Government of Western Australia
Department of Health

Guideline on distribution of medicines

1. Background

The primary objective of medicines distribution throughout public health service facilities is to ensure the right medicine is available to treat every patient in a timely manner, with the least potential for error. However, systems to distribute medicines in public health service facilities should also minimise the cost of medicines stored throughout the facility, minimise wastage, minimise opportunities for diversion, identify unusual medicines usage patterns and provide data on medicines utilisation[1].

Action 4.14 of the national Medication Safety Standard[2] includes requirements for public health service facilities to identify risks associated with the distribution of medicines across their organisation and ensure evidence based policies, procedures and protocols for the safe distribution of medicines are in place. This part of the Standard specifically mentions implementing "end to end" delivery of accountable medicines, such as Schedule 8 medicines, and placing limits on the range of medicines suitable for pneumatic tube delivery. The Standard requires compliance audits and recommends review of incidents associated with distribution of medicines.

The focus of this Guideline is on aspects of distribution related to reducing the risks of misappropriation of medicines during distribution and provides information to guide public health service facilities in developing suitable policies and procedures.

This Guideline is intended to be read in conjunction with MP 0139/20 *Medicines Handling Policy*. The Guideline is not intended to be used as a substitute for compliance with legislation, Policy Frameworks or the policies and procedures of health service providers (HSP).

2. Fundamental principles

When distributing scheduled medicines across public health service facilities, particularly scheduled medicines designated as Schedule 4 Restricted or Schedule 8, the following fundamental principles apply:

- scheduled medicines are securely managed throughout the medication management cycle, from the point of ordering to the time of administration or disposal
- accurate and complete records of all transactions involving scheduled medicines are maintained in a timely manner, such that later audit of records can be undertaken
- distribution systems are set up to ensure each user is uniquely identified and every transaction can be traced to a user

[1] O'Leary K, Burke R, Kirsa S. SHPA Standards of Practice for the distribution of medicines in Australian hospitals. J Pharm Pract Res. 2006;36(2):143-149.

[2] Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. 2nd ed. Sydney: ACSQHC; 2017. (Standard 4: Medication Safety Standard Available at: https://www.safetyandquality.gov.au/standards/nsqhs-standards/medication-safety-standard)

- for Schedule 4 Restricted and Schedule 8 medicines, a clear chain of custody is maintained such that the person responsible for custody of these medicines can be determined at each transition point
- wherever possible, separation of duties is implemented for critical functions with significant opportunities for diversion. These functions include all parts of the distribution process for Schedule 4 Restricted and Schedule 8 medicines including ordering, order processing, order delivery and order receival
- each person involved in the distribution of scheduled medicines takes personal responsibility for ensuring tasks are carried out in a safe and secure manner, including reporting incidents and being empowered to "stop the line"[3] (speak up and halt processes when they sense or discover an essential safety or security breach).

3. Standards and Guidelines

Society of Hospital Pharmacists of Australia (SHPA) Standards of Practice for the distribution of medicines in Australian hospitals, 2006. Available in: J Pharm Pract Res. 2006;36(2):143-149.
Note: This standard and the SHPA Standards of Practice for hospital pharmacy outpatient services are currently under revision and will be replaced by a Dispensing and Distribution Standard.

Australian Commission on Safety and Quality in Health Care Standard 4: Medication Safety Standard.[4]

Guidelines published in other countries about diversion of controlled drugs may also be informative, even though the detail of regulatory controls will be different to those in Western Australia. Such guidelines include:

- American Society of Health-System Pharmacists ASHP Guidelines on preventing diversion of controlled substances (2017)[5]
- Canadian Society of Hospital Pharmacists CHSP Controlled drugs and substances in hospitals and public health service facilities: Guidelines on secure management and diversion prevention (2019)[6]
- "White paper" published by the Association of Healthcare Internal Auditors: Drug diversion prevention and detection: Using a comprehensive risk and internal audit approach (2018)[7]
- Institute of Safe Medication Practices (ISMP) Guidelines for the safe use of automated dispensing cabinets (2019)[8]

[3] The concept of "stop the line" started in the manufacturing sector and is attributed to Taiichi Ohno, a Japanese industrial engineer associated with the Toyota Corporation. Assembly line workers were entrusted with responsibility to stop processing if they noticed something wrong – the aim being to catch problems early. Bell SK, Martinez W. Every patient should be enabled to stop the line. BMJ Qual Saf 2019;28:172-176.
[4] Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. 2nd ed. Sydney: ACSQHC; 2017. (Standard 4: Medication Safety Standard)
[5] American Society of Health-System Pharmacists. ASHP guidelines on preventing diversion of controlled substances. Am J Health-Syst Pharm 2017; 74:325-48.
[6] Canadian Society of Hospital Pharmacists. Controlled drugs and substances in hospitals and public health service facilities: Guidelines on secure management and diversion prevention. Published March 2019.
[7] Janice Ahlstrom. AHIA White Paper: Drug diversion prevention and detection: Using a comprehensive risk and internal audit approach. Published 2018.
[8] Institute of Safe Medication Practices. ISMP Guidelines for the safe use of automated dispensing cabinets. Published February 2019.

