquiry Chair, raised concerns about the proposals for revalidation of all doctors, a process that had been due to commence in April 2005, but which was placed on hold at the request of Ministers.

14. Shortly after publication of the Fifth Report of the Shipman Inquiry, the then Secretary of State for Health asked Sir Liam Donaldson, Chief Medical Officer (CMO) for England, to carry out a review of medical regulation and advise Ministers on the actions that should be taken to strengthen the procedures currently in place. Subsequently, the Government announced a parallel review of regulation of the non-medical professions to be carried out by Andrew Foster, who was then, Director of Human Resources of the Department of Health. This second review was needed to ensure consistency across the regulation of all the different health professions, and to ensure that the developing system of regulation remained fit for purpose.

15. The most recent reforms of professional regulation began in 2001 with the establishment of the Nursing and Midwifery Council and the Health Professions Council. Legislative change has been under way for the other professions, based on the same principles of patient protection and responsiveness to the public interest.

Impact of the changes to statutory regulation

16. The proposals dealing with statutory regulation will affect all doctors working in the private and public sectors within the United Kingdom and many of those organisations that enter into contracts with these doctors. We expect that those proposals affecting the National Health Service will apply in England but the other parts of the United Kingdom may wish to consider adopting them.

17. The most direct impact will be on existing regulatory bodies. As statutory bodies they need to be viewed in regulatory impact terms as part of the public sector. There will be some changes to their governance and they will need to carry out new regulatory tasks in relation to revalidation and possibly the regulation of small new groups of staff.

18. There will also be an impact on individual health professionals. Over time they will be required to revalidate at intervals, probably five years, by

producing evidence of their continuing fitness to practise. Where relevant, appraisal and assessment by their employer will be used for this. The small number of people in the new groups will come under statutory regulation and have to meet these requirements also. Nearly all are members of existing regulated professions, but in future direct entry to the new groups will be possible.

19. Employers of health professionals, whether in the public or private sectors, will be affected in the same ways. As revalidation is progressively introduced, they will need to keep appropriate records to support it, so that they can be accepted as reliable partners in the revalidation process. Where they do not or cannot, their professional employees will need to make direct arrangements with the regulator to supply the necessary revalidation evidence.

20. Users of health services will benefit by experiencing more reliable services in which they can have greater confidence since the professional staff will be engaged in a process of continued professional education and development.

Consultation

21. Responses to *Good Doctors, Safer Patients* and the review of the regulation of the other health professions demonstrated a real recognition for the need for change. Patient and public groups were supportive of the proposals in the two reports, with some pressing for more radical changes. There was broad support for the concept of revalidation among most of the professions and their regulators, provided that its operation was proportionate to the benefits that it was seeking to secure. While there were different views among the professions about the extent to which the governance arrangements for the national professional regulators should be changed there was a general acceptance that there was a need to adapt to a new environment. For doctors, there was a general recognition that the gap between local employers and the national professional regulator needed to be bridged for a fairer and more effective system, but there was debate about the most effective and cost-effective means of doing so. A report on the outcome of the consultation is published with the White Paper.

Costs

22. Costings are provisional at this stage. Estimates of the cost of implementing the key recommendations and the assumptions underlying these estimates are detailed in the annexes. A summary of the costs in Part I of this RIA are given in the table below.

Estimated costs	<i>Set-up costs (£m)</i>	<i>Running costs (£m pa)</i>
Revalidation of healthcare professionals ²	4.0 (pilot)	5.3 – 18.3
National Clinical Advisory Group ³	-	3.2
GMC Affiliates	0.11 (pilot)	15.2
Remediation & rehabilitation	-	7.3
Independent Adjudication	4.05	11.95
Medical Education	-	nil
Language testing	0.05	0.12

Equity and fairness

23. Regulatory effort should be proportional to the risk posed. For example, with revalidation of doctors, the recommendations provide scope for variable intensity and format of regulatory intervention across the different medical specialties.

24. The Department of Health does not believe that these proposals will result in any disproportionate negative impact on, or disadvantage to, any particular social or ethnic group. Indeed, a more standardised and transparent approach to medical regulation is likely to aid correction of any bias in current processes.

Small Firms Impact Assessment

25. A number of providers of healthcare services may fall into the category of 'small firms.' These include general practitioners and independent community pharmacies. Our view is that the proposed actions do not have a disproportionate impact upon 'small firms'.

Competition Assessment

No impact.

Enforcements, Sanctions & Monitoring

See individual annexes.

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² a range is given as implementation will be staged.

³ Figure represents 50% increase on existing costs

Annex A

REVALIDATION OF HEALTH PROFESSIONALS

Revalidation

Revalidation is a mechanism that allows health professionals to demonstrate that they remain up to date and fit to practise. For the large majority, revalidation will provide reassurance and reinforcement of their performance, and encourage continued improvement. For a small minority the scheme would provide a method of identifying problems and an opportunity to put things right. The evidence to support revalidation could come from a number of sources, including any strengthened appraisal arrangements that may be introduced.

Background

The Department introduced appraisal for consultants in 2001 and for GPs in 2002. It was made clear that appraisal would be the vehicle for the delivery of the GMC's revalidation requirements. In 2004 however, Ministers asked the Chief Medical Officer to review the GMC's proposed new system of revalidation in the light of criticisms made in the fifth Shipman Inquiry report. The Inquiry felt that the proposed standards were too low and that revalidation needed to be objective. This meant the postponement of the intended launch of revalidation, which was due to begin in April 2005.

Now that the Chief Medical Officer has reported and the White Paper has been published we intend to relaunch the appraisal and revalidation process. This will start with doctors in 2009 and be extended to other healthcare professionals at a later date.

Objectives

- To create a system that will provide objective and robust assurance that health professionals remain fit to practise both generically and, where appropriate, in their specific area of specialist practice.
- To standardise the content and enhance the value of workplace appraisal

Rationale for Government Intervention

Recent high-profile cases of medical and systems failures in the NHS have heightened interest in developing methods for regular assessment of the clinical performance of doctors and other health professionals. Such arrangements would be to assure the public that medical care is safe and

require individual clinicians to show that they can provide healthcare that meets current standards

The Department of Health review, *The regulation of non-medical healthcare professions*, made the point that revalidation is necessary for all professionals. The intensity and frequency needs to be proportionate to the risks inherent in each profession and the individual's scope of practice. We intend to have discussions with each profession and their regulator to develop the most appropriate arrangements for them. We want to ensure that revalidation is seen as a welcome addition to improving both patient safety and the performance of health professionals, and not as a bureaucratic burden on them.

Options - description

Option 1 (do nothing)

Do not introduce any system of revalidation.

Option 2 (preferred)

We intend to have a phased introduction of revalidation. For doctors only, there will be a two-stranded model of revalidation that includes re-licensure for all and re-certification for those on the specialist and GP registers. Other health professionals will only require relicensure. Doctors will be the first group to take part in the revalidation process. Nurses and then other health professionals will follow them. We intend, where possible, to review and develop existing appraisal and performance review systems where it is sensible to do so.

Re-licensure for all registered health professionals would occur every five years and involve:

- participation in annual NHS appraisal or equivalent, which will be further developed and standardised;
- satisfactory resolution of any issues known to the registrant's General Medical Council Affiliate or regulatory body;
- participation in a standardised round of multi-source, 360 degree, appraisal; and
- demonstrating that they meet the required standard.

Re-certification for doctors would occur in conjunction with the relevant Royal College, or other professional body, and would include GPs and those on specialist registers. Each specialty would design standards and develop assessment tools to assess performance against those standards. The re-

certification period may vary between specialties but would not exceed five years.

Option 3 (alternative)

Limit revalidation to the groups operating in the most high-risk areas, concentrating on staff with the most specialised skills.

Options - costs and benefits

Option 1 (do nothing)

No direct additional costs compared to status quo. No benefit.

Option 2 (preferred)

We intend to introduce appraisal systems for all health professionals over time. This avoids the risk of the NHS being overwhelmed by process and ensures that revalidation is seen as a welcome addition to improving both patient safety and the performance of health professionals. We do not want appraisal to be seen as a bureaucratic burden on health professionals. We envisage that appraisal will become part of normal working life and health professionals will make time to participate, with the majority of costs being absorbed as part of the normal clinical governance arrangements. An inclusive system of appraisal will provide an assurance that every health professional is fit to practise and is providing good clinical care.

There will be a phased introduction of recertification for both GPs and doctors on the specialist registers. Our assumption is that doctors will start the process in the second half of 2009/10, and numbers will gradually increase so that a fifth will be relicensed every year. This will tie in with the five-year relicensure cycle.

Our estimate of costs is £5.3 million in 2009/10 and this will include elements of relicensure and recertification for doctors. That should rise to £14.7 million in 2010/11 and again will include elements of relicensure and recertification for doctors. We expect that some nurses will start the relicensure process in the second half of that year with estimated costs of £3.6 million. That will give total costs of £18.3 million for doctors and nurses in 2010/11.

Quality Assurance

In order to ensure that relicensure is robust, and not just a rubber-stamping exercise, a proportion of portfolios could be selected at random and examined in detail by the regulator to ensure that standards were being met. For the

General Medical Council that could mean examining up to five per cent of the 24,000 portfolios produced in any given year.

