Health Facilities Scotland

STATUS IN NHS SCOTLAND

BEST PRACTICE GUIDANCE

Health Building Note 14-02

Medicines storage in clinical areas

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NHS Scotland use

Medicines storage in clinical areas (HBN 14-02)

This attached NHS England document must be read in conjunction with current Scottish Government Policy and NHS Scotland Guidance which take precedence. These include publications in www.sehd.scot.nhs.uk/; plus www.nss.nhs.scot/publications and www.hps.scot.nhs.uk/guidance/

Specific updates for NHSScotland use:

Chapter 1

Legal requirements and basic principles

1.13 replace with:

In Scotland Healthcare Improvement Scotland (HIS) and the Care Inspectorate are the relevant bodies for inspection and ensuring application of quality standards and legislation within their respective sectors. The Health & Safety Executive (HSE) Scotland enforce health and safety legislation in Scotland which can apply in certain circumstances to patient safety. While they do not generally have a role in regulating clinical care, they may investigate where a failure to manage the control of medicines has led to uncontrolled risk, and/or ill health or death.

Chapter 3 & 5

Injectable medicines & Covid-19 Vaccines

3.17 – 3.19 & 5.7 note added:

Drafting of these paragraphs on injectable medicines storage pre-date the deployment of Covid-19 vaccines. It provides general guidance on the storage of refrigerated items and the storage of injectable medicines in standard clinical premises. There are unique handling issues related to vaccines that require storage in a wide range of locations, including in non-healthcare premises used as temporary vaccination centres. Immunisation against Infectious Diseases 'the Green Book' provides current guidance on the storage of these vaccines in its latest UK updates.

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Health Building Note 14-02 – Medicines storage in clinical areas

Preface

About Health Building Notes

Health Building Notes (HBNs) give best practice guidance on the design and planning of new healthcare buildings and on the adaptation/extension of existing facilities.

They provide information to support the briefing and design processes for individual projects in the NHS building programme.

Language usage in technical guidance

In HTMs and HBNs, modal verbs such as "must", "should" and "may" are used to convey notions of obligation, recommendation or permission. The choice of modal verb will reflect the level of obligation needed to be compliant.

The following describes the implications and use of these modal verbs in HTMs/HBNs (readers should note that these meanings may differ from those of industry standards and legal documents):

- "Must" is used when indicating compliance with the law.
- "Should" is used to indicate a recommendation (not mandatory/ obligatory), i.e. among several possibilities or methods, one is recommended as being particularly suitable – without excluding other possibilities or methods.
- "May" is used for permission, i.e. to indicate a course of action permissible within the limits of the HBN or HTM.

Typical usage examples

- "All publicly-funded organisations must ensure that all contracts established to collect and treat waste conform to the Public Contracts Regulations." [obligation]
- "All low voltage (LV) distributions should be configured as TN systems." [recommendation]
- "Alcohol hand gels that do not contain siloxanes may be rinsed out and the packaging recycled or placed into the municipal waste stream." [permission]

"Shall", in the obligatory sense of the word, is never used in current HTMs/HBNs.

Project derogations from the Technical Guidance

Healthcare facilities built for the NHS are expected to support the provision of high-quality healthcare and ensure the NHS Constitution right to a clean, safe and secure environment. It is therefore critical that they are designed and constructed to the highest and most appropriate technical standards and guidance. This applies when organisations, providers or commissioners invest in healthcare accommodation

(irrespective of status, e.g. Foundation and non-Foundation trusts).

Statutory standards plus technical standards and guidance specific to NHS facilities:

- Health Building Notes
- Health Technical Memoranda
- Complete list of NHS estates related guidance

The need to demonstrate a robust process for agreeing any derogation from Technical Guidance is a core component of the business case assurance process.

The starting point for all NHS healthcare projects at Project Initiation Document (PID) and/or Strategic Outline Case (SOC) stage is one of full compliance.

Derogations to standards will potentially jeopardise business case approval and will only be considered in exceptional circumstances. A schedule of derogations will be required for any project requiring external business case approval and may be requested for those that have gone through an internal approvals process.

While it is recognised that derogation is required in some cases, this must be risk-assessed and documented in order that it may be considered within the appraisal and approval process.

Derogations must be properly authorised by the project's senior responsible owner and informed and supported by appropriate technical advice (irrespective of a project's internal or external approval processes).

Sustainability and 'Net Zero Carbon' targets

Healthcare provision is a significant contributor to the UK's carbon footprint. (In 2019, this was estimated to be around 5.4% of our greenhouse gases.) Accordingly, all NHS organisations have their part to play in meeting Net Zero Carbon targets alongside other sustainability measures.

