



Final report

Safe Management and Use of Controlled Drugs in Prison Health in England

**National Prescribing Centre
Provided by the National Institute for Health and Clinical Excellence**

February 2012

Fieldwork and interviews for this project were conducted in the spring and early summer of 2010. Therefore, this report captures and reflects the issues relevant at that time. Field work was completed prior to the recent Home Office consultation on the proposed consolidation of the Misuse of Drugs Regulations 2001. This report could not therefore take account of those latest proposals, but references to relevant proposals within the consultation that map to the recommendations have been included.

In July 2010 the Government published a White Paper 'Equity and Excellence: Liberating the NHS' and more recently in January 2011, the Health and Social Care Bill, proposing extensive legislative changes to the architecture of the NHS. Upon completion of the Parliamentary process for that Bill, the findings and recommendations set out in this document will need to be considered and assessed in the context of organisational changes in the NHS. The ways in which the use of controlled drugs in the community is monitored and audited will need to continue to be adequately addressed.

Contents

Executive summary

1. Introduction

1.1 Background to controlled drugs legislative framework

1.2 Background to healthcare arrangements within prisons

2. Scope of the project

3. Project methodology

4. Pharmaceutical service delivery models within prison healthcare

5. Findings, conclusions and recommendations

5.1 Commissioning

5.2 Controlled drugs governance arrangements

5.3 Legislation

5.4 Operational issues in the prison healthcare setting

5.5 Education and training

6. Summary of recommendations

Appendices

Appendix 1: Contributors

Appendix 2: Glossary

References

Executive summary

This project, commissioned by the Department of Health in response to issues raised by key stakeholders, was undertaken to identify potential problems with the safer management and use of controlled drugs (CDs) in the prison healthcare setting in England. The issues that informed the project have been used to develop recommendations to reduce the risks associated with the identified problems.

The project was undertaken to identify potential problems resulting from either gaps in legislation or challenges in the interpretation of the legislation for the safer management and use of CDs prescribed when necessary for the healthcare of prisoners.

The legislative framework for CD governance is comprehensive, but the prison setting is not specifically mentioned within some specific pieces of legislation. In particular, the detail within the Misuse of Drugs Act 1973 and Misuse of Drugs Regulations (MDR) 2001 can be difficult to implement for the prison environment. Interpretation of the regulations has been required to develop safe practices and procedures to minimise the risks associated with diversion, inappropriate use or illegal use of CDs.

As a result of a range of complex commissioning and contracting models with a multiplicity of providers that now exist for prison healthcare services, lines of accountability have become blurred. Pharmaceutical expertise to advise on safe systems and processes for all medicines used within prisons is required. Undertaking a pharmaceutical needs assessment for each prison would provide commissioners with the necessary information to identify areas of risk associated with the safe management and use of CDs prescribed for healthcare treatment and ensure robust CD governance arrangements are included within commissioning agreements.

The scoping project has identified that a small number of operational personnel within the prison sector may not have a good understanding of the legislation relating to the safe use and management of CDs. Clarification of the detail of legislation is required for some operational staff, as well as providing education and training to support wider understanding within the prison sector of the legislation and its requirements.

The identification within the prison healthcare service of a nominated CD governance lead could provide the necessary leadership for ensuring robust standard operating procedures (SOPs) are in place for each aspect of CD management in these settings. The CD governance lead could also provide a single point of contact between the prison healthcare service and the Primary Care Trust (PCT) CD Accountable Officer (CD AO) who has responsibility to

assure the safe management and use of CDs for all contracted and commissioned services within the PCT boundary.

Some of the issues identified through the project could be addressed by additional education and training to ensure responsible and accountable personnel understand the requirements of the legislation. The use of SOPs, regular staff training and staff induction programmes could be embedded more widely within prisons.

The role and responsibilities of the PCT CD AO must continue to be discharged effectively in accordance with legislation to provide the necessary scrutiny of the CD related activities undertaken within their organisation. CD AOs should continue to work collaboratively with professional regulators, CD Local Intelligence Network (LIN) members and the police to share appropriate information and to encourage the raising of concerns by practitioners.

The recommendations in this report aim to provide workable solutions to the problems identified without a requirement for legislation or amendments to regulations where this is possible. However, where necessary, areas where changes to the current legislation may be required are identified.

1.0 Introduction

1.1 Background to controlled drugs legislative framework

Controlled drugs (CDs) are subject to special legislative controls because there is a potential for them to be misused, diverted or cause harm. As a result of the detailed inquiry led by Lady Justice Smith following the murders committed by Harold Shipman, a series of legislative changes were introduced to strengthen the arrangements for the safe management and use of CDs in health and social care settings including healthcare within prisons.

The Health Act 2006¹ and associated Controlled Drugs (Supervision of Management and Use) Regulations 2006² (England) made provision for designated bodies (Primary Care Trusts (PCTs), NHS Trusts, Foundation Trusts and Independent Hospitals) to appoint a Controlled Drugs Accountable Officer (CD AO) to take organisational responsibility for assuring the safe use and management of CDs within their organisations. As a result of this legislation, PCT CD AOs have the responsibility to assure the CD governance arrangements within all commissioned services within the geographical boundaries of the PCT. As Prisons are not defined in legislation as a CD designated body and therefore do not require the appointment of a CD AO, the PCT CD AO has responsibility for assuring the CD governance arrangements within prison healthcare services.

PCT CD AOs require an assurance that processes such as review, audit and monitoring of CD related activities are being undertaken within their organisation and take appropriate action where cause for concern is identified relating to the activities of personnel within that setting. The Health Act regulations also require the PCT CD AO to establish a CD Local Intelligence Network (CD LIN) for the sharing of relevant information across a network of designated bodies, regulatory and statutory agencies for a defined geographical area. The information shared within the CD LIN should include any relevant details of activities causing concern within a prison.

The supply arrangements for medicines including CDs can vary between prisons and may require CDs to be requisitioned, or occasionally, privately prescribed and dispensed from an external pharmacy. The regulatory framework introduced following the government command paper in response to the Shipman Inquiry's Fourth Report³, sets out the arrangements for the requisitioning and private prescribing of CDs. The clinical settings in which these supply arrangements take place in some cases may be directly commissioned by an NHS organisation. In all cases all healthcare professionals have personal responsibility for their own safe management and use of CDs and will be accountable to their professional regulator for their professional activities.

1.2 Background to healthcare arrangements within prisons

As at 2nd September 2011 the total prison population was 86,710 with a total prison capacity of 88,554⁴. There are currently 133 prisons in England and Wales. The management of 11 of these are contracted to private sector partners and the remainder are run by the public sector through Her Majesty's Prison Service⁵. Data from 2008 shows that approximately 55% of the prison population are likely to be substance misusers⁶.

Privately managed prisons were introduced in England and Wales in the 1990s and now account for 8% of establishments in England and Wales⁵. The proportion of private sector prisons is growing as contracts for public sector prisons become available⁷. To maintain strategic links between the government and the private sector prisons, a 'Controller' is appointed from the private organisation whose role is to link to the Ministry of Justice.

In 2003, responsibility for funding prison health services transferred from the Home Office to the Department of Health. PCTs as the statutory commissioning organisation for a defined geographical area are responsible for ensuring adequate provision of healthcare services for the prison population within publicly funded prisons in their area. To commission healthcare services for prisoners effectively, PCT commissioners need to have an appreciation of the multiplicity of providers and potential contractual arrangements and models of pharmaceutical service provision. For example, healthcare services can be either directly commissioned by the PCT or in some circumstances a company operating a privately managed prison may contract for the healthcare service.

Health services provided within prisons require a pharmaceutical service to support the delivery of healthcare and the supply of medicines. The unique nature of the environment and the predominance of certain clinical services in some prisons such as substance misuse services and the internal transfer of medicines to defined wings or units makes the settings in which the pharmaceutical service is provided a hybrid between primary and secondary care provision.

In all prisons where prisoners are being supplied medicines for either management of long term conditions or for the treatment of acute clinical conditions the safe use of medicines is important. A high level of medicines management expertise is required to provide advice, guidance and recommendations to healthcare managers and clinicians relating to both clinical procedures and governance arrangements.

The requirements for the handling of CDs are set out in the Misuse of Drugs Regulations (2001)⁸, the Misuse of Drugs (as amended) Regulations 2006⁹ and the Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007¹⁰. All personnel within the prison must comply with both primary and secondary legislation and guidance. The detailed requirements governing medicines and CDs apply equally to all settings.

