National Medication

PRACTICE STANDARDS

Maldivian Nurses Association
Male', Republic of Maldives

World Health Organisation

Ministry of Health & Family
Male', Republic of Maldives

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From the authors

We would like to express our sincere thanks to Maldivian Nurses' Association for giving us this opportunity to write the National Medication Practice Standard and to World Health Organization for funding the venture.

Heartfelt gratitude is extended to all the participants who took time out on a holiday to attend the workshop and provide their valuable contributions. The management of Ministry of Health and Family, Department of Medical Services, Medical Council, Nursing Council, Faculty of Health Sciences, Indhira Gandhi Memorial Hospital, HUlhumale' Hospital, Male' Health Centre, Villingili Health Centre, Thalasaemia Centre, Kulhudhuffushi Regional Hospital, Muli Regional Hospital, Gan Regional Hospital, Thinadhoo Regional Hospital and Hithadhoo Regional Hospital are included in this gratitude for all the managerial support given in ensuring the participants' presence in the workshop.

Special appreciation goes to Ms. Aishath Samiya and Ms. Aishath Shirna Shafeeq for all the help provide throughout the whole phase of writing this document.

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Foreword

The Ministry of Health & Family (MOHF) places great emphasis on ensuring that health care services provided to Maldivians are safe and of high quality. This can be achieved through well developed standards of care including necessary protocols, practice guideline and relevant training to health staff. Given the high risk to patients from potential medication safety issues, through the funding assistance from World Health Organization (WHO), in June 2008 we had initiated the development of a national standard for safe medication practices.

I am pleased that we are publishing the first national standard for medication practices in the Maldives. I would like to congratulate all those who have made this publication a reality. I take this opportunity to profoundly thank WHO for their continuous commitment to support initiatives to improve and develop our health care system. This project was outsourced to the Maldivian Nurses Association and I would like to congratulate them for their valuable input and dedication to develop this standard. I convey my sincere gratitude to the senior management of MOHF and the relevant staff from Planning & Policy Division of MOHF for their dedicated efforts in facilitating the compilation of this publication. This national standard is planned to be reviewed every 3 years and published with amendments.

I hope that health care professionals and health care administrators will use this national standard in their areas of work to improve medication practices in the private and public health care services in the Maldives.

Dr. Ibrahim Yasir Ahmed
Director General of Health Services
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The overall project management & coordination was carried out by the project team for 'Health Services Policy, planning & development/HSP' at the Policy Planning Division of the Ministry of Health & Family (MOHF). I wish to convey special thanks to Ms. Aishath Shirna Shafeeq for acting as the MOHF focal point in communicating and coordinating project work with all the stakeholders.

This standard was developed by the knowledgeable & expert team of the Maldivian Nurses Association. We greatly appreciate the Maldivian Nurses Associations interest and commitment to developing this important national standard.

I hope that this national standard will act as a useful guide for health professionals in standardizing their medication practices and making health care services safer for patients in the Maldives.

May 19, 2009
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Abbreviations

BID	bis in die (2 times a day)
CHW	Community Health Worker
IGMH	Indhira Gandhi Memorial Hospital
MFDA	Maldives Food and Drug Authority
MO	Medical Officer
MOHF	Ministry of Health and Family
QID	quater in die (4 times a day)
STO	State Training Organization
TID	ter in die (3 times a day)

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Introduction

Medicine: any product considered a medicine including prescription medications, sample medications, herbal remedies, vitamins, nonprescription medications, vaccines, diagnostic and contrast agents, radioactive medications, respiratory therapy treatments, parenteral nutrient solutions, blood derivatives, intravenous solutions (with or without electrolytes and other drugs), oxygen and other medical gases.

Medication process: all steps related to medicines including selection, procurement, distribution, storage, transportation, disposal, ordering, transcribing, preparation/compounding, dispensing, administering, documenting, monitoring of effects, evaluation and quality assurance.

One of the critical components of patient care is safe, effective and ethical medication practice. The fact that medicines are the most frequently used therapeutic interventions for patients in any health care facility, highlights its importance. Furthermore, the general public expects to receive the right medicine at the right time under the right conditions (Armitage & Knapman, 2003). However, administration of medication is one of the high risk areas for any health professional making medication safety one of the most high priority areas in healthcare services (Yu, Nation & Dooley, 2005).

