

**Updating the RPS Professional Guidance
on the Safe and Secure Handling of
Medicines: Literature Review**

27 September – 20 October 2017

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1. Identify search question

What has changed since The Safe and Secure Handling of Medicines: a team approach was published in March 2005? Are there additional areas of practice that the revised guidance could cover?

2. Search strategy

This included systematic searching to identify key updates as described in the RPS standards, guidance and frameworks process development manual:

<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Manuals/How%20the%20RPS%20develops%20standards%20and%20guidance.pdf>.

Additionally, the advisory group provided details of relevant resources.

Due to the nature of the guidance that is being updated, the search was of grey literature looking for standards and guidance that deals with the physical handling of medicines, rather than searching databases using particular terms.

Inclusion criteria

Processes associated with the physical handling of medicines (including controlled drugs) including

- obtaining medicines
- receipt of medicines
- manufacture or manipulation of medicines
- near patient preparation of medicines
- use or administration of medicines
- removal and disposal of medicines
- transport of medicines
- storage of medicines
- security of medicines
- maintaining integrity of medicines.

Exclusion criteria

- Clinical elements of the prescribing, use and administration of medicines
- Legal mechanisms for supply or administration of medicines (e.g. prescription requirements, patient group directions etc.)
- Guidance for manufacturers and wholesalers of medicines
- Handling of medicines that are obtained and stored in patients own homes
- Medical devices
- Blood and blood components
- Processes and procedures for individual services
- Practice outside the United Kingdom.

The websites of the following UK or GB regulatory bodies were searched for relevant standards and guidance:

- Care Quality Commission
- Healthcare Inspectorate Wales
- Healthcare Improvement Scotland
- Care and Social Services Inspectorate Wales
- Care Inspectorate Scotland

- Professional Standards Authority
- Medicines and Healthcare Products Regulatory Authority
- Home Office
- NHS Improvement
- Ofsted
- Department for Education
- General Medical Council
- Nursing and Midwifery Council
- Health Care Professions Council
- General Pharmaceutical Council
- General Optical Council
- General Dental Council
- NHS Litigation Authority
- NHS National Services Scotland
- Shared Services Partnership Wales: Legal and Risks Service.

The websites the following UK or GB healthcare organisations (including relevant Royal Colleges, non-government organisations and registered charities):

- Department of Health
- Scottish Government
- Welsh Government
- NHS England
- NHS Improvement
- NHS Health Scotland
- NHS National Services Scotland
- NHS Wales Primary Care Services
- Royal Pharmaceutical Society
- Academy of Medical Royal Colleges
- Society and College of Radiographers
- Royal College of Midwifery
- Royal College of Nursing
- Royal College of Anaesthetists
- College of Paramedics
- Association of Independent Healthcare organisations
- Independent Doctor's Federation
- Royal College of General Practitioners
- Royal College of Physicians
- United Kingdom Homecare Association
- National Care Association
- National Care Forum
- Registered Nursing Home Association
- Care England
- The Association for Perioperative Practice
- School and Public Health Nurses Association
- The College of Operating Department Practitioners
- Royal College of Paediatrics and Child Health
- The College of Podiatry
- Association of Independent Healthcare Organisations
- Guild of Healthcare Pharmacists
- NHS Pharmaceutical Quality Assurance Committee
- Dispensing Doctors Association
- NHS Protect

- The Faculty of Forensic & Legal Medicine of the Royal College of Physicians
- National Institute for Health and Care Excellence
- Scottish Intercollegiate Guidelines Network
- All Wales Medicines Strategy Group
- Accountable Officers Network Scotland.

3. Evaluation of the evidence

As described, due to the nature of the guidance that is being updated, the search was of grey literature looking for standards and guidance that deals with the physical handling of medicines, rather than searching databases for papers and studies. As a result, using the SIGN grading system, the evidence reviewed was mainly level 4 expert opinion, with some of the patient safety notices and patient safety alerts and reports being level 3 non-analytical studies (e.g. case reports, case series).

4. Discussion of publications from the regulatory bodies

Care Quality Commission (CQC)

CQC set fundamental standards and the following fundamental standards are particularly relevant to the safe and secure handling of medicines: safety, premises and equipment, good governance, staffing and fit and proper staff.

CQC has published guidance for providers on meeting the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and the Care Quality Commission (Registration) Regulations 2009 (Part 4) [<http://www.cqc.org.uk/guidance-providers/regulations-enforcement/about-guidance>] CQC advises that the guidance on the specific requirements of specific components of the regulation should not be considered exhaustive as there may be other ways that providers can show that they meet each component of the regulation.

CQC describes the intention of Regulation 12 of the HSCA (RA) Regulations 2008 as being to prevent people from receiving unsafe care and treatment and to prevent avoidable harm or risk of harm. In particular, they provide a summary of Regulation 12 which states that 'medicines must be supplied in sufficient quantities, managed safely and administered appropriately to make sure people are safe.'

[<http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment>]

CQC 'understands that there may be inherent risks in carrying out care and treatment, and we will not consider it to be unsafe if providers can demonstrate that they have taken all reasonable steps to ensure the health and safety of people using their services and to manage risks that may arise during care and treatment.'

Regulation 12 states:

- '1. Care and treatment must be provided in a safe way for service users.
2. Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include—
 - g. the proper and safe management of medicines'

The guidance that CQC provide to support this point (g) in Regulation 12 include statements that staff must be suitably trained and competent and that this should be kept under review, that staff must follow policies and procedures about managing medicines, including those related to infection control. They also advise that these policies and procedures should be in line with current legislation and guidance and address supply and ordering, storage, dispensing and preparation, administration, disposal and recording.

[<http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment#guidance>]

CQC describes the intention of Regulation 15 as 'to make sure that the premises where care and treatment are delivered are clean, suitable for the intended purpose, maintained and where required, appropriately located, and that the equipment that is used to deliver care and treatment is clean, suitable for the intended purpose, maintained, stored securely and used properly.'

Regulation 15(1)(b) states that 'All premises and equipment used by the service provider must be 'secure' and the guidance that accompanies this describes that security arrangements must make sure that people are safe while receiving care and this includes providing appropriate access to and exit from protected or controlled areas and using the appropriate level of security needed in relation to the services being delivered. CQC also include guidance on use of surveillance which advises that the provider must make sure that any surveillance is done in the best interests of people using their service, while remaining mindful of their responsibilities for the safety of their staff. CQC has published guidance on the use of surveillance: <http://www.cqc.org.uk/content/using-surveillance-information-service-providers> [<http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-15-premises-equipment#guidance>]

Regulation 15(1)(c) states that 'All premises and equipment used by the service provider must be 'suitable for the purpose for which they are being used'.

CQC describe that to meet Regulation 17 (good governance) that 'providers must have effective governance, including assurance and auditing systems or processes,' that 'these must assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service. The systems and processes must also assess, monitor and mitigate any risks relating the health, safety and welfare of people using services and others. Providers must continually evaluate and seek to improve their governance and auditing practice.' CQC provide further guidance on meeting these requirements [<http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-17-good-governance#guidance>]

CQC describe the intention of Regulation 18 (staffing) as 'to make sure that providers deploy enough suitably qualified, competent and experienced staff.' The guidance expands on this and states that 'providers must deploy sufficient numbers of suitably qualified, competent, skilled and experienced staff and that staffing levels and skill mix must be reviewed continuously and adapted'. It also covers training, learning and development needs of individual staff members. [<http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-18-staffing>]

CQC describe the intention of Regulation 19 (fit and proper persons employed) as ensuring that providers 'only employ 'fit and proper' staff who are able to provide care and treatment appropriate to their role and to enable them to provide the regulated activity.' [<http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-19-fit-proper-persons-employed#guidance>]

CQC also provide guidance for the different types of providers that they regulate. This includes key lines of enquiry (KLOE) that are specific to the type of providers. KLOE that are likely to be particularly relevant to the safe and secure handling of medicines are included for all types of provider and include statements such as:

Does the service follow current and relevant professional guidance about the management and review of medicines?

