Department of
Health, Social Services and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

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Improving Patient Safety: Building Public Confidence

A Response by the Department of Health, Social Services and Public Safety to the Recommendations contained in Shipman Inquiry Reports 3, 4 and 5

November 2006

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EXECUTIVE SUMMARY

It is reported that most people in Northern Ireland are satisfied with the health and social care they receive, but high profile cases, such as the murders carried out by Harold Shipman, naturally lead to public concerns. The Department of Health, Social Services and Public Safety (DHSSPS) recognises the need to respond to these concerns, to improve systems and processes, and to learn from such catastrophic adverse events.

This document represents a DHSSPS response and Action Plan to Shipman Inquiry recommendations taking into account the Government's response to Shipman Inquiry Reports. Implementation of the action plan will involve health and social care professionals, the public, educational establishments, Health and Social Services (HSS) organisations and the DHSSPS.

The broad thrust of this DHSSPS response and action plan is to improve:-

- death certification (3rd Shipman Inquiry Report);
- systems and processes relating to controlled drugs (4th Report); and
- accountability, professional and organisational performance (5thReport).

Clear guidance for health and social care professionals and managers, strengthened governance arrangements and robust regulation will support the good work of professionals and build public confidence.

It should be noted that the DHSSPS response and Action Plan does not extend to the content of *Good Doctors, Safer Patients (July 2006)* which was written by Professor Sir Liam Donaldson in response to some of the recommendations contained in fifth Shipman Inquiry Report. Published alongside this report is another report – *The Regulation of Non –Medical Healthcare Professions.* Both of these documents are currently being consulted upon across the United Kingdom. Once the outcome of consultation is known in 2006/2007, the DHSSPS will assist in the implementation of UK-wide changes, especially those which have local impact.

Much work has already been done to promote clinical and social care governance and to improve the quality and safety of HSS services; these are described in Section 2 of this DHSSPS response.

Section 3 describes changes to improve the verification and recording of the fact of death and completion of the death certificate on the cause of death, referrals to the Coroners Service, registration of deaths and investigations of unexpected deaths. In addition, it recognises the need to work with other government departments, agencies and establishments to further promote appropriate post mortem examinations and compliance with the Human Tissue Act.

Section 4 outlines improvements to the regulation of controlled drugs, enhancements to local monitoring and inspection arrangements, and the need to improve information for patients and carers. It outlines legislative changes to the Misuse of Drugs Regulations and the need for further policy and regulatory changes to develop the role of the Accountable Officer for controlled drugs taking account of different health and social care settings.

Section 5 highlights work already underway to further embed clinical and social governance in general practice and to encourage reporting and learning from adverse incidents and near misses. In addition, it deals with other quality improvement initiatives, such as improving the monitoring of prescribing, medical appraisal, complaints procedures, whistleblowing, the handling of concerns and the GP practice mortality project. It outlines legislative changes to improve the regulation of family practitioner services. In addition it recognises the need to improve recruitment and employment practices and to improve support and governance arrangements in single –handed GP practices.

Information, education and training form a key component of the local action plan. This will include information for the public as well as training for professionals. The commitment to education and training throughout the action plan reflects the importance of supporting individuals and organisations to constantly improve their practice and promote safe, high quality services.

Patient and public safety are at the heart of the work of the Department of Health, Social Services and Public Safety (DHSSPS). This Response and Action Plan to Shipman Inquiry Reports are part of a much wider reform and modernisation programme of health and social services, and of public services in general. The Action Plan (2006/7- 2008/9) will contribute to ongoing efforts to ensure that the best possible quality of care is provided across the Health and Personal Social Services (HPSS) in Northern Ireland.

A detailed Action Plan is available on pages 39 to 48. This Action Plan identifies which organisations are responsible for specific actions, the anticipated outcome and the timeframe for completion. In summary, the actions cover:

Education and Training

- improve quality and safety through education and training;

Death Certification (Section 3)

- improve verification and recording of fact of death;
- enhance completion of medical certification of cause of death;
- improve referral of death to the coroner;
- enhance use of death certification information;
- promote appropriate post mortem examinations; and
- implement Human Tissue Authority's Codes of Practice.

Controlled Drugs (Section 4)

- improve regulation of controlled drugs;
- improve quality in prescribing through enhanced information systems;
- enhance a centralised pharmaceutical inspectorate;
- develop local arrangements for Accountable Officers for controlled drugs;
- promote liaison with other regulatory bodies;
- improve education and training; and
- provide better information for patients and carers.

Improved Governance Systems and Professional Performance (Section 5)

- convene local group to take forward the outcome of consultation on *Good Doctors, Safer Patients* and *The Regulation of Non-Medical Healthcare Professions*;
- enhance and produce an electronic version of Clinical and Social Care Governance portfolios for general practice and actively encourage their use and positive outcomes;
- amend legislation and develop local standards for private general medical and dental practice;
- clarify reporting arrangements for the management of adverse incidents in primary care and promote the cascade of learning arising from incidents;
- develop an incremental approach to improving the quality of prescribing and the attribution of prescribing data to individual GPs and groups, and support these changes through education and training;
- consult on a revised HPSS complaints procedure;
- produce new guidance on how to raise concerns about professional performance in primary care;
- produce further guidance on the handling of concerns about professional performance, to harmonise procedures across the HPSS;
- improve local regulation of family practitioner services;
- further develop and improve recruitment and employment procedures in general practice;
- improve governance arrangements in single-handed general practices;
- extend the scope of the GP Practice Mortality Project in Northern Ireland; and
- continue to work to enhance medical appraisal systems, taking account of the outcome of consultation of *Good Doctors, Safer Patients*.

SECTION 1
OVERVIEW of SHIPMAN INQUIRY RECOMMENDATIONS

1.0 INTRODUCTION

The aim of this document is to set out the response and action plan of the Department of Health, Social Services and Public Safety (DHSSPS) to the Shipman Inquiry recommendations, taking account of developments at national level and local Health and Social Services (HSS) arrangements.

Public safety and confidence in health and social services, and quality improvement, are at the heart of this document. This focus is set in the context of the Shipman Inquiry Reports and recommendations on:

Death Certification – enhanced processes (3rd Report);

Controlled drugs- enhanced inspection and monitoring arrangements (4th Report); and

Safeguarding patients- enhanced systems to improve clinical governance, professional regulation and performance (5th Report).

In addition to the unlawful activities of Harold Shipman, there are three other major reports which highlight the need to make continued progress to improve the quality and safety of service provision. These are Inquiries into the activities of Clifford Ayling, Richard Neale, and William Kerr and Michael Haslam. The common thread of all of these reports is the failure to protect patients and detect, at an early stage, unacceptable professional performance and to make timely interventions in order to promote patient safety.

1.1 SHIPMAN INQUIRY RECOMMENDATIONS

Dame Janet Smith was appointed chair of the Government Inquiry into the activities of a GP named Harold Shipman. The Terms of Reference of the Inquiry are included in Appendix A. The first two Reports related to the extent of the unlawful killing of patients by Shipman and the police investigation of 1998 into allegations of an unusually high death rate in Shipman's single handed GP practice.

The 3rd Report - *Death Certification and the Investigation of Deaths by the Coroner (July 2003)* considered the present system of death and cremation certification and variation in practice by coroners together with how a lack of regulation, awareness, training and guidance put patients at risk. There are 48 recommendations contained in the Shipman 3 report. Appendix B provides a summary of these recommendations.

The 4th report – *The Regulation of Controlled Drugs in the Community* was published in July 2004. It considered how the systems for regulating controlled drugs allowed Shipman to gather large quantities of diamorphine, a

controlled drug, which he then used to kill patients. There are 33 recommendations (Appendix C), which are aimed at improving the regulation, inspection, control, monitoring and audit arrangements of controlled drugs, and of the healthcare professionals who prescribe them.

The 5th Report – *Safeguarding Patients: Lessons from the Past, Proposals for the Future,* was published in December 2004. This explores how systems within the health service, including complaints procedures, concerns raised (whistleblowing), together with the fitness to practise procedures enabled Shipman to evade the notice of the authorities responsible for general practitioners. There are 109 recommendations contained in Shipman 5 *(Appendix D*) which cover a range of initiatives aimed at improving clinical governance arrangements so that underperforming doctors can be detected early and those doctors who are performing well can continue to improve. The scope of these recommendations is complex and far reaching; a number of recommendations relate to reforming the General Medical Council and its disciplinary procedures. These particular recommendations are UK wide issues, and are covered by *Good Doctors, Safer Patients*, a report written by the Chief Medical Officer for England, Professor Sir Liam Donaldson. It outlines major changes at local and national levels to enhance public safety. The consultation on this document closed on 10 November 2006.

The 6th report was published in January 2005. This mainly documented the extent of Shipman's unlawful activities during his career as a junior hospital doctor between 1970 and 1974.

In total, the Shipman Inquiry concluded that Harold Shipman killed about 250 patients between 1971- 1998. Of these deaths, Dame Janet Smith was able to positively identify 218.

1.2 STRUCTURE TO SUPPORT A LOCAL NORTHERN IRELAND RESPONSE

A local Shipman Programme Board was convened by the Department of Health Social Services and Public Safety to provide an integrated response to Shipman Inquiry Reports' recommendations. Its terms of reference and accountability arrangements are included in Appendix E. In addition to the Programme Board, a number of sub-groups have been formed to discuss specific complex issues. There are subgroups on:

a) Education and training, (recognising that this is the major component of the local action plan);

b) Development of whistleblowing policies in primary care;

c) Enhancement of underperformance procedures in General Medical and Dental Practice, taking account of new procedures already in place in the secondary sector, and links with the National Clinical Assessment Service; and

d) Enhancing data collection and analysis of prescriptions in general medical practice.

In addition to the above, the work of the DHSSPS Shipman Programme Board links to other departmental groups and activities, including the Review of the HPSS Complaints Procedures, the Northern Ireland Medicines Governance Team, the Safety in Health and Social Care Steering Group, the Medical Appraisal Working Group and the Review of Public Administration Steering Group.

SECTION 2

QUALITY AND SAFETY- KEY HPSS PRIORITIES

2.0 INTRODUCTION

Northern Ireland is unique in UK terms in having integrated health and social services; this, together with certain legislative, regulatory, funding and service commissioning and provision differences facilitates a slightly different perspective to be taken to Shipman Inquiry Reports' recommendations. However, as with national and international quality developments in health and social care in recent years, there has been a greater local emphasis on quality and safety.

Any local response to Shipman Inquiry Reports' recommendations has to be seen in the wider context of developments, which are currently being undertaken, to continually improve the quality of care and performance of health and social care services.

2.1 SUMMARY OF PROGRESS ON QUALITY AND SAFETY

Quality and safety is at the heart of the work of the Department of Health, Social Services and Public Safety (DHSSPS). *Best Practice, Best Care, (2001) s*et out the framework of the DHSSPS to improve quality and safety. Included in this framework was an emphasis on the need to set standards, improve service delivery, and the monitoring and regulation of Health and Personal Social Services (HPSS). This document contained a commitment to:-

A new system of clinical and social care governance for the HPSS;

A statutory duty of the HPSS for the quality of services provided;

Enhanced regulation of the HPSS, through the formation of a new Authority, (Regulation and Quality Improvement Authority); and

Formal links with national standard setting bodies such as the National Institute for Social Care Excellence (SCIE), and the National Institute for Health and Clinical Excellence (NICE).

Since then, the breadth of change to promote quality and safety in health and social care provision has been extensive. These include:-

- the imposition, from 1 April 2003, of a statutory duty of quality on the HSS Boards and Trusts;
- opening of the social care register, operated by the Northern Ireland Social Care Council (NISCC), which was established to regulate the social care workforce;

- the establishment, from 1 April 2005, of the Regulation and Quality Improvement Authority (RQIA);
- the development of *The Quality Standards for health and Social Care(2006)* to help ensure greater consistency in the quality of services and governance;
- the development of a range of other standards, e.g. Controls Assurance Standards;
- the establishment of the Clinical and Social Care Governance Support Team to support the HPSS in implementing the statutory duty of quality;
- the establishment of links with a range of national best practice and standard setting bodies e.g. NICE and SCIE;
- publication of *Safety First: A Framework for Sustainable Improvement in the HPSS(2006)* ; and
- the development of new arrangements for monitoring and learning from serious adverse incidents in the HPSS.

In addition, the Department has taken action on a wide range of other issues to drive improvements in quality and enhance safety in the HPSS. This has included, for example, reviews undertaken by the Social Services Inspectorate, reviews commissioned from the Regulation and Quality Improvement Authority and other organisations, and a major reform programme to reduce hospital waiting times.

2.2 REVIEW OF PUBLIC ADMINISTRATION

In November 2005, the Secretary of State for Northern Ireland announced sweeping changes to reform public administration. This includes reform to health and social care systems which has at it heart the approach of putting patients first. Changes will include a reduction in the number of Trusts to five by April 2007; functions of HPSS Boards and some functions of the Department being taken on by a new Health and Social Services Authority, by April 2008, and the formation of a new Patient and Client Council to replace the four Health and Social Services Councils. All of these changes are designed to improve the quality of care commissioned or provided by the HPSS. They will also facilitate integration of governance arrangements within larger organisations and enhance working relationships and the exchange of information between professional groups.

SECTION 3 – DEATH CERTIFICATION

3.0 DEATH CERTIFICATION, REGISTRATION AND INVESTIGATION

The 3rd Shipman Inquiry Report made 48 recommendations (Appendix B) on significant changes to death certification, registration and investigation. Recommendations included that all deaths be formally verified by a healthcare professional; that the medical certificate of cause of death (MCCD) become more detailed including a summary of medical history and the chain of events leading to death; that all deaths be referred to the coroner service for investigation including consultation with the deceased's family; random and targeted checks on MCCDs should be carried out by the coroner service; and that all deaths should undergo the same system of certification regardless of whether disposal was to be by burial or cremation.

In March 2004 the Home Office issued a position paper "Reforming the Coroner and Death Certification Service". This made proposals for changes for England and Wales, taking into consideration recommendations from the Shipman Inquiry and the 2003 Report of a Fundamental Review of Death Certification and Investigation in England, Wales and Northern Ireland. This position paper supported the concept of formal verification of death, certification of the medical cause of death by a treating doctor and confirmation of the cause of death by a Medical Examiner within the coroner service.

In a ministerial statement in February 2006, the Department of Constitutional Affairs gave an overview of reform of the coroner service. This included the creation of a service made up of full-time coroners with national leadership across England and Wales, with increased powers of investigation, increased rights and interaction with bereaved families and improved medical support. However, it was not intended to introduce a requirement to report every death to the coroner for second scrutiny.

3.1 NORTHERN IRELAND RESPONSE TO RECOMMENDATIONS IN THE THIRD REPORT

An Interdepartmental Working Group (DHSSPS and NI Court Service, General Register Office and PSNI) was formed in 2004 to consider the application of Home Office proposals to Northern Ireland. Interdepartmental meetings will continue to consider the relevance of the Department for Constitutional Affairs proposals for England and Wales to Northern Ireland. Implementation of local actions will focus on education and training of healthcare professionals who work within the HPSS. These will be part of the comprehensive educational framework to support implementation the DHSSPS Action Plan in response to Shipman Inquiry Reports 3, 4 and 5.

ACTION: Produce comprehensive education and training framework as a major part of the DHSSPS action plan in response to Shipman Inquiry Reports' recommendations contained in Reports 3, 4 and 5.

3.2 THE CORONERS SERVICE FOR NORTHERN IRELAND

Many of the recommendations relate to the coroners service *(Recommendations 1-12, 18-36, 44-46).* The new Coroners Service for Northern Ireland, which was launched in April 2006, has addressed many of the recommendations from the Shipman Inquiry, including the creation of a new regional service with full time Coroners and lead by a High Court Judge *(Recommendations 3, 10, 11)*, and improving information for the public *(Recommendation 44).*

It is recognised, however, that further work needs to be undertaken to ensure appropriate access to independent medical advice for the new Coroners Service.

ACTION: DHSSPS will support the NI Court Service to consider how the Coroners Service might best obtain appropriate medical advice.

3.3 VERIFICATION OF FACT OF DEATH

Healthcare professionals including doctors, nurses and ambulance personnel can, with appropriate training, verify the fact of death but there is variability in how verification of death is recorded.

ACTION: DHSSPS will issue guidance on appropriate verification and recording of the fact of death (*Recommendation 14)*.

3.4 COMPLETION of MEDICAL CERTIFICATE of CAUSE of DEATH (MCCD)

At present there are no plans to significantly change the forms used for death certification across the UK (*Recommendations 13-15*). However training is required at both undergraduate and postgraduate level to ensure that doctors complete the MCCD appropriately.

Discussion is taking place with those responsible for teaching the medical undergraduate curriculum to see how major clinical and social care governance issues might be enhanced; this will include professional responsibilities in relation to appropriate completion of death certification.

In addition, updated guidance on the completion of MCCDs will be developed and cascaded to all doctors in Northern Ireland. Implementation of this will be supported by education and audit.

ACTION: Guidance for doctors on the completion of MCCDs will be developed by DHSSPS in conjunction with the Coroners Service and General Register Office.

3.5 REFERRAL OF DEATHS TO THE CORONER

Doctors, registrars, police officers and funeral directors are required by the Coroners Act (Northern Ireland) 1959 to refer certain deaths to the coroner. These include death by violence or misadventure, as a result of negligence or misconduct or malpractice, due to a work related disease, or if the person has not been seen and treated for the disease causing death within 28 days prior to their death *(Recommendation 42).* Undergraduate and postgraduate training should facilitate appropriate reporting of deaths to the coroner and cascade advice on how to provide appropriate information to the coroner.

An inter agency group, chaired by the Northern Ireland Office, with input from DHSSPS, is developing a Best Practice Guide for Referring Deaths to the Coroner. This guide will include sections for various professions likely to be involved with deaths that should be referred to the coroner, including doctors, ambulance personnel, police and funeral directors.

ACTION: DHSSPS will contribute to the Interagency Group, chaired by the Northern Ireland Office, to produce Best Practice Guide for referring deaths to the Coroner.

3.6 REGISTRATION OF DEATHS (*Recommendations 42-44)*

Where a death has not been reported to the coroner, a relative will register the death by taking the MCCD to the local registrar's office. Information, based on registration of death, is useful for public health planning, and may also be able to indicate clusters of deaths which would merit investigation.

DHSSPS will work with the General Register Office and the Coroners Service to ensure appropriate completion of MCCD and referral of deaths to the Coroner and consider how information might best be utilised to enhance public health and safety.

ACTION: DHSSPS will issue guidance for doctors and registrars on completion of MCCD and referral to coroners.

3.7 INVESTIGATION OF UNEXPECTED DEATH (*Recommendations 32-35)*

A Memorandum of Understanding on Investigation of Serious Incidents Including Untoward Death was launched in Northern Ireland in February 2006. This was a joint initiative by the DHSSPS, the Police Service of Northern Ireland (PSNI), Health and Safety Executive for Northern Ireland (HSENI) and Northern Ireland Court Service, to bring together relevant agencies in order to improve co-ordination of investigations into serious patient incidents. The Memorandum will take effect in the event of an unexpected death or serious untoward harm to a patient requiring joint or simultaneous investigation by the PSNI, the coroner or the HSENI. This will normally happen if an incident involves criminal intent, recklessness and/or gross negligence or, in the

context of health & safety, involves a work-related death or serious injury. Such incidents will be serious and may have significant public safety implications.

In addition, a number of other reports have emphasised the need for procedures to inform the investigation of sudden and unexpected deaths in infants and children. In response to this the DHSSPS established an interdepartmental, interagency and multidisciplinary working group. A draft regional multidisciplinary protocol to be followed in cases of sudden or unexpected child deaths from birth to eighteen years will be published for consultation in early 2007.

3.8 INTEGRATED PATHOLOGY SERVICES

Northern Ireland already has a State Pathology Department which provides dedicated forensic pathology service to the Coroners *(Recommendation 41).* The DHSSPS will work with the Northern Ireland Office, which has responsibility for the State Pathology Department, to ensure appropriate post mortem examinations *(Recommendations 37-39)*.

ACTION : DHSSPS will work with the Northern Ireland Office, to promote appropriate post mortem examination, taking account of recommendations (37- 39) contained in the 3rd Shipman Inquiry Report.

3.9 RETENTION OF ORGANS AND TISSUES

Following the report of the NI Human Organs Inquiry (2002), the DHSSPS issued guidance on post mortem examination, retention and disposal of organs and tissues, and bereavement services *(Recommendation 40)*.

The new Regional Bereavement Network was launched in early 2006. It comprises five Area Bereavement Co-ordinators, based in local hospitals, but who will cover each Health and Social Services Board area. This will help to ensure the standards for consent to post mortem examination and use or disposal of organs and tissues are met.

The Human Tissue Act 2004 established the Human Tissue Authority (HTA), a UK- wide regulatory body. The HTA has developed codes of practice

- covering:
- Consent;
- Donation for transplantation;
- Post Mortem examinations;
- Anatomical examination; and
- Removal, storage and disposal of human organs and tissues.

The Coroners Service for Northern Ireland has appointed Coroners Liaison Officers to explain Coroners investigations, post mortem findings and the retention of any organs and tissues after a post mortem examination, including relative's options for their further use or disposal after the coroner has released them *(Recommendation 40 & 44).*

ACTION: All organisations will be required to practise in line with Human Tissue Authority Codes of Practice (September 2006)

3.10 CONCLUSION

The Department of Health, Social Services and Public Safety will work with the Coroners Service for Northern Ireland, the General Register Office for Northern Ireland, State Pathology Department and the HPSS to consider how improvements in each of the stages of death certification, investigation and registration described above can be improved to ensure effective and proportionate investigation of deaths and an improved service for bereaved families.

SECTION 4 - CONTROLLED DRUGS

4.0 WHAT IS A CONTROLLED DRUG?

Controlled drugs are an essential part of modern clinical care. They are medicines used to in a wide variety of clinical settings, for example:

- The relief of acute pain after a heart attack or fracture;
- The relief of severe chronic pain;
- Palliative care, for example, for patients with terminal cancer;
- The treatment of drug dependence; and
- Anaesthesia.

Controlled drugs, by their nature have the potential for diversion and misuse, with associated harm. Controlled drugs are already subject to specific controls under the Misuse of Drugs Act 1971 and its associated regulations. The Government, as part of its response to the Fourth Shipman Report, is introducing additional measures to strengthen the controls applying to controlled drugs and to improve safety in their use.

4.1 PRESCRIBING OF CONTROLLED DRUGS

There are considerable overlaps between the recommendations contained in the Shipman Inquiry Fourth and Fifth Reports (see Appendix C & D). Many of the recommendations on enhanced governance arrangements for prescribing supply, administration and disposal of controlled drugs should be seen in the overall context of a clinical and social care governance framework which supports quality improvement, education, informed patient choice and enhanced professional regulation.

The Fourth Shipman Inquiry Report considered whether it would be prudent to impose some restrictions on what is, at present, virtually total freedom of doctors to prescribe controlled drugs (*Recommendations 2 to 6*). It recommended restrictions in four main areas:

- Restrictions on doctors who have no legitimate reason to prescribe controlled drugs as part of their normal clinical practice;
- Restrictions on prescribing controlled drugs for oneself or for one's immediate family;
- Restrictions on doctors who have been convicted of a controlled drug offence or cautioned in relation to a potential offence; and
- Restrictions on the total quantity that can be prescribed and the length of time for which a prescription remains valid.

Following on from this, the Government's response to the Fourth Report was published in December 2004 - *Safer Management of Controlled Drugs*. This response acknowledged the need to improve current governance arrangements but emphasised the need to do this in a way which did not

hinder patients from accessing the treatment that they needed. It recognised the need to work alongside existing NHS systems for improving and ensuring quality of care. In addition to supporting enhanced arrangements for the prescribing of controlled drugs, *Safer Management of Controlled Drugs* also contains a number of proposals in relation to changes to prescriptions and the prescribing process. The purpose of these proposals is to promote the safe and effective use of all controlled drugs and to strengthen the governance arrangements for controlled drugs.

The DHSSPS supported the broad thrust of recommendations contained in the Government's response outlined in *Safer Management of Controlled Drugs.* However, it also recognised that there were inherent strengths in the centralised Northern Ireland system for monitoring and inspection of controlled drugs, which the Inquiry Chair, Dame Janet Smith, specifically mentioned in the Fourth Report (Section 4.4, paragraph 3).

4.2 DHSSPS ACTION TO IMPROVE THE REGULATION OF CONTROLLED DRUGS

The DHSSPS is responsible for amendments to the Misuse of Drugs Regulations in Northern Ireland. These amendments are consistent with amendments to the Regulations in Great Britain, thus ensuring uniformity of approach across the United Kingdom.

The Fourth Report made a number of recommendations to enhance data capture including electronic controlled drug registers, the use of prescriber and patients identifiers on prescriptions, supply of a patient drug record card (PDRC) [1] and the use of standardised forms for controlled drug (CD) prescriptions.

In summary, these recommendations will:

- Enable prescriptions to be written in any form, including typing, printing and any other mode of reproducing words in a visible form, with only the signature necessarily being handwritten.*
- Provide that records may be preserved in a computerised form in accordance with specified best practice.
- Enable the Department or an Authorised Person to request that a register, which is kept in a computerised form, be produced by sending a copy of it in computerised form to the appropriate person.
- Change the maximum validity of prescriptions for Schedule 2, 3 and 4 controlled drugs to 28 days.
- Limit the amount of controlled drug dispensed on a single prescription to 30 days supply.
- Require the inclusion of unique prescriber and patient identifiers on prescription forms. Whilst this proposal relates to controlled drugs it

[1] The Patient Drug Record Card has been piloted in three sites in England. Early report would indicate that these pilots have been successful. Further studies would be required before full implementation.

will also enable prescribing data in general to be more accurately attributed to individual prescribers.

- Require the issue of a new private prescription form to allow the capture of data relating to private prescriptions for controlled drugs.**
- Require the keeping of electronic records of controlled drugs prescriptions.
- Assist in the capturing information on GP requisitions for controlled drugs (a mechanism for this data capture is already in place in Northern Ireland).
- Require analysis of GP controlled drugs registers.
- Require Standard Operating Procedures (SOPs) for all organisations which stock, handle or administer controlled drugs.
- Require keeping a running balance of stocks of controlled drugs in the controlled drugs register (this will become mandatory with electronic controlled drugs registers).
- Require pharmacists to seek and record the identity of persons collecting Schedule 2 controlled drugs.
- Require those supplying controlled drugs to prepare and supply a patient drug record card (PDRC) for all patients receiving injectable Schedule 2 controlled drugs. The PDRC would record the supply and administration for these medicines and would form part of the audit trail.
- Allow pharmacists to amend technical errors on controlled drugs prescription forms (This may require changes to the Medicines Act 1968).

* Computer generated prescriptions are less prone to error and therefore enhance patient safety and provide greater flexibility for monitoring and audit purposes *(Recommendation 16).*

** In conjunction with the CSA, a private prescription form for controlled drugs was introduced in July 2006 to facilitate the monitoring of private prescribing of controlled drugs.

These changes are being facilitated by amendments to the 2002 Regulations and are being introduced in a phased approach during 2006.7 (*Recommendations 9 to 15, 17, 20 to 27, 29 and 30).* The first two phases of amendments were introduced in January and July 2006. Further amendments will be introduced in 2007/08 in common with the Home Office Controlled Drugs Legislation Programme.

ACTION: The Misuse of Drugs Regulations will need updating with each new phase of changes to the regulation of controlled drugs.

4.3 ENHANCEMENT OF LOCAL MONITORING AND INSPECTION ARRANGEMENTS

The Inquiry's recommendations concerning monitoring and inspection relate to the situation in Great Britain at the time of the Inquiry, which differs from that in Northern Ireland. These differences were commented upon by Dame

Janet Smith, who considered that there was a lack of co-ordination and expertise of inspectorate arrangements in Great Britain, to oversee appropriate governance arrangements both in the healthcare system and the private sector. The Inquiry recommended replacing the current uncoordinated arrangements in Great Britain with a single, integrated, multi-professional inspectorate (*Recommendation 1*).

During the Inquiry, Dame Janet Smith positively acknowledged the existing arrangements in Northern Ireland. She commented:

"*I was very impressed with the way the system of inspection of arrangements for controlled drugs operates in Northern Ireland. The centralised nature of the inspectorate, and its integration with the Department, confer undoubted benefits.….It seems to me that the main advantage of the system in Northern Ireland is that the Inspectorate covers all aspects of the use and abuse of controlled drugs. On the mainland, the arrangements for inspection are fragmented…..It seems to me that there is much to be said for an inspectorate, like that in Northern Ireland, which is focussed solely on its responsibility for the inspection and monitoring of all aspects of controlled drug use."*

ACTION: DHSSPS intends to build on its current strength of a centralised inspectorate, taking account of the developments at national level through the development of enhanced local governance arrangements, as outlined in the Health Act 2006.

4.4 THE HEALTH ACT 2006 AND ITS LOCAL IMPLICATIONS

The Health Act 2006, contains three provisions in relation to the Fourth Report of the Shipman Inquiry: -

- The appointment of an Accountable Officer by Designated Bodies. In the context of the proposed legislation, the Accountable Officer will be responsible for ensuring the safe and effective use and management of controlled drugs within the organisation.
- A duty to collaborate and share intelligence on controlled drugs. This will place a legal duty on Responsible Bodies to share information and intelligence, within certain constraints, about the use of controlled drugs in the health and social care sector.
- A power of entry and inspection for certain Authorised Persons, which will facilitate the inspection of controlled drugs.

It is envisaged that these provisions will allow the management and use of controlled drugs within healthcare organisations to be more effectively monitored and audited, without impacting on patient care.

The DHSSPS is enjoined in UK-wide legislation to enhance governance arrangements through the appointment of Accountable Officers within HPSS organisations, the establishment of a statutory duty of collaboration between organisations and increasing powers of entry and inspection for certain

Authorised Persons. This primary legislation will enable the DHSSPS to develop regulations to meet HPSS needs and service configuration.

ACTION: DHSSPS to develop Regulations, to underpin the primary legislation relating to the role and function of the Accountable Officer, taking account of to HPSS needs and organisational structures. These will be consulted upon.

In order to clarify for the HPSS the role and responsibilities of the Accountable Officer and the linkages to other organisations and governance structures, the DHSSPS will develop guidance.

ACTION: Guidance will be issued by the DHSSPS to enable local arrangements for the Accountable Officer to be put in place. This will be consulted upon.

4.4 A CONSOLIDATED AND COMPREHENSIVE APPROACH TO IMPROVING GOVERNANCE OF CONTROLLED DRUGS

Against the backdrop of the recommendations contained in the Fourth and Fifth Shipman Inquiry Reports the DHSSPS proposes to build upon the current arrangements in Northern Ireland, that is:

a. The Departmental Inspectorate, based in the Pharmaceutical Branch of the Department of Health Social Services and Public Safety, will consolidate and augment their current inspection and investigative function both within and out-with the HPSS;
b. Designated Bodies will appoint an Accountable Officer who will have responsibility for compliance with governance arrangements in relation to controlled drugs.

This two-stranded approach builds on existing good practice and the expertise and respect for existing inspection arrangements built up over many years. It will arguably provide the most comprehensive system in the United Kingdom. However, the Department also recognises that these have to be complementary to other regulatory and HPSS governance activities carried out by other regulators including the Regulation and Quality Improvement Authority (RQIA). The legislation underpinning RQIA makes provision for collaborative action in areas where there is duality of interest or responsibility. Discussions have been initiated with RQIA relative to its interface with the Pharmacy Inspectorate of the DHSSPS.

ACTION: Progress discussions with RQIA relative to its interface with the Pharmacy Inspectorate of the DHSSPS.

To implement these new inspectorate arrangements, common standards will be developed for developmental and inspection visits, as will be a competency framework for those involved in developmental inspection and/or enforcement visits.

ACTION: Based on an agreed competency framework, the Department will work with professional and educational organisations to ensure access to suitable initial and update training for those involved in developmental, inspection and/or enforcement work. Where possible, such training will be multiprofessional.

4.5 EDUCATION AND TRAINING

The Department of Health in England, in consultation with professional regulatory bodies and education providers, as appropriate, are reviewing the extent to which the undergraduate and postgraduate curricula for healthcare professionals meets the need for training in the basic principles of the safe use and handling of controlled drugs. It is anticipated that all training will incorporate the requirements of the Misuse of Drugs Act 1971 and its associated regulations as well as the responsibilities of the different healthcare professionals.

Emphasis on good communication between all healthcare professionals and between healthcare professionals and their patients will be a key element in all education and training which will be in the following areas, in the first instance:

- Undergraduate education
- Postgraduate training
- Inspection and Monitoring
- Accountable Officers.

ACTION: As part of the local development of an educational framework, in support the DHSSPS action plan, discussions will be held with stakeholders to ensure effective adaptation of local training programmes, where appropriate, and to facilitate local implementation of best practice.

4.6 INFORMATION FOR PATIENTS AND CARERS

The Department of Health in England, is developing a communications strategy and programme, working in conjunction with colleagues across the UK, to improve the information available to patients and carers in relation to controlled drugs, particularly in areas around safe storage in the home, risk of harm if given to anyone other than the patient for whom they were prescribed and safe return of unwanted medicines to a pharmacy.

It is anticipated that healthcare professionals involved in prescribing, dispensing, supplying and administering controlled drugs to patients should convey any specific information about the legal status of controlled drugs in the context of therapeutic value, shared decision taking and discussion of the appropriate use of medicines. This will be backed up by access to factual information either about controlled drugs in general or about particular drugs.

The strategy will look at access to information through various media including suitable leaflets and internet material.

ACTION: Building on the work that is currently underway at national level, the DHSSPS will ensure information for patients and carers is available to meet local need.

4.7 CONCLUSION

Controlled drugs remain an integral part of patient and client care in a number of health and social care settings.

The DHSSPS fully accepts the need to strengthen arrangements on the use of controlled drugs in the HPSS, and in the private/community and voluntary sectors. However, any changes to current arrangements will be directed to improving patient safety and will not hinder patients from accessing the treatment that they need.

The DHSSPS proposes:

- To make clear that responsibility for the proper management of controlled drugs is an integral part of the clinical and social care governance arrangements of the HPSS, and of private and voluntary sector health and social care organisations;
- To augment and strengthen the DHSSPS's controlled drug monitoring and inspection function;
- To ensure that all prescribing of controlled drugs – which in future will include prescribing by healthcare professionals other than doctors and dentists – takes place in the context of good prescribing practice backed by robust clinical governance frameworks, the appointment of Accountable Officers to Designated Bodies, cooperation between Responsible Bodies and appropriate professional regulatory sanctions;
- To further enhance the capturing of information on prescribing and requisitioning of controlled drugs, including private prescribing, and to provide additional analyses of prescribing patterns;
- To set up information systems which enable an audit trail for the movement of certain controlled drugs, including, for example, injectable Schedule 2 drugs such as diamorphine (subject to satisfactory piloting in other parts in the UK), the supply and administration of drugs to the patient; and
- To ensure that patients receive appropriate information about controlled drugs in the context of an informed discussion with the healthcare professionals involved in their care and against a background of information about the safe handling of prescription medicines more generally.

SECTION 5

IMPROVING GOVERNANCE SYSTEMS AND PROFESSIONAL PERFORMANCE

5.0 INTRODUCTION

In the fifth Report, the main emphasis is on systems and legislative approaches to improvement in performance, and enhanced arrangements for the detection and management of underperformance. There are 109 recommendations in this Report which cover:-

a) Improvements in clinical governance systems in general practice and primary care organisations,

b) Changes to complaints procedures;

c) Dealing with concerns about GP performance, including whistleblowing by other professionals (and their protection);

d) Attribution and monitoring of prescribing in general practice;

e) A system for the monitoring of GP practice mortality rates and improving use of death registers;

f) Improvement in medical appraisal systems;

g) Accreditation of GP practices;

h) Improvement in recruitment arrangements into GP practices;

i) Improved monitoring of doctors' performance, data analysis and exchange of information at local and national levels; and

j) Changes to local and national disciplinary procedures.

5.1 GOOD DOCTORS, SAFER PATIENTS

In July 2006, *Good Doctors, Safer Patients* was published for consultation on a UK wide basis. It was developed by Professor Sir Liam Donaldson to respond to the recommendations contained in the fifth Shipman Report, (primarily those relating to improving medical regulation and medical performance). The consultation closed on 10th November 2006. Published alongside this report was another report called -*The Regulation of the Non – Medical Healthcare Professions.*

The potential impact of *Good Doctors, Safer Patients* is far reaching, not just in terms of changes to medical regulation at national level but also in its emphasis on quality improvement and patient safety arrangements in NHS

organisations and GP practices, and on the role of employers in local regulation.

ACTION Once the outcome of the consultation on *Good Doctors, Safer patients* is known, the DHSSPS will convene a local group to determine how best the recommendations might be taken forward locally, taking into account different HPSS organisational structures, legislation and governance arrangements.

ACTION: Local changes emerging from the outcome of the review of *The Regulation of the Non Medical Healthcare Professions*, will be taken forward, in collaboration with the different professional groups.

5.2 A FOCUS ON QUALITY AND SAFETY IN THE HPSS

In support of good governance and best practice in the HPSS, *The Quality Standards for Health and Social Care* were published in March 2006. These are complemented by *Safety First; A framework for Sustainable Improvement in the HPSS (2006).* The latter document sets out the Department's policy to promote safety and this is supported by a comprehensive action plan, one element being the development of specific actions relating to Shipman Inquiry Report recommendations. Many of the themes, identified in the 5th Shipman Report overlap with both of these documents, which are designed to raise standards of care, recognising that public involvement in the commissioning, delivery, monitoring and evaluation of health and social care services is essential in order to have a greater understanding of mutual needs and to improve patient experiences and outcomes.

5.3 CLINICAL AND SOCIAL CARE GOVERNANCE IN GENERAL PRACTICE

Dame Janet Smith placed significant emphasis on the role of clinical governance in primary care recognising that this was relatively underdeveloped. *"It seems to be clear that there is indeed some way to go before clinical governance is fully implemented in primary care"* (12.136 – Inquiry Fifth Report). In the context of Shipman, Dame Janet Smith envisaged "clinical governance" as a means to detect underperformance. However, it is recognised that clinical governance has much broader aims relating to both accountability and the general improvement in quality of care. This is about "shifting the mean" on the quality curve so that good practitioners (the majority) strive towards excellence and poor performance is either improved or removed. To do this requires an understanding of the variation in practice and a system that promotes, learns, and shares best practice, and detects, manages and minimises the impact of errors.

5.4 DEVELOPMENT OF CLINICAL AND SOCIAL CARE GOVERNANCE (CSCG) IN GENERAL PRACTICE

The current culture in general practice in Northern Ireland is no different from the rest of the UK in that CSCG is relatively underdeveloped at practice level.

In 05/06, a baseline assessment across the majority of GP practices took place. The assessment looked at the level of practice involvement in the following areas:

- Continuing professional and personal development;
- Audit;
- Risk assessment and risk management;
- Complaints management;
- Evidence-based practice;
- User involvement;
- Identifying, promoting and sharing good practice, learning lessons from best practices as well as poor performance;
- Significant event auditing;
- Professional regulation.

The work to develop clinical and social care governance is designed to bring these and other relevant components together to secure a co-ordinated approach to the provision of high quality care and treatment, while ensuring a focus on the standard of clinical and social care practice. Such an approach will promote high quality effective treatment and care and will ensure that where things go wrong, they are quickly addressed and lessons are learnt to help prevent reoccurrence.

Many CSCG activities have become well established in GP practices over the years, such as, clinical audit and evidence-based chronic disease management programmes. Some of the activities have been more recently introduced e.g. GP appraisal.

Governance in any family practitioner service extends beyond contractual arrangements. It involves GP practices participating in new Northern Ireland arrangements for the promotion of public safety, for example, adverse incident reporting and the further strengthening of whistle blowing policies. It is, however, important that regulatory changes (see below) underpinning good governance are continually reviewed and updated.

5.4.1 General Practice CSCG Toolkit and Portfolio

The CSCG portfolio, as it is known, has been developed on a multi-agency basis involving Clinical and Social Care Governance Support Team (CSCGST), Northern Ireland Medical and Dental Training Agency (NIMDTA), Boards, General Practices and DHSSPS. It provides a set of resource material and practical guidance, taking account of important clinical and social care governance areas, as identified above. It also provides a structured recording format to allow practices to demonstrate their CSCG activities. It includes a section on good practice in the management of controlled drugs. The portfolio will be regularly revised to keep it up to date, taking account of local and national developments on quality and safety.

5.4.2 The Portfolio in 06/07

The portfolio is now being produced on disk following learning from practices in 05/06. In addition, it is to be amended to include guidance on particular areas identified as "gaps" in 05/06 e.g. how to check that an employed nurse is registered. The portfolio will also be streamlined to better fit with the DHSSPS five key quality themes, as identified in the *Quality Standards for Health and Social Care* and will be continually updated electronically.

ACTION: HSS Boards/NIMDTA to produce portfolio electronically in 06/07, and thereafter maintain and develop the CSCG portfolio to take account of local and national developments on quality and safety.

ACTION: All GP practices will be actively encouraged to use the portfolio as part of their practice clinical governance commitment and as evidence of participation in quality improvement and continuing professional development.

5.4.3 Assessment of GP Practices in 05/06

92% of GP practices in Northern Ireland participated in the assessment of clinical and social care governance. The results over the eight domains of CSCG activity, as identified above, have been analysed across each of the four HSS Boards. These results drill down within each of the eight domains into sub domains.

ACTION: HSS Boards will provide a feedback report to all GP practices by Autumn 2006

ACTION: Development needs arising from this process will be supported by regional and/or local education and training, where appropriate, for example, on risk management and the use of risk registers in general practice.

5.5 DEVELOPMENT OF QUALITY STANDANDS

The HPSS Quality Standards, which underpin clinical and social care governance, were published in March 2006. These will be used by RQIA to publicly report on the quality of care provided by the HPSS. RQIA has recently published its methodology for undertaking HPSS clinical and social care governance reviews in 2006/7. Further work will be done to clarify how the Quality Standards might be adapted for general medical services, taking account of GP contractual arrangements and existing CSCG initiatives in primary care.

ACTION: DHSSPS/HSS Boards to consider how the Quality Standards might be made more meaningful to a general practice setting, taking account of existing contractual commitments and clinical and social care governance mechanisms already in place.

5.5.1 CSCG in Primary Dental Care

Considerable work has already been undertaken to progress clinical and social care governance in general dental practice. This includes the development of a local quality assurance manual, an established quality assurance and monitoring system and education and training programme. A clinical and social care governance action plan has been developed to promote governance in primary dental care.

5.5.2 Private general dental and general medical practice

It is acknowledged that further work is required in respect of the development of standards to enhance the regulation and inspection of private general dental (and medical) practice. These practices should be subject to regulation and assessment by the Regulation and Quality Improvement Authority (RQIA), but to do this requires legislative change and the development of specific standards. Development of such standards would draw on the content of the Care Standards already produced for independent hospitals and clinics. Legislative changes will require consultation.

ACTION: Consult on amendments to legislation, and develop local standards for private general dental (and medical) practice, to enhance governance arrangements through inspection and regulation by the Regulation and Quality Improvement Authority, by April 2008.

5.6 REPORTING, MANAGING AND LEARNING FROM ADVERSE INCIDENTS AND NEAR MISSES IN FAMILY PRACTITIONER SERVICES

Both the *Quality Standards for Health and Social Care* and *the Safety First Framework* recognise the importance of culture change to promote quality improvements. Part of this culture change is the promotion of a reporting and learning culture so that adverse incidents can be appropriately managed and investigated and that lessons can be cascaded to others, in order to prevent reoccurrence of incidents. A Regional Reporting Systems Project, led by the Regional Governance Adviser, is underway to standardise definitions, reporting forms and the coding of incidents. Initially commenced in the secondary sector, this project will extend to primary care in 2006/2007.

It is recognised that the promotion of culture change requires education and support. For example, there is different terminology used in general practice, including “significant event analysis”, “adverse incident/events” and “serious adverse incidents”. All of these have slightly different meaning for those involved in the reporting and learning from such incidents. However, the common thread is participation in a system which facilitates quality improvement and the cascade of learning and best practice.

ACTION: Regional Governance Adviser, in collaboration with HSS Boards/HSS Authority and primary care professionals, to clarify reporting and management arrangements for adverse incidents in primary care, as part of the wider HPSS project to promote and standardise reporting and learning from adverse incidents.

ACTION Reporting and learning from adverse incidents in the Family Practitioner Services will be supported by a multidisciplinary education and training programme.

5.7 ENHANCED MONITORING OF PRESCRIBING IN GENERAL PRACTICE

Recommendation *20 and 21* of the Shipman 5 Report relate to the attribution of all prescribing data to individual practitioners, paying particular attention to enhanced arrangements for the monitoring of controlled drugs. 27 million prescriptions per annum are dispensed in the community at a cost of £375 million in 2005. COMPASS reports, which monitor trends in prescribing, and supplies general practitioners and others with useful information about prescribing at practice level, does not yield information about individual prescribers.

The main focus for further development of data collection and analyses of prescriptions will be to improve the effectiveness and efficiency of prescribing, recognising that although there will be many new prescribers in the HPSS in the future, the current systems and reports on prescribing in general practice do not provide a comprehensive picture of prescribing. Changes would improve clinical and social care governance arrangements at GP practice and HPSS Board/Authority level and provide additional data for individual practitioners which could be used, for example, as part of appraisal and continuing professional development.

The production of individual prescribing reports for “principals” in general practice, would require little enhancement to the current COMPASS system. But the success of such a system is dependent on a GP, responsible for the care of an individual patient, writing a prescription on his/her prescription pad containing the correct cipher number. Given the complexities of general practice, with the vast majority of prescriptions generated being computer repeat prescriptions, this is not always easily achieved. In addition, further consideration will have to be given to how to capture the prescribing patterns of locums and other sessional doctors, who, at present, do not have individual cipher numbers and have no monitoring undertaken.

In order to give further consideration to these areas, the Department has convened a subgroup, chaired by the Central Services Agency, to determine how some of these issues might be addressed. Whilst it envisaged that in the longer term electronic prescribing will provide major opportunities to improve prescribing systems, there is a need to develop an incremental approach to enhance the attribution of all prescribing data as part of clinical and social care governance arrangements at individual, GP practice and Health and

Social Services Board/Authority levels. This may include development of individual prescribing reports to GP "principals"; standardised reports on prescribing in single handed GP practices and the provision of GP practice reports on the prescribing patterns of locums employed by the practice.

ACTION: Through the subgroup on prescribing, produce recommendations on an incremental approach to the attribution of prescribing data as part of the commitment to providing timely clinical governance data to individual GPs, GP practices and the HPSS Boards/Authority.

It is recognised that such changes will only be successful if they are accompanied by changes in GP prescribing systems at practice level and supported by changes in GP prescribing behaviour. This will require support, education and training.

ACTION: Support any changes to prescribing systems with an education and support programme to enhance the validity of the data and promote its uses.

5.8 HPSS COMPLAINTS PROCEDURES

The fifth Shipman Inquiry Report included recommendations *(1-18*) which impact on complaints procedures. Whilst the focus is on GPs, some of the recommendations are generic in nature and could have applicability across the HPSS.

The DHSSPS has recently published, for consultation, a revised HPSS Complaints procedure. This revised HPSS complaints procedure has taken into account some of the recommendations made in the fifth Shipman Inquiry Report. The revised complaints procedure is based on the principles of:

- Open and easy access;
- Fair and independent;
- Responsive;
- Promotion of a culture of learning.

The document aims to:

- Raise the standards of complaints handling - by removing barriers to access, strengthening local resolution, clarifying roles and responsibilities and emphasising the importance of learning and improving; and

- Advise and support patients and users – by providing choice, encouraging conciliation and advocacy services and ensuring training.

It considers the tiers of complaints' investigation and links the HPSS complaints procedures to other statutory obligations under the Children (Northern Ireland) Order 1995, whistleblowing procedures (internal

complaints) and the need to offer a timely apology and explanation, if appropriate, of what went wrong and remedial treatment, where necessary.

ACTION: DHSSPS to consult on revised HPSS complaints procedures in 2006. Analyse responses and produce final document by early 2007.

5.9 RAISING CONCERNS (WHISTLE BLOWING)

The fifth Report made a number of recommendations relating to provision of advice, policies and procedures in NHS and private healthcare sectors, to enable staff to raise concerns about the clinical practice or behaviour of individual members of staff *(recommendation 34-38).* This important issue is also highlighted in other Inquiry Reports, such as Kerr/ Haslam.

The DHSSPS is mindful that sometimes staff can have serious concerns about what is happening within their place of work but are too afraid, or unsure how to raise them. Failure to heed warnings has, on occasions, led to devastating consequences for patients, families, staff and healthcare professionals. It is recognised that staff need to be aware of how to raise their concerns and to feel confident to do so.

In January 2000, the Department issued guidance to Health and Social Services Boards and Trusts on the Public Interest Disclosure (Northern Ireland) Order 1998 and the responsibilities of employers. Whilst the underpinning legislation covered all HPSS staff, the guidance did not extend to healthcare professionals working in family practitioner services. This is currently being developed. The DHSSPS intends to issue this guidance to GPs, Dentists, Pharmacists and Opticians by early 2007.

ACTION: DHSSPS to produce policy guidance for HSS Boards/HSS Authority and family practitioner services on how to raise concerns when the performance of an individual primary care practitioner gives rise to concern. This guidance will be accompanied by practice –based leaflets for cascade to staff at local level.

5.10 HANDLING OF CONCERNS ABOUT HEALTH AND SOCIAL CARE PROFESSIONALS

All HPSS organisations have structures and procedures in place for the handling of concerns about the performance of health and social care professionals.

The National Clinical Assessment Service (NCAS) provides expert support to HPSS organisations when concern is expressed about the performance of a HPSS doctor or dentist. This support can range from advice, when the problem first arises, through to formal assessment of performance.
In November 2005, the Department issued "*Maintaining High Professional Standards in the modern HPSS*. This document is a framework for the handling of concerns about doctors and dentists in the secondary sector. It

outlines formal and informal processes that need to be in place in order to improve public safety.

Building on the expertise of NCAS and on the new procedures developed for the secondary sector, guidance will be developed for the primary care sector, to harmonise procedures across the HPSS. A subgroup has been formed to take forward this work. Where formal fitness to practise procedures have to be embarked upon, these will need to take account any new procedures, which emerge following consultation on *Good Doctors, Safer Patients.*

ACTION: DHSSPS to produce guidance on the handling of concerns about performance of general medical and general dental practitioners in the HPSS to harmonise procedures across the HPSS.

5.11 IMPROVING LOCAL REGULATION OF FAMILY PRACTITIONERS SERVICES

Taking account of the issues raised from the Shipman Inquiry, along with its broader health care responsibilities, the DHSSPS proposes to further strengthen the quality of primary care services. In this respect, work is already in hand to introduce Primary Legislation before the end of 2006. The legislative provisions include: -

extending the functions of the Health Service Tribunal and the powers of the four Health and Social Services Boards in order to address issues regarding suitability, efficiency and probity of GPs, Dentists, Opticians and pharmacists; and

introducing a requirement for practitioners applying to join a Health and Social Services Board List or for those already on such a List to provide certain additional information to the relevant HPSS Board or Boards. This will help demonstrate their fitness to be listed and thus improve the treatment and care of patients.

Currently, for a GP to work in general practice in Northern Ireland, for example, as a locum, out of hours practitioner or contracted GP, the GP needs to be included in the Performers List, which is underpinned by Regulation. A Regional Primary Medical Performers List Advisory Committee has been formed with wide stakeholder involvement, including lay representation, to act in an advisory capacity to HSS Boards, as HSS Boards currently remain accountable for the management of the Performers List within their geographical area. This new Committee advises on changes to procedures and processes to standardise application of the Performers List. Where necessary, the Advisory Committee will provide advice to a HPSS Board where an application to the Performers List raises specific concerns. Such an approach will improve the systems for the sharing of information and best practice across the region and will enhance the quality of general practitioners approved for inclusion in the Performers List.

ACTION: Regional Primary Medical Performers List Advisory Committee to provide HSS Boards with ongoing advice to enhance systems approaches to the management of the Performers List and to advise on specific applications.

When applying to the Performer's List, a GP is required to declare any reasons for dismal from previous employment, criminal convictions, removals from Performers Lists or disqualifications *(Recommendation 44).* In addition, he/she must provide information about any investigation being undertaken against him/her as part of the conditions for continued inclusion of their name on the List. A police check is now also undertaken for new applicants.

5.12 IMPROVEMENT IN RECRUITMENT AND EMPLOYMENT PROCEDURES (*Recommendations 30-33)*

Any application to the medical Performers List requires a new GP to include references to enable checking to take place before an application is endorsed. In addition, the GP contract requires GP practices to follow statutory requirements in respect of employment of individuals. All practices should have clinical governance systems in place which enables quality assurance of its services and promote quality improvement and enhanced patient safety. These systems are reviewed by the contracting HSS Board as part of their commitment to clinical and social care governance in general practice.

In order to enhance employment procedures and to encourage the checking of references, information on good recruitment practices, sample job specifications and advertisements and a standard recruitment form will be included in the Clinical and Social Care Governance portfolio for general practice.

ACTION: Provide further information for GP practices within the CSCG portfolio to enhance recruitment practices and the taking up of references.

5.13 IMPROVING GOVERNANCE ARRANGEMENTS IN SINGLE HANDED PRACTICES (*Recommendation 29)*

Of the 371 GP practices in Northern Ireland, 73 are single-handed. Proportionately, this is similar to other areas in the UK.

Single handed general practitioners are subject to the same contractual, professional and clinical governance arrangements as other GP practices. It is acknowledged that being a single handed GP does not necessarily imply any diminution of service to registered patients. However, any working environment which facilitates professional isolation has the potential to generate clinical and social care governance problems. Within the current General Medical Services arrangements, HPSS Boards are reluctant to endorse the commencement of a new single-handed GP practice, for example, when there is a split in a practice partnership. When a partnership split occurs, some HPSS Boards canvass the registered patients to determine

satisfaction with proposed new services prior to reconfiguring local GP services.

Whilst HPSS Boards do provide additional support, when needed, for single – handed practices, for example, placement of a mentor in a practice, this is mainly a reactive rather than a proactive approach to the promotion of good governance. There has been no formal attempt to identify the needs of individual single-handed GP practitioners in the context of support or professional or service development with the aim of improving the quality of care.

ACTION: An assessment of the needs of single-handed GP practices will be done, with the involvement of single-handed GPs and others, with the aim of improving quality and governance arrangements through support and networking for single-handed practices.

The Shipman Reports identified prescribing as a major area of risk. As part of the sub-group work on prescribing, due consideration will be given to extending standardised prescribing reports to singe-handed GP practices to facilitate comparison and learning between single-handed practices.

5.14 PRACTICE MORTALITY MONITORING AND ENHANCED USE OF DEATH REGISTERS (*Recommendations 22-24)*

A project on the monitoring of GP practice mortality data commenced in 2002. The project included the collation, linking and analysis of routine mortality data and involved partnership working between the HSS Boards, the Central Services Agency and the University of Birmingham.

In addition to this, the Eastern Health and Social Services Board carried out further analysis and developed a methodology and process for investigation of high and low mortality at practice level. This was published in September 2005 in the British Journal of General Practice. It concluded that it was possible to explain all outlying practice mortality rates and, most importantly, retain the confidence of practices and GPs.

Further work will be undertaken in 2006 - 2008 to extend the scope of this project with the aim of having a greater understanding of the variation of mortality rates across Northern Ireland. Implementation of the outcomes of this extended project would lead to annual mortality monitoring and would facilitate enhanced use of death registers in practices. In addition it is recognised that the wider application of the methodology used in this project may support quality improvements in other areas.

Improvement in monitoring of GP practice mortality would mean that all GP practices would routinely receive mortality data which would contribute to clinical and social care governance at practice level.

ACTION: HSS Boards to extend the scope of the of the GP Practice Mortality Project to enhance knowledge of variation in GP practice mortality rates across Northern Ireland.

ACTION: Support extension of this project with an educational programme for general practice staff to highlight the benefits and uses of mortality data and the methodology as applied to other routinely collected primary care data.

5.15 MEDICAL APPRAISAL *(Recommendation 25-26)*

Good Doctors, Safer Patients makes a number of recommendations relating to increasing the objectivity of medical appraisal, as part of the 2- stage approach to the revalidation of individuals. The document recognises that there is a need for standardisation within appraisal systems. It also recognises the contribution that appraisal can make to professional development of the individual, and service and quality improvement.

From April 2006, operational responsibility for GP appraisal transferred from HSS Boards and the Regional GP Appraisal Group to a management committee led by Northern Ireland Medical and Dental Training Agency (NIMDTA). This arrangement is underpinned by a formal agreement between HSS Boards and NIMDTA. Appraisers are now employed by NIMDTA to provide high quality appraisals in line with their employment contract. This centralised approach provides an opportunity to standardise the GP appraisal system and to regularly review and update skills and knowledge of appraisers. In addition, further work is being undertaken to enhance the quality assurance of appraisal content and documentation.

A Review of Medical Appraisal in Northern Ireland was commissioned by the DHSSPS in 2005. This Report (January 2006) highlights the need to continue to work towards improving local appraisal systems, not just in general practice but also for all groups of doctors who work within HSS Trusts and Boards, including doctors in training and employed locum doctors.

ACTION: HSS Boards, Trusts and NIMDTA will continue to work to enhance current appraisal systems, recognising that appraisal systems will undergo further change once the outcome of the consultation on *Good Doctors, Safer Patients* is known.

5.16 CONCLUSION

At a time of organisational change within the HPSS, there remains a need to continue to promote quality improvements, professional performance and public safety. Much has already been achieved to promote clinical and social care governance within the HPSS. But more can always be done. The fifth Shipman Inquiry Report provides an opportunity to improve governance arrangements and professional performance in family practitioner services. A greater understanding of variation in practice will shift the “quality curve”

towards excellence. The actions identified in this section will be supported by the sharing of best practice and educational and training programmes.

Good Doctors, Safer Patients is a UK wide consultation document which promotes major changes to the professional regulation of doctors. Following completion of this consultation, the DHSSPS will work with local and national organisations to implement change. A complementary UK document on improving non medical regulation will also facilitate change.

ACTION PLAN 2006/2007- 2008/2009

IMPROVING QUALITY THROUGH EDUCATION AND TRAINING				
Action	**Responsibility**	**Outcome**	**Shipman Inquiry Recommendation(s)**	**Completion date**
Produce comprehensive education and training framework in response to Shipman Inquiry Reports' recommendations contained in Reports 3, 4 and 5.	DHSSPS (lead HRD working with professional groups)	Support professionals and facilitate change in death certification processes, controlled drugs management and specific aspects of clinical and social care governance	All relevant recommendations which have local impact	Implement framework by April 2008
DEATH CERTIFICATION - 3RD SHIPMAN INQUIRY REPORT				
Support the NI Court Service to consider how the Coroners Service might best obtain appropriate medical advice.	DHSSPS (Medical and Allied Group) with Coroners Service	Complete scoping exercise on provision of independent medical advice to Coroners Service	1-12, 18-36 & 44-46	September 2007
Issue guidance on appropriate verification and recording of the fact of death.	DHSSPS with NI Ambulance Service and HPSS Professional groups OOH Services	Reduce variability in how verification of death is recorded Develop and cascade best practice	14	April 2007

DEATH CERTIFICATION - 3RD SHIPMAN INQUIRY REPORT *(Continued)*				
Action	**Responsibility**	**Outcome**	**Related Shipman (3rd) Recommendations**	**Completion date**
Produce guidance for doctors on the completion of Medical Certificate of Cause of Death (MCCD).	DHSSPS with Coroners Service and General Register Office	Clarity of best practice for the completion of MCCDs	13-15	September 2007
Develop a best practice guide for referring deaths to the Coroner.	NIO with Coroners Service, PSNI, Ambulance Service & DHSSPS	Convene Interagency Group- agree best practice and produce guidance Appropriate referrals to coroners- service improvement	42	June 2007
Issue guidance for doctors and Registrars on MCCDs and referral to the coroner.	DHSSPS, Coroners Service and General Register Office	Improvement in referrals to Coroner Improvement in usefulness of information for public health	42-44	October 2007
Promote appropriate post mortem examination.	DHSSPS with Northern Ireland Office	Improved autopsy standards and appropriate use of pathology services	37-39	June 2007
HPSS to practice in line with Human Tissue Authority Codes of Practice (Sept. 2006).	HPSS Trusts	Compliance with obligations under the Human Tissue Act 2004	40-44	November 2006

ENHANCING PRESCRIBING, REGULATION, CONTROL AND MONITORING OF CONTROLLED DRUGS				
Action	**Responsibility**	**Outcome**	**Related Shipman (4th) Recommendation(s)**	**Completion date**
Amend Misuse of Drugs Regulations (Northern Ireland) 2002. (Amendments to Regulations implemented 16th January 2006 and 7th July 2006) Further amendments to be introduced during 2007/08 to mirror changes introduced by the Home Office for GB.	DHSSPS (lead Pharmaceutical Inspectorate with Health Development Directorate) in conjunction with amendments introduced by the Home Office for GB	Improvement in prescribing, regulation, control and monitoring of controlled drugs in the statutory, voluntary, community and independent healthcare sectors,	9-15, 17, 20-27, 29 & 30	Ongoing
Build on the current strength of the centralised inspectorate taking account of developments at national level, including the Health Act and local governance arrangements.	DHSSPS (lead Pharmaceutical Inspectorate with HSS organisations and RQIA)	As above. Improved governance arrangements and collaborative working	1	April 2008

ENHANCING PRESCRIBING, REGULATION, CONTROL AND MONITORING OF CONTROLLED DRUGS				
Action	**Responsibility**	**Outcome**	**Related Shipman (4th) Recommendations**	**Completion date**
Develop Regulations, to underpin the primary legislation, relating to the role and function of the Accountable Officer, taking account of HPSS needs and organisational structures and to issue guidance to the HPSS and other organisations to enable the Accountable Officer function to be put in place. Consultation paper to be issued by April 2007 and Regulations to be enacted by April 2008.	DHSSPS (leads Pharmaceutical Inspectorate and PCCD)	Promote safer use and management of controlled drugs within HPSS organisations, through Accountable Officer. Commence legal duty on responsible bodies to share information and intelligence about the use of controlled drugs. Increase powers of entry and inspection of controlled drugs.	1	Guidance - April 2007 Regulations April 2008
Progress discussions about monitoring and regulation of pharmaceutical services. *Agree the areas of commonality between the DHSSPS Inspectorate and RQIA and the essential components of the inspection process.*	DHSSPS (lead pharmaceutical Services with PPMD) and RQIA	Avoidance of duplication of inspection arrangements Consistency of the inspection process across inspection bodies Sharing of information	1	December 2006

ENHANCING PRESCRIBING, REGULATION, CONTROL AND MONITORING OF CONTROLLED DRUGS				
Action	**Responsibility**	**Outcome**	**Related Shipman (4th) Recommendations**	**Completion date**
Agree a competency framework to ensure access to suitable initial and update training for those involved in, inspection and/or enforcement work.	DHSSPS (lead pharmaceutical Services) with educational establishments	Standardisation of pharmaceutical inspection Enhanced skills and competence of inspectors	1	April 2007
Adapt local training programmes to enhance safe use and handling of controlled drugs. *(A CPD programme for the postgraduate training of pharmacists was delivered between September and November 2006).*	DHSSPS (lead Pharmaceutical inspectorate with Dept of Health England) Local professional groups, educational establishments universities	Safe and effective use of controlled drugs through enhanced → Undergraduate training → Postgraduate education Enhanced knowledge of changes to Misuse of Drugs regulation and local governance arrangements for controlled drugs	General	April 2008
Improve information on controlled drugs for patients and carers *Participate in the national programme to improve information to patients and carers*	DHSSPS (lead pharmaceutical inspectorate with Dept. of Health in England), HSS Councils and patient support groups	Improved patient and carer information and involvement in the safe and effective use of controlled drugs	General	April 2007

IMPROVING GOVERNANCE, SYSTEMS AND PROFESSIONAL PERFORMANCE (5th Report)				
Action	**Responsibility**	**Outcome**	**Related Shipman (5th) Recommendation(s)**	**Completion date**
Convene local group to consider local implications following consultation on "Good Doctors, Safer Patients".	DHSSPS (lead Medical and Allied Group with HRD)	Commence implementation of recommendations, consider local legislative impact, and organisational structures and governance arrangements	49- 109 (and may impact on others)	February 2007 / onwards
The outcome of the review of "The Regulation of the Non Medical Healthcare Professions" will be taken forward.	DHSSPS (lead HRD with professional groups)	Enhanced regulation of professionals	Note above, Review was strongly influenced by Shipman Inquiry	February 2007 / onwards
Produce CSCG portfolio for general practice electronically.	CSCGST & NIMDTA	Improve quality of general practice and enhance continuing professional development of practitioners	General	September 2006/ onwards
Encourage GP practices to use CSCG portfolio.	HSS Boards with DHSSPS (lead Medical and Allied with CSGST and NIMDTA)	Demonstration of commitment to implementation of CSCG in general practice Improve quality of care and enhance professional development of practice staff	General	Ongoing
Produce CSCG feedback report following baseline assessment in 2005/6	HSS Boards with DHSSPS (lead Medical and Allied with CSGST)	Identification of best practice and gaps to promote continuing professional development	General	October 2006

IMPROVING GOVERNANCE, SYSTEMS AND PROFESSIONAL PERFORMANCE (5th Report)				
Action	**Responsibility**	**Outcome**	**Related Shipman Inquiry (5th) Recommendations**	**Completion date**
Analyse development needs and gaps emerging from CSCG base line assessment and produce local support and educational programme.	HSS Boards, GP practices, NIMDTA and CSCGST with DHSSPS (lead Medical and Allied Group)	Improve practice performance by addressing CSCG gaps and development needs through education and support	General	December 2006
Make Quality Standards for Health and social care meaningful to a general practice setting.	DHSSPS(lead Medical and Allied with PPMD), HSS Boards, CSCGST	Promote and embed common standards of quality in HPSS general practice, yet avoid duplication Improve quality of general practice	General	April 2007
Develop care standards for private dental practice (and medical). *Amend legislation to facilitate implementation of standards.*	DHSSPS (lead PPMD with Dental and Medical Groups)	Improve registration, regulation and inspection of private establishments by RQIA	General	December 2008
Develop an incremental approach to the attribution of all prescribing in general practice.	DHSSPS (lead Medical and Allied with CSA, PCCD and Pharmaceutical Inspectorate)	Improve the quality of prescribing Facilitate the monitoring of prescribing at individual GP level Standardise monitoring across single handed practices and GP locums	20-21	April 2007/ onwards

IMPROVING GOVERNANCE, SYSTEMS AND PROFESSIONAL PERFORMANCE (5th Report)				
Action	**Responsibility**	**Outcome**	**Related Shipman Inquiry (5th) Recommendations**	**Completion date**
Support changes to prescribing systems in general practice.	HSS Boards/HSS Authority, NIMDTA, DHSSPS (lead Medical and Allied with CSA, PCCD and Pharmaceutical Inspectorate)	Enhance validity of prescribing data and promote its use	20- 21	April 2007/ onwards
Consult on revised HPSS complaints procedures. Analyse responses and produce final document.	DHSSPS (lead PPMD with HSS Authority)	Improved reporting, investigation and learning from complaints Provide greater clarity and ease of access for the public	1-18	March 2007
Clarify arrangements for staff, where clinical practice or behaviour of an individual is causing concern in the family practitioner services.	DHSSPS (lead PCCD with HRD	Improved arrangements for the early recognition of underperformance in family practitioner services Clarification of arrangements and additional information for staff	34-38	February 2007

IMPROVING GOVERNANCE, SYSTEMS AND PROFESSIONAL PERFORMANCE (5th Report)				
Action	**Responsibility**	**Outcome**	**Related Shipman Inquiry (5th) Recommendations**	**Completion date**
Produce guidance on the handling of concerns in general medical and dental practice.	DHSSPS (lead Medical and Allied with HRD)	Harmonise procedures for the handling of concerns in the HPSS building on the expertise of National Clinical Assessment Service	34-38	February 2007
Enhance systems approaches to the management of the Medical Performers List.	HSS Boards with CSA and other stakeholders	Convene Regional Primary Medical Performers List Advisory Committee Advise on specific applications and improve information flows	44 and general	September 2006 / onwards
Provide further information for GP practices to improve recruitment processes and the take-up of references.	HSS Boards with DHSSPS (lead Medical and Allied with CSGST)	Improve recruitment procedures and the exchange of information from employer to employer	30-33	April 2007
Assess need in single-handed GP practices and improve governance arrangements through support and networking arrangements.	HSS Boards with DHSSPS (lead Medical and Allied Group and CSCGST)	Reduce professional isolation of established single –handed practices Improve quality of care	29	April 2008
Extend the scope of the GP practice mortality project.	HSS Boards with DHSSPS (lead M&A)	Enhance knowledge of the variation in GP practice mortality rates	22-24	December 2008

IMPROVING GOVERNANCE, SYSTEMS AND PROFESSIONAL PERFORMANCE (5th Report)				
Action	**Responsibility**	**Outcome**	**Related Shipman Inquiry (5th) Recommendations**	**Completion date**
Support extension of the GP practice mortality project with an education programme.	HSS Boards with DHSSPS (lead Medical and Allied Group)	Improve understanding of the benefits of data collection and analysis	22-24	December 2008
Work to improve medical appraisal systems in the HPSS. *Take account of Good Doctors, Safer Patients in development of appraisal systems.*	HSS Boards, Trusts, NIMDTA (with DHSSPS)	Improve quality of care in the HPSS through appraisal systems and identification of service and professional needs	26	April 2006 and onwards to end of 2008

GLOSSARY

Accountable Officer
Person responsible for ensuring the safe and effective use and management of controlled drugs within a designated body.

Accountability
Being completely responsible for particular actions and being made to publicly explain and justify those actions.

Adverse Incidents
Any event or circumstances that could have or did lead to unintended or unexpected harm, loss or damage to people, property, environment or reputation.

Bureaucracy
A system for controlling or managing that is operated by a large number of officials who are employed to follow rules carefully.

Cipher Number
A number on a prescription which is attributed to an individual prescriber, such as a general practitioner.

Clinical and Social Care Governance
A framework through which local organisations are accountable for the quality of service they provide or commission.

Commissioning
Formally choosing/requesting an organisation or an individual to undertake a piece of work or service.

Controlled Drugs
Controlled drugs are medicines used to treat a variety of clinical conditions. They are subject to special legislative controls because of their potential for harm if wrongly used.

Coroner
Coroners are independent judicial officers who are available to deal with matters relating to deaths that may require further investigation to establish the cause of death.

Cremation
To burn a dead person's body, usually as part of a funeral ceremony.

Data Capture
The collection of data for processing and analysis.

Death Certificate
A certificate issued by the Registrar. It contains the information recorded on the Register of Deaths including the persons name, date and place of death; date and place of birth; occupation and usual address; cause of death. It acts as confirmation of the death to allow burial, cremation, and management of the person's estate.

Forensic Pathology
Forensic pathology is the legal branch of pathology concerned with: determining cause of death (including murder, accident or unexpected death), examination of some wounds and injuries due to crime or negligence; and examination of tissue specimens that may be relevant to rape, or other crimes.

Governance
The rules, processes and behaviour that affect the way in which openness, participation, accountability, effectiveness and coherence are reinforced.

Inherent
Existing as a natural or basic part of something.

Incremental
A series of small advances / increases.

Legitimate
Allowed by law; reasonable and acceptable.

Locum Doctor
A doctor who does the job of another doctor who, for example, is ill or on holiday.

Malpractice
Failure to act correctly or legally when doing a job, sometimes causing injury or death.

Medical Appraisal
Annual appraisal for doctors is a requirement for doctors under contract in the HPSS. In its most basic form, appraisal activities include documenting achieved results (including use of examples to clarify documentation) and indicating if standards were met or not. The appraisal usually includes a development plan to address professional needs. Completion of this plan is then reviewed the following year.

Medical Certificate of Cause of Death
A certificate issued by a doctor recording the main cause of death, and other major medical conditions. It is taken by the family to the Registrar to allow the death to be registered.

Misconduct
Unacceptable or immoral behaviour by someone in a position of authority or responsibility.

Negligence
Not being careful or giving enough attention to people or things that are your responsibility.

Palliative care
Care that aims to relieve suffering and improve the quality of living and dying.

Pathology
The scientific study of disease.

"Principal" GP
A general practitioner who is an independent contractor and one who provides general medical services, under contract, to a registered population of patients. He/she is not a locum or sessional doctor.

Post Mortem Examination
Examination and dissection of a body after death to determine the cause of death or the presence of disease. Sometimes also called an autopsy.

Primary Care
The first point of contact for people outside hospitals in local settings. Primary care health professionals include local GP's, community nurses, social workers, pharmacists, physiotherapists, occupational/speech/language therapists, opticians and dentists among others.

Schedule 2 & Schedule 3 Drugs
It is illegal to possess drugs in schedules 2 or 3 without a prescription or other authority and a Home Office licence is required to produce, import, export or supply substances in these schedules.
Schedule 2 drugs include heroin, cocaine, morphine, pethidine, quinalbarbitone and amphetamine.
Schedule 3 drugs include the majority of barbiturates (excluding quinalbarbitone) Diethylporpion, Mazindol, Phentermine and Buprenorphine.

