HANDLING HIGH RISK MEDICATION MODULE

Pharmaceutical Services Division

Ministry of Health Malaysia

Medication Safety Committee 2023
Pharmacy Practice and Development Division
Ministry of Health Malaysia

CONTENTS

1. Introduction to HAM
2. HAM Risk Reduction Strategies
3. Introduction to LASA
4. LASA Risk Reduction Strategies
5. Common Drugs Causing Severe Allergy reaction/ ADR

1

INTRODUCTION TO HAM

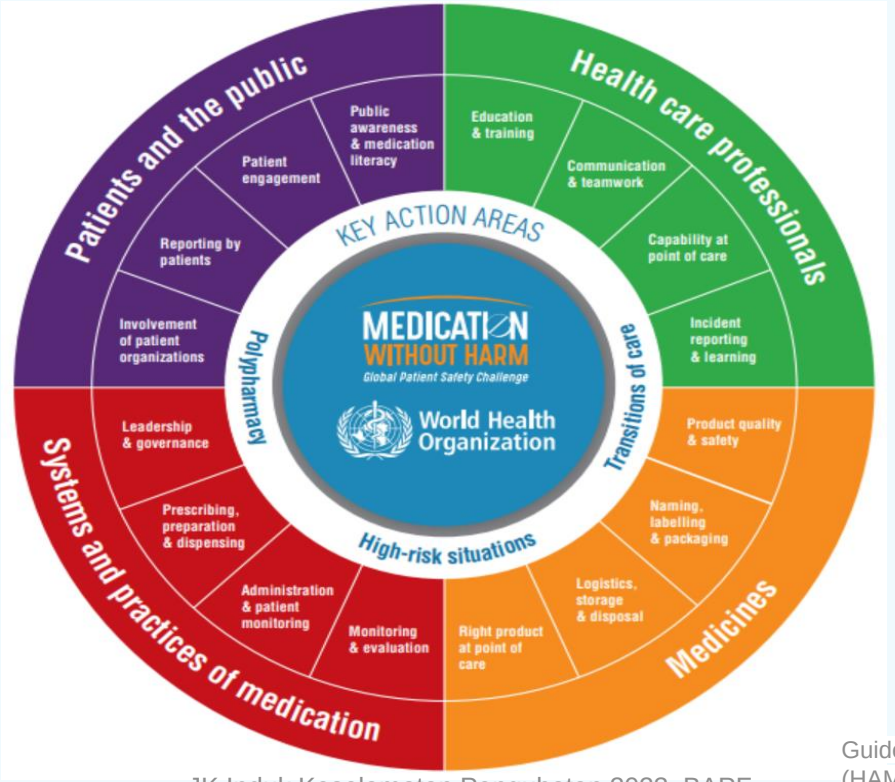
DEFINITION OF HAMs

Medications that bear a heightened risk of causing significant patient harm when these medications are used in error.

HAMs

- Medications identified in the list of HAMs may vary between healthcare settings.
- Specific high-risk medications list has been drawn up based on reported cases submitted to National Medication Error Reporting System (MERS).
- HAMs warrant special safeguards to reduce the risk of unnecessary patient harm associated with adverse medication events such as preventable medication errors.

4 DOMAINS THAT INFLUENCE SAFE USE OF HAMs



Guideline on Safe Use of High Alert Medications (HAMs) 2nd Edition (2020)

CATEGORIES OF HAMs

1. Adrenergic agonists, IV (e.g. adrenaline, phenylephrine, noradrenaline)
2. Adrenergic antagonists, IV (e.g. propranolol, labetalol)
3. Anaesthetic agents, general, inhaled and IV (e.g. propofol, ketamine)
4. Antiarrhythmics, IV (e.g. lignocaine (lidocaine), amiodarone)
5. Antithrombotic agents (e.g. warfarin, heparin, enoxaparin, dabigatran, rivaroxaban, apixaban, fondaparinux, tirofiban, tenecteplase)
6. Antivenom (e.g. sea snake, cobra, pit viper antivenom)
7. Chemotherapeutic agents, parenteral and oral

CATEGORIES OF HAMs

8. Epidural and intrathecal medications
9. Glyceryl Trinitrate Injection
10. Immunosuppressant agents (e.g. azathioprine, cyclosporine, tacrolimus)
11. Inotropic medications, IV (e.g. digoxin, dobutamine, dopamine)
12. Insulin, subcutaneous and IV
13. Magnesium sulfate injection
14. Moderate and minimal sedation agents, oral, for children (e.g. chloral hydrate, midazolam, ketamine [using the parenteral form])