Are medicines stored, given to people and disposed of safely, in line with current and relevant regulations and guidance?

What systems, processes and practices are in place to protect people from unsafe use of equipment, materials and medicines?

How does the provider ensure the proper and safe use of medicines, where the service is responsible?

Are there reliable systems, processes and practices in place to keep people safe and safeguarded from abuse? And one of the prompts is 'Do arrangements for managing medicines, medical gases and contrast media keep people safe? (This includes obtaining, prescribing, recording, handling, storage and security, dispensing, safe administration and disposal.)'

CQC also includes guidance for some specific settings such as Nigel's surgery: Tips and mythbusters for GP practices: <http://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-tips-mythbusters-gp-practices>
Topics covered include vaccine storage and fridges in GP practices, emergency drugs, management of controlled drugs and reporting patient safety incidents. Mythbusters and tips for dentists include guidance on storage of glucagon injections, drugs and equipment required for a medical emergency <http://www.cqc.org.uk/guidance-providers/dentists/mythbusters-tips-dentists>.

Healthcare Inspectorate Wales (HIW)

The HIW NHS Hospital Inspections Annual Report 2015-16 describes a poor standard of medicines management at wards within the majority of Health Boards that were inspected. In particular, the report describes a number of 'storage errors' relating to medication rooms being unlocked, unattended medicines, temperatures of fridges not being monitored, out of date medicines in an emergency kit and poor Controlled Drug management. The document also reports that medicines management policies were frequently unavailable. [<http://hiw.org.uk/docs/hiw/reports/161005hospital1516en.pdf>]

Care and Social Services Inspectorate Wales (CISWW)

CISWW provide national minimum standards of care that registered providers should provide and aim to exceed - these include standards for handling of medicines:

- Welsh Assembly Government. National Minimum Standards for care homes for younger adults. 2002. <http://cssiw.org.uk/docs/cssiw/general/131009nmsyoungadultsen.pdf>
- Welsh Assembly Government. National Minimum Standards for care homes for older people. 2004. <http://cssiw.org.uk/docs/cssiw/general/131009nmsolderadultsen.pdf>
- Welsh Assembly Government. National Minimum Standards for domiciliary care agencies. 2004. <http://cssiw.org.uk/docs/cssiw/general/131009nmsdomcareen.pdf>
- Welsh Assembly Government. National Minimum Standards for nurses' agencies [no date]. <http://cssiw.org.uk/docs/cssiw/general/131009nmsnursesen.pdf>

Care Inspectorate Scotland

Care Inspectorate Scotland provide guidance for care settings on:

- Care Inspectorate. 2015. Prompting, assisting and administration of medication in a care setting: guidance for professionals. <http://www.careinspectorate.com/images/documents/2786/prompting-assisting-and-administration-of-medication-in-a-care-setting-guidance-for-professionals.pdf>
- Care Inspectorate. 2016. The temperature requirements for medicines storage. http://www.careinspectorate.com/images/documents/1915/Temperature%20Reqs%20for%20Medicine%20Storage_HCR0316099.pdf
- Care Inspectorate. 2015. Management of medication in day care of children and childminding services. <http://www.careinspectorate.com/images/documents/1427/Childrens%20service%20medication%20guidance.pdf>

Medicines and Healthcare Products Regulatory Authority (MHRA)

A search of MHRA Drug Safety updates (storage, security, handling, administration) gave many product specific results – relevant articles included the following which highlight the availability of specific medicines in more than one strength, the importance of risk assessment and the steps that should be taken to reduce the risks of prescribing, dispensing or administering an incorrect strength.

- Insulin degludec (Tresiba): available in additional higher strength. April 2013. <https://www.gov.uk/drug-safety-update/insulin-degludec-tresiba-available-in-additional-higher-strength>

- High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error. April 2015. <https://www.gov.uk/drug-safety-update/high-strength-fixed-combination-and-biosimilar-insulin-products-minimising-the-risk-of-medication-error>
- Caffeine citrate: 2 products of different strengths now available. June 2012. <https://www.gov.uk/drug-safety-update/caffeine-citrate-2-products-of-different-strengths-now-available>

The MHRA has published guidance on the supply of unlicensed medicinal products 'specials', MHRA guidance note 14 (May 2014): <https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials> which provides advice on the manufacture, importation, distribution and supply of unlicensed medicinal products for human use.

Although intended as guidance for manufacturers, the MHRA December 2014 Best practice guidance on the labelling and packaging of medicines may be relevant as its aim is to ensure that medicines can be used safely by all patients, the public and healthcare professionals. It also reflects the expectations of healthcare professionals, patients and regulators with respect to reduction in medication errors, and safe selection and use of medicines by all users.

MHRA also provide recommendations on the control and monitoring of storage and transportation temperatures of medicinal products: www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007569.pdf.

Home Office

The Home Office Drug Licensing team, MHRA, Mountain Rescue of England and Wales and Mountain Rescue Committee of Scotland have produced a controlled drugs factsheet for mountain rescue teams: <https://www.gov.uk/government/publications/mountain-rescue-teams-controlled-drugs-factsheet>.

In this publication, the Home Office and MHRA describe their roles as 'enablers' who do not wish to prevent or prohibit either MREW or MRCoS undertaking their work. They state that licensing is a legal requirement that must be delivered in robust yet proportionate fashion. They advise that their role is not to determine clinical competence but is to manage the inherent risks associated with Controlled Drugs (potential for abuse, misuse and diversion). In turn, licensees must satisfy the HO and MHRA that they are competent as individuals and 'corporately' that they are competent to hold a licence. This document also describes the person who is ultimately responsible for Controlled Drug governance in this type of organisation and emphasises that 'the significance of this position, and associated responsibility must not be underestimated.'

Department for Education

The Department for Education advises that the governing body of a school should ensure that the school's policy is clear about the procedures to be followed for managing medicines, including a procedure for safe storage ensuring that children know where their medicines are at all times and that they are able to access them immediately and a procedure for returning medicines to the parent to arrange for safe disposal.

Supporting pupils with medical conditions at school. (September 2014)
<https://www.gov.uk/government/publications/supporting-pupils-at-school-with-medical-conditions--3>

General Medical Council (GMC)

In their good practice in prescribing and managing medicines and devices guidance, the GMC include statements around reporting of incidents and near misses involving medicines and that this can allow performance and systems issues to be investigated, problems rectified and lessons learned.

Good practice in prescribing and managing medicines and devices (2013) http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp

Nursing and Midwifery Council

The Nursing and Midwifery Council Code for nurses and midwives (January 2015) <https://www.nmc.org.uk/standards/code/> states that registrants must take all steps to keep medicines stored securely.

Their Standards for medicines management (2007) <https://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/> include standards on patients' own medicines, self-administration, storage and transportation, preparing medication in advance, disposal of medicinal products and controlled drugs.

The following standards are of particular interest to this review:

Standard 6 states that 'Registrants must ensure all medicinal products are stored in accordance with the patient information leaflet, summary of product characteristics document found in dispensed UK-licensed medication, and in accordance with any instruction on the label.'

The guidance that accompanies this standard emphasises that policies should be in place to ensure that storage meets the required standards and that registrants are responsible for checking that such policies are in place and being adhered to. Particular reference is made to temperatures that need to be stored within a limited temperature range, for example refrigeration of vaccines.