Prisons in which CDs may be prescribed for patients must have appropriate policies and standard operating procedures (SOPs) for all aspects of CD related activities. Although the pharmaceutical supply arrangements within the prison environment may be complex and may not map directly to either a primary care or a secondary care model, guidance to practitioners and managers is available within both [*A guide to good practice in the management of controlled drugs in primary care \(England\)*](#)¹¹ (December 2009) and [*Safer Management of Controlled Drugs; A guide to good practice in secondary care \(England\)*](#)¹² (October 2007).

Guidance describing the requirements for SOPs for CDs is also available from the Department of Health Website. [*Safer management of controlled drugs: Guidance on standard operating procedures for controlled drugs.*](#)¹³ Department of Health. (January 2007).

The Home Office recently consulted (5th August to 28th October 2011) on proposals to, update and review aspects of the Misuse of Drugs Regulations¹⁴. This included proposals relevant to discussions in Section 5 of this report. Subject to the outcome of that consultation, the Home Office expect final proposals to come into force within 2012.

2.0 Scope of the project

The project was established in spring 2010 to identify problems affecting prison pharmacy and healthcare services in England arising from the interpretation of the current legislation concerning the safe management and use of CDs within the prison setting.

The scope of this project was to identify the key areas requiring further clarification to support prison healthcare in complying with legislation for safe management and use of prescribed CDs and make recommendations where necessary.

Other offender health and secure environment settings such as young offenders' institutes, police custody suites and immigration removal centres are outside the scope of this project. However, the learning and recommendations gained from this project for the prison setting are likely to

be relevant and applicable to other closed establishments.

The aims of the scoping project were to:-

- Consider how the current legislation is interpreted and implemented within the prison health environment, as this is not specifically referenced in the Misuse of Drugs Regulations 2001⁸ (MDR), and identify areas requiring further clarification.
- Identify where further guidance may be required, through additional support to those that work in prisons.
- Provide cross-government recommendations where applicable for strengthening legislative arrangements where gaps are identified.

Fieldwork and interviews for this study were conducted in the spring and early summer of 2010. Therefore, this report captures and reflects the issues relevant at that time. Field work was completed prior to the recent Home Office consultation on the proposed update and review of the Misuse of Drugs Regulations 2001. This report could not therefore take account of those latest proposals.

In July 2010 the Government published a White Paper *Equity and Excellence: Liberating the NHS* and more recently in January 2011, the Health and Social Care Bill, proposing extensive legislative changes to the architecture of the NHS. Upon completion of the Parliamentary process for that Bill, the findings and recommendations set out in this document will need to be considered and assessed in the context of organisational changes in the NHS. The ways in which the use of CDs is monitored and audited will need to continue to be adequately addressed.

The recommendations in this report aim to provide workable solutions to the problems identified without a requirement for additional legislation or amendments to regulations. However, where necessary, changes to the current legislation to address the gaps that present a barrier to the safe management and use of CDs and effective patient care may be required.

3.0 Project methodology

The project was led by the National Prescribing Centre (NPC) on behalf of the Department of Health (DH). Parkwood Associates were commissioned to provide support to the NPC for the project.

To set the direction for the scoping project, provide advice on key issues identified and validate final recommendations, a steering group of national leads and sector specific advisors was established. The detailed operational

information used to inform this scoping document and formulate recommendations was collated through two focus groups and an additional thirteen telephone and face-to-face interviews. The participants for all discussion activities included front-line practitioners, senior advisers from national agencies and CD AOs responsible for the monitoring of all CD activity within the geographical boundaries of their organisation.

The steering group approved a common framework of discussion points to be explored for all focus group meetings and telephone interviews. The questioning framework included introductory questions to introduce a general discussion and give the participants an opportunity to reflect on experiences concerning the overall topic. These questions provided the opportunity to promote interaction between the participants. The key questions that formed the main focus of the review were framed according to the main subject areas of the MDR.

Data was collected from the focus groups and one to one interviews in the form of field notes which were transcribed electronically to create a formal record. The data collected was analysed by reading the field and electronic notes several times and identifying and categorising recurrent themes using a grounded theory approach.

The participants in the focus groups and interviews discussed potential solutions to address the issues raised. The solutions were developed into recommendations by the participants. The suggested recommendations were recorded, and where appropriate, included within the draft scoping report. Key stakeholder organisations from the steering group assessed the recommendations and either accepted, refined or dismissed the proposals based on agreed criteria of the recommendation being realistic, implementable, non-bureaucratic and likely to bring about strengthened systems. Proposed recommendations that met all the criteria except for the non-bureaucratic element as legislative changes would be required, were also included where it was considered that such changes would strengthen systems and provide additional safeguards against CDs being misused or diverted by health or social care professionals.

The information gained from the focus groups was triangulated through a stakeholder survey, using similar questions to those used within the focus groups. The survey was distributed through the NPC database to 1005 CD AOs within England and 220 CD AOs completed and returned the survey (response rate 22%). Further verification of the issues identified by the project participants was undertaken using representatives from professional regulators and the Secure Environment Pharmacists Group.

Membership of the project expert group and focus groups are shown in

Appendix 1

The issues identified through the project have been set out in this document in the following manner:

- Findings – these are the key issues that emerged from the project work. The experiences and observations of the focus group participants have been captured and collated within the themed sections.
- Conclusions - to address some of the issues raised from the findings of the project, conclusions have been drawn from the findings indicating specific actions that could be undertaken by identifiable parties such as CD AOs, primary care commissioners, policy makers and professional leadership organisations.
- Recommendations – a specific recommendation has been made where an issue has been identified by the participants in the scoping project and validated by the steering group. The recommendation requires either a national or Government response, such as, policy amendment, targeted action, additional guidance or amendment to regulations, or a necessary action for a defined professional group.

Field work was completed prior to the recent Home Office consultation on the update and review of the Misuse of Drugs legislation. This report could not therefore take account of those latest proposals and where recommendations have been made that align with the Home Office consultation these have been marked with an asterix (*)

The timespan for the development to the conclusion of this project overlapped the integration of NPC into the National Institute for Health and Clinical Excellence (NICE) that became effective from April 2011.

Intended audience:

This report should be read by:-

- National policy makers with responsibility for legislation relating to all aspects of CD use in a healthcare setting.
- Professional and healthcare service regulatory bodies
- Professional support organisations
- PCT CD AOs in England (and their support personnel) with responsibility for assuring the safe management and use of CDs within prisons
- Healthcare professionals working within prison health services

4.0 Pharmaceutical services delivery models within prison healthcare

Findings

Over recent years the range of pharmacy providers in prisons has diversified, as have the models of pharmaceutical service provision. Providers now include secondary care organisations, community pharmacies, independent healthcare providers and community trusts.

For the purposes of this document, the term *pharmaceutical service* refers to the professional expertise provided by an appropriately trained and competent pharmacist with expertise in dispensing, clinical pharmacy, medicines management and prison healthcare, and is not the same as that defined in the National Health Services (Pharmaceutical Services) Regulations 2005 as amended¹⁵.

The project group agreed that the requirements of a full pharmaceutical service to a prison include:

- The supply of medicines (dispensing service) **and**
- Medicines management advice from a pharmacist relating to the general use and management of medicines **and**
- Medicines management advice and recommendations from a pharmacist with specialist knowledge of the use of medicines within a prison healthcare environment. This last role may be supported by a registered pharmacy technician.

Various pharmaceutical service models support this provision; some examples are provided below:-_

- All three elements provided from an on-site internal prison pharmacy. The pharmacy may provide this service not only to the prison where it is located but also to other prisons under formal contractual arrangements.
- All three elements provided from an on-site pharmacy established as a 'satellite' of a prison pharmacy based within a large prison within the region. The pharmacist based within the main prison pharmacy will provide the expert prison related medicines management advice and recommendations.
- The supply of medicines from an off-site pharmacy (prison, community, acute hospital or community trust) as well as medicines management advice from a pharmacist relating to general use and management of

medicines, **and including** expert prison related medicines management advice secured through this commissioning agreement.

- The supply of medicines from an off-site pharmacy, for example community or acute hospital or community trust **including** medicines management advice from a pharmacist relating to general use and management of medicines **and** secured through a separate commissioning agreement expert prison related medicines management advice e.g. from a prison pharmacy/independent consultant pharmacist.
- A medicines supply only function – medicines are dispensed and delivered from a pharmacy, with pharmacist input relating solely to the safe supply of the medicines prescribed. Separate commissioning arrangements will need to be put in place for the provision of general and expert prison related medicines management advice to ensure all medicines are used safely and effectively within the prison healthcare environment.