In January 2020, Health chief Sir Simon Stevens announced three steps the NHS will take during 2020 to tackle this problem:

a. NHS England has established an expert panel to chart a practical route map to enable the NHS to get to 'net zero';

b. the NHS Long Term Plan commits to better use of technologies to make up to 30 million out-patient appointments redundant, sparing patients thousands of unnecessary trips to and from hospital. It is estimated that 6.7 billion road miles each year are from patients and their visitors travelling to the NHS;

c. the panel will consider changes that can be made in the NHS's medical devices, consumables and pharmaceutical supply, and areas the NHS can influence such as the energy sector as the health service moves to using more renewable energy.

This guidance is not mandatory (unless specifically stated). However, any departures/ derogations from this HBN – including the measures implemented – should provide a degree of safety not less than that achieved by following the guidance set out in this HBN.

Executive summary

Health Building Note (HBN) 14-02 provides best practice guidance on storage facilities for medicines (including controlled drugs) in clinical areas.

This guidance was first published as a stand-alone chapter in Health Building Note 00-01 – 'General design principles' in 2012. When HBN 00-01 was revised in 2014, the chapter on medicines storage was removed to become an HBN its own right.

The guidance is largely related to acute hospitals, but the general principles are the same whatever the clinical setting.

Health Building Note 14-02:

- clarifies the legislative controls around medicines storage;
- provides new guidance on automated drug storage cupboards;
- clarifies storage temperatures and temperature monitoring;
- provides, in table format, a summary of major requirements for medicines storage for easy reference.

It covers the storage requirements for the following specific categories of medicines:

- controlled drugs;
- epidural infusions and other high-risk medicines (wards only);
- intrathecal chemotherapy;
- oral solid medicines;
- injectable medicines;
- injectable anti-cancer medicines;
- oral liquid medicines;
- medicines to take home;
- flammable medicines;
- medicines requiring refrigerated/ freezer storage;
- medicines administered rectally and external medicines and dressings;
- IV fluids;
- patients' own medicines.

On the construction of medicines cupboards (except automated drug dispensing cupboards and those used for patients' own medicines), the HBN recommends that all cupboards should be made of metal in order to be able to comply with BS 2881. However, existing installations that do not comply need not be replaced immediately, but rather when plans for upgrading are being prepared (unless patient or staff safety would otherwise be compromised).

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Contents

1.0 Introduction

1.1 Health Building Note (HBN) 14-02 provides best practice guidance on storage facilities for medicines (including controlled drugs) in clinical areas and is based on the legislative and regulatory requirements currently in place. It should be read in conjunction with the Royal Pharmaceutical Society's (RPS) (2018) 'Professional guidance on the safe and secure handling of medicines'.

1.2 The guidance given in this HBN should be followed for all new installations, and for refurbishment or upgrading of existing installations.

Scope

1.3 The guidance is largely related to acute hospitals but may also be applicable to other healthcare settings (for example, community health services, care homes and mental health settings). Storage requirements for medicines will differ depending on local risk assessments, ward/area type and medicines usage profile.

1.4 With regard to medicines storage requirements for specialised areas (for example operating theatre departments, day-case units, critical care facilities), all the principles in this document apply, although some space requirements may be different. Clear dialogue with healthcare staff, led by the healthcare organisation's lead pharmacist, is essential.

1.5 The References section includes the relevant legislative and regulatory standards, national best practice and patient safety recommendations that apply to the safe and secure storage of medicines in clinical areas.

Exclusions

1.6 This HBN does not cover the safe and secure storage of medical gas cylinders. Refer to the following:

- Health Technical Memorandum 02-01 Part B – 'Medical gas pipeline systems: operational management'.
- The Royal Pharmaceutical Society's (2018) guidance 'Professional guidance on the safe and secure handling of medicines'.
- NHS Protect has published guidance on the security and storage of medical gas cylinders. At the time of writing, this document is currently being revised by the National Association for Healthcare Security in partnership with the British Compressed Gases Association.

1.7 The classification and storage requirements for medicinal waste are covered in Health Technical Memorandum 07-01 – 'Safe management of healthcare waste'.

1.8 This document does not cover storage requirements for saline ampoules and water for injection.

1.9 The centralised bulk storage of medicines is covered in Health Building Note 14-01 – 'Pharmacy and radiopharmacy facilities'.

1.10 Guidance on the storage of drugs in anaesthetic rooms is provided by the Royal College of Anaesthetists and The Association of Anaesthetists of Great Britain & Ireland (2016).

Legal requirements and basic principles

1.11 There are important patient safety, legal, professional and security requirements to meet when providing medicines storage facilities in clinical areas.

1.12 The Misuse of Drugs (Safe Custody) Regulations 1973 detail the storage and safe custody requirements for controlled drugs.

1.13 The Care Quality Commission (CQC) regulates against all Regulations of the Health and Social Care Act 2008 (Regulated Activities). The aim of Regulation 12 of the Act is to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. It sets out that medicines must be supplied in sufficient quantities, managed safely and administered appropriately to make sure people are safe. This regulation also forms part of the CQC fundamental standards. The CQC can take regulatory action for a breach of this regulation or a breach of part of the regulation, if a failure results in avoidable harm to a person using the service or if a person using the service is exposed to significant risk of harm.