If we assume that it would take the examiner one session then the overall cost would be of the order of 1,200 x £263 or £316,000. There will be extra costs for administration and to resolve queries. That would push the costs up to around £750,000 per year and could be paid for by adding a few pounds to the subscription fee for each doctor on the register. This model could be used for the other regulators as they come on stream.

Recertification

We propose that recertification should be informed by a formal assessment of the specialist skills needed by both GPs and doctors on the GMC's specialist registers. This might involve an examination of a folder of evidence by someone independent of the appraisal and relicensing processes. There are approximately 28,000 GPs in practice and 32,000 doctors on the GMC's registers. This could mean about 12,000 assessments being completed each year, based on a five-year cycle to cover all doctors.

We estimate that there would be a gradual introduction for GPs in 2009/10. We estimate that would give rise to extra costs of £1.8 million in that year. Once the programme of recertification is fully operational we expect that annual costs would increase to around £7.7 million a year.

We will have discussions with stakeholders to explore the best way of funding recertification. The costs could be met by the employer, the regulator or the individual doctor, or some combination of the three. The charge could be levied by the examining body directly, or through the GMC registration fee. It would only be levied when the doctor was due for recertification.

An alternative model of recertification would be to use a computer-based assessment with questions tailored to the speciality under review. The costs of developing the NHS appraisal toolkit, a comparable national support tool, were about £2.4 million over four years, with about £350 - £500k per year for ongoing updating of the questions, recording the results etc. Placing the development process and assessment function in a 'not for profit' organisation might avoid the need to pay royalties or licence fees for each doctor or test. The extra administrative costs for the organisation will be recouped by charging the doctor an assessment fee.

A random proportion of the candidates, say one per cent, could be asked to provide their revalidation portfolios for closer examination and scrutiny by an independent assessor. Again, there would have to be a process to deal with those who failed this independent assessment. As the total population is smaller, the costs would be proportionately less.

Doctors who failed the assessment for whatever reason may need retraining and remediation depending on the issues that are identified before they could return to practice. Current referrals to NCAS and the GMC might give some indication of the likely level of future work in such cases. Between January 2001 and October 2004, around 1,160 doctors faced formal GMC proceedings. In a four-year period covering 2001 to 2005, 1,772 doctors were referred to NCAS. This gives an average of around 700 annually with identified performance problems where formal action was taken.

Although not all would be GPs or specialists there would still be a proportion that was. Costs for remediating and training these doctors could be substantial, but would depend on the individual circumstances in each case. In general, where a doctor is employed, the expectation would be that they would pay for any services or training that fell outside the normal healthcare, occupational health or training programmes provided by the NHS or other employer organisations.

Pilot Project (costs & benefits)

In order to make sure that revalidation is introduced in a coherent and managed way, and to ensure that we get value for the money that would need to be invested, we may establish a national revalidation steering group. The group could undertake development, piloting, testing etc and ensure that the revalidation process covered both formative and summative aspects. To develop a sufficiently robust model it would be sensible to have a large-scale pilot to test the assumptions we have made. It could include up to 5,000 staff, cover different occupational groups and working environments, and test the value and underlying assumptions. It could need funds of up to £4 million to take this forward i.e. 5,000 sessions at an average of £400 each, plus development and administration costs.

Option 3 (alternative)

There will have to be further analysis and discussion to agree which groups of professionals are in the highest risk category. If we work on the assumption that this will cover around 20% of the health professional population that could give rise to costs of up to £3.5 million e.g. £1.4 million for doctors, £1.4 million for nurses and £0.7 million for other groups when all the categories of staff had been identified and became engaged in the process.

Total benefit

It is very difficult to cost direct benefits. A properly appraised and relicensed workforce however, might give rise to both fewer exclusion from work cases and a reduction in clinical negligence claims in the longer term. In 2005/2006, for example, the NHS Litigation Authority made payments totalling £592 million in respect of NHS negligence claims.

By the time revalidation is fully embedded we could anticipate that clinical negligence costs would be on a downward curve with the reduction in claims helping to offset the costs of revalidation. The National Audit Office in their report, *The Management of Suspensions of Clinical Staff in NHS Hospital and Ambulance Trusts in England*, estimated that the average cost of excluding a doctor was £188,000.

Equity and Fairness

Revalidation will help to maintain and improve patient care in all settings. The preferred option will be undertaken by all practitioners so should not affect any group disproportionately.

Small Firms Impact Assessment

The preferred option will affect self-employed professionals e.g. GPs, pharmacists, opticians etc, although PCTs already have funding in their baseline to pay appraisal costs. It is likely to impact less on those who already have good quality processes in place.

Competition assessment

We do not believe that the preferred option will have any significant impact on competition.

Enforcement, Sanctions and Monitoring

We plan that there will be a statutory duty on health professionals to participate in the revalidation process. Health professionals will be unable to practice unless they take part in appraisal and revalidation and are relicensed successfully at the end of the process. The legislative framework for this already exists for doctors. It has not yet been brought into force.

Annex B

NATIONAL CLINICAL AUDIT ADVISORY GROUP

Objective

To drive the further development of national clinical audit programmes through revitalization of the existing framework.

Background

Developing reliable and objective information about the clinical outcomes of doctors' work will be important to the recertification process, but will also support wider quality improvement in the NHS by providing better information about effective and ineffective clinical practice.

Rationale for Government Intervention

Reinvigorating audit and improving integration between national and local audit will provide high calibre data which can be used to improve the quality of NHS care provision. Developing this process at a national level will ensure that there is clear coordination and integration of processes.

Options – descriptions

Option 1 – do nothing

No further action taken on improvement of clinical audit.

Option 2 - preferred

Department of Health to establish a National Clinical Audit Advisory Group to further develop National Clinical Audit programmes. This group will be able to coordinate the development, implementation and action planning of National Audits. Furthermore, it will provide a forum for discussing the priorities that should be set for audit.

Local clinical audit to be revitalized within the framework of clinical governance. To achieve this, there needs to be more use of national audit data at the local level. In addition, there should a clearer framework for the development of local audit, to ensure that audits that are done are worthwhile and benefit maximized.

The Department will also establish an expert group to examine whether the quality of local clinical governance and audit processes could be linked to the premiums paid to the NHS Litigation Authority and the relationship between individual practitioners and the premium paid by them to medical insurers/protection societies. This work will cover all health professions.

Options - costs

Option 1

No additional cost.

Option 2

Total new money needed to fund the new advisory group, stimulate reinvigoration and assess the potential usefulness of audit to the litigation authority will require an increase equivalent to 50% of current £6.4m expenditure -£3.2 million per annum. This is made up as follows:

£200,000 to fund the development of the Advisory Group

£2.8 million to fund the initiation of reinvigoration and integration of Audit.

£200,000 to fund the expert group

Option – Benefits

Option 1

No additional benefit as audit function continues as it is. This option has the potential to undermine both quality improvement and the revalidation of health professions. There is also risk that without improvement of data there could be an impact on the patient choice agenda and Payment by Results implementation.

Option 2

This option will ensure a reinvigorated and integrated system of clinical audit. This in turn is a crucial element, to underpinning quality assurance of clinicians and part of the process of providing data to assess health performance. Patients will benefit by their practitioners learning from audit and applying best practice rather than the treatment the practitioner has become accustomed to providing.

Sectors and Groups Affected

- Institutional Level
Local audit departments and clinicians who carry out audit
Clinicians who collect data, evaluate and develop action plans
- PCT and SHA Level
Use of data secondary to audits as tools for benchmarking institutional quality of care
- National Level
Use of benchmarking data
Pooling data for national standards

Equity and Fairness

These proposals will allow inequality and variation in practice to be identified better and will thus have the potential to improve equity. One of the major problems facing medicine and health today is variation in practice. This affects every stage and process of healthcare. Understanding the differences, examining causation and addressing whether these are surmountable differences is an important issue. Audit is a crucial to achieve this, especially if it is coordinated nationally so that findings can be converted to policy.

Small Firms Impact Assessment

The technical expertise will be developed from within current NHS resources. However there may be some need to utilize external contractors to reinvigorate local audit. It is not possible at this stage i.e. until the advisory group is created, to assess the exact requirement at this time.

Competition Assessment

Efforts will be made to ensure that resources are sourced initially from within the NHS, however if it is necessary to use external resources the normal procurement procedures of the NHS will be followed.

Enforcements, Sanctions & Monitoring

Normal NHS governance procedures will be utilized to ensure that the objectives are achieved, monitored and performance managed.

Annex C

GMC AFFILIATES

Objective

Reassures the public, through giving power to a locally based GMC licensed affiliate, that the work of the national regulator is closely attuned with activity by employers and Primary Care Trusts (PCTs) in the process of scrutiny of medical practitioners.

Background

The White Paper explains the recent developments in giving the NHS the tools to safeguard the public by providing for disciplinary processes for employed doctors and those in primary care. We have concluded that on their own they are insufficient to:

- a. Enhance public confidence;
- b. Enhance confidence of the profession;
- c. Bridge the regulatory gap.

Rationale for Government Intervention

The response to the consultation drew a mixed response. On the one hand there was little disagreement that there was a regulatory gap but this was balanced with concerns that the proposed solution was complex, would be difficult to staff and had high cost impact. The majority of respondents thought that the role should be aligned closely to the duties of medical directors and integrated into local systems of clinical governance.