Even within the service models outlined above there can be a range of providers and commissioning agreements for the pharmaceutical service. As a result of the potential complexities of the arrangements, there is a risk of a lack of clarity for the lines of accountability. The governance arrangements for CDs must be considered at the time of commissioning (and included within service specifications) with clear governance and lines of accountability embedded within the contractual arrangements. Although the PCT CD AO has overarching accountability to assure the safe management and use of CDs used within PCT commissioned or contracted services, it is essential that personnel working within the prison setting including senior prison personnel and healthcare providers understand their roles and responsibilities relating to CD governance. The importance of robust arrangements for prescribing, requisitioning, storing, administration, recording and disposal of CDs must remain a priority at all times.

Conclusion

As models for healthcare delivery within prisons have developed over recent years, commissioners will need to consider the most appropriate pharmaceutical supply arrangements to fit the healthcare services for the specific prison. The provision of each of the three elements of the pharmaceutical service may be provided from one provider or from several providers. Commissioners will wish to ensure that this is supported through contractual arrangements. Irrespective of the scope and scale of the pharmaceutical service commissioned, CD governance must be an intrinsic feature of the commissioning agreement.

5.0 Legal, regulatory and operational practice

5.1 Commissioning

Findings

PCTs are currently responsible for commissioning prison healthcare services, although changes to the NHS commissioning landscape as a result of the Health and Social Care Bill currently passing through Parliament, would change these arrangements.

There are a number of different commissioning arrangements for prison healthcare services across England. PCTs may commission these services through NHS-employed staff or from prison-employed staff or from private companies¹⁶.

Participants in the scoping project reported that they were aware of many PCTs that have recognised that managing medicines, especially CDs in prisons, is a high risk activity and have added this to their risk registers.

The following are examples where better commissioning could have improved patient care:

- Lack of accessibility to CDs that require safe storage by prisoners in segregation wings because some prisons do not have a CD cabinet on the segregation wing.
- Lack of accessibility to single dose treatments for prisoners to take out on transfer or to court hearings.
- Poor access to pharmacy services in the evening in some prisons. It is not uncommon for prisoners to arrive after daytime healthcare and pharmacy services within the prison have ended.

Participants in the project reported that pharmacist leadership and expertise along with multidisciplinary collaboration within a prison is an essential element for the safe and effective management of medicines including CDs. Participants reported that in areas where PCT pharmaceutical advisers supported specific prisons in managing medicines, there were indications that CD governance improved.

The consensus view of the participants was that commissioning agreements do not always specify requirements for pharmaceutical expertise and input. Outcome 16 of the *Essential standards of quality and safety*¹⁷ which are

central to the work of CQC in regulating health and adult social care refers to a service having regard to appropriate professional and expert advice. This standard is structured to support registered persons and services to comply with the regulated activities.

As part of the prison inspection process, CQC now supports Her Majesty's Inspectorate of Prisons (HMIP) looking at the health outcomes for prisoners. A previous remit for CQC was to work with HMIP to assess how PCTs commission healthcare for prisoners. A joint report from HMIP and CQC on PCTs' commissioning arrangements in 2008/2009 summarised the findings from a sample of 21 PCTs that commission prison healthcare¹⁸. The document reports that improvement had been made in some areas but significant progress had not been made in services provided for drug misusers.

In addition, the practice of secondary dispensing^a was reported in the HMIP Annual report 2008-09¹⁶ as being a high risk activity and should be avoided. Secondary dispensing is most likely to occur in prisons that do not have a pharmacist on-site and healthcare staff transfer medicines from the container that has been dispensed for a named patient to an alternative container for an individual patient supply. Such a container is unlikely to be labeled with the name of medicine and appropriate dose, warning or storage instructions. The requirements for labeling of medicines are set out in the Medicines Act 1968¹⁹ and transfer of medicines between containers for an individual supply should not be undertaken without the supervision of a pharmacist.

Conclusion

Contract details and service level agreements (SLAs) relating to prison pharmacy services should include specific references about the need for robust CD governance and for the provider to assure the commissioner that this has been implemented.

The commissioning organisation is responsible for defining the standards of governance for medicines management. These standards should be contained within the contractual framework or SLA with the prison healthcare provider. The provider should ensure that appropriate professional expertise from a pharmacist is secured, as recommended in the 2003 report *A Pharmacy Service for Prisoners*²⁰.

This document provides a suitable performance management framework for

^a Secondary dispensing is the action of transferring medicine that has been dispensed for a named patient into a separate, non-labelled container for either the same or a different patient.

the commissioning of prison pharmacy services that includes the safe management and use of CDs. The document also recommends that for a prisoner to benefit from primary care focused, patient centred services, as in the community, it is necessary for pharmacy staff to be both accessible to the prisoner and have access to the prisoner.

Commissioners of prison pharmacy services should undertake a pharmaceutical needs assessment to identify what is needed at a local level to support the commissioning intentions for pharmaceutical and other services that could be delivered by pharmacy. In particular, the needs assessment should consider activities that are likely to be undertaken that could pose a risk to patient care from inappropriate use of a medicine.

A robust pharmaceutical needs assessment would inform resource planning and service development in line with national recommendations. In particular, a prison pharmacy service should not be limited to the supply of medication; pharmacists should also meet and advise patients²¹. Such contacts have been shown to improve compliance and are recommended in national guidance^{20,21}

Consideration should be given to the specific patient profile within the prison and the classification of the prison itself. It may be necessary to commission services to manage the treatment requirements for new prisoners arriving throughout the day and night.

Recommendation 1

The Department of Health Chief Pharmacist should write to PCT Directors of Commissioning and Chief Executive Officers (CEOs) to reinforce the recommendations that pharmaceutical expertise is integral to the effective commissioning of pharmacy services for prisons. The requirements for a service to have regard to appropriate professional and expert advice are set out in Outcome 16 of the *Essential standards of quality and safety*¹⁷, which are central to the work of CQC in regulating health and adult social care.

The 2003 publication *A Pharmacy Service for Prisoners* can help to provide a framework for pharmaceutical provision for commissioners to consider.

The letter should refer to outcome 16¹⁷ and the findings from the joint HMIP/CQC report 2008-2009¹⁸ and emphasise the importance of pharmaceutical expertise to ensure robust CD governance within the prison

5.2 Governance, accountability, monitoring and inspection

5.2.1 CD governance arrangements

Findings

Prisons, public or private, are not defined in the Controlled Drugs (Supervision and Management of Use) Regulations 2006² as a CD Designated Body and so are not required to appoint an individual to be the CD AO. However, as with all healthcare providers, senior prison and healthcare managers have a responsibility to ensure robust arrangements are in place for CD management as part of organisational clinical governance requirements¹⁶. The PCT CD AO is responsible for assuring that prisons within the PCT geographical area have suitable arrangements in place for the safe management and use of CDs. The details of implementation of governance arrangements in practice are for local determination within the prison, but all aspects of CD use and management must be compliant with MDR⁸ and processes for monitoring such activities must fulfil the requirements of the Controlled Drugs (Supervision and Management of Use) Regulations 2006².

Participants in this project indicated that in some PCT areas senior prison healthcare staff did not appear to be actively engaged with the PCT CD AO and as a result information flows between the prison healthcare management and the CD AO was limited. Participants considered the limited engagement to be due to limited mutual understanding regarding the responsibilities of the PCT CD AO with respect to CD governance in the prison. Participants also reported examples where there appeared to be a lack of awareness amongst operational staff of the need to maintain CD standard operating procedures and for such procedures to be audited.

A number of prison healthcare staff who informed the scoping project reported feeling professionally isolated from either primary care or secondary care professional peers and therefore would often seek advice regarding areas of practice from informal networks and colleagues working in the same sector. However, it was acknowledged by participants that there is a risk that this approach may not be sufficiently robust to ensure the highest standards of practice.

In areas where the PCT CD AO had good communication links and a collaborative approach to supporting robust governance arrangements within the prison, a strategic shared partnership board (or equivalent) had been established. Membership of the board included representation from senior prison healthcare and security managers, medicines management committee as well as the PCT CD AO and external agencies. Prison governors who participated in the scoping project reported that these forums were beneficial

in raising and addressing CD governance issues.

The CQC report 'Commissioning healthcare in prisons'¹⁸ published in 2009 reported that governance systems appear to be well established, within the sampled PCTs (sample of 21 PCTs) holding regular strategic shared partnership boards between the prison and the PCT.

Conclusion

The establishment of a strategic partnership board (or equivalent) can provide an appropriate formal multidisciplinary group to oversee the governance arrangements and medicines policies for CDs with the prison.