1.14 Healthcare organisations have a duty of care for safe medicines management. This will require risk assessments of the storage, distribution, preparation and administration of medicines for the purposes of security and for patient, visitor and staff safety. This duty of care is vested in the board of directors and its supporting structure. Though compliance with legal requirements and the recommendations in this guidance may be delegated to staff, accountability cannot be delegated.

1.15 Records of decision-making and governance arrangements should be in place, updated and accessible. This should consider both health and safety with multi-disciplinary input from key stakeholders (for example, lead pharmacist, lead nurse or health professional, health and safety adviser, clinical governance lead, security adviser, estates) and should be proportionate to all risks (for example, reduce the risk of accidental access as well as unauthorised intentional access, whilst balancing the need for swift access to a limited number of medicines in clinical emergency situations). Contingency plans and/or training should be considered for most likely scenarios (for example, key loss, ambient temperatures above 25°C, a refrigerator breakdown).

1.16 The medicines storage capacity and preparation areas required for any clinical area should be calculated based on:

- regulatory and legislative requirements;
- risk assessment;
- local policies;
- clinical knowledge (for example, whether bedside storage is included); and
- nature of the clinical area (for example, critical care area versus older care assessment unit).

1.17 The size/number of medicines cupboards should be determined locally and will depend on the different types of medication and anticipated volume of medication to be stored (see Chapter 3 for more detailed guidance). The assessment should include a regular review of medicines cupboards to confirm the

suitability (including size and design) for the purpose of the clinical area.

1.18 Height and dimensions of any shelving used should relate to the size and weight of items stored and the frequency with which they are handled.

Note:

Health Building Note 00-03 – 'Clinical and clinical support spaces' provides design guidance and indicative room layouts on medicine stores and preparation rooms in acute settings. The size and dimensions of the room layouts in the HBN, and the components (for example, cupboards) installed in these areas, are standardised but can be adapted (sized up or down) depending on the number of patients served and patient case mix.

Health Building Note 04-01 – 'Acute in-patient facilities' provides example schedules of accommodation for in-patient areas in which examples of quantities (per 24-bed ward) and the total area of medicine store preparation rooms are given.

1.19 The organisation's lead pharmacist, local security management specialist, medication safety officer and relevant lead nurse together with other healthcare professionals are involved at an early stage in any plans to upgrade or build new medicines storage facilities in clinical areas and approve final plans prior to placing orders for storage systems or security arrangements for existing systems (for example, digital locks). Failure to do this may result in the provision of unsafe, inefficient and potentially illegal storage solutions, which may result in costly retrofits. Consideration should be given to changing models of medicines usage to ensure the facilities are flexible and able to meet future needs. It is important therefore that the design process takes account of flexibility and continuous change.

1.20 Periodic review of medicines storage and risk assessment of security arrangements should be undertaken in organisations to ensure these meet the latest published standards. These should be reflected in organisational policy and procedures and monitored to minimise risk of misuse or diversion, whilst maintaining safe, easy and appropriate access to medicines, in order to meet clinical care requirements.

1.21 Clinical areas require suitably sized storage facilities for all medicines used in the care of patients in these settings. Medicines should be adequately segregated, clearly displayed and accessible to reduce the risk of incorrect medicine selection. This may include the following (non-exhaustive list):

- controlled drugs (see paragraph 3.4);
- epidural infusions and other high-risk medicines (wards only);
- intrathecal chemotherapy;
- oral solid medicines;
- injectable medicines;
- injectable anti-cancer medicines;
- oral liquid medicines;
- medicines to take home;
- flammable medicines;
- medicines requiring refrigerated/ freezer storage;
- medicines administered rectally and external medicines and dressings;
- IV fluids;
- patients' own medicines.

1.22 Medicines storage facilities should be well-designed to encourage good practice.

Issues to consider include location of the room, layout, and environmental conditions (for example, temperature, lighting).

Location of medicines cupboards

1.23 For increased security, the following should be considered when siting medicines cupboards, medicines trolleys, etc. Where possible, depending on the service provided, they should:

- be in a clean utility room – the room should be lockable and accessible to authorised staff only;
- not be visible from an outside window at ground level;
- not be positioned near sources of heat (for example, radiators), and where there are windows in a room, blinds should be fitted to support temperature management on sunny days;
- have running water and a wash-hand basin nearby; and
- the height of the top shelf of the cupboard should be safely accessible by staff.

1.24 When installing medicines cupboards, consideration needs to be given to the structure of the wall/partition, construction and weight of the cupboard, and fitting. Note that storage for controlled drugs must meet the requirements of the Misuse of Drugs (Safe Custody) Regulations 1973. Some medicines containing controlled drugs will also require refrigeration.

1.25 The room or space where medicines are stored should be provided with internet and intranet access (physical or Wi-Fi) and power where activities may require this (for example, access to electronic references on medicines preparation, barcode scanning and electronic controlled-drug register entry).