CATEGORIES OF HAMs

15. Moderate sedation agents, IV (e.g. dexmedetomidine, midazolam, lorazepam)
16. Neuromuscular blocking agents (e.g. pancuronium, atracurium, rocuronium, vecuronium)
17. Opiods, including: • IV • oral (including liquid concentrates, immediate- and sustained-release formulation • transdermal
18. Oxytocin, IV
19. Parenteral Nutrition preparations

CATEGORIES OF HAMs

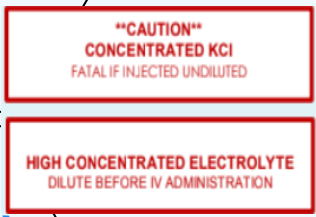
20. Potassium salt injections
21. Sodium Chloride for injection, hypertonic (greater than 0.9% concentration)
22. Dextrose, Hypertonic (20% or greater)

POTENTIAL HAMs

Potassium Chloride (KCL) Injection

Incorrect Preparation Of Drugs

- Develop a clear guideline for the use of KCl injection.
- Ensure complete prescribing information for KCl injection (e.g. 0.5 gram in 50ml NS over 1 hour)
- Add special label



Insulin

Look-alike sound-alike medication (Mixtard vs Insulatard, Insugen N vs Insugen R)

- Limit the variability of insulin in the facility.
- Add a cautionary label to differentiate the type of insulin.
- Spell out the word “units” instead of “U” (mistaken with “0”)

Guideline on Safe Use of High Alert Medications (HAMs) 2nd Edition (2020)

POTENTIAL HAMs

Lignocaine HCl (Lidocaine HCl) Injection

Confusion of strength, route of administration (IV vs IM), indication & preparation of medication

- Keep update different brand of lignocaine and the dilution.
- Read the labels/package insert before preparing the reconstitution/dilution.
- Perform independent countercheck on dosing ,infusion pump programming, concentration & dilution
- Add auxiliary label: 

or 

POTENTIAL HAMs

Chloral hydrate mixture

Prescribe/administer incorrect dose due to inaccurate body weight or incorrect calculation
Supply incorrect strength & Administer intravenously instead of orally

- Clearly label the medication:
  “FOR ORAL USE ONLY”
- The use of an oral syringe may help to reduce the incorrect route of administration of an oral medication into a vein.

JK Induk Keselamatan Pengubatan 2023, BAPF

Guideline on Safe Use of High Alert Medications (HAMs) 2nd Edition (2020)

POTENTIAL HAMs

Enoxaparin & Fondaparinux

- The dosage prescribed is not based on the patient's weight
- Inaccurate renal dose adjustment
- Look-alike packaging (40mg vs 60mg)
- Look-alike medication

Heparin

- The complexity of dosing regimen & monitoring
- Look-alike medication
- Availability of multiple strength

Warfarin

- The complexity of dosing regimen & monitoring
- Look-alike medication
- Availability of multiple strength

JK Induk Keselamatan Pengubatan 2023, BAPF

Guideline on Safe Use of High Alert Medications (HAMs) 2nd Edition (2020)

...RECOMMENDED STRATEGIES

- Develop a clear guideline & keep an up-to-date list of all available strengths of these medications in the facility.
- Standardize the baseline information, such as weight in kilograms and renal function, needed during the ordering of anticoagulants.
- Use Tall-man lettering and store look-alike medications separately.
- Be diligent in anticoagulant calculations.
- Using auxiliary labels or cautionary labels.
- Always practice counterchecking

Guideline on Safe Use of High Alert Medications (HAMs) 2nd Edition (2020)

POTENTIAL HAMs

Noradrenaline

- Inadequate knowledge of noradrenaline/ adrenaline calculation
- Inaccurate dose prescribed (e.g. 0.2mcg/hour instead of 0.2mcg/kg/min)
- Look-alike sound alike medication

Adrenaline

- Specify the dose, route and rate of infusion on the prescription.
- Prescribers must have proficient knowledge of the dose and potential side effects
- The correct medication, dose, route, and rate of infusion should be independently counter-checked by another healthcare personnel prior to administration.
- Using auxiliary labels or cautionary labels.