The medication process is a multidisciplinary process in regard to the many steps comprising it and the various categories of healthcare professionals involved in these steps. Many healthcare professionals such as general practitioners, specialists, consultants, nurses, pharmacists, community health workers and family health workers are all involved. The multidisciplinary aspect of the medication process is further enhanced as many non healthcare personnel are also involved in some of the steps in the medication process like in selection, procurement, distribution, transport, disposal, quality assurance etc.

Furthermore, the steps in the medication process involve more than just technical tasks. Competent medication administration requires the ability to assess the appropriateness of the medication for a particular patient. Evaluation of the appropriateness of a medication requires knowledge of the actions, interactions, side effects (including allergic reactions), usual dose, route and approved use, basic pharmacokinetics of the drug and the patient's response to it. Additionally, knowledge and skills are also needed in preparing the medicine according to directions, administering the medicine, monitoring the patient while administering the medication, appropriately intervening as necessary, evaluating the outcome of the medication on the patient's health status and documenting the process (Saskatchewan Registered Nurses' Association, 2007).

Armitage, G., Knapman, H., 2003. Adverse events in drug administration: A literature review. *Journal of Nursing Management*, [Online] 11, p. 130-140. Available at: http://web.ebscohost.com/ehost/pdf?vid=24&hid=106&sid=40ba399d-e8ae-4847-a557-374e4694425e%40SRCSM2 [Accessed 13 January 2009]

Yu, K.H, Nation, R.L., Dooley, M.J., 2005. Multiplicity of medication safety terms, definitions and functional meanings: when is enough. *Quartely Safe Health Care* [Online]14, p. 358-363. Available at: http://web.ebscohost.com/ehost/detail?vid=14&hid=7&sid=211fa632-2f3c-4804-9c42-20da3c8f0f52%40sessionmgr107&bdata=JnNpdGU9ZWhvc3QtbGl2ZQ%3d%3d#db=c8h&AN=2009117557 [Accessed 14 January 2009]

Saskatchewan Registered Nurses Association. 2007. Medication administration: Guidelines for registered nurses [Online] Available at: http://www.srna.org/nurse_resources/medication_admin.pdf [Accessed 14 January 2009]

These complexities in the medication process expose it to errors. Evidence shows that although medication errors can occur throughout the whole medication process, they occur most frequently during the prescribing and administering stages (Institute of Medicine, 2006). Contributing factors to medication errors include distractions, lack of focus, ambiguous and incomplete medication orders, incorrect dose calculations and failure to follow standard procedures (Pape et al, 2005). Additionally, there are system based causes of medication error as well as errors due to inadequate communication (JCAHO, 2007). Although no formal studies have been done, experiences and incidences shows that these hold true in the Maldivian context as well.

There is evidence to suggest that there is room for improvement in the medication process (Armitage & Knapman, 2003). Consensus from evidence is that medication practice standards is a key for reducing medication errors and an important aspect of quality improvement in patient care (JCAHO, 2007).

Unavailability of such a medication practice standards in Maldives may lead to gaps in patient care and make the medication process error prone. Therefore, establishing a National Medication Practice Standards is expected to improve the current situation in Maldives.

This document provides information to all healthcare professionals involved in all steps of the medication process at all levels of healthcare settings. Each standard includes elements of performance by which adherence to standards can be measured or evaluated. This document is intended to be used as a basis to develop the necessary policies and procedures necessary for safe and effective medication practices. This document will also serve as a guide on how to establish safe, effective and comprehensive medication practice policies, guidelines and procedures.

Institute of Medicine of the National Academics. Preventing medication errors, 2006. [Online]. Available at: http://www.nap.edu/webcast/webcast_detail.php?webcast_id=329 [Accessed 25 December 2008].

Pape, T. M. et al, 2005. Innovative approaches to reducing nurses' distraction during medication practices. *The Journal of Continuing Education in Nursing,* [Online]36(3), p.108-116. Available at: http://web.ebscohost.com/ehost/pdf?vid=8&hid=115&sid=211fa632-2f3c-4804-9c42-20da3c8f0f52%40sessionmgr107 [Accessed 14 January 2009]

Joint Commission on Accreditation of Healthcare Organizations (JCAHO). A guide to the Joint Commission's medication management standard, 2nd edition, 2008. [Online]. Available at: file:///C:/Documents%20settings/user.PC724357132466.000/My%20Documents/medication/Medication%20managment%20standards.htm#PPR3,M1 [Accessed 30 December 2008].