Standard 7 states that 'Registrants may transport medication to patients including controlled drugs, where patients, their carers or representatives are unable to collect them, provided the registrant is conveying the medication to a patient for whom the medicinal product has been prescribed, (for example, from a pharmacy to the patient's home).'

The guidance that accompanies this standard advises that registrants should not routinely transport Controlled Drugs in the course of their practice and that this should only be undertaken in circumstances where there is no other reasonable mechanism available.

Standard 14 states that 'registrants must not prepare substances for injection in advance of their immediate use or administer medication drawn into a syringe or container by another practitioner when not in their presence.'

The guidance that accompanies this standard provides some exceptions – these include an 'already established infusion', medication prepared under the direction of a pharmacist from a central intravenous additive service and where the specific SPC or PIL indicates that a medicine should be prepared in advance (e.g. some chemotherapy treatments). The guidance also advises that a registrant may delegate administration of a medicine to a named individual who has been assessed and documented as competent, provided that a full risk assessment is undertaken and documented. The last exception that is described in the guidance is preparation of substances by a doctor and the example given is 'in an emergency situation'.

The document includes a standard on delegation and provides specific standards and guidance on administration and supply of medicines by students which talks about how students may be given opportunities to achieve the outcomes and standards required for registration. It also includes guidance on delegation to unregistered practitioners.

Standard 21 states that 'a registrant must dispose of medicinal products in accordance with legislation'

In this document the NMC 'welcomes and supports the self-administration of medicinal products and the administration of medication by carers wherever it is appropriate.' It also states that registrants have a responsibility to ensure 'that suitable facilities are provided to store patients' own medicinal products for their safe storage', that 'that the medicines cabinet or locker is kept locked and that the master key is kept secure' and 'that if the patient is self-

administering, consent is obtained from the patient to keep the individual medicines cabinet/locker locked and the key secure with the patient'. The standards also provide statements on some specific scenarios, for example, 'In a hospital setting, best practice indicates that stock medicines should not be placed in the patient's locked cabinet or locker as they are not labelled for that individual patient.'

Note that in June 2017 the NMC consulted on a proposal to withdraw their standards for medicines management <https://www.nmc.org.uk/about-us/consultations/past-consultations/2017-consultations/education-consultation/>.

General Pharmaceutical Council (GPhC)

GPhC have standards for registered pharmacies and principles 1 of these states that the governance arrangements of the pharmacy safeguard the health, safety and wellbeing of patients and the public. This goes on to advise that there needs to be clear definition of roles and responsibilities of staff, clear lines of accountability and arrangements are in place for identifying and managing the risks associated with providing pharmacy services. It also includes a standard that the safety and quality of pharmacy services are reviewed and monitored.

Principle 3 of the GPhC standards for registered pharmacies is 'The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.' They advise that any associated premises, for example non-registered premises used to store medicines, must also comply with these standards where applicable.

Principle 4 advises that the management of medicines for registered pharmacies must include arrangements for obtaining, keeping, handling, using, and supplying medicines, security and waste management and that the way medicines are managed is fundamental to ensuring the health, safety and wellbeing of patients and the public who receive pharmacy services. Standard 4.3 and 4.4 state that medicines are obtained from a reputable source, safe and fit for purpose, stored securely, safeguarded from unauthorised access, supplied to the patient safely, disposed of safely and securely and that concerns are raised when it is suspected that medicines are not fit for purpose.

September 2012. Standards for registered pharmacies. September 2012:

https://www.pharmacyregulation.org/sites/default/files/standards_for_registered_pharmacies_september_2012.pdf

To support the standards for pharmacies, GPhC have also issued April 2015. Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet which advises that risk assessment should be undertaken to ensure that medicines are managed and supplied safely to the correct person when they need them and that steps should be taken to manage these risks:

https://www.pharmacyregulation.org/sites/default/files/guidance_for_registered_pharmacies_providing_pharmacy_services_at_a_distance_including_on_the_internet_april_2015.pdf

May 2014. Guidance for registered pharmacies preparing unlicensed medicines to support the standards:

https://www.pharmacyregulation.org/sites/default/files/guidance_for_registered_pharmacies_preparing_unlicensed_medicines_may_2014.pdf

GPhC has also published guidance on minimising the risk of making a dispensing error as part of their September 2010. Responding to complaints and concerns. This includes guidance on dispensary layout and the dispensing process:

https://www.pharmacyregulation.org/sites/default/files/responding_to_complaints_and_concerns_september_2010_0.pdf

NHS Litigation Authority

The NHS Litigation Authority published Risk management standards 2013-14 for NHS Trusts providing acute, community, or mental health and learning disability services and non-NHS providers of NHS care. These state

that 'organisations providing acute and community services and non-NHS providers must have an approved documented process for learning from medication errors.' The document provides the following rationale 'There needs to be clear lines of responsibility and accountability for managing risk and clear systems that ensure the prescribing, procurement, production, acquisition, storage, distribution, dispensing, preparation, administration and the safe handling and disposal of medicines occurs'.

Accessed online 29 September 2017. Risk management standards 2013-14 for NHS Trusts providing acute, community, or mental health and learning disability services and non-NHS providers of NHS care. <http://www.nhs.uk/Safety/Documents/NHS%20LA%20Risk%20Management%20Standards%202013-14.doc>

5. Discussion of standards and guidance from the following UK or GB healthcare organisations (including relevant Royal Colleges, non-government organisations and registered charities)

Department of Health (DH)

DH published a letter in February 2012 from the NHS Medical Director, Chief Nursing officer and Chief Pharmaceutical Officer reminding NHS Trusts of the importance of handling and storing medicines in a safe and secure manner. It makes reference to the 2005 Safe and Secure Handling of Medicines and advises that CQC expect to see evidence of compliance with this document during its visits. February 2012.

<https://www.gov.uk/government/publications/medicines-security>

Guidance: Administration of medicines in care homes (with nursing) or older people by care assistants. 2016. <https://www.gov.uk/government/publications/administration-of-medicine-in-care-homes>. DH has published guidance for care home providers, managers and staff on the legal framework for the administration of prescribed medicines for a named individual by care assistants and the requirements for safety and quality assurance.

Hackett. M. Homecare Medicines: Towards a vision for the future. 2011.

<https://www.gov.uk/government/publications/improving-homecare-medicine-supply-services>

A review of homecare medicine supply services was published by DH in 2011 which included recommendations to improve these.

In February 2012 the Department of Health asked all NHS acute hospitals to submit the results of recent audits of their compliance with the 2005 guidance the safe and secure handling of medicines to CQC.

<https://www.gov.uk/government/publications/medicines-security-audit-results-requested>

In 2010, DH published guidance on mixing of medicines prior to administration in clinical practice: medical and non-medical prescribing. 2010. <https://www.gov.uk/government/publications/mixing-of-medicines-prior-to-administration-in-clinical-practice-medical-and-non-medical-prescribing>

Independent Expert Working Group (2017) Drug misuse and dependence: UK guidelines on clinical management. London: Department of Health. <https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management>. In 2017 DH published Drug misuse and dependence: UK guidelines on clinical management which deals mainly with clinical aspects of management of drug misuse and dependence and references to safe storage in patients' homes (which is outside the scope of this review). However, the document does state that '*the usual approaches for safe prescribing, storage and monitoring of controlled drug use apply equally for these patients*'

DH, MHRA, PHE. Guidance Widening the availability of naloxone. 2017.