There are various aspects to the "regulatory gap":

- The GMC is often not made aware of local action and may feel obliged to initiate an investigation when effective action is already being taken;
- linked to the above, this can lead to a proliferation of investigations not fit for all purposes;
- evasion of disciplinary action by moving on specifically where action has only been taken at local level;
- variable standards of disciplinary action;
- variable expertise at a local level;
- little lay involvement in local disciplinary processes compared to national level;
- the GMC can sometimes appear remote to the individual doctor

In *Good doctors, safer patients*, CMO made a ground-breaking suggestion to fill the "regulatory gap" by introducing a new role undertaken by GMC affiliates. The prime aim would be to ensure consistency of approach and fitness for purpose of actions taken by all concerned. It would also

demonstrate that, at least for doctors, we are tackling public safety with the same intensity and seriousness as in other safety critical industries.

Options – descriptions

Option 1: (do nothing)

Continue with the current system whereby the actions of employers and PCTs are not co-ordinated with those of the General Medical Council (GMC). This perpetuates the “regulatory gap” which is confusing to the public and enables practitioners to evade action both nationally and locally. Information on actions taken locally is not shared amongst employers nor with the GMC.

Option 2: Independent affiliates in each trust

The recommendation in CMO’s original report was for a GMC affiliate in every Trust to bridge the gap between the national regulator and local action where fitness to practise of medical staff was an issue. Under this proposal, the affiliate would be employed by the GMC and entirely accountable to them. This is the most expensive option, requiring extra time of relatively well-experienced medical staff to carry out the role. They would be withdrawn from service provision.

Option 3: Regional affiliates and some area affiliates-(preferred)

Under this model, a full-time medically-qualified affiliate would be established to cover each SHA area. The affiliates would be employed directly by the GMC and entirely accountable to it. Trusts would need to have clear lines of accountability to the affiliate to include PCTs and the private health sector. In some locations where there was a concentration of medical staff a case could be made for an area affiliate. The need for such an approach would be tested in a pilot of affiliates.

Option 4: Enhanced roles for Medical Directors

It has been argued, in the response to the consultation, that while using doctors in active practice would be effective in gaining the confidence of colleagues the task is too great in addition to clinical responsibilities. Rather than creating a new system from scratch it would make sense to reinforce the role of existing structures. Local Clinical and Medical Directors could be asked to combine responsibility for “local regulation” with their existing responsibilities for clinical governance structures.

Cost and Benefits of Options

Option 1

No direct additional financial cost compared to status quo. No benefits. The opportunities for better co-ordination are lost and ineffective action is taken which is wasted money. Practitioners left without a local GMC contact.

Option 2

Based on a figure of 460 posts together with secretarial and voluntary lay support it is estimated that this would represent a financial pressure across the NHS and private sector totalling some £43.3m a year, with possible extra set up costs in the first year of operation of £1.6m.

The role of the affiliate is not just about discipline and fitness to practise. The affiliate would play a fundamental and important part in the local quality and clinical governance arrangements. The full implementation of this recommendation was the basis of many of CMO's recommendations.

There would be prohibitive costs and difficulties over the supply of suitably qualified professionals to fill these positions. An affiliate in each Trust might not achieve uniformity of approach given the potential for the affiliate to develop strong loyalties to his or her Trust over a period of time or suffer isolation from other affiliates.

The cost of establishing an affiliate in each Trust, including the opportunity costs in terms of frontline care by suitably qualified medical staff, as against the benefits it is likely to bring suggests this is not justified. In its response to the consultation, the National Clinical Assessment Authority expressed serious doubts "that there is sufficient pool of willing, able and skilled senior doctors to fill the number of posts required.

This model will be harder to create in the independent sector and further work and discussion with them would be needed to develop sensible implementation plans. However, we could probably further enhance standards applied by the Healthcare Commission in ensuring that clinical governance and safety standards are adhered to in the private sector which would link the private sector more closely with the regional affiliate role.

An affiliate in every trust would demonstrate to the public the close working of employers and the GMC thus reduce the number of referrals made to the GMC when effective action is already been taken locally. However, this might be detrimental to the perception of the impartiality of the GMC and independence from the NHS.

Option 3 - Agreed option

The overall cost is estimated to be a £15.2m, of which £10.6m would fall on the NHS in England.

Whilst the primary focus for local activity would be at Medical Director level, depending on the size of the Trust it is envisaged that duties would be spread across several suitably trained medical personnel, so emphasising the need to embed activity within existing clinical governance procedures. The GMC would monitor and re-accredit affiliates.

This model would fit with the views of respondents to the consultation, who felt that a completely new role of affiliates was excessive in dealing with the perceived 'regulatory gap'.

This model would ensure a strong leadership role embedded in the Regional Affiliate carried out through the Regional Medical Regulation Support Team (RMRST). Regional affiliates would more easily coordinate their work than models involving large numbers of affiliates; SHAs already have a disciplinary role for employed doctors and dentists under *Maintaining High Professional Standards in the modern NHS* and all regulated professions under the *Alert Notice Direction 2005*.

The Regional Affiliates could be perceived as just as distant from the frontline as the GMC. The affiliate would need to forge good working links with each Trust sufficient to make a real difference: this may prove difficult.

Links with the private sector to ensure correct action is taken at local level could be relatively easily established relating to private health providers in the same way as the GMC itself. Accountability to the Regional Affiliate for local processes and actions could perhaps be further strengthened through Health Care Commissioner responsibilities for *Standards for better health*.

At present there are nearly 5,000 complaints made to the GMC which in 2005 resulted in 36 erasures, 92 suspensions, 4 warnings, 16 reprimands and conditions being imposed in 80 cases. The intervention of the GMC affiliate will give a quick conclusion to cases without the need to refer to the GMC and if a recorded concern is issued a clear signal to the complainant that effective action has been taken and recorded on the doctor's record.

Option 4

The cost of this model is similar to the costs attached to Option 3 above, but without the regional element and represents a £9.22m a year pressure on the NHS over a full year. This representing a considerably reduced 'new' resource/time element to the functions which would largely be taken forward as part of existing clinical governance and management structures.

In this model any affiliates would be accredited by the GMC and would therefore have to meet the same standards of training and competence in the new role. While their accountability for their main duties would be to their employer, they would have additional lines of accountability to the GMC for their roles on revalidation and the issue of recorded concerns.

Under this model no specific dedicated new roles would be developed, but rather there would be enhancement of existing roles across the public and private health sector. For the private sector this could probably be achieved through monitoring by the Healthcare Commission and its successor body.

Medical Directors already have a disciplinary role and an interest in maintaining competency of medical staff. Accountability of Medical Directors for disciplinary issues could be reinforced by making it a personal statutory duty, similar to that for the controlled drugs Responsible Officer. It would have added advantages in serving to underline the importance of local clinical governance procedures, placing further welcome emphasis on fitness to practice procedures locally and constructive interaction with the GMC

Although the roles would necessarily need to be accredited by the GMC to ensure the right level of training and degree of competence, it would be difficult for the GMC to remove accreditation from a Medical Director who otherwise retains the confidence of his employer. Like Option 2, there would be difficulty in establishing a uniform approach across the NHS. In addition there might be difficulties for Medical Directors in reconciling their service role with that of an accredited affiliate, particularly where meeting demanding service targets is in conflict with taking forward concerns about a particular staff member.

This model would need to be considered further and discussed with the private sector to consider implementation issues as it affected them. Similarly we would need to explore the feasibility of strengthening the clinical governance standards applied to the private health sector by the Healthcare Commission.

Sectors and Groups Affected

The regulatory body (GMC), the NHS, armed service medical services and private sectors would all be affected by this proposal

Equity and Fairness

No issues. The work of the affiliate will not be undertaken in isolation from professional or lay involvement at a local level and certain activity such as the issue of recorded concerns will be the subject of scrutiny by a GMC committee.

Small Firms Impact Assessment

There will be limited impact on small private providers which will need to respond to queries from the GMC affiliate.

Competition Assessment

No impact.

Enforcements, Sanctions & Monitoring

The work of the GMC affiliate will be scrutinised by the GMC. Affiliates will only be able to continue whilst licensed by the GMC and such licensure can be removed.

Annex D

REMIEDIATION AND REHABILITATION OF DOCTORS

Background

For all health professionals, it is important that regulatory processes have built-in mechanisms to help them retain or regain their fitness to practise, when that is appropriate. Processes should help tackle the root cause of poor performance, whether this is by identifying the need for professional training, or the need for medical help for mental ill health or addiction problems. Fitness to practise investigations should act as a gateway to rehabilitation, where this is possible and realistic.

The Government will ensure that the General Medical Council works closely with NCAS and employers to deliver this new emphasis on support and rehabilitation for doctors. Doctors will be referred to a fitness to practise panel where they are uncooperative or do not comply with the agreed conditions on practice.

We anticipate that as appraisal and relicensing systems become more mature then doctors with performance issues will be identified and dealt with more quickly. In terms of the overall NHS medical workforce, only a tiny minority are referred to either the GMC or NCAS. Between January 2001 and October 2004 around 1,160 faced formal GMC proceedings. In a four year period covering 2001 to 2005 1,772 doctors were referred to NCAS. We would expect, in future, that a proportion of these cases would be dealt with locally by the GMC affiliate.