4. Risk assessment

A risk assessment should consider the vulnerability to diversion at each point in the distribution process. The first step in any risk management process is to identify the risks – their nature, their consequences and their likelihood. Once specific risks have been identified, an evaluation can determine whether strategies can be implemented to eliminate the risk altogether or whether action can be taken to reduce, minimise or eliminate the risk. *WA Health Risk Assessment Tables* are available. These tables describe consequence and likelihood ratings as well as providing a matrix for assigning risk level.

In the medicines distribution context, there are many factors which may influence the likelihood of a medicine being diverted. Factors include:

- how, when and by whom orders are generated
- how, when and by whom orders are processed (picked, packaged and recorded)
- how, when and by whom record keeping is undertaken
- systems used to identify staff undertaking each task in the distribution process
- systems used to determine which staff are eligible to participate in medicines distribution
- the attributes of personnel involved with each step of the distribution process
- staffing levels when orders for medicines are being processed and delivered
- physical layout of the public health service facility or facilities, including security measures such as proximity card access (linked to individual staff members) and CCTV
- how stock is transported both within a single site and to multiple sites, including where sites are a considerable distance from the site of origin
- the type and quantity of particular scheduled medicines in each area
- movement of larger quantities of medicines and movement of “goods of high illicit value”, particularly Schedule 4 Restricted and Schedule 8 medicines
- methods used to determine whether stock was received
- the time when distribution occurs, including distribution outside usual working hours such as at weekends or overnight
- distribution to particular patient care areas such as operating theatres, emergency departments, labour and delivery areas, clinical areas that are only operational some of the time (e.g. during daytime hours or on weekdays)
- situations where standard processes may be unsuitable or unable to be used, such as during an external disaster (Code Brown), during an infrastructure or other internal emergency (Code Yellow) or where a medicine is urgently required for patient care (and is not already *in situ* in the patient care area).

Consideration should also be given to how often a risk management plan in relation to medicines distribution needs to be reviewed. Other entities which distribute significant quantities of medicines, such as wholesalers, usually undertake an annual review of their risk management plans. Any changes in practices, systems or the environment should also trigger a review of the previous risk management plan.

5. Minimising diversion

5.1 Stock management

Minimising quantities of medicines on wards can reduce risk of misappropriation.
Using an imprest system means stock levels can be tailored to the expected casemix and patient acuity. Imprest lists should be regularly reviewed to ensure the type and quantity of

medicines stored in patient care areas are those necessary for appropriate and timely patient care.

Use of an imprest system with a defined stock list, maximum and minimum levels and regular restocking may reduce the risk of diversion in that:

- changes in usage can be more readily identified and investigated
- requests for non-imprest items can be verified as being required for immediate patient care e.g. the requested item has been ordered on a current patient's medication chart.

Usually tasks relating to checking stock levels for imprested items will be assigned to pharmacy technician or assistant level staff rather than registered pharmacists. For Schedule 4 Restricted and Schedule 8 medicines, the current balance recorded in the relevant registers may be used as a surrogate for opening storage cupboards/safes to physically check stock.

5.2 Use of automated medicines distribution systems

Automated distribution systems for medicines include:

- dispensing robots within the Pharmacy Department
- automated dispensing cabinets (ADCs) in patient care areas, including ADCs specifically tailored to the needs of anaesthetists within operating theatres
- unit dose packaging equipment controlled substances cabinets, which incorporate an electronic controlled substances register.

The Society of Hospital Pharmacists of Australia has recently published a practice update on *Factors to consider for implementation of Automated Pharmacy Distribution Systems in Hospitals and Health Services*.
Automated distribution systems can:

- lower administration error rates,
- minimise opportunity for medicines diversion,
- support audits of doses supplied vs doses administered and
- reduce cost of distributed inventory and medicines wastage.

However, the benefits of these systems in improving safety and reducing risk will only be fully realised where both design and use are carefully planned and implemented. In February 2019, the US based Institute of Safe Medications Practices (ISMP) has updated their *Guidelines detailing core safety processes when using ADCs*.

