Government of Western Australia
Department of Health

Guideline on administration and record keeping for Schedule 4 Restricted and Schedule 8 medicines

1. Background

A fundamental principle in the secure management of Schedule 4 Restricted and Schedule 8 medicines is that there are accurate and complete records of all transactions involving these medicines, including when they are being administered to patients. Records must be able to show the 'chain of custody' has been maintained and allow later audit to be undertaken.

For Schedule 8 medicines, the Medicines and Poisons Regulations 2016 require a patient specific record in a Schedule 8 register (whether on paper or electronically) whenever a Schedule 8 medicine is administered to a patient.

Leftover amounts of Schedule 4 Restricted and Schedule 8 medicines, associated with administration to a patient, such as partly used ampoules or partly administered infusions, are recognised as a diversion risk.

This Guideline is intended to support the development of workable and consistent policies about managing administration of Schedule 4 Restricted and Schedule 8 medicines, from the perspective of managing risks of misappropriation and diversion. This Guideline does not focus on other aspects of the quality use of medicines, such as best practice methods for minimising medication errors.

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. Second check for transactions and inventories

Schedule 8 medicines are recognised as 'high risk' medications by Action 4.15 of the national Medication Safety Standard[1]. Some Schedule 4 Restricted medicines will also be captured by the Medication Safety Standard's definition of a 'high risk' medicine. For example, benzodiazepines have sedative effects. Further information about managing high risk medications from a quality use of medicines perspective is available from the Office of Patient Safety and Clinical Quality.

When using a 'second checker' for work processes involving Schedule 4 Restricted and Schedule 8 medicines, the purpose of the double check and the risks the double check is attempting to manage should be clearly articulated.

[1] 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)

Double checks are most effective at preventing errors when they are performed independently[2]. The value of double checks lies in these checks remaining an independent cognitive task and not something that becomes superficial and routine. By its nature, double checking is resource intensive and a significant burden, particularly for nursing and midwifery staff.

For example, a double check where two people independently calculate the correct volume to administer to a patient from an ampoule or bottle of oral liquid medicine and then compare their results is different to a second person simply verifying the first person's calculation.

Similarly when a second person is witnessing the discarding of a part ampoule as part of administering a dose to a patient, the checking staff member needs to be confident that what they are witnessing being discarded is actually the unused contents of the ampoule. Usually this will require the person to be working in close proximity to the other staff member throughout the drawing up of the contents of the ampoule, be present when any dilution and mixing is undertaken and possibly also during the actual physical administration of the dose (or dose aliquots) to the patient.

Section 3.4 describes the handling of discards in procedural areas, where it is less likely that a witness who has been working in close proximity to the other health practitioner (such as an anaesthetist) will be available.

Ideally, all tasks involving Schedule 8 medicines should require a second check. This includes when preparing medicines for administration and when taking an inventory, as well as when processing orders, receiving stock and when discarding unusable portions (in conjunction with administering doses). When S8 medicines are being destroyed, two authorised persons must be involved, in accordance with the Medicines and Poisons Regulations 2016.

Schedule 4 Restricted medicines are so designated due to the risks are around misappropriation of these medicines. A second check may be useful as a risk mitigation strategy where work processes carry a risk of misappropriation.

Medicines classified as Schedule 4 Restricted may also be classified as 'high risk medications' in accordance with MP0131/20 *High Risk Medication Policy*. This may mean a second check is instituted for some tasks to enhance patient safety rather than primarily to mitigate the risk of misappropriation.

2.1 Factors to consider when determining which staff perform checks

Both staff members involved in transactions (including taking an inventory) with Schedule 4 Restricted and Schedule 8 medicines need appropriate skills and knowledge to be able to undertake the required work processes.

When determining which staff will undertake particular work processes for Schedule 4 Restricted and Schedule 8 medicines, public health service facilities should consider:

- whether the staff member is an authorised person under the Medicines and Poisons Regulations 2016

[2] Australian Commission on Safety and Quality in Health Care Evidence Briefings on Interventions to Improve Medication Safety. Volume 1, Issue 3: August 2013. Double-checking medication administration.

- whether the staff member has appropriate skills and knowledge to be able to undertake the work processes. For example, if the staff member is not an authorised person, do they understand the responsibilities they have when checking or witnessing transactions involving Schedule 4 Restricted and Schedule 8 medicines and have they been trained to undertake the relevant work processes
- whether the staff member's job description is compatible with the work processes they will undertake
- what level of supervision will be provided to the staff member undertaking the "second check", such as by an authorised person
- the consequences for all staff involved in the work process(es) and the public health service facility as an organisation, if a discrepancy is detected and/or diversion is found to have occurred.