Armitage, G., Knapman, H., 2003. Adverse events in drug administration: A literature review. *Journal of Nursing Management*, [Online] 11, p. 130-140. Available at: http://web.ebscohost.com/ehost/pdf?vid=24&hid=106&sid=40ba399d-e8ae-4847-a557-374e4694425e%40SRCSM2 [Accessed 13 January 2009]

Aim

Develop National Medication Practice Standard to be used in the Maldivian health care system to decrease medication errors.

Objectives

- Explore the existing literature and research to identify medication practice standards and protocols used in other countries.
- Collect information from different levels of healthcare facilities in Maldives regarding medication policies and procedures currently being followed.
- Use these as guidelines to develop medication practice standards suitable for Maldives.
- Discuss, review and obtain feedback on the developed National Medication Practice Standards from stake holders and various categories of health care professionals working in health related areas and at all the levels of health care facilities.

Methodology

Initially an extensive literature search was carried out for journal articles and textbook information on existing medication practice standards of other countries such as United States of America (USA), United Kigndom (UK), Canada, and Australia. Aditionally, to search for information that would be more relevant to Maldivian context, journal articles from Pakistan and India were also looked into. Information on medication policies and guidelines currently being used in different healthcare facilities including Indhira Gandhi Memorial Hospital (IGMH), a regional hospital, an atoll hospital, State Training Organization (STO) pharmacy, Maldives Food and Drug Authority (MFDA), a private clinic and a private pharmacy were also collected.

After reviewing these, medication practice standards suitable for Maldives were developed. All the steps in the medication process including selection, procurement, distribution, storage, transportation, disposal, ordering, transcribing, preparation/ compounding, dispensing, administering, documenting, monitoring of effects, evaluation and quality assurance were analyzed in the process. Finally nine standards were developed and performance criteria for each standard were formulated.

Once the medication practice standards were developed a one day workshop was conducted with attendees from health related organizations, institutions and various healthcare facilities. Feedback and suggestions from this workshop was incorporated into the initial document to construct a final document.

This final document was handed over to Ministry of Health and Family for feedback. These feedback were again integrated into the document to produce the finished document. Before this document was finalized and submitted, the document was edited by a linguistic expert.

STANDARD 1:

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.

Performance criteria

Selection: choosing medicines appropriate for the Maldivian health context from products which have authorization for its marketing based on essentiality, quality, affordability, safety and efficacy.

Procurement: purchasing medicines of reliable quality at economical prices.

Distribution: systematic and reliable delivery of medicines to all health care facilities.

a) The most current or updated Maldivian National Medicine Policy, developed by Ministry of Health should be followed in selection, procurement and distribution of medicines.

b) List of medicines for procurement should be compiled after deliberations with experts in the field and pre-approved by the relevant authorities.

c) For each medicine in the list, its indication for use, effectiveness, risks for errors/abuse, strength, dosage form and cost should be included.

d) This list should be readily available to all personnel involved in the medication process.

e) This list should be reviewed and updated regularly as per National Medicine Policy, by an appointed group of experts.

f) A specific guideline should be established to handle medicine shortages.

STANDARD 2:

Proper safety measures should be followed in storing, during transportation and disposing of all medicines.

Performance criteria

Storage

Storage: the site/place and conditions under which medicines are kept until dispensing or administration.

a) All necessary medicines should be routinely stocked and stored.

b) All medicines should be stored in their original packaging to render protection to the medicine and to retain information regarding batch numbers and expiry dates.

c) Guidelines for proper and safe storage of medicines should be available in all places, such as health care facilities and pharmacies.

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

e) 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.

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

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

h) Periodic inspections should be carried out of all places where medicines are stocked and stored to ensure safe storage of medicines.

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

j) Medicines stored in the wards, especially medicines in the emergency trolley, should be in the most ready-to-administer form.

k) Health care facility's/pharmacy's policies should be followed in storing controlled substances.

l) Patients should be educated on the correct storage of medicines.