1.26 Where electronic records for administration of medicines are used, mobile access to IT will be necessary where this takes place at the point of care.

1.27 Where medicines trolleys (this includes trolleys for phlebotomy and cannulation) are used to store medicines:

- they should be lockable;
- they should be secured at an anchor point (that is, a point at which trolleys can be secured to the floor or wall) when not in use, or they should be stored securely in a locked room when not in use.

2.0 Construction of medicines cupboards

Note:

Medicines must be stored safely and securely in the correct type of cupboard, meeting the Misuse of Drugs (Safe Custody) Regulations 1973 where applicable.

These Regulations set out the British Standard specifications referred to below (see also paragraphs 1.11–1.13 on the regulatory background to the safe storage of medicines).

2.1 Metal cupboards should be provided for the storage of medicines to ensure compliance with BS 2881. This excludes patients' bedside medicines storage and automated drug dispensing cupboards.

Security for medicines cupboards and pharmaceutical refrigerators

2.2 Medicines storage areas should be secure and risk-assessed. Cupboards and all rooms should be locked and secure. All cupboards, closed storage units and medicines storage rooms (that is, those with doors) and pharmaceutical refrigerators in which medicines are stored should be lockable and should be locked closed when not being accessed. Locks for metal cupboards (except patients' medicines cupboards) should comply with BS 3621.

2.3 Locking mechanisms other than mechanical keys may be used as a control provided they comply with BS 3621, where appropriate. Keypads, biometric access (for example, fingerprint recognition), electronic keys or swipe cards can be used to open medicines cupboards. Systems should be in place to ensure codes are regularly changed or swipe cards updated (for example, following an incident or staff dismissal, or when staff leave) and dissemination of codes are restricted on a "need to know" basis. Doors should lock automatically on closing. Electronic keys and appropriate electronic access cards are preferred to ensure suitable audit trails of storage access can be maintained. (See the Royal Pharmaceutical Society's (2018) 'Professional guidance on the safe and secure handling of medicines' for more guidance on electronic locking mechanisms.)

2.4 All stock medicines cupboards (except cupboards for controlled drugs) in a distinct clinical area or department (for example, a ward) can have locks that use identical keys or the same key suite. Multiple key copies may be available (except cupboards for controlled drugs), to reduce the time needed for authorised staff to unlock the cupboards.

2.5 Each patient should have access to their own bedside medicines cupboard to facilitate self-administration of their medicines, where this is appropriate. The Royal Pharmaceutical Society's (2018) 'Professional guidance on the safe and secure handling of medicines' states: "The level of security to be applied in the storage of patients' own drugs, including controlled drugs, and the way in which this is achieved, is balanced against the need to ensure timely access to medicines when they are required".

3.0 Storage requirements for specific categories of medicines

3.1 The following sections provide guidelines for the storage of specific categories of medicines. It is recommended that there is appropriate segregation of medicines to reduce the risk of incorrect medicines being selected.

3.2 The cupboard sizes should be determined locally, based on the clinical nature of the ward and the agreed stock of medicines required within each area. All sizes shown are in mm and represent height x width x depth of the storage cupboard or unit.

3.3 The table on the following page provides a quick reference guide for the different categories of medicines and their storage requirements with regard to security level, access and temperature.

Note:

Other storage facilities including those for hazardous materials (for example, inhalation anaesthetics) may be required based on local requirements.

	Medicines storage (major requirements)			
	Patients' own medicines	**Medicines (excluding Controlled Drugs)**	**Medicines requiring cold storage[1]**	**Controlled drugs**
Temperature	Ambient (not above 25°C): reduce days held	Ambient (not above 25°C)	Refrigerator (2°C–8°C), or freezer	Ambient (not above 25°C)
Regulatory and standard security levels (BS 2881 or Sold Secure Standard (SS) 314)	Not applicable	BS 2881 Security Level 1 (i.e. no entry in 5 min. knife attack & in medical or staff observed location & resistant to 980 Newtons downward force); or SS 314 'bronze' + C.2.2* (i.e. no entry in 5 min. manual attack in medical or observed location).	Solid or glass door (to facilitate product selection).	Misuse of Drugs (Safe Custody) Regulations 1973. BS 2881 Security Level 2 (i.e. no entry in 15 min. planned attack & resistant to 980 Newtons downward force); or SS 314 'silver' + C.2, C.3 & C.4* (i.e. no entry in 5 min. planned attack). The requirement for alarm systems and other additional security measures (e.g. CCTV) for controlled drugs in clinical areas within hospitals will require a local risk assessment and will be dependent on the quantity stored and 24-hour presence of staff.
Access control[2]	Should be locked with patient access but risk assess for clinical safety e.g. inhalers & insulin	Lock to comply to BS 3621 (room or cupboard) & to be locked when not in use. Electronic keys and appropriate electronic access cards preferred to ensure suitable audit trails of storage access can be maintained.	Based on risk assessment: Lock to ensure content is secure and door automatically locks when closes, or use auditable electronic control/monitoring. Electronic keys and appropriate electronic access cards are preferred to ensure suitable audit trails of storage access can be maintained.	Lock to comply with BS 3621 (room or cupboard) & to be locked when not in use. Electronic keys and appropriate electronic access cards are preferred to ensure suitable audit trails of storage access can be maintained.
Other guidance:		"Professional guidance on the safe and secure handling of medicines" (RPS, 2018)	• "Professional guidance on the safe and secure handling of medicines" (RPS, 2018) • "Control of medicinal product temperatures" (MHRA)	"Professional guidance on the safe and secure handling of medicines" (RPS, 2018)