Senior healthcare and pharmacy managers should encourage the use of established professional support networks by prison healthcare staff, so that group discussion and advice can be supported by experienced and appropriately qualified healthcare professionals. Examples of these are the Secure Environment Pharmacists Group (hosted by the Royal Pharmaceutical Society) and the Royal College of General Practitioners (RCGP) Secure Environment Group.

Prison healthcare services should be encouraged to nominate a CD governance lead from within the healthcare team to take responsibility for specific aspects of the safe management and use of CDs within the prison. This leadership role would provide a point of contact for the PCT CD AO as well as ensuring SOPs and governance arrangements are established, maintained and audited appropriately.

5.2.2 Accountability

Findings

Within each prison a senior governor, has overall accountability including healthcare within the prison. The responsibility for system wide CD management is an intrinsic aspect of the roles and functions of the Senior Management Team who delegate operational tasks to key managers. For example, the Security Governor may be responsible for assuring the safe transportation of CDs around the prison. In most prisons a named senior manager will be assigned the responsibility for daily CD management and this is usually the healthcare service lead. Tasks should include ensuring all personnel working with or coming into contact with prescribed CDs adhere to safe operating procedures. This involves regular review and monitoring of

procedures and appropriate dialogue and a feedback mechanism to the PCT CD AO.

The responsibility to assure that CD arrangements are robust and all concerns are fully reported remains with the PCT CD AO.

The following areas of concern relating to governance arrangements within prisons and the accountability for CDs, were provided as examples by participants in this project:-

- Operational staff sometimes lack understanding of their personal accountability and the role of the lead person for CD management.
- Whilst prison governors carry onerous responsibilities, there is a need to highlight to some governors their key role in relation to CDs and medicines management.
- SOPs may not always be in place or complete. Examples provided by participants included the arrangements for transporting stock CDs following a delivery left at the prison gate, and arrangements for safe disposal and destruction of patients own CDs.
- Trends and themes from CD incidents may not always be identified and lessons not routinely shared or learned because key staff have not been trained to undertake incident investigation and root cause analysis.

Conclusion

The establishment and continued audit of robust operational procedures are essential to ensure all CD related activities are undertaken in a manner that minimise risks of diversion and compromise to patient or public safety. Accountabilities and responsibilities for CDs should be included with the prison medicines management policy, supported by SOPs where appropriate. Where not yet undertaken, key staff should be trained to undertake incident investigation and root cause analysis. Systems should be developed to implement findings from these actions.

Lines of accountability need to be clear and accessible. Prison personnel in senior positions must be aware of the nature of the risks associated with CDs and recognise the responsibilities each member of the team holds within the system. The potential benefits of having a nominated CD governance lead

should be explored to ensure robust arrangements are embedded within services and activities.

5.2.3 Monitoring

Findings

Monitoring of CD related activities should be routine for both the lead manager within the prison with responsibility for daily CD governance arrangements, and the PCT CD AO with responsibility for assuring the safe management and use of CDs throughout the prison estate.

Regular stock checks, weekly audits, running balances and end of shift checks are just some of the monitoring procedures that should be undertaken routinely within the prison, the treatment areas and the pharmacy. Participants in the scoping project reported that such checks, recording and audits did not appear to be embedded in operational practice in some establishments.

CD AOs may need to ask for evidence that arrangements are being monitored across a range of service providers for any one prison. Each provider using or handling CDs must have established robust SOPs for their CD arrangements. The complex commissioning arrangements can make monitoring of activities challenging for CD AOs. This can be managed through effective process mapping and identification of lines of accountability. The '*Handbook for Controlled Drugs Accountable Officers*' published by NPC in 2011²² provides details of the monitoring requirements as well as a set of aide-memoir checklists for recording actions taken by the CD AO.

The majority of governance, accountability and monitoring issues identified through the scoping project have the potential to be addressed through the PCT CD AO being assured that adequate education and training is provided to the relevant personnel within the prison.

Recommendation 2

PCT CD AOs should be reminded to discharge their duties in accordance with the Controlled Drugs (Supervision and Management of Use) Regulations 2006 through effective process mapping, and be aware of all public and private prisons using and handling CDs within the PCT geographical area.

- CD AOs should establish systems and processes that will enable all prisons to provide assurance to the AOs that they are compliant with legislative requirements for the safe management and use of controlled drugs.

- CD AOs must assure that prison healthcare and pharmacy service providers have robust CD policies and standard operating procedures in place.
- CD AOs must assure that appropriate training is being provided to prison and healthcare personnel for the safe use and management of CDs.

5.2.4 Inspection

Findings

All prisons are inspected by Her Majesty's Inspectorate of Prisons (HMIP) and both public sector and private prisons must comply with the same set of standards for all aspects of prisoner care. The document '*Expectations*'²³ sets out the detailed criteria HMIP uses to appraise and inspect prisons.

The following criteria are used to examine every area of prison life, from reception to resettlement, including:-

- Safe custody
- Health services
- Good order
- Work
- Diversity
- Resettlement.

Healthcare services are included within the inspection process, and this includes inspection of pharmacy services within the prison. This aspect is supported by the General Pharmaceutical Council (GPhC) through a memorandum of understanding (MOU) between the two bodies. GPhC provide assistance with prison inspections with regard to the handling of medicines, as detailed in the MoU, but this is not part of the GPhC's statutory regulatory function.

The GPhC would normally provide a report to the HMIP inspector, information from which would then be included for publication within the prison inspection report.

A separate CD report is routinely completed when the GPhC inspect a prison pharmacy, but it does not directly form part of the prison report. This is normally shared with the HMIP inspector, the CD section shared with the PCT CD AO and a copy may be sent to the prison. It would not normally be copied to the pharmacy provider as it may not have any relevance to their role. However, if the provider had an active medicines management role within the prison then they should access a copy of the report from the prison governance lead.

Conclusion

There was a view by participants in this project that observations made by the pharmacy inspectors at the time of the inspection provide useful informal feedback on relevant issues to pharmacy and healthcare personnel who may be present at the time of inspection. The report could usefully be reviewed by the strategic partnership board (or equivalent) – see section 5.2.1. Pharmacy providers and prison healthcare staff are not always aware that they can check and clarify any issues highlighted in the draft inspection report prior to final publication.

5.3 Legislation

Findings

The legal framework permitting individuals and organisations to possess, supply and administer CDs is complex and cuts across a number of different pieces of legislation and government departments. The key legislative frameworks are:-

- Medicines Act 1968¹⁹ [Medicines Healthcare Products Regulatory Authority responsibility]
- Misuse of Drugs Act (MDA) 1971²⁴ [Home Office responsibility]
- Misuse of Drugs Regulations (MDR) 2001⁸ [Home Office responsibility]
- Controlled Drugs (Supervision of Management and Use) Regulations (CDR) 2006² [Department of Health responsibility]

Further detail of the legislative frameworks may be found through the external links on the NPC website http://www.npc.nhs.uk/controlled_drugs/

Many prisons have developed medicines policies and procedures to navigate their way through the complexities of the MDR in order to ensure that practice is compliant with the law. The development of policies and SOPs underpinned by risk assessment facilitates the safe management and use of CDs. Each

prison healthcare department should have an overarching CD policy and SOPs for each aspect of CD management. All staff should know the practice they should be following and where to find policies and procedures.

The consensus view from participants in this project was that because prisons are not specifically mentioned in the MDR⁸ variation in interpretation has led to variation in practice. Prison staff endeavour to comply with legislation but would welcome environment-specific guidance on the safe management and use of CDs.

Conclusion

Knowledge gaps of personnel working with CDs relating to legislation have the potential to undermine safe working practices and should be assessed and addressed through education and training by the service provider. The PCT CD AO may be consulted on the development of such training to ensure key areas of risk are included.

5.3.1 Specific problems relating to requisitions

Findings

Prisons need to keep stock supplies of CDs necessary for the treatment of prisoners in their custody. For prisons with on-site pharmacies, the pharmacist is responsible for ordering pharmacy CD stocks from a pharmaceutical wholesaler in the same manner as hospital or community pharmacies. The wings / treatment areas will then order from the pharmacy using a hospital style requisition book or equivalent. This arrangement mirrors the same procedures established in secondary care hospitals.

The Government's response to the Shipman Inquiry Fourth Report made changes to the MDR⁹ supported by amendments to introduce standard forms (FP10CDF) for requisitioning stocks of CDs in primary care, or requisitions from prisons directly to a community pharmacy¹⁰. The requisition form must be signed by a doctor who is employed or engaged by the prison²⁵. The DH has issued guidance on the use of the requisition form for CDs to accompany legislative changes introduced in 2006 and 2007²⁶. The use of the FP10CDF is not mandatory although all the information contained within a legal requisition must be the same and must comply with the requirements set out in regulation 14 of the MDR⁸.

