Maldives National Medication Practice Standard

Ministry of Health
Republic of Maldives

World Health Organization
Maldives

Contents

Stakeholder Consultation

Aishath Shamila Mohamed, Deputy Director Nursing, IGMH

Aminath Waheeda, SRN, H.dh. Makunudhoo Health Center

Aminath Shiyama, Head Nurse Emergency, Treetop Hospital

Aminath Samha, Pharmacist, Chairperson, Maldives Pharmacy Professionals Alliance

Assistant Professor Asma Ibrahim Sulaiman, Dean Faculty of Health Sciences, Villa College

Dr Ali Aafee, Neuro Surgeon IGMH

Fathimath Limya, Health Quality & Safety Compliance Analyst, Quality Assurance and Regulations Division, Ministry of Health

Gulisthan Esa, General Nurse, Quality Assurance and Regulations Division, Ministry of Health

Huzaimath Shakir, SRN, ASMH

Haleemath Athiza, SRN, Sh. Kanditheemu Health Center

Khadheeja Abdul Majeed, CN, Fuahmmulah Hospital

Mariyam Zulfa, AEH

Mariyam Shifana Hussain, RN, MNA

Mariam Gasim, CN, KRH

Mariyam Huda, Director Nursing, ADK Hospital

Mariyam Sama, RN, Society for Health Education

Nasfa Ibrahim, SRN, IGMH

Sheereena Ahmed, Nursing Director, KRH

Sheela Mufeed, SRN, Fuahmmulah Hospital

Thasleema Usman, Commissioner of Quality Assurance, Ministry of Health

Thoiba Abdul Hakeem, Head Critical care Nursing, ADK

Working group members

Dr Fathimath Shifaza, Flinders University, South Australia, Adjunct EBPHC Maldives

Ms Aminath Zeeniya, Aasandha Company Limited

Ms Aishath Hamid, EBPHC Maldives.

DOCUMENT RECORD

Version No	Version Date	Description of change
1	19th May 2009	Initial release
2	9th May 2024	Second release

DOCUMENT NUMBER: **MOH-QA/S/24/167-0**

AUTHOR EBPHC Maldives

ENDORSED BY: Uza. Thasleema Usman
Commissioner of Quality Assurance

PUBLISHED BY: Ministry of Health in collaboration with WHO Maldives

Acknowledgement

Medication practice standards are crucial guidelines that ensure safe, effective, and responsible use of medications in healthcare settings. It also outlines accountabilities and responsibilities when performing all activities like, but not limited to storage, administration, dispensing, inventory management and safe disposal. These standards help reduce medication errors, adverse drug reactions, and other safety risks, ultimately safeguarding patient well-being and ensuring staff safety. Standardized medication practices facilitate communication and collaboration among healthcare team members, including physicians, nurses, pharmacists, and other allied health professionals. Consistent practices will ensure that everyone involved in patient care understands their roles and responsibilities regarding medication management. Additionally, having a consistent reporting system and providing care based on guidelines can help prevent 75% of occurrence of harm in to hospitalized patients (Mohammed et al., 2022)

Compliance with medication practice standards demonstrates commitment to patient safety and quality of care, fostering trust and confidence among patients, their families, and the broader community. Patients are more likely to trust healthcare providers and institutions that adhere to recognized standards of practice. Updating and publishing these standards also bring about accountability of Ministry of Health to orient staff on these standards and conduct audits to ensure compliance.

I sincerely appreciate the ongoing support provided by the World health organization, throughout the development of this standard, I would like to acknowledge EBPHC Maldives For the scoping review and development of the current guideline. I also extend my gratitude to all stakeholders, individuals and my team at Quality Assurance and Regulatory Division of Ministry of Health who have contributed to the development of this standard.

The effectiveness of this standard hinges upon its adoption by healthcare professionals and stakeholders across both government and the public sector. I urge all health care professionals to use the standards for safety and quality of patient care.

Thasleema Usman

Commissioner of Quality Assurance

Abbreviations

ADR- Adverse Drug Reaction

AEH: Addu Equatorial Hospital

ASMH: Abdul Samadh Memorial Hospital

CN: Clinical Nurse

CPD: Continuing Professional Development

IGMH: Indira Ghandi Memorial Hospital

IMAC-Interim Medication Administration Chart

KRH: Kulhudhufushi Regional Hospital

LASA: Look-alike, sound-alike

MNA: Maldivian Nursing Association

MR- Medicine Reconciliation

MFDA: Maldives Food and Drug Authority

OPD: Outpatient Department

PFML-Patient Friendly Medication List

POM: Prescription Only Medicines

QI: Quality Improvement

SRN: Senior Registered Nurse

SA: Self- administration

SOP: Standard of Practice

WHO: World Health Organization

Glossary

For the purpose of this standard, the following terms are defined as stated below.

Adverse drug reaction (ADR) is defined as a noxious or unintended reaction to drug or agent which occurs at doses used in humans for prophylaxis, diagnosis, therapy or for the modification of physiological function. This excludes accidental/unintentional overdose (Coleman & Pontefract, 2016).

Patients: The people, patients or residents who benefit from registered nursing care. A patient may be an individual, a family, group, community, or population.

Controlled Drugs: medicines that can only be supplied by a pharmacist on prescription and are subject to tight restrictions because of their potential to produce addiction. These includes Buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone, talpentadol and pethidine (Yun et al., 2015).

Compound: means for the purpose of these guidelines, the extemporaneous preparation and supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need. The practice of compounding is classified in these guidelines as either simple or complex compounding. Unless otherwise stated, the guidance provided in these guidelines applies to both simple and complex compounding (Australian Commition on Safety and Quality in Healthcare, 2022; Pharmacy Board of Australia, 2017).

Simple compounding means the preparation and supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need. It routinely involves the compounding of products from formulations published in reputable reference (Australian Commition on Safety and Quality in Healthcare, 2022; Pharmacy Board of Australia, 2017).

Complex compounding means the preparation and supply of a single 'unit of issue' of a therapeutic product that is intended for supply for a specific patient and that requires or involves special competencies, equipment, processes or facilities. Examples are sterile preparations and preparations containing ingredients that pose an occupational health and safety hazard (such as cytotoxins or hormones), micro-dose single unit dosage forms containing less than 25mg (or up to 25 per cent by weight or volume) of active ingredient and sustained-release or other modified-release preparations (Pharmacy Board of Australia, 2017).

Cold chain management: the system of transporting and storing temperature-sensitive medicines and vaccines, within their defined temperature range at all times, from point of origin (manufacture) to point of administration, to ensure that the integrity of the product is maintained (Gogou et al., 2015).