Storage of drugs in wards

a) All medicine trolleys, fridge and ward store room should be locked.

b) Controlled medicine cupboard key should be kept separately from the other keys.

c) The keys should be kept with the shift-in-charge or the senior most nurse on duty. These keys should never leave the ward.

d) If any of these keys are lost, it should be notified immediately and locks replaced as soon as possible.

e) If a fridge is used in wards to store medicines, food or other material should not be kept in these refrigerators.

f) Medicines should not be over stocked.

g) Stock rotation should be used to avoid wastage of medicines due to expired medicines.

h) Written policies should be in place for stock rotation between wards of the health care facility and should be followed accordingly.

i) If any medicines are identified as missing, this should be notified immediately and a decision should also be taken to whether police are to be notified as well.

Transportation

Transportation: carrying medicines from one place to another.

a) Guidelines for proper and safe transport of medicines should be available.

b) All conditions necessary to maintain the stability of medicines (ie. temperature, humidity, light) should be followed when transporting medicines.

c) Extra care should be taken during transportation of temperature sensitive medicines (eg. vaccines) and light sensitive medicines (eg. chemotherapy agents).

d) Cold chain should be maintained at all times during transportation of vaccines. Vaccines should be unpacked immediately after transportation and stored appropriately.

Disposal

Disposal: the way in which medicines are destroyed.

a) Maldives Food and Drug Authority Guidelines for proper and safe disposal of medicines should be available in all health care facilities and pharmacies.

b) All medicines for disposal (ie. all expired, contaminated, damaged and unusable medicines) should be isolated until disposal.

c) As soon as any medicine is identified as being unusable, it should be separated from other medicines.

d) If an unclear issue (such as questionable storage conditions that may have affected the medicine) is identified for any medicine, it should be further evaluated for effectiveness before disposal.

e) If a medicine is dropped and gets contaminated, it should be isolated for disposal. This should also be recorded in the patient file to account for all medicine prescribed.

f) Care must be taken in handling and disposing specific medicines which may cause harm to the person handling or disposing.

g) Dangerous/ harmful medicine spills (eg. spillage of chemotherapy agents) should be handled according to the health care facility's policies.

h) As specified in Maldives Food and Drug Authority Guidelines, in Male' medicines should be disposed in front of a designated staff of Maldives Food and Drug Authority.

i) In other islands, it should be disposed in front of a designated person of the health care facility, island office or island development committee.

j) For all disposed medicine, its brand name, generic name, dose, batch number, expiry date, amount and method of disposal should be documented in the appropriate form and filed, as per Maldives Food and Drug Authority Guidelines.

k) According to Maldives Food and Drug Authority Guidelines, medicines should be disposed according to the following:

- Medicines to be incinerated: antibiotics, vaccine, vitamins/minerals, cytotoxics, liquid vitamins, all other medicines
- Medicines to be buried: vitamins and minerals
- Medicines to be poured down the drain: liquid vitamins

STANDARD 3:

All medication orders should be clear, include appropriate medicines needed to treat the conditions of the patient and should be accurately transcribed.

Performance criteria

Medication orders (Prescriptions)

Order: an instruction or authorization regarding medicine(s) for a specific patient given by a prescriber.

Prescriber: a health personnel authorized to prescribe medicines. In Maldives prescribers include doctors and community health workers (CHWs) authorized by Ministry of Health and Family.

a) Medication orders should be legible.

b) Medication orders should include name of patient, hospital number and ward (if admitted), age and gender.

c) Medication orders should include, wherever possible, weight of patient so that drug and dosage could be double checked by the person dispensing the medication.

d) Medication orders should use the generic name of the medicine as far as possible, clearly state dose, frequency, route and duration.

e) Medication orders should be written in metric system except for medications that use standard unit (eg. Insulin).

f) Health care facilities should have written down policies with regard to acceptable abbreviations, symbols etc for all health personnel prescribing or administering medicines. Whenever possible, full name of the medication should be written and use of abbreviations should be avoided (eg. instead of writing mg or µg, write full form of milligrams or micrograms).

g) Prescribers should avoid fractions in writing dosage (1/2 can mean half or 1 of 2). Fractions should be written in words and strength should be stated.

h) Allergies to any medicine should be recorded on the medication order.

i) Medication orders should have clear specific instructions for health personnel administering the medication or for patient if taking medicines at home.

j) Medication orders should include the name, registration number and signature of the prescriber and should be dated.

k) Medicines should only be sold if the medication order is complete. Medication orders should at least have the patients name, age, gender, name of the medicine, dose, frequency, route, duration, name of the prescriber, registration number, signature of the prescriber and prescription date. If any information is missing, pharmacist or person dispensing should check with prescriber or ask patient to check with prescriber.

