Learning from tragedy, keeping patients safe

Overview of the Government's action programme in response to the recommendations of the Shipman Inquiry

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Foreword
from the Secretary of State for Health, the Minister of State for Policing, Security and Community Safety, and the Minister of State for Constitutional Affairs



There can be few people in the United Kingdom who are unaware of Harold Shipman, a respected GP from Hyde in Greater Manchester who, over a period of 20 or more years, was responsible for the murder of around 250 of his patients. In the years since Shipman was convicted, two questions are continuously debated. Firstly, what made an apparently caring, competent doctor turn to murder on such a horrific scale? And secondly, why did nobody in authority realise what was going on?

The Shipman Inquiry was set up in January 2001, following Shipman's conviction the previous year for the murder of 15 of his patients. The Inquiry was tasked with investigating the extent of Shipman's unlawful activities, enquiring into the activities of the statutory authorities and other organisations involved, and making recommendations on the steps needed to protect patients for the future.

The Inquiry published a total of six reports. The first and last addressed the extent of Shipman's criminal activities, as a general practitioner (First Report) and in the early part of his career as a junior hospital doctor (Sixth Report). The other reports considered the various processes and systems which failed to detect his activities at an earlier stage – the 1998 investigation by the Greater Manchester Police (Second Report), death certification and the coroner system (Third Report), the systems for ensuring the safe and appropriate use of controlled drugs (Fourth report), and the arrangements for monitoring and disciplining GPs including arrangements for whistleblowing and handling complaints in the NHS (Fifth Report).

We owe an immense debt of gratitude to Dame Janet Smith and her team for their meticulous analysis of the weaknesses in existing systems which Shipman was able to exploit for his criminal purposes, and for the skill with which her recommendations balance the need to safeguard the normal processes of patient care and the need to protect the public from professional abuse.

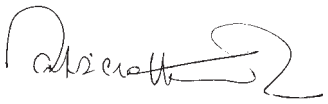
As the Shipman Inquiry acknowledged, the NHS today is in many ways very different from the NHS in which Shipman practised. Among many other changes, there is a far greater acceptance of the view that the quality and safety of patient care is not just the responsibility of individual doctors, nurses and other health professionals – important though that is – but a shared responsibility of all healthcare organisations. New structures and processes have been put in place to ensure the quality of care, to focus healthcare organisations on continuous quality improvement, and to ensure that seriously deficient clinical performance is rapidly identified and dealt with. In this new climate, it seems unlikely that the activities of a Shipman would have gone unrecognised for long.

It is also vital to keep a sense of proportion. The overwhelming majority of health professionals are committed to providing the best care they can to their patients. We need to celebrate their commitment, support their efforts, and provide them with the means to seek even further improvement in the quality of the care they provide. It would be a tragedy if, in trying to protect

patients from the small minority of professionals who pose a threat to them through incompetence, ill health or deliberate malevolence, we were to put obstacles in the way of the vast majority of caring and competent professionals.

Nevertheless, the Government has always accepted the need to strengthen the existing safeguards in all the areas covered in the Inquiry's reports. We have already responded formally to the recommendations on controlled drugs in the Inquiry's Fourth Report and action on reform of the coroners' system is underway. Today we are publishing a full response to the Inquiry's Fifth Report, covering also the related recommendations of the Ayling, Neale and Kerr/Haslam Inquiries; a major White Paper with proposals for reform of the regulation of health professionals; and outline proposals for reform of the processes for scrutiny of death certificates. This paper provides an overview of all the action the Government is taking, summarising all these publications and spanning the responsibilities of four government departments, to respond to the challenges posed by the Inquiry reports.

As Dame Janet has acknowledged, no system can offer complete security against abuse from minds as devious as Shipman's. We believe however that the government's comprehensive programme of action will provide patients with robust safeguards against abuse, without imposing additional burdens on health professionals or impeding access of patients to modern patient care.



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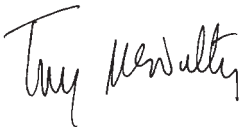

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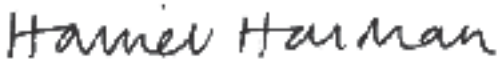

Harriet Harman

Chapter 1
Introduction

Harold Shipman

1.1 In January 2000 Harold Shipman, a single-handed GP practising in Hyde, Greater Manchester, was convicted at Preston Crown Court of murdering 15 of his patients. He committed these murders by injecting his patients with lethal doses of diamorphine, a strong painkiller related to heroin which has legitimate and widespread use in the treatment of the terminal stages of cancer and in other medical conditions. As further information came out both during and after the trial, including the results of an audit of Shipman's mortality data commissioned by the Department[1], it became apparent that these were not isolated crimes but merely a small sample of a horrific series of murders committed over as long as 25 years and spanning virtually the whole of Shipman's professional life.

1.2 We will never know exactly what motivated an apparently caring doctor – a doctor who in some respects was in the vanguard of medical practice[i] and who was popular with his patients and respected by his local community – to commit such atrocious crimes. The priority now must be to ask how Shipman's crimes could have gone undetected for so long and why a number of potential warning signals were ignored or overlooked. We need to learn the lessons from the Shipman case, and to put into practice those reasonable safeguards needed to protect patients and the general public from any possible recurrence.

1.3 There are still people who say that Shipman was unique; that it is futile to attempt to strengthen the existing safeguards, because any future individual who wanted to harm patients would evade them by using different methods; and that any additional safeguards will only have the effect of undermining the bond of trust between patient and health professional and of impeding the delivery of patient care.

1.4 The Government does not accept this point of view. Regrettably, there *have* been other recent examples, both in the United Kingdom and abroad, of health professionals who have abused the trust of their patients[ii]. Annex A summarises the findings of three recent inquiries which in some respects raise very similar issues to those of Shipman. It would be deeply irresponsible for the Government to turn a blind eye to the issues raised by these cases and to pretend that such crimes could never happen again.

1.5 The Government does, however, fully accept that any additional safeguards have to be proportionate to the risk and that they must be carefully designed to minimise the impact on patient care and on the relation between patients and health professionals. In addition, there have been significant changes in the NHS since Shipman's day which, as the Shipman Inquiry recognised,

i For instance, Shipman started prescribing statins for patients with heart disease before this was commonly recognised as good practice.

ii For instance, Benjamin Green, a nurse at Horton Hospital, Banbury was found guilty in April 2006 of murdering two patients and causing grievous bodily harm to 15 others.

provide many of the safeguards needed (see Chapter 3 below). This paper sets out a brief summary of the further action which the Government is taking – in various fields and spanning the responsibilities of four separate government departments – to learn from the lessons of the Shipman case. Further details can be found in the various documents listed in Annex B.

Early action

1.6 The Government took early action to strengthen the powers available to primary care trusts to safeguard patients. This included:

- **introducing checks on the qualifications, professional history and police record of candidates for GP positions;**
- **securing undertakings that GPs would participate in appraisal and cooperate with assessment by the National Clinical Assessment Service (see para 3.10 below); and**
- **introducing new powers to enable Primary Care Trusts (PCTs) to suspend GPs or remove them from the local list (see para 3.11).**

But it was recognised that this action, necessary as it was, could only be a starting point in considering the additional safeguards that might be needed.

Setting up the Shipman Inquiry

1.7 A public inquiry into the circumstances surrounding Shipman's activities was announced in September 2000 and established the following January. Dame Janet Smith (now Lady Justice Smith) was invited to chair the inquiry and, in addition to the inquiry's legal investigation team, the inquiry also had access to expert medical and epidemiological advice.

The inquiry's reports

1.8 The Shipman Inquiry published six reports in all. Two reports, the first report of July 2002[2] and the sixth report of January 2005[3], are essentially factual and seek to establish, as far as is now possible, which of the patients who died under Shipman's care died of natural causes and which as a result of his wrongdoing.