Distribution: systematic and reliable delivery of medicines to all health care facilities (Pharmacy Board of Australia, 2017).

Guideline: a principle or criterion that guides or directs action. Guideline development emphasises using clear evidence from the existing literature, rather than expert opinion alone, as the basis for advisor materials (Nursing and Midwifery Board Ireland, 2020)

Healthcare Professional: professionals who are qualified by education and/or experience to provide health care and are practicing medical practitioners, dental practitioners, nurses, midwives, allied health professionals (Healthcare Professional Act, 2015).

High-risk medicines: Are those medicines that have a high risk of causing significant patient harm or death when used in error. Although errors may or may not be more common than with other medicines, the consequences of errors with these medicines can be more devastating (Pharmacy Board of Australia, 2017).

Interval frequencies: are hourly frequencies such as 4 hourly, 6 hourly, 8 hourly.

Medication: In this document, medication refers to all scheduled drugs, over the counter medication, blood and blood products, biologics, vaccines, and natural health products (Department of Health, 2020) .

Medicines Management: Medicines management covers a number of tasks including prescribing, ordering, dispensing, receiving/transporting, storing, assessing, preparing, assisting, administering, disposing and reviewing individuals with their medicines (Nursing and Midwifery Board Ireland, 2020; Pharmacy Board of Australia, 2017).

Medication Reconciliation: A process for obtaining and documenting a complete and accurate list of a patient's current medicines upon admission and comparing this list to the prescriber's admission, transfer and/or discharge orders to identify and resolve discrepancies(Stark et al., 2020).

Near Miss: An event, situation, or error that took place but was captured before reaching the patient (Institute for Safe Medication Practices, 2009).

Over the counter medications: Medications that can be sold without prescription (Department of Health, 2020).

Omission: failure to do something, especially something that a person has a moral or legal obligation to do.

Procurement: purchasing medicines of reliable quality at economical prices (Stevenson, 2010).

Protocol: an established set of rules used to complete tasks or a set of tasks (Stevenson, 2010).

Scheduled frequencies are frequencies such as TWICE a day, THREE times a day.

Storage: the site/place and conditions under which medicines are kept until dispensing or administration (Pharmacy Board of Australia, 2017).

Scheduled medications include all maintenance doses administered according to a standard, repeated cycle of frequency (e.g., q4h, QID, TID, BID, daily, weekly, monthly, annually) (Australian Commition on Safety and Quality in Healthcare, 2022; Stark et al., 2020).

Self-administration: the independent use of a medication by a patient in a manner that supports the management and administration of their medications.

Time critical medicines are defined as medicines were early or delayed administration by more than 30 minutes from the prescribed time for administration may cause harm to the patient or compromise the therapeutic effect resulting in suboptimal therapy (Pharmacy Board of Australia, 2017).

Introduction

Within the framework of healthcare, medications stand as an integral component, playing a vital role in the prevention and treatment of illnesses, enhancement of life quality, and overall extension of life expectancy (World Health Organization, 2017). The responsibility for ensuring the judicious use of medicine rests on healthcare professionals, who actively influence treatment decisions, communicate effectively with patients, and collaborate with fellow healthcare practitioners. Despite the significant benefits of medications, challenges arise at various stages, from prescription to dispensing and administration, introducing potential risks to individuals (Wood, 2020). The consequences of unsafe medication management extend to both patient and healthcare system levels, manifesting in injuries, therapy failure, exacerbated illnesses, increased healthcare service utilization, and substantial financial burdens (Ahern et al., 2014; Hwabejire et al., 2013; Panagioti et al., 2019). Hence to mitigate this increased patient safety risk, healthcare experts recommend the use of medication standards to ensure that clinicians safely prescribe, dispense, and administer appropriate medications and monitor their use of them. It is also intended to ensure that patients are informed about medicines and empowered to achieve the best practices in medication management through the implementation of proven and sustainable strategies integrated across all health settings. Since 2017, medication safety in transitions of patient care has become a key priority area for the third WHO's Global Patient Safety Challenge 'medication without harm'(Olsen & Sletvold, 2022). Moreover, medication safety is central to the WHOs Global Patient Safety Action Plan 2021–2030, where the goal is to achieve the maximum possible reduction in avoidable harm due to unsafe healthcare(World Health Organization, 2020).

This document serves as a comprehensive guide, addressing a wide spectrum of aspects related to medications, from their development and manufacturing to distribution, prescription, and administration. By outlining standardized protocols and criteria, the National Medication Standard Document aims to harmonize practices across the healthcare system, fostering consistency and accountability.

Key features of the National Medication Standard Document include:

- **Quality Assurance:** Establishing benchmarks for the quality of pharmaceutical ingredients, manufacturing processes, and finished products to guarantee the safety and efficacy of medications.
- **Regulatory Compliance:** Providing a framework for compliance with national regulations, ensuring that all stakeholders in the medication supply chain adhere to legal requirements and industry best practices.
- **Safety Protocols:** Outlining safety standards and protocols for the prescription, dispensing, and administration of medications to minimize adverse events and enhance patient safety.
- **Interoperability:** Promoting compatibility and interoperability between different healthcare systems, allowing for seamless information exchange and coordination in medication management.
- **Innovation and Research:** Encouraging advancements in medication development by incorporating provisions for research, development, and the introduction of novel therapies while maintaining a robust regulatory oversight.
- **Education and Training**: Facilitating the continuous education and training of healthcare professionals to ensure a knowledgeable workforce capable of implementing and adhering to the established standards.

  These standards always apply to all regulated members regardless of role or practice setting and are specific to medication management. The standards are grounded to code of ethics in Health Professionals Act HPA.

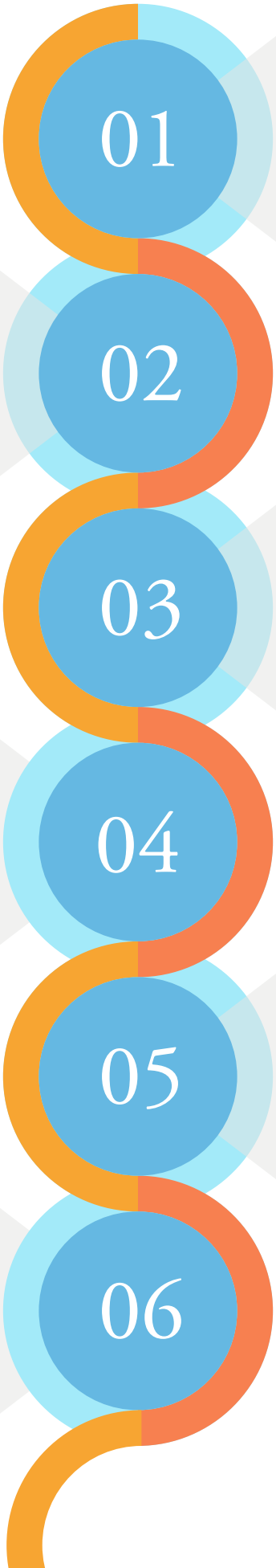
Methodology

A scoping review was conducted in accordance with the JBI methodology (Peters et al., 2017) for scoping reviews to assess the national standards worldwide. An initial draft of the Maldives national medication standard was developed and an online and face-to-face Delphi study was used to reach consensus between a panel of stakeholders. The Delphi technique involves an iterative process in which respondents anonymously respond to questions or items in an attempt to reach a group consensus (Barrett & Heale, 2020).