Verbal orders / Telephone orders (Emergency orders);

Verbal order: an order taken by an authorized health personnel from an authorized prescriber and written in the patient's chart as a verbal order.

Telephone order: is a verbal order that is taken from an authorized prescriber over the telephone.

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

b) Verbal and telephone orders should be accepted only when circumstances require doing so and if there are no other reasonable options.

c) Verbal orders should only be issued when a medicine is to be discontinued or when medicine is to be increased/decreased for a short period of time

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

e) The health personnel who receives the telephone order should have knowledge of patient condition and medication before accepting the order.

f) When recording a verbal/telephone order, the following should be followed:

- record the time and date on the order sheet.
- record the order given by the prescriber.
- counter check the order by a second person
- read the order back to the prescriber to confirm it is complete and accurate.
- record the authorized prescriber's name on the order sheet, state "telephone order from _____ (name of health professional)," print the name of the person receiving the order, sign the entry and identify status (e.g. registered nurse). The name and designation of the person who counter checked should also be included.

g) Verbal orders should be assessed for appropriateness for the patient in the particular situation.

h) 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.

i) Faxed and printed email orders should be filed in patients charts.

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

Standing orders

Standing orders: are treatment protocols that are routinely carried out if the patient fits certain diagnostic criteria or is admitted for specific treatment.

a) Protocols developed by the hospitals should be in the written form signed by appropriate senior medical personnel. These protocols should have sufficient detail on each medicine including medicine name, strength, dose, route, frequency of administration, indications, contraindications, any restrictions of categories of staff who may administer the medicine and any other necessary information.

b) The health personnel should put the signature after administering medication and the medical personnel should also confirm by putting signature within 24 hours.

Transcribing

Transcribing: to copy a medication order from the order form to a medication administration record/ patient medication chart.

a) Transcribing medicine orders should be done by a qualified health professional.

b) The transcriber will be responsible for the accuracy and completeness of the order when transcribing. A supervisor should be responsible for validation.

c) When scheduling, drug interactions and efficacy in relation to food should be considered if patient is on multiple regimes.

STANDARD 4:

All medicines should be prepared safely and dispensed effectively.

Performance criteria

Preparation/compounding

Compound: to mix a drug with one or more other ingredients.

a) Medications should be prepared safely without contamination.

b) The area used for medication preparation should be clean.

c) Appropriate equipment should be used for dilution of medicines.

d) After preparing medicines, eg. after drawing injection, it should be administered immediately. If it is not administered immediately, it should be appropriately labeled with medicine name, dose, patient name, bed number and time prepared, stored properly and administered as soon as possible.

Dispensing

Dispense: To supply medicine(s) according to an authorized prescription.

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

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

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

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

e) Dispensing should involve;

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

STANDARD 5:

All medicines should be safely administered.

Performance criteria

Administration: to give medicines to another individual orally or by another route.

a) Health personnel administering any medicine should have current knowledge on indication, mechanism of action, dosage, precautions, and contraindications, interactions with food or other medicines and side effects of the medication.

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

c) 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.

d) Health care facilities' policies should outline standardized medication administration times to accommodate the timing of meals, minimize disturbances to night sleep of the patient (last dose should not be later than 10 pm) and to eliminate the need for individual interpretation of when the medications should be given. 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 at 8 am and 8 pm. These times should also be used in transcribing.

e) The patient should be properly identified before any medicine is administered (asking name for conscious patients who can talk and asking parent/relative or checking from chart if patient unconscious, cannot talk or is a child).

f) The patient's medication chart should be checked to confirm that the medicine has not been administered yet.

g) For proper assessment before administering any medicine, all personnel administering medicines should have adequate information about the patient

(including history, any allergies, treatment plan). Time of last meal should also be noted.

h) If, for any reason medicines are withheld, the prescriber should be informed. If the prescriber is unavailable for consultation, the MO on duty should be consulted.

i) Proper dosage should be calculated prior to administration.