1.9 That leaves four reports which form the basis of this paper and which, between them, seek to answer the question: how was it possible for Shipman to continue his murderous career for so long without apparently arousing suspicion? These are:

- the second report of July 2003[4], which examines the shortcomings in the original police investigation by Greater Manchester Police in March and April 1998;
- the third report, also of July 2003[5], which examines the processes for death certification and the coroners' system, and asks whether more clues could have been found by better scrutiny either of individual deaths or of the pattern of deaths among Shipman's patients;
- the fourth report of July 2004[6], which looks at the then current safeguards on access to controlled drugs such as diamorphine and asks how Shipman was able to evade these controls and to amass such large quantities of lethal drugs;

- the fifth report of December 2004[7], which looks at current systems for monitoring the performance of doctors in general practice, at the handling of complaints from members of the general public and concerns of fellow professionals, and at the systems operated by the General Medical Council (GMC) for ensuring that doctors are and remain competent to practise.

1.10 The inquiry's reports confirm that Shipman was a devious and unscrupulous character who used his professional reputation and plausible manner to conceal most of the traces of his criminal actions. Nevertheless, the inquiry found that he did let his guard slip on a number of occasions, leaving clues that could and should have been picked up at an earlier stage. On one occasion, two of Shipman's professional colleagues noticed his use of diamorphine in a condition for which it is not appropriate – but failed to report their concerns. Other people, including a colleague in a neighbouring general practice who countersigned his cremation certificates, eventually noticed the apparently high rate of deaths among his patients – but their concerns were not taken seriously. Only when Shipman forged the will of one of his victims was serious action taken to unmask his activities.

1.11 The inquiry concluded that, if stronger safeguards had been in place, either Shipman might have been deterred from his criminal career or at least he would have been detected sooner. The further safeguards proposed by the inquiry are summarised in the next chapter.

Chapter 2
Main themes of the Inquiry's reports

2.1 The Shipman Inquiry's second, third, fourth and fifth reports are meticulous and detailed and contain a total of 190 recommendations. Details of the inquiry's recommendations and of the way in which they are being taken forward are given in the documents listed at Annex B. However, the main themes from the four reports can be summarised as follows.

The 1998 police investigation (second report)

2.2 The main conclusion of the second report was that the Greater Manchester Police investigation was delegated to an officer who was too inexperienced to work without direction and supervision. As a result, the officer in question failed to understand the nature of the concerns he was asked to investigate and failed to follow up what could have been vital leads.

2.3 The report makes no formal recommendations. It does, however, suggest that it would be helpful to issue guidance to detective officers who have to investigate allegations of wrongdoing by health professionals, and commends work already under way to develop guidance of this kind.

Death certification and the coroners' system (third report)

2.4 Under current arrangements, the doctor responsible for a patient's care during their final illness completes a "medical certificate of the cause of death" (MCCD), and this is the basis of the registration of the death. Doctors refer the case to the coroner if they have any suspicions over the cause of death or in other specified circumstances, for example if the death appears to have occurred during an operation or to result from an industrial disease. The registrar of births and deaths checks the MCCD to ensure that it is correctly completed and must report any cases to the coroner where the MCCD or information from the family of the deceased suggests that further investigation is needed, for instance if there was an unexplained injury or uncertainty over the cause of death. However registrars are not medically qualified, do not have access to medical records, and are not in a position to make informed judgements about the validity of the stated cause of death.

2.5 Where the bereaved family choose a burial, there are no further checks on the MCCD. For cremations, statutory forms are completed by two doctors, namely the treating doctor and an independent experienced doctor who makes enquiries and examines the body. The applicant for cremation (usually the next of kin) also completes a form. The medical referee at the crematorium authorises cremation in the light of the information on the forms completed by the applicant and the two doctors but does not examine the MCCD; nor does the medical referee have access to the medical records of the deceased. Either of the two doctors may refer the case to the coroner in cases of doubt. The medical referee is entitled to refuse to authorise the cremation if these doubts are not resolved but must give reasons for such a refusal.

2.6 The inquiry concluded that this system provided inadequate safeguards, particularly against the very unlikely (but sadly not unthinkable) possibility that the doctor completing the MCCD was responsible for the patient's death. It proposed a radical overhaul both of the coroners' system and of the arrangements for death certification, in which

- a single system for **oversight of death certificates** would be established, regardless of whether the deceased is to be buried or cremated;
- the certifying doctor would provide a **description of the chain of events leading to death** and an opinion on the cause of death and would refer all deaths to the coroners' service;
- a new **national coroners' service** under a Chief Coroner would be established at arm's length from national government, replacing the current system of local coroners appointed and funded by local authorities. This service would be responsible for the final certification of death and for deciding whether further investigation was necessary in all deaths; and
- the new system would contain both **medical coroners** who would be responsible for establishing the medical cause of death and **judicial coroners** who would carry out further investigations where necessary (eg in the case of suspicious deaths).

An independent Home Office review, the Tom Luce review, came to broadly similar conclusions[8] about the shortcomings of the current arrangements, although proposing rather different solutions.

Use of routine monitoring data (fifth report)

2.7 At the time Shipman was committing his crimes, very little systematic data was collected on the performance of health professionals, especially in general practice where the "independent status" of GPs was (and to a large extent still is) greatly valued by GPs and their patients alike. From the 1980s onwards data on prescribing patterns was collected, but mainly to encourage appropriate and cost-effective prescribing. Information on complaints and concerns about individual GPs was held, if at all, in informal files held in the offices of directors of public health in primary care organisations[iii]. There were no systematic arrangements for sharing information between healthcare organisations, even when doctors worked for more than one organisation[iv].

2.8 Research carried out on behalf of the Shipman Inquiry[9] suggested that, if data on the number and pattern of deaths of Shipman's patients had been analysed, some unusual features would have come to light – for instance, the high proportion who died in the afternoon when Shipman carried out his home visits. The inquiry concluded that the NHS needed to adopt a much more systematic approach to collecting and monitoring information on the performance of doctors, including

- more accurate ascription of **prescribing data** to individual doctors;
- routine monitoring of **mortality rates** by GP practice;
- closer specification of the information on **individual doctors** to be held in personnel files of NHS organisations; and

iii Over the period covered by Shipman's crimes there were several changes in the organisation of primary care. For much of the relevant period GPs like Shipman were accountable to "family health service authorities" (FHSAs), which were responsible for aspects of monitoring, discipline and complaints. The role is now exercised by primary care trusts (PCTs).

iv This was a major weakness of NHS systems in the case of Clifford Ayling – see Annex A.

- setting up a **central database** containing a subset of this information on all doctors so as to enable – subject to strict safeguards on access – better sharing of information between NHS organisations.

Responding to complaints and concerns (fifth report)

2.9 Complaints from patients, and expressions of concern from fellow professionals, are potentially a rich source of information to help healthcare organisations detect early signs of poor or malicious performance in health professionals. In Shipman's time there were already avenues open to complaints from patients, and from 1987 onwards doctors had an explicit ethical duty to report any concerns about their colleagues. But these potential safeguards were ineffective, for various reasons:

- a reluctance on the part of patients or members of the general public to voice complaints about health professionals, in part because of the prevailing culture of deference to authority;
- a professional culture which prized loyalty to one's fellow professionals, even if the safety of patients might be at risk;
- a perception (largely correct) that primary care organisations had little influence over GPs and that there was little point in raising concerns if no action was likely to follow.