Standards

These standards identify the expectations for regulated members for medication management. The criteria in the following standards illustrate how the regulated member must meet the standard, and all criteria must be met to achieve the standard. It is e criteria are not written in order of importance.

Maldives National Medication Practice Standard



01 Clinical governance and application of quality improvement systems

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- Quality improvement systems

02 Standardised processes for prescribing, admisnistering and monotoring medicines

- Prescribing
- Verbal/Telephone Orders
- Administering
- Monitoring medication
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03 Safe preparation, dispersing, storing & disposal of medication

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04 Shared Decicion making & partnering with consumers

- Shared Decision making
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- Medication reconciliation
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06 Professional responsibility and accountability

- Scope of practice
- Responsibility
- Accountability

Standard 1 : Clinical governance and application of quality improvement systems

1.1 Criteria: Quality improvement systems
1.2 Criteria: Governing body

Clinical governance is an integrated set of leadership behaviours, policies, procedures, responsibilities, relationships, planning, monitoring and improvement mechanisms that are implemented to support safe, quality clinical care and good clinical outcomes for each patient.

1.1 Criteria: Quality improvement systems

1.1.1 Use of shelf reminders, checklists, and alerts. These should be built into information technology systems where possible in all the healthcare services.

1.1.2 Low-level risk-reduction strategies (i.e. staff education and information) should be used together with high-leverage risk-reduction strategies, such as forcing functions and fail safes (such as limiting access or use, constraints, barriers or standardisation.

1.1.3 A regular review of incidents and near-misses and the use of prospective analysis and re-design of systems to prevent recurrence of the same errors.

1.1.4 Pharmacists who compound products must have appropriate risk management processes in place to manage risks associated with the compounded product and the workplace (for maintenance of facilities, quality assurance of products including microbial testing, occupational health and safety adherence, professional indemnity insurance arrangements, etc.).

1.1.5 Conduct routine audits of medication management practices to ensure safe and effective care for patients.

1.1.6 The healthcare service to develop an information system to collect and review data related to medication practices for improvement.

1.2 Criteria: Governing body

1.2.1 The healthcare service sets up and uses clinical governance systems to improve the safety and quality of healthcare for patients and uses its systems to support the workforce to address and mitigate clinical safety risks.

1.2.2 The healthcare service has processes to support its workforce to understand and fulfill their assigned safety and quality roles and responsibilities.

1.2.3 Develop clear roles and responsibilities for clinical governance within the health care service. Number of people who fill these roles depends on the size of the service. (In a health center or small clinic- One person can fulfill all of these roles, while atoll hospital few people can fill all of these roles).

- Patients - participate as partners to the extent that they choose. This can be about their health care, and in service design and governance.

- Healthcare professionals: Work within, and are supported by, well designed clinical systems to deliver safe, high-quality clinical care. Healthcare providers are responsible for the safety and quality of their own professional practice and codes of conduct.

- Managers: Are primarily responsible for ensuring that the systems that support the delivery of health care are well-designed and perform effectively. Where managers are not owners, they advise and inform the owners/ governing body, and operate the service within the agreed strategic and policy parameters.

- Governing body: Are ultimately responsible for ensuring the service is well run and delivers safe, high-quality health care. They do this by establishing a strong safety culture through an effective clinical governance system, satisfying themselves that this system operates effectively, and ensuring there is an ongoing focus on quality improvement.

1.2.4 The healthcare service provides its workforce with orientation and training for their safety and quality roles on commencement with the service when safety and quality responsibilities change and when new healthcare services are introduced.

Standard 2 : Standardised processes for prescribing, administering, and monitoring medicines.

2.1 Criteria: Prescribing

2.1.1 Accurate patient weight should be documented on the medication chart for all patients.

2.1.2 The route of administration for the medicine must be clearly identified. The use of multiple routes of administration in one prescription should be avoided for the same medicine (for example, intravenous paracetamol / oral paracetamol)

2.1.3 Where required, the strengths of medicines must be clearly visible in terms of the dosage unit or dose per volume of liquid, for example, mg per ml.

2.1.4 Dose adjustments must be considered when prescribing a high-risk medicine for patient groups such as overweight or underweight patients, and patients with existing clinical conditions (such as renal or hepatic impairment) that may affect drug metabolism and excretion.

2.1.5 Therapeutic guidelines should be followed for medicines where dosing is complex and the duration of therapy substantially increases the risk of toxicity, for example, aminoglycosides.

2.1.6 When prescribing IV antibiotics, use hourly (known as interval) frequencies (e.g., 6 hourly), rather than scheduled frequencies (e.g. FOUR times a day). This will reduce the risk of additional, unintended doses being scheduled and the nurses having to do extensive rescheduling.

2.1.7 Local health service policy/ guidelines will outline when nurses can initiate medicines and will specify a limitation on nurse-initiated medicines such as “for one dose only” or “for a maximum of 24 hours only”. Generally, the capacity applies to a limited list of medicines only. Typically, this includes simple analgesics, aperients, antacids, cough suppressants, sublingual nitrates, inhaled bronchodilators, artificial tears, sodium chloride 0.9% flush, or IV infusion to keep IV-line(s) patent as per local policy.

List of Standard Abbreviation to be used in a prescription

Once Daily	OD
Night	HS
Twice a day	BD
Three times a day	TDS
	8hrly
Four times a day	QID
	6hrly
Every hourly	QH
Every two hourly	Q2H
Every three hourly	Q3H
As needed	SOS
Immediate	STAT

2.2 Criteria: Verbal/Telephone Orders

2.2.1 Only an authorized health care professionals (i.e., doctor, registered nurse, CHW) can take telephone orders.

2.2.2 Local Health service policy/guidelines will outline whether telephone orders are allowed and under what circumstances they are to be used.