Notes:

1. For medicines that require freezer storage, specialist advice will be required on the appropriate storage requirements.
2. There is a need to identify the requirement for suitable access-controlled key storage for medicines storage in areas not staffed 24/7 e.g. imaging or day case etc. This is essential for controlled-drug storage and may require a key safe in a staffed area.

* References to C.2, C.3 and C.4 are to clauses (and sub-clauses) in Appendix C of BS 2881 on the siting and fixing & installation of cupboards, and alarm systems to be used.

A departure from the recommendations in this Table must be by risk assessment and supported by the responsible lead pharmacist & other relevant clinical staff.

Where medicines storage is not in a continually monitored area, consideration should be given to installing BS 2881 Security Level 3 or SS 314 'gold' together with other additional security including alarms and monitoring.

Definitions/abbreviations:
Patient's own medicine = held by/for them, e.g. in bedside cupboard or a self-dispenser
Medicines storage = held communally for distribution to multiple users; usually held in a dedicated room, cupboard, refrigerator or freezer

Ambient = room temperature

IV = Intravenous

Controlled drugs[1]

For the legal position or minimum standard on facilities requirements for storage of controlled drugs, see the Misuse of Drugs (Safe Custody) Regulations 1973 and the Department of Health's (2007) 'Safer management of controlled drugs: a guide to good practice in secondary care (England)'.

The fixing methodology of controlled-drug cupboards is stipulated within the Misuse of Drugs (Safe Custody) Regulations 1973. Partition walls are a particular issue requiring detailed internal wall fixing enhancements including metal plates and bolt systems.

3.4 In recent years the range and amount of controlled drugs required to be stored in clinical areas has increased. Traditional designs of quarter-size cupboards within full-sized cupboards are too small to provide suitable controlled-drug storage. To provide some guidance, the lists in this section apply to a 24-bed ward, but all quantities and nominal sizes (H x W x D) need to be assessed locally and agreed for their specific clinical service and storage requirements:

- A 24-bed ward area will generally only have one controlled-drug cupboard. Nominal size: 550 × 500 × 300 mm. (A cupboard within a cupboard is not recommended.)
- High doses (30 mg or greater) of morphine and diamorphine should be stored on a separate shelf in cupboards used to store controlled drugs. See Safer Practice Notice – 'High dose morphine and diamorphine injections' (NPSA, 2006).
- In clinical areas that use large quantities of controlled drugs (for example surgical or renal wards), a larger controlled-drug cupboard or multiple controlled-drug cupboards will be required. In clinical areas that use smaller quantities, this should be risk-assessed.

Note:
Although some medicines are exempt from safe custody and therefore do not need to be stored in a controlled drugs cupboard or be recorded in the controlled drugs register, it may be local policy to choose to store these drugs securely and record them in the register in order to keep a tighter control on them and for audit purposes. It is important that the local medicines policy should always be followed when storing and recording controlled drugs.

- All controlled-drug cupboards should meet the "silver level" outlined in Sold Secure Standard (SS) 314 – 'Specification for security cabinets', or BS 2881 Security Level 2. Where local discussions identify additional risks, it may be necessary to consider further precautions to the surrounding environment where the controlled-drug cupboard is located. This can include placing the controlled-drug cupboard in an access-controlled room or an area that is monitored by CCTV. The access control system used should be auditable.
- Following local risk assessment, controlled-drug cupboards may be linked to an alarm/indicator system that shows to staff when the door to the cupboard is open. Where fitted, the alarm should display at the staff communication base, or if the ward is not operational, at an alternative suitable location, for example a 24-hour security desk.

1 Although controlled drugs are classified into five schedules according to the Misuse of Drugs Regulations 2001, in the context of this section, only schedule 2 and some schedule 3 drugs are being referred to. Consult the British National Formulary for information on drugs in each schedule.

Note:

Nothing should be displayed outside the cupboard that would indicate that controlled drugs are kept inside it.

Epidural infusions and other high-risk medications (wards only)

3.5 Epidural infusions and other high-risk medications should be stored in separate cupboards or pharmaceutical refrigerators from those holding intravenous and other types of infusion to reduce the risk of the wrong medicines being selected. See Patient Safety Alert 21 – 'Epidural injections and infusions' (NPSA, 2007).

3.6 As some epidural infusions are controlled drugs, it is recommended that cupboards used to store these medicines be constructed to the same standard as controlled-drug cupboards.