Guideline on Safe Use of High Alert Medications (HAMs) 2nd Edition (2020)

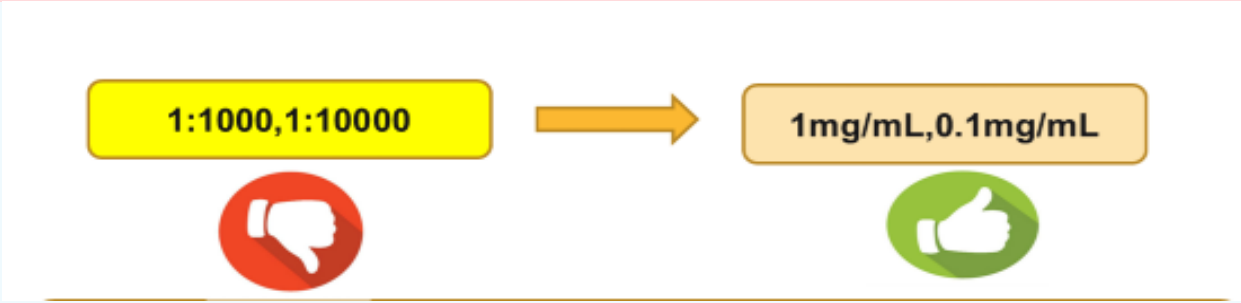
EXAMPLE OF INCIDENT

Wrong Dose of IV Adrenaline – Strength/ Unit
1. Patient went desaturated and asystole after IV Rocuronium was given prior to intubation.
2. Chest compression commenced and 4 intubations were attempted. IV Adrenaline was given between 3rd and 4th attempt of intubation.
3. Child was successfully reverted but noted she was hypertensive and tachycardic.
4. Noted that wrong dose of IV Adrenaline was given – pure IV Adrenaline 0.5mL (1:1000) instead of 1 in 10,000.

ISSUE: PRESCRIBING ADRENALINE INJECTION

According to ISMP, ratio expressions (1:1000 & 1:10,000) of adrenaline (epinephrine) concentrations are prohibited. Currently, the strength of Inj. Adrenaline available in mg/mL.

Therefore, adrenaline should be prescribed in mg/mL instead of ratio expressions. (ISMP, 2015)



ISMP 2015

2

HAM RISK REDUCTION STRATEGIES

SPECIAL CONSIDERATION IN USING HIGH ALERT MEDICATIONS

- Devastating consequences of errors associated with these medications.

Cohen, H., & Mandrack, M. M. (2002). Application of the 80/20 rule in safeguarding the use of high-alert medications. Critical Care Nursing Clinics, 14(4), 369-374.

COMMON RISK FACTORS ASSOCIATED WITH HAMs

1.	**Different routes of administration** Confusion between IM, IV, intrathecal, epidural preparations
2.	**Incorrect preparation of drug** Incorrect dilution, diluent, dose/strength or calculations
3.	**Misinterpretation of medications order** Use of abbreviations (“U” vs. “units”) and trailing zeros (5.0 vs. 50)
4.	**Wrong infusion rates** Miscalculation of infusion rates or incorrect infusion rate programmed on the infusion pumps

COMMON RISK FACTORS ASSOCIATED WITH HAMs

5.	**Look Alike Sound Alike** Look alike or sound alike product and similar packaging
6.	**Availability of products variation** Confusion of different strengths/ multiple formulations/ brands/ colours of the same drug
7.	**Ambiguous labelling** Unclear concentration and total volume information on the container/ syringe label

MANAGEMENT OF HAMs

Ensure safe handling of HAMs at all stages:

- Procurement
- Storage
- Prescribing
- Preparation
- Dispensing
- Administration
- Monitoring

MANAGEMENT OF HAM

01 List of HAMs

List of medications should be identified, updated and disseminated

02 Cautionary labels

HAMs to be labelled with cautionary stickers or designated envelopes.

03 Counterchecking

Verification by another healthcare professional prior to dispensing and administration

04 Safety Controls

Standardize drug dosing, use of oral syringes and computerized system for medication orders and documentation.

05 Monitoring

Monitor and report ADRs related to HAMs

MAIN PRINCIPLES TO SAFEGUARD THE USE OF HAMs

1. Reduce or eliminate the possibility of error

- Limit the number of high alert medications on the hospital/ health clinic drug formulary.
- Limit the concentration/ strength of medication available.

2. Make errors visible

- Having 2 individuals to counter check on the medications, calculations, preparations, administration etc.
- Practice 5 Rights – Know Your Medicines
  (Right patient, Right medication, Right dose, Right route, Right time)
- "Know, Check, Ask" before giving medications to the patient.