Whilst automated distribution systems can minimise opportunities for diversion of medicines and improve the chance of identifying anyone seeking to misappropriate medicines, they should not be considered a panacea for eliminating diversion. The level of system security will influence how effective automated distribution systems are in minimising diversion. For example, use of biometric user identification to allow access to medicines in ADCs in patient care areas is considered more secure than use of passwords. Similarly, how user privileges are determined and assigned is an important step. Even the physical location of such devices needs to be considered.

Automated distribution systems support 'end to end' documentation of ordering, delivery and receipt of medicines, with capacity to set up alerts to Pharmacy Department staff if stock is not documented as received in the patient care area for which it was ordered within a certain time frame, such as within 24 hours.

If an automated distribution system will be used for Schedule 8 medicines, including where records form an electronic Schedule 8 register, approval from the CEO of Health[9] is required. The 'health service permit' holder should apply to the Medicines and Poisons Regulation Branch for alternative Schedule 8 storage and, if applicable, for approval of an electronic Schedule 8 register.

5.3 Requisitions – paper based and electronic

Paper based requisition forms, often referred to as 'pink slips', have been used for ordering Schedule 8 medicines in Western Australian public hospitals for many years. Unlike electronic systems for requisitioning medicines, maintaining 'end to end' processes for paper based requisition systems relies on human intervention at each stage of the process. The risk of diversion related to the use of paper based requisition forms will only be minimised if each individual staff member with responsibility for generating orders, processing orders, delivering orders and receiving orders adheres to public health service facility policies about the handling of Schedule 8 medicines.

An alternative to paper based forms, even when comprehensive automated distribution systems are not in use, is to use a secure system of electronic requisitions. When set up with appropriate security controls, electronic requisition systems can:

- improve identification of the staff member involved in each step of the requisition process,
- be set up to only allow certain staff members to perform particular tasks in the requisition process,
- more efficiently maintain 'end to end' processing of requisitions and
- allow audits for compliance to be conducted more easily.

Although paper based forms can be successfully used to document 'end to end' distribution of medicines, this does rely on manual prospective and retrospective checks to ensure medicines are ordered by authorised staff, orders are processed by authorised staff and the full quantity of each medicine supplied by the Pharmacy Department reached its intended destination.

A fundamental principle when distributing higher risk medicines, such as those classified as Schedule 4 Restricted and Schedule 8, is that the identity of the staff member involved in each transaction is clear. With paper based requisitions, ensuring all staff both sign forms and print their name allows both validation during the distribution process and later audit to ensure each person involved was authorised to generate, process, deliver or receive orders for medicines.

Regular reconciliation between Schedule 4 Restricted and Schedule 8 medicines supplied from the Pharmacy Department and requisition forms documenting receipt by the intended site is recommended, to determine whether requisition forms have been returned to the Pharmacy Department (and are therefore available for use in the event of a later compliance audit or investigation). The frequency with which this process is carried out will depend on the number of orders being processed and the turnaround times for order delivery. It is recommended that this type of reconciliation be undertaken at least weekly. This reconciliation process is different to performing a full 'end to end' audit of the distribution Schedule 4 Restricted and/or Schedule 8 medicines which would also include checks that deliveries had been recorded in the relevant register.

[9] Approval is required by the Medicines and Poisons Regulations 2016 and the CEO of Health (Director General) or their delegate is the decision maker.

5.4 Separation of duties

Separation of duties is the concept of having more than one person complete a process and is a key part of internal controls in any organisation to protect against fraud and error. Separation of duties has been embedded in the financial accounting sector for many years.

In the handling of medicines, requiring the various tasks that are part of the medicines distribution process to be undertaken by different staff members is widely acknowledged as a method for reducing the risk of diversion. Requiring two staff members to work together for particular tasks also achieves the outcome of separation of duties.

Further information about factors to consider when determining which staff members should undertake work processes involving Schedule 4 Restricted and Schedule 8 medicines is included in the *Guideline on administration and record keeping for Schedule 4 Restricted and Schedule 8 medicines*.

Where transactions relate to order processing within the Pharmacy Department or order delivery to patient care areas, pharmacy staff (other than pharmacists) can be involved, provided their job description includes these type of tasks and supervision is provided where necessary (such as where the Schedule 8 storage receptacle is being accessed).

If separation of duties is not possible, there is a need to increase other controls to compensate.

Examples of where separation of duties may not be possible include:

- a very small public health service facility with limited staff authorised to handle scheduled medicines, particularly Schedule 4 Restricted and Schedule 8 medicines or
- where the on-call pharmacist needs to supply higher risk medicines after hours.

Compensatory controls could include:

- limiting the range and quantity of stock available at particular sites
- increased physical security such as CCTV monitoring where tasks involving Schedule 4 Restricted and Schedule 8 medicines are carried out
- increased internal audits, including complete reconciliation of documents related to supply of higher risk medicines (requisitions, iPharmacy entries, register entries at both Pharmacy Department and ward level).