<https://www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone>

In 2017, DH, MHRA and PHE published guidance on widening the availability of naloxone which highlights that the 2015 regulations on this do not create any legal requirements or make recommendations to services on the

clinical governance procedures they should have in place covering the acquisition, storage of use of naloxone but that relevant 'authoritative guidance' has been produced (Drug misuse and dependence: UK guidelines on clinical management). It advises that relevant 'advice and training should be provided alongside arrangements for supply of naloxone and that this may include developing local protocols covering choice and supply of naloxone (which may include summarising indications for supply locally, product choice, training, storage, monitoring and record keeping)'

DH has published guidance for schools on the use of emergency salbutamol inhalers and adrenaline auto-injectors.

- Guidance on the use of emergency salbutamol inhalers in schools. 2014.
<https://www.gov.uk/government/publications/emergency-asthma-inhalers-for-use-in-schools>
- DH. Guidance on the use of adrenaline auto-injectors in schools. 2017.
<https://www.gov.uk/government/publications/using-emergency-adrenaline-auto-injectors-in-schools>

DH has published guidance on the management of controlled drugs – in particular on the Controlled Drugs (Supervision of management and use) Regulations 2013 that apply to England and Scotland and older guidance documents on use of controlled drugs in primary and secondary care that have since been archived.

- DH. Controlled Drugs (Supervision of management and use) Regulations 2013: Information about the Regulations. 2013. <https://www.gov.uk/government/publications/information-about-controlled-drugs-regulations>
- DH. Safer Management of Controlled Drugs A guide to good practice in secondary care (England) (2007) archived
http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@d_h/@en/documents/digitalasset/dh_074511.pdf
- NPC. A guide to good practice in the management of controlled drugs in primary care (England) Third edition. 2009. Archived
https://www.webarchive.org.uk/wayback/archive/20140627111125/http://www.npc.nhs.uk/controlled_drugs/resources/controlled_drugs_third_edition.pdf

DH has published guidance on the storage, distribution and disposal of vaccines in The Green Book.

- Department of Health. The Green Book. September 2013.
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

DH has published a Health Technical Memorandum which provides information on the management of waste medicines.

- Department of Health (2013). Health Technical Memorandum 07-01: Safe management of healthcare waste: <https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste>

Scottish Government

The Scottish Executive Health Department published a report in 2006 that was commissioned in response to an action point from The Right Medicine – A Strategy for Pharmaceutical Care in Scotland. This provides guidance on improving systems of control for the management of medicines in hospital:

- Scottish Executive Health Department. 2006. Patients and their medicines in hospital.
<http://www.gov.scot/Resource/Doc/94894/0022817.pdf>

The Scottish Government has published National Care Standards which refer to comprehensive systems being in place for ordering, storage, administration and disposal.

- The Scottish Government. Care Homes for people with learning difficulties. 2005.
<http://www.gov.scot/Resource/Doc/349553/0116839.pdf>
- The Scottish Government. National Care Standards. Care homes for older people. 2005.
<http://www.gov.scot/Resource/Doc/349525/0116836.pdf>
- National care standards. Care homes for children and young people. 2011.
<http://www.gov.scot/Publications/2011/05/16141058/9>

- National care standards. Short breaks and respite care services for adult. 2011. <http://www.gov.scot/Publications/2011/05/16142700/0>
- National care standards. Care homes for people with physical and sensory impairment. 2011. <http://www.gov.scot/Publications/2011/05/16140909/4>

NHS England

In 2013 NHS England published the Controlled Drugs (Supervision of Management and Use) Regulations 2013 NHS England Single Operating Model to support NHS England Area Teams with their responsibilities for establishing and managing arrangements for Controlled Drugs. <https://www.england.nhs.uk/wp-content/uploads/2013/11/som-cont-drugs.pdf>

NHS Improvement

In 2017 NHS Improvement published (June 2017) 'case studies on improving arrangements for managing medicines safely including obtaining, prescribing, recording, handling, storage and security dispensing, safe administration and disposal.' <https://improvement.nhs.uk/resources/improving-quality-and-safety-healthcare-medicines-management/> These include case studies on self-administration of medicines, using effective governance to ensure safe use of PGDs and improve timely access to medicines, ensuring medicines are stored under appropriate environmental conditions.

NHS Improvement has also published the following Patient Safety Alerts that are relevant to the safe and secure handling of medicines: <https://improvement.nhs.uk/news-alerts/?keywords=&articletype=patient-safety-alert&after=&before=>

- Resources to support safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks. 2017. <https://improvement.nhs.uk/news-alerts/resources-support-safe-transition-luer-connector-nrfit-intrathecal-and-epidural-procedures-and-delivery-regional-blocks/>
- Risk of severe harm and death due to withdrawing insulin from pen devices. 2016. <https://improvement.nhs.uk/news-alerts/risk-severe-harm-and-death-withdrawing-insulin-pen-devices/>
- Risk of death and severe harm from error with injectable phenytoin. 2016. <https://improvement.nhs.uk/news-alerts/risk-death-and-severe-harm-error-injectable-phenytoin/>
- Reducing the risk of oxygen tubing being connected to air flowmeters. 2017. <https://improvement.nhs.uk/news-alerts/reducing-risk-oxygen-tubing-being-connected-air-flowmeters/>
- Restricted use of open systems for injectable medication. 2016. <https://improvement.nhs.uk/news-alerts/restricted-use-open-systems-injectable-medication/>
- Patient safety incident reporting and responding to patient safety alerts. 2016. <https://improvement.nhs.uk/news-alerts/patient-safety-incident-reporting-and-responding-patient-safety-alerts/> Describes transfer of the statutory patient safety functions previously delivered within NHS England to NHS Improvement.
- Risk of death or severe harm due to inadvertent injection of skin preparation solution. 2015. <https://improvement.nhs.uk/news-alerts/risk-death-or-severe-harm-due-inadvertent-injection-skin-preparation-solution/>
- Risk of death or serious harm from accidental ingestion of potassium permanganate preparations. 2016. <https://improvement.nhs.uk/news-alerts/risk-death-serious-harm-from-accidental-ingestion-potassium-permanganate-preparations/>
- Residual anaesthetic drugs in cannulae and intravenous lines. 2014. <https://improvement.nhs.uk/news-alerts/residual-anaesthetic-drugs-cannulae-and-intravenous-lines/>
- Patient safety alert on risk of hypothermia for patients on continuous renal replacement therapy. 2014. <https://improvement.nhs.uk/news-alerts/patient-safety-alert-risk-hypothermia-patients-continuous-renal-replacement-therapy/>
- Improving medication error incident reporting and learning. 2014. <https://improvement.nhs.uk/news-alerts/improving-medication-error-incident-reporting-and-learning/>

- Patient safety alert on non-Luer spinal (intrathecal) devices for chemotherapy. 2014. <https://improvement.nhs.uk/news-alerts/patient-safety-alert-non-luer-spinal-intrathecal-devices-chemotherapy/>

NHS Scotland

- Health Facilities Scotland has published guidance on the management of waste medicines.
- Health Facilities Scotland (2015). NHS Scotland Waste Management Guidance: <http://www.hfs.scot.nhs.uk/publications-/guidance-publications/>
- Health Facilities Scotland. Scottish Health Technical Note 3 NHS Scotland waste management guidance Part D: Guidance and example text for waste procedures. 2015. <http://www.hfs.scot.nhs.uk/publications/1475232612-SHTN3%20Part%20D%20NHSScotland%20waste%20management%20guidance..pdf>
- As above part A <http://www.hfs.scot.nhs.uk/publications/1481115906-SHTN3%20Part%20A%20NHSScotland%20waste%20management%20guidance..pdf>
- As above part C <http://www.hfs.scot.nhs.uk/publications/1475232418-SHTN3%20Part%20C%20NHSScotland%20waste%20management%20guidance..pdf>

NHS Wales Primary Care Services

In 2016, NHS Shared Services Partnership published guidance for GP practices and community pharmacies on waste management (including management of waste medicines).