3. Minimize the consequences of error

- Stock high alert medications in smaller volume/ unit

OTHER COMMON RISK REDUCTION STRATEGIES

TALL-man Lettering

Use of TALL-man lettering to emphasize differences in medication names (e.g. DOBUTamine and DOPAmine)

Avoid Product Changes

Avoid frequent changes of brand or product strengths, notify changes (if any)

OTHER COMMON RISK REDUCTION STRATEGIES

Standardized Order Communication

Use standardized forms for written orders, verbal orders should be discouraged

Verbal orders (if unavoidable) must be verified and immediately documented and countersigned by the prescriber

Reduce Variation

Limit ward's floor stock medications - reduce quantity or variation in strengths/preparation where possible

Cohen, H., & Mandrack, M. M. (2002). Application of the 80/20 rule in safeguarding the use of high-alert medications. Critical Care Nursing Clinics, 14(4), 369-374.

OTHER COMMON RISK REDUCTION STRATEGIES

Avoid abbreviations	Accurate dosing	Medication labels	Safe administration
Do not use abbreviations and acronym.	Always take note of body weight (paediatrics) and body surface area (cytotoxic medications) to ensure dose accuracy	Diluted medications must be labelled with the name and strength of the preparation	No distraction during HAM drug administrations

Other things to consider:

- High alert medications dispensed to patient **do not require** HAM labels
- Keep antidotes and resuscitation equipments in wards/emergency room/units

Guideline on Safe Use of High Alert Medications (HAMs)
2nd Edition (2020)

RISK REDUCTION STRATEGIES IN HIGH-RISK POPULATION

Elderly

Paediatrics

Operation Theatres

RISK REDUCTION STRATEGIES IN CHILDREN

Child's weight should be recorded to avoid miscalculation

Use of correct measuring devices and proper dosing instructions

Dispense oral liquid medications with dose specified in milligrams

Always monitor for ADRs if administering high doses in children

How-to Guide: Prevent Harm from High-Alert Medications. Cambridge, MA: Institute for Healthcare Improvement; 2012. (Available at www.ihi.org).

RISK REDUCTION STRATEGIES IN ELDERLY

Hepatic/ Renal Impairment
affects metabolism of drugs

Comorbidities
Multiple comorbidity associated with increased risk of prescribing errors and patient safety incidents

Polypharmacy
Number of items prescribed are related to increased risk of medication errors

Predisposing Factors

Common Issues

Vancomycin rapid infusion
Higher risk of anaphylaxis in older population

Monitoring of ADRs
Always pay more attention for any adverse effects related to high-alert medications if they are given to older adults

Patient/ Caregiver Education
Family members/ caregivers should be counselled on 5 Rights Concept while taking HAM medications

How-to Guide: Prevent Harm from High-Alert Medications. Cambridge, MA: Institute for Healthcare Improvement; 2012. (Available at www.ihi.org).

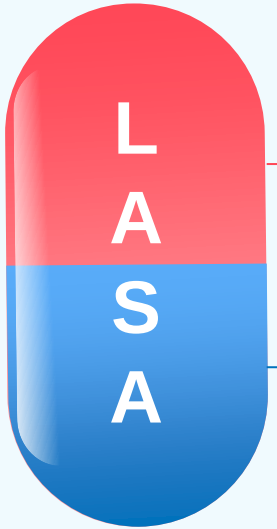
RISK REDUCTION STRATEGIES IN OPERATION ROOM

Safe use of anaesthesia
1. Avoid interruptions during preparing and administering medication
2. Staffs should be sufficiently rested in ORs
3. Cautionary labels on packages and storage bins of HAMs
4. Avoid look-alike sound-alive HAMs being placed next to each other
5. Label distal ends of all access lines to distinguish IV from epidural lines
6. Label distal ends of all access lines to distinguish IV from epidural lines
7. Medication on infusion pumps should be labelled and programmed correctly

How-to Guide: Prevent Harm from High-Alert Medications. Cambridge, MA: Institute for Healthcare Improvement; 2012. (Available at www.ihi.org).