5.5 Transportation methods

Whatever system is chosen to transport medicines from one area of the public health service facility to another or from a hub hospital (such as in a regional or remote area) to other smaller public health service facilities, the system should be able to protect the medicine from breakage, spoilage or pilferage/theft.

Automated guided vehicles (AGVs) are a technology based transport solution that can be configured to fulfil the requirements for secure transport of medicines. Other transport methods include use of hospital staff, outsourcing to dedicated courier businesses and, within a single public health service facility, use of pneumatic tube systems.

5.5.1 Use of couriers or hospital staff

The *Medicines and Poisons Act 2014* allows possession of Schedule 4 and 8 medicines for the purpose of transporting these medicines to authorised persons, including to registered health practitioners with possession, administration, prescribing or supply rights.

Notwithstanding the Medicines and Poisons Regulations 2016 which limit who can administer doses, prescribe, supply and dispense medicines to patients, staff members of a public health service facility can be involved in the transport of medicines within and between public health service facilities. However, the *Medicines and Poisons Act 2014* only allows staff members to handle scheduled medicines within their individual "actual or apparent authority". In practice, this means a staff member's job description form (JDF) would need to include clauses indicating that undertaking deliveries was a regular part of their job.

If commercial couriers are used, tracking of packages and obtaining proof of delivery is important. Contracted couriers should be required to keep vehicles secured when unattended and have procedures for dealing with incidents such as vehicle accidents where medicines may be in transit. Contracted couriers should only be used if they are able to ensure safe, secure and timely delivery of medicines.

Public health service facilities should also consider how delivery or transport of medicines will be undertaken when a medicine is required urgently or in an emergency. Procedures for delivery or transport in this situation should maintain 'chain of custody' for Schedule 4 Restricted and Schedule 8 medicines.

Where scheduled medicines are being transported outside a single facility (such as from a hub hospital to a smaller rural/remote hospital or nursing post), they should be packaged in a manner that does not indicate the contents of the package. The Medicines and Poisons Regulations 2016 mandate this for Schedule 8 medicines.

5.5.2 Use of pneumatic tube systems

Pneumatic tube systems can be used to transport many medicines in a rapid and efficient manner. However, some products are unsuitable for transport via a pneumatic tube system.

Reasons medicines may be deemed unsuitable for transport via pneumatic tube systems include:

- adverse effects on product being transported: protein based products which may be denatured by shaking, breakable products, cold chain products
- potential loss: Schedule 4 Recordable and Schedule 8 medicines, high cost medicines
- potential harm to tube system: excess weight, liquid spills
- potential harm to environment or personnel: cytotoxic agents, flammable or explosive agents.

Some pneumatic tube systems have real-time tracking and have additional security options such as access codes or biometric identification before tubes can be removed at the delivery station. The attributes of these type of pneumatic tube systems may allow them to be used where "end to end" documentation of distribution is required.

6. Obtaining medicines when the Pharmacy Department is closed

Various options can be used for patient care areas to obtain medicines required to treat a patient before the Pharmacy Department is next open, including but not limited to:

1. an on-call pharmacist service
2. an after-hours store with replenishment of stock through impresting
3. availability of imprest lists for all accessible patient care locations so stock can be transferred between patient care areas when the Pharmacy Department is closed.

Acquiring stock through after hours access to the Pharmacy Department itself, other than by an on-call pharmacist, should only be considered where the particular item required is not available via other means and there is a clinical imperative to commence treatment before the Pharmacy Department is next open. It is considered inappropriate for non-pharmacy staff to have access to storage within the Pharmacy Department of Schedule 4 Restricted or Schedule 8 medicines.

Even where an on-call pharmacist service is not routinely available, there should be some mechanism by which the Chief Pharmacist (or another senior pharmacist) can be contacted in the event that an urgently required medicine is not available from anywhere else in the public health service facility outside normal Pharmacy Department opening hours.

Particularly when public health service facility policies allow transfer of medicines between patient care areas, safety can only be maintained when any stock transferred is adequately labelled, with details to both identify the medicine and include the expiry date. This is most easily achieved by only allowing either manufacturers original packs or pharmacy labelled packs to be transferred between patient care areas. Repackaging in patient care areas is not supported.

The *Guideline on Pharmacy Department access* also includes relevant information.

7. Definitions

Term	Definition
automated dispensing cabinet (ADC)	Computerised drug storage device or cabinet that allow medications to be stored and dispensed near the point of care, while controlling and tracking drug distribution.

This document can be made available in alternative formats on request for a person with a disability.