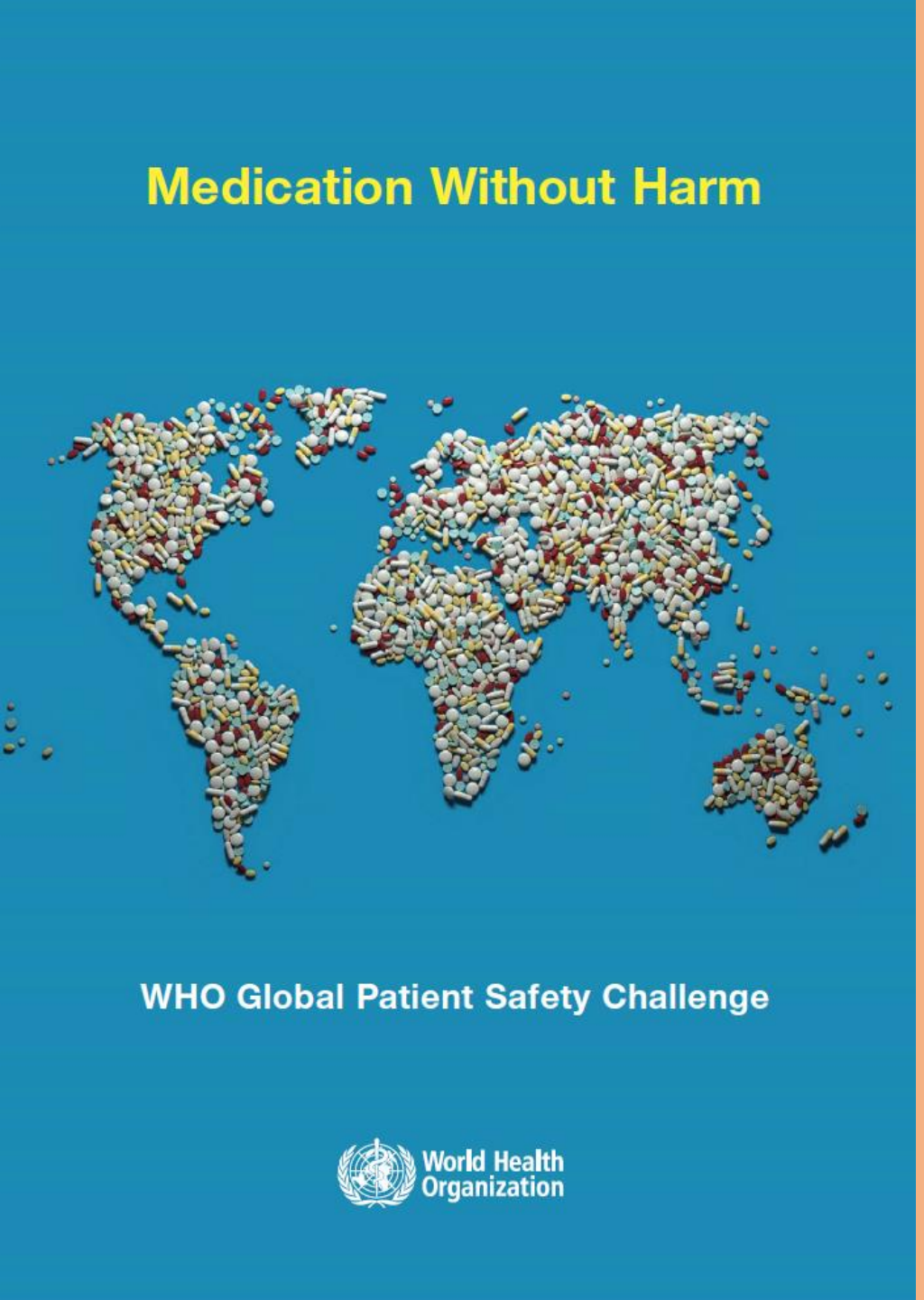


Medication Safety Webinar

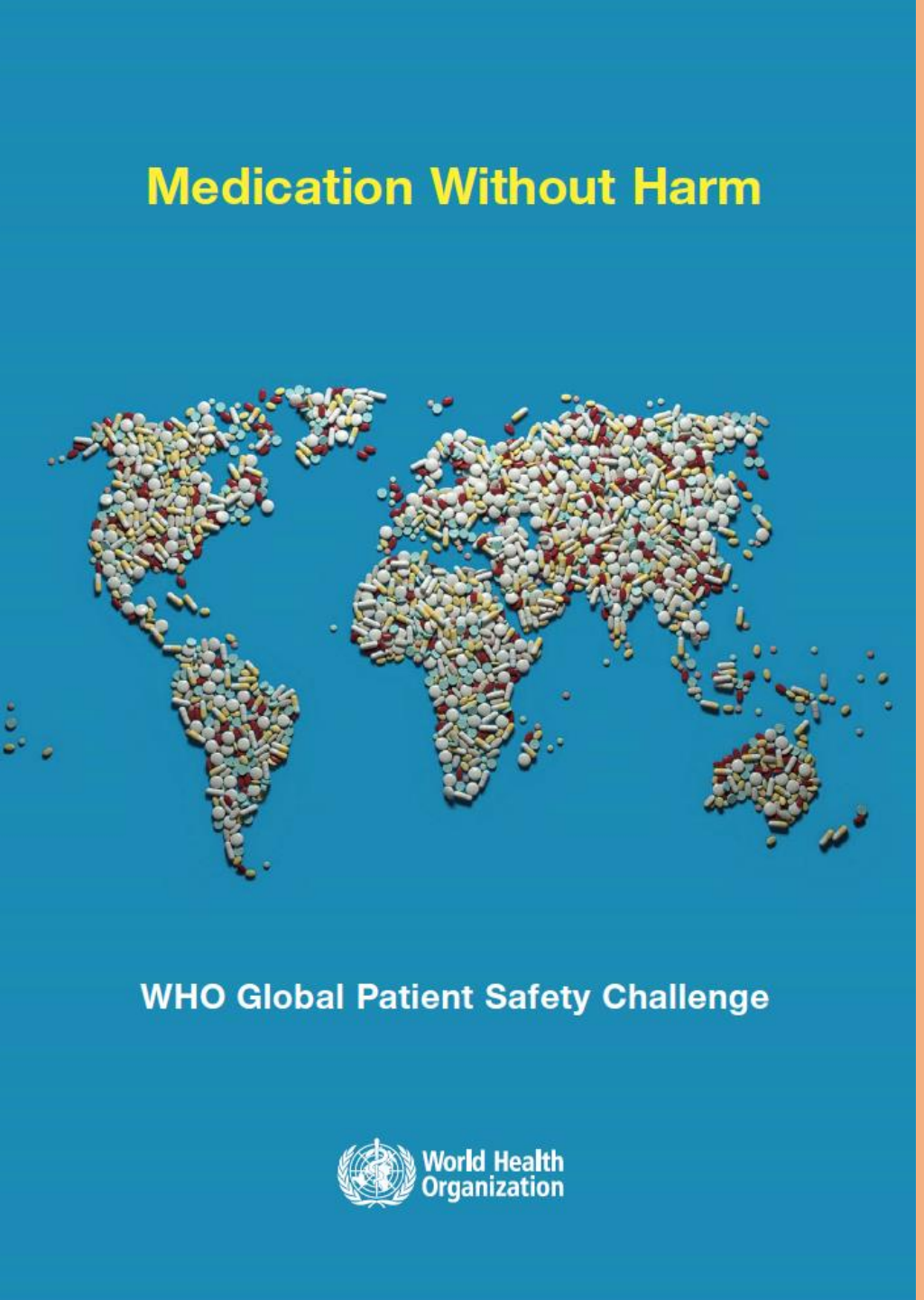
Medication Safety for Look-alike, Sound Alike Medicines

Friday, 20 October 2023
14:00 – 15:30 CEST

World Health Organization

Patient Safety

MEDICATION WITHOUT HARM
Global Patient Safety Challenge



Welcome to the webinar

Dr Neelam Dhingra

Unit Head
Patient Safety Flagship

WHO headquarters

Geneva

World Health Organization

Patient Safety

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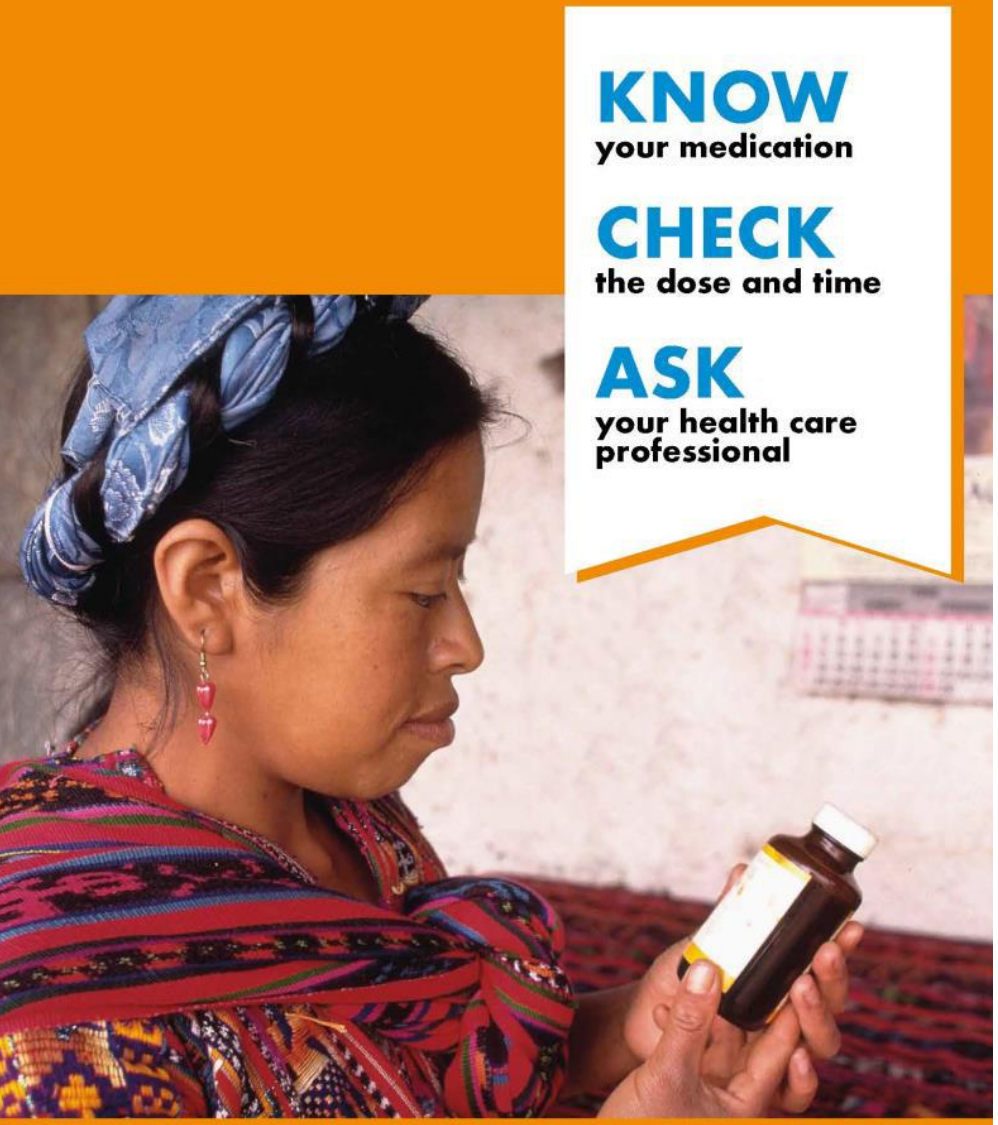
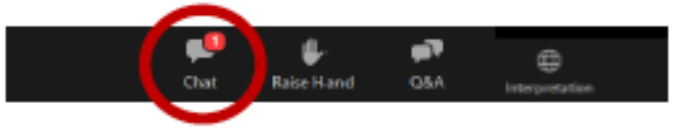
Global Patient Safety Challenge

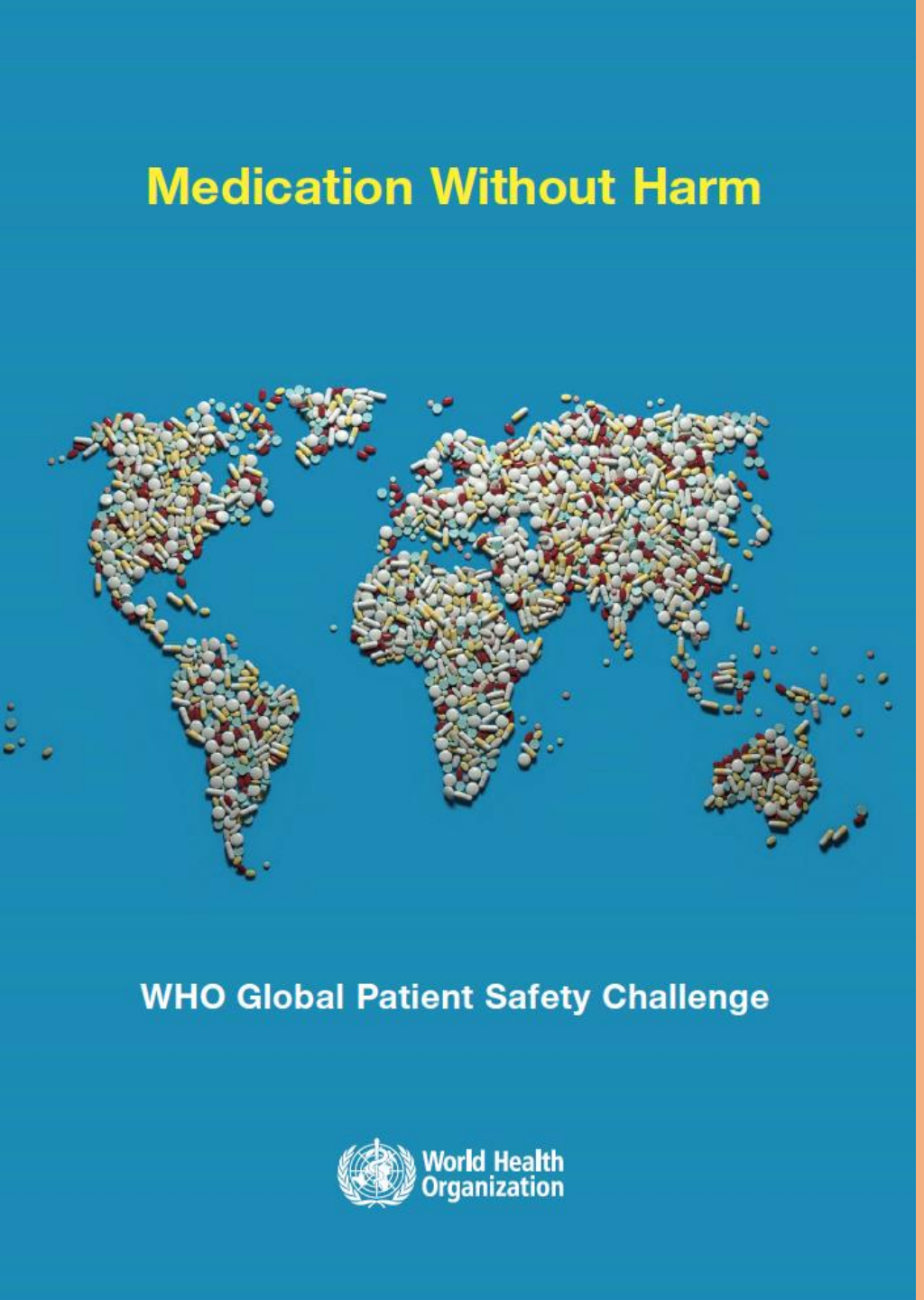


Medication safety for look-alike, sound-alike medicines

- This session is being recorded and your attendance is consent to be recorded.
- Your microphone will be muted during the session, please use the Q&A and Chat features to communicate:
  - Use **Q&A** feature for questions regarding the topic and presentations

  - Use the **Chat** feature for questions regarding connectivity, logistics, IT





Medication safety for look-alike, sound-alike medicines and launch of the publication

Sir Liam Donaldson

WHO Envoy for Patient Safety

World Health Organization

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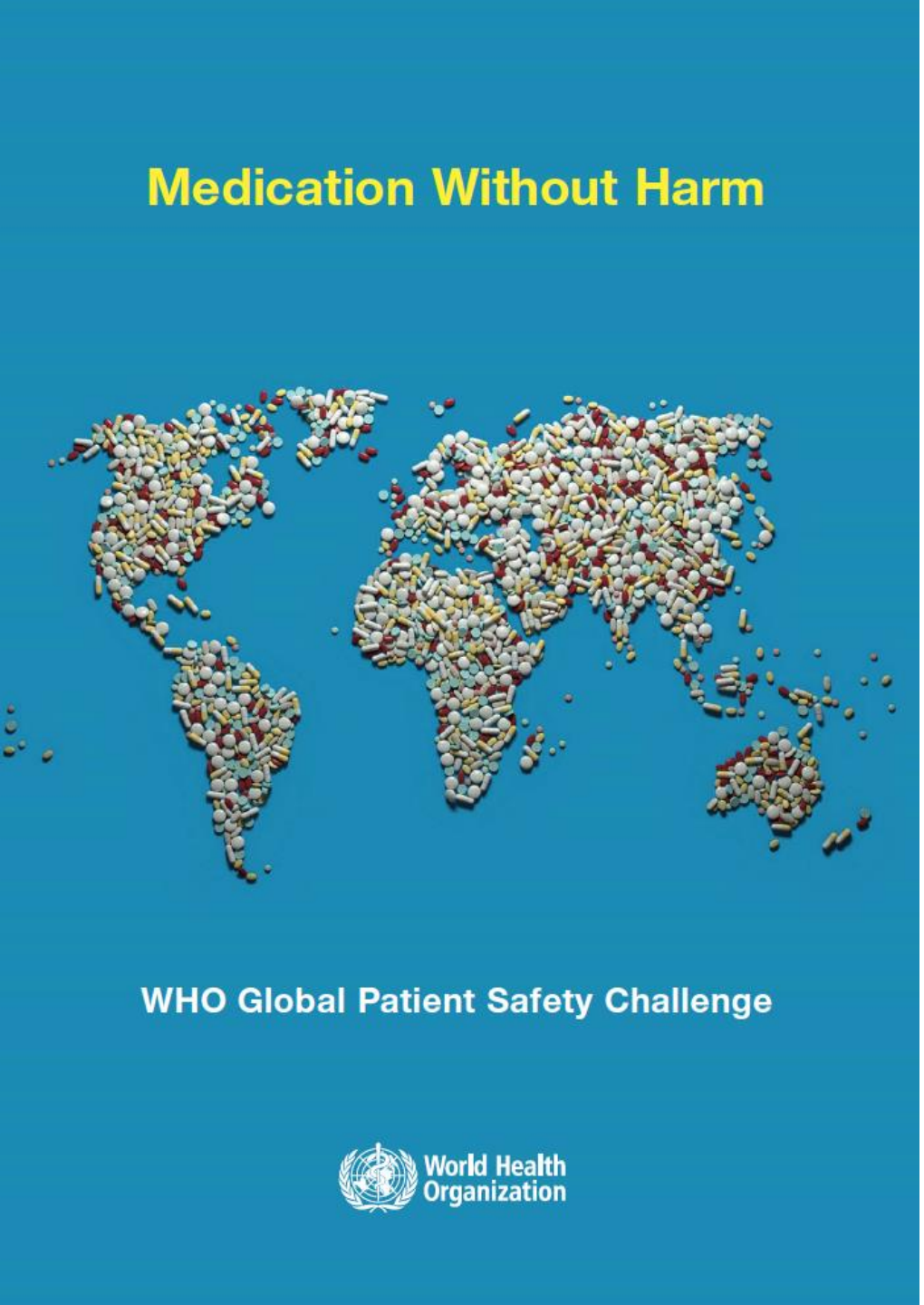
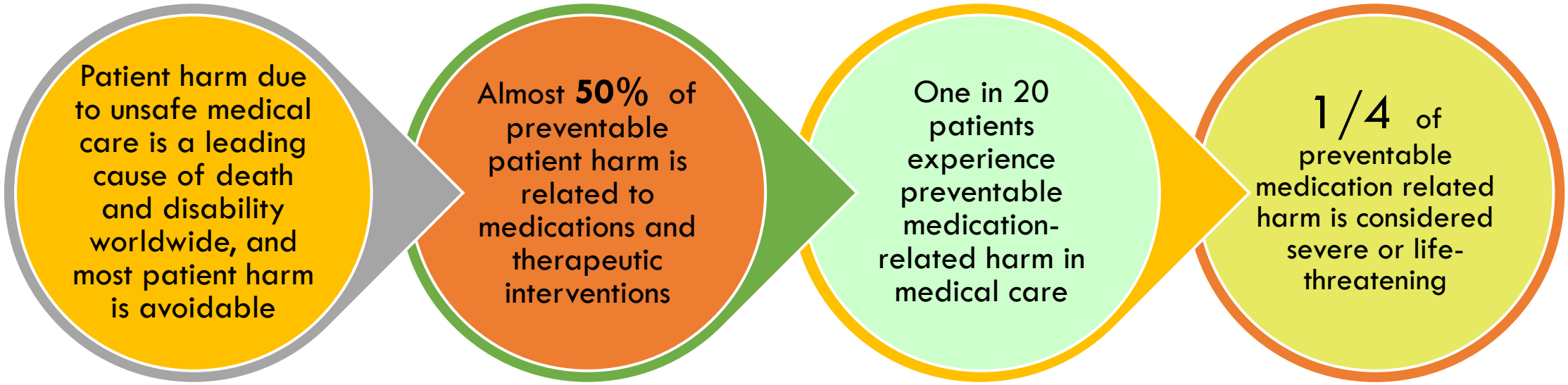
Global Patient Safety Challenge



Medication Without Harm

- WHO third Global Patient Safety Challenge
- Prevent severe patient harm due to medication errors and unsafe medication practices globally
- Four domains and three key action areas

Key data on medication-related harm



- *Panagioti M, et al. Prevalence, severity, and nature of preventable patient harm across medical care settings: Systematic review and meta-analysis. BMJ. 2019*
- *Hodkinson et al. Preventable medication harm across health care settings: a systematic review and meta-analysis. BMC Med. 2020*
- *WHO report: Global burden of preventable medication-related harm in health care : A systematic review*

Vulnerable patients and medicines causing severe harm due to LASA errors

Extremes of age or frailty

Kidney or liver impairment

Paediatric patients

Patients in ICU

High-risk medicines e.g., insulin, warfarin

Medicines with a narrow therapeutic index - lithium, digoxin

Relatively more toxic medicines, such as cancer medicines

- The use of acronyms to refer to cancer chemotherapy agents is also a potential source of error

Stakeholders for preventing LASA medication errors

- Medicines regulators
- Medication safety organizations – e.g., ISMP
- Pharmaceutical manufacturers
- Policy makers
- Hospital administrators
- Health and care workers
- Patient support groups
- Patients and families


World Health
Organization


Patient
Safety

Patient Safety

World Health Organization

Medication safety for look-alike, sound-alike medicines

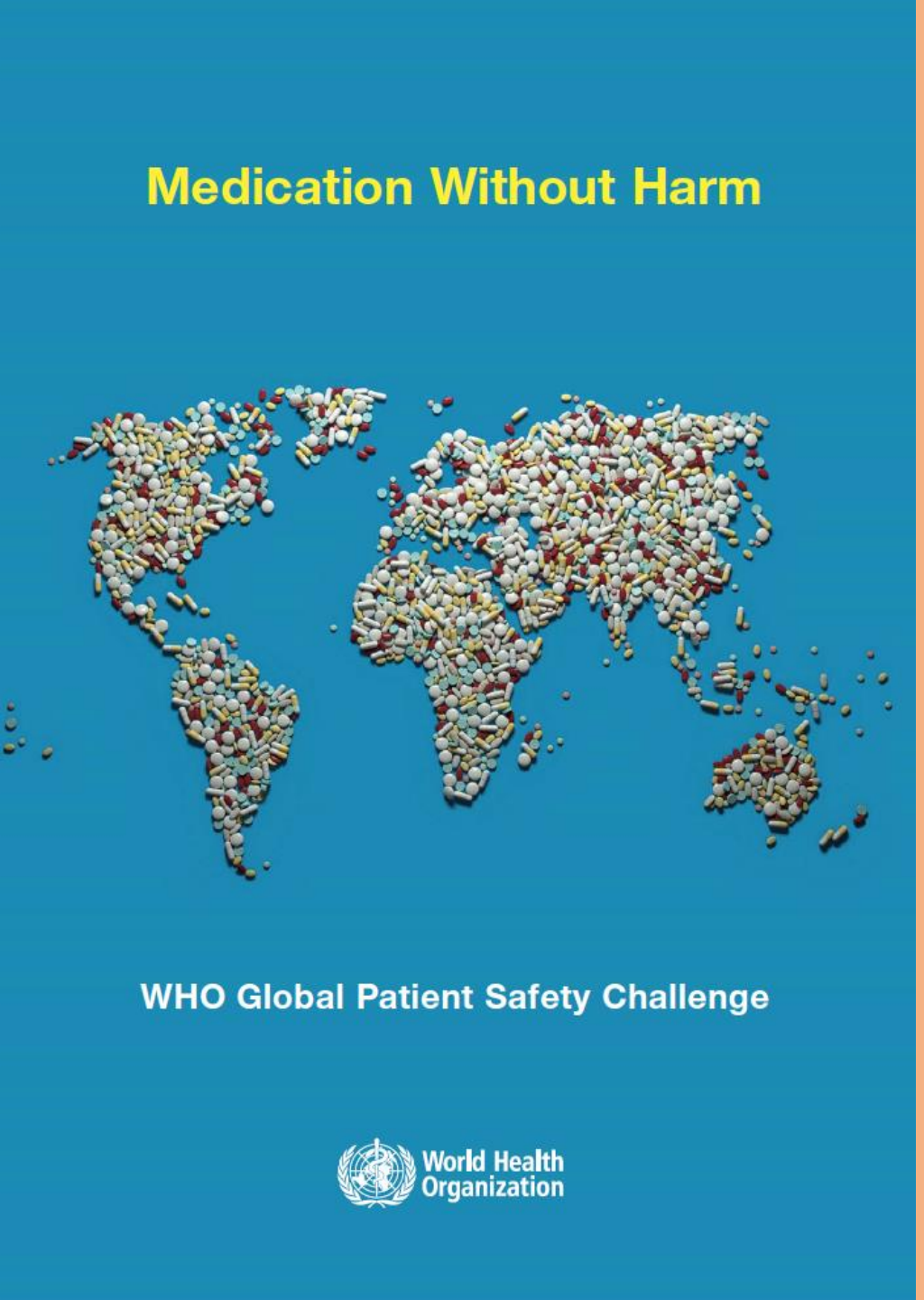
Technical Series on Medication Safety Solutions

MEDICATION WITHOUT HARM

Global Patient Safety Challenge

WHO LASA document QR code

https://iris.who.int/bitstream/handle/10665/373495/9789240058897-eng.pdf?sequence=1



Introduction

Medication Safety Solution Series

Look-alike Sound-alike (LASA) Medicines

Dr Neelam Dhingra

Unit Head
Patient Safety Flagship

WHO headquarters

Geneva

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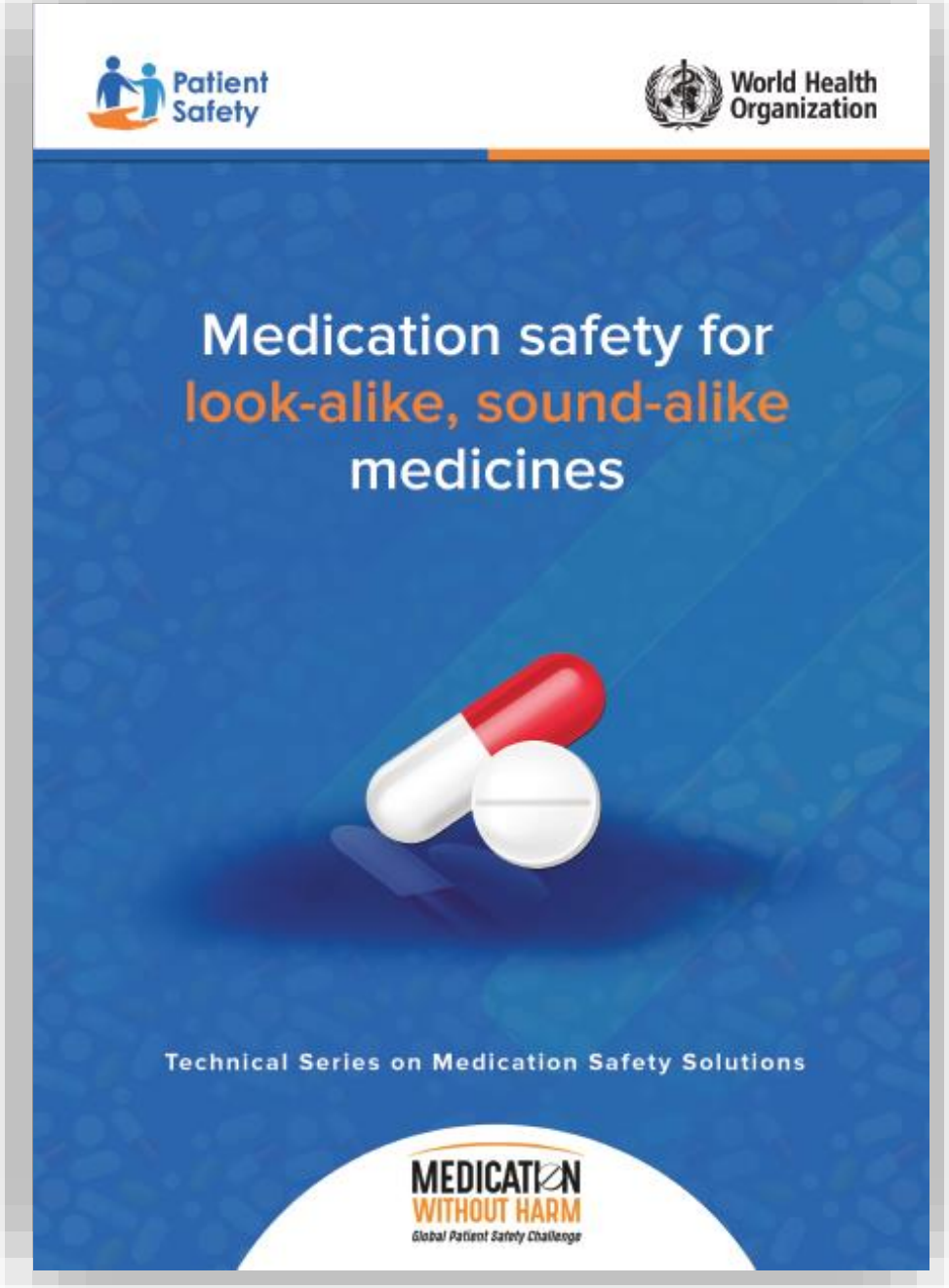
Global Patient Safety Challenge

World Patient Safety Day 17 September 2022

Medication Safety webinar series Initiated in WPSD 2022

Covered several important topics on medication safety

- High risk situations
- Polypharmacy
- Transitions of care
- Medication error reporting and learning
- Patient engagement



WHO technical series *'Medication Safety Solutions'*

Many technical products planned on medication safety

- One of the first – Look-alike, sound-alike (LASA) medicines
- Maternal and newborn care
- Perioperative care
- Older persons
- Traditional and complementary medicines

Burden of medication-related harm

Medication harm accounts for **50% of overall avoidable harm** in medical care

Medication errors are one of the main causes of avoidable medication-related harm

US$ 42 billion of annual global health spending can be avoided if medication errors are prevented

The highest rates of avoidable **medication harm** occur in three stages of medication use:

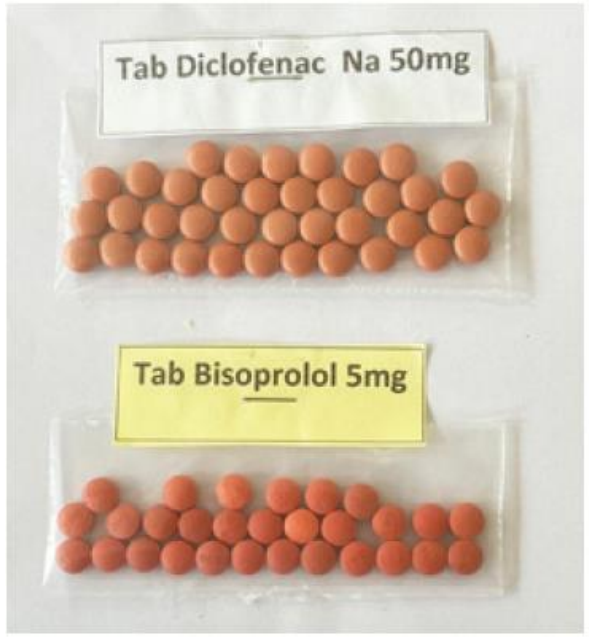
Prescribing

Administering

Monitoring

LASA medicines

- Have orthographic (look-alike) and phonetic (sound-alike) similarities between medicines
- Look-alike medicines appear visually the same with respect to packaging, shape, colour and/ or size



LASA medicines

- Sound-alike medicines are similar in the phonetics of their names, doses and/or strengths

Table 2: Mistaken letters in names of medicines

Location in the name	Letters	Examples of medicines
Beginning	Am	**Am**iloride, **Am**itriptyline, **Am**lodipine, **Am**iodarone
	Az	**Az**athioprine, **Az**ithromycin
	Carb	**Carb**imazole, **Carb**amazepine
	Pr	**Pr**ochlorperazine, **Pr**opranolol, **Pr**ednisolone, **Pr**omethazine
Middle	gaba	Pre**gaba**lin, Vi**gaba**trin
End	azole	Metronida**zole**, Omepra**zole**

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Medication safety for look-alike, sound-alike medicines

Technical Series on Medication Safety Solutions

MEDICATION WITHOUT HARM
Global Patient Safety Challenge

Contents

Causes for LASA errors during Prescribing

- Illegible or poorly legible prescriptions
- Incorrect selection of medicines from drop down menus in computers
- Verbal and telephone orders for medications
- Inappropriate use of error-prone abbreviations
- Use of a trailing zero - **5.0 mg** can be interpreted as **50 mg**
- Non-use of a zero - **.5 mg** instead of **0.5 mg** can be interpreted as **5 mg**

Causes of LASA errors

Stage of medication use	Causes
Transcribing or documenting	- Incorrect transcription of a LASA medicine name - Wrong interpretation of the abbreviation
Dispensing	Storage of LASA medicines on the same shelf next to each other
Administering	- Unclear instructions e.g., “as directed”, leaving instructions open to misinterpretation - Selection of a product according to familiarity with the packaging or strength
Monitoring	Failure to monitor outcomes of medication by relevant clinical observations or biochemistry

Consequences of LASA errors

Depends on the medicine administered and the condition of the patient

- Administration of the wrong medicine
- Administering incorrect dose of the intended medicine
- Toxic effects or other adverse effects of the administered medicine
- Exacerbation of the disease for which the medicine was not given
- Severe harm if error involves high-risk medicines

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Table 1: Actions suggested for reducing LASA errors

Actions on medicines as products	Actions by patients, families and caregivers	Actions by health and care workers	Actions by health care facilities, institutions and countries
1. Use "tall man" lettering (TML) to label medicines with which a risk has been identified. 2. Segregate storage of identified LASA medicine pairs or groups. 3. Develop and use tools and skills to identify LASA medicine pairs to prevent registration of such products, minimize approval of several strengths of the same medicine, and approve only dosage forms and strengths with different appearances and packaging. 4. Identify LASA medicines when including them in formularies and during purchase for institutions and countries. 5. Prioritize LASA errors involving high-risk medicines with greater potential for severe harm. 6. Label all raw and processed T&CM products including the botanical names of plants	1. Know each medicine prescribed, dispensed and administered, including the name, indication, strengths of medicines dispensed and the dose to be used. 2. Be aware of potential errors with LASA medicines, and be vigilant about such errors. 3. Learn to label and store medicines appropriately at home to avoid LASA errors with the medicines dispensed to the patient. 4. Check with the health care provider if in doubt, about a prescribed, dispensed or administered LASA medicine.	1. Educate themselves and the patients about the LASA medicines that are prone to errors, and address them in practice. (The section on improving medication safety of the WHO patient safety curriculum guide is a good resource for this purpose). 2. Pay attention to LASA medicines when prescribing, dispensing and administering medicines and during medication reconciliation at transitions of care. 3. Use generic names during prescribing and transcribing to minimize errors due to brand name confusion. 4. Write legibly when prescribing and transcribing. 5. Attach clear labels for LASA medicines, with TML for medicines that could be confused.	1. Promote a just, trusting culture in facilities so that staff are at ease in discussing and reporting LASA medication errors and near misses. 2. Identify the most common pairs of LASA medicines in the country or organization, and update the list regularly. 3. Label clearly, use TML, and segregate storage of LASA medicines. 4. Take measures to avoid interrupting and distracting health and care workers while they are dispensing and administering medicines. 5. Include technology-based solutions, such as CPOE and barcoded dispensing, to avoid LASA errors. 6. Apply quality control measures to ensure proper use of authentic herbal medicines.

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Medication Without Harm

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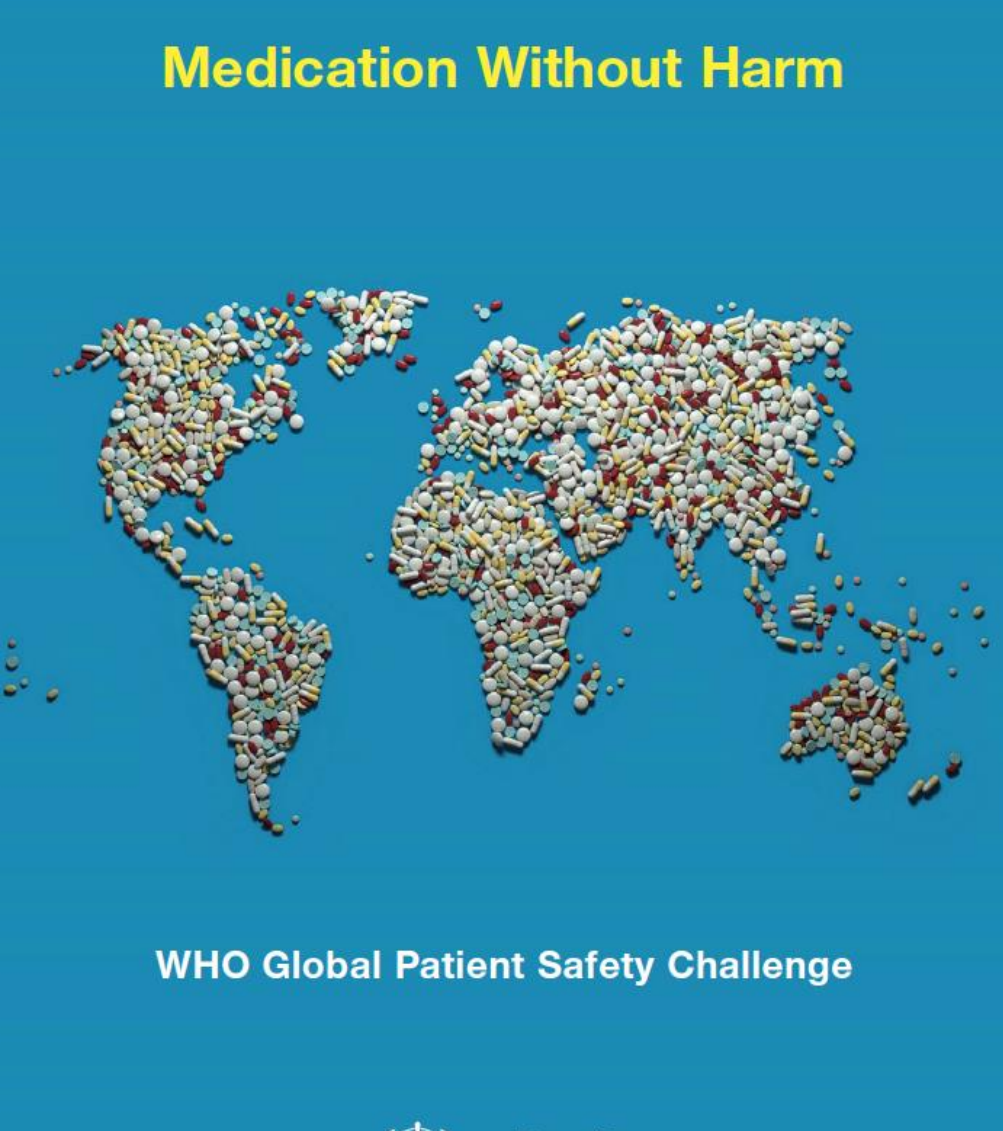


Look-alike Sound-alike (LASA) Medicines: Interventions to prevent errors

Michael R. Cohen

President Emeritus

Institute for Safe Medication Practices (ISMP)

Chairperson, International Medication Safety Network

United States of America

World Health Organization

MEDICATION WITHOUT HARM
Global Patient Safety Challenge

November 29, 2018 ▪ Volume 23 Issue 24

ISMP

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Are national efforts to reduce drug name confusion paying off?

Introduction

One in every 1,000 medication orders in a hospital, and one in every 1,000 prescriptions in a pharmacy, have been associated with selecting the wrong drug while prescribing, transcribing, dispensing, or administering medications.[1-4] Drug name similarities are a primary cause of these errors.[5] Orthographic (spelling) factors that increase visual resemblance among drug names include similarities in the length of the names and the number of groups of similar or the same characters within the names.[6] Phonological (sound) factors that increase auditory resemblance among drug names include similarities in the number of syllables, the stressed syllable, the initial or terminal syllable, and the stressed vowel.[6] Other factors that increase the risk of drug name confusion include similarities in strength, dosing, route of administration, dosage forms, indication, and other factors, such as the environment in which the drugs are used, the frequency of use, and product labeling.[7]

Sources of name confusion. Sources of drug name confusion errors include: memory, perceptual, and motor control errors.[6] Memory errors can arise when practitioners make a mistake during recall or recognition of a drug name. Perceptual errors occur when practitioners misread or mishear a drug name. Motor control errors occur upon selection of a drug. For example, this type of error occurs when an adjacent drug with a similar name is selected in error from a list, such as a drop-down set of choices on a computer screen.

Drug naming processes. Generic (nonproprietary) drug names are based upon a collection of standard stems used as prefixes, suffixes, and infixes to identify the pharmacologic property and/or chemical structure of the medication. In the US, generic names are assigned by the United States Adopted Names (USAN) Council. In the global arena, the World Health Organization (WHO) International Nonproprietary Name (INN) members work with international naming authorities like USAN to harmonize generic names between different countries. Proposed generic names are released for public review and comment. Sometimes, the drug name stems embedded in generic names contribute to mix-ups among names with the same stem. However, the stem helps position an unfamiliar drug with others in a class and provides clues as to its use and effects.

Brand (proprietary) names for drugs are selected by the manufacturer. As part of the drug product approval process, the US Food and Drug Administration (FDA) reviews the proposed brand name and determines its acceptability. Brand names are intended to be unique and memorable to identify products and distinguish one manufacturer's product from its competitors. However, brand names that look or sound alike can contribute to name confusion errors.

Name safety testing. For generic drug names, USAN Council members (one each from the American Medical Association, USP, American Pharmacists Association, FDA, and a member at large) conduct an evaluation during the naming process to reduce the risk of similarities with existing brand or generic drug names. One of the guiding principles associated with the USAN Council naming process includes criteria that the name should not conflict, mislead, or be confused with other nonproprietary or proprietary drug names.

continued on page 2—Drug name confusion >

SAFETY briefs

Generic EPINEPHrine autoinjectors. EPINEPHrine is dosed by weight when used to treat an allergic reaction or anaphylaxis, not by whether the patient is an adult or child. Thus, generic brands of the EPINEPHrine autoinjector do not use the abbreviation "Jr" for the 0.15 mg dosage strength (Figure 1). The abbreviation "Jr" is already part of the EPIPEN trademark used for that strength. However, given that dosing is weight-based, please be sure staff are aware that generics will list the metric strength only, 0.3 mg or 0.15 mg. Patients 30 kg (approximately 66 pounds) or heavier should use a 0.3 mg injector. Those who

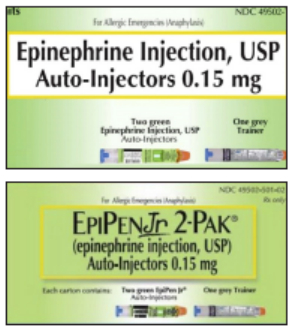
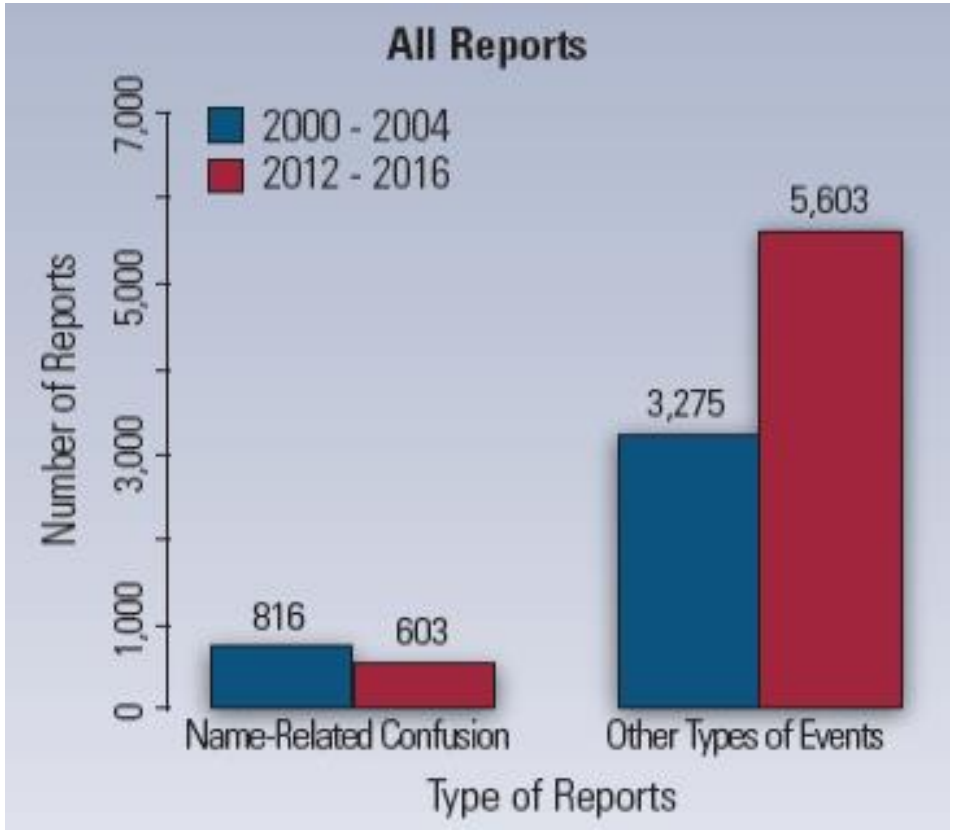


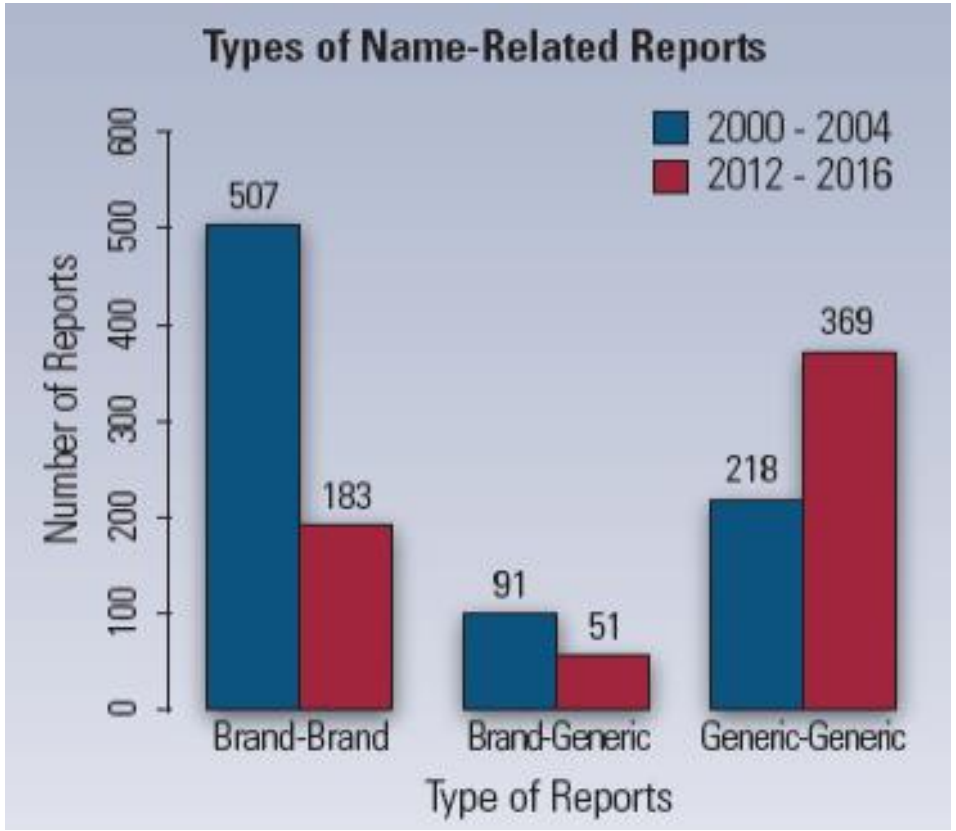
Figure 1. Generic **EPINEPH**rine autoinjectors (top) do not refer to the 0.15 mg strength as "Jr" as does the brand version, EpiPen Jr (bottom). Other generics also will not designate the 0.15 mg strength as "Jr."

weigh between 15 to 30 kg (33 pounds to 66 pounds) need to use a 0.15 mg injector. Both strengths should be available for treatment in healthcare facilities. A pharmacist expressed concern that practitioners unfamiliar with EPINEPHrine dