Safer management of controlled drugs – draft guidance on strengthened governance arrangements

Introduction

1. This draft guidance sets out the strengthened governance arrangements for controlled drugs in England. It is for:
    - PCTs and NHS and Foundation Trusts – those who will have a responsibility for ensuring that systems are in place for the safe and effective management of controlled drugs and that these are working effectively
    - 'Inspectors' - those who will be monitoring and inspecting controlled drugs
    - Individuals and organisations in the health and social care sectors – those who may have their use of controlled drugs monitored and inspected

   The guidance may also help patients and the public understand how the new arrangements will work and how any concerns they may raise about controlled drugs will be handled.

2. Controlled drugs are medicines used to treat a variety of clinical conditions, such as the relief of acute pain in myocardial infarction and the relief of severe chronic pain in palliative care. They are subject to special legislative controls because of their potential for harm if wrongly used. This potential, illustrated by Harold Shipman, has led the Government to introduce strengthened measures to ensure the safe management of controlled drugs.

3. The purpose of this guide is to promote the safe and effective use of controlled drugs. The new governance arrangements must be implemented in a way that supports professionals in their clinical practice and does not deter them from prescribing these important medicines when clinically required by patients.

4. Central to the Government's proposed measures for the safe management of controlled drugs are new monitoring and inspection arrangements which will work within and alongside existing governance systems and should be seen as an integral part of the overall drive to improve quality in healthcare. This guidance explains how these arrangements will work.

The overall philosophy

5. The Shipman Inquiry was set up on 31 January 2001 and was chaired by Lady Justice Janet Smith DBE as an independent public inquiry into the issues arising from the case of Harold Shipman. The Inquiry's Fourth Report was published on 14 July 2004. It focuses on the methods used by Harold Shipman to divert large quantities of potentially lethal controlled drugs and the reasons it was possible for him to do so for so long without detection.

6. The Shipman Inquiry concluded that there were serious shortcomings in the systems used for the safe management of controlled drugs and made a number of recommendations to improve the management of controlled drugs. It found that there was no overall co-ordination of the monitoring and inspection of controlled drugs with various bodies inspecting different organisations and different aspects of the management of controlled drugs. Controlled drugs in community pharmacies were inspected by police Chemist Inspection Officers, other aspects of professional practice were inspected by inspectors from the Royal Pharmaceutical Society of Great Britain (RPSGB), and prescribing of controlled drugs in GP practices was monitored by prescribing advisors of the local health authority. It also found that Chemist Inspection Officers did not have the professional training or expertise to pick up unusual clinical practice, and that there was no routine inspection of the management of controlled drugs in GP practices. The Inquiry recommended the creation of a separate controlled drugs inspectorate comprising small multi-disciplinary inspection teams, operating regionally but co-ordinated nationally.

7. *Safer management of controlled drugs - the Government's response to the Fourth Report of the Shipman Inquiry* was published in December 2004. This response makes clear that the Government fully agrees with the Inquiry that the current systems for managing controlled drugs need strengthening to minimise the risks to patient safety of the inappropriate use of controlled drugs. However, the Government considers that a separate controlled drugs inspectorate outside of existing clinical governance arrangements would not be the best option. A discrete inspectorate could lead to duplication of work and inspections. The management of controlled drugs should be seen within the overall context of clinical quality rather than an issue by itself.

8. The Government favours instead a system working within and alongside existing governance arrangements. This will build on the expertise of organisations that currently monitor and inspect aspects of the management of controlled drugs. This will also maximise the ability to detect poor practice in controlled drugs management by combining this with information on other aspects of clinical practice. PCTs, NHS Trusts, Foundation Trusts and independent hospitals[1] will have a responsibility to assure the quality of their controlled drugs management as an integral part of their processes, with external inspection where appropriate as an additional safeguard. Healthcare organisations, police services, social services, the National Clinical Assessment Service and the relevant inspection bodies will also be under a statutory duty to work together in local networks to share intelligence on controlled drugs issues where there are concerns. The overall arrangements will be subject to assurance by the Healthcare Commission.

9. The new arrangements will result in a significant improvement to the current piecemeal arrangements, being better co-ordinated and integrated within the overall framework for improving quality in healthcare. The arrangements should encourage good practice in the management of controlled drugs as well as help to detect unusual or poor clinical practice or systems, or criminal activity.

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[1] An independent hospital is as defined under the Care Standards Act 2000 (Part 1, s2 (2) and (3))

10. Subject to the Government's planned legislative programme and parliamentary approval, the Government expects the new arrangements to be in place by April 2006.

Overview of new arrangements

11. At local level, all healthcare organisations will be accountable for ensuring the safe management of controlled drugs. Organisations directly providing clinical services will be required to complete a self-assessment and declaration on whether they use controlled drugs. These assessments will inform occasional random inspections to provide an additional check that controlled drugs are being managed safely.

12. PCTs, NHS Trusts, Foundation Trusts and independent hospitals will be accountable for the monitoring of all aspects of the use and management of controlled drugs by all healthcare professionals who they employ or with whom they contract. They will do this through normal governance arrangements such as analysing baseline data and clinical governance visits.

13. To support accountability, a specific individual of appropriate authority – an Accountable Officer - will be identified in each Primary Care Trust, NHS Trust, Foundation Trust and independent hospital to monitor the use of controlled drugs within their organisation and take action where necessary. Subject to Parliamentary approval, the requirement to nominate an Accountable Officer will become a statutory duty.

14. The Accountable Officer will be responsible for ensuring the safe and effective use and management of controlled drugs within local organisations subject to their oversight. For example, an out-of-hours service contracted with the PCT would fall under the remit of the PCT Accountable Officer. Where an individual mainly works for a provider contracted with the PCT but also in the private sector, the PCT should ensure arrangements are in place to monitor their overall use of controlled drugs. In the private and voluntary sector, registered managers will remain accountable for the day-to-day management of controlled drugs and the Healthcare Commission and Commission for Social Care Inspection (CSCI) will be responsible, as they are now, for assessing the management of controlled drugs as part of their regular inspections and taking appropriate action.

15. The Government also plans, subject to Parliamentary approval, to place a legal duty on local agencies to share information and intelligence about the use of controlled drugs in the health care sector. The local agencies required to share information will include healthcare organisations, the police, social service authorities and relevant inspectorates (Healthcare Commission, Commission for Social Care Inspection (CSCI, and the Royal Pharmaceutical Society of Great Britain (RPSGB)).

16. To put this duty into practice, Accountable Officers in PCTs will act as the hub of a local network involving the key local agencies. We envisage that networks will normally be established on the basis of a health community, spanning several PCTs. SHAs may wish to broker arrangements. Members of the network will meet regularly to agree and update protocols and to review trends. The network will also enable agencies that have a cause for concern about the activities of any healthcare professional or organisation to share them as soon as possible with any other local agencies who may be affected or who may have complementary information. Where several agencies are concerned, the PCT Accountable Officer may consider setting up an Incident Panel to consider specific serious concerns. Each agency will retain responsibility for taking appropriate action where required.

17. New audit tools will be made available by the Prescribing Support Unit to help healthcare organisations monitor and analyse prescribing patterns and to pick up unusual patterns of prescribing. The National Clinical Governance Support Team and the National Clinical Assessment Service have also produced a toolkit to provide support in routinely monitoring the use of controlled drugs and taking action. This toolkit is for use in the primary care sector, predominately general practice, though can equally be used in other settings and with other professional groups. **[web reference to be inserted when available]**

18. At national level, in England, the new arrangements will be subject to external scrutiny by the Healthcare Commission. The Head of Operations is the person responsible for ensuring that all healthcare organisations (public, private and voluntary) have satisfactory arrangements in place for the safe management of controlled drugs. The Commission will also ensure that local governance arrangements, intelligence networks and provisions for incident panels are satisfactory. Where appropriate the Commission will use its existing powers to inspect or investigate systems failures, or registration issues in the private and voluntary sector. The Commission will monitor national trends and innovation in the management of controlled drugs and will publish its findings to promote improvement in this field. The Government also plan to establish a small group under the leadership of the Healthcare Commission and involving the National Patient Safety Agency, the Prescribing Support Unit, the National Clinical Governance Support Team and the police to look at national trends in controlled drugs use.

Routine monitoring and inspection

The role of the 'Accountable Officer'

19. Subject to Parliamentary approval, it is proposed to place a statutory responsibility on PCTs, NHS Trusts, Foundation Trusts and independent hospitals to nominate a specific individual to be responsible for the monitoring of all aspects of the use and management of controlled drugs in their organisation. The specific individual – the Accountable Officer – should have appropriate professional standing and be a senior executive officer of the organisation (ie they should be an Executive Director or report directly to an Executive Director). They should have credibility with all healthcare professionals and sufficient seniority to be able to take action

regardless of how a concern is raised. Wherever possible, they should be independent of the organisation's day-to-day use of controlled drugs.

20. The Accountable Officer's responsibilities are listed in more detail at Annex A. The Accountable Officer will need to possess or have access to certain skills and expertise, including data analysis, investigative skills and networking. They will require some investigative and administrative support and will need support from others such as the clinical governance lead and for PCTs the prescribing adviser. The National Prescribing Centre is producing a modular training package to support the training and development of those working with controlled drugs.

21. Accountable Officers will need to develop and implement systems for routinely monitoring the use of controlled drugs, through pro-active analysis and identifying triggers for concern, and taking action. Accountable Officers will also need to ensure that appropriate arrangements for inspections are in place and that they are alerted to any significant findings.

22. PCTs are encouraged to consider consortia arrangements for the support required by Accountable Officers, such as data analysis and investigative skills. Decisions on the arrangements will be for local determination but will be influenced by previous history of concerns about controlled drugs misuse, predictions of the likely workload and the need for coterminosity with partner organisations, such as the police service, SHAs and Healthcare Commission and CSCI regions. Responsibility for ensuring that systems are in place and that Accountable Officers are appointed and supported will rest with individual organisations. Organisations should notify their SHA of the name of their Accountable Officer and the Healthcare Commission will maintain a national list.

23. Healthcare organisations should ensure that the structures set up around the Accountable Officer are fully integrated with existing local performance structures. For PCTs, *Local GP performance procedures* provides information on local procedures for handling concerns about the performance of general practitioners **[insert web reference when available]**. The model it recommends separates investigating from decision-making. Specialist knowledge and investigative skills are provided by a Performance Advisory Group and decisions on action are made by a Decision-making Group. In this model, the Accountable Officer may be a member of the Decision-making Group and use it for making decisions on controlled drugs. The Performance Advisory Group may be able to provide the necessary analytical and investigative support. For NHS trusts, *Maintaining High Professional Standards in the Modern NHS* provides a framework for investigating serious concerns about performance (see http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4072773&chk=oI83Ov).

24. A toolkit developed by the Clinical Governance Support Team and the National Clinical Assessment Service **[insert web reference when available]** provides further support and guidance on how Accountable Officers might routinely monitor the use of controlled drugs and take action, but the principles are set out below.

Routine monitoring

25. Accountable Officers should ensure the use of controlled drugs is monitored through routine processes such as data analysis and clinical governance, as an integral part of normal clinical governance arrangements. For PCTs, relevant data to be analysed would include prescribing data, for secondary care, supply details and for out-of-hours services, signed orders. The Prescribing Support Unit has audit tools to help with this monitoring (see http://www.psu.nhs.uk/oth_iss.htm#cds). Accountable Officers should also make sure suitable arrangements are in place for the disposal of controlled drugs in the community. They should also check that systems are in place to identify and act on other triggers such as a patient complaint or a healthcare professional raising a concern.

Self-assessment and controlled drugs declaration statement

26. All healthcare organisations providing clinical services and relevant social care organisations will need to complete a regular declaration and self-assessment on whether or not their organisation keeps stocks of controlled drugs and whether there are any special circumstances that might explain any seemingly unusual patterns of prescribing or supply. The declaration and self-assessment questionnaire will be sent to organisations by the relevant agency, and may be included in other assessments or planning tools, for example where PCTs request practice development plans. A template for declaration and self-assessment is available at **[insert web reference when available**].

27. Organisations should return their declaration and self-assessment to the agency responsible for monitoring their use of controlled drugs. For example, where a general practice is contracted to provide services to the PCT, the declaration/self-assessment should be returned to the PCT. NHS Trusts and the private and voluntary healthcare sector should return their declaration/self-assessment to the Healthcare Commission. Care homes should return their declaration/self-assessment to CSCI. Private pharmacies (those not contracted with a PCT) should return their self-assessment to the RPSGB.

28. Self-assessment will help inform other monitoring and inspection activities.

Controlled drugs review

29. Information from the declaration and self-assessment, routine monitoring and other sources will be brought together and reviewed to decide whether any further action, in the form of additional monitoring or inspection, is necessary. The review will assess the organisation's clinical standards in the prescribing, supply, administration, storage and disposal of controlled drugs and assure that it was complying with the Misuse of Drugs Act and the associated regulations, and any relevant guidance and professional codes of practice.

30. For primary care providers, contracted with the PCT (for example, GP surgeries and community pharmacies), the PCT's Accountable Officer will be responsible for ensuring that this review is carried out once a year. This review will be based on benchmark analysis derived from existing information, the organisation's self-assessment and declaration, and reports from any routine visits by prescribing

advisers and/or clinical governance leads. The review can be conducted as part of existing clinical governance reviews.

31. For NHS Trusts and the private and voluntary healthcare sector, the Healthcare Commission will use the self-assessment as useful evidence for assessing whether healthcare organisations are meeting national standards. A core standard in the national *Standards for Better Health* is that 'Healthcare organisations keep patients, staff and visitors safe by having systems to ensure medicines are handled safely and securely. The Healthcare Commission will corroborate the self-assessment/declaration with local organisations such as the PCT, the patients' forum and the local authority's overview and scrutiny committee. Information will then be checked against other regulator's findings and national data before making a decision on further action.