In patient care areas, this will mean work processes involving Schedule 4 Restricted and Schedule 8 medicines will almost always only involve authorised persons. In particular, where work processes are directly related to administration of doses to patients (including recording any discarded amounts), only authorised persons should be involved to ensure compliance with the requirements of the Medicines and Poisons Legislation.

Where transactions relate to order processing within the Pharmacy Department or order delivery to and from 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 when the Schedule 8 storage receptacle is being accessed).

2.2 When a second check is not routinely available

In some smaller hospitals, a second authorised person may not always be available to check transactions involving Schedule 4 Restricted and Schedule 8 medicines. Where this is routinely the case, such as overnight or on weekends, public health service facilities need to consider how the risk of misappropriation and diversion can be managed on an ongoing basis.

If the use of two persons in work processes is not available to reduce the risk of misappropriation and diversion, increased efforts are required to detect misappropriation and diversion in a timely manner. This may include:

- use of automated systems such as those that require biometric identification for access
- use of automated systems that detect delivery or receipt not occurring within a specified time frame
- increased frequency of stock counts (inventory), preferably at a time when two authorised staff are available
- use of additional physical security measures such as CCTV (with regular independent review of footage)
- regular 'end to end' reconciliation of records, such as comparison of stock of particular items supplied by the Pharmacy Department, register records and doses recorded on medication charts over a particular time period
- independent audits and random checks by staff who do not normally work at the public health service facility or within that part of the public health service facility.

3. Recording unusable portions (discards) of Schedule 4 Restricted and Schedule 8 medicines

It is reasonably common for the dose administered to a patient from an ampoule/vial to be less than the full ampoule/vial available as stock in the patient care area. For example, a 5 mg dose of morphine may be administered but a 10 mg in 1 mL ampoule will be used. In this circumstance, a portion of the ampoule/vial will need to be 'discarded'.

Ideally discards should be witnessed and recorded by the same two authorised persons involved in other aspects of the administration of the dose, including completion of any register entries. The paper-based Schedule 8 register designed for use in patient care areas (HA14) has specific columns to facilitate recording of 'discards'. This register was amended to better accommodate recording of discards following a recommendation of the State Coroner[3].

It is recognised there are some patient care areas where work flow processes for administration of medicines are such that the staff documenting removal of the medicine from the storage receptacle will be different staff to those administering doses to the patient and managing any unusable portions after administration. However, this does not diminish the need to take steps to minimise misappropriation and diversion, including maintaining the chain of custody.

The required outcome is to ensure every movement of Schedule 4 Restricted and Schedule 8 medicines can be easily audited, whilst supporting patient safety, staff safety and optimal patient care.

When witnessing discarded medicines, the witness should:

- verify the medicine label,
- consider whether the amount to be discarded matches the documentation and
- observe disposal of the medicine into the appropriate waste container.

Measurement of the amount to be discarded will not usually be practicable. However, those undertaking and witnessing discards should consider whether the amount being discarded is consistent with the expected quantity or volume.

Preparation and disposal of Schedule 4 Restricted and Schedule 8 medicines should occur in an open and observable area specifically designated for the preparation of drugs.

3.1 Routine immediate dosing

In this circumstance, the staff involved in administering the dose should be the same staff who witness any discards and record this in the register (whether paper-based or electronic). Where a single dose is being administered, excess drug to be discarded will usually be completed before administration of the dose at the patient's bedside.

3.2 Infusions

Where an infusion is prepared, there may be an amount to be discarded when the required amount is added to the syringe or bag and there may also be an amount of diluted infusion solution to be discarded if the infusion is ceased prior to completion or is otherwise not used (for example, where only a part-syringe of patient controlled analgesia is used).

When an infusion is being initially prepared, the two authorised persons who prepare the infusion should also witness and record the discarded amount. The discarding of unusable

[3] Western Australian Department of Health, Office of Safety and Quality in Healthcare. From death we learn 2010.

portions should occur at the time the infusion is being prepared. Any discarded amount needs to be recorded in the relevant register (whether paper-based or electronic).

Once diluted, further record keeping of unused portions of the diluted preparation may be made on the relevant part of the patient's medication chart, including the Intravenous (IV) Fluid chart or Acute Pain chart if applicable. If there is fluid remaining in the syringe or bag after cessation of an infusion, the discarding of this infusion solution should be witnessed and documented by two authorised persons. It is acknowledged that discarding at the cessation of an infusion will be by the staff ceasing the infusion, who may be different staff to those who commenced the infusion.

Recording discards on the patient's medication chart (or equivalent administration chart) means the record of the discarded infusion solution will be included in the patient's medical record and be available in the event of any later queries or investigations.