Schedule 4 Drugs
For drugs in schedule 4 (which includes benzodiazepines and pemoline) no prescription or other authority is required to legally possess them, so long as they are in the form of a medicinal product. No licence is needed to import or export schedule 4 drugs, but authority is required for production and supply.

Sessional Doctor
A qualified doctor who is not working as a partner in a GP practice.

Statutory Duty
A duty or action which is required by law

Underperformance
When someone is not producing the minimum standards required by their profession or their employing organisation.

Whistleblowing
Raising a concern about clinical practice, behaviour or conduct, usually within the employing organisation, or through an independent structure associated with it.

ACRONYMS

BMA – British Medical Association

CSA – Central Services Agency

CSCG – Clinical and Social Care Governance

CSCGST - Clinical and Social Care Governance Support Team

DHSSPS – Department of Health, Social Services and Public Safety

FTP – Fitness to Practice

GMC – General Medical Committee

GPC – General Practice Committee

HPSS - Health and Personal Social Services

HRD – Human Resource Directorate

HSS - Health and Social Services

HSENI - Health and Safety Executive for Northern Ireland

HTA - Human Tissue Authority

M&A – Medical and Allied Group

MCCD - Medical Certificate of Cause of Death

NCSA - National Clinical Assessment Service

NHS – National Health Services

NICE - National Institute for Health and Clinical Excellence

NIMDTA - Northern Ireland Medical and Dental Training Agency

NIO – Northern Ireland Office

NISCC - Northern Ireland Social Care Council

OOH – Out of Hours Services

PCCD – Primary and Community Care Directorate

PCO – Primary Care Organisation

PCT – Primary Care Trust

PDRC - Patient Drug Record Card

PPA – Prescription Pricing Authority

PPMD – Planning & Performance Management Directorate

PSNI – Police Service of Northern Ireland

PSNI – Pharmaceutical Society of Northern Ireland

RQIA - Regulation and Quality Improvement Authority

SCIE - National Institute for Social Care Excellence

SOP - Standard Operating Procedures

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APPENDIX A – TERMS OF REFERENCE OF SHIPMAN

Terms of reference published – www.dh.gov.uk (3rd January 2001)

Secretary of State for Health Alan Milburn, today announced the appointment by the Prime Minister of Dame Janet Smith as the Chair of the public inquiry into the circumstances surrounding the crimes of Harold Shipman.

The appointment comes after the announcement in September last year that, subject to parliamentary agreement, the inquiry will be held under the 1921 Tribunals of Inquiry (Evidence) Act.

Harold Shipman, a former GP from Hyde, Greater Manchester, was found guilty on January 31st of 15 charges of murder and of forging the will of one of his patients.

Subject to parliamentary agreement, the terms of reference for the inquiry are:

- After receiving the existing evidence and hearing such further evidence as necessary, to consider the extent of Harold Shipman's unlawful activities.
- To enquire into the actions of the statutory bodies, authorities, other organisations and responsible individuals concerned in the procedures which followed the deaths of those of Harold Shipman's patients who died in unlawful or suspicious circumstances.
- By reference to the case of Harold Shipman to enquire into the performance of the functions of those statutory bodies, authorities, other organisations and individuals concerned with responsibility for monitoring primary care provision and the use of controlled drugs.
- Following those enquiries, to recommend what, if any, steps should be taken to protect patients; and to report to the Secretary of State for Home Affairs and to the Secretary of State for Health.

APPENDIX B - SUMMARY RECOMMENDATIONS FROM SHIPMAN INQUIRY 3RD REPORT

No.	Shipman Report 3
	Recommendations
1.	Coronial system should be entirely different from at present.
2.	The new Coroner Service should be to provide an independent, cohesive system of death investigation and certification.
3.	The Coroner Service should provide leadership, training and guidance for coroners.
4.	The Coroner Service requires medical, legal and investigative expertise.
5.	Both the medical and judicial coroners should be independent office-holders under the Crown.
6.	The Coroner Service should have a corps of trained investigators.
7.	The Coroner Service must be independent of Government and of all other sectional interest.
8.	The Coroner Service should be governed by a Board. Three of the members of the Board would be the Chief Judicial Coroner, the Chief Medical Coroner and the Chief Coroner's investigator.
9.	The Service should also have an Advisory Council.
10.	The Coroner Service should be administered through a regional and district structure, with a regional medical coroner and at least one judicial coroner assigned to each region.
11.	Each region should be divided into between three and seven districts, each with a population of about a million. The staff would operate a service outside the usual office hours.
12.	The Coroner Service should have jurisdiction over every death and over every dead body brought within the boundaries.
13.	There should be one system of death certification applicable to all deaths, whether the death is to be followed by burial or cremation.
14.	The fact that a death has occurred should be confirmed and certified.
15.	The basis for the certification system would be the completion of two forms. Form 1 would record the fact and circumstance of death. Form 2 would contain a summary of the recent medical history and the option of expressing an opinion as to the cause of death.
16.	A statutory duty to complete Form 2 should be imposed upon the consultant responsible for the care of the deceased or the general practitioner with whom the deceased had been registered.
17.	General Medical Council should impose upon doctors a professional duty to co-operate with the death certification system, requiring them to provide an opinion as to the cause of death on Form 2 in cases where it is appropriate to do so.

No.	Shipman Report 3
	Recommendations
18.	All deaths should be reported to the Coroner Service. Deaths where the doctor completing Form 2 had expressed an opinion as to the cause of death would be considered for certification by a coroner's investigator after consultation with the deceased's family.
19.	The coroner Service would take primary responsibility for all post-death procedures.
20.	A proportion of all deaths certified by a coroner's investigator on the basis of the opinion of the Form 2 doctor should be selected randomly for fuller investigation at the discretion of the medical coroner.
21.	A new certificate of cause of death should be designed for completion by a coroner's investigator or by the medical coroner.
22.	Coroner's investigators should be trained to recognise the type of circumstances which make it appropriate for a death to be investigated by the medical coroner.
23.	There should be an inquest only in a case in which the public interest requires it.
24.	In other cases, the product of the further investigation of a death would be a report explaining how and why the deceased died.
25.	Any recommendation made by a judicial or medical coroner should be submitted to the Chief Coroners.
26.	Procedures for Investigation need clarification.
27.	The judicial coroner should be given powers to order entry and search of premises and seizure of property and documents. The medical coroner should be given powers to order the seizure of medical records and drugs.
28.	There should not be an automatic resort to autopsy.
29.	The medical coroner should seek to establish the cause of death to a high degree of confidence.
30.	Disposal of the body should be permitted as soon as possible.
31.	Judicial coroners should direct the investigation but responsibility for the collection of evidence should devolve onto a legally qualified person.
32.	If criminal proceedings have been commenced, there should be no need for an inquest.
33.	If any other agency were to investigate a death the medical coroner would establish the cause of death.
34.	Deaths contributed to by medical error should be investigated by the Coroner Service.
35.	Case of possible medical error should be investigated initially by the medical coroner
36.	Cases of medical error transferred to the regional coroner's office would be investigated under the direction of a legally qualified person.
37.	All autopsies should be carried out to the standards recommended by the Royal College of Pathologists.
38.	Greater use should be made of toxicology.

No.	Shipman Report 3
	Recommendations
39.	It should be possible for a medical coroner to authorise a partial autopsy.
40.	Retention of organs and tissues.
41.	The provision of a unified pathology service.
42.	A statutory duty to report concerns about a death.
43.	Employers should encourage their employees to report any concerns.
44.	Educate the public about the functions of the Service.
45.	Systematic audit of every function of the medical and judicial coroners.
46.	Decision made by a medical or judicial coroner would be subject to judicial review. Quicker and cheaper means of appeal should also be provided.
47.	Cremation certification procedures should be strengthened.

APPENDIX C - SUMMARY RECOMMENDATIONS FROM SHIPMAN INQUIRY 4TH REPORT

No.	Shipman Report 4
	Recommendations
1.	A controlled drugs inspectorate should be created, comprising small multidisciplinary inspection teams, operating regionally but co-ordinated nationally.
2.	A medical practitioner should be entitled to prescribe or administer controlled drugs only she s/he needs to do so for the purposes of the 'actual clinical practice' in which s/he is engaged.
3.	It should be a criminal offence for a doctor to prescribe a controlled drug for him/herself or to self administer a controlled drug from his/her own or practice stock.
4.	When a general practitioner (GP) has members of his/her immediate family on his/her list (which should happen only rarely), s/he should inform his/her local primary care trust (PCT) of the position.
5.	The General Medical Council (GMC) should make plain it will be regarded as professional misconduct for a doctor to prescribe controlled drugs for anyone whom s/he does not have a genuine professional relationship.
6.	A medical practitioner convicted or cautioned in connection with a controlled drugs offence should be under a professional duty to report the conviction or caution to the GMC.
7.	The Government should commission an independent review and audit of the way in which the GMC and PCTs are using their powers to restrict the rights of medical practitioners involved in controlled drugs offences to prescribe and administer controlled drugs.
8.	Whenever a restriction is placed on a doctor's prescribing powers, this information must promptly be made available (preferably by electronic means) to those who need to know it, especially pharmacists who require access to such information at all times.
9.	A special printed form should be introduced for use when prescribing a controlled drug, whether within the NHS or on a private basis.
10.	The special form should be in such format as will enable the Prescription Pricing Authority (PPA) to scan the prescribing information into its database so as to permit subsequent analysis and monitoring.
11.	The special form should show the GMC registration number of the medical practitioner to whom the pad of forms has been issued.
12.	The special form should provide the prescriber with a space in which to record a brief description of the condition for which the controlled drug has been prescribed.
13.	Consideration should be given to requiring that the patient's NHS number or some other patient-specific identifier should be included on the special form.
14.	The amount of a controlled drug that can be dispensed on a single prescription should be limited to a supply sufficient to last 28 days.

No.	Shipman Report 4
	Recommendations
15.	The duration of validity of a prescription for controlled drugs should be limited to 28 days. This restriction would not apply to drugs in Schedule 5 to the MDR 2001.
16.	When computer generated prescriptions are in genera; use for controlled drugs and when the electronic transmission of prescriptions is introduced, the software should be so designed as to ensure that both the time of issue of a prescription and the time at which it is dispensed are recorded.
17.	The purchase of all stocks of controlled drugs for practice use should follow a procedure that is capable of being monitored.
18.	GPs who keep a stock of Schedule 2 controlled drugs should be required (as now) to keep a CDR and to observe existing safe custody requirements.
19.	When the new arrangements for the provision of out of hours services come into effect, PCTs should establish protocols governing responsibility for the provision of Schedule 2 drugs and for the keeping of any CDR.
20.	There should be some relaxation of the strict requirements that a pharmacist is not permitted to dispense a controlled drug prescription unless there is full compliance with every technical requirements of the MDR 2001.
21.	In the case of a controlled drug supply that must be recorded in the pharmacy CDR, a pharmacist should be required to ask the name and address of the person collection the drugs, unless that information is already known to him/her.
22.	Any healthcare professional, acting in his/her professional capacity, presenting a prescription or requisition for a controlled drug, the supply of which must be recorded in the pharmacy CDR, should, if not known to the pharmacist, be required to provide identification, preferably his/her professional registration card.
23.	Any person collecting controlled drugs in Schedules 3 and 4 from the pharmacy should be required to write and sign his/her name of the back of the prescription form.
24.	Pharmacies should be permitted to keep their CDRs in electronic form.
25.	The keeping of a running balance in pharmacy CDRs should henceforth be regarded as good practice.
26.	The name and professional registration number of the prescriber should be entered in the CDR, as should the name of the pharmacist, responsible for supplying controlled drugs to a patient or his/her representative.
27.	The current requirement that a pharmacy CDR be kept for two years should be amended and the period should be extended to seven or, possibly, ten years.
28.	The RPSGB should provide guidance to its members as to the information and advice to be given to patients and their representatives when receiving a supply of a controlled drug.
29.	Pharmacists should be required to prepare a statutory patient drug record card (PDRC) to accompany every supply of injectable Schedule 2 drugs leaving the pharmacy.

No.	Shipman Report 4
	Recommendations
30.	The healthcare professionals who administer such Schedule 2 injectable drugs should be obliged to enter every administration and new supply of such a drug on a master PDRC and should keep a running balance of the remaining stock.
31.	Consideration should be given to changing the law so that all controlled drugs would become the property of the Crown on the death of the patient for whom they were prescribed.
32.	There should be increased formality attaching to the destruction of injectable Schedule 2 controlled drugs dispensed for administration in the community.
33.	It should be the responsibility of PCTs to ensure that suitable arrangements are in place for the disposal of controlled drugs.

APPENDIX D - SUMMARY RECOMMENDATIONS FROM SHIPMAN INQUIRY 5TH REPORT

No.	Shipman Report 5
	Recommendations
1.	"I endorse the provision contained in the draft National Health Service (Complaints) Regulations (the draft Complaints Regulations), whereby patients and their representatives who wish to make a complaint against a general practitioner (GP) will be permitted to choose lodgements with GP practices of PCT".
2.	Steps should be taken to improve the standard of complaints handling by GP practices.
3.	Draft regulation 30 of the draft Complaints Regulations, which would require GP practices to provide primary care trusts (PCTs) with limited information about complaints received by the practice at intervals to be specified by the PCT, should be amended …
4	There should be statutory recognition of the importance of the proper investigation of complaints to the processes of clinical governance and of monitoring the quality of health care.
5.	On receipt by a PCT of a complaint about a GP, a 'triage' (the first triage) of the complaint should be conducted by a member of the PCT's staff who is appropriately experienced and has access to relevant clinical advice. The object of the first triage is to assess whether complaints are purely private grievance or Clinical Governance issues.
6.	'Private grievance complaints' should be dealt with by appropriately trained PCT staff. The objectives in dealing with such complaints should be the satisfaction of the patient and, where possible, restoration of the relationship of trust and confidence.
7.	'Clinical governance complaints' should be investigated with the dual objectives of patient protection satisfaction and fairness to doctors. They should be referred for a further triage (the second triage) to a small group comprising two or three people. Second triage should be to decide whether complaint is investigated by PCT or national body.
8.	The investigation of 'clinical governance complaints' should not be undertaken by PCT staff. Instead, groups of PCTs should set up joint teams of investigators, who should be properly trained in the techniques of investigation and should adopt an objective approach.