3.7 Epidural medicines containing controlled drugs that also require refrigerated storage need to be stored in lockable pharmaceutical refrigerators.

Intrathecal chemotherapy

3.8 Intrathecal chemotherapy drugs should be held prior to administration in a designated holding area.

3.9 Intrathecal chemotherapy drugs should be stored separately from other medicines and visibly labelled.

3.10 Emergency stocks should never be stored on wards.

3.11 If the intrathecal chemotherapy drugs have to be issued and there will be a short delay before administration, the intrathecal chemotherapy drugs should be stored in a dedicated container/refrigerator reserved for this purpose alone.

3.12 The dedicated container/refrigerator should be lockable and the key kept with a member of staff in charge of the clinical area. It should be locked at all times unless an authorised member of staff is collecting drugs.

3.13 Intrathecal medicines containing controlled drugs that also require refrigerated storage need to be stored in lockable pharmaceutical refrigerators.

Note:

See the Department of Health's (2008) Health Service Circular HSC 2008/001 – 'Updated national guidance on the safe administration of intrathecal chemotherapy' for further guidance on the storage of intrathecal chemotherapy drugs.

Oral solid medicines

3.14 It should be possible to adjust the position of the shelves within these cupboards to allow for the wide range of product sizes. Physical barriers (for example, dividers) should be used to separate products with similar names.

3.15 Typical 24-bed wards will require multiple oral solid medicines cupboards depending on the patient groups being treated. This will need to be determined locally depending on service requirements, but typically may be between three and five double wall cupboards, or equivalent. Nominal wall cupboard size: 550 × 1000 × 300 mm.

3.16 Some departments may benefit from tall cupboards for oral solid medicines due to the range of these products required. Quantity to suit. Nominal tall cupboard size: 1800 × 500 × 600 mm.

Injectable medicines

3.17 It should be possible to adjust the position of the shelves within these cupboards to allow for the wide range of product sizes. Physical barriers (dividers) should be used to separate products with similar names or packaging.

3.18 Quantities will need to be determined locally depending on service requirements, but typically may be between two double wall cupboards, or equivalent. Nominal wall cupboard size: 550 × 1000 × 300 mm.

3.19 Some departments may benefit from tall cupboards for injectable medicines due to the volume of these products. Nominal tall cupboard size: 1800 × 500 × 600 mm.

Injectable anti-cancer medicines

3.20 Storage should be designed in a manner that will prevent containers from falling. Such storage areas should be clearly labelled with anti-cancer warning labels.

3.21 Where possible, parenteral anti-cancer medicines should be stored in a designated cupboard. Those requiring refrigerated storage should be stored in a lockable pharmaceutical refrigerator.

Oral liquid medicines

3.22 It should be possible to adjust the position of the shelves within these cupboards to allow for the wide range of product sizes. Physical barriers (dividers) should be used to separate products with similar names or packaging.

3.23 Nominal wall cupboard size: 550 × 500 × 300 mm (based on 24-bed ward).

Note:

Oral liquid medicines should be able to be stored upright after opening.

Medicines to take home

3.24 This cupboard (where applicable) will be used for storing discharge medicines dispensed by the pharmacy and awaiting discharge of the patient, and therefore these medicines may be bulky.

3.25 Nominal floor cupboard size: 750 × 500 × 550 mm (based on 24-bed ward).

3.26 This will be determined locally based on the clinical nature of the ward/area. Wards/areas where patients are discharged on large numbers of medicines (for example, renal wards) will require larger or multiple cupboards based on local assessment.

Flammable medicines

3.27 Flammable medicines should be stored in lockable metal cupboards. A risk assessment should be undertaken to ascertain whether a fire-resisting cupboard is required. This will depend on the quantity and flammability of the medicines. Such storage areas should be clearly labelled with flammable warning labels.

3.28 Nominal wall cupboard size: 550 × 500 × 300 mm.

Medicines requiring refrigerated/freezer storage

3.29 A specially designed pharmaceutical refrigerator should be used. It should be fitted with a lock and fan-assisted cooling and have a temperature range of 2°C–8°C.

3.30 Nominal size for under-counter pharmaceutical refrigerator: 850 × 595 × 550 mm (based on 24-bed ward).

3.31 For large use areas, for example renal wards or surgical wards with three-litre total parenteral nutrition (TPN) bags, or wards that use ready-made injectable medicines that need to be stored in a refrigerator, a larger pharmaceutical refrigerator would typically be more suitable. Nominal tall fridge size: 1900 × 595 × 600 mm.

3.32 Such refrigerators should have an integral or stand-alone digital thermometer with maximum and minimum recording and audible alarm, where appropriate.

3.33 Controlled drugs requiring cold storage can be placed in a pharmaceutical refrigerator with other medicines but should be stored separately (that is, in a separate lockable box).