j) Pre-printed dosing charts (eg. calculated IV drops) should be available during medicine administration to prevent medication errors related to miscalculation of medicine dose.

k) Medicines should never be decanted prior to the medicine time and should always be removed from packaging only at time of administration.

l) Whenever a new medicine packet or bottle is opened, the date of opening should be recorded on the packet or bottle. Expiry date should also be included for medicines that have short expiry dates once opened (eg. ear or eye preparations).

m) All infusion solutions to which substances have been added should be accurately and adequately labeled. The label should include the patient's name, name and volume of IV fluid, name of medicine and dose added, date and time of addition, date and time to be discarded, name and signature of health personnel making addition and personnel checking.

n) The medicines should never be directly handled or touched during administration to prevent contamination. Medicine cups should be used.

o) Relevant information to patient and/or relatives regarding the medicines (name of medicine, related indication, common side effects including any major or special side effects) should be provided by appropriate health personnel (doctor, registered nurse and CHW) before administering any medicine.

p) Principles of infection prevention and control should be applied during administration of medicine.

q) Medicines should be administered only after ensuring medicines are stable, stored and labeled properly specially when they are reconstituted or mixed.

r) A new supply of medication should be obtained if there is any doubt about how medication has been kept.

s) The 8 rights of medicine administration should be confirmed, which include;

- right patient
- right medicine
- right reason
- right dose
- right time
- right frequency
- right route/site
- right documentation

t) 3 checks (checking before, during and after administration) should be carried out in administration of medicine.

u) A suitable environment should be available for medicine administration such as proper lighting, adequate temperature,etc. Noise level and distractions from telephone or other people should be minimal.

v) For admitted patients, all medicine should be taken in the presence of a health care professional.

w) Medicines ordered for one patient should not be administered to another patient.

x) Medicines should never be administered to restrain patient except only under special conditions.

y) Medicines should never be given to the patient to take later.

z) All personnel administering medicines should be careful of sound-alike, look-alike medicines.

aa) The same health personnel must perform all the steps of medicine administration (except in an emergency) to avoid or minimize medication errors.

Patients own medicines

a) For admitted patients, any medicine(s) the patient is already taking on admission, should only be administered if medication order is available with the patient and if medicine is labeled properly. These should be included in the patient's medicine chart (ie. if the patient is admitted all medicines should be included in the medicine chart).

b) Patient's medicines should not be disposed or destroyed without the patient's consent.

Patient refusal for medicine administration

a) Patient has the right to refuse medicine, and in such situations they should never be forced.

b) In these situations alternate ways should be identified to persuade patient to take medicine such as;

- finding out the reasons for refusal and trying to respect their reasons
- finding proper explanation of the indication and benefits
- gentle persuasion
- trying to administer the medicine at a later time, when patient is more settled/relaxed

c) If medicine has already been decanted, it should be isolated until proper disposal.

d) Even if after persuasion patient misses a single dose, prescriber should be informed.

e) All relevant information and actions taken should be recorded in the patient record.

f) Medicine should never be crushed or disguised to get around patient's refusal for medicine.

Covert administration of medicines

Covert administration of medicines: administering medicines to patient against his/her knowledge by disguising a dosage form in some way so that the patient is unaware of the administration

a) For patients' who actively refuse medicines considered essential for the patient's health and well being but who do not have the mental capacity to understand the consequences of their refusal, covert administration of medicines can be considered.

b) The decision to covertly administer medicines should not be routine and should be reached after in depth discussion among the relevant health personnel involved in the patient's care.

c) Even in such situations, patient should be encouraged to take their medicines.

Controlled drugs

Controlled drugs: include psychotropic and narcotics

a) Controlled drugs should be stored separately under lock, even if it belongs to patients and be removed from storage only at the time of administration.

b) Double prescription should be used in ordering controlled drugs.

c) When a controlled medicine is due, it should be signed and checked out of the controlled drug cupboard. This should be countersigned by another health personnel.

d) A separate register should be maintained for psychotropics and narcotic drugs. If contents of a drug container is not used at one time and need to be discarded or stored, details of this should be documented and counter signed.

e) This medicine should then be checked against the patient's treatment chart before administering.

f) Two appropriately trained health personnel should be involved in all steps of administering a controlled drug. One of them should witness the removal of drug from the cupboard, transfer to the patient, administration to the patient and discarding of any unused portion of the drug.

g) Report on these drugs should be sent to Maldives Food and Drug Authority every 3 months, as per their guidelines.