2.2.3 Verbal orders should not be given to administer an unprescribed medicine, except in an emergency.

2.2.4 When recording a verbal/telephone order, the following must be documented:

- 2.2.4.1 date and time prescribed
- 2.2.4.2 generic name of medicine
- 2.2.4.3 route of administration
- 2.2.4.4 dose to be administered.
- 2.2.4.5 frequency medicine is to be administered.
- 2.2.4.6 initials of two healthcare practitioners to confirm the verbal order heard and double-checked.
- 2.2.4.7 - name of the doctor giving verbal order
- 2.2.4.8 - time of administration
- 2.2.4.9 - initials of person who administers the medicine

2.2.5 Authentic electronic mail orders and orders given through telemedicine can be accepted (text messages from prescriber's mobile phone should not be accepted). However, verification must be made whenever necessary.

2.2.6 Faxed and printed email orders should be filed in patient's charts.

2.2.7 The prescriber should confirm the order by signing in the patient's chart as soon as possible and not later than 6 hours.

2.3 Criteria: Administering

2.3.1 The healthcare practitioner administering the medication should review the patient's medication chart before administering the medication to the patient.

2.3.2 Healthcare professionals administering any medicine should have current knowledge of indication, mechanism of action, dosage, precautions, contraindications, interactions with food or other medicines, and side effects of the medication.

2.3.3 All healthcare professionals administering medicines should have knowledge of and skills if using any equipment for administering medicine (eg. nebulisers, infusion pumps etc).

2.3.4 Medicines should be scheduled so that medicine is administered on the same times each day and doses are spaced appropriately so that medicine levels are stable. When a new medicine is started outside the regime, then a stat dose can be given.

2.3.5 All healthcare services ensure policies should outline standardized medication administration times to accommodate the timing of meals, minimize disturbances to night sleep of the patient (last dose any scheduled medications should not be later than 10 pm) and to eliminate the need for individual interpretation of when the medications should be given.

2.3.6 Exceptions to standard drug administration times may be appropriate for patients who self-administer chronic medications, stagger numerous piggyback IV medications, or keep a time-critical chronic medication on the same schedule used before admission. (While it may seem best to try to keep patients who take any type of chronic medication on the same administration schedule they were using at home, medication administration throughout the day during nonstandard times is prone to omissions; thus, administration during standard times is recommended. QID medicines should be given at 6 am, 12 pm, 6 pm, and 10 pm. TID medicines should be given at 6 am, 2 pm and 10 pm. BID medicines should be given at 6 am and 6 pm or 8 am and 8 pm. These times should also be used in transcribing.

2.3.7 The healthcare practitioner writing the order must enter the frequency and administration time(s) when writing the medication order. Time should be entered using the 24-clock (this nomenclature is the global standard).

2.3.8 Disposable syringes must not be reused, single-dose vials should not be used for multiple dosages, and a new syringe must be used each time to draw medication from a multi-dose vial (Limya, 2020).

Morning	OD	0800			
Night	HS			1800 or 2000	
Twice a day	bd	0800		2000	
Three times a day	tds	0800	1400	2000	
*Antibiotics 6 hourly	6hrly	0600	1200	1800	2400
Antibiotics 8 hourly	8hrly	0800	1400	2200	
Four times a day	qid	0600	1200	1800	2200

Adapted from Australian Commission on Safety and Quality in Health Care(Australian Commision on Safety and Quality in Healthcare, 2019)

Recommendation is that all medication needs to be administrated by 2200hrs

2.3.9 Health services should also define targeted timeframes for administering first doses and loading doses of key medications, such as IV anti-infective agents, IV anticoagulants, and IV antiepileptic medications, where timeliness is critical (e.g., an emergency department patient with suspected sepsis should not wait several hours for the administration of a prescribed anti-infective). The targeted timeframes for first or loading doses of medications should be accompanied by procedures that facilitate achievement of the administration time goals.

2.3.10 Health services establish procedures for healthcare practitioners to follow if the administration of a time-critical scheduled medication will be or has been delayed or administered early beyond allowable expectations.

This procedure should include:

- prescriber notification when an adverse outcome is anticipated or has occurred
- documentation in the patient's chart regarding the reason administration of the dose was early or delayed, and
- evaluation of the need to change the timing of future doses.

2.4 Criteria: Monitoring medication

An essential component of the medication process related to the administration of medications is monitoring and assessing the patient by healthcare practitioners.

2.4.1 Patient should be monitored after medicine administration in accordance with local protocols and guidelines.

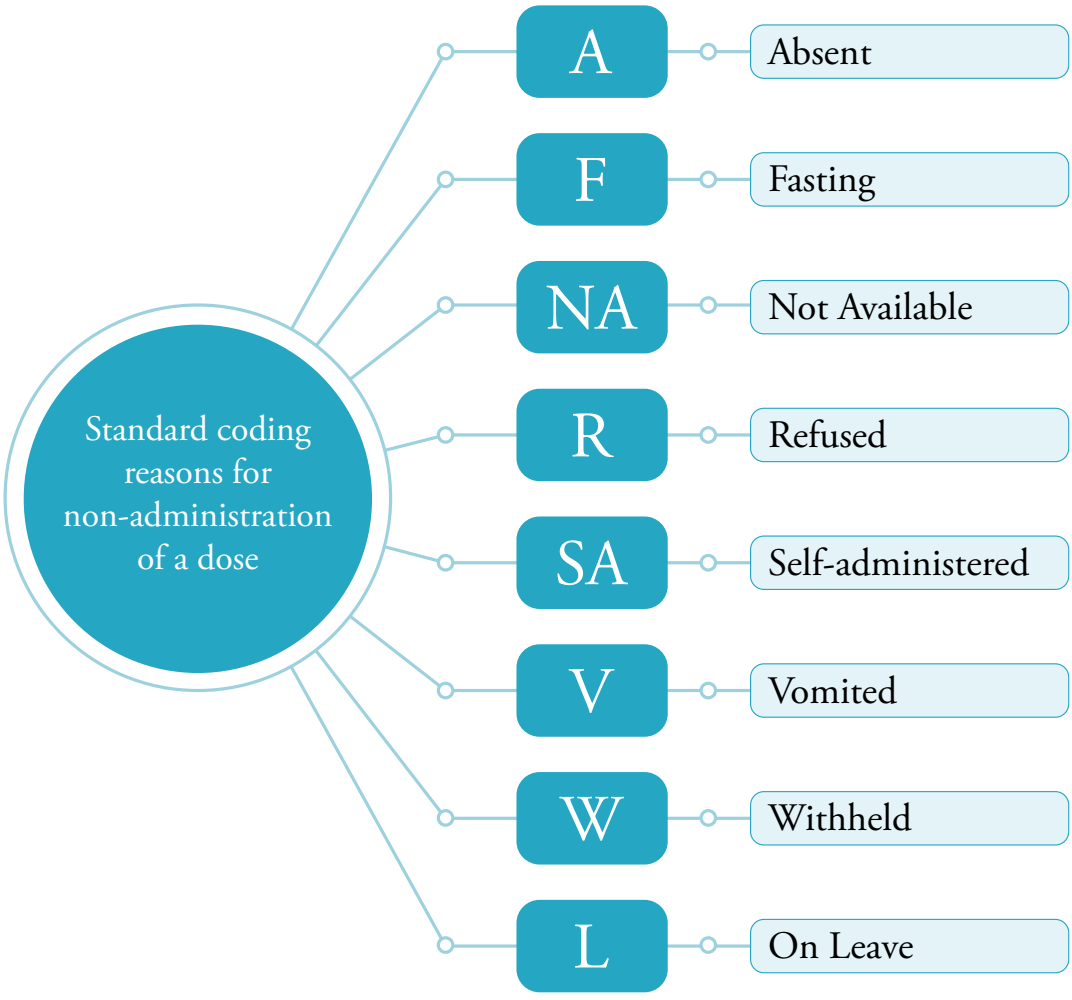
2.4.2 Health care Practitioners should be alerted in clinical handover to the use of any high-risk medicines.