No.	Shipman Report 5
	Recommendations
9.	All 'clinical governance complaints' (save those which do not involve serious issues of patient safety and where the underlying facts giving rise to the complaint are clear and undisputed) should be referred to the inter-PCT investigation team. The objective should be to reach a conclusion and to set out the evidence reports which should go to the PCT.
10.	On receipt of the report, the PCT group which carried out the second triage should consider what action to take. It might be appropriate to refer the matter to another body, such as the GMC or the NCAA. Alternatively, it might be appropriate for the PCT to take action itself, if an inconclusive investigation, it should be referred to Health Care Commission.
11.	Neither an intention on the part of the complainant to take legal proceedings, nor the fact that such proceedings have begun, should be a bar to the investigation by a NHS body of a complaint. In circumstances where the NHS body is taking disciplinary proceedings, a complainant should be entitled to see the substance of the report.
12.	In some circumstances, it may be necessary for a NHS body to defer or discontinue its own investigation of a complaint if the matter is being investigated by the police, a regulatory body, a statutory inquiry or some other process. Relevant provisions of the draft complaints regulations should be amended to reflect these principals.
13.	The draft Complaints Regulations, when implemented, should include a power enabling PCTs to refer a complaint to the Health Commission for investigation at any point during the first stage of the complaints procedures. Cases raising difficult or complex issues might be referred to the Health Care Commission for investigation at the time of the second triage.
14.	The draft Complaints Regulations, when implemented, should include a power enabling PCTs to refer a complaint to the Health Commission for investigation at any point during the first stage of the complaints procedures. Cases raising difficult or complex issues might be referred to the Health Care Commission for investigation at the time of the second triage.
15.	Concerns expressed about a GP by someone other than a patient or patient's representative (e.g. by a fellow healthcare professional) should be dealt with in the same way as patient complaints. Such concerns should be investigated (where necessary) by the inter-PCT investigating team or if complex the Health Care Commission.

No.	Shipman Report 5
	Recommendations
16.	Objective standards, by reference to which complaints can be judged, should be established as a matter of urgency. These standards should be applied by those making the decision whether to uphold or reject a complaint and by PCTs and other NHS bodies.
17.	In order to ensure that, so far as possible, complaints about healthcare can reach the appropriate destinations, there should be a 'single portal' by which complaints or concerns can be directed or redirected to the appropriate quarter. This service should also provide information about the various advice services available.
18.	About two years after the Complaints regulations come into force in their entirety, an independent review should be commissioned into the operation of the new arrangements for advising and supporting patients who wish to make a complaint.
19.	The powers of PCTs should be extended so as to enable them to issue warnings to GPs and to impose financial penalties on GPs in respect of misconduct, deficient professional performance or deficient clinical practice which falls below the thresholds for referral to the GMC or PCT list management powers.
20.	Steps should be taken to ensure that every prescription generated by a GP can be accurately attributed to an individual doctor. Only then will the data resulting from the monitoring of prescribing information constitute a reliable clinical governance tool.
21.	Regular monitoring of GPs' prescribing should be undertaken by PCTs. Special attention should be paid to the prescribing of controlled drugs by GPs. Doctors who have had a problem of drug misuse in the past or who are suspected of having a current problem should be subject to close scrutiny. When a restriction is placed on a doctor's prescribing powers, this information must be made available to those who need to know, especially pharmacists.
22.	The Department of Health (DoH) should make provision for a national system for monitoring GP patient mortality rates. The system should be supported by a well organised, consistent and objective means of investigating those cases where a GP's patient mortality rates signal as been above the norm.
23.	Every GP practice should keep a death register in which the particulars of the deaths of patients of the practice should be recorded for use in audit and for other purposes.

No.	Shipman Report 5
	Recommendations
24.	PCTs should undertake reviews of the medical records of deceased patients, either on a routine periodic basis (if resources permit) or on a targeted basis limited to those GPs whose performance gives rise to concern.
25.	The purpose of GP appraisal must be made clear. A decision must be taken as to whether it is intended to be a purely formative (i.e. education) process or whether it is intended to serve several purposes: part formative, part summative (i.e. pass/fail) and/or part performance management.
26.	If appraisal is intended to be a clinical governance tool, it must be 'toughened up'. If that is to be done, the following steps will be necessary. Appraiser should be more thoroughly trained and accredited following some form of test or assessment. Standards for appraisal should be set and there should be nationally agreed core verifiable information supplied by the PCT both to the appraiser and appraisee.
27.	The Family Health Services Authority (Special Health Authority) or its proposed successor, the NHS Litigation Authority, should collect and analyse information relating to the use made by PCTs of their list management powers. Such analysis would assist the DOH in providing guidance to PCTs.
28.	The Government should consider the feasibility of providing a financial incentive for the achievement of GP practice accreditation by means of a scheme similar to that operated by the Royal College of General Practitioners in Scotland.
29.	The policy of the DoH and PCTs should be to focus on the resolution of the problems inherent in single-handed and small practices. More support and encouragement should be given to GPs running single-handed and small practices. In return, more should be expected of such GPs in terms of group activity and mutual supervision.
30.	PCTs should be willing and able to provide advice to GP practices on good recruitment practice and should also be willing to offer support in drafting job specifications and advertisements. They should be prepared, if requested, to assist in sifting applications and in making the necessary checks on applicants before the interview stage.
31.	A standard reference form should be developed for use in connection with appointments to GP practices. PCTs should insist that a reference is obtained from the doctor's previous employer or PCT. In the case of a PCT, the reference should be signed by the medical director or Clinical Governance Lead.

No.	Shipman Report 5
	Recommendations
32.	When recruiting a new member, GP practices should canvass and take account of the views of their patients about the kind of doctor the practice needs.
33.	PCTs should keep a separate file for each individual GP on their lists. That file should hold all material relating to the doctor which could have any possible relevance to clinical governance. If a doctor moves from one PCT to another, the file should be sent to the new PCT.
34a.	Every GP practice should have a written policy, setting out the procedure to be followed by a member of the practice staff who wishes to raise concerns, in particular concerns about the clinical practice or conduct of a healthcare professional within the practice.
34b.	Staff should be encouraged to bring forward any concerns they may have openly, routinely, and without fear of criticism. If unable to raise concerns he should be able to approach a person designated by the PCT for the purpose. The contact details of that person should appear in the written policy.
35.	The written policy should contain details of organisations from which staff can obtain free independent advice. If the 'single portal' is created, in whatever form, the policy should set out contact details of that also.
36.	It should be a statutory requirement for all private healthcare organisations to have a clear written policy for the raising of concerns. Steps should be taken to foster in the private sector the same culture of openness that is being encouraged in the NHS.
37.	Consideration should be given to amending the Public Interest Disclosure Act 1998 in order to give greater protection to persons disclosing information, the disclosure of which is in the public interest.
38.	Written policies setting out procedures for raising concerns in the healthcare sector should be capable of being used in relation to persons who do not share a common employment.
39.	There should be some national provision (probably a telephone helpline) to enable any person, whether working within heath care or not, to obtain advice about the best way to raise a concern about a healthcare matter and about the legal implications of doing so. It might be possible to link this helpline with the single portal previously referred to.

No.	Shipman Report 5
	Recommendations
40.	There should be a central database containing information about every doctor working in the UK. This should be accessible to the officers of NHS bodies and to accredited employers in the private sector, as well as to other bodies with a legitimate interest.
41.	The database would contain, or provide links to, information held by the GMC, the Criminal Records Bureau (CRB) and the NHS Counter Fraud and Security Management Service. It would also contain records of disciplinary action by employers, details of list management action by PCTs any adverse reports following the investigation of complaint, adverse findings by the Health Care Commission/Ombudsman and details of any finding of negligence in a clinical negligence action. Doctors should be able to access their own entries.
42.	Private sector employers should be required to provide relevant information as a condition of registration with the Healthcare Commission. Deputising services should also be required to provide information and should be able to access the database through the relevant PCT.
43.	Information about unsubstantiated allegations or concerns should not be included on the central database. Instead, the doctor's entry on the database should be flagged to indicate that confidential information is held by a named body.
44.	GPs should be required to disclose to the relevant PCT the fact that a clinical negligence claim has been brought against them, the gist of the allegation made and, when the time comes, the outcome of the claim." A failure by a doctor to make full declarations to a PCO as required by the Regulations 2004 should be regarded as misconduct of sufficient gravity to warrant referral to the GMC.
45.	The GMC should adopt a policy of tiered disclosure to apply to all persons seeking information about a doctor.
46.	The first tier should relate to information which is relevant to the doctor's current registration status, together with certain information about his/her past fitness to practise (FTP) history. First tier information should be posted on the GMC website... and should also be disclosed to anyone who requests any information about the doctor's registration...
47.	Disclosure of information at the second tier should be made to any person who makes a request about a doctor's FTP history. All information which has at any time been in the public domain should remain available to enquirers at the second tier for as long as the doctor remains on the register.

No.	Shipman Report 5
	Recommendations
48.	In all cases where a GP's registration is subject to conditions, or where s/he has resumed practice after a period of suspension or erasure, patients of any practice in which the GP works should be told. A letter of explanation which has been approved by the PCT should be sent to all patients...
49.	The GMC should ensure that its publications contain accurate and readily understandable guidance as to the types of case that do and do not fall within the remit of its FTP procedures.
50.	There must be complete separation of the GMC's casework and governance functions at the investigation stage of the new FTP procedures and this must be reflected in the Rules.
51.	The adjudication stage of the FTP procedures must be undertaken by a body independent of the GMC. This body should appoint and train lay and medically qualified panellists and take on the task of appointing case managers, legal assessors and any necessary specialist advisers.
52.	Consideration should be given to appointing a body of full-time, or nearly full-time, panellists who could sit on the FTP panels of all the healthcare regulatory bodies.
53.	"The GMC should adopt clear, objective tests to be applied by decision-makers at the investigation and adjudication stages of the FTP procedures. The tests that I recommend are set out at paragraphs 25.63 and 25.67-25.68. The tests should be incorporated into the Medical Act 1983 and/or the Rules..."
54.	The Medical Act 1983 should be amended to add a further route by which there might be a finding of impairment of fitness to practise, namely 'deficient clinical practise'.
55.	Urgent steps should be taken to develop standards, criteria and thresholds so that decision-makers will be able to reach reasonably consistent decisions at both the investigation and the adjudication stages of the FTP procedures and on restoration applications.
56.	The Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence (CRHP/CHRE)) should be invited to set up a panel of professional and lay people (similar in nature to the Sentencing Advisory Panel)...
57.	Steps should be taken to ensure that FTP panels determining cases in which issues of deficient professional performance arise apply a standard which is no lower than that set for admission to general practice.

No.	Shipman Report 5
	Recommendations
58.	Rule 4 of the General Medical Council (Fitness to Practise) Rules Order of Council 2004 (the November 2004 Rules), which sets out the test to be applied by the Registrar on receipt of an allegation, should be amended to give greater clarity.
59.	The November 2004 Rules should be amended to make formal provision for the GMC routinely to communicate with employers and with primary care organisations (PCOs) before deciding what action should be taken in response to an allegation and giving the GMC power to require from the doctor the necessary details to enable it to make such communication....
60.	Where a doctor has committed a criminal offence in respect of which a court has imposed a conditional discharge, that offence should be dealt with by the GMC in the same way as if it were a criminal conviction.
61.	The November 2004 Rules should be amended so as to give case examiners, and Investigation Committee (IC) panels in cases where the case examiners have disagreed, the power to direct investigations.
62.	Case examiners should be advised that they should not take mitigation into account when making their decisions and that they should consult a lawyer if they are in any doubt as to whether the available evidence is such that there is a realistic prospect of proving the allegation
63.	The November 2004 Rules should be amended to give case examiners, and Investigation Committee (IC) panels in cases where the case examiners have disagreed, the power to direct that an assessment of a doctor's performance and/or health should be carried out.
64.	The GMC should develop an abridged performance assessment to be used as a screening tool in any case in which an allegation is made which potentially calls into question the quality of a doctor's clinical practice.
65.	In order to avoid doctors undergoing multiple performance assessments, the GMC should investigate the development of a modular assessment.
66.	The November 2004 Rules should be amended to include a provision whereby reports of performance assessments should be disclosed by the GMC to doctor's employers or PCOs as soon as possible after receipt.
67.	The power to send letters of advice should be incorporated into the Rules and clear criteria for the sending of such letters should be prepared.
68.	The GMC should reconsider its proposals for the issuing of warnings at the investigation stage.

No.	Shipman Report 5
	Recommendations
69.	Rule 28 of the November 2004 Rules, which provides for the cancellation of hearings before a FTP panel, should be amended so as to provide that a decision to cancel must be taken by an IC panel and that the reasons for the cancellation must be formally recorded...
70.	There should be regular monitoring and audit of the number of applications to cancel FTP panel hearings and of the decisions to cancel and the reasons for those applications and decisions. Those reasons should be scrutinised with a view to taking steps to minimise the number of cases in which referrals are subsequently cancelled.
71.	If the GMC pursues its present intention to extend the use of voluntary undertakings to cases other than those raising issues of adverse health or deficient performance, the disposal of such cases should take place in public at the adjudication stage and not in private.
72.	The November 2004 Rules should be amended to make provision for the revival of closed allegations. The usual 'cut-off' period should be five years but it should be possible, in exceptional circumstances and in the interests of patient protection, to reopen a case at any time.
73.	Reviews of investigation stage decisions should be carried out by an independent external commissioner. The circumstances in which a review may take place should be extended to cover decisions of the Registrar to reject an allegation rather than to refer it to a case examiner.
74.	The November 2004 Rules should be amended so as to provide that the arrangements for the obtaining and consideration of health assessments and for the management and supervision of doctors who are the subject of voluntary undertakings relating to health assessments...
75.	The November 2004 Rules should be amended so as to provide that the arrangements for the obtaining and consideration of performance assessments and for the management and supervision of doctors who are the subject of voluntary undertakings relating to performance should be directed by a medically qualified case examiner...
76.	There should be an explicit power in the Rules to allow the GMC to undertake any further investigations it considers necessary after a case has been referred to a FTP panel and before the panel hearing.
77.	In the event that the GMC retains control of the adjudication stage, the GMC committee charged with governance of the adjudication stage should audit the work of case managers. Case management should apply to cases with a performance element.

No.	Shipman Report 5
	Recommendations
78.	FTP panellists should be warned that they should exercise caution about drawing adverse inferences from a failure to comply with case management orders.
79.	In the event that the GMC retains control of the adjudication stage, it should appoint a number of legally qualified chairmen who should, as an experiment or pilot, preside over the more complex FTP panel hearings...
80.	As part of their training, FTP panellists should be advised about their discretion to admit hearsay evidence and other forms of evidence not admissible in a criminal trial…
81.	The GMC should reopen its debate about the standard of proof to be applied by FTP panels. It should consider introducing a rule that the civil standard of proof should apply unless the doctor faces an allegation of misconduct which also amounts to a serious criminal offence.
82.	The GMC should abandon its intention to notify doctors, at the same time as sending notice of referral of their case to a FTP panel, of the outcome it will be seeking at the FTP panel hearing.
83.	FTP panels should be required to give brief reasons for their main findings of fact.
84.	Rule 17(5)(b) of the November 2004 Rules (which permits a FTP panel, on receipt of a report of a health or performance assessment, to refer the allegation back into the investigation stage for consideration of voluntary undertakings) should be revoked.
85.	Rule 17(2)(j) of the November 2004 Rules should be amended to make clear what types of further evidence should be received before a FTP panel decides whether a doctor's fitness to practise is impaired….
86.	The Medical Act 1983 should be amended to permit a FTP panel to issue a warning in a case where it has found that a doctor's fitness to practice is impaired but not to a degree justifying action on registration.
87.	Rule 17(2)(m) of the November 2004 Rules, which permits a FTP panel to take into account written undertakings entered into by a doctor when deciding how to deal with the doctor's case, should be revoked. If it is to be retained, the rule should be amended to make clear that undertakings can be taken into account only at the stage of deciding on sanction...