Rationale for government intervention

The Government's 2002 reforms gave the GMC powers to agree actions with the doctor that would protect the public and these powers now need to be used more effectively. The sanctions available include undertakings to comply with a wider range of practice conditions, rehabilitation and training programmes. Interim suspension will remain for the most urgent cases. Once these systems are established and used to full effect, it is anticipated that the number of cases reaching formal adjudication will fall. Serious impairment of fitness to practise that directly threatens patient safety would not fall within this approach.

Where health professionals working in clinical practice fail to satisfy the requirements of either element of revalidation, then they should spend a period in supervised practice or out of practice, prior to assessment. This will allow a tailored plan of remediation and rehabilitation to be put in place.

Option 1

No change to the status quo. No costs or benefits.

Option 2 (preferred)

Doctors with performance issues will be dealt with sympathetically and, wherever practical, be offered a package of remediation and rehabilitation. The Department will take action to explore the issues and practicalities around introducing remediation and rehabilitation packages.

Options – costs and benefits

Option 1

No direct additional costs compared to the status quo. No benefits.

Option 2 (preferred)

The Department of Health will establish a working group of stakeholders to establish and oversee a pilot service in London for ensuring effective referral and treatment of doctors who are in difficulty for all health reasons, not just mental health or addictions. The Department will consider in the light of evaluation of the pilot whether this should be rolled out nationally and the costs and benefits of extending its reach to other health professions. The Devolved Administrations will make a similar assessment in relation to Scotland, Wales and Northern Ireland.

The Department of Health will consider ways to ensure that occupational health practitioners in England have sufficient training to understand and recognise common mental health problems for all health professionals, the environmental and organisational factors that may contribute to their development, their potential impact, and what additional help and advice may be needed.

In general, where a doctor is employed, the expectation would be that they would pay for any services or training that fell outside the normal healthcare, occupational health or training programmes provided by the NHS or other employer organisations. This would also apply to those doctors who had been working abroad for extended periods e.g. for a charity or voluntary organisation. Employers would be expected to assist in identifying suitable placements and referrals. An estimated £7.3m would be required if the prevalence of underperforming doctors was 1% of NHS doctors.

The Government will discuss the detailed arrangements with the GMC, NCAS, the profession and employers and will also examine whether professional indemnity insurance might be extended to address the costs of such packages.

Total benefit

There will be a culture shift in the NHS so that there is a change from a punitive to a rehabilitative outlook in terms of dealing with doctors and other health professionals who have performance problems.

Equity and Fairness

All health professionals will, in time, be able to benefit from improved rehabilitation services.

Small Firms Impact Assessment

The preferred option will not affect small firms.

Competition assessment

We do not believe that the preferred option will have any significant impact on competition.

Enforcement, Sanctions and Monitoring

Employers and regulatory bodies will take a close interest in professionals who have performance problems and ensure that effective remedial action is taken.

Annex E

INDEPENDENT ADJUDICATION

Objective

- Provide for the separation of investigation, prosecution and adjudication of fitness to practise cases.
- Introduce a transparent and demonstrably independent adjudicatory body on fitness to practise cases, initially for the GMC.

Background

In the past, the General Medical Council has acted as lawmaker, investigator, assessor, formulator of charges, prosecutor, judge and jury in fitness to practise cases. While there have been significant changes to address this in recent years, there are difficulties inherent in this approach. The consistency of the decisions of General Medical Council panels was a source of comment in the past. Recent changes to the composition of fitness to practise panels initiated by the GMC itself, whilst representing a significant improvement was a partial solution.

Rationale for Government Intervention

The creation of an independently appointed pool from which regulatory bodies can draw panellists will require legislation. A separate and specialised body to undertake formal adjudication (in place of the General Medical Council carrying this out as an internal function) will further enhance public and professional confidence whilst also providing objective independence from both the General Medical Council and the Government. It was a change recommended in the Fifth Report and is a trend across the world.

Options - description

Option 1: Adjudication remains with Regulatory Bodies

All health profession regulators have full internal separation of adjudication with no council members on panels, and use of panellists from an independent pool, appointed by the Appointments Commission and administered by CHRE which would organise training independently to ensure a common approach across the professions. Panels would comprise a chair, a professional member and a lay member. The Chair could be legally qualified should it be deemed necessary. The professional member will hold a current registration with the regulatory body with whom the defendant is registered.

Option 2: GMC adjudication independent, remainder have internal separation

Creation of a new independent body to carry the adjudication of fitness to practise cases brought before it by the GMC.

Other health profession regulators will move to full internal separation of adjudication with no council members on panels, and use of panellists drawn from an independent pool appointed by the Appointments Commission and administered by the independent adjudicator which would organise training independently to ensure a common approach across the professions.

Other health profession regulators will have the option to move their adjudication processes to the independent regulator should they so wish.

Option 3: GMC independent first, others follow.

Full separation of adjudication from GMC into a new body as in Option 2.

Other health profession regulators will move to full internal separation of adjudication with no council members on panels, and use of panellists drawn from central pool, appointed by the Appointments Commission and administered by the independent adjudicator which would organise training independently to ensure a common approach across the professions.

Adjudication processes would then be moved to the new body in a phased manner once common rules had been made across the professions.

Options - costs and benefits

Option 1 (alternative)

The costs of appointing up to 1000 panel members for fitness to practise panels for all regulatory bodies has been estimated at some £2m, based on an average cost per appointment of £2k. This figure is based on the average cost per appointment to NHS national bodies, as set out in the Appointments Commission Accounts for 2005/6. Whilst this would of necessity be incurred in total for the first appointment process, it would be possible to stage costs in later years by making the appointments of differing length, i.e. some 3 some 4 and some 5 years in duration. This would include provision for the appointment of legally qualified chairs, where deemed necessary.

Training costs are estimated at £350k per annum, based on Department of Constitution Affairs (DCA) figures for the training of Tribunal members.

Option 2 (preferred)

Setup costs are estimated at £4.05m, spread over two years. These include: £0.2m for the creation of the body, based on DCA estimates; £2m to recruit panel members; £0.35m for training them; and estimated transitional running costs of £1.5m.

The cost of running the new independent adjudication system when fully operational is estimated at £11.95m pa, based on 80% of current GMC costs (£11.2m) plus the cost of recruiting (£0.4m) and training (£0.35m) panellists for all the regulators.

Option 3 (alternative)

In addition to the costs set out under Option 2, there would be the additional costs associated with the administration of the remaining regulatory bodies FTP cases.

The cost of administering these additional cases is estimated at £20.8m per annum.

Benefits of each option

Option 1

This is the low impact option. It provides for increased consistency across the Regulatory Bodies and will provide additional assurance about the impartiality of FTP adjudication.

It does not meet the recommendations of the Fifth Report or public expectation as expressed in the response to the Consultation with regard to separation of investigation and adjudication.

Option 2

This will meet the recommendations of the Fifth Report and CMO on the separation of functions.

Other regulatory bodies will benefit from the consistency of standards across the bodies.

Option 3

In addition to the benefits of Option 2, this will, over time, allow adjudication to be moved to a fully independent basis. As such it will enable all regulatory bodies to operate more efficiently and will address perceptions around impartiality across all bodies.

Equity and Fairness

Option 1

Provides assurance of increased equity in treatment of FTP cases across regulatory bodies, but does not fully address perception of lack of fairness in regulatory bodies acting as both investigator and adjudicator.

Option 2

Under the preferred option, the full separation of functions for the GMC, there will be increased equity as under Option 1, with the additional benefit of greater clarity for the public about adjudication in respect of doctors.

Option 3

With the provision of the possible extension of the Independent Adjudicator to all bodies, there will be the greatest degree of clarity regarding the full separation.

Small Firms Impact Assessment

No impact foreseen

Competition Assessment

No impact foreseen

Enforcements, Sanctions & Monitoring

Monitoring carried out in annual reports

Sectors and Groups Affected

All Regulatory Bodies and Appointments Commission.

Annex F

UNDERGRADUATE AND POSTGRADUATE MEDICAL EDUCATION

Objective

The efficient and effective management of medical education and training at both undergraduate and postgraduate levels.

Background

The production and development of a medical workforce that is of high quality, fit for purpose and capable of adapting to change is an essential feature of good health care in the UK. The education and training of that workforce must have a clear legal and regulatory framework to assure standards.

Rationale for Government Intervention

The continuum of medical education and training is managed by two statutory bodies: the General Medical Council (GMC) through its Education Committee and the Postgraduate Medical Education and Training Board (PMETB). The GMC has a longstanding statutory duty to co-ordinate all stages of medical education in the United Kingdom. Both bodies are established by law and if any change is required in their constitution or governance it must be initiated by the Government and agreed by Parliament.

Options – descriptions

Option 1: Transfer the functions of the GMC's Education Committee to PMETB.

Under this option the GMC would lose its duty to oversee and quality assure undergraduate medical education which would transfer to PMETB who already have similar functions in relation to postgraduate education. It would also be appropriate for PMETB to take over the GMC's functions in relation to co-ordinating education as a whole and also in relation to Continuing Professional Development.

This option would see one body with clear responsibility for the medical education continuum.

Option 2: Transfer PMETB's functions in relation to postgraduate medical education (all its functions) to the GMC and close down PMETB.

This option is the reverse of Option 1. The GMC would take over all PMETB's functions and the latter body would be abolished under law.