INTRODUCTION TO LASA

LOOK ALIKE SOUND ALIKE MEDICATIONS



Similar physical appearance / packaging

Spelling similarities / similar phonetics

JK Induk Keselamatan Pengubatan 2023, BAPF

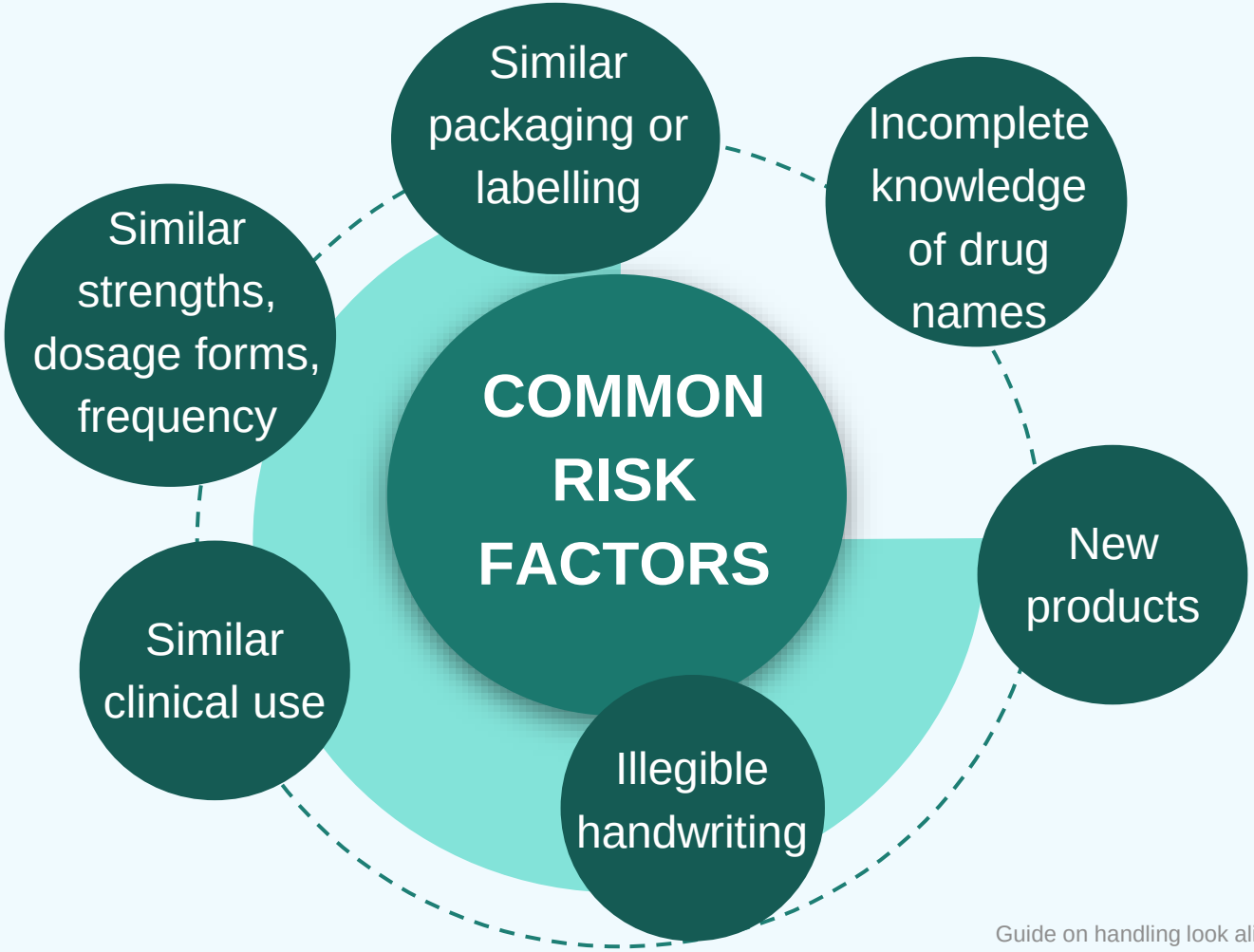
Guide on handling look alike, sound alike medications, 2012

LOOK ALIKE SOUND ALIKE MEDICATIONS

- More medicines and new brands are being marketed, many of these medications names may look or sound alike.
- Confusing medication names and similar product packaging may lead to potentially harmful medication errors.
- Approximately 6% of medication error were associated with look like or sound alike medications.
- Solutions to LASA errors can target people or systems.