No.	Shipman Report 5
	Recommendations
88.	Throughout the period that a doctor's registration is subject to conditions imposed by a FTP panel or to voluntary undertakings, someone within the GMC (preferably a case examiner) should take responsibility for the doctor's progress and for ensuring that he is compiling with conditions imposed or undertakings given.
89.	In every case where a doctor is continuing to practise subject to conditions or voluntary undertakings, a professional supervisor should be appointed to oversee and report on the doctor's progress and on his/her compliance with the conditions or undertakings...
90.	Any breach of a condition imposed by a FTP panel or of a voluntary undertaking (save for the most minor breach) should result in the doctor being referred back (or referred) to a FTP panel so that consideration can be given to imposing a sanction.
91.	The November 2004 Rules should be amended to ensure that there is at least one review hearing in all cases where a period of suspension or conditions on registration have been imposed, unless there are exceptional reasons why no such hearing should take place.
92.	The arrangements set out in the 2003 draft Rules, whereby any necessary gathering of evidence in preparation for a review hearing would be undertaken by a specially appointed case examiner, should be reinstated.
93.	In all but exceptional cases, a doctor whose registration has been suspended should be required to undergo an objective assessment of his/her fitness to practise before being permitted to return to practice. That assessment should be considered by a FTP panel...
94.	The GMC's primary role should be one, not of remediation of doctors, but of protection of patients. If a doctor who is subject to conditions or voluntary undertakings undergoes an assessment in the circumstances described above, and the assessment reveals that he does not meet the required standard consideration should be given to taking the steps necessary to remove the doctor from practice...
95.	The arrangements set out in the 2003 draft Rules, whereby any necessary gathering of evidence in preparation for a restoration hearing should be undertaken by a specially appointed case examiner, should be reinstated.
96.	Every doctor whose application for restoration to the register has reached the second stage of the procedure should be required to undergo an objective assessment of every aspect of his/her fitness to practise. The doctor should not be restored to the register unless he has met the required standard

No.	Shipman Report 5
	Recommendations
97.	Doctors who are restored to the register should be required to have a mentor whose task it will be to monitor, and report to the GMC on, their progress in practice.
98.	A thorough investigation of the circumstances underlying allegations of misconduct involving drug abuse should be conducted. The full facts should be established, including the circumstances in which the abuse began.
99.	The GMC should commission research into drug abusing doctors and their outcomes following supervision under the health procedures.
100.	Every aspect of the FTP procedures in which either doctors or makers of allegations have direct interest should be set out in the Rules. In addition, the GMC should publish a FTP manual, containing all its relevant Rules and its guidance for panellists...
101.	Clear statistical information should be collected and published by the GMC. The GMC should publish an annual report which should amount to a transparent statement of the year's activities in respect of the FTP procedures.
102.	The GMC should carry out audits of various aspects of its procedures, in addition to its other routine auditing activities.
103.	The arrangements for revalidation should be amended so that revalidation comprises, as required by section 29A of the Medical Act 1983, an evaluation of an individual doctor's fitness to practise.
104.	The annual report referred to at 101 above should include clear statistical information about the number of applications for revalidation and their outcomes. It should amount to a transparent statement of the year's revalidation activities.
105.	In three to four year's time, there should be a thorough review of the operation of the new FTP procedures, to be carried out by an independent organisation. This task should be undertaken by or on the instructions of the CRHP/CHRE.
106.	The GMC's constitution should be reconsidered, with view to changing its balance, so that elected medical members do not have an overall majority. Medical and lay members who are to be appointed (by the Privy Council) should be selected for nomination to the privy council.

No.	Shipman Report 5
	Recommendations
107.	The GMC should be directly accountable to Parliament and should publish an annual report which should be scrutinised by a Parliamentary Select Committee.
108.	Section 29 of the National Health Service Reform and Health Care Professions Act 2002 should be amended so as to clarify that the Act provides for the CRHP/CHRE to appeal against 'acquittals' and findings of no impairment of fitness to practise, as well as in respect of sanctions which it believes were unduly lenient.
109.	There should in the future be a review of the powers of the CRHP/CHRE with a view to ascertaining whether any extension of its powers and functions is necessary in order to enable it to act effectively to ensure that patients are sufficiently protected by the GMC

APPENDIX E – TERMS OF REFERENCE of DHSSPS SHIPMAN PROGRAMME BOARD

Background

1. The 3rd, 4th and 5th Shipman Inquiry Reports were published between July 2003 and December 2004. These reports presented a major challenge to all UK Health Departments to determine how best to implement the numerous recommendations in ways that were timely and effective, thus securing maximum public confidence in professional performance and service provision.

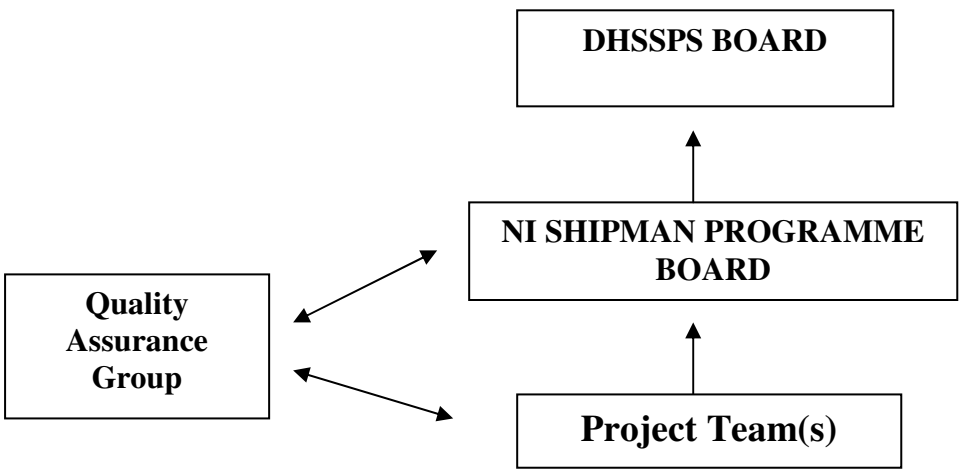
2. The focus of the DHSSPS response to these Shipman Inquiry Reports is to consider the recommendations in the context of local implications, acknowledging that there are different HPSS structures, local policies, procedures, and legislation in place, which is different to other parts of the United Kingdom.

Process

3. In 2005, the DHSSPS Shipman Programme Board was convened to oversee production of a timely and effective local implementation plan. Its remit was to co-ordinate and facilitate: -

    - a review of relevant Shipman inquiry recommendations and their applicability to health and social care in Northern Ireland;
    - liaison with national and local organisations and groups, involved in the wider clinical and social care governance agenda; and
    - development of an appropriate review mechanism to ensure that all elements of the Plan are implemented within their specified timeframes.

4. The following structure was put in place to aid in the development of a DHSSPSNI response:



5. The Programme Board was jointly chaired by the Chief Medical Officer and the Deputy Secretary of the Department, Mr Andrew Hamilton. Membership comprised a range of internal and external stakeholders. The external stakeholders played an important role in promoting awareness of the issues and will facilitate implementation of the recommendations in the future. The Programme Board reported to the Departmental Board and also provided regular updates to the Best Practice, Best Care Implementation Steering Group.

6. Within the Project Team, Core Team members had an intensive and continuous role in developing the final document.

7. The role of the Quality Assurance Group was to take receipt of and provide comment on Project Team papers produced in draft prior to submission to the Programme Board for signing off as acceptable products. The Quality Assurance Group represented the interests of additional external stakeholders.

8. Administrative support was provided by the Primary and Community Care Directorate, DHSSPS, who ensured that there was good communication across work streams.

9. The second phase which will focus on the actual implementation of the recommendations is outside the remit of this project, other than to establish the review mechanism for ensuring effective implementation.

Membership of Steering Group

Mr Andrew Hamilton (Co-chair) - Deputy Secretary, DHSSPS
Dr Michael McBride – Chief Medical Officer, DHSSPS
Dr Ian Carson (Co-chair) – Deputy/Acting Chief Medical Officer (until Apr 2006)
Ms Christine Jendoubi - Primary & Community Care Directorate, DHSSPS
Mr Noel McCann - Planning and Performance Management, (until Nov 2006)
Mr David Bingham - Human Resources Directorate, DHSSPS
Dr Norman Morrow - Chief Pharmaceutical Officer, DHSSPS
Mr Martin Bradley - Chief Nursing Officer, DHSSPS
Mrs Doreen Wilson - Chief Dental Officer (until Sept 2006)
Dr Paula Kilbane – Chief Exec., Eastern Health and Social Services Board
Ms Ann Bowen - Pharmaceutical Society of Northern Ireland
Dr Brian Dunn - BMA (GPC)
Mrs Stella Burnside – Chief Exec., Reg. & Quality Improvement Authority
Dr Colin Fitzpatrick - National Clinical Assessment Service Advisor (NI)
Prof Alastair Scotland - National Clinical Assessment Service (GB)
Mr John Knape – Royal College of Nursing (Northern Ireland)
Ms Lynne Cairns – Southern Health and Social Services Council
Ms Elaine Way – former Chief Executive, Altnagelvin HSS Trust

Membership of Core Team

Dr Maura Briscoe (project lead) - Medical and Allied Group, DHSSPS
Mr John Farrell - Primary & Community Care Directorate, DHSSPS
Dr Kathryn Booth - Medical and Allied Group, DHSSPS
Mr Gerry Gault – Directorate Information Systems, DHSSPS
Dr Michael Mawhinney - Pharmaceutical Advice & Services, DHSSPS
Mr Joe Gault - Pharmaceutical Advice & Services, DHSSPS
Ms Diane Taylor - Education & Training, HR Directorate, DHSSPS
Mr Donncha O'Carolan - Dental Group, DHSSPS
Mrs Margaret O'Hagan - Nursing & Midwifery Group, DHSSPS
Ms Michelle McCorry - Pharmaceutical Advice & Services, DHSSPS
Mr Jonathan Bill - Planning and Perf. Management Directorate, DHSSPS
Dr Heather Neagle - Medical and Allied, DHSSPS
Secretariat - Primary & Community Care Directorate, DHSSPS

APPENDIX F

EQUALITY AND HUMAN RIGHTS IMPLICATIONS

1.0 Introduction

Section 75 of the Northern Ireland Act 1998 requires all public authorities, in carrying out their functions relating to Northern Ireland, to have due regard to the need to promote equality of opportunity:

- Between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- Between men and women generally;
- Between persons with a disability and persons without; and
- Between persons with dependants and persons without.

In addition, without prejudice to the above, a public authority is also required, in carrying out its functions, to have due regard to the desirability of promoting good relations between persons of different religious belief, political opinion or racial group.

2.0 Human Rights

The Human Rights Act 1998 came into force in October 2000, giving further effect to the rights enshrined in the European Convention on Human Rights. It is important that human rights issues are adequately addressed in the implementation of this action plan. For example, it is acknowledged that when underperformance is alleged or identified, individuals have a right to have a fair assessment undertaken within a reasonable timeframe; however, the safety of the public is of paramount importance.

The main articles which are likely to be relevant to this action plan are Article 6 (right to a fair trial), Article 8 (right to respect for private and family life), Article 10 (freedom of expression), and Article 14 (prohibition of discrimination in enjoyment of Convention rights).

3.0 Purpose of discussion

On the 19th July 2006, the project team met to consider the equality implications of the DHSSPS response to recommendations contained in Shipman Inquiry Reports 3, 4 and 5, having due regard to Section 75 of the NI Act 1998 and the Department's commitment to promote equality of opportunity.

4.0 Discussion

The Group considered the screening criteria as set out in paragraph 4.2 of the Department's Equality Scheme.

4.1 Is there any evidence of higher or lower participation or uptake by different groups?

The document has positive benefits for all services users irrespective of their classification under Section 75 and there is no adverse differential participation by any group.

The focus of the entire report is on the promotion of quality and safety for service users, the public, and HPSS staff by enhancing legislation, systems and procedures, professional performance and by promoting a culture of quality improvement and learning through clinical and social care governance.

4.2 Is there any evidence that different groups have different needs, experience, issues and priorities in relation to the particular policy?

The issues addressed in this report and action plan are global ones and do not specifically impact on groups with different needs, for example, lower socioeconomic groups, different genders or younger people. Systems changes are designed to improve public protection across all groups, especially, for example, those at greater risk in society as a consequence of age, social circumstances or disability. Public information will be provided to highlight changes in the current systems, for example, in relation to changes to improve governance in the use of controlled drugs.

There is no differential or adverse impact on any group as a consequence of this report or action plan, for example,

Men and women generally;
Persons of different marital status;
Person of different religious beliefs;
Persons with or without dependents;
Persons of different political opinions;
Persons of different racial groups;
Persons of different sexual orientation

4.3 Is there an opportunity to better promote equality of opportunity or good relations by altering policy or working with others in government or the community at large?

Within this report and action plan, there is a clear message from the Department that quality of service, patient safety and public confidence are high priorities. There are opportunities within this policy and action plan to promote good relations and to work with other government departments, both locally and nationally, especially in relation to enhanced death certification processes, improved governance in use of

controlled drugs and improved professional regulation and performance.

4.4 How will this impact on complementary policy areas?

This report and action plan are complementary to other local and national policy areas on quality and safety and improving public confidence in service provision. For example;

Review of Public Administration, which has as a core principle improvement in quality and safety;
Reform and modernisation of HPSS services (as above)
Best, Practice Best Care (2001):
Safety First: A Framework for Sustainable Improvement in the HPSS (2006) - the DHSSPS safety policy and action plan. Part of this action plan is to develop a response to Shipman Inquiry recommendations.
Good Doctors, Safer Patients (DH London)
The Regulation of Non Medical Health Care Professions.

5.0 Conclusion

The group concluded that there was no adverse effect on one or more equality groups through development of this document. No potential differential impact has been identified. The action plan is designed to promote quality and safety of care, systems and legislative changes to give greater public protection.

The Group considered that there was no need to complete a full equality impact assessment; however, there remained a need to ensure appropriate and ongoing monitoring of equality implications during the course of implementation of the action plan.

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