Regulation 14(5A)(b) of the MDR⁹ currently requires community pharmacies

(but not wholesalers) supplying CDs on requisition to send the original CD requisition on forms FP10CDF (other than veterinary requisitions) to the NHS Business Services Authority Prescription Services (NHSBSA Prescription Services). The original policy intent regarding the use of FP10CDF was to strengthen the audit trail for the private supply of controlled drugs and this is critical to compiling a complete picture of the supply of CDs in the community²⁶.

Participants in this project reported examples of confusion within some prisons as to who was eligible to be an authorised signatory for a requisition of CDs from external suppliers. This apparent lack of understanding of the regulations has in some circumstances resulted in an unauthorised member of the healthcare team signing the requisition. It is unlawful for a supplier of a CD to supply to someone who cannot lawfully possess the medicine. In this situation the pharmacist would be in breach of regulations and could face professional discipline and potentially criminal charges.

Conclusion

Prison CD policies and SOPs should clearly state who is authorised to order CDs to ensure compliance with regulations. Knowledge gaps should be addressed through training and awareness raising within the prison and should also include community pharmacies.

5.3.2 Specific problems relating to controlled drug registers

Findings

Under Regulation 20(d) of the MDR⁸, organisations must keep a separate compliant CD register of receipts and supplies of Schedule 2 CDs at each location where they carry out business. Legally, there must only be one CD register for each class of drugs, unless, in exceptional circumstances, prior permission has been obtained from the Secretary of State. In prisons where there is an on-site pharmacy the single compliant register may be kept and maintained in the pharmacy. In prisons that provide the integrated drug treatment system (IDTS) it may be more pragmatic to keep the compliant CD register for specific treatments such as methadone and buprenorphine in the drug treatment centre/wing to avoid the additional risks of transfer of stocks within the prison. Robust audit controls of all stock transfers must be maintained, irrespective of where the register is held.

The IDTS provides a standardised framework for the provision of a full range of evidence based clinical interventions, including stabilisation, detoxification and maintenance, to be available to prisoners in England.

The practical arrangements for managing one single compliant register could be compromised in prisons where there are dual storage sites because large quantities of CDs are dispensed as part of the IDTS. Participants in the scoping project reported a perceived lack of awareness of the requirement for a single compliant CD register.

Participants also reported that in prisons where governance arrangements for CDs are robust and well established, the prison wings or treatment areas will be supplied by the on-site pharmacy upon receipt of an order signed and countersigned by two senior members of staff (usually a nurse and a senior nurse or doctor).

Conclusion

Where dual storage sites exist within the prison estate care should be taken to ensure separate CD registers are not maintained. Specific register arrangements may be necessary depending on the pharmaceutical supply arrangements for the individual establishment, but advice should be sought from the Home Office in these circumstances.

Robust governance arrangements for maintenance of a single compliant register and processes for signed orders for transfer of CDs from pharmacy to units or wings should be detailed in the SOP. Prison wings/units should use the signed order forms contained in the (hospital type) CD Order Books (or equivalent) wherever possible to ensure recording of stock transfers and audit trails are maintained.

5. 4 Operational issues in the prison healthcare setting

5.4.1 Possession of controlled drugs

Findings

Under the Misuse of Drugs Act 1971²⁴, possession means having physical custody or control of a substance with knowledge of its nature and quality. The MDR⁸ allow for only two professional groups to have the authority to be in possession of CDs, doctors and pharmacists. Therefore, when requisitioning CDs, from an external pharmacy supplier, for use in the prison, the requisition form can only be signed by either a doctor or pharmacist. Once CDs have been received into the prison, the senior pharmacist or doctor would be in possession of those medicines and have overall responsibility for their safe use and management.

Participants in the scoping project reported an apparent lack of understanding regarding the definition of possession and individual professional responsibilities within some prisons. In particular, in some prisons there appears to be some confusion regarding the legally acceptable signatories for a requisition. Pharmacy suppliers are unable to accept requisitions signed by healthcare professionals other than pharmacists or doctors and have to return the requisition back to the prison for the correct signature. This can delay delivery of the medicines.

Conclusion

Misunderstandings of legislation should be addressed through accessible education and training of both pre and post registration healthcare professionals.

In addition, specific legal requirements for the requisition process should be detailed in the relevant SOP. All SOPs should be regularly reviewed by a suitably experienced healthcare professional, ideally the nominated CD governance lead for the prison healthcare service, to ensure they remain relevant. Understanding and adherence to SOPs which define local practice should be integral to all training programmes including induction and annual update training.

5.4.2 Transportation and stock control of controlled drugs

Findings

Safe custody at all times is a legal requirement for CDs, the level of which depends on which schedule within the MDR they are classified. Health care professionals handling CDs have a professional duty of care to take all reasonable steps to maintain safe custody of that CD.

Transportation of CDs between different areas in the prison and from off-site suppliers to the prison was identified in the scoping project as an area of risk of diversion. Participants in this project outlined a number of risk reduction strategies that had been implemented in prisons in their area.

Guidance for the transfer of CDs within secondary care environments is available within the [*Safer Management of Controlled Drugs; A guide to good practice in secondary care*](#)¹² (England) October 2007. The principles of this guidance for maintaining an audit trail of CDs are applicable to the prison environment.

Conclusion

The following approaches could be more widely implemented:-

- Close liaison with prison security staff to provide escorts during transportation.
- Multidisciplinary training for prison healthcare and security staff.
- Development of robust SOPs to include ordering, receipt and transportation issues, in collaboration with prison security managers.

5.4.3 Storage of controlled drugs

Findings

The Misuse of Drugs, Safe Custody Regulations 1973 (SI 1973 No 798)²⁷ detail the cabinet or cupboard, the room in which the cabinet is situated and the doors/windows and treatment hatches where the CDs are stored within a community pharmacy or care homes. These regulations do not specify the requirements for prisons and therefore healthcare and pharmacy managers must interpret the regulations and use them as a set of minimum requirements alongside the prison service security requirements to establish safe storage arrangements.

The minimum requirements may not be sufficient for areas where large amounts of medicines are in stock at a given time and/or where there is not a 24-hour staff presence. In this case, a security cabinet evaluated against the *sold secure* standard SS304 is used [www.soldsecure.com]. Prison building regulations specify the details of the robust nature required for all rooms which store CDs. The details for safe storage are contained in the Ministry of Justice (2010) PSI 45/2010 Prison Service Order for IDTS document²⁸.

The HMIP Annual report 2008-09¹⁶ highlighted that there are some deficiencies in the storage of CDs and this was reiterated by the participants of the scoping project, where it was evident that some staff have a lack of understanding of the legal and good practice requirements. Participants considered that if legal and good practice requirements were followed staff would be more vigilant in securing CDs appropriately and in a timely manner.

The participants also reported their awareness of healthcare units operating the IDTS, using automated dispensing machines that found compliance with the storage requirement particularly challenging. Many establishments have addressed this by detailing appropriate practice in robust SOPs to ensure risks are considered and managed.

Guidance for safe storage of CDs within secondary care environments is available within the [Safer Management of Controlled Drugs; A guide to good practice in secondary care](#)¹² (England) October 2007. The principles of this guidance are applicable to the prison environment.

Conclusion

The following approaches could be more widely implemented to ensure safe storage requirements are met:

- Multidisciplinary training for both prison healthcare and security staff to highlight the importance of adherence to both the legal requirements for storage and the details contained within the Prison Service Order.
- Development of robust local SOPs for managing the storage of CDs, including access and key handling within the prison estate, in collaboration with prison security managers. All SOPs should be regularly reviewed by a suitably experienced pharmacist or CD governance lead to ensure they remain relevant. Understanding and adherence to SOPs should be integral to all training programmes including induction and annual update training.

5.4.4 Prescribing governance

Findings

NHS Connecting for Health (CfH) has led the implementation of the Prison Health IT programme

www.connectingforhealth.nhs.uk/systemsandservices/prisonhealth

Many prisons still maintain a dual system of part electronic records with duplicate or additional recording on paper-based prescriptions. Prescribers within prisons generally do not use NHS prescription pads (FP10CD) but prescribe on prescription charts issued through the prison service similar to those used within a secondary care hospital setting.