2.4.3 The health service practice should develop processes for managing high-risk, high-alert medications and Look-alike, sound-alike (LASA) medications.

2.4.4 In case of an adverse drug reaction, emergency medicines and equipment should be easily available.

2.5 Criteria: Documentation

2.5.1 In the event of non-administration of a medicine, standard abbreviations must be used consistently and circled to avoid confusion between the code and practitioner's initial (See Figure 1). A blank record provides no information about the reason for non-administration but may also indicate that the medicine was given but not signed. It is recommended that the reason for non-administration is documented and communicated in the notes.



Standard coding reasons for non-administration of a dose

Code	Explanation	Action
A Absent	The patient is temporarily away from the ward due to reasons such as undergoing diagnostic tests, procedures, or treatments, or in cases where the patient is unaccounted for or has left the ward.	Administer delayed dose if possible; record the time. Verify next scheduled medication time and administer it before the patient leaves for scheduled procedures, tests, or treatments, including dialysis. Inform patients of their regular medication times and encourage presence in the ward during these periods.
F Fasting	The patient is fasting for a procedure or surgery.	Prescriber guidance (e.g., from an anaesthetist/ treating doctor) is essential to determine medicines for fasting, fasting duration, and therapy resumption. An anesthetist team may create a local guidance document for fasting patients. Document and communicate directions. This is not a preventable omission unless the dose was intended to be given even during fasting. *Fasting should not be confused with or considered the same as "nil by mouth." Use "Withheld (W)" coding when "nil by mouth" applies briefly; otherwise, relevant oral prescriptions should be canceled by, or at the direction of, the prescriber.
NA Not Available	the required medication is inaccessible for administration or use.	Pharmacy: Maintain stock and supply of approved medicines. For out-of-stock items, make alternative arrangements, communicate with prescribers and wards about the situation. Nurse: obtain ward supply if possible. Contact the prescriber if necessary. Document and communicate actions in the notes. Commence appropriate therapy once the stock is obtained.
R Refused	Patient refusing to take a regular medication	Document the patient's refusal to take their regular medication in the medical records, including the reason provided by the patient if applicable. Notify the attending healthcare provider and discuss alternative options with the patient, such as further education on the importance of the medication, potential side effects, or alternative treatment options.
SA Self-administered	This code is utilized to signify when a patient has independently taken a medication.	During the hospitalization, it is crucial to highlight that nursing/midwifery staff must observe and approve all medication administrations.
V Vomited	Vomiting code is used to indicate both before (unable to take) and after (dose not absorbed) medication dosing omission.	Apply the vomiting code to indicate medication dosing omission, capturing instances both before (due to inability to take) and after (due to non-absorption) administration. Top of Form
W Withheld	Used when there is a clinical reason to withhold a dose	withholding the dose should be documented and communicated to the prescriber as soon as practicable.
L On Leave	when the patient has approved leave from hospital for a day	Assign an 'L' code when a patient has approved leave from the hospital for a day or a week, as medication administration is not observed during this period.

Hospitals should provide clear guidelines about the appropriate actions to be taken when a medicine is not administered within the accepted period of tolerance.

2.5.2 Health Service should provide clear guidelines about the appropriate actions to be taken when a medicine is not administered within the accepted period of tolerance.

2.5.3 If there is any change in the patient treatment plan, the reason for this change and the person(s) notified should be documented.

2.5.4 All aspects of controlled drug administration should be recorded properly in the patient chart and then countersigned.

2.5.5 Documentation should be stored in a safe, systematic and secure manner that allows timely and accurate retrieval, while reducing the risk of unauthorised access and failure of confidentiality. All documents must be securely stored in accordance with professional standards and relevant legislation.

Standard 3 : Safe preparation, dispensing, storing & disposal of medication.

Selection, procurement and distribution of medicines should be done based on the most current or updated National Medicine Policy to ensure safe, effective, affordable and good quality medicines are readily available for dispensing and administration.

3.1 Criteria: Preparation

3.1.1 Healthcare practitioners needs to be vigilant when preparing medications (avoid distractions and interruptions).

3.1.2 Healthcare practitioners needs to be diligent in all medication calculations.

3.2 compounding

3.2.1 In preparing a compounded medicine, a corresponding formulation in a reputable reference should be used by the pharmacist when available (refer to Reference texts and other sources of information relevant to compounding in these guidelines for examples of reputable references).

3.2.2

3.2.2.1 A compounded medicine should be prepared only in circumstances where:

3.2.2.2 an appropriate commercial product is unavailable.

3.2.2.3 a commercial product is unsuitable (e.g., if a patient experienced an allergy to an excipient in the commercial product), or

3.2.2.4 when undertaking research sanctioned by a recognised National Health Research Council.

3.2.2.5 Pharmacists entering the profession are expected to have had the appropriate education and training to compound medicines and are deemed competent to undertake 'simple compounding'. Simple compounding may routinely involve compounding products using other formulations for which information confirming quality, stability, safety, efficacy and rationality is available.

When pharmacists extend their scope of practice to include complex compounding, they must be able to demonstrate that they have met the requirements of the Continuing Professional Development (CPD) registration standard by maintaining evidence of the CPD activities they have done to achieve competence to undertake complex compounding.