3.34 Consideration should be given to providing temperature-logging capability, especially where high-value stocks are held. This may be achieved via removable data loggers or Wi-Fi/hard-wired network monitoring devices.

3.35 Refrigerators should be hard-wired into a fused spur with a nearby, accessible and identified indicator lamp and switch for isolation.

3.36 To avoid accidentally interrupting the electricity supply, a switchless socket-outlet should be used. Or the plug should be clearly labelled with a cautionary notice, for example: "Do not unplug/switch off".

3.37 Glass doors can save time in product selection and reduce the time the door is open, particularly in areas that have large stocks.

3.38 In clinical areas that store anti-cancer drugs, a separate refrigerator dedicated to the storage of these drugs should be provided.

3.39 For medicines that require freezer storage, specialist advice will be required on the appropriate storage requirements.

Medicines administered rectally and external medicines and dressings

3.40 Lockable closed storage units with trays or baskets may be used for these lower-risk medicines.

IV fluids

3.41 Lockable closed storage units with trays or baskets or open shelving can be used for bulk storage of IV fluids (for example, boxes of 20 or 50 bags). Open shelving, where used, should be in a locked room. IV fluids should be stored off the ground.

3.42 Quantity of storage required will depend on the nature of the clinical area. Nominal tall storage unit size: 1800 × 500 × 600 mm; or nominal floor cupboard size: 750 x 500 x 550 mm.

3.43 There are significant health and safety (manual handling) issues linked to IV fluids. Designs should minimise double handling and lifting at height. Space for access of lifting devices and trolleys should be included.

3.44 Decanting bulk IV fluids from boxes into open trays or baskets needs to be risk-assessed and clear quality labelling implemented.

Patients' own medicines

3.45 Patients' own medicines should be stored in locked medicines cupboards beside the patients' beds.

3.46 One per bed, but size to be determined locally. Nominal metal cupboard size: 300 × 400 × 150 mm.

3.47 Positioning of cupboards should be carefully considered to minimise health and safety risks, heat sources and interference with other furniture.

3.48 Medicines cupboards may be permanently attached to a wall or to a detachable wall plate to allow them to be transferred with patients. A risk assessment should be carried out to determine the most appropriate fixing method.

3.49 Following local risk assessment, medicines may be stored in locked bedside cupboards to facilitate access (for example, for self-administration by patients who are unable to reach wall-mounted cupboards). Following risk assessment, some time-dependent medicines (for example, inhalers, insulin) may not need locking away.

Note:

Care is needed if medicines cupboards are integrated into bedside lockers to ensure that transposition of lockers between patients does not occur.

4.0 Automated drug dispensing cupboards

4.1 Automated systems for the storage of medicines should be designed in line with the expectations and principles of the current BS 2881. It is essential that such systems are designed to protect medicines from potential diversion and misuse whilst providing the opportunity to use new and innovative technology to improve use of medicines.

4.2 Floors should be capable of handling the loading capacity of an automated drug dispensing cupboard.

4.3 The Institute of Safe Medication Practice's (2019) guidelines state: "select the size and quantity of [automated drug dispensing cupboards] based on the selected distribution model, considering the variety of medications and formulations necessary, including those that require significant space".

4.4 Sufficient socket-outlets should be provided to cope with the number of cupboards needed and to avoid the use of adaptors and extension leads.

For non-controlled drug stocks

4.5 Cupboards should be located in an area that is easily accessible to authorised staff and near patients to support safe and efficient workflow, reducing the distance and time needed for staff to reach the location and potential workarounds by staff (for example, removing medicines for more than one patient at a time).

4.6 There should be adequate space around the cupboard to allow for the complete opening of the doors and drawers, and to protect staff from possible injury during the opening of medicine room doors.

4.7 Appropriate ventilation, temperature controls and monitoring should be provided to ensure the internal storage temperature does not exceed 25°C. Refer to manufacturers' instructions for specific requirements. If temperature-controlled automated drug dispensing cupboards become available, then consideration should be given to providing temperature-logging capability, especially where high-value stocks are held. This may be achieved via removable data loggers or Wi-Fi/hard-wired network monitoring devices.

4.8 Sufficient and appropriate lighting should be provided in the area to allow for easy reading of the screen and to support the safe and accurate verification of medication orders, and the reading of medication labels and administration documentation.

4.9 Locks used within the system should comply with BS 3621.

4.10 Unauthorised persons should not be permitted to access the cupboard. Access rights and access privileges should be locally determined. There should be a robust locally produced procedure in place regarding the use of temporary access. Audits of access should be in place. There should be a locally agreed time-out period which needs to be risk-assessed.

4.11 All such storage requires mains power and suitable data connections. There should also be a system-failure procedure in place should the power supply or communication be interrupted. Many automated dispensing systems incorporate internal batteries that allow continuous uninterrupted function in the event of a mains power failure (see also Health Technical Memorandum 06-01 – 'Electrical services supply and distribution' on the resilience, safety and integrity of electrical supply and distribution systems and associated equipment).