If recording on the patient's medication chart (or equivalent administration chart) is considered unsuitable or unworkable, public health service facilities can consider other recording methods. Use of other methods will require local policy and procedures. Any alternative recording methods must be able to maintain the integrity of the record and ensure the record is available for later viewing, for at least the statutory periods for records involving Schedule 8 medicines (five years from the date the record was made).

3.3 Incremental doses in procedural areas

Procedural areas, such as operating rooms (including recovery areas) and labour and delivery areas, present particular challenges for safe and auditable medicines management. This is recognised by the *Australian and New Zealand College of Anaesthetists (ANZCA) 2018 Guidelines for the Safe Management and Use of Medications in Anaesthesia* (ANZCA Medication Guidelines).[4] This document acknowledges that 'measures to reduce the opportunity to misdirect drugs' are part of the safe administration of drugs in anaesthesia.

Technological solutions such as automated dispensing cabinets (ADCs), specifically designed for use during anaesthesia, can be helpful for tracking Schedule 4 Restricted and Schedule 8 medicines and will usually include mechanisms for documenting waste (discards). Implementation of such technology requires consideration of how it will be integrated into existing workflows but ultimately, ADCs can provide benefits from the perspective of having a secure audit trail for transactions involving all medicines.

3.3.1 Documenting medicines to be administered

The Medicines and Poisons Regulations 2016 require Schedule 8 medicines be written out of the Schedule 8 register in a manner that attributes each product to be administered to a particular patient. Ideally this should also be the case for Schedule 4 Restricted medicines. The ANZCA Medication Guidelines also recommend the contents of any one ampoule or vial should be administered to only one patient to minimise the risk of cross infection between patients and for compliance with drug registers.

There may be circumstances where stock is transferred from a central location (such as within an operating theatre complex) for use within a single theatre, such as for all cases during a

[4] Available at: http://www.anzca.edu.au/documents/ps51-2009-guidelines-for-the-safe-administration-o.pdf

theatre session. Where this occurs, an option is to record that the stock went to a particular location for use by a particular medical practitioner and then a second register within the receiving location should be used to record the details of each product used for each patient.

3.3.2 Documenting discards

Reconciliation of drug utilisation at the conclusion of anaesthesia, including completion of the anaesthetic record is standard practice. Discarding unused portions of medicines will occur after this reconciliation. The ANZCA Medication Guidelines state that disposal of containers, syringes and unused medications is the responsibility of the anaesthetist (Section 5.7.1 of the ANZCA Medication Guidelines). The ANZCA Medication Guidelines also recommend that disposal of medications that have the potential for diversion and abuse, such as opioids, benzodiazepines and propofol should be in a manner that minimises this risk (Section 5.7.3 of the ANZCA Medication Guidelines).

Where a documented risk assessment (in accordance with Section 10 of the *Risk based requirements for medicines handling*) has determined that using the relevant register (hard-copy or electronic, including the recording of wastage functions of anaesthetic ADCs) will compromise best practice patient care in the procedural setting, the anaesthesia record could be considered a suitable alternative on which to record Schedule 4 Restricted and Schedule 8 discards.

If a paper-based register is being used and discarded amounts are being documented by different staff to the documentation of the medicines to be administered, for clarity, it is preferable for a separate line to be used, so the full names of the staff involved can be recorded.

3.3.3 Recording discards within the anaesthesia record

If the anaesthesia record is to be used for the purpose of recording discards the following should be considered:

- the relevant Schedule 4 Restricted or Schedule 8 register, where the amount issued for administration to the patient is recorded, should clearly state that the discarded amount is recorded on the anaesthesia record for that patient
- the actual amount discarded for each medicine should be recorded on the anaesthesia record
- it is considered good practice for the amount to be discarded to be witnessed by a second authorised person. However, in procedural areas, including operating theatres, it is acknowledged this may not be practicable. For example, as anaesthetists independently administer aliquots of medicines, there may be no other authorised person who will be able to verify the identity or quantity of the medicine at the point of discarding
- the amounts discarded should be signed by the anaesthetist and, if applicable, the witness.

Public health service facilities need to be aware that using the anaesthesia record for documenting discarded portions of medicines means this part of the patient's clinical record will likely need to be accessed by authorised officers from the Department of Health, when performing routine compliance audits or when conducting an investigation. Public health service facilities will be required to make this part of the patient's clinical record available to Departmental investigators on request, in a timely manner.

3.4 Administration during medical emergencies

In a medical emergency, where incremental doses of Schedule 4 Restricted or Schedule 8 medicines are being administered, it may be necessary to complete the 'dose administered' and 'amount discarded' columns in any registers immediately post-administration rather than prior to administration.

If there are amounts of Schedule 4 Restricted or Schedule 8 medicines to be discarded after a treatment of a patient as part of a medical emergency, these should ideally be documented in the register where the record of use is also recorded.