3.3 Criteria: Dispensing

3.3.1 Medicines should be dispensed only by a qualified and authorized pharmacist at the proper time.

3.3.2 The dispensers should have the knowledge, skill and judgment to dispense the medicine safely, effectively and ethically.

3.3.3 All orders must be reviewed for appropriateness before a medicine is dispensed. Medicine order evaluation includes interactions, allergies, and contraindications.

3.3.4 If any problem is identified with the medicine order, it should be communicated with the prescriber and resolved before the medicine is dispensed.

3.3.5 Dispensing for inpatients, discharges and outpatients complies with all legislative, professional and best practice requirements for dispensing.

3.3.6 Dispensing should be involve.

- Receiving and reading the prescription
- Selecting the drug to dispense
- Checking expiry date
- Label the product clearly and appropriately with name, proper route, dosage, for how long to take, and also the expiry date.
- Completing a final check for accuracy

3.3.7 Such requirements include:

- Identification of patient using approved identifiers (3 points of identification required)
- Labeling and relevant cautionary advisory label requirements (for discharge and outpatients) to optimise the correct medication storage, handling and administration.
- Maintenance of patient privacy/confidentiality.
- Barcode scanning of dispensing label and original pack to ensure the correct selection of medication, strength, brand, and dose form as per each label. This safety check is carried out for all inpatient, outpatient and discharge medications, where possible.
- Barcode scanning does not identify all errors, so a manual check must also occur.
- In the absence of barcode scanning capability, a manual verification process is required.
- An independent accuracy check of prescriptions dispensed by a pharmacist.
- Provision of medication information at an appropriate level of patients' and/or staff's knowledge.
- Provision of a patient friendly medication list and other administration charts, e.g., complex dosing chart, interim medication administration chart, where appropriate.

3.4 Criteria: Storing

3.4.1 All essential medicines should be routinely stocked and stored in their original packaging to render protection to the medicine and to retain information regarding batch numbers and expiry dates.

3.4.2 Guidelines for proper and safe storage of medicines should be available in all places, such as healthcare facilities and pharmacies.

3.4.3 All conditions necessary to maintain the stability of medicines should be followed when storing medicines. These conditions include appropriate temperature, and humidity and prevent exposure to harmful light. Pharmacists' advice should be sought in identifying these conditions.

3.4.4 The cold chain should be maintained during all aspects of vaccine storage. Vaccines should not be stored in the door, in the bottom drawers, or adjacent to the freezer plate of refrigerators

3.4.5 Healthcare service ensure that refrigerators (or cool rooms) of adequate size are available for the exclusive storage of vaccines or medicines that require storage between 2 ºC and 8 ºC.

3.4.6 Medicine stock should be replenished so as not to hinder availability for dispensing or administration of medicine.

3.4.7 To minimize medication errors, look-alike and sound alike medicines should be stored separately.

3.4.8 Perform a risk assessment of the processes in place for the handling, storage and distribution of medicines using validated or locally endorsed audit and risk tools.

3.4.9 Once a medication is prepared for administration but not administered, it should be considered as a stored medicine until administration.

3.4.10 Medicines stored in the wards, especially medicines in the emergency trolley, should be in the readiest to- administer form.

3.4.11 Health care facility's/pharmacy's policies should be followed in storing controlled drugs.

3.5 Criteria: High risk medications

3.5.1 A healthcare service that prescribes, stores, supplies and/or administers medicines has processes to:

- Identify high-risk medicines within the service (see table 1)
- Any alterations or additions to the High-Risk Medicine Register require endorsement from the Ministry of Health.
- Safely store, prescribe, supply, administer and dispose of high-risk medicines.

	High-Risk Medicine Groups
A	Anti-infectives
P	Potassium and other electrolytes
I	Insulin
N	Narcotics and other sedatives
C	Chemotherapeutic agents
H	Heparin and anticoagulants
other	High-risk medicines identified at a unit level which do not fit the above categories

3.5.2 Each high-risk medicine included on the High-Risk Medicine Register along with its associated individual standard will be assigned a maximum 2-year review date.

3.6 Criteria: Medication Safety Committee & High-Risk Medicines Register

3.6.1 The Medication Safety Committee in the healthcare service will be responsible for maintaining the High-Risk Medicine Register and ensuring risk reduction strategies are effective.

3.6.2 The High-Risk Medicines Register and individual high-risk medicine standards will be made easily accessible to all staff involved in the management of medicines via the Policy and Guidance Documents Register on the intranet.

3.6.3 Each medicine on the high-risk medicines register will be subjected to a comprehensive risk assessment to reduce the risk of errors that can occur across all phases of the medicine.

3.7 Controlled Drugs

3.7.1 All controlled drugs are exclusively imported through STO. The Ministry of Health collaborates with STO and the Narcotic Control Board to formulate the annual national demands for controlled substances, which are then submitted to NCB (Narcotics Control Board). NCB notifies the Ministry of Health based on these requirements, and subsequent authorization for the importation of controlled substances is granted to STO.

3.7.2 Every establishment handling controlled drugs must adhere to storage guidelines outlined by the MFDA. This ensures that the stocked drugs are securely maintained on the premises, minimizing accessibility to individuals likely to misappropriate them. The security measures implemented should meet the MFDA standards to protect both the controlled substances and the personnel working within the establishment(Ministry of Health).

3.7.3 Maintain accurate records of controlled drugs as per MFDA guidelines, regularly cross-check stock records, retain blue prescriptions quarterly, and keep all related records for at least two years.

3.7.4 The handling of controlled drugs must adhere to the guidelines provided by MDFA.

3.8 Criteria: Disposing

3.8.1 All healthcare services implement policies, procedures, and guidelines for the disposal of unused, unwanted, or expired medicines.

38.2 Controlled drugs are legislated to be destroyed by an authorized health practitioner and witnessed by a second authorized healthcare practitioner in accordance with MFDA (Ministry of Health).

3.8.3 Controlled drug waste waiting to be destroyed must be kept secure in a safe, separated from other medicines in the safe, clearly marked for destruction, and may only be removed immediately before destruction or being transferred for destruction.

3.8.4 Every healthcare facility should have designated personnel responsible for notifying the Ministry of Health if controlled drugs expire or are withheld from use for any reason.

3.8.5 Upon closure or cessation of operations, the pharmacy must dispose of or transfer all records, files, and drug stock in compliance with the directives provided by the Ministry of Health.