4.12 Override keys should be securely stored and access-controlled.

4.13 As with all medicines, those stored within automated cupboards are subject to temperature monitoring requirements.

4.14 Where cupboards are designed to be mobile, suitable anchor points should be provided. If the cupboards are small and could be removed from the clinical area, they should be secured to floors or walls.

4.15 Users should undergo training in how to access medicines from the cupboard and what to do in an emergency to ensure access in a timely manner.

For controlled drugs

4.16 Automated electronic medicines storage and issuing systems are now available for all types of medicines, including controlled drugs. Local discussions are essential regarding such requirements.

4.17 Regulator guidance is currently limited as to security levels and approval. Discussion with local police and home office inspectors is recommended before implementation together with risk assessment.

Other useful guidance: The Institute of Safe Medication Practice's (2019) 'Guidelines for the safe use of automated dispensing cabinets'.

5.0 Other considerations

Temperature

5.1 Many medicines are temperature-sensitive and require medicines storage that should not exceed 25°C. Pharmaceutical particulars are available from the manufacturers or from the electronic medicines compendium at www.medicines.org.uk/emc.

5.2 Temperature excursions for medicines storage above 25°C or below 0°C should be avoided. A risk assessment of the damage to stock and the harm to patients caused by such storage temperature excursions should be carried out. Where an excursion is likely to occur (for example, heatwave), temperatures should be monitored ideally daily –
although the most appropriate frequency of temperature monitoring will depend on the risk assessment – and action taken swiftly to correct or minimise safety risks. Both monitoring and the action taken should be recorded.

5.3 Some medicines may require refrigerated storage and transport (for example, 2°C–8°C). A written standard operating procedure should be available and include a process for daily temperature monitoring: for example, an integral or stand-alone maximum-minimum thermometer, the staff responsible for undertaking this and the action required when temperature excursions occur (see the Royal Pharmaceutical Society's (2018) 'Professional guidance on the safe and secure handling of medicines' for further guidance).

5.4 Pharmaceutical refrigerators/freezers should not be overloaded and should be defrosted as required (if not self-defrosting), cleaned and maintained. They should not be located next to direct heat sources (for example, radiators or direct sunlight).

Lighting

5.5 In order to reduce the incidence of human errors when selecting and preparing medicines, good lighting levels should be provided to medicines storage and worktop planes (see CIBSE's (2019) LG02/19 'Lighting guide'). Appropriate switching should be provided to allow this to be operated together or as stand-alone, for example at night.

CCTV

5.6 CCTV should be considered in areas that are closed or unmanned for periods of time.

Working space

5.7 Sufficient space to allow safe working is required, especially for the safe preparation of injectable medicines. Work surfaces should be easily cleaned and not cluttered. At least two metres of such worktop is required for medicine preparation in a typical 24-bed ward area.

Infection prevention and control

5.8 Infection prevention and control teams should be consulted on storage proposals for robustness of design and materials, to enable both easy daily use and regular cleaning. Consideration should be given to:

- a 100 mm coved skirting/sealed floor plinth;
- handwashing facilities;
- pull-out baskets, pull-out shelving or drawer units; and
- wall/tall cupboards to have either sloping tops or preferably a sealed fascia panel to ceiling level.

Refer to Health Building Note 00-09 – 'Infection control in the built environment' for further guidance.

Sustainability

5.9 Pharmaceutical refrigerators and freezers are in continuous use and need constant power, therefore should be chosen sustainably. For example, annual energy consumption (kW/h) should be as efficient as possible for the function required, such as A++ or above (EU Directive 92/75/EEC); and/or a low global warming potential (GWP) refrigerant such as R600a. Also consider specifying a glass door to reduce door opening and/or open door sensor to further reduce energy use. Low noise pollution should also be a consideration (for example, $\leq$38 dB(A)).

Glossary

Anti-cancer medicines – all medicines that have a direct anti-tumour action including cytotoxic drugs and targeted agents (for example, monoclonal antibody drugs).

Automated drug dispensing cupboard – computerised drug storage cupboard that allows medications to be stored and dispensed near the point of care, while controlling and tracking drug distribution.

Control – a mechanism such as a key, keypad, biometric lock (for example, fingerprint recognition), digital lock or swipe card, which is used to control access to a cupboard or room.

Controlled drug – as defined by the Misuse of Drugs Regulations 2001.

Medicines storage – a specialist cupboard, pharmaceutical refrigerator or room where clinical drugs, fluids, inhalers, TPNs, etc. are normally held, usually medium- to long-term storage.

Patient's own medicines – not included in the above "Medicines storage" term, i.e. in use or short-term storage, often held in a bedside cupboard or a self-dispenser.

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Acts and Regulations

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Alerts and safety notices

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Health Building Notes

Health Building Note 00-03. Clinical and clinical support spaces.

Health Building Note 00-09. Infection control in the built environment.

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Health Building Note 14-01. Pharmacy and radiopharmacy facilities.

Health Technical Memoranda

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Further reading

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