The HMIP Annual Report 2008-09¹⁶ highlighted that electronic prescribing is not always used. In some instances participants in the scoping project reported having identified potential risks if several different prescribing methods were in use. The CQC report: *Commissioning health care in prisons 2008/09*¹⁸ highlighted that improving electronic information management systems is a priority for PCT commissioners.

Examples of problems arising from the lack of a fully established electronic prescribing system provided by the project participants include:-

- There is a potential loophole if supplies of medicines which prisoners allege they have lost are reissued without detailed investigation or audit trails.
- When prisoners are released from prison they may be issued with a prescription that can be dispensed by a community pharmacy. This may require transcribing information from an electronic prescribing system to a paper prescription and could result in transcription errors.

Conclusion

The lack of an integrated electronic prescribing system is an inherent risk to both public and patient safety as it does not permit robust collation of prescribing data for the purpose of clinical audit and reflective practice. This is now the object of a specific project within the CfH prison health IT programme

The CfH work programme to implement a comprehensive and universal electronic system within all prisons in England should be supported in accordance with the programme timescales.

5.4.5. Prescribing of substitution treatment for the management of drug dependence

Findings

Initiation of substitution treatment should always be undertaken by a medical prescriber experienced in initiation and stabilisation of substance misuse medicine in line with the clinical guidelines 'Clinical Management of Drug Dependence in the Adult Prison Setting'²⁹. Supplementary non-medical prescribers, working in accordance with an agreed clinical management plan, can prescribe for continuation of treatment provided they are working within their competency.³⁰

Although recommendations regarding medication review are included in clinical guidance²⁹ and other good practice guidance,³¹ reports from participants indicate that medication reviews for patients prescribed CDs are not always provided in a timely and effective manner.

The recently published 'Safer Prescribing in Prisons Guidance for clinicians'³², Published by the RCGP Secure Environments Group (November 2011), provides a guide to safe prescribing practices for all clinicians working within a prison healthcare environment.

Conclusion

Senior prison clinicians should review the treatment pathways currently provided within the prison healthcare service to ensure all relevant guidance is being adopted and there is appropriate use of the professional skills and qualifications of all members of the healthcare team. As all NMPs have a duty to prescribe in accordance with their clinical competency, appropriate changes should be made to service delivery if the prescriber is undertaking duties that could compromise patient care.

It is the duty of service commissioners to performance manage the commissioned services and where areas of clinical practice are not in accordance with national guidance this should be addressed through the service review process.

5.4.6. Supply and administration of controlled drugs

Findings

Due to the nature of the environment CDs are very rarely issued to prisoners for self-medication for the treatment of substance misuse. The Prison Service Order (PSO) for clinical services for substance misuser's states that administration and consumption of controlled drugs and other medicines subject to misuse within prison must be directly observed³³. This should ensure that the prescribed dose has actually been taken by the prisoner and cannot be concealed for the purpose of diversion. Schedule 2 and 3 CDs therefore are not permitted in-possession (see Section 5.4.7) without completion of a risk assessment.

Legislation allows doctors, dentists or supplementary non-medical prescribers acting in accordance with a clinical management plan and any person acting in accordance with the directions of a doctor, dentist or supplementary prescriber to administer any drug specified in Schedule 2, 3 or 4 of the MDR to a patient.

As the administration of medicines for the treatment or maintenance of substance misuse in prisons will be directly observed, most doses are

administered from stock supplies held within the prison. It is important therefore that provision is made for the pharmacist to assess the clinical appropriateness of **all** of the related prescriptions. In prisons that have an established IDTS in operation there will be two prescription records, one electronic as part of the IDTS and a second written prescription chart. Pharmacists must take extra care to access both records when assessing the clinical appropriateness of medication.

Examples of problems that were reported by the project participants include:

- Some operational prison staff included in the scoping project were uncertain of the application of legislation relating to the supply and administration of CDs in the prison setting and the difference between the two processes. In addition, there was some uncertainty as to which staff members may administer CDs and in particular whether pharmacy technicians could administer CDs to prisoners.
- In the prison setting it is usual practice for one member of staff to administer the CD with another person witnessing the activity. Both staff members would then sign the administration record. Some operational staff participating in the project appeared to have a lack of understanding of the role and responsibilities of the second signatory in the administration process and the competencies required for an appropriate person to undertake the task of witness.
- Ensuring suitable arrangements are in place administering the last dose for the day of a controlled drug can be problematic when the medicine round is undertaken at night with limited staff resource, prisoners are locked in cells and healthcare staff must conduct the medicines round on the wing. Such a situation leads to difficulty in appropriate direct observation of supervised doses. Care should be appropriate and ensure that the prison regime supports the timing of the administration round. The scoping project highlighted that in some establishments this is not always the case.

A number of specific issues were reported by participants in the scoping project relating to administration within an IDTS unit:-

- Due to the large number of prisoners receiving treatment each day, correct prisoner identification is a challenge for staff administering CDs. Many establishments specify that prisoners should be identified using photographic identification as a minimum.

- The large number of single dose administrations undertaken in prisons with significant IDTS provision can increase the risk of errors occurring, particularly if staffing levels are under resourced at treatment times.
- Security of electronic IDTS administration data has been compromised on occasion, for example, destruction by fire, which poses a governance risk and may be a safety issue if prisoners' most up to date treatment details cannot be accessed.
- It is common practice for administration of liquid medicines, such as methadone, to be via an automated or computerised pump dispensing system that verifies the identity of a patient by way of a biometric scanning device. This significantly reduces the risk of errors in both the dispensing and administration of the medicine. Some prisons frequently encounter difficulties in recruiting sufficiently experienced and competent staff to operate these systems to ensure that patient care is not compromised. The project participants acknowledged that this issue could be addressed through structured induction training programmes.

Conclusion

Participants in the scoping project concluded that the implementation of a number of actions could improve the arrangements for supply and administration by prisons providing IDTS:-

- Healthcare managers with a responsibility for the IDTS should ensure that effective operational preparation and planning is embedded within the service. The use of process mapping and risk assessment tools to identify areas of weakness should be used to develop SOPs in collaboration with senior healthcare and security managers. Operational SOPs should be reviewed by a suitably experienced pharmacist to ensure the process detailed is in accordance with CD legislation and clinical practice guidance. SOPs should be routinely audited and reviewed and adjustments made where justified.
- Senior prison healthcare managers should ensure equipment training programmes are made available to personnel. Managers must ensure training is accessed both on induction and as routine update where appropriate. In circumstances where training modules or resources are knowingly incomplete or inadequate, managers should escalate this to a higher authority and commissioners should be made aware of any limitations in quality of the service being provided. These can be addressed as part of the commissioned service review.

5.4.7 Supply of CDs for 'in-possession'

Findings

On occasions, the risk assessment of individual situations may enable a patient to possess his/her own supply of prescribed CDs, for example for treatment of severe pain as part of palliative care. The CD is then supplied to an individual named prisoner with provision for a single day's doses. This is known within the prison healthcare service as being 'in possession'.

A *Pharmacy Service for Prisoners*²⁰ recommends that in-possession medication should be the routine where possible for the treatment of some specific clinical conditions and that risk assessment should identify if in-possession is not appropriate. The NPC good practice guidance covering in-possession risk assessment published in 2005 is available from NPC.³⁴

Conclusion

No specific issues were raised during the scoping project by the participants. The group concluded that, in their experience, in-possession assessments, supply and governance work well.

5.4.8 Destruction of controlled drugs

Findings

The MDR⁸ and Controlled Drugs (Supervision of Management and Use) Regulations 2006² set out the requirements for authorised witnesses for destruction of obsolete, expired and unwanted stocks of schedule 2 controlled drugs. The 2006 regulations defining the roles and responsibilities for the CD AO include the responsibility of the CD AO to authorise suitable person(s) to witness destructions of relevant CDs. This applies equally to destructions undertaken within the prison and a suitable person will be authorised to carry out this task on behalf of the CD AO.

Stock CDs for destruction should not be returned to the pharmacy from the wing or treatment area but should be separated out, identified for destruction and placed in the CD storage cupboard [on the wing]. This is particularly relevant where the pharmacy belongs to a separate organisation to the prison healthcare service, even though in some prisons they may be located within the same building.

The prison pharmacy is only allowed to denature/destroy a patient's own supply of a CD medication. It is good practice that a CD destruction record book or equivalent is used and a second person acts as witness to the destruction.

Participants in the scoping project reported that operational staff may be unclear of the difference between the requirements for destruction of patient's own medication and that of unused or expired stock CDs. The group also reported examples of confusion whether expired CD stocks should be destroyed on the wings or returned to the pharmacy for destruction. Further examples were reported of nurses and other prison staff who were not aware of the appropriate process for destruction of patients' own CDs when new prisoners are admitted.