NHS Shared Services Partnership. 2016. Waste management aid to compliance. Supporting GP Practices Developing Systems. <http://www.primarycareservices.wales.nhs.uk/waste-management-complain>

NHS Shared Services Partnership. 2016. Waste management aid to compliance. Supporting Community Pharmacies Developing Systems. <http://www.primarycareservices.wales.nhs.uk/waste-management-compliance-pharmacy-ser>

Patient Safety Wales <http://www.patientsafety.wales.nhs.uk/safety-solutions>

Patient Safety Wales has published the following patient safety alerts and notices that are relevant to the safe and secure handling of medicines.

Patient safety alerts:

- PSA003. Update to National Patient Safety Agency (NPSA) alert for safer spinal (intrathecal), epidural and regional devices. 2016. <http://www.patientsafety.wales.nhs.uk/opendoc/291018>
- PSA004. Ensuring the safe administration of Insulin. 2016. <http://www.patientsafety.wales.nhs.uk/opendoc/293137>
- PSA005. Minimising the risk of medication errors with high strength, fixed combination and biosimilar insulin products. 2016. <http://www.patientsafety.wales.nhs.uk/opendoc/293605>
- PSA006. Risk of death and severe harm from error with injectable phenytoin. 2017. <http://www.patientsafety.wales.nhs.uk/opendoc/301279>
- PSA007. Restricted use of open systems for injectable medication. 2017. <http://www.patientsafety.wales.nhs.uk/opendoc/301280>

Patient safety notices

- PSN006. Risk of hypothermia for patients on continuous renal replacement therapy. 2015. <http://www.patientsafety.wales.nhs.uk/opendoc/261006>
- PSN007. Risk of death or serious harm from accidental ingestion of potassium permanganate. 2015. <http://www.patientsafety.wales.nhs.uk/opendoc/265749>
- PSN013. Managing risks during the transition period to new ISO connectors for medical devices used for enteral feeding and neuraxial procedures. 2015. <http://www.patientsafety.wales.nhs.uk/opendoc/271258>

- PSN014. Residual anaesthetic drugs in cannulae and intravenous lines. 2015. <http://www.patientsafety.wales.nhs.uk/opendoc/271263>
- PSN015. The storage of medicines: Refrigerators. 2015. <http://www.patientsafety.wales.nhs.uk/opendoc/271529>
- PSN022. Risk of harm from the inappropriate use and disposal of fentanyl patches. 2016. <http://www.patientsafety.wales.nhs.uk/opendoc/280993>
- PSN025. Risk of death or severe harm due to inadvertent injection of skin preparation solution. 2016. <http://www.patientsafety.wales.nhs.uk/opendoc/284532>
- PSN030. The safe storage of medicines: Cupboards. <http://www.patientsafety.wales.nhs.uk/opendoc/288619>
- PSN036. Reducing the risk of oxygen tubing being connected to air flowmeters. <http://www.patientsafety.wales.nhs.uk/opendoc/298349>

Royal Pharmaceutical Society (RPS)

The following RPS publications are relevant to the safe and secure handling of medicines:

- Royal Pharmaceutical Society (2014). Professional Standards for Hospital Pharmacy Services.
- Royal Pharmaceutical Society (2013). Professional Standards for Homecare Services
- Royal Pharmaceutical Society (2017). Professional Standards for Optimising Medicines for People in Secure Environments
- Royal Pharmaceutical Society and the NHS Pharmaceutical Quality Assurance Committee (2016). Quality Assurance of Aseptic Preparation Services: Standards.
- Royal Pharmaceutical Society (2016). Professional Standards for the Reporting, Learning, Sharing, Taking Action and Review of Incidents
- Royal Pharmaceutical Society (2013). Medicines Optimisation: Helping patients to make the most of medicines. Good practice guidance for healthcare professionals in England
- Royal Pharmaceutical Society (2017). Medicines Ethics and Practice – the professional guide for pharmacists edition 41
- Royal Pharmaceutical Society (2014). New Medicines, Better Medicines, Better Use of Medicines (2017) <https://www.rpharms.com/resources/reports/new-medicines-guide?Search=new%20medicines.%20better>

Society and College of Radiographers

The Society and College of Radiographers has published Practice Guidance for Radiographer Independent and/or Supplementary Prescribers which includes a section on medicines governance. This covers dispensing, storage, transport, disposal, error reporting and clinical governance. It also published a member only resource in 2009 'Assistant Practitioners and the supply, administration and prescribing of medicines'.

Practice Guidance for Radiographer Independent and/or Supplementary Prescribers. 2016. <https://www.sor.org/learning/document-library/practice-guidance-radiographer-independent-and-or-supplementary-prescribers>

Assistant Practitioners and the supply, administration and prescribing of medicines. 2009 [member only] https://www.sor.org/learning/document-library?sort=by=field_date_published_value&title=medicines&taxonomy_topics_tid=All&field_archive_value=0

Royal College of Nursing

The Royal College of Nursing has published guidance for the management and administration of medicines 'in-flight'.

- In-flight medicines: guidance for management and administration. 2011. <https://www.rcn.org.uk/professional-development/publications/pub-004120>

Royal College of Anaesthetists

The Royal College of Anaesthetists has published the following guidance relating to the safe and secure handling of medicines.

- Royal College of Anaesthetists (2017). Guidelines for the Provision of Anaesthesia Services for Intra-operative care 2017 <https://www.rcoa.ac.uk/document-store/guidelines-the-provision-of-anaesthesia-services-intra-operative-care-2017>
- Royal College of Anaesthetists. Can an Operating Department Practitioner, Anaesthetic Nurse or Physicians' Assistant (Anaesthesia) draw up drugs for the anaesthetist in the operating theatre? <https://www.rcoa.ac.uk/clinical-standards-quality/faqs#CODP>
- The Royal College of Anaesthetists and The Association of Anaesthetists of Great Britain and Ireland (2016) have published guidance on Storage of Drugs in Anaesthetic Rooms. This is guidance for a specific area that was not covered in the 2005 guidance [<http://www.rcoa.ac.uk/document-store/storage-of-drugs-anaesthetic-rooms-guidance-best-practice-the-rcoa-and-aagbi>]
- Royal College of Anaesthetists (2017). Guidance on the provision of anaesthesia services for acute pain services. <https://www.rcoa.ac.uk/system/files/GPAS-2017-11-ACUTEPAIN.pdf>
- Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland (2016). Storage of drugs in anaesthetic rooms. <https://www.rcoa.ac.uk/document-store/storage-of-drugs-anaesthetic-rooms-guidance-best-practice-the-rcoa-and-aagbi>

National Care Forum

The National Care Forum has published resources <http://www.nationalcareforum.org.uk/medsafetyresources.asp> for supporting the safe use of medicines in care facilities including a framework and a guide for employers on training for safer medication.

- Framework: Making the best of medicines across all care settings. <http://www.nationalcareforum.org.uk/documentLibraryDocument.asp?ID=260>
- A guide for employers: training for safer medication <http://www.nationalcareforum.org.uk/documentLibraryDocument.asp?ID=263>

The College of Podiatry

The College of Podiatry has published good practice in prescribing and medicines management for podiatrists which provides guidance on dispensing, storage, transport and disposal of medicines for podiatrist independent and supplementary prescribers.