JK Induk Keselamatan Pengubatan 2023, BAPF

Guide on handling look alike, sound alike medications, 2012



JK Induk Keselamatan Pengubatan 2023, BAPF

Guide on handling look alike, sound alike medications, 2012

EXAMPLES OF MEDICATIONS WITH SIMILAR LOOKING/ SOUNDING NAMES

Madopar	Methyldopa
Chlorpromazine	Carbamazepine
Cycloserine	Cyclosporine
Progyluton	Progynova
Cotrimoxazole	Clotrimazole

Amlodipine	Felodipine
Difflam	Daflon
Enalapril	Perindopril
Neurobion	Neurontin
Imipenem	Meropenem

JK Induk Keselamatan Pengubatan 2023, BAPF

Guide on handling look alike, sound alike medications, 2012

LASA RISK REDUCTION & STRATEGIES

STRATEGIES TO AVOID ERRORS WITH LASA MEDICATIONS

1. PROCUREMENT	2. STORAGE	3. PRESCRIBING
4. DISPENSING/ SUPPLY	5. ADMINISTRATION	6. MONITORING
7. INFORMATION	8. PATIENT EDUCATION	9. EVALUATION

JK Induk Keselamatan Pengubatan 2023, BAPF

Guide on handling look alike, sound alike medications, 2012

1. PROCUREMENT

i. Limit the medication strengths available in the formulary of each healthcare facility.

ii. Avoid frequent changes of brand or colour. Notify the end users whenever there are changes.

iii. Whenever possible, avoid purchase of medicines with similar packaging and appearance. As new products or packages are introduced, compare them with existing packaging.

2. STORAGE

i. Use Tall Man lettering to emphasize differences in medication name
e.g: cefOTAXime and cefTAZIDime

TALL-man lettering has the potential to reduce LASA errors in written/typed, but not spoken, communications, and it differentiates look-alike packaging.

Guide on handling look alike, sound alike medications, 2012

TALL-man lettering							
No	Medication	No	Medication	No	Medication	No	Medication
1	**ATRA**curium	13	**DOBUT**amine	25	**LO**sartan	37	**PANTO**prazole
2	**BISO**prolol	14	**DOXO**rubicin	26	**LOVA**statin	38	**PERINDO**pril
3	**BUPI**vacaine	15	**DOP**amine	27	met**FORMIN**	39	progy**LUTON**
4	car**BAMAZ**epine	16	Duph**ASTON**	28	**METO**prolol	40	Progy**NOVA**
5	car**BIM**azole	17	Duspa**TALIN**	29	**NE**ostigmine	41	Pro**SCAR**
6	cef**OTAXi**me	18	**ENALA**pril	30	Neuro**BION**	42	**PRO**zac
7	cef**TAZID**ime	19	**ESOME**prazole	31	Neuro**NTIN**	43	**RO**curonium
8	cef**TRIAX**one	20	**FORT**zaar	32	ni**FED**ipine	44	**ROPI**vacaine
9	chlorpro**MAZINE**	21	gli**BEN**clamide	33	ni**MOD**ipine	45	**SETRA**line
10	chlorpro**PAMIDE**	22	gli**CLA**zide	34	nitro**GLYCERIN**e	46	**STELLA**zine
11	**CO**zaar	23	**LANSO**prazole	35	nitro**PRUSSID**e	47	**VE**curonium
12	**DAUNO**rubicin	24	**LIGNO**caine	36	**PAN**curonium	48	vin**BLAS**tine

Guide on handling look alike, sound alike medications, 2012

2. STORAGE

ii. Use additional warning labels for look-alike medicines. Warning labels should be uniform throughout the respective facility to facilitate identification.