Conclusion

Procedures for CD destruction must be outlined in a detailed SOP, developed in collaboration with appropriate prison staff. The SOP should be embedded within practice and routinely monitored and audited for compliance. CD denaturing processes must also comply with the Environmental Permitting Regulations (England and Wales) 2007³⁵.

5.5 Education and training

Findings

Many of the issues highlighted in this document relate to a lack of understanding amongst some prison healthcare and security operational staff of both CD legislation and safe and effective practice. Insufficient knowledge of legislative and good practice amongst health professionals potentially may lead to errors or poor governance in the care and safe use of CDs, which in turn may compromise public safety through an increased risk of medication errors, diversion and misuse of CDs.

In April 2004, at the request of the DH, the Centre for Pharmacy Postgraduate Education (CPPE) carried out a learning needs analysis of the prison pharmacy workforce. Subsequently, from March 2005, prison pharmacy teams were able to access CPPE learning programmes. CPPE were commissioned to deliver risk management learning events for prison pharmacists and pharmacy technicians in November 2005. In 2009 CPPE launched the *learning @lunch* and *focal point* programmes, which are accessible to prison pharmacy teams. These programmes cover a range of clinical and pharmacy practice topics and whilst many are relevant they are not specific to the prison setting.

This project found continuing disparity at local level around training provision and resource. The project participants reported examples of insufficient training, both pre- and post-registration, covering the safe management and use of CDs.

Participants also highlighted the following specific training gaps:-

- Particular patient groups and the care and use of CDs, especially access to training in end of life care, palliative care and the use of syringe drivers for the administration of medicines. This can be a particular problem in establishments that have a relatively static, ageing population and may lead to poor care of vulnerable patients.
- Access to training for the administration of naloxone in opioid overdose for all staff, clinical and non-clinical can be challenging. The National Treatment Agency (NTA) provide training and project participants suggested that this should be a mandatory requirement for all prison healthcare staff and desirable training for prison security personnel.
- Limited availability of resources specific to secure environments. In particular, access to resources for prisons that provide support and guidance in dealing with illicit substances in secure environments was identified.

Conclusion

Training needs assessments should be used to assess the skill and competency requirements of personnel using and handling CDs. The outcome of such an assessment will indicate the scope and nature of the training and developments needs of prison personnel involved in working with CDs

One of the responsibilities of the PCT CD AO is to be assured that relevant individuals receive appropriate training². It is important that relevant guidance documents for the safe management and use of CDs are disseminated to operational staff working in the prison setting. The NPC have educational resources and support tools to facilitate the work of CD AOs in carrying out this responsibility (http://www.npc.nhs.uk/controlled_drugs/).

Recommendation 3

Senior prison healthcare managers should provide appropriate training for handling medicines for healthcare, pharmacy and prison personnel and should ensure that clinical and operational guidance published by professional bodies is included in SOPs and made available to relevant personnel. Training and development plans within the prison healthcare service should make reference to published guidance.

PCT CD AOs must assure adequate training is provided for any personnel using or handling CDs within the prison estate.

6.0 Summary of recommendations

	Recommendations
1	<p>The Department of Health Chief Pharmacist should write to PCT Directors of Commissioning and Chief Executive Officers (CEOs) to reinforce the recommendations that pharmaceutical expertise is integral to the effective commissioning of pharmacy services for prisons. The requirements for a service to have regard to appropriate professional and expert advice are set out in Outcome 16 of the <i>Essential standards of quality and safety</i>¹⁷, which are central to the work of CQC in regulating health and adult social care.</p> <p>The 2003 publication <i>A Pharmacy Service for Prisoners</i> can help to provide a framework for pharmaceutical provision for commissioners to consider.</p> <p>The letter should refer to outcome 16¹⁷ and the findings from the joint HMIP/CQC report 2008-2009¹⁸ and emphasise the importance of pharmaceutical expertise to ensure robust CD governance within the prison</p>
2	<p>PCT CD AOs should be reminded to discharge their duties in accordance with the Controlled Drugs (Supervision and Management of Use) Regulations 2006, through effective process mapping and be aware of all public and private prisons using and handling CDs within the PCT geographical area.</p> <ul style="list-style-type: none"> • CD AOs should establish systems and processes that will enable all prisons to provide assurance to the AOs that they are compliant with legislative requirements for the safe management and use of controlled drugs. • CD AOs should assure that prison healthcare and pharmacy service providers have robust CD policies and standard operating procedures in place. • CD AOs should assure that appropriate training is being provided to prison and healthcare personnel for the safe use and management of CDs.
3	<p>Senior prison healthcare managers should provide appropriate training for handling medicines for healthcare, pharmacy and prison personnel and should ensure that clinical and operational guidance published by professional bodies is included in SOPs and made available to relevant personnel. Training and development plans within the prison healthcare service should make reference to published guidance.</p> <p>PCT CD AOs must assure adequate training is provided for any personnel using or handling CDs within the prison estate.</p>

Appendix 1: Contributors –

Membership of the original steering group

Robert Allan	Controlled Drugs Policy Team	Department of Health
Gillian Arr-Jones	Chief Pharmacist	Care Quality Commission
Jane Brown	Director of Policy and Implementation	National Prescribing Centre
Cathy Cooke	Head of Medicine Management	Bristol Community Health
Michael Davis	North West Representative	IMB National Council
Sarah Dennison	Controlled Drugs National Manager	Care Quality Commission
Denise Farmer	Associate Director (NHS East of England)	Clinical Pharmacy Service
Chris Harris	Controlled Drugs Policy Lead	Department of Health
Carol Lange	IDTS Pharmacy Advisor	Department of Health
Harriet Lewis	Head of Implementation and Project Support	National Prescribing Centre
Ian Littler	Orderly Officer for Offender Health	Kalyx Services
Susan Melvin	Professional Standards Inspector	General Pharmaceutical Council
Brian Miller	Accountable Officer (CDs)	NHS Hertfordshire
Desmond Niimoi	Drug Legislation Team	Home Office
Christine Rowlands	Clinical and Medicines Manager	Leeds Prisons (City Wide)
Paula Wilkinson (Chair)	Chief Pharmacist	NHS Mid-Essex

Membership of the focus groups

Julie Bedford	Prison IDTS Nurse	HMP Leeds
Jane Brown	Director of Policy and Implementation	National Prescribing Centre
Gus Fernandez	Clinical pharmacist	Western Sussex Hospital Trust
Lisa Gettings	Pharmacy Manager	HMP Manchester
Jane Hodges	Controlled Drugs Manager	NHS Eastern and Coastal Kent
Jane Howard	Pharmacist	HMP Central Lancashire
Harriet Lewis	Head of Implementation and Project Support	National Prescribing Centre
Sadia Lohan	Specialist Pharmacist	HMP & YOI New Hall
Trevor Jenkins	Community Health Pharmacy Lead	Bedfordshire Community Health Services
Ian Littler	Orderly Officer for Offender Health	Kalyx Services
Dr Luxman Parimelalagan	IDTS Lead GP	HMP Bedford
Chris Street	Head of Prison Pharmacy	HMP Norwich
Joanne White	Prison IDTS Nurse	HMP Leeds

Additional advice, document review and one to one interviews

Angela Krige	Head of Pharmacy and Clinical Materials Management	Care UK
Helen Knight	Interim Assistant Director Medicine Management	NHS Leicester City
Professor Nat Wright	Clinical Director Substance Misuse Service	HMP Leeds
	GP advisor	Department of Health Prison Policy Unit
Matthew Thomas	Controlled Drugs Accountable Officer	NHS Hampshire and Hampshire Community Healthcare

Linda Harris	Medical Director	Wakefield Integrated Substance Misuse and IDTS Service
Andrew Smith	NW and Scotland Regional Inspector,	General Pharmaceutical Council
Cary McDowell	Head of Offender Management	HMP The Mount
Steve Ridd	Clinical Business Development Manager, Prison Sector Lead	Lloyds Pharmacy
Sheetal Koetcha	Pharmacy Healthcare Manager	Lloyds Pharmacy
Clare Watson	Lead Nurse, Prison Healthcare Commissioning	Norfolk PCT
Andrew Marsden	Head of Healthcare	HMP Wakefield
Sally Campbell	Pharmaceutical Advisor	Local Care Direct
Sue Wright	Senior Pharmaceutical & Prescribing Advisor	NHS Rotherham