- 2013. Good Practice in Prescribing and Medicines Management for Podiatrists. <https://www.scpod.org/EasysiteWeb/getresource.axd?AssetID=36739&type=Full&servicetype=Attachment>

NHS Pharmaceutical Quality Assurance Committee

The NHS Pharmaceutical Quality Assurance Committee (accessed via the Specialist Pharmacy Services website) has published several Yellow Cover Documents that are relevant to the safe and secure handling of medicines. These include the following: <https://www.sps.nhs.uk/articles/content-page-for-yellow-cover-documents-yellow-cover/>

The following Yellow Cover Documents (require user to be logged in to the SPS website with an NHS access level:

- (ATMPs)- The Role of Pharmacy in the Successful Delivery of Advanced Therapy Medicinal Products Information for Chief Pharmacists
- Good Practices for the Preparation of Medicinal Products in Healthcare Establishments 1st Edition: Positional Statement by the NHSPQA Committee PIC/S
- Medical gases
- Monoclonal Antibody (mAb) Products: Guidance on Handling
- Multiple Use of Injections 3rd Edition
- Procurement – Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines
- Purchase and Supply of Unlicensed Medicinal Products Guidance Notes for Prescribers and Pharmacists
- Purchase, Receipt, Storage, Supply and Disposal of Radiopharmaceuticals: The Responsibilities of Chief Pharmacists
- Quality Assessment of Unlicensed Medicine
- Raw Materials: Guidance for the Approval of Suppliers of Raw Materials Used in the Manufacture of Unlicensed Medicinal Products 2nd Edition
- Risk Management of Medicines Stored in Clinical Areas: Temperature Control
- Sourcing and Supply of Ready-to-Administer Chemotherapy Doses for the NHS
- Temperature Control in Medicines Storage Areas
- Testing of Piped Medical Gases 2nd Edition
- Vial Sharing in Aseptic Services 1st Edition August 2014.

The Dispensing Doctors Association

The Dispensing Doctors Association have resources on their website to support dispensing doctors' practices but these are only available to members.

NHS Protect

NHS Protect has published a medicine security self-assessment tool which is designed for use by providers of hospital based pharmacy services in the acute, mental health and community settings. The tool focuses on the security and governance arrangements of all medicines within the organisation. This includes a medicine security checklist for pharmacy, one for wards and departments and an action plan template. <https://www.nhsbsa.nhs.uk/crime-prevention/guidance>

NHS Protect has published a guide for the better protection of lone workers in the NHS. This highlights carrying of medicines as a lone worker risk factor. https://www.nhsbsa.nhs.uk/sites/default/files/2017-04/Lone%20worker%20guidance_Final%20March%202017.pdf

NHS Protect has published guidance on the security and storage of medical gas cylinders which provides security advice to those responsible for the management and use of medical gas cylinders in healthcare organisations across England. https://cms.nhsbsa.nhs.uk/sites/default/files/2017-04/Security%20of%20medical%20gas%20cylinders_Updated%20March%202017.pdf

NHS Protect has published security standards and guidance for the management and control of controlled drugs in the ambulance sector. https://www.nhsbsa.nhs.uk/sites/default/files/2017-03/Security%20standards%20for%20the%20management%20and%20control%20of%20CDs%20in%20ambulance_v3%20-%20March%202017.pdf

The Faculty of Forensic & Legal Medicine of the Royal College of Physicians

The Faculty of Forensic & Legal Medicine of the Royal College of Physicians has published guidance on the safe and secure administration of medication in police custody.

Safe and Secure Administration of Medication in Police Custody. 2016.

<https://fflm.ac.uk/publications/recommendations-safe-and-secure-administration-of-medication-in-police-custody/>

National Institute for Health and Care Excellence (NICE)

The following documents from NICE include guidance on the safe and secure handling of medicines.

Managing medicines in care homes. March 2014 <https://www.nice.org.uk/guidance/sc1/chapter/1-Recommendations#receiving-storing-and-disposing-of-medicines>

NICE provide guidance for care homes on receiving, storing and disposing of medicines which includes details of the information they should include in their processes for storing medicines safely, ensuring that only authorised care home staff have access to medicines. They also state that storage should be provided that meets the resident's needs, choices, risk assessment and type of medicines system that they are using. Processes should also be in place for prompt disposal of medicines and records kept. They also include guidance on self-administration and the individual risk assessment that should be carried out. They also provide guidance on administration of medicines. And on ensuring competency of care home staff.

As part of this guidance NICE advise that commissioners and providers of organisations that directly provide health or social care services should ensure that their policies, processes and local governance arrangements make clear who is accountable and responsible for the safe and effective use of medicines in care homes. The guidance includes recommendations for the handling of controlled drugs in care homes.

Managing medicines for adults receiving social care in the community. March 2017.

<https://www.nice.org.uk/guidance/ng67/chapter/Recommendations#governance-for-managing-medicines-safely-and-effectively>

Although much of this is out scope (handling of medicines in patients' homes) the section on transporting, storing and disposing of medicines may be relevant – this includes reference to a risk assessment being carried out of transport arrangements if a social care provider is involved.

Physical health of people in prison. November 2016. <https://www.nice.org.uk/guidance/ng57>

NICE have published guidance on the physical health of people in prison – this advises carrying out individual risk assessment to determine if a person can hold their medicines in-possession and to review and repeat risk assessment if a person's circumstances change. They advise considering the provision of storage for in-possession medicines in prison cells and provide an example of a locked cupboard. They also advise working with prison staff to ensure a system is in place to reduce diversion of medicines.

Controlled drugs: safe use and management. April 2016.

<https://www.nice.org.uk/guidance/ng46/chapter/Recommendations>

In 2016 NICE published guidance on the safe use and management of Controlled Drugs. This covers systems and processes for using and managing controlled drugs safely in all NHS settings except care homes. It provides recommendations for organisations on developing and establishing systems and processes including governance arrangements, storage, stock checks, transportation and destruction and disposal of controlled drugs. Recommendations for organisations on record keeping, risk assessment and reporting controlled drug-related incidents for organisations. It also provides recommendations for health professionals on prescribing, obtaining and supplying, administering and handling controlled drugs and monitoring use, including governance and systems for reporting concerns and incidents.

It includes statements that organisations should agree governance arrangements with clear lines of responsibility and accountability, that designated bodies must appoint a controlled drugs accountable officer and should consider appointing a nominated person in organisations that are not required to appoint a CDAO.

The guidance also covers policies, processes and procedures (including details of standard operating procedures) and the systems and processes that non-healthcare settings such as schools should have in place.

Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes. March 2015. <https://www.nice.org.uk/guidance/ng5>

Although this guideline is not focussed on the physical handling of medicines, it includes recommendations on systems for identifying, reporting and learning from medicines-related patient safety incidents that are relevant.

All Wales Medicines Strategy Group (AWMSG)

The AWMSG published an All Wales Policy for Medicines Administration, Recording, Review, Storage and Disposal in November 2015.

<http://www.awmsg.org/docs/awmsg/medman/All%20Wales%20Policy%20for%20Medicines%20Administration,%20Recording,%20Review,%20Storage%20and%20Disposal.pdf>

This was in response to the medicines practice issues identified as part of the *Trusted to Care* report, published in 2014 and sets out minimum standards of practice that must be adopted by all healthcare employees involved in the administration, recording, review, storage and disposal of medicines in Welsh hospitals. The storage section includes standards for segregation of medicines, arrangements for self-administration schemes and medicines for clinical emergencies.