STANDARD 6:

All relevant information regarding the medication process should be timely and appropriately documented.

Performance criteria

Documentation: any written or electronically generated information about a patient that describes the care or service provided to that patient.

a) Documenting should be done by the appropriate health personnel who carried out the specific step in the medication process.

b) Record on patient chart immediately after administering medicine(s) or even if non-administered (due to unavailability of medicine, patient refusing or any other situation). Recording should never be done in advance or retrospectively.

c) Documentation of medicine administered should include patient name, medicine name, dose, route and/or site, date and time of administration, name and signature of health personnel administering the medicine.

d) Use of abbreviations and symbols that are error prone in recording on patient chart should be avoided.

e) If any dose is missed, this should be clearly recorded in the patient's chart and informed to the appropriate personnel as soon as possible.

f) When medications are withheld or omitted, the reasons for this should be documented.

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

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

STANDARD 7:

The effects of the medicines administered should be monitored closely and effectively.

Performance criteria

Monitor: watching patient attentively for effects of the medicine and any changes in patient condition.

Adverse drug reaction: undesirable physical reaction to the medicine.

a) Patient should be monitored after medicine administration.

b) Health personnel should have knowledge and skills to identify and properly manage adverse drug reactions.

c) If discharged with medications, on discharge, patients and/or relatives should be provided with a list of medicines and given appropriate information regarding these medications, including how to recognize any adverse drug reactions and actions to take in such a situation.

d) The hospital should develop processes for managing high risk or high alert medications.

e) Psychotropic and narcotics use should be monitored closely.

f) In case of an adverse drug reaction, emergency medicines and equipments should be easily available.

STANDARD 8:

Proper safety measures should be followed at all times to prevent medication errors.

Performance criteria

Medication errors: any preventable event that may cause or lead to inappropriate medication use or patient harm during the prescribing, ordering, processing, dispensing, administering and/or documenting phases of drug preparation and distribution.

A medication error occurs when:

- medicine ordered for one patient is given to another patient (wrong patient)
- the medicine administered is not the medicine prescribed or is the wrong form of the prescribed medicine (wrong medicine)
- the amount of the medicine administered is not the prescribed dose or rate of infusion, or is a contraindicated dose (wrong dose)
- the medicine is not given reasonably close to the time it was ordered (wrong time)
- the medicine is administered via an incorrect route (wrong route)
- the medicine is not appropriate to treat the patient's disease or symptoms (wrong reason)
- an ordered dose is not given (omission)
- the medicine is not documented or is documented incorrectly (wrong documentation).

a) Regular continuing education/ in-service sessions should be held to update on new findings on medication errors. All health personnel should know the following common causes of medication errors:

- lack of knowledge about the medicine by prescriber or health personnel administering it
- lack of readily available drug information
- failure to ensure the 8 rights and 3 checks of medication administration
- miscommunication among health personnel
- ambiguity in product names, appearance or packaging
- incomplete patient information
- unclear and confusing directions for use
- use of error-prone abbreviations
- transitions in care such as meal breaks
- heavy workload
- inadequate number of staff
- orders not transcribed accurately
- illegible and incomplete orders
- interruptions during the preparation or administration of medications
- pharmacy dispensing and labeling errors

b) Medicines that have a greater risk of causing significant harm when used in error, should be double checked and given more importance

c) Specific forms should be available to report all actual and potential medication errors.

d) A conducive and non-blaming environment should be provided for medication error reporting.

e) Guidelines to be followed in case of a medication error, such as procedure for disclosure of such events, identification and evaluation of actual and potential causes of errors for its analysis and recommendations

to prevent such errors in future etc. should be in place for quality improvement of the medication process and prevent medication errors.

f) Proper actions to be taken in case of a medication error should be identified and written as policies.

g) The condition under which the medication error occurred should be evaluated properly before taking any disciplinary action, to differentiate between errors due to human error or pressures of work or unsafe practice .

h) A database should be established for collection of information regarding medication errors.