2.10 The Shipman Inquiry recommended a number of improvements both to encourage the raising of complaints and concerns and to ensure that primary care organisations took effective action on them. Key proposals were:

- arrangements for making complaints about professional performance should be **simplified**, with a "single portal" rather than the current confusing arrangements;
- patients should have the right to express complaints **directly to the primary care trust** (PCT), and in any case all complaints (even if originally directed to the GP practice) should be copied to the PCT;
- PCTs should **scrutinise all complaints** and **investigate systematically** those which appear to relate to issues of professional performance or patient safety, referring on to the professional regulator where needed;
- PCTs should treat **expressions of concern** as seriously, and in the same way, as complaints;
- healthcare organisations (including GP practices) should clarify the arrangements for raising **concerns about fellow professionals**;
- the **statutory protection** for whistleblowers should be strengthened.

2.11 The inquiry noted that the powers of primary care organisations to discipline GPs (including suspension or removal from the "Performers List", the list of GPs practising in the PCT area) had been considerably strengthened since Shipman's day. But the inquiry proposed some **further strengthening**, including lesser sanctions to enable PCTs to deal with issues not sufficiently serious to require referral to the GMC or use of the list management powers.

The controlled drugs audit trail (fourth report)

2.12 Diamorphine, the drug used by Shipman for his murders, is a "controlled drug" (CD). CDs are subject to special controls because of their potential for diversion and abuse[v]. Shipman however was able to evade the controls and to amass a lethal quantity of diamorphine, in two main ways:

- by offering to collect prescriptions on behalf of his patients but then diverting some or all of the drugs to his own use;
- by collecting unused drugs from the homes of deceased patients, promising to return them for destruction (but in fact keeping them himself).

2.13 The inquiry proposed a number of changes to strengthen the audit trail, to restrict the number of prescribers authorised to prescribe CDs, and to provide oversight of the whole system. Key proposals were

- the creation of a new **CD inspectorate** with the skills to detect unusual prescribing patterns or other evidence of diversion;
- creation of a special **register** of prescribers authorised to prescribe CDs as part of their normal clinical practice;
- collection and collation of information on **private prescribing** of CDs and on **requisitions** (bulk orders) of CDs by GP practices for personal administration to patients;
- creation of an **audit trail** when health professionals or others collect CDs **on behalf of a patient**;
- special safeguards on the most dangerous CDs (injectable "schedule 2" CDs) dispensed for **use in the community**, eg for palliative care in terminal cancer.

Regulation of doctors (fifth report)

Appraisal and revalidation

2.14 Shortly before the Shipman Inquiry started work the GMC published proposals for a five yearly "revalidation" of doctors[10]. This was widely promoted as the equivalent of an "MOT for doctors", ie a means by which doctors could assure their patients that they had maintained their skills and remained fit to practise. An effective revalidation cycle would provide a further opportunity for concerns about a doctor's performance to be aired and for remedial action to be taken as needed.

2.15 The inquiry reviewed the way in which the GMC was intending to implement these proposals, including the use of an annual peer review process ("appraisal") introduced in 2001. The inquiry concluded that the original concept of revalidation had been seriously watered down to the point at which it would no longer provide any independent assurance of fitness to practise. It recommended **a complete review of both appraisal and revalidation** so that revalidation would provide the safeguards originally intended.

v See for example the article on controlled drugs on the NHS Direct website http://www.nhsdirect.nhs.uk

Fitness to practise processes

2.16 Once a doctor has been referred to the GMC – for instance, by a primary care organisation – the GMC initiates a series of processes to determine whether the doctor remains fit to practise or whether some sanction is required (in the most serious cases, erasure from the medical register). These processes comprise, in essence:

- a screening process, to see whether the allegation is sufficiently serious to proceed further;
- an investigation by GMC staff, leading to a preliminary hearing; and then if necessary
- a formal hearing by an adjudication panel set up by the GMC.

These processes have been substantially revised in recent years.

2.17 The inquiry studied in detail the recent changes in the processes and the guidance given to GMC officials and panels at the various stages. It concluded that, where choices had to be made, there was a consistent tendency to place a higher premium on the fair treatment of the doctor than on the protection of patients. It proposed a large number of detailed changes to the processes, of which the most significant were

- the adoption of the **civil standard of proof** ("on the balance of probabilities") rather than the criminal standard ("beyond reasonable doubt") in fitness to practise cases;
- publishing **clear and explicit standards** to be applied at each stage in the process;
- setting up an **independent adjudication panel** (ie completely independent of the GMC) to carry out the final adjudication stage of the process.

The inquiry saw these as the essential preconditions for re-establishing public confidence in the regulation of doctors.

Chapter 3
Developments in the NHS since Shipman's day

3.1 As the Shipman Inquiry recognised, the NHS of today is in some respects very different from the NHS in which Shipman practised. Some of these changes have happened because of – or at least have been accelerated by – the reaction to the Shipman case and other high-profile cases in which patients' trust in health professionals has been betrayed. Other changes reflect wider changes in society, for instance attitudes towards traditional authority figures, and changes prompted by a vigorous debate within the health professions themselves of what constitutes high-quality healthcare. Many of these changes derive from the wide-ranging strategy *A first class service: quality in the new NHS*, issued as a consultation document in 1998[11]. This chapter reviews some of the developments that are particularly relevant to the issues raised by the Shipman case.

Clinical governance

3.2 The concept of clinical governance was first introduced in *The new NHS – modern, dependable* in 1997[12] and developed further in A first class service and other publications in the following years[13]. The concept describes both an attitude – the acceptance that healthcare organisations have a *corporate* responsibility to provide safe and effective services and to strive for continuous quality improvement – and a set of structures and processes which help to put that attitude into effect. One definition is "a unifying concept for quality which provides organisations with a systematic means for ensuring that they comply with their statutory duty [for quality]"[14].

3.3 At the heart of clinical governance is the requirement for clinicians and clinical teams

- to assess the quality of the care they provide, using a combination of clinical outcomes and measures of patients' experience;
- to reflect on this experience, including both successes and failures; and
- to apply the lessons learnt in order to improve the quality of services.

3.4 At the level of the individual clinician or clinical team this process includes participation in *clinical audit*. But healthcare organisations as a whole – and PCTs in relation to the primary care services which they commission on behalf of their populations – need to carry out *a similar process of assessment* in order to identify poor-quality services and to encourage and reward the good. Identifying poor performance, and taking whatever steps are needed to protect patients from its results, is therefore an integral part of clinical governance.

3.5 This represents a radical shift from Shipman's day, when the dominant view was that GPs were independent practitioners accountable only to their own patients and to the GMC. Such a major cultural change cannot be expected to take place overnight. A recent National Audit Office report has[15] found that, in late 2005 when the fieldwork was carried out, **most PCTs had made good**

progress in establishing the basic structures and processes of clinical governance but that there was less evidence of the underlying cultural change needed. The next chapter describes the action the Government is taking to promote the further development of clinical governance concepts throughout the NHS.

Patient safety – *An organisation with a memory*

3.6 Patient safety is one vital aspect of clinical quality. It has two complementary facets:

- ensuring that the appropriate treatments are offered with as near as possible to 100% reliability; and
- minimising the risk of errors leading to avoidable adverse effects of treatment.

3.7 Much healthcare is intrinsically risky, especially in emergency situations, and some degree of error is inevitable. However, study of other high-risk "industries" has shown that error rates can be very significantly reduced by a combination of

- careful design of processes, assessing and minimising the intrinsic risk; and
- open reporting of safety incidents (adverse events and "near misses"), followed by a detailed "root cause" analysis of what went wrong and why.

Moreover, in an organisation as large as the NHS even rare accidents can be repeated over and over in different parts of the organisation unless information is shared and common lessons learnt. Patient safety incidents should therefore be reported not only locally but also to a national "reporting and learning system" so that lessons learnt can be disseminated throughout the NHS. These principles were first set out in the seminal report *An organisation with a memory*[16] and are now an integral part of NHS clinical governance processes.