If this is not possible, such as where the patient has been transferred to another ward or even another public health service facility and escorting staff are not returning to the original patient care area, a record should be made by two authorised persons in the register in the receiving patient care area. An explanatory note should be included to indicate the origin of the medicines and the register in the patient care area where the patient originated should also be suitably annotated.

Note: Schedule 4 Restricted medicines included in a designated resuscitation box or trolley are exempted from the additional record keeping requirements that apply to other Schedule 4 Restricted medicines.

4. Frequency of inventories

The monthly interval between inventories mandated through the Medicines and Poisons Regulations 2016 for Schedule 8 medicines will usually be insufficient to manage the risks associated with these medicines in the public health service facility setting.

Aspects to consider when undertaking a risk assessment to determine the frequency of inventories for both Schedule 4 Restricted and Schedule 8 medicines include:

- the volume of transactions
- the type of transactions that occur (for example, administration of doses on a ward compared to dispensing and supply in the Pharmacy Department)
- the variety of medicines, strengths and dosage forms kept in the storage receptacle
- the casemix and acuity of patients being treated in patient care areas
- the location of the storage receptacle and security of the location
- whether a manual paper-based system or an automated distribution system is used and
- the number and type of staff routinely accessing the storage receptacle.

Where traditional paper-based recording systems are in use, it is standard practice for wards in tertiary hospitals to take an inventory of both Schedule 4 Restricted and Schedule 8 medicines at least once per 24 hours. In procedural areas (which do not generally operate 24/7), an inventory at the end of each clinical session may be appropriate with another inventory when the area next opens for patient care.

Where automated dispensing cabinets (ADCs) are in use, an alternative to performing a daily inventory is to use blind counts each time a medicine in the ADC is accessed for use and an independent inventory less often (for example, weekly), including at refill.

See also information about inventories for oral liquid Schedule 4 Restricted and Schedule 8 medicines in the *Guideline on oral liquid Schedule 4 Restricted and Schedule 8 medicines*.

In smaller public health service facilities with lower patient acuity and turnover, less Schedule 4 Restricted and Schedule 8 medicines stored on wards and lower numbers of authorised staff, a risk assessment may determine that less frequent inventories will not impede the detection and reporting of any stock discrepancies.

5. Schedule 8 medicines for chronic conditions when patients attend the emergency department

There are times where a patient will present to the Emergency Department requesting Schedule 8 medicines for the ongoing treatment of a chronic pain condition or other health condition treated with Schedule 8 medicines, such as attention deficit hyperactivity disorder (ADHD). This can occur where the patient is experiencing genuine difficulty accessing medicines in the community but may also be an indicator of drug seeking behaviour associated with drug dependency or drug diversion.

The Medicines and Poisons Legislation differentiates between administration of doses and the writing of a prescription for use of Schedule 8 medicines in the community. Where Schedule 8 medicines will be supplied to the patient for use in the community, prescribers must comply with the Schedule 8 Medicines Prescribing Code and in some circumstances, prescriptions for Schedule 8 medicines cannot be written until approval from the Department of Health has been obtained.

If a medical practitioner or other authorised prescriber, such as a nurse practitioner, is contemplating writing a prescription for a Schedule 8 medicine, for a patient leaving the Emergency Department, they should consider contacting the Medicines and Poisons Regulation Branch's prescriber information service on 9222 4424 (Monday to Friday, 8.30 am to 4.30 pm) to determine the patient's prior history in relation to Schedule 8 medicines. Prescribers are required to comply with the requirements of the *Schedule 8 Medicines Prescribing Code*, as this Code is issued under the Medicines and Poisons Legislation.

6. Definitions

Term	Definition
blind count	When a dose of a Schedule 4 Restricted or Schedule 8 medicine is removed from an ADC, the ADC prompts the user to physically count the number of remaining products in that location and enter this count at the time of drug removal. The ADC does not provide the user with an indication of the correct count as part of this process.
discarded Schedule 8	Any unusable amounts of S8 medicines remaining after the administration of a dose, such as a part ampoule, which are discarded in a manner that results in the S8 being irretrievable and unusable. Another term for 'discards' is 'wasting'.

disposal	The act of rendering a Schedule 4 Restricted or Schedule 8 medicine, for which destruction has been recorded, unusable and irretrievable. Also refers to activities relating to transfer of medicines to waste management contractors for incineration.
storage receptacle	Place where Schedule 4 Restricted or Schedule 8 medicines are stored. For Schedule 8 medicines the type of storage receptacle is mandated by the Medicines and Poisons Regulations 2016, which allow a locked cupboard to be used in patient care areas that are operational 24/7 but require a safe to be used in other locations.

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