While some PMETB staff might compete successfully for jobs in a reconstituted GMC there would inevitably be redundancies.

Like Option 1 this too would see one body overseeing the entire education continuum.

Option 3: Enhanced status quo. (preferred)

In terms of their management of education and training both the GMC's Education Committee and PMETB are considered to be successful. They co-operate effectively when necessary, for example in overseeing the Foundation Programme. There is some reciprocal membership between the Education Committee and PMETB.

Sectors and Groups Affected

The members of the Education Committee and the Board, and staff of the GMC and PMETB would be directly affected. Other major stakeholders such as patients and the public, individual practitioners, medical students, universities (medical schools), the medical Royal Colleges and the National Health Service may be affected in respect of the influence and involvement they have in policy decisions.

Costs for each option

Option 1: Transfer the functions of the GMC's Education Committee to the PMETB.

Transferring GMC's functions to PMETB would incur additional burdens on the public purse. The GMC is self-financing through its registration fees and various other charges it makes for its services (like language testing). PMETB however is not yet self-financing and is dependent on a grant from DH and the devolved administrations (£2.3m in 2006/7). It plans to be self-financing within three years but any transfer of functions from GMC would mean that government support would probably have to be prolonged. While GMC can draw on annual registration fees, PMETB cannot. It would have to devise a new framework for charging for quality assuring undergraduate medical education and impose a charge on medical schools (to be met from the public purse).

The GMC would not be able to absorb easily all the displaced staff and while some might compete successfully for jobs in a reconstituted PMETB there might be redundancies. No accurate estimate is possible yet but as the change would be government inspired we have assumed that a contribution to costs from DH would be necessary.

Option 2: Transferring functions from PMETB to GMC.

As the functions of the two bodies would in effect be merged, staff in both organisations would compete for the same jobs and both organisations would suffer redundancies. However, as PMETB would be closed down and is subject to government support during the period of likely redundancies the burden of this would fall on DH and on the Devolved Administrations. No accurate figure can be given here but we estimate that 20-30 redundancies would be possible – perhaps £2-3m.

Since, under current plans, PMETB would be due to become financially independent in three years' time, there would be no additional saving from that source if GMC took over the function.

Since GMC registration fees are tax deductible, any increase in those fees by GMC to pay for the extra functions it took on from PMETB would impact on the public purse (indirectly). Estimate about £1.6m.

Option 3: Enhanced status quo

There are no substantial additional costs to this option. Government grants to PMETB would continue as planned and cease when that body became independent of central funding.

Benefits of each option

Option 1: The benefit of this option is that the education function of the GMC would be brought into line with the operating methods of PMETB. PMETB through its founding Order has a wide range of interests on its Board including lay members, patients and the NHS. Bringing the functions together in a relatively new body (PMETB was launched in 2005) would offer the option of a new approach to curriculum development and quality assurance at an undergraduate level. Single management of the continuum would be achieved.

Option 2: The benefit here is, like Option 1, that we would achieve management of the education continuum through a single body. There are no significant savings and extra costs involved.

Option 3: The benefit here is that we would preserve the expertise and experience of both organisations. By introducing a Board for continuing professional development (CPD) we will ensure that CPD activity can be channelled in the most effective way for patient protection and to meet the needs of revalidation of doctors. The two bodies will be encouraged to co-operate effectively to manage education. PMETB would continue to fully develop and support Government reforms of medical training. PMETB would get the period of stability it needs to focus on its core tasks under *Modernising Medical Careers*. Administrative and legislative changes would not be necessary. There are no substantial cost consequences for this option.

Equity and Fairness

The options considered here relate to the relative positioning of existing legal functions in existing organisations. There are no new functions proposed.

Small Firms Impact Assessment

There is no impact.

Competition Assessment

The organisations discussed here are unique independent bodies they are not in competition with each other or with any other bodies.

Enforcements, Sanctions & Monitoring

As above, no new measures are proposed.

Annex G:

INTRODUCTION OF ENGLISH LANGUAGE TESTING PRIOR TO FIRST EMPLOYMENT WITH THE NATIONAL HEALTH SERVICE

Objective

To assure that all health professionals treating NHS patients have sufficient English Language skills to enable communication with patients and colleagues

Background

Poor communication may contribute to professional error, poor relationships within teams, patient complaints and performance problems. English language proficiency is one aspect of good communication. At present, the regulators assess the English language proficiency of some potential registrants but European Law effectively prevents the testing of doctors from within the European Economic Area by the statutory regulator prior to registration as this is perceived as a barrier to free movement of EEA nationals. Pre-employment checks are legally acceptable but these are used to a variable extent within the NHS.

Rationale for Government Intervention

As the provider of NHS services, the Government is able to require all organisations providing services to NHS patients to ensure that health professionals with whom they contract have at some point successfully completed an accredited assessment of English language proficiency in a clinical context. Such a uniform pre-employment requirement will ensure linguistic competence and will also ensure that the test is applied equitably (to all health professionals working with NHS patients).

Options - description

Option 1 (do nothing)

Continue with the current situation whereby only health professionals from outside the European Economic Area are required to demonstrate their English language competency on registration.

Option 2 (preferred)

Require all organisations providing care to NHS patients to ensure that the *doctors* with whom they contract have sufficient knowledge of English Language and where doubts arise as to the doctors' proficiency, require the doctor to undergo a language test in the clinical context.

Option 3

Require all organisations providing care to NHS patients to ensure that all *health professionals* with whom they contact have sufficient knowledge of English Language and where doubts arise as to the professional's proficiency, require the doctor to undergo a language test in the clinical context.

Sectors and groups affected

Health professionals from EU Member States

Options - costs

Option 1 (do nothing)

No direct additional costs compared to the status quo. No benefit.

Option 2

Modest cost to regulators for updating the tests of £50k. Further costs to NHS Employers to test doctors of around £120k.

Option 3 (preferred)

Modest cost to regulators for updating the tests of **£50k**. Further costs to NHS Employers to test all professionals of around **£1million**.

Options – Benefits

Option 1

This option retains the status quo.

Option 2

A legal practical way in which all doctors could reach an appropriate standard of English language proficiency. Patients will be reassured that their doctor can correctly explain the diagnosis to them and clinical colleagues and that mistakes caused by defects in communication will be minimised.

Option 3

A legal practical way in which all health professionals could reach an appropriate standard of English language proficiency. Patients will be reassured that their doctor can correctly explain the diagnosis to them and clinical colleagues and that mistakes caused by defects in communication will be minimised.

Equity & Fairness

The policy does not discriminate on grounds of race or religion.

Small Firms Impact Assessment

Should have no impact

Competition Assessment

The policy will have no effect

Enforcements, Sanctions & Monitoring

Build in to Healthcare Commissions standard assessment of NHS Organisations

PARTIAL REGULATORY IMPACT ASSESSMENT

PART II: SAFEGUARDING PATIENTS: THE GOVERNMENT'S RESPONSE TO THE RECOMMENDATIONS OF THE SHIPMAN INQUIRY'S FIFTH REPORT AND THE REPORTS OF THE AYLING, NEALE AND KERR/HASLAM INQUIRIES

Introduction and overview

1. The Shipman Inquiry's Fifth Report, *Safeguarding patients: lessons from the past, proposals for the future*⁴, was published in December 2004. It is the last of three reports which between them seek to answer the questions: how was it possible for Harold Shipman to continue to murder patients for so many years without detection; and what needs to be done to protect patients for the future? Very similar issues have been raised in the reports of the inquiries into the cases of Clifford Ayling⁵, Richard Neale⁶, and William Kerr and Michael Haslam⁷.

2. Shortly after publication of the Fifth Report, the then Secretary of State for Health announced that he had asked Professor Sir Liam Donaldson, the Chief Medical Officer (CMO), to carry out a review of some aspects of medical regulation and to give his personal advice to ministers on his conclusions. Subsequently, the government announced a parallel review of regulation of the non-medical professions to be carried out by Andrew Foster, Director of Human Resources of the Department of Health.

3. The conclusions of the two reviews were published in July 2006^{8,9} and were followed by a 3-month consultation which ended in November. In parallel with this formal response to the recommendations of the four inquiries, the Government is today publishing a White Paper *Trust, assurance and safety – the regulation of health professionals in the 21st century*¹⁰ setting out its decisions on the future arrangements for the regulation of the healthcare professions. Many of the detailed recommendations in the Shipman Inquiry's Fifth Report are either addressed directly in this White Paper, or will fall to the regulators of the individual professions to take

⁴Shipman Inquiry *Safeguarding patients: lessons from the past – proposals for the future*, Cm 6394 (TSO, December 2004)

⁵ Ayling Inquiry *Independent investigation into how the NHS handled allegations about the conduct of Clifford Ayling*, Cm 6298 (TSO, September 2004)

⁶ Neale Inquiry *Independent investigation into how the NHS handled allegations about the conduct of Richard Neale*, Cm 6315 (TSO, September 2004)

⁷ Kerr/Haslam Inquiry *Independent investigation into how the NHS handled allegations about the conduct of William Kerr and Michael Haslam*, Cm 6640 (TSO, July 2005)

⁸ *Good doctors, safer patients: proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients – a report by the Chief Medical Officer* (Department of Health, July 2006)

⁹ *The regulation of the non-medical healthcare professions: a review by the Department of Health* (Department of Health, July 2006)

¹⁰ *The regulation of health professionals in the 21st century – trust, assurance and safety* (Department of Health, February 2007)

forward in the light of the general framework which it sets out. The regulatory impact of *Trust, assurance and safety* is addressed in Part I of this RIA.