3.8 One key element of a patient safety culture is the upward reporting of "significant events", ie patient safety incidents involving serious harm or death. In general practice, all **unexpected** deaths should be regarded as "significant events" in this sense and should result in both

- analysis and learning at the practice level; and
- upward reporting to the PCT for further analysis of patterns and trends.

In a mature patient safety culture of this kind, a cluster of unexpected deaths of the kind perpetrated by Shipman would be far more likely to be identified.

3.9 Although much progress has been made since the publication of *An organisation with a memory*, much more is still needed to establish a true patient safety culture in every NHS organisation. The recent report *Safety first*[17] proposes a number of further steps to re-affirm the priority of patient safety, including

- establishing a national patient safety forum;
- developing patient safety action teams in strategic health authorities, providing a specialist resource to support NHS organisations in investigating patient safety incidents; and

- making more effective use of reports of incidents and other information which could help to identify sources of unsafe care.

Handling performance issues and the National Clinical Assessment Service

3.10 Setting up systems to monitor and evaluate the outcomes of treatment would be of limited value in itself. NHS organisations also need effective processes to deal with the rare cases of poor professional performance which those systems will occasionally throw up. There have been important developments recently in both primary and secondary care:

- **In primary care, new *list management powers* were introduced in 2001**[18] to enable PCTs to suspend doctors while investigating concerns about their practice, and where necessary to remove them from the PCT's list of doctors authorised to provide care for that community;

- **In secondary care, new guidance was issued in 2005 on performance processes for employed doctors and dentists**.[19] This established the principle of a clear separation between the *investigation* of allegations and the formal machinery for *determining what action is needed* to protect patients. **A similar model for primary care has been published**.[20]

3.11 In dealing with performance issues NHS employers and PCTs will often need expert advice in deciding what action is needed, for instance whether the apparent deficiency can be relatively easily corrected by some form of remediation or whether the problem is more deep-seated. **The National Clinical Assessment Authority (now the National Clinical Assessment Service (NCAS) of the National Patient Safety Agency) was set up in 2001 to provide this service**[21]. National policies require NHS employers and PCTs to seek NCAS advice at all key stages of investigations and disciplinary procedures, and NCAS can also, if invited, carry out a full assessment of the clinician's performance. Final responsibility for action remains with the employer or PCT.

Towards a "patient-led NHS"

3.12 In Shipman's day, the predominant assumption in medicine was one of benevolent paternalism: health professionals were the experts on the treatment of disease and had the responsibility to use this expertise in deciding what was best for their patients.

3.13 We now live in a very different era. Patients have ready access, through the internet and by other means, to information about their condition and its treatment, and many patients (especially those with longer-term conditions) are now "expert patients", fully able to engage in informed discussion with their clinicians. **The Government has encouraged and supported this development through its "expert patients programme"**[22]. With the development of more powerful treatments clinicians are more aware that the choice of treatment can involve a difficult weighing up of the benefits, risks and adverse effects of different treatments and that the "right" choice depends crucially on the value judgements of patients and carers rather than on those of the clinician. There is also a wider recognition that patients, carers and the general public have key insights into the design of services and into the steps needed to improve quality and safety[23].

3.14 In this changing climate of opinion, feedback from patients and carers – whether in the form of complaints or commendations – is now recognised as a positive input to improving the quality of services rather than as a "nuisance" to be dealt with. If this had been the mentality in the health service of Shipman's day, his story might have been very different.

Regulation of healthcare organisations

3.15 For many years, private healthcare organisations have been subject to inspection to ensure that they meet national standards of quality and safety. The principle of external assessment, to clear national standards, was extended to NHS organisations as a result of the proposals in *A first class service*[11]. The Commission for Healthcare Inspection (later the Healthcare Commission) was set up to provide this external assessment against national standards, published in 2004 as *Standards for Better Health*[14]. Each year the Healthcare Commission published its assessment of the performance of all specialist trusts and primary care trusts against these standards, leading to an overall rating based on the balance of performance across all the standards.

3.16 Further developments of these arrangements were recently announced in *The regulation of health and adult social care in England*[24]. With effect from 2009-10 all healthcare providers, NHS and private sector, will need to be "registered" with the regulator and assessed against national standards of quality and safety. Organisations failing to meet the standards will need to take urgent remedial action and could, in the last resort, lose their registration.

Summary

3.17 This chapter has surveyed some of the changes which have already taken place in the NHS since Shipman's day. If the processes and attitudes described had been in place then, it is very likely that Shipman's misdeeds would have been detected far earlier. However, the Government accepts that more needs to be done to embed these processes and, more importantly, to achieve the change in culture needed to instil a true patient focus throughout the NHS. The next chapter describes the Government's proposals for further strengthening the safeguards needed to ensure the safety of patients and the general public.

Chapter 4
The Government's action programme

4.1 This chapter summarises the action which the Government has set in hand to take forward the recommendations of the Shipman Inquiry and of the "three inquiries" described in Annex A. It includes a brief summary of the complementary action on the regulation of the health professions, following consultation on the reviews of medical[25] and non-medical[26] regulation which were in part prompted by the inquiry's fifth report. This is a comprehensive action programme spanning the work of several government departments. Further detail on individual components of the work programme can be found in the documents listed in Annex B, including a White Paper on the future of professional regulation, *Trust, assurance and safety: the regulation of health professionals in the 21st century*, which is also published today.

4.2 In approaching the recommendations of the various inquiries, the Government adopted four overarching 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 health professions and not just to doctors.

4.3 The Shipman Inquiry was of course fully aware of the need to protect patients' access to services and of the need to build on existing NHS structures. Nevertheless, the NHS has continued to evolve rapidly even in the relatively short period since the inquiry carried out its fieldwork. And consideration of the implications for secondary care and for the non-medical professions was outside the inquiry's terms of reference. The Government believes that the actions set out below are faithful to the spirit of the Shipman Inquiry's recommendations, even if the detailed implementation differs in some respects.

Police investigation of cases involving health professionals

4.4 As noted above (para 2.3), the Shipman Inquiry's Second Report made no formal recommendation but commended work already under way to develop guidance for police officers carrying out investigations of unexpected deaths – or other incidents leading to serious harm – of patients following treatment by health professionals. This work has now been completed; there is

a relevant entry on this issue in the 2006 edition of the *Murder Investigation Manual*, and to complement this the Association of Police Officers, the NHS and the Health and Safety Executive have published a "Memorandum of Understanding", following widespread consultation with the NHS, patient groups, and professional and police interests[27]. Key points in the memorandum are:

- the differing roles of the three parties, with the presumption that the NHS will lead any investigation into patient safety issues unless there is clear evidence that harm was deliberately intended or was the result of gross negligence or recklessness;
- early liaison between the three parties through an initial meeting of an "incident coordination group";
- clarity over the responsibility for initial investigation;
- securing and preserving evidence;
- sharing information; and
- supporting those harmed, other patients, relatives and NHS staff.

The national development group which was responsible for drafting the protocol will review the use made of it at the end of the first year after publication.

Reform of the coroners' system

4.5 The Government announced its plans for reform of the coroners' system in February 2006[28] and published a draft Coroners Bill in June 2006[29]. A substantive bill will be introduced as soon as Parliamentary time allows. Reform will bring five main benefits:

- **bereaved people will be able to contribute more to coroners' investigations**, and there will be **a new appeals system** if they are unhappy about decisions taken;
- **national leadership will be introduced through a new Chief Coroner and an advisory Coronial Council;**
- coroners will continue to be funded by local authorities, but **posts will be whole time** and current boundaries will be **reshaped to ensure a fair distribution of work** and good links with relevant agencies;
- coroners will have **new powers to obtain information and to summon witnesses**, ensuring better investigations and inquests;
- coroners will have better **medical support and advice** at both local and national levels.