Guide on handling look alike, sound alike medications, 2012

2. STORAGE

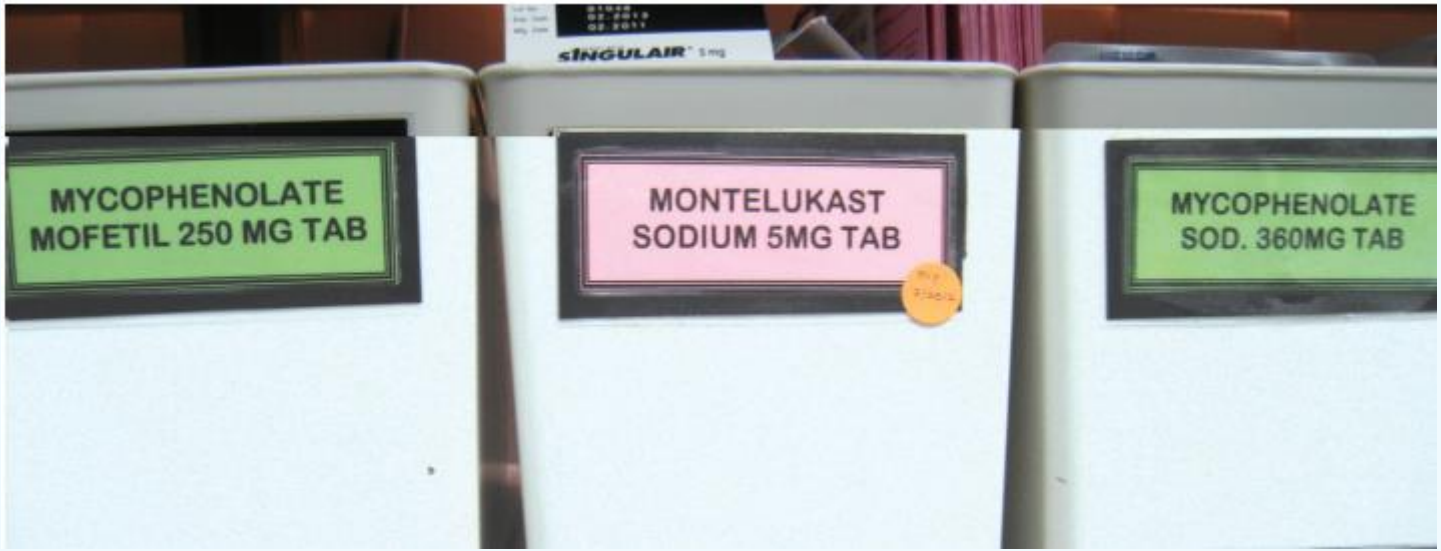
iii. For sound-alike medications where Tall Man lettering is not applicable, proprietary (brand or trademarked) names may be added to distinguish between the medications. The non-proprietary names should be in larger font size than the brand names.

JK Induk Keselamatan Pengubatan 2023, BAPF

Guide on handling look alike, sound alike medications, 2012

2. STORAGE

iv. Store LASA medications separately from their LASA pair. Whenever possible, avoid storing the products in immediate proximity to one another.



3. PRESCRIBING

Write legibly, write clearly whether on an in-patient order or on a prescription.

Include the diagnosis or medication's indication for use. This information helps to differentiate possible choices in illegible orders.

Communicate clearly. Take your time to pronouncing the drug name whenever an oral order has to be made. Ask that the recipient of the oral communication repeat the medication name and dose. Verbal orders should be limited to emergency situations only.

Computerized alerts can be introduced into software to alert the user to potential LASA medication pairs and to intercept LASA errors.

Prescription should clearly specify name of medication, dosage form, dose and complete direction for use.

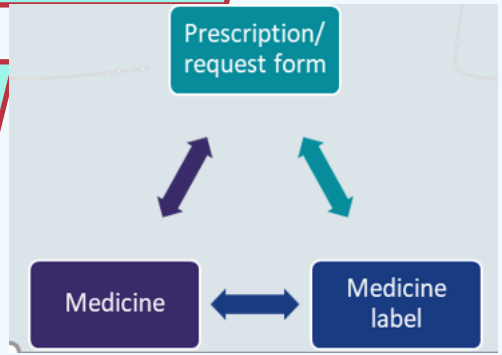
JK Induk Keselamatan Pengubatan 2023, BAPF

Guide on handling look alike, sound alike medications, 2012

4. DISPENSING

1. Identify medicines based on its name and strength and not by its appearance or location.

3. Read medication labels carefully at all dispensing stages and perform triangle check. Triangle check is to check actual medicines against the medicines' labels and against the prescription.



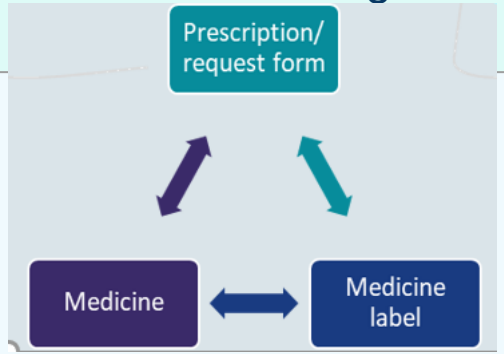
2. Check the appropriateness of dose for the medicines dispensed.

4. Double checking should be conducted during the dispensing and supply process.

Guide on handling look alike, sound alike medications, 2012

5. ADMINISTRATION

i. Emphasize the need to read labels rather than relying on visual recognition or location.
ii. Make read back clarification of verbal orders a requirement. The staff receiving the verbal orders must repeat the orders and ensure that they are verified.
iii. Read medication labels carefully during the administration process and perform triangle check. Triangle check is to check actual medicines against the medication labels and against the prescription.