3.8.6 Pharmacies and healthcare facilities across the islands should forward lists of expired controlled drugs to the nearby regional hospital or health center.|

3.8.7 Healthcare facilities handling cytotoxic drugs must:

3.8.7.1 Establish and label specific color-coded bins or use recognizable symbols (e.g., purple) for disposing of cytotoxic drugs, ensuring clear identification in areas where these drugs are handled.

3.8.7.2 Ensure easy accessibility and strategic placement of these designated bins or symbols in preparation, administration, and waste generation areas, complying with safety standards.

3.8.7.3 Provide training to staff for proper identification and exclusive use of these bins or symbols for cytotoxic drug waste, along with regular awareness programs.

3.8.7.4 Conduct routine inspections and audits to monitor compliance, promptly rectifying any deviations from standard procedures.

3.8.7.5 Uphold this standard to guarantee safe disposal practices and review it periodically to align with evolving regulatory requirements.

Clinical outcomes and patient satisfaction are likely to be better when decisions about medicines are made jointly between the person taking the medicine and the prescriber (shared decision making)(Montori et al., 2017; Stiggelbout et al., 2012).

4.1 Criteria: Shared Decision making

4.1.1 All service providers (such as hospitals, clinics, and pharmacies) ensure that people are allowed to be involved in making decisions about their medicines in partnership with professionals who prescribe medicines.

4.1.2 Healthcare professionals (such as prescribers, and pharmacists) ensure that people are allowed to be involved in making decisions about their medicines. For example, healthcare professionals can use patient decision aids to support shared decision-making and they should ensure that people who take medicines have information about the potential benefits and harms.

4.1.3 Healthcare professionals should take account of a person's values and preferences by discussing what is important to them about treating or managing their condition(s) and their medicines.

4.1.4 Address concerns of problematic polypharmacy with the client, the inter-professional team, and the authorized prescriber or most responsible healthcare practitioner.

4.2 Criteria: Partnering with patients

4.2.1 Ministry of Health provides guidance and resources to health services to support them to become more person-centered in the context of National Quality and Safety Standards.

4.2.2 The healthcare service has processes for healthcare providers to partner with patients and/or their substitute decision-maker to plan, communicate, set, and review goals, make decisions, and document their preferences about their current and future healthcare.

4.2.3 Healthcare service fosters partnerships with patients, carers, and families, promoting active patient involvement, while professionals communicate tailored information addressing patient needs, preferences, and ongoing healthcare requirements.

4.2.4 The healthcare service collaborates with patients, carers, and families to incorporate their views and experiences into service planning, design, monitoring, and evaluation while providing information on services, hours, costs, feedback mechanisms, and contact details for healthcare complaints.

4.2.5 If a patient questions or expresses concern regarding a medication, stop and explore the patient's concerns, review the doctor's order, and, if necessary, notify the practitioner in charge. If the issue is not resolved, the patient could notify MFDA.

Medication reconciliation means that the medicines the patient should be prescribed match those that are prescribed. Transition points of care are particularly prone to unintended changes in medication regimes and other medication errors.

5.1 Criteria: Medication reconciliation

5.1.1 All registered healthcare practitioners involved in Medicine Reconciliation (MR) are responsible and accountable for the accuracy and quality of information provided to support the medicine reconciliation process at a given point in time.

5.1.2 Each organisation ensures that each healthcare practitioner involved with medicine reconciliation meets minimum education and training requirements every year. Learnings from the measures are incorporated into ongoing implementation and education and training requirements.

5.1.3 An all-encompassing staff training initiative is regarded as one of the essential elements contributing to the success of medication reconciliation.

5.1.4 Training should prioritize two fundamental aspects: the method of conducting patient interviews to construct accurate and comprehensive best possible medication histories, and the development of critical thinking skills needed for effective medication reconciliation(World Health Organization, 2014).

5.1.5 The healthcare practitioner compares the collected medicines, allergies and ADR list against the prescribed information, such as the medication chart, identifying and documenting any discrepancies.

5.1.6 Adopt a standardised form for collecting pre-admission medicines and reconciling variances.

5.1.7 At each transition point all changes that have occurred to the patient's medicines, allergies and ADR list will be documented, dated, and communicated to ensure the care of the patient is continued.

5.1.8 Establish specific time frames within which medicines should be reconciled for all patients (< 24 hours, within 4 hours for high-risk medicines) of admission, transfer, and discharge.

5.1.9 Provide clinicians ready access to drug information and a pharmacist consult when needed

5.1.10 Patients should comprehend the significance of engaging in medication reconciliation by:

5.1.10.1 Maintaining an updated medication list or bringing their medications during hospital admission, preadmission visits, or outpatient appointments, presenting this list to healthcare providers during each encounter. This can be facilitated through educational materials and tools designed to assist patients in independently managing their medication lists. The Medication Reconciliation SOP Implementation Guide offers examples of educational resources and tools to involve patients effectively

5.1.10.2 Advocating for themselves by voicing concerns if they suspect an error has occurred with their medications.

5.1.11 When transferring a patient from one facility to another the following must be included with the transfer documents

5.1.11.1 A copy of all current medication charts

5.1.11.2 A completed transfer summary with the key elements relating to medications that are applicable to the discharge summary.

5.2 Criteria: Adverse drug reaction

5.2.1 The healthcare practitioner collects the most accurate list of medicines, allergies, and adverse drug reactions (ADRs) using a minimum of two source types.

5.2.2 The healthcare practitioner must elicit, and document known medicine allergies and ADRs experienced by a patient before their current admission.

5.2.3 Organizational policies, procedures, and guidelines on recording known medication allergies must be available and up to date. These documents should:

- Identify the healthcare practitioner responsible for recording information on known drug allergies and ADRs. (Patients may be more familiar with the term allergy, than ADR, so this may be a better prompt).
- Provide a clear outline of information needed (for example, type of reaction, severity, and how it was managed)
- Describe where and when it is appropriate to record a known allergy or adverse reaction to substances other than medicines, such as food, in the patient's medicine allergy and ADR history.

5.2.4 Provide orientation, training, and education to healthcare practitioners, and review the work practices for:

- Documenting known drug allergies and ADRs in the patient's ADR history
- Referring to a patient's medicine allergy/ADR history before, or at the point of, decision-making when prescribing, dispensing, or administering medicines.

5.2.5 Conduct audits of medicine allergies and ADRs and provide information to healthcare practitioners through medication safety bulletins, in-service orientation sessions, case reports, or grand rounds.