Trusted to Care: An independent Review of the Princess of Wales Hospital and Neath Port Talbot Hospital at Abertawe Bro Morgannwg University Health Board. Professor June and Andrews Mark Butler. <http://gov.wales/topics/health/publications/health/reports/care/?lang=en>

6. Review of literature for specific sections

Storage

The scoping day highlighted that the physical storage of medicines was an area of the 2005 guidance that needed updating. The list of types of medicines cupboards provided in the 2005 guidance were from previous editions of the relevant Department of Health Health Building Notes. The current editions of these publications do not include this detail or any such guidance on cupboard types or detailed advice on the storage of medicines anywhere outside Pharmacy or Radiopharmacy facilities.

There has not been any update to the British Standards for medicines cupboards since the 2005 guidance.

The 2013 Welsh version of HBN 00-01 General Design Principles (superseded in October 2107) included the following statement on page 19
<http://www.wales.nhs.uk/sites3/Documents/254/WHBN%2000-01.pdf>

Construction of medicines cupboards

5.22 Metal cupboards are recommended for the storage of medicines to ensure compliance with BS 2881. 'The safe and secure handling of medicines: A team approach' states that medicines storage systems should comply with BS 2881. The Welsh Government advises all hospitals to take this report into consideration.'

The style of Health Building Notes for England and Wales have since changed significantly and none of this detail is provided anymore, nor is there any signposting as to where this information can be found.

The Welsh Government and NHS Wales have published Patient Safety Notice PSN 030. The Safe Storage of Medicines: Cupboards. April 2016 which 'highlights legal standards, best practice and patient safety recommendations that apply to the safe and secure storage of medicines on hospital wards.'
[<http://www.patientsafety.wales.nhs.uk/sitesplus/documents/1104/PSN030%20Safe%20storage%20of%20medicines%20cupboards.pdf>]

General references on storage and buildings are given below:

- Department of Health. Health Building Notes.
<https://www.gov.uk/government/collections/health-building-notes-core-elements>
- Department of Health. Health Building Note 00-03: Clinical and clinical support spaces. 2013.
- Welsh Health Building Note 00-03 – Clinical and clinical support spaces. 2013.
<https://www.gov.uk/government/publications/design-and-layout-of-generic-clinical-and-clinical-support-spaces>
<https://www.wales.nhs.uk/sites3/Documents/254/WHBN%2000-03.pdf>.

Chapter 8 of these Health Building Notes includes a room description and layout for clean utility rooms and advises that these rooms are suitable for storing sterile supplies and consumables, including infusion fluids and for storing and preparing medicines, including controlled drugs.

Department of Health. Health Building Note 14-01: Pharmacy and radiopharmacy facilities 2013. <https://www.gov.uk/government/publications/guidance-on-the-design-and-layout-of-pharmacy-and-radiopharmacy-facilities> and NHS Wales Welsh Health Building Note 14-01: Pharmacy and radiopharmacy facilities 2013. <https://www.wales.nhs.uk/sites3/Documents/254/WHBN%2014-01.pdf> set out best practice guidance on the design and layout of pharmacy and radiopharmacy facilities in hospitals – they do not cover medicines storage facilities on wards or in clinical spaces, community pharmacies, GP dispensing practices, satellite dispensaries or pharmaceutical quality assurance services.

The NHS Wales Health Building Notes and Welsh Health Building Notes <http://www.wales.nhs.uk/sites3/page.cfm?orgid=254&pid=64096> and the Health Facilities Scotland. Scottish Health Planning Notes. <http://www.hfs.scot.nhs.uk/publications-/guidance-publications/> refer to many of the DH Health Building Notes, including the ones described above. In addition the following are also relevant Scotland Notes:

- Scottish Health Planning Note 36 Part 3. Community Pharmacy Premises in Scotland - Providing NHS Pharmaceutical Services. 2008. <http://www.hfs.scot.nhs.uk/publications/1476434831-SHPN36Part3%20Final.pdf>
- Scottish Health Technical Memorandum 08-04: Specialist services Pneumatic tube transport systems Part A: Overview and management responsibilities 2011
<http://www.hfs.scot.nhs.uk/publications/1475761502-SHTM%2008-04%20V1%20Part%20A.pdf>
- Pneumatic Tube Transport Systems: Design Considerations and Good Practice Guide (SHTM 08-04 Part B) <http://www.hfs.scot.nhs.uk/publications/1475761580-SHTM%2008-04%20V1%20Part%20B.pdf> 2011

British Standards

- British Standards Institution. British Standard Specification for Cupboards for the Storage of Medicines in Health Care Premises BS 2881: 1989.
- British Standards Institution. British Standard Specification for Thief resistant lock assembly. Key Egress. 3621: 2007.

Other relevant resources for storage

- NHS Protect. Medicine Security Self-Assessment Tool. (2014). <https://www.nhsbsa.nhs.uk/crime-prevention/guidance>
- National Patient Safety Agency. Design for Patient Safety Series: <http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/>
- National Patient Safety Agency (2006). Ensuring safer practice with high dose ampoules of diamorphine and morphine. <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59803>
- National Patient Safety Agency (2006). Improving Compliance with Oral Methotrexate Guidelines. <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800>
- National Patient Safety Agency (2008). Reducing Risk of Overdose with Midazolam Injection in Adults. <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59896>
- National Patient Safety Agency (2002). Potassium solutions: risks to patients from errors occurring during intravenous administration. <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59882>
- Nursing and Midwifery Council (2007). Standards for Medicines Management. <https://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/>

The Royal College of Anaesthetists and The Association of Anaesthetists of Great Britain and Ireland (2016) have published guidance on Storage of Drugs in Anaesthetic Rooms. This is guidance for a specific area that was not covered in the 2005 guidance [<http://www.rcoa.ac.uk/document-store/storage-of-drugs-anaesthetic-rooms-guidance-best-practice-the-rcoa-and-aagbi>]

An important theme from the scoping day was ensuring access to medicines in an emergency. The Resuscitation Council (UK) have published a position statement 'Keeping Resuscitation Drugs Locked Away' November 2016. <https://www.resus.org.uk/statements/keeping-resuscitation-drugs-locked-away/>

The following references provide guidance on temperature control of medicines:

- NHS Pharmaceutical Quality Assurance Committee. Risk Management of Medicines in Clinical Areas: Temperature Control. June 2015. <https://www.sps.nhs.uk/articles/content-page-for-yellow-cover-documents-yellow-cover/>
- Department of Health. The Green Book. September 2013. <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>
- Welsh Government and NHS Wales (2015). Patient Safety Notice PSN015. The Storage of Medicines: Refrigerators. <http://www.patientsafety.wales.nhs.uk/safety-solutions>
- ImmForm (2014). Helpsheet 18 Fridge Failures and Stock Incidents.
- South East London Vaccine Incident Working Group (2006). When the Cold Chain is breached – A risk assessment tool to help decision making.
- Pharmaceutical & Healthcare Sciences Society (2013). Guidance Document for Cold Storage Temperature Monitoring and Mapping for Blood Products
- Quality Control West Midlands. Guidance for Validation of Temperature Controlled Storage.
- World Health Organisation (2006). Temperature Sensitivity of Vaccines.
- Ambulance Pharmacist Network (2014). Guideline for the Management of Injectable Medicines at Extremes of Temperature.