4. This part of the RIA therefore considers the impact of the complementary proposals set out in *Safeguarding patients*, the government's formal response to the Shipman Inquiry's Fifth Report and by the Ayling, Neale and Kerr/Haslam Inquiries (the "three inquiries"). Broadly speaking, these address the measures which NHS and other healthcare organisations will need to take to improve the systems for recruitment, monitoring and management of health professionals employed by them (or providing services under contract to them).

5. Although the government's proposed actions to protect patients is being set out in two separate publications, implementation of all the various strands will need to be very carefully coordinated. The Department of Health will therefore be publishing an *integrated implementation programme* later this year, after consulting stakeholders on individual elements of the programme.

Purpose and intended effect

Objective

6. The principal objective of the action programme set out in *Safeguarding patients* is to protect patients by ensuring that all healthcare organisations operate effective systems to identify and deal with instances of poor performance by healthcare professionals. We aim to do this in a way which

- i assures patients and carers that their complaints are listened to and taken seriously
- ii recognises and celebrates the high standards of service delivered by the vast majority of healthcare professionals
- iii supports learning and continuous improvement in all services provided to NHS patients.

Background

7. Harold Shipman practised for much of his professional life as a single-handed general practitioner. In the culture of that time, there was relatively little oversight by NHS organisations. Shipman was a respected and apparently conscientious doctor and very few of Shipman's patients or colleagues could conceive that he would deliberately set out to harm his patients. Nevertheless, there were a number of concerns raised from various quarters, but no effective action was taken until the last few months before Shipman's final arrest.

8. The Shipman Inquiry's Fifth Report reviews the sequence of events and looks more generally at the arrangements for safeguarding

patients from incompetent or aberrant performance by healthcare professionals. In particular, the Fifth Report reviews

- the arrangements in NHS primary care for *monitoring the standards of care* of healthcare professionals and for taking action to protect patients where there is cause for concern;
- the handling of *complaints* from patients and *expressions of concern* from fellow professionals;
- the developing proposals from the General Medical Council (GMC) for a system for periodic *revalidation* of doctors' license to practise;
- the GMC's procedures for dealing with doctors whose *fitness to practise* has been called into question.

9. The Inquiry recognised that all these systems, as well as the general context in which they are operating, are in a state of change. It therefore considered not only the systems operating at the time of Shipman's crimes but also the extent to which recent developments might have provided better safeguards. In doing so, the Inquiry recognised that the vast majority of healthcare professionals are committed to providing good care for their patients. The Inquiry therefore emphasised that their recommendations are intended to work alongside the more general systems and processes, collectively known as clinical governance, through which the NHS seeks to promote high standards of clinical care.

10. Similar issues are raised in the reports of the Ayling, Neale and Kerr/Haslam inquiries. In each case there was a failure on the part of health organisations

- to take seriously complaints from patients or concerns from fellow professionals
- to join up information held in different organisations which, taken together, would have given a fuller picture at an earlier stage of the extent of the risks to patient safety
- to take effective action.

The report of the Neale Inquiry also raises issues about the rigour of the processes used by health organisations (and professional regulators) in checking the qualifications and record of professionals applying for appointments in the UK.

11. The Government accepts much of the analysis in these reports. In particular the Government welcomes the endorsement by the Shipman Inquiry of the central importance of clinical governance, both for improving standards in the NHS generally and for protecting patients from the rare instances of poor performance. In taking forward the recommendations of the four reports the government has therefore adopted the following broad principles:

- the *protection of patients and of the general public* should be the overriding priority;
- this should however be done in a way that minimises any potential impact on *the delivery of patient care* and *affirms and supports those health professionals* – the overwhelming majority – who aspire to do the best for their patients;
- any additional safeguards should *build on the existing processes in the NHS for ensuring clinical quality and safety*, that is to say on existing clinical governance processes;
- these additional safeguards should also *apply consistently across all sectors of healthcare* – in particular, to secondary as well as to primary care – and, on a proportionate basis, to all healthcare professions and not just to doctors

The Government accepts that further work is needed to ensure that clinical governance fulfils its objectives and that the lessons of the four inquiries have been learnt.

Risk assessment

12. Instances of deliberate attempts to harm patients are fortunately extremely rare, although there have been other regrettable instances in recent years. What is relatively more common is unacceptable professional behaviour resulting in abuse of patients, as in the cases of Ayling, Kerr and Haslam; deficiencies in technical competence, as at the Bristol Royal Infirmary¹¹; and poor communications skills.

13. Estimates vary widely of the incidence or prevalence of performance which could put patient safety at risk. The FHSAA annual account for 2004-05 reported that PCTs had notified it of 73 suspensions of GPs, 66 removals and 12 contingent removals, an incidence of about 0.5% of all GPs in England. Others have estimated the prevalence of unacceptable professional performance as up to 5%.

14. Whatever the precise level, the Department considers that is unacceptable for patients to be exposed to any degree of avoidable poor performance. The NHS has made considerable progress in gripping this issue in recent years and we agree with the Shipman Inquiry that more still needs to be done.

¹¹ Bristol Royal Infirmary Inquiry *Learning from Bristol*, Cm 5207 (TSO, July 2001).

Options

15. The recommendations of the four inquiries fall into six broad areas:
- i recruitment processes;
 - ii clinical governance processes in healthcare organisations, including the capacity to identify poor performance and to carry out effective and professional investigations;
 - iii handling complaints;
 - iv special issues relating to “boundary transgressions” (deliberate infringements of the proper boundary which health professionals should maintain between themselves and their patients) and to care for people with mental illness;
 - v information on professional performance, including routine monitoring and the way in which information is held and shared between healthcare organisations and professional regulators;
 - vi regulation of the healthcare professions, including revalidation and fitness to practise procedures.

Our general approach to the first five of these areas is set out in Annexes H to L. In each case we have considered, as a minimum, the “default” option of no change and the recommendations of the relevant inquiries; in some cases we have also looked at alternative ways of achieving the same end by different means. Issues relating to professional regulation are considered in Part I of this RIA.

Benefits

16. The principal benefit will be to the safety of patients, in particular a lower risk of exposure to abuse, incompetence or unacceptable behaviour from a small minority healthcare professionals. We also expect to achieve
- i a higher level of satisfaction in the handling of complaints
 - ii a further strengthening of the processes through which healthcare organisations learn from mistakes and strive for continuous improvement in the quality of services they deliver for patients
 - iii substantial offsetting savings from quicker identification and resolution of problems, including reduced costs of remediation (estimated at £100,000 for each individual doctor) and of clinical negligence litigation.

Costs

17. Costs are uncertain at this stage, since the Government response is in many instances setting out the broad direction of travel and the precise changes will depend on further work in consultation with stakeholders (and will be subject to more detailed option appraisal at that stage). However, our preliminary estimates of the cost of implementing the government's proposals are as follows:

	<i>Set-up costs (£m)</i>	<i>Running costs (£m pa)</i>
Recruitment processes	0.2	0.4
Strengthening clinical governance	0.6	2.7
Better handling of complaints	3.8	7.8
Boundary transgressions and special issues in mental health services	0.7	0.0
Information for monitoring	9.0	6.5
Total	14.3	17.4

All these costs represent "policy costs" (the cost of complying with the proposed policy) rather than "administration costs" (the costs of providing information associated with regulation and inspection) except where noted below.

Equity and fairness

18. Any changes in the final action programme will impact equally on all healthcare providers, whether in the NHS or in the independent or voluntary sector, carrying out equivalent activities. It is our intention that any regulatory impact should be proportionate to risk; more robust precautions may therefore be needed for activities which are inherently more risky, eg administration of chemotherapy, or where practitioners are working in isolation rather than as members of clinical teams.

The impact on small firms

19. A number of providers of healthcare services fall into the category of "small firms", for instance independent community pharmacies. We will consult stakeholder organisations representing small firms, including the National Pharmaceutical Association and the General Practice Committee of the British Medical Association, on the detailed aspects of the action programme affecting them. In the meanwhile our provisional view is that the action programme is unlikely to have a disproportionate impact on small firms. Indeed, some of the Shipman Inquiry's recommendations, which the government has accepted, would give additional support to small practices.

Competition assessment

20. See the individual annexes. Overall, our assessment is that none of the measures likely to be included in the action programme will impact on the competitiveness of the various healthcare markets.

Enforcement and sanctions

21. Clinical governance is as much a culture as a set of specific processes and behaviours; for many of the measures likely to be included in the action programme, implementation will therefore involve support and guidance rather than “enforcement”. However, some specific measures will require a measure of enforcement. Our preferred approach is to use a combination of

- professional guidance and sanctions (eg underlining the obligation already laid on members of all healthcare professions to raise concerns about fellow-professionals) and
- contracts (eg in relation to the Inquiry’s recommendation that GP practices should be required to copy all letters of complaint to their Primary Care Trust (PCT))

underpinned by the general approach to regulation of the healthcare sector set out in *The future regulation of health and adult social care in England*¹².