32. In care homes, controlled drugs are prescribed, dispensed and supplied for individual residents and in very few cases will a care home offering nursing care obtain a stock of controlled drugs. CSCI already regularly inspects care homes and other types of residential establishments which may use controlled drugs. The inspection process is being altered and from 2006 will reflect a more proportional approach. Intelligence will be collated from the annual self-assessment by the care-provider; service user questionnaires; complaints and reports of untoward incidents. The PCT will be responsible for monitoring prescribing in care homes.

33. Registered midwives may supply and administer, on their own initiative, any of the substances that are specified in medicines legislation under midwives exemptions, provided it is in the course of their professional midwifery practice and they have received appropriate training. A midwife's records related to administration of medicines should be regularly audited by their named supervisor of midwives and any concerns should be reported to the Accountable Officer.

Routine inspections

34. Formal inspection of healthcare and social care providers involving an 'on-site' visit to the provider's premises is only part of the new monitoring and inspection arrangements. Nonetheless, inspection remains a useful tool to check physical arrangements for the storage, record-keeping and management of controlled drugs, to support individual and organisational development, and to identify and investigate concerns.

35. Inspections will comply with the ten principles of inspection set out in *The Government's Policy on Inspection of Public Services* (http://www.cabinetoffice.gov.uk/opsr/documents/pdf/policy.pdf)

36. Inspections will take place in various settings:

Primary care

37. PCTs will arrange for a small number of routine inspection of a random sample of those GP practices and other contracted primary care providers where CDs are stored, dispensed, supplied or used on the premises. Inspections will be announced and could be combined with other visits where appropriate. To avoid duplication, community pharmacies will be inspected, as now, by the RPSGB who

will start to include inspection of controlled drugs in a sample of their routine inspections of community pharmacies. Inspections will be informed by self-assessment, controlled drugs reviews and other monitoring.

38. Prescribing advisors or clinical governance leads should continue to visit all GP practices to provide advice and support on a wide range of issues, including the safe and effective prescribing of medicines and the development of practice formularies. They can discuss controlled drugs issues on these visits if appropriate and use information from these visits to share good practice and to inform monitoring and inspection activities.

Secondary care

39. The Healthcare Commission will report specifically on any points of concern as part of their routine assessment of whether the Trust is meeting core standards and through their clinical audit programme, particularly the Acute Hospital Portfolio, which asks specific questions on controlled drugs and medicines management. Trusts may also wish to arrange mutual audits with other Trusts. At their own cost, Trusts can also invite the RPSGB to carry out occasional inspections or inspect a pharmacy where they have concerns.

Independent healthcare sector

40. All private and voluntary healthcare providers are required to register with the Healthcare Commission and are subject to periodic inspection as a condition of their continued registration. As part of these regular inspections, the Healthcare Commission will include an assessment of the adequacy of arrangements for the management of controlled drugs. The Healthcare Commission will also approve standard operating procedures for GPs in private practice and ensure compliance.

Care Homes

41. At present, regular inspections by CSCI look at arrangements for managing controlled drugs. In future, self-assessment and other corroborating information will be used to determine whether a targeted visit should take place. Targeted controlled drug inspections will be undertaken by CSCI pharmacist inspectors.

Standards

42. To ensure consistency in the new arrangements, common standards for inspection visits have been developed. A working group of representatives from the Royal Pharmaceutical Society of Great Britain (RPSGB), Healthcare Commission, CSCI, the police and the NHS has agreed the standards. The standards set out the core activities which should be included in an inspection and cover areas such as ensuring safe storage arrangements and proper record-keeping. They also suggest a frequency for visits: a ten per cent random sample to be inspected each year. Notice should be given of routine inspections. The standards template can be found at: **[insert web reference when available]**

43. Visits and inspections should be recorded and a report should be made available to the inspected premises as soon as possible after a visit. Where concerns are raised, the relevant Accountable Officer should be made aware of this and given a copy of the report.

Information-sharing

Duty of collaboration

44. To maximise the effectiveness of the new arrangements, it is important that healthcare organisations, police services, the inspection bodies (RPSGB, Healthcare Commission and CSCI), regulatory bodies and others work together to share intelligence on controlled drugs issues. To reinforce this need for co-operation, the Government plans (subject to Parliamentary approval) to place a statutory duty of collaboration on healthcare organisations, police forces, social services authorities, National Clinical Assessment Service and the relevant inspection bodies to require them to share information about potential controlled drugs offences and potential or actual systems failures.

45. It is planned that the duty will require the sharing of information which could give rise to concern over the use of controlled drugs by any healthcare or social care professional or careworker employed by another healthcare organisation or in contract with it.

46. In sharing information, organisations must have regard to the Data Protection Act 1998 and codes of practice on confidentiality, in particular the Caldicott principles. PCTs and contractor services may find the *Confidentiality and disclosure of information: GMS, PMS and APMS Code of Practice* helpful. (see http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4107303&chk=GiJc0B)

47. Information should be anonymised where possible. If an organisation wishes to share patient identifiable information, they may do so where required to by statute, but patient identifiable information should rarely be shared. The patient's consent should be sought or they should be notified of the disclosure unless such action would prejudice an investigation. Further advice on information-sharing will be made available.

48. Organisations will also be required to agree effective action within their remits. Action might include the further investigation of issues of concern or the initiation of processes to protect the safety of the public, including professional disciplinary processes. Each organisation will be separately accountable for action within its own proper sphere. In addition the appropriate PCT Accountable Officer will be responsible for ensuring that, overall, appropriate action is being taken in response to the concerns that have been raised and shared.

Intelligence network

49. To fulfil the duty of collaboration, PCT Accountable Officers will be responsible for establishing and operating an intelligence network for sharing information. Membership of the network will need to be decided locally. Networks may often be based on a locally recognised health community spanning several PCTs and SHAs may wish to help broker arrangements. As a minimum the network should involve:

Local PCTs
NHS and Foundation Trusts
RPSGB inspectors
Healthcare Commission (through regional and area teams)
CSCI (through regional teams)
Local police services
Social service authorities
SHA
Lay involvement, such as a PCT non-executive director

50. There may be instances where the Accountable Officer may consider the involvement of the local authority's vulnerable adult or child protection team.

51. The PCT's Accountable Officer (or an Accountable Officer on behalf of a cluster of PCTs) will act as the hub of the network and assist with setting up and managing the network. They will need to set up a standing forum of all members of the network to agree and maintain joint protocols and to review trends. They will also need to establish mechanisms to share information quickly between relevant partners. This will include considering how best to contact organisations quickly, and possibly out-of-hours, and making cover arrangements for holidays and sickness leave.

Intelligence database

52. Work is underway on how police intelligence on controlled drugs is best shared between police services. The Fifth Report of the Shipman Inquiry recommended the establishment of a national database of NHS information about the performance of healthcare professionals and this is being considered by the Government.

Investigating concerns

53. The Accountable Officer will need to ensure that robust systems are in place for logging concerns about controlled drugs, alerting themselves where appropriate and investigating these concerns. Where possible, existing mechanisms for identifying and managing concerns about performance should be used. *Local GP performance procedures* and *Maintaining high professional standards in the modern NHS* provide guidance on performance procedures in general practice and the NHS.

54. Concerns may come to light through a variety of routes – including routine monitoring of prescribing data, a routine inspection, a patient complaint, or from a health or social care professional. Where concerns are serious, if for example, patient safety is at risk or the professional's fitness to practise may be impaired, they should be passed on to the relevant body immediately (see paragraph 57 and section on escalating concerns). Where concerns appear to be more minor, further local investigation may be more appropriate.

55. Accountable Officers need to ensure that there is a clear separation between investigating and decision-making. They may like to draw on the model

recommended in *Local GP performance procedures* **[insert web reference when available]** which has a local Decision-making Group which decides on action to be taken, informed by a Performance Advisory Group which can provide advice on general trends and undertake more detailed investigations.

56. The Clinical Governance toolkit for controlled drug management in primary care will be a useful tool for investigating concerns **[insert web-reference]**. The document sets out a standard approach to investigating problems, covering routine monitoring of controlled drugs, investigating specific concerns and taking action once the investigation is completed. Whilst the document is aimed at primary care, it will also be useful for other settings. The Accountable Officer may wish to obtain information and advice from others in the local controlled drugs network.

57. Where the concern relates directly to a doctor or dentist, the National Clinical Assessment Service can offer help and run a 24 hour help-line. The General Dental Council, the General Medical Council, the Nursing and Midwifery Council, and the Royal Pharmaceutical Society of Great Britain offer guidance on how concerns about poor performance by professionals can be investigated locally and when to involve the regulatory body. Useful guidance can be found on their web-sites and some helpful documents are listed below. Support and guidance can be obtained from the General Social Care Council where concerns relate to a social care professional.

General Dental Council, *Our Guide to Local Practitioner Advice and Support Schemes*
http://www.gdc-uk.org/NR/rdonlyres/9F525505-9AAC-4507-A148-A5E48DA37932/15677/guide_to_pass.pdf

General Medical Council, *Referring a doctor to the GMC: A guide for individual doctors, medical directors and clinical governance managers*
http://www.gmc-uk.org/probdocs/fitness_to_practise_guidance/factsheets/guide_for_directors.pdf

Nursing and Midwifery Council, *Reporting unfitness to practise: A guide for employers and managers*,
http://www.nmc-uk.org/nmc/main/publications/Reporting_unfitness.pdf

Royal Pharmaceutical Society of Great Britain, *Interim guidance - Identifying and Remedying Poor Pharmacist Performance in England and Wales*
http://www.rpsgb.org/pdfs/pharmpoorperf0501.pdf

58. In analysing the reasons underlying an event and determining next steps the National Patient Safety Agency (NPSA)'s Incident Decision Tree will be helpful in many cases (see http://www.npsa.nhs.uk/idt). The Incident Decision Tree has been developed by the NPSA to help NHS managers decide on the appropriateness of suspension (exclusion) when dealing with staff involved in a serious patient safety incident.

59. Use of the tool is voluntary and the tree does not aim to provide firm ‘answers’ or ‘solutions’, but rather to identify a range of possible options. The Incident Decision Tree comprises an electronic flowchart with accompanying illustrations and guidance notes and leads the manager through a series of structured questions about the individual’s actions, motives and behaviour at the time of the incident.

60. The existing version of the tool relates to the secondary care sector. However, a new version is currently under development for use by all NHS managers. This will enable the user to select the healthcare setting the individual was working in and access guidance notes and advice specific to that sector. Once the user has completed the questions he or she will be led to guidance that reflects not only the care setting but also the individual’s role (community pharmacist, GP etc). Release of the new version is scheduled for summer 2005.

Serious concerns

61. There may be occasions where serious concerns come to light, either initially or through further investigation of a minor concern.

62. Depending on the nature of the concern, various options may apply:
    - Immediate action to protect patients
    - Initial consultation with other members of the network
    - Incident panels
    - Formal inspection

63. Care should be taken to ensure that any evidence collected during the course of an investigation is preserved in an appropriate manner to ensure its integrity in case it is required at a later stage for proceedings instituted by the police, other enforcement agencies and/or regulatory bodies. In such circumstances, it is strongly recommended that early advice be sought from the police or another appropriate enforcement authority.

Immediate action to protect patients

64. If patient safety is thought to be at risk, immediate action should be taken. NHS bodies should follow their local serious incident procedures. Immediate referral to the relevant regulatory body must be considered where there are serious concerns about an individual’s fitness to practise.

Initial consultation with other members of the network

65. Where concerns have come to light, initial consultation with other members of the network who may have relevant information may be helpful as an alternative or prior step to establishing an Incident Panel

Incident Panels

66. The Accountable Officer may decide to form an Incident Panel where it is felt that there is a need to move swiftly because patient safety may be at risk, or that the initial concern is likely to be a symptom of a wider problem. An Incident Panel provides for more structured consultation. The individual membership would depend on local circumstances and the nature of the concern but should include

key members of the local network. For PCTs, the Panel may comprise the Decision-making group with additional members as required. The police would normally expect to be involved at this stage if they have not been previously.

Targeted inspection

67. Either following an Incident Panel or as a direct result of a concern being raised, the Accountable Officer may decide to ensure a formal inspection of the premises takes place. The formal inspection could be undertaken by any body which has the power to inspect the management of controlled drugs: the PCT, RPSGB, Healthcare Commission, CSCI or police or a mixture of the above. Information-sharing between organisations will be necessary and PCTs in particular should be involved for their local knowledge. Depending on the nature of the concern, inspection teams involving members of different organisations may be helpful to bring expertise and knowledge together.

Remedial actions: dealing at local level

68. Many concerns can be rectified at local level. Examples may be a 'false positive' where an apparent prescribing anomaly is due to the case-load of a particular prescriber. In other cases, a minor lapse may be put right locally, where for example an organisation's storage arrangements for controlled drugs could be improved. If there is a minor concern about a healthcare professional's performance, they may require support or training. Additional visits from a prescribing adviser or clinical governance lead may be sufficient to rectify any minor issues. *Local GP performance procedures* provides examples of appropriate action following local investigation.

Remedial actions: escalating concerns

69. However there may be cases where concerns can not be resolved satisfactorily at local level and need to be formally escalated or passed on to another organisation.

70. The NPSA incident decision tree offers help and support in deciding how issues should be passed on. The table summarises where issues should normally be referred. There may well be occasions where concerns need to passed to more than one organisation.

Concern	***Refer to:***
Criminality suspected	Police
Fraud suspected	Police, NHS Counter-Fraud Service
Individual fitness to practise issue	Professional regulatory body
Organisational/systems issue	RPSGB (in case of pharmacy) HC (in case of NHS body, private or voluntary healthcare organisation) CSCI (in case of care home) HC and inform Monitor (in case of Foundation Trust)
For any of the above, additionally inform the SHA	

71. Where there are serious concerns about any element of the management and use of controlled drugs, the SHA should be informed. They will be members of the intelligence network and have a performance management role for PCTs.

72. If a concern is formally passed on to another organisation, the relevant Accountable Officer retains responsibility for monitoring the case and ensuring that a decision and any appropriate action is taken. Where a near-miss or an adverse incident has taken place, the NPSA should be informed so that wider learning can take place.

Support for healthcare professional

73. It can be very stressful for a health or social care professional to have concerns raised about their practice and be investigated. Individuals should be supported where concerns are raised about them. Individuals should also be supported where they wish to raise concerns about their own performance. *Local GP performance procedures* and *Maintaining high professional standards in the modern NHS* provide some advice on supporting professionals.

Closure of cases

74. Cases which have been considered by an Accountable Officer and/or the intelligence network should be recorded with a clear account of the findings and any action taken. The SHA should be informed. Where there has been serious systemic failure, the Healthcare Commission will wish to return to check that action has been taken. Regulatory bodies such as the Healthcare Commission, Health and Safety Executive and the National Audit Office are currently working together to produce a collective approach to action planning to reduce the burden of regulation and prevent contradictory recommendations.

Training and development

75. The National Prescribing Centre (NPC) has published *A guide to good practice in the management of controlled drugs in primary care (England)* to provide support for professionals on good practice and legislative requirements in the prescribing, supply, administration, storage and disposal of controlled drugs. It will be regularly updated to reflect legislative changes and good practice, (see http://www.npc.co.uk/background_for_cd.htm)

76. The NPC has also produced a competency framework for the competencies needed by individuals and teams undertaking monitoring and inspection functions under the new arrangements. It can be found at **[insert web reference when available]**.

77. The NPC is also producing a modular training and development package to support those working with controlled drugs. Modules will cover legislative requirements, good practice, the new monitoring and inspection arrangements and the specific knowledge and skills that different professions may need. The Royal College of General Practitioners runs a training programme specifically on the management of drug misusers (see http://www.rcgp.org.uk/drug/index.asp).

Central oversight

78. At national level, in England, the new arrangements will be subject to external scrutiny by the Healthcare Commission. The Head of Operations is the individual responsible at the Commission for ensuring that all healthcare organisations (public, private and voluntary) have satisfactory arrangements in place for the safe management of controlled drugs. This judgement will be informed by the findings of the other regulators (eg RPSGB, CSCI) and national data sets alongside the Commission's own work. The Commission will also ensure that local governance arrangements, intelligence networks and provisions for incident panels are satisfactory – this will include a review of the partnership arrangements with other agencies. Where appropriate the Commission will use its existing powers to inspect or investigate systems failures, or registration issues in the private and voluntary sector.

79. In England, the Healthcare Commission will annually publish its findings on the management of controlled drugs. It will share trends both in good practice and in common systems errors.

Support

80. Various organisations can provide support with developing and operating the new governance arrangements for the management of controlled drugs. The NPC will be offering a range of training and development modules and its guide to good practice in the management of controlled drugs may be helpful (see http://www.npc.co.uk/background_for_cd.htm) The Clinical Governance Support Team/ National Clinical Assessment Service's toolkit **[insert web reference when available]** provides help in implementing the arrangements, and the NPSA's incident decision tree (see http://www.npsa.nhs.uk/idt) will help with analysing the reasons behind an event and determining next steps.

81. It is planned to establish a small group under the leadership of the Healthcare Commission and involving the National Patient Safety Agency, the Prescribing Support Unit, the National Clinical Governance Support Team and the police to provide a central intelligence and analysis function. The group would not be involved with individual cases but would analyse national trends in the use and management of controlled drugs.

82. Accountable Officers may find it helpful to network with other Accountable Officers to share their experiences and the Department of Health will consider whether national networking events would be useful.

Consultation

83. This draft guidance has been produced by a working group involving a range of stakeholders, including NHS organisations, regulatory bodies, and the police service. Comments are invited both on the detailed proposals for the new governance arrangements and in particular on:
- whether the right balance has been struck between strengthening controls and ensuring patient access to the drugs they clinically require
- whether the new arrangements make the best use of existing mechanisms.

84. The information you send to us may need to be shared with colleagues within the Department of Health and/or published in a summary of responses to this consultation. We will assume that you are content for us to do this and if you are replying by e-mail, that your consent overrides any confidentiality disclaimer generated by your organisation's IT system, unless you specifically include a request to the contrary in the main text of your submission to us.

85. Comments should be sent by 30th September 2005 to:

Helen Causley
Fourth Floor
Skipton House
80 London Road
London
SE1 6LH
Tel: 020 7972 3113
Fax: 020 7972 1186
Email: helen.causley@dh.gsi.gov.uk

Consultation criteria
This consultation follows the Code of Practice on Consultation; the consultation criteria are set below.

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure that your consultation is clear, concise and widely accessible.
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.
6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The full code of practice is available at: http://www.cabinet-office.gov.uk/regulation/Consultation/introduction.htm

Consultation Coordinator

If you have any complaints or comments about the consultation process, you should contact the Department of Health's consultation co-ordinator, Steve Wells.

Steve Wells
Consultations Coordinator
Department of Health
Skipton House
80 London Road
London SE1 6LH
Email: steve.wells@dh.gsi.gov.uk

Annex A

Accountability, roles and responsibilities of the Accountable Officer

Accountability

NHS Accountable Officers are accountable through their organisation's management to their Strategic Health Authority

Foundation Trust Accountable Officers are accountable through their organisation's management to Monitor, the independent regulator of Foundation Trusts.

Private or voluntary healthcare or social care organisations are accountable ultimately to the Healthcare Commission or CSCI.

Responsibilities of the Accountable Officer

Responsibility	**Support arrangements required**
Ensures monitoring arrangements are in place for management and use of controlled drugs	Data analysis – prescribing data, supply details etc Analysis of organisational self-assessment System for identifying other triggers
Establishes mechanisms for the very quick sharing of intelligence and joint action in cases of urgency (where patient safety is at risk or evidence may be destroyed)	Administrative support
Ensures clear routes, such as the NHS complaints system, are available for any healthcare professional, patient or member of the general public to raise matters of concern, within a framework of appropriate confidentiality. This includes routes for healthcare professionals to self-refer if they have concerns about their own performance.	Complaints/ raising concerns function
Establishes mechanism for further investigation of causes for concern	Investigative function
Determines whether a targeted inspection is required and those who should be involved (May do this as part of a Decision-making Group)	Investigative advice Investigative function
Determines remedial action to be taken (eg no action required, support to healthcare professional or organisation, referral to regulatory body, Healthcare Commission, CSCI, police) (May do this as part of a Decision-making Group)	Access to NPSA, regulatory bodies etc HR support

Ensures remedial action is followed through (though police services retain responsibility for determining whether the evidence for possible criminal behaviour warrants a criminal investigation with a view to subsequent prosecution)	?Managerial support
Plays full part in intelligence network (bearing in mind the need to separate the investigative and decision-making functions).	Cross-referencing intelligence from other members of the network
Encourages good practice and development in management of controlled drugs	Monitoring and inspection to identify good practice Organising meetings/events/publications to share good practice

Additionally for PCT Accountable Officers:

Sets up and operates an intelligence network for the sharing of information between the PCT and neighbouring PCTs, NHS and Foundation Trusts, inspectors from the RPSGB, other healthcare regulatory bodies, Healthcare Commission and CSCI and local police forces. The intelligence network will have the aim of identifying individual healthcare professionals or organisations where there is serious cause for concern over the management of controlled drugs and agreeing what remedial action is needed.	Administrative and management support – organising meetings, record-keeping
Determines when an Incident Panel should be set up. (May do this as part of a Decision-making Group)	Investigative advice
Ensures a formal controlled drugs review is carried out once a year of each primary care provider in contract with the PCT. This will involve reviewing benchmark analysis derived from existing information, the provider's self-assessment of their clinical standards in prescribing, administering, storage and disposal of controlled drugs, and a statement that they comply with the Misuse	Data analysis – prescribing data, supply details Analysis of organisational self-assessments Knowledge of MDA and regulations

of Drugs Act and associated regulations. Reviews cases where concerns come to light.	
Ensures inspection is carried out of arrangements for handling controlled drugs at random sample of dispensing practices, other GP practices and out-of-hours services where stocks of controlled drugs are held.	Inspection team
Ensures arrangements are in place for proper disposal of unwanted controlled drugs in patient's homes.	Management and clinical support in establishing protocols (adherence to be checked through monitoring and inspection)

Annex B

Supporting documents

A guide to good practice in the management of controlled drugs in primary care (England)
http://www.npc.co.uk/background_for_cd.htm

Confidentiality and disclosure of information: GMS, PMS and APMS Code of Practice
http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4107303&chk=GiJc0B

Local GP performance procedures [draft]

Maintaining high professional standards in the NHS
http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4072773&chk=oI83Ov

Monitoring and Inspection standards [draft]

NCGST/ NCAS Controlled Drugs Toolkit [draft]

NPC Competency framework [draft]

NPSA incident decision tree
http://www.npsa.nhs.uk/health/resources/incident_decision_tree