- National Patient Safety Agency (2010). Rapid Response Alert. Vaccine Cold Storage. <http://www.nrls.npsa.nhs.uk/alerts/?entryid45=66111>
- Public Health England (PHE) has published guidance regarding ordering, storing and handling vaccines. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering_storing_and_handling_vaccines_March_2014.pdf

The following references provide guidance on the storage of medical gases:

- NHS Protect. Guidance on the Security and Storage of Medical Gases: <https://www.nhsbsa.nhs.uk/crime-prevention/guidance>
- Department of Health (2006). NHS Estates Guidance for Medical Gas Pipeline Systems (HTM 02-01): <https://www.gov.uk/government/publications/medical-gas-pipeline-systems-part-a-design-installation-validation-and-verification>
- Health Facilities Scotland (2012). Medical Gas Pipeline Systems: Design, Installation, Validation and Verification (SHTM 02-01 Part A)
- Health Facilities Scotland (2012). Medical Gas Pipeline Systems: Operational Management (SHTM 02-01 Part B): <http://www.hfs.scot.nhs.uk/publications-/guidance-publications/>
- NHS Wales (2006). Medical Gas Pipeline Systems – Part A: Design, Installation, Validation and Verification (WHTM 02-01)
- NHS Wales (2006). Medical Gas Pipeline Systems – Part B: Operational Management (WHTM 02-01): <http://www.wales.nhs.uk/sites3/page.cfm?orgid=254&pid=64101>
- National Patient Safety Agency (2009). Oxygen Safety in Hospitals: Rapid Response Alert: <http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=62811&q=0%C2%ACoxygen%C2%AC>
- Health and Safety Executive: <http://www.hse.gov.uk/index.htm>

Controlled Drugs legislation

- The Misuse of Drugs Act 1971
- The Misuse of Drugs Regulations 2001
- The Misuse of Drugs (Safe Custody) Regulations 1973
- The Health Act 2006
- Controlled Drugs (Supervision of Management and Use) Regulations 2013

Controlled Drugs resources

- Safer Management of Controlled Drugs: A Guide to Good Practice in Secondary Care (Scotland) 2008
- Home Office Guidance for the safe custody of controlled drugs and drug precursors in transit 2013
- Home Office Security guidance for all existing or prospective Home Office Controlled Drug Licensees and/or Precursor Chemical Licensees or Registrants 2014
- NHS England The Controlled Drugs (Supervision of Management and Use) Regulations 2013 Single Operating Model
- Letter to All-England Chief Pharmacists Group Controlled Drugs and Wholesale Dealer's Authorisation for human use/wholesale dealers' 2014
- Supplementary Information on Wholesale Dealer and Controlled Drugs Licences in the Health and Justice system in England
- NICE Controlled drugs: safe use and management 2016
- NHS Protect Controlled Drugs Security Audit Checklist
- Department of Health. Controlled Drugs (Supervision of management and use) Regulations 2013: Information about the Regulations

- National Prescribing Centre (UK Web Archive). A guide to good practice in the management of Controlled Drugs in primary care (England). December 2009. https://www.webarchive.org.uk/wayback/archive/20140627111322/http://www.npc.nhs.uk/controlled_drugs/
- National Prescribing Centre (UK Web Archive). Handbook for Controlled Drugs accountable officers in England. March 2011. www.webarchive.org.uk/wayback/archive/20140627111322/http://www.npc.nhs.uk/controlled_drugs/
- Department of Health (National Archives). Safer management of Controlled Drugs: a guide to good practice in secondary care (England). October 2007. (http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074513)
- Department of Health (2017) Drug misuse and dependence: UK guidelines on clinical management. London: Department of Health. <https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management>.
- Ministry of Justice. PSI 45/2010: Prison Service Order for Integrated Drug Treatment System. September 2010. (www.justice.gov.uk)
- NHS England. Guidance for the handling of tramadol in health and justice residential sites. June 2014. (www.england.nhs.uk/commissioning/health-just/hj-resources/)
- Accountable Officers Network Scotland. A guide to good practice in the management of Controlled Drugs in primary care – Scotland. September 2014. (www.knowledge.scot.nhs.uk/accountableofficers/resources.aspx)
- The Scottish Government. Safer management of controlled drugs: A Guide to Good Practice in Secondary Care (Scotland). February 2008. (www.sehd.scot.nhs.uk)
- NICE. Managing medicines in care homes. March 2014. (www.nice.org.uk)
- Home Office. Guidance for the safe custody of Controlled Drugs and drug precursors in transit. September 2013. (www.gov.uk/government/publications/transporting-controlled-drugsguidance-on-security-measures)
- Home Office. General security guidance for Controlled Drug suppliers. January 2014. (www.gov.uk/government/publications/general-securityguidance-for-controlled-drug-suppliers)
- Care Quality Commission. The safer management of Controlled Drugs annual report. (www.cqc.org.uk/content/controlled-drugs)
- Care Quality Commission. Controlled Drugs governance self assessment tools. (www.cqc.org.uk/content/controlled-drugs)
- Ambulance Pharmacists Network and NHS Protect Security standards and guidance for the management and control of controlled drugs in the ambulance sector.

The Accountable Officers Network Scotland also has a number of additional relevant resources. <http://www.knowledge.scot.nhs.uk/accountableofficers.aspx>

Guidance for operating theatres

The following references provide guidance on the safe and secure handling of medicines in operating theatres

- National Patient Safety Agency. Safe Anaesthesia Liaison Group (2012). Patient Safety Update including the summary of reported incidents relating to anaesthesia | January 2012 to 30 March 2012. <https://www.aagbi.org/sites/default/files/images/PATIENT%20SAFETY%20UPDATE%20-%20Mar%202012.pdf>
- Royal College of Anaesthetists (2017). Guidelines for the Provision of Anaesthesia Services for Intra-operative care 2017 <https://www.rcoa.ac.uk/document-store/guidelines-the-provision-of-anaesthesia-services-intra-operative-care-2017>
- Royal College of Anaesthetists. Can an Operating Department Practitioner, Anaesthetic Nurse or Physicians' Assistant (Anaesthesia) draw up drugs for the anaesthetist in the operating theatre? <https://www.rcoa.ac.uk/clinical-standards-quality/faqs#CODP>

- College of Operating Department Practitioners (2009). Scope of Practice. <https://www.rcoa.ac.uk/sites/default/files/CODP-Scope-Practice2009.pdf>
- National Patient Safety Agency (2007). Patient Safety Alert: Promoting safer use of injectable medicines <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59812>
- NHS England (2016). Patient Safety Alert: Restricted use of open systems for injectable medication. 2016. https://improvement.nhs.uk/uploads/documents/NHSI_Patient_Safety_Alert_-_Restricted_use_of_open_systems.pdf
- NHS England (2015). Patient Safety Alert: Risk of death or severe harm due to inadvertent injection of skin preparation solution <https://www.england.nhs.uk/wp-content/uploads/2015/05/psa-skin-prep-solutions-may15.pdf>
- National Patient Safety Agency (2007). Safer practice with epidural injections and infusions. <http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60063&>
- Royal College of Anaesthetists (2017). Guidance on the provision of anaesthesia services for acute pain services. <https://www.rcoa.ac.uk/system/files/GPAS-2017-11-ACUTEPAIN.pdf>
- Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland (2016). Storage of drugs in anaesthetic rooms. <https://www.rcoa.ac.uk/document-store/storage-of-drugs-anaesthetic-rooms-guidance-best-practice-the-rcoa-and-aagbi>

Guidance for ambulances

The following references provide guidance on the safe and secure handling of medicines in the ambulance sector.

- Ambulance Pharmacists Network and NHS Protect Security standards and guidance for the management and control of controlled drugs in the ambulance sector.
- Ambulance Pharmacists Network Air Ambulance Standards Resource Kit August 2014
- Ambulance Pharmacist Network Guideline for the management of injectable medicines at extremes of temperature September 2014.

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The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists and pharmacy in Great Britain. We represent all sectors and specialisms of pharmacy in Great Britain and we lead and support the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science, practice, education and knowledge in pharmacy and the provision of professional standards and guidance to promote and deliver excellence. In addition we promote the profession's policies and views to a range of external stakeholders in a number of different forums.



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