22. Legislation may be required for some parts of the action programme (eg the proposal to extend the concept of a “duty of collaboration” in sharing information relating to potential risks to patient safety from controlled drugs to clinical governance issues generally); in this case we will consult fully, with a further and more detailed RIA, before introducing legislation.

Monitoring and review

23. The Department of Health will be setting up a national advisory group with key external stakeholders to help us develop the details of the integrated action programme, review its progress, and monitor the impact on front-line staff. See *Trust, assurance and safety* chapter 8 for further details.

Consultation

24. The government consulted on the two reviews of medical and non-medical regulation and over 2,000 responses were received. Other aspects of the proposed action programme, for instance on complaints handling, have also involved stakeholder consultation at appropriate points. We will consult further on individual strands of the proposed action programme as appropriate.

¹² *The future regulation of health and adult social care in England* (Department of Health, December 2006)

Summary

25. The Harold Shipman tragedy drew attention to major deficiencies in the way in which the NHS of the 1980s and 1990s responded to complaints and concerns and in the professional overview of single-handed practitioners. Much has already changed since then – the introduction of the concept of “clinical governance” throughout the NHS, the new list management powers for PCTs, a greater awareness of need for healthcare organisations to learn from complaints and concerns. But more is needed to ensure that these changes are embedded throughout the NHS and to achieve a real change in culture as well as in systems and processes.

26. The reports of the Shipman, Ayling, Neale and Kerr/Haslam inquiries have cogently pointed up a number of ways in which existing programmes and policies could be enhanced. Doing nothing would not be a credible option. Instead, we are developing an action programme which we believe represents a proportionate and reasonable response to the challenges posed by the four inquiries.

Department of Health
February 2007

ANNEX H RECRUITMENT PROCESSES

Objective

To ensure that guidance on recruitment processes covers the specific risks to patient safety identified in the report of the Neale Inquiry and is proportionate to these risks; and to promote the uptake of best practice in all health organisations.

Background

Guidance on recruitment issues for NHS organisations is issued by NHS Employers (part of the NHS Confederation) and was updated most recently in January 2007. Some aspects are mandated through regulations. In future, we would envisage promoting good practice through use of the principles set out in *The future regulation of health and adult social care in England* (see reference 10), for instance by making good practice part of the standards against which healthcare organisations (including private sector providers) are registered by the new healthcare regulator.

Risk assessment

Neale was an obstetrician who was able to obtain employment in the UK despite having been struck off the medical register in Canada for poor clinical performance. In the UK, several patients suffered severe adverse effects from operations he performed. Unless recruitment processes are tightened up there is a risk of similar tragedies recurring.

Options

The Department has considered the options of (a) do nothing, (b) asking NHS Employers to update existing guidance and promoting through the normal processes for assuring quality and safety in the NHS, and (c) imposing specific legislative requirements. We consider that option (a) does not give sufficient weight to the risks to patient safety and that option (c) would be disproportionate and potentially confusing to healthcare organisations. Option (b) addresses the risks in a way which will build on existing or proposed structures and processes for promoting patient safety.

Costs and benefits

We estimate the costs of compliance with best practice guidance, under either options (b) or (c), at around £0.6m pa. The main assumption is that 20% of healthcare organisations are not currently following best practice, and would need to devote an additional 2 hours on average per recruitment. The main benefits would be improved patient safety and improved public reassurance.

Equity and fairness

The proposed changes will impact equally on all healthcare sectors and on all sectors of society.

Impact on small firms

Small primary care providers (eg GP practices) may find it more difficult to apply the proposed recruitment checks in full. The existing performers list arrangements mean that some checks are already carried out by Primary Care Trusts. The Government is sympathetic to proposals in the Shipman Inquiry's 5th report that PCTs should provide support to GP practices, especially smaller practices, for administrative functions including recruitment processes.

Competition

We have applied the competition filter tests and consider that the proposed option will have no impact on competition.

Enforcement

Through the new regulatory arrangements proposed in reference 12.

ANNEX I STRENGTHENING CLINICAL GOVERNANCE IN HEALTHCARE ORGANISATIONS

Objective

To strengthen the capacity of healthcare organisations to promote the quality of the clinical services which they provide or for which they contract, to identify possible instances of poor professional performance, and to take effective action to protect patients and (where possible) to help the individuals concerned to remedy any weaknesses.

Background

All NHS healthcare organisations are already required to appoint a clinical governance lead; primary care medical and dental practices are accountable to PCTs for their clinical governance processes. NHS employers and PCTs have a range of powers to deal with poor performance by individual health professionals, and for doctors and dentists guidance is available from the National Clinical Assessment Service (NCAS) on how to use these powers effectively.

The Shipman Inquiry noted these developments with approval, but considered that clinical governance was not yet sufficiently embedded in primary care (the particular focus of the Inquiry). In particular, they considered that PCTs should strengthen their capacity to carry out effective investigation of complaints and recommended setting up multi-PCT teams with specialist expertise. They also recommended (a) giving statutory recognition to the importance of investigation of complaints as part of PCTs' clinical governance processes, (b) widening the range of sanctions available to PCTs to include lesser sanctions such as warnings and training requirements. The Ayling and Kerr/Haslam inquiries made similar recommendations about the need to improve the capacity of healthcare organisations in both primary and secondary care to investigate complaints and concerns and to take effective action.

A recent NAO study of clinical governance in primary care¹³ suggest that PCTs have made good progress in establishing appropriate *processes* but less good progress in the underlying *cultural change* required.

Risk assessment

The Department agrees that more needs to be done to embed the culture and processes of clinical governance in healthcare organisations in order to minimise the risk to patient safety from poor professional performance. There is a particular risk that PCTs and Strategic Health Authorities (SHAs) will lose continuity and expertise in performance management as a result of their recent restructuring.

¹³ *Improving quality and safety: progress in implementing clinical governance in primary care – lessons for the new Primary Care Trusts* (NAO, January 2007)

Options

The Department has considered the options of (a) do nothing, (b) guidance and support to the NHS and (c) imposing further legislative requirements. In general, we consider that "do nothing" would fail to take sufficiently seriously the threat to patient safety, and that legislation would not in itself address the need for culture change. The action programme is therefore concentrates on guidance, support and training for hospital trusts, PCTs and front-line primary care providers. Ministers are however considering strengthening the statutory "duty of quality" placed on all NHS organisations¹⁴, and extending this principle to private sector providers, in order to clarify accountability and emphasise the importance which they place on quality and patient safety.

Costs and benefits

A deeper commitment to clinical governance principles and processes will help to protect patients from poor performance and to raise standards of clinical care more generally. We estimate potential costs at £3m pa in addition to the specific costs for improving complaints handling discussed in the next Annex. The main component would be the cost of an additional senior manager in each of some 150 PCTs and 270 specialist trusts.

Equity and fairness

The main impact will be on hospital trusts and PCTs. Any indirect impact on front-line primary care providers will be similar for all organisations providing similar services and will impact equally on all sectors of society.

Impact on small firms

All GP practices, dental practices and community pharmacies, whatever their size, are already required to participate in clinical governance activities. The proposed action will not add to these requirements. As noted in Annex A ministers are sympathetic to the Shipman Inquiry's recommendations for additional support for small and single-handed GP practices, which will help them more effectively comply with existing requirements.

Competition

We have applied the competition filter tests and consider that the likely action programme will have no impact on competition.

Enforcement

The only new statutory requirement under consideration is the extended role in relation to the "duty of quality". Under the new arrangements for regulation of the healthcare system in England¹⁵ PCTs will secure through contracts the quality of the services they commission, and key national

¹⁴ Section 45 of the Health and Social Care (Community Health and Standards) Act 2003

¹⁵ *The future regulation of health and adult social care in England* (Department of Health, December 2006)

requirements of quality and patient safety will be enforced through the proposed system of registration with the new healthcare regulator.

ANNEX J COMPLAINTS HANDLING

Objective

To improve the handling of complaints from patients and carers; specifically (in primary medical care) to enable PCTs to take an overview and if necessary intervene in the case of complaints indicating a possible problem of poor performance.

Background

Current policy is that patient complaints should be handled by the front-line healthcare organisation, i.e. in the case of primary care by the GP practice, community pharmacy etc. The Shipman Inquiry considered that this posed risks especially where the complaint related to what they called "clinical governance issues" (i.e. complaints which could indicate a problem of unacceptable professional behaviour or incompetence). They recommended that (a) patients should be free to complain directly to the PCT, (b) all complaints to GP practices should be copied to the PCT and (c) the PCT should take over the handling of any complaints which it considered to raise clinical governance issues.

More generally, the Shipman Inquiry recommended support to improve the standards of complaints handling in primary care, backed up by statutory recognition of the importance of investigation of complaints as part of clinical governance. There are related recommendations relating to secondary care in the reports of the Ayling and Kerr/Haslam inquiries.

The Department is currently planning a major reform of the complaints system for both health and social care, to improve standards and to make it easier for patients/users with complaints spanning the two sectors. This will subsume the recommendations from the four inquiries. In this part of the RIA we deal principally with the changes responding to the inquiries.