4.6 The Government fully recognises the importance of additional medical advice to the coroners' service. **A new Medical Adviser to the Chief Coroner will**

- **provide advice on strategic issues**, such as whether the right cases are being reported to the coroner under the proposed new statutory duty on the medical profession to report specified deaths, or the provision of pathology services and the use of post mortems; and

- **act as consultant to the Chief Coroner** on particularly complex medical cases on which he or she may be required, for example, to determine appeals.

4.7 The Government will set aside additional funds to provide coroners with similar advice at a local level. Each coroner will, in consultation with his or her local authority, determine precisely what medical support and advice they would like to access to benefit the service, within budget constraints. In doing so, coroners will need to ensure that for any given investigation the source of this advice is a doctor who is independent of the healthcare organisations responsible for the final care of the patient whose death has been referred; with this proviso, coroners may wish to use the expertise of doctors who are involved in the initial scrutiny of deaths in PCTs and hospital trusts (see below). The Government believes that these are positive proposals which will have a real benefit for the bereaved.

4.8 We will also be consulting shortly on modernising and consolidating the Cremation Regulations. These will include a **new right for families to examine the medical forms prior to authorisation of the cremation by the medical referee**, and to challenge or query their accuracy with a view to further investigation of the cause of death by the medical referee or the coroner. Furthermore, **we will publicise the opportunity that bereaved relatives already have to ask a coroner to investigate a cause of death**, if they have concerns about the reasons given for death, by a doctor, on a death certificate.

Improvements in the process for death certification

4.9 The Government accepts the Shipman Inquiry's conclusion[30] that the existing arrangements for scrutinising the medical certificate of cause of death (MCCD) are confusing and inadequate. The key problems are that

- there is **no** independent medical scrutiny of the MCCD at all in the case of burials, unless the doctor signing the MCCD specifically refers the case to the coroner, or the registrar refers to the coroner before registering the death;

- in contrast, although there are successive checks by two successive doctors in cremation cases, the scrutiny is not always sufficiently independent of the doctor signing the MCCD and is not subject to effective quality assurance. The existing processes were criticised both by the Shipman Inquiry and by the independent report commissioned by the Home Office[8];

- there is no routine system for analysis for local clinical governance purposes of the information on the MCCDs or on the additional forms completed for cremations, and no explicit link to clinical governance processes in hospitals or in PCTs.

4.10 The Government therefore proposes a variant of the Shipman Inquiry's key recommendation[vi] in order to create a rigorous, unified system covering both burials and cremations. The proposal is that:

- MCCDs, for burials and cremations alike, would be subject to scrutiny by an independent "medical examiner" attached to the clinical governance team in the hospital trust (secondary care) or PCT (primary care);

vi These proposals would apply in England and Wales. The existing system in Scotland is rather different, and a separate review of Scottish burial and cremation legislation will announce its conclusions later this year.

- where the medical examiner was not satisfied that the MCCD told the full story or felt that there were other unusual circumstances, he or she would refer the case to the coroner for further investigation, along with his or her reasons for doing so;

- the medical examiner would have full access to medical records and would be empowered to discuss the circumstances of the death with the doctor signing the MCCD and with the family of the deceased;

- the clinical governance team would collate information from MCCDs and would use this to analyse trends and patterns, looking out for unusual features such as those revealed by Shipman's pattern of deaths;

- the clinical governance team would ensure that all unexpected deaths were treated as significant events and followed up in individual and team clinical audit. This would link well with the proposals from *Good doctors, safer patients*[25] for the monitoring of all significant events in general practice (see below para 4.17).

4.11 The Government believes that arrangements along these lines will be fair to families and will provide much more effective safeguards for *both* burial and cremation cases than the current arrangements. Further details are will be published shortly in a consultation paper.

Safer management of controlled drugs

4.12 The Government's action programme for strengthening the safeguards relating to controlled drugs was published in 2004 as *Safer management of controlled drugs*[31], and action is now well under way. The main components of the action programme are:

i. *New governance arrangements.* The Government carefully considered the inquiry's recommendation of a new controlled drugs inspectorate (see para 2.13) but decided that **it would be better to build on existing governance arrangements** in the NHS. Details were set out in guidance to the NHS in March 2006[32], and the legislative underpinning was provided by a section in the 2006 Health Act and in subsequent regulations[33]. The key features are

   – **requiring health organisations** (including hospital trusts and PCTs) **to appoint an "accountable officer" with personal responsibility for the safe management and use of CDs** within the organisation;

   – **requiring health organisations, police forces and health professions regulators to share information** about potential CD offences and to collaborate in any action needed to protect the public; and

   – **creating clearer arrangements for the monitoring and inspection of the use of CDs by health and social care organisations**, including clarifying or in some cases extending the right of entry for accountable officers and their staff, health professions regulators and police.

ii. *Restrictions on prescribing CDs.* The Government has worked with professional organisations to place a clear professional requirement on all professionals who prescribe CDs to work within their professional competence. **Guidance has now been issued or reissued by all relevant health professions regulators.** Any significant breaches will be followed up by the regulator. The Government considers that this is more practicable than attempting to create a special cadre of professionals who could or could not prescribe CDs[34], given that the great majority of doctors and other prescribers will have a legitimate need to prescribe CDs as some part of their professional practice.

iii *Strengthening the audit trail.* The Government has accepted essentially all the inquiry's proposals for strengthening the audit trail[35]. The Government has already

– **developed and implemented a new system for capturing and analysing information on private prescribing of CDs**[36];

– **introduced new checks on patients or health professionals who claim to be collecting CDs on behalf of a patient**[36];

and will shortly

– **introduce a statutory requirement for all GP practices** to develop and agree with their PCT a **standing operating requirement** setting out clear protocols for their use of CDs; and

– **develop and implement an audit trail for GP requisitions** of CDs for use within the practice.

The most potentially difficult recommendations relate to the audit trail for drugs dispensed into the community (see para 2.13 above); a small-scale pilot gave encouraging results and the **Department of Health is now proceeding to a larger-scale pilot before final decisions are taken**. In the longer term, the Government considers that the best way of strengthening the audit trail will be through promoting the use of electronic generation (and ultimately electronic transmission) of CD prescriptions and electronic CD registers, and **legislative changes to allow this are under way**[37].

iv *Information for patients.* The Government agrees with the inquiry[38] that patients need to be better informed about the special status of CDs and the need to ensure that they do not fall into the wrong hands. This, however, needs to be done in a way that does not unduly alarm patients or discourage them from taking the medicines they need. In collaboration with other organisations and information providers, **the Department of Health**

- **has used a number of routes to convey *generic* information on the safe handling of all medicines; and**

- **has commissioned guidance giving *specific* information about the therapeutic uses and special status of CDs;** the first of these "medicines guides" have recently been published[39].

v *Professional education.* The Government considers that one of the best safeguards for patients will lie in better education for health professionals in the appropriate use of CDs and in the special precautions needed in handling them. **The Department of Health is therefore working with the health professions regulators and with the authorities responsible for undergraduate and postgraduate training to ensure that these principles are fully reflected in initial and postgraduate education and in continuing professional development.**

Clinical governance and the identification of potential performance issues

4.13 The crucial first step in any system for managing professional performance is the initial identification of cause for concern. In Shipman's case, despite the ingenuity with which he attempted to cover his traces, a number of potential clues were missed (see para 1.10). As Annex A describes in more detail, similar lessons emerge from the Ayling and Kerr/Haslam inquiries of failure to recognise the significance of concerns expressed, coupled – in Ayling's case – with the failure of different NHS organisations to combine the information they had.