JK Induk Keselamatan Pengubatan 2023, BAPF

Guide on handling look alike, sound alike medications, 2012

6. MONITORING

- All facilities need to identify medications that is look alike or sound alike in its organization. The LASA list needs to be reviewed and updated periodically at least once a year.
- Implement feedback mechanism to inform on look-alike medications.

7. INFORMATION

- All relevant personnel have access to the LASA list.
- Staff are informed on new medications listed as LASA in the hospital or clinic. Example: Displaying information on LASA in the facility's website.

8. PATIENT EDUCATION

- Inform patients on changes in medication appearances.
- Educate patients and their caregivers to alert healthcare providers whenever a medication appears to vary from what is usually taken or administered.
- Encourage patients and their caregivers to learn the names of their medications.

9. EVALUATION

- Evaluate medication errors related to LASA medications.

5

COMMON DRUGS THAT CAUSES SEVERE ADR

PREVENTING ADVERSE DRUG REACTION

- Some ADRs are unpredictable e.g. anaphylaxis
- Many are preventable with adequate foresight and monitoring
- Interventions that reduce probability of ADR occurring can be an important way to reduce the risk of patient harm
- Allergy card can be given to severe ADR cases to avoid preventable harm

JK Induk Keselamatan Pengubatan 2023, BAPF

Coleman JJ, Pontefract SK. Adverse drug reactions. Clin Med (Lond). 2016 Oct;16(5):481-485

EXAMPLES OF ADR AND INTERVENTION

Warfarin

Bleeding if supratherapeutic dose, clotting if under therapeutic dose

Intervention

- Dose adjustment based on routine INR monitoring
- Ensure patients are always aware of their current dose while dispensing
- Ensure correct patient and correct dose prior to dose administration

JK Induk Keselamatan Pengubatan 2023, BAPF

Anticoagulation MTAC (AC MTAC) protocol. 2nd edition 2020

EXAMPLES OF ADR AND INTERVENTION

Allopurinol

Associated with Steven Johnson's Syndrome, TEN

Intervention

- Inform patient to seek immediate medical attention if patient developed any sudden rashes or any ulcers in/around mouth/genital area
- Ensure that allopurinol is not prescribed for asymptomatic hyperuricemia

JK Induk Keselamatan Pengubatan 2023, BAPF

1. Langkah-langkah pengurangan risiko kesan advers kulit serius susulan penggunaan allopurinol. ruj (47)dlm.BPFK/PASCA/FV/2 jilid 17
2. MADRAC newsletter August 2012

EXAMPLES OF ADR AND INTERVENTION

Carbamazepine

Associated with risk of Steven Johnson's Syndrome, TEN, narrow therapeutic window leading to toxicity

Intervention

- Always confirm with patient the indication of the medication prior to dispensing
- Be alert if come across prescription with abbreviation for CBZ/CPZ
- Be alert when it comes to IR and CR formulation of carbamazepine

1. Guide on handling look alike, sound alike medications. Pharmaceutical services division, Ministry of Health Malaysia. 2012
2. Guide to good dispensing practice. Pharmaceutical Services Division, Ministry of Health Malaysia. 2016

EXAMPLES OF ADR AND INTERVENTION

Parenteral Anticoagulants (Enoxaparin, Fondaparinux, Heparin)

Bleeding if supratherapeutic dose, clotting if under therapeutic dose

Intervention

- Ensure that parenteral anticoagulants overlap with warfarin for no longer than 3 days generally (exact length of overlap depends on bridging therapy indication)
- Check on patients renal status to determine the correct dosing
- Heparin - ensure APTT/PT levels are monitored for dose titration purposes
- Monitor patients for heparin-induced thrombocytopenia (HIT)
- Ensure correct patient and correct dose prior to dose administration

Garcia DA, Baglin TP, Weitz JI, Samama MM. Parenteral anticoagulants: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012 Feb;141(2 Suppl):e24S-e43S

ACKNOWLEDGEMENT

External Reviewers

1. Dr. Norkasihan Ibrahim (Universiti Teknologi MARA)
2. Pn. Nalina Darsini A/P Panderengen (JKWPKL & Putrajaya)

THANK YOU

Acknowledgement:
Medication Safety Liaison Officer 2023-2024