Appendix 2 - Glossary

CD AO – Controlled Drug Accountable Officer
CD - Controlled Drug(s)
CPPE - Centre for Postgraduate Pharmacy Education
CQC - Care Quality Commission
DH - Department of Health
FP10CDF - Requisition Form Controlled Drugs (England)
FP10PCD – private CD prescription form (England)
GPhC – General Pharmaceutical Council
HMIP - Her Majesty's Inspectorate of Prisons
HO - Home Office
IDTS - Integrated Drug treatment Service
LIN - Local Intelligence Network
MDR - Misuse of Drugs Regulations
NIP - Nurse Independent Prescribers
NMC - Nursing and Midwifery Council
NMP - Non-Medical Prescriber
NPC - National Prescribing Centre
NTA - National Treatment Agency
PCT - Primary Care Trust
PGD - Patient Group Direction
RCGP – Royal College of general Practitioners
RPS - Royal Pharmaceutical Society
SOP - Standard Operating Procedures
UK - United Kingdom
YOI - Young Offender Institution

References

Reference documents for legislative and good practice requirements highlighted in the course of the scoping project are:

- 1 The Health Act 2006. Available from:
<http://www.legislation.gov.uk/ukpga/2006/28/contents> (last accessed 7/2/12)
- 2 The Controlled Drugs (Supervision of Management and Use) Regulations 2006. Available from:
<http://www.legislation.gov.uk/uksi/2006/3148/contents/made> (last accessed 7/2/12)
- 3 Shipman Inquiry Fourth Report, July 2004
Available from: www.shipman-inquiry.org.uk/fourthreport.asp (last accessed 7/2/12)
- 4 Population and Capacity Briefing for 2 September 2011, Ministry of Justice, National Offender Management Service. Available from
<http://www.justice.gov.uk/publications/statistics-and-data/prisons-and-probation/prison-population-figures/index.htm> (last accessed 7/2/12)
- 5 Information from Ministry of Justice webpage relating to the National Offender Management Service: <http://www.justice.gov.uk/about/noms/> (last accessed 7/2/12)
- 6 National Offender Management Drug Strategy 2008-2011. Recovery. Ministry of Justice, 2008. Available from:
<http://www.justice.gov.uk/publications/noms-drug-strategy-2008-2011.htm> (last accessed 7/2/12)
- 7 Bromley Briefings Prison fact file December 2010, Prison Reform Trust
Available from:
http://www.prisonreformtrust.org.uk/Portals/0/Documents/FactfileDec10s_mall.pdf (last accessed 7/2/12)
- 8 The Misuse of Drugs Regulations 2001. Available from:
<http://www.legislation.gov.uk/uksi/2001/3998/contents/made> (last accessed 7/2/12)
- 9 The Misuse of Drugs (amendment) Regulations 2006. Available from:
<http://www.legislation.gov.uk/uksi/2006/986/contents/made> (last accessed 7/2/12)
- 10 The Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007,
Available from:

- <http://www.legislation.gov.uk/ukxi/2007/2154/contents/made> (last accessed 7/2/12)
- 11 A guide to good practice in the management of Controlled Drugs in primary care (England), 2009. National Prescribing Centre Available from:
http://www.npc.nhs.uk/controlled_drugs/resources/controlled_drugs_third_edition.pdf (last accessed 7/2/12)
 - 12 Safer Management of Controlled Drugs – A guide to good practice in secondary care (England). Department of Health. 2007 Available from:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079618 (last accessed 7/2/12)
 - 13 Safer management of controlled drugs: guidance on Standard Operating Procedures for controlled drugs, Department of Health, 2007 Available from:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064824 (last accessed 7/2/12)
 - 14 Home Office consultation on the consolidation and review of the misuse of drugs regulations 2001, 4th August – 28th October 2011. Available from <http://www.homeoffice.gov.uk/publications/about-us/consultations/misuse-drugs-regulations/> (last accessed 7/2/12)
 - 15 The NHS (Pharmaceutical Services) Regulations 2005 : see information for Primary Care Trusts, Department of Health, 2009. Available from http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_105361 (last accessed 7/2/12)
 - 16 HM Chief Inspector of Prisons for England and Wales Annual Report 2008–09, Her Majesty’s Inspectorate of Prisons, 2010. Available from:
<http://iapdeathsincustody.independent.gov.uk/wp-content/uploads/2010/02/HMIP-Annual-Report-2008-09.pdf> (last accessed 7/2/12)
 - 17 Guidance about compliance: Essential standards of quality and safety. Care Quality Commission, 2010. Available from
http://www.cqc.org.uk/sites/default/files/media/documents/gac_-_dec_2011_update.pdf (last accessed 7/2/12)
 - 18 Commissioning health care in prisons 2008/09. Key findings from our analysis of primary care trusts as commissioners of prison health care, Care Quality Commission and Her Majesty’s Inspectorate of Prisons. 2010. Available from:
<http://www.cqc.org.uk/sites/default/files/media/documents/commissioninghealthcareinprisons2008-09.pdf> (last accessed 7/2/12)

- 19 The Medicines Act 1968. Available from:
<http://www.legislation.gov.uk/ukpga/1968/67> (last accessed 7/2/12)
- 20 A Pharmacy Service for Prisoners, Department of Health. 2003. Available from:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_078502 (last accessed 7/2/12)
- 21 Williams J. Inspection of pharmaceutical services in prisons. Pharm.J. 1999; **263**: 634-635. Available from:
<http://www.pharmj.com/Editorial/19991016/society/prisons.html>
[Accessed 10th October, 2010]
- 22 Handbook for controlled drugs accountable officers in England, 1st Edition (v1.1), National Prescribing Centre, 2011. Available from:
http://www.npc.nhs.uk/controlled_drugs/ao_handbook.php (last accessed 7/2/12)
- 23 Expectations, Her Majesty's Inspectorate of Prisons. Available from:
http://www.justice.gov.uk/downloads/publications/inspectorate-reports/hmipris/expectations_2009.pdf (last accessed 25/11/11)
- 24 The Misuse of Drugs Act 1971. Available from:
<http://www.legislation.gov.uk/ukpga/1971/38/contents> (last accessed 7/2/12)
- 25 Niimoi D, drug legislation team, Home Office, 15th July 2010. Re: CD project prison work stream. Personal communication to A.Parkin
- 26 Safe Management of Controlled Drugs: Changes to Requirements for Requisitions for the Supply of Schedule 1, 2 and 3 Controlled Drugs. Final Guidance; Department of Health. 2007. Available from:
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_081539.pdf (last accessed 7/2/12)
- 27 The Misuse of Drugs (Safe Custody) Regulations 1973. Available from:
<http://www.legislation.gov.uk/uksi/1973/798/contents/made> (last accessed 7/2/12)
- 28 Integrated drug treatment system PSI 45/2010, Ministry of Justice, National Offender Management Service, 2010
- 29 Clinical Management of Drug Dependence in the Adult Prison Setting. Department of Health, 2006. Available from:
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_115004.pdf (last accessed 7/2/12)

- 30 Frequently Asked Questions (FAQs) on non-medical prescribing. National Prescribing Centre; 2011. Available from: http://www.npc.nhs.uk/faqs_nmp.php#CON (last accessed 7/2/12)
- 31 A Guide to Medication Review, National Prescribing Centre, 2008. Available from: http://www.npc.nhs.uk/review_medicines/intro/resources/agtmr_web1.pdf (last accessed 7/2/12)
- 32 Safer Prescribing in Prisons - Guidance for clinicians, RCGP Secure Environments Group, Royal Pharmaceutical Society and Royal College of General Practitioners, 2011. Available from http://www.rcgp.org.uk/PDF/Safer_Prescribing_in_Prison.pdf (last accessed 7/2/12)
- 33 HM Prison Service. Clinical services for substance misusers. Issue No.116. HM Prison Service Order number 3550. Available from: http://pso.hmprisonservice.gov.uk/PSO_3550_clinical_services.doc (last accessed 7/2/12)
- 34 Medication In-Possession: A guide to improving practice in secure environments. The National Prescribing Centre. 2005.
- 35 The Environmental Permitting (England and Wales) Regulations 2007 Available from <http://www.legislation.gov.uk/ukxi/2007/3538/contents/made> (last accessed 7/2/12)

'The National Prescribing Centre (NPC) is responsible for helping the NHS to optimise its use of medicines. NPC is part of the National Institute for Health and Clinical Excellence (NICE), an independent organisation providing national guidance on promoting good health and preventing and treating ill health.

© National Institute for Health and Clinical Excellence, 2012. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of NICE.'