When a medication error occurs;

a) All medication errors and near misses should be reported.

b) Nurse incharge and nursing shift supervisor should be informed immediately.

c) Physician/MO should be contacted to determine if any intervention is required.

d) Health care facility policies must outline guidelines for notifying the prescriber in the event of an adverse drug reaction or medication error.

e) The personnel who did the error and/or discovered the error should complete a medication error/incident reporting form and follow the guidelines for medication errors.

f) Medication incident reports should include the following details:

- name and title of the person discovering the error
- date, time, place and patient's name
- original medication order as written by prescriber
- identification of type of error – prescribing transcribing, dispensing, administering or documenting
- characteristics of the error – wrong patient, dose, drug, time, route
- factors contributing to the error – a brief explanation of the facts
- assessment data, including an evaluation of the patient's response/condition following the error

- names and titles of personnel or individuals involved in the error
- immediate action taken to safeguard the patient, with patient responses.

g) The medication error, personnel informed, assessment of patient condition and interventions taken (if any), should all be recorded in the patient's record.

h) The supervisor(s) of the personnel who did the error should assess the individual to identify whether she/ he needs further training, supervision or support.

STANDARD 9:

All health care facilities should have a Medication Quality Assuarance Committee to evaluate effectiveness of medication process and for quality assurance of the medication process.

Performance criteria

Evaluation: assessing all aspects related to medication process.

Quality assurance: a system for evaluating performance of the medication process.

Medication Quality Assuarance Committee: a responsible body to carry out evaluation and quality assurance of all aspects of the medication process. All health care facilities should have a Medication Quality Assuarance Committee.

a) The medication process should be evaluated routinely.

b) Risk prone points in the medication process should be identified and improvements made.

c) Literature should be continuously reviewed for the most recent best practices in medication processes.

d) Quality and cost-effective drug use should be promoted.

e) Analysis of medication incident reports should be carried out by the Medication Quality Assuarance Committee.

f) Strategies for medication error prevention as part of the health care facility's quality improvement program should be developed.

g) All relevant information related to medication process should be communicated throughout the health care facility.

h) Audits on medication ordering should be routinely carried out.

Recommendations

1. Carry out regular monitoring to ensure the quality of medicines imported into Maldives.
2. Strengthen rules in regard to selling medicines to only prescriptions which are legitimate and complete in regard to appropriate information of patient and medicine to be dispensed.
3. Establish a drug information system database so that health personnel prescribing, transcribing, dispensing or administering can look up information on drug indications, mechanism of action, dosage, precautions, and contraindications, interactions with food or other medicines and side effects of the medication.
4. Formulate policies on acceptable abbreviations, symbols etc for all health personnel prescribing or administering medicines.
5. Keep a drug formulary and dosing charts at the ward level (maybe in the drug trolley) to be checked whenever needed.
6. Make policies on how to handle spillage of dangerous or harmful medicines like chemotherapy agents.
7. All health care facilities should have a pharmacy and a qualified pharmacist who would be responsible to identify whether all appropriate investigations are being done to monitor effects of medicines (eg. creatinine levels).
8. In examining patients and writing medicine orders, there should be a separate record of patient's history and disease or condition related information and a separate record for medicine related orders.
9. Establish a mechanism for adverse drug reaction notification.
10. Introduce patient identification bands to all admitted patients.
11. Early reporting to the concerned authority if any health professional is found misusing a controlled drug.
12. Minimize problems related with difficulties in communication with expatriate staffs, by allocating one local nurse to be on duty in each shift.

13. Make Dhivehi language communication skills compulsory for all expatriate health personnel.

14. Conduct regular continuing education for health professionals on medication process.

15. Develop printed material for patients regarding effects and side effects of commonly used medicines.

16. Establish a Medicine Act.

17. Emphasize usage of National Medicine Policy.

18. Emphasize implementation of Maldives Food and Drug Authority Guidelines.

19. Establish a digital system for recording storage and disposal of medicines. This system can also be used as a reporting mechanism.

20. Identify the magnitude of medication errors in our current medication practices by using an appropriate method like a survey or a clinical audit.

21. Prepare and implement policies and specific guidelines to be followed in case of a medication error, such as forms for reporting of actual and potential medication errors, procedure for disclosure of such events, identification and evaluation of actual and potential causes of errors for its analysis and recommendations.

22. Develop a comprehensive database for collection of information on medication errors.

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