4.14 The Government considers that establishing strong clinical governance processes and culture is the key to this initial identification of potential problems. Considerable progress has already been made in establishing the underlying structures and processes, although more is needed to embed the cultural change required[40]. The Department has recently carried out a review of NHS clinical governance arrangements and confirmed that there is still a need for central support to help healthcare organisations enhance their clinical governance processes.

4.15 To identify potential performance issues, clinical governance units in PCTs and specialist trusts need to work with two different kinds of information:

- indicators of clinical processes and outcomes which, taken together, give a broad view of the clinical competence and performance of clinical teams and (where appropriate) individual clinicians;

- information derived from complaints from patients and carers, expressions of concern from fellow professionals, and information from other organisations that have employed the professional.

4.16 *Clinical process and outcome data.* In general practice, a number of PCTs have experimented with the use of "scorecards" combining routinely available data and comparing all GPs within the PCT. Hospitals can similarly "benchmark" clinical indicators for their own clinicians or clinical teams against indicators in other comparable units or against international best practice. In either case an unusual score on any one indicator may have a perfectly innocuous explanation, but extreme scores on a number of complementary indicators would indicate the need for further investigation. As recommended in the CMO's review of medical regulation[41], **the Department will work with professional bodies both in general practice and in hospital specialties to develop such indicator sets for all major clinical specialties, and in particular to explore the use of prescribing data and the monitoring of significant events, including death monitoring.** Information from the proposed additional scrutiny of death certificates (see above para 4.10) will be very valuable for this purpose.

4.17 *Other intelligence.* The use of other forms of intelligence raises difficult issues. Some complaints and expressions of concern may be malicious or based on a genuine misunderstanding, and such information must be subject to very strict safeguards to ensure that professionals' reputations are not unfairly impugned. On the other hand, both the Shipman and the Ayling cases demonstrate that the safety of patients may depend on joining up pieces of "soft" information which individually would not justify taking action. And where, following a fair and thorough investigation, a complaint has been upheld and action taken – for instance, where this has led to formal disciplinary action or, for doctors, the issuing of a "recorded concern" (see para 4.26 below) – this is information which could well be relevant to handling any further complaints or concerns. **The Government will work with the health professions regulators, as recommended by the Shipman Inquiry, to agree guidance to the NHS on**

- **what information should be held in the personnel files of NHS organisations; and**

- **the safeguards under which such information may be shared between organisations.**

4.18 For the medical profession, special safeguards may be needed because many doctors in both general and hospital practice are working without direct supervision and have access to powerful drugs and other treatments. **The Government is therefore implementing the proposal in the CMO's review[42] to set up a network of "GMC affiliates" and lay associates, trained by the GMC but working alongside clinical governance units in NHS organisations.** They will help to assess the significance of information relating to the performance of individual doctors and to determine which issues should be referred to the GMC and which can be handled locally, including by use of the "recorded concern" procedure described in para 4.26 below.

4.19 In addition, the Government will work with the GMC and other stakeholders to make the Medical Register the prime source of information about the registration status of doctors, including any "recorded concerns" or information about disciplinary issues affecting their practice[43]. Some of this information will be freely available; other information will be accessible only to the doctors themselves, to GMC affiliates and their teams, and to approved employers.

A new approach to complaints and concerns

4.20 As already noted, complaints from patients and carers and expressions of concern from fellow professionals and other sources form an important source of information which may indicate poor professional performance or (in very rare cases) deliberate abuse of patients. For this to work properly, there are two requirements:

- supporting people who want to make complaints or raise concerns, so that they know where to go and can be assured that their story will be listened to and acted on;

- ensuring that healthcare organisations have the processes and skills to act effectively on what they hear.

The Department of Health will be addressing both these aspects in a consultation document, to be published in the near future, proposing a comprehensive reform of the complaints system for health and social care. Key aspects relevant to professional performance issues are as follows.

4.21 *Supporting people with complaints and concerns.* Subject to consultation, **the Government proposes:**

- **to introduce a right for patients with complaints against a GP to go directly to the PCT rather than to the GP practice**, as recommended by the Shipman Inquiry and endorsed by the CMO's review[44];

- **to create for patients with complaints or concerns about a doctor the opportunity to discuss their concerns with a GMC affiliate paired with a lay person** (current GMC procedures do not provide such an opportunity);

- **to consider parallel arrangements for patients with a complaint against a local hospital** who have inhibitions about going direct to the hospital management;

- **to agree a concordat** between organisations likely to receive complaints from patients **to ensure that complaints are speedily routed, with the complainant's permission, to the most appropriate body**;

- **to develop good practice on the need to keep complainants informed about the process which will be adopted to investigate the complaint, and about the subsequent progress of the investigation;**

- **to ensure widespread dissemination of the arrangements to enable fellow professionals or members of the general public to raise concerns**, including arrangements to cater for situations in which the person raising the complaint feels unable to go to their own management or organisation.

4.22 *Acting on complaints and concerns.* The government proposes:

- **to issue guidance on the level at which complaints should be investigated**, in particular ensuring that those which may raise more general issues about the performance or conduct of health professionals are investigated at a sufficient level of seniority, and that complaints from more vulnerable people who may find it difficult to articulate their true concerns are taken seriously;

- **to place a responsibility on PCTs to maintain an overview of complaints against GPs**, including where necessary taking over the investigation of complaints even where they were lodged with the practice in the first instance, as recommended by the Shipman Inquiry[45];

- **to work with the NHS to build capacity and skills** in practices, PCTs and hospital trusts to investigate serious allegations, including collaboration between PCTs where this would help to concentrate skills and experience;

- **to develop more robust arrangements for the performance management of complaints handling in healthcare organisations.**

Underpinning these specific measures, **the Government proposes, as Parliamentary time allows, to strengthen the statutory responsibility for quality of healthcare organisations, including a specific responsibility for ensuring that lessons are learnt from medical errors and complaints.** This fulfils recommendations from the Shipman Inquiry and from the CMO's review[46].

Local handling of identified performance issues

4.23 Where local information suggests a potential performance issue, and further investigation shows that there is indeed a significant cause for concern, then local NHS organisations (hospital trusts and PCTs) have a statutory obligation to take whatever action is needed to protect patients and the public. The basic structures are already in place. For doctors and dentists, referral to the NCAS at this stage may be indicated (see above para 3.11), and the GMC affiliate should be involved (para 4.18). In some cases – particularly where the health professional accepts the need for improvement – it may be sufficient to agree a remediation plan.

4.24 In cases in which there is a possible need for more formal disciplinary action, PCTs and employers need to be able to act promptly to protect patients. **The Government has recently agreed new arrangements with the professions to clarify and simplify the process** (see para 3.10). The new guidance emphasises that

- decisions should be taken by the organisation's board, on advice from a panel chaired by a board member;

- the decision-making process should be clearly separated from the initial investigation; and

- health professionals should be fully informed about the allegations against them and have the opportunity to present their side of the case.

Possible sanctions available to hospital trusts include oral and written warnings, placing formal conditions on continuing practice (eg restriction to certain clinical areas or requirement for monitoring/supervision), dismissal, and referral to the health profession regulator. For GPs the equivalent sanctions include suspension from the list, the imposition of conditions (eg an undertaking not to use certain types of drugs), "contingent removal" from the list (removal which will become effective if the GP breaks certain conditions), removal from the local PCT list, and a national ban from appearing on any list.