Risk assessment

The Department agrees that patients may be deterred from making legitimate complaints if they are required to complain in every instance directly to the practice. We also agree that complaints, or patterns of complaints, indicating potentially serious problems could be overlooked if the PCT receives (as at present) only aggregate statistics and not copies of individual complaints. We also accept that current standards of complaints handling are variable and there is still a mind-set which regards a complaint as a nuisance to be minimised rather than as an opportunity to improve services. For all these reasons, the NHS does not currently use complaints as effectively as it should as part of its overall commitment to quality, and there is a risk that serious problems of professional performance will continue to go unheeded (as with Ayling, Kerr and Haslam).

Options

We have considered the Inquiry's recommendations against the "default option" of no change. We continue to believe that complaints, of whatever their nature, should in the first instance be handled and if possible resolved by the front-line provider. However, ministers are minded to agree that the Inquiry's recommendations (a) and (b) would strengthen existing safeguards without imposing an excessive burden on practices or weakening significantly the principle of local resolution. We will need to consult formally on these changes with professional interests.

More generally, we have considered three main options for improving standards: (a) no change, (b) guidance supported by explicit national standards for complaints handling, and (c) legislation. Clarifying the existing national standard for complaints handling¹⁶ would go with the grain of the Department's recent proposals set out in *The future regulation of health and adult social care in England*¹⁷. However, in view of the strong recommendation from the Shipman Inquiry, and the similar recommendation in CMO's review of medical regulation¹⁸, ministers agree that it would be helpful to underpin these standards by clarifying the statutory responsibility on health organisations to learn from complaints and medical errors.

Costs and benefits

The proposed changes will

- improve the standards of complaints handling,
- improve the ability of the NHS to learn from errors; and
- reduce the risk that patients will be inhibited from raising serious concerns, or that significant complaints will be overlooked.

This will protect patients from poor performance, increase levels of patient satisfaction and help to create a learning culture in the NHS thus improving the quality of services. The main components of the additional costs are expected to be:

- i set-up costs in GP practices of complying with new standards for complaints handling (around £2m, assuming that 50% of GP practices need to make improvements at an average cost of £500 per practice);
- ii additional running costs in GP practices (about £2m pa, assuming that that practices have to increase the average time spent per complaints by around 2 hours);
- iii some additional running costs for hospital trusts and PCTs (up to £3m pa, assuming on average an additional 1 hour per case).

¹⁶ *Standards for Better Health* (Department of Health, July 2004) standard 14

¹⁷ *The future regulation of health and adult social care in England* (Department of Health, December 2006)

¹⁸ *Good doctors, safer patients: proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients – a report by the Chief Medical Officer* (Department of Health, July 2006)

The additional costs are likely to be largely offset (on average) by the ability to take earlier action to deal with poor performance – once a case requires formal clinical assessment the average cost for assessment and remedial action is around £100,000.

Equity and fairness

The changes will impact equally on all health professionals; on all GP practices and other front-line providers of primary healthcare; and on all sectors of society.

Impact on small firms

The additional burden on GP practices and other small healthcare providers is likely to be minimal (see above) and offset by the additional support for small practices discussed in the previous section.

Competition

We have applied the competition filter tests and consider that the likely action programme will have no impact on competition.

Enforcement

Changes to the initial handling of complaints against GPs would be enforced through the national GP contract and equivalent local contracts. Improvements to the general standard of complaints handling would be enforced through new national standards and the proposed new regulatory system for health organisations.

ANNEX K BOUNDARY TRANSGRESSIONS AND SPECIAL ISSUES IN MENTAL HEALTH SERVICES

Objective

To harmonise the guidance drawn up by the various professional regulators on boundary violations; to raise awareness of the issues; and to promote good practice in healthcare organisations

Background

Both the Ayling and Kerr/Haslam inquiries concerned allegations of sexual assault on female patients over prolonged periods of time, and the failure of health organisations to take these allegations seriously or to take effective action to protect patients. Since then, partly through the work of organisations such as *Witness*, there is much more awareness of the issues of “boundary transgressions” (health professionals overstepping the proper boundaries between themselves and their patients) and sexual or other abuse. Some of the health profession regulators have issued guidance to their members or to their fitness to practise (ftp) committees, but there are inconsistencies and practice is still variable.

Mental health patients are particularly vulnerable to this kind of abuse, as the activities of Kerr and Haslam show. The Kerr/Haslam inquiry has a number of recommendations for specific precautions in this area, for instance on the uptake of innovative or unusual treatments.

Risk assessment

There are no systematic data in the UK (one of the recommendations in the Kerr/Haslam report is for further research in this area) but estimates from other countries suggest that the prevalence of abuse against patients could be as high as 6-7% of health professionals¹⁹. In some cases, abuse can initially manifest as a minor infringement of the proper boundaries and progress imperceptibly to more serious abuse. This will always remain a risk unless appropriate professional standards can be unambiguously defined and understood throughout the NHS.

Options

The government has considered three broad options for safeguarding patients against sexual and other abuse: (a) do nothing, (b) issue professional and NHS guidance, and (c) specific legislation. The government considers that legislation would be disproportionate to the risks involved, given the increasing awareness of the issues.

On mental health issues, the government’s general view is that the clinical governance systems needed to protect patients in other settings should once

¹⁹ Cited in *Witness* “A comparison of UK health regulators’ guidance on professional boundaries” (CHRE January 2005)

fully developed be sufficient in mental health settings also. However, the government agrees that some further guidance may be helpful on specific aspects, eg the use of information disclosed in therapeutic situations and advocacy support for mental health patients who wish to raise complaints.

Costs and benefits

Potential costs amount at the outside to £0.6m for central government and £0.1m to the professional regulators (all one-off costs) for developing guidance and further research on prevalence. There is not expected to be any increase in running costs (in the longer term) since it is reasonable to assume that all serious cases of abuse will come to light sooner rather than later; if anything there is likely to be a reduction in costs though better deterrence and earlier detection. The main benefit is the reduction in the risk to patients from abuse.

Equity and fairness

The guidance should impact equally on all health providers and all sectors of society.

Impact on small firms

In general, there will be no particular impact on small firms. Provision of chaperoning for intimate examinations (one particular aspect of the precautions needed in this area) may be relatively more difficult to arrange for small GP practices; we are not proposing any new guidance in this area (guidance on chaperoning in primary care was issued in 2006).

Competition

We have applied the competition filter tests and consider that the likely action programme will have no impact on competition.

Enforcement

The main form of enforcement will be through the professions' fitness to practise procedures.

ANNEX L

INFORMATION FOR CLINICAL GOVERNANCE

Objective

To ensure that employers and PCTs have access to the information they need to protect patients.

Background

One thread running through the reports of the Shipman Inquiry – and also the Ayling and Kerr/Haslam inquiries – is the failure of NHS management to put together separate pieces of information which, taken as a whole, would have indicated serious cause for concern. The Shipman Inquiry proposed that (a) PCTs should maintain a file for each GP containing all information relevant for clinical governance purposes (including, for instance, complaints and allegations) (b) core information should be held on a national database to which all PCTs and NHS employers would have access, with suitable safeguards for employees. The Inquiry also made recommendations about specific data which should be monitored locally, including mortality data and prescribing data.

Risk assessment

We agree that, without proper integration of the available information, there is a high degree of risk that poor performance will not be identified (or will be picked up at a later stage) and patients will be harmed.

Options

The options are, broadly, (a) do nothing, (b) a collection of local datasets perhaps with common standards and clear protocols for sharing information, and (c) a combination of local datasets and the central database recommended by the Shipman Inquiry. There are sensitive issues of confidentiality and the right of healthcare professionals to protect their reputation from unproven allegations, which need to be balanced against the need to protect patients.

On local datasets, the government agrees with the Shipman Inquiry that it would be helpful to give further guidance to healthcare organisations on the data which should be held locally and the conditions under which it should be shared, backed by a statutory duty to share information with other organisations where needed to protect patient safety, modelled on the provisions in the 2006 Health Act relating specifically to controlled drugs.

The proposal for a central database was studied in depth in the CMO's review of medical regulation and is addressed in his proposals for a system of "recorded concerns" (performance issues which are admitted by the doctor but are not sufficiently serious to warrant referral to the central GMC) and for relevant disciplinary information to be held on the GMC register and accessible to NHS and other accredited employers. The government has

accepted these proposals and they are described more fully in *Trust, assurance and safety*.

Finally the government agrees with the recommendations in the CMO's review for further work on the data needed by PCTs to monitor the quality of services provided by GPs, building on the successful experience in some areas.

Costs and benefits

There would be significant set up costs in improving information systems in NHS organisations (around £8m) and some additional running costs both for NHS organisations (around £4m pa) and for GP practices (around £2m pa). The running costs would be classified as "administrative costs" on the definitions of the Better Regulation Executive. There would be offsetting savings in the earlier identification of performance problems. The main benefits would be in improved patient safety and improved quality of services.

Equity and fairness

The Shipman Inquiry's recommendations would in the first instance impact on PCTs, not on individual GP practices. Any consequential changes in secondary care would impact equally on all providers, NHS and independent sector. Impact would be broadly similar across all sectors of society – it is likely that standards would improve faster in deprived areas where poor practice tends to be concentrated.

Impact on small firms

There would be some additional costs to GP practices and other front-line primary care providers, mainly from responding to requests for information when potential problems were identified.

Competition

We have applied the competition filter tests and consider that the likely action programme will have no impact on competition.

Enforcement

Enforcement would be an issue only for independent providers of secondary care. In this case, enforcement would be through contracts or through the requirements for registration with the Healthcare Commission.