Standard 6 : Professional responsibility and accountability

6.1 Criteria: Scope of practice

6.1.1 The healthcare service has processes to ensure that healthcare providers have the qualifications, knowledge and skills required to perform their role by:

6.1.1.1 Describing the scope of clinical practice for healthcare providers practicing in the healthcare service

6.1.1.2 Monitoring healthcare providers' practices to ensure they are operating within their designated scope of clinical practice.

6.1.1.3 Reviewing healthcare providers' scope of clinical practice when a clinical service, procedure or technology is introduced or substantially altered.

6.2 Criteria: Responsibility & Accountability

Healthcare professionals must:

6.2.1 act within the law and adhere to Maldives Food and Drug Authority standards and professional guidance when administering medicines to patients. It is expected that all nurses and midwives have current nursing registration and licensing.

6.2.2 comply with local policies, protocols, guidelines and standards for high-risk medicines.

6.2.3 be knowledgeable about the therapeutic effects and side effects of the medication, its interactions with food or other medications, and contraindications indication, mechanism of action, dosage, precautions, and contraindications.

6.2.4 be knowledgeable about the medications they administer and those that their clients are taking, whether prescribed, over the counter, or natural health products.

6.2.5 work together with individuals and/or their carers to prevent and/or manage risks, incidents and adverse reactions associated with medicine use.

6.2.6 the knowledge, skill, and competence to recommend an appropriate over-the-counter medication in accordance with employer requirements.

6.2.7 should recognize their level of competence in relation to medication administration and take measures to develop their competence.

6.2.8 are expected to honor patients' rights and autonomy during the informed consent process, acknowledging their right to refuse medication. The decision to withhold a medication may be made by the nurse or midwife, guided by specific clinical rationale(s).

6.3 Nurturing Trusting Patient Relationships and Ensuring Safety

6.3.1 Healthcare professionals should establish and maintain trusting relationships with patients

6.3.2 Prompt reporting of any medication-related errors, whether actual or potential, is imperative. Immediate corrective action must be taken.

6.3.3 Healthcare professionals should exercise professional judgment responsibly when asked to disclose confidential information about patients or administered medications.

6.3.4 Honest and truthful information and guidance must be provided to patients, families, or legal guardians. Communication should be tailored to the age and cognitive ability of the recipient.

6.3.5 In the event of an adverse occurrence, nurses and midwives are obligated to prioritize patient safety. This involves promptly monitoring the patient's health status and taking necessary actions to minimize or prevent further harm.

Recommendations

Safe preparation, dispensing, storing & disposal of medication.

1. Medication errors are significantly influenced by similar-looking or sounding drug names, ambiguous labels, and indistinct packaging. Implementing clear labeling and employing unit-dose systems in hospitals can notably decrease the occurrence of these errors.

2. Healthcare organisations to develop no-interruption zone policy for safe preparation and administration of medication.

3. Healthcare organisations ensure that specific recommendations for the safe procurement and storage of anaesthetic medicines are included in any policies, procedures, or protocols, to minimise risks from these medicines.

4. Evaluate the use and implementation of storage or delivery systems for safety, quality, and security risks.

5. Ensure that policies, procedures and protocols for safe handling, storage and distribution of medicines are evidence based and comply with legislative requirements.

6. Perform audits of compliance with policies, procedures and protocols for handling, storage, and distribution of medicines. Consider temperature-sensitive medicines and safety controls, such as separating look-alike packaging or electronic alerts.

7. Develop guidance on effective processes to ensure the integrity of the cold chain that includes:

    - Audits of temperature control of storage facilities, including room temperature, refrigeration, and frozen storage
    - Regular testing and maintenance schedules for temperature alarms and temperature recording devices
    - Transportation or transfer of temperature-sensitive medicines between storage areas or facilities
    - Workforce orientation and training on cold chain management
    - Action required in the event of a cold chain breach or temperature excursion.

8. Install alarms to monitor refrigerators and cold rooms, as well as medicine storage areas (including pharmacy departments), where temperatures would ideally be maintained below 25 °C (according to the manufacturer's instructions)

9. Health services ensures ADR Alert stickers are available.

10. Establish systems for identifying, reporting, and learning from medicines-related patient safety incidents.

    - Organisations should support a person-centred, 'fair blame' culture that encourages reporting and learning from medicines-related patient safety incidents.
    - Health care practitioners should explain to patients, and their family members or carers where appropriate, how to identify and report medicines-related patient safety incidents.

Medication reconciliation:

11. In an hospital setting, accurately list all the person's medicines (including prescribed, over-the-counter and complementary medicines) and carry out medicine's reconciliation within 24 hours or sooner if clinically necessary, when the person moves from one care setting to another – for example, if they are admitted to hospital.

12. All health care settings should ensure that a designated healthcare professional has overall organisational responsibility for the medicine's reconciliation process. The process should be determined locally and include:

    - organisational responsibilities
    - responsibilities of healthcare practitioners involved in the process (including who they are accountable to)
    - individual training and competency needs.

13. Organisations should ensure that medicines reconciliation is carried out by a trained and competent health professional – ideally a pharmacist, pharmacy technician, nurse or doctor – with the necessary knowledge, skills and expertise including:

    a. effective communication skills
    b. technical knowledge of processes for managing medicines
    c. therapeutic knowledge of medicines uses.

14. Health Clinics or small hospitals that are part of a local health network or private hospital group should adopt or adapt and use the established process for documenting a patient's history of medicine allergies and ADRs, as a component of past medical history.

15. In outpatients' departments (OPD) or clinics, healthcare professionals must elicitelicit, and document known medicine allergies and ADRs experienced by a patient before their admission.

16. Organisations should consider involving a pharmacist with relevant clinical knowledge and skills when making strategic decisions about medicines use or when developing care pathways that involve medicines use.

17. Ministry of Health to develop a tool kit that provide information, resources and quality improvement (QI) tools for managers and clinicians to improve Med Rec in health services.

18. Ministry of Health to collate a High-Risk Medication Register.

Partnering with Patients

19. Support people to be partners in their own care by promoting shared decision making, improving health literacy, and developing information about safety and quality for patients and patients, particularly for people with vulnerabilities.

20. Communicate with patients in a way that supports effective partnerships and shared decision making, to the extent that the patient chooses.

21. Patients can play a vital role in preventing medication errors when they have been encouraged to ask questions and seek answers about their medications.

Documentation

22. National standard medication charts should be introduced to healthcare facilities to improve the safe use of medicines. The charts support the delivery of appropriate care for hospitalised patients to help communicate information consistently between clinicians on the intended use of medicines for an individual patient.

23. National standard medication charts can be adapted into different versions for adults

24. Healthcare professionals are advised to use clinical discretion and consideration of the circumstances for individual patients when using the charts for patient medication management in acute care settings.

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