4.25 The Shipman Inquiry considered that, despite recent reforms, the powers of PCTs to protect patients in the case of poor performance by GPs were still inadequate. Similarly, the early experience of PCT chief executives in using the new powers, as reported in the CMO's review, suggests that these arrangements are seen as too inflexible to deal with all but the most serious cases[47]. **The Government agrees and intends to strengthen these existing arrangements in three ways:**

i following a proposal in the CMO's review[48], **the Department of Health will clarify any ambiguity over the right of access of PCT staff to individual patient records**, subject to reasonable safeguards, where this is needed in the context of an investigation to protect patient safety;

ii during 2007 **the Department will review the operation of the Performers List system** in the light of other developments, including the introduction of GMC affiliates and "recorded concerns" (see para 4.26) and the proposed introduction of a system of registration of healthcare organisations (see para 3.16 above);

iii as part of this review, **the Department will discuss with GP interests a range of lesser sanctions** (short of suspension or placing formal conditions on remaining on the Performers List) that could be applied to GPs, including issuing formal warning notices and financial withholdings.

Reform of professional regulation

4.26 As already noted, the Government is today publishing a White Paper, *Trust, assurance and safety: the regulation of health professionals in the 21st century*, which sets out a comprehensive programme of reform of the system of professional regulation. Some of the key themes relevant to the issues raised by the Shipman case are as follows:

i *Clear standards.* As recommended by the Shipman Inquiry[49], **the GMC will be asked to develop clear generic standards to determine whether a doctor is or remains fit to practise**. For doctors wishing to record additional specialist qualifications on the GMC's specialist register, **similar specialty-specific standards will be drawn up by the appropriate Royal Medical College**.

ii *Local and national coordination.* **The Government will establish better arrangements to ensure that action by the local NHS employer (or PCT in the case of GPs and other primary care contractors) is coordinated with action by the national health professions regulator:**

– for doctors, **this will be ensured by means of the network of "GMC affiliates" described above (para 4.18)**. GMC affiliates will receive information from local employers/PCTs relating to the performance of individual doctors and will be responsible for deciding whether particular performance issues should be formally recorded on the doctor's record (with the doctor's agreement) as a "recorded concern" or be referred to the GMC's national fitness to practise procedures;

– for other health professionals working as employees of a healthcare organisation, **the employer will have a direct role in checking qualifications at initial registration and in operating local revalidation processes** (see next section), referring to the national regulator as at present for serious performance issues which could bring registration into question;

– for health professionals providing dental, pharmacy or optometry primary care services commissioned by the NHS (often alongside provision of private services), **we will discuss with the relevant regulatory bodies how best to involve PCTs in the routine monitoring of the quality of services and in the revalidation process**.

iii *National fitness to practise processes.* As recommended by the Shipman Inquiry, an independent tribunal will be set up to adjudicate in the final stage of fitness to practise procedures against doctors. The other health professions regulators will be invited to establish a clear separation between adjudication and their other functions and to draw members of their fitness to practise panels from a list maintained by the independent tribunal.

Making a reality of revalidation

4.27 As noted above, the Shipman Inquiry was critical of the GMC's proposals for implementing the concept of "revalidation" and considered that they fell far short of what was needed to ensure that doctors were periodically assessed as fit to practise. Market research carried out by the Department of Health in October 2005[50] showed that the majority of the public not only agreed that doctors should undergo an "MOT" of this kind, but believed that this was already the case.

4.28 *Trust, assurance and safety: the regulation of health professionals in the 21st century* also addresses this issue, and future arrangements will be as follows:

- **all health professionals will undergo periodic reassessment of their continuing fitness to practise**, although the frequency and rigour of the process will depend on an assessment of the intrinsic risk;

- for doctors, **the current NHS appraisal system will be strengthened to include an explicit judgement about performance in relation to the required standards**. Revalidation will have two components. *Relicensing* (revalidation against the generic standards) will be based on the recommendation of a local clinical governance and patient safety committee, informed by the results of appraisals and any recorded concerns. Separate *recertification* of specialist professional qualifications will be needed and will be based on recommendations from the appropriate Royal Medical College;

- for other health professions, **revalidation will be based on existing information available to employers, supplemented where needed by additional information or assessments**. The Department will work with interested parties to determine the form of this additional information and the circumstances in which it would be needed, bearing in mind the general principles of proportionality described above. For health professionals not working as employees of health organisations (eg primary care contractors) we will support the relevant regulatory bodies in developing proportionate revalidation procedures, building on existing developments such as the mandatory recertification introduced by the General Dental Council in 2002[51].

The Government believes that a system of revalidation along these lines will provide the assurance that patients and the general public are looking for, and will help to identify the very small number of professionals who are failing to maintain their skills, without imposing an undue burden on the rest of the profession.

Chapter 5
Taking the action forward

5.1 This paper has surveyed a wide range of action spanning the responsibilities of four separate government departments. Much of this action has already been completed or is already under way, in particular action relating to the Shipman Inquiry's second and fourth reports.

5.2 As noted above (para 4.11), the Government will shortly be issuing a consultation document spelling out in more detail our proposals for more rigorous scrutiny of death certificates, as proposed in the inquiry's third report, and for use of this information for local clinical governance purposes. During the consultation period, we will work with stakeholders and experts in this field to design a pilot study of the proposed arrangements. Final proposals, including proposals for the legislative changes that would be needed to put these ideas into effect, will be published later this year.

5.3 In relation to the inquiry's fifth report, the action set out in the Government's formal response *Safeguarding patients* and in the White Paper on professional regulation *Trust, assurance and safety* (see Annex B for detailed references) should be seen as a single programme of action. The overall objective must be to ensure patient safety, and to reassure the public that in future any behaviour by health professionals which puts that safety at risk will be swiftly identified, investigated, and dealt with. Although the broad thrust of the action programme is clear, many issues of detail remain which the Department of Health will need to discuss with patient, NHS, and professional groups. The Department will

- in due course publish an integrated action plan setting out a timetable for all the action envisaged in the two documents; and
- establish a national advisory group with all relevant stakeholders to advise the Department on implementation.

5.4 As the Shipman Inquiry noted, it will never be possible to give absolute assurances against the possibility of criminal action like that perpetrated by Shipman. The Government believes however that the actions summarised in this paper

- represent a proportionate response to the challenges posed by the Shipman case;
- will make it highly unlikely that any future criminal could go long without being detected; and
- will achieve this without putting undue obstacles in the way of that overwhelming majority of health professionals who want to give the best possible service to their patients.

References

[1] Richard Baker *Harold Shipman's clinical practice 1974-1998: a clinical audit commissioned by the Chief Medical Officer* (December 2000)

[2] Shipman Inquiry *Death disguised* (TSO July 2002)

[3] Shipman Inquiry *Shipman: the final report* (TSO January 2005)

[4] Shipman Inquiry *The police investigation of March 1998* (TSO, July 2003)

[5] Shipman Inquiry *Death certification and the investigation of deaths by coroners* (TSO, July 2003)

[6] Shipman Inquiry *The regulation of controlled drugs in the community* (TSO, July 2004)

[7] Shipman Inquiry *Safeguarding patients: lessons from the past – proposals for the future* (TSO, December 2004)

[8] *Death certification and investigation in England, Wales and Northern Ireland: the report of a fundamental review* (TSO, June 2003)

[9] See reference 1 and additional analyses in reference 2

[10] *Revalidating doctors, ensuring standards, securing the future* (General Medical Council, June 2000)

[11] *A first class service: quality in the new NHS* (Department of Health, July 1998)

[12] *The new NHS – modern, dependable* (Department of Health, December 1997)

[13] *Steps towards clinical governance* (Department of Health, January 1999); *Clinical governance – a practical guide for primary care teams* (Department of Health, January 1999); Liam Donaldson and Aidan Halligan *Implementing clinical governance: turning vision into reality* (BMJ, June 2001 **322** 1413-1417)

[14] *Standards for better health*, Annex A to *National standards, local action* (Department of Health, July 2004)

[15] *Improving quality and safety – progress in implementing clinical governance in primary care* (National Audit Office, January 2007)

[16] *An organisation with a memory* (Department of Health, June 2000)

[17] *Safety first* (Department of Health, December 2006)

[18] Health and Social Care Act 2001

[19] *Maintaining high professional standards in the modern NHS* (Department of Health, February 2005)

[20] *Local GP performance procedures*, available on the NCAS website www.ncas.npsa.nhs.uk/toolkit

[21] *Supporting doctors, protecting patients* (Department of Health, November 1999); *Assuring the quality of medical practice: implementing 'Supporting doctors, protecting patients'* (Department of Health, January 2001)

[22] *The expert patient: a new approach to chronic disease management for the 21st century* (Department of Health, June 2004)

[23] *Creating a patient-led NHS – delivering the NHS improvement plan* (Department of Health, March 2005); *Our health, our care, our say: a new direction for community services* (Department of Health, January 2006); *A stronger local voice* (Department of Health, July 2006)

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

[25] *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)

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

[27] *Memorandum of understanding: investigating patient safety incidents involving unexpected death or serious untoward harm* (Association of Police Officers, Department of Health and Health and Safety Executive, February 2006)

[28] Oral Statement by the Minister of State for Constitutional Affairs, 6 February 2006; briefing note *Coroners service reform* (Department for Constitutional Affairs, February 2006)

[29] *Coroner reform: the Government's draft bill – improving death investigation in England and Wales* (Department for Constitutional Affairs, June 2006)

[30] See reference 5 summary paras 13–20; recommendations 13–20

[31] *Safer management of controlled drugs: the government response to the Fourth Report of the Shipman Inquiry*, Cm 6343 (TSO, December 2004)

[32] *Safer management of controlled drugs: guidance on strengthened governance arrangements* (Department of Health, updated January 2007)

[33] Health Act 2006, Part 3, Chapter 1, Supervision of management and use of controlled drugs; Controlled drugs (supervision of management and use) regulations 2006 (SI 2006/3148)

[34] See reference 6 recommendation 2

[35] See reference 6 recommendations 9-13, 16-27 and 29-33

[36] *Safer management of controlled drugs: private CD prescriptions and other changes to the prescribing and dispensing of CDs* (Department of Health, July 2006)

[37] Initial changes were made in the Misuse of drugs and the misuse of drugs (supply to addicts) (amendment) regulations 2005 (SI 2005/2864), and the Government will make further changes to allow the electronic transmission of CD prescriptions once it is satisfied that the systems are secure.

[38] See reference 6 recommendation 28

[39] See the Medicines Guides website http://medguides.medicines.org.uk/

[40] See *Achieving improvements through clinical governance: a progress report on implementation by NHS Trusts* (National Audit Office, September 2003); reference 15; and chapter 2 of reference 25

[41] See reference 25 recommendation 34

[42] See reference 25 recommendations 2 (GMC affiliates) and 4 (recorded concerns)

[43] See reference 25 recommendations 38 and 39, reflecting similar recommendations in the Shipman Inquiry's fifth report (recommendations 40 and 45–7)

[44] Shipman Inquiry, fifth report, recommendation 1; *Good doctors, safer patients* recommendation 8

[45] Shipman Inquiry, fifth report, recommendation 3

[46] Shipman Inquiry, fifth report, recommendation 4; *Good doctors, safer patients* recommendation 35

[47] *Good doctors, safer patients* chapter 2, para 60

[48] *Good doctors, safer patients* recommendation 36

[49] See reference 7 recommendations 55 and 56; see also recommendation 16

[50] DH Press Release 2005/0344, Monday 10 October 2005

[51] *Continuing professional development for dentists* (General Dental Council, available on their website www.gdc-uk.org)

List of abbreviations

Abbreviation	Meaning	First reference at paragraph
CD	Controlled Drug	2.12
GMC	General Medical Council	1.9
MCCD	Medical Certificate of the Cause of Death	2.4
NCAS	National Clinical Assessment Service	3.11
PCT	Primary Care Trust	1.6

Annex A
The "three inquiries": Ayling, Neale, and Kerr and Haslam

Three inquiries into the activities of Richard Neale, Clifford Ayling, and William Kerr and Michael Haslam were announced on 13 July 2001 by Alan Milburn MP. The purpose of each inquiry was to consider the procedures in place in the NHS to enable patients and others to raise concerns or complaints against health service professionals.

Richard Neale

Richard Neale was a consultant obstetrician and gynaecologist practising mainly in Yorkshire from 1984 until 1996. He was struck off by the GMC in July 2000. One focus of the Neale Inquiry was on the way that Richard Neale was appointed in the UK, having been the subject of disciplinary proceedings in Canada that eventually led to him being struck off the Canadian medical register, as well as how complaints about him were handled by the NHS.

The inquiry found that he had misled his employers on a number of occasions, including in his applications for appointments. The inquiry questioned his judgement and reliability and the failure of his employers to recognise or address concerns about his conduct.

The recommendations cover the need for coherent guidance on all aspects of the appointment and employment of doctors, including careful checking of information offered during the appointment process and declarations about criminal cautions or convictions and other matters known to the applicant; information for patients; complaints handling and the patient advice and liaison service (PALS); and reporting of adverse events.

Clifford Ayling

Clifford Ayling was a GP and part-time clinical assistant practising in Folkestone from 1981 until 2000, when he was found guilty on a number of charges of indecent assault against former patients. The Ayling Inquiry focused on what it referred to as "sexualised behaviour". This is defined by the inquiry as overtly sexual behaviour that broke the boundaries of trust and integrity that patients have the right to expect from their doctor. This behaviour was mainly inappropriate touching or examination of women patients. Other concerns raised included his manner – being overly intimate, being unprofessional and failing to treat patients with dignity.

The inquiry's recommendations cover the need for guidance and training on the issue of sexualised behaviour for health professionals and organisations; improved training for staff in the patient advice and liaison service and the independent complaints advocacy service; better tracking of the employment and performance of health professionals; and systematic analysis of individual complaints and trends. The report also recommends support programmes for single-handed practitioners, the development of policies on chaperones, clarity around the roles of local medical

committees, and the development of protocols with other agencies and professional bodies for handling complaints in the NHS.

William Kerr and Michael Haslam

William Kerr and Michael Haslam were psychiatrists working in the NHS in Yorkshire. Complaints were made against both of them concerning inappropriate behaviour towards their patients.

Following police investigations, William Kerr was found, on a "trial of the facts" in December 2000, to have indecently assaulted a highly vulnerable psychiatric patient. He was placed on the sex offenders register. Michael Haslam was found guilty on four charges of indecent assault and one charge of rape against former patients, with the conviction for rape being found unsafe on appeal. His total sentence was three years on the outstanding charges of indecent assault, and he was released from prison on 14 June 2006. Both men sought voluntary erasure from the medical register.

The recommendations include improvements to appointment procedures; the monitoring of mental health therapies; guidance on the reporting of sexualised behaviour; handling of complaints, including record management; guidance on boundaries in long-term therapeutic relationships; professional training; and keeping and sharing information.

Annex B
Publications setting out further detail of the Government's action programme

Death certification and the coroners' system (Shipman Inquiry third report)

Coroner reform: the Government's draft bill – improving death investigation in England and Wales (Department for Constitutional Affairs, June 2006)

A consultation paper on reform of the system of death certification will follow shortly

Safeguards on controlled drugs (Shipman Inquiry fourth report)

Safer management of controlled drugs: the Government's response to the fourth report of the Shipman Inquiry (TSO, December 2004)

Section 3 of the Health Act 2006

Safer management of controlled drugs: guidance on strengthened governance arrangements (Department of Health, updated January 2007)

Monitoring of professional performance, complaints, and discipline (Shipman Inquiry fifth report)

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 (TSO, February 2007)

Trust, assurance and safety: the regulation of health professionals in the 21st century (TSO, February 2007)

A consultation paper on reform of the complaints system for NHS and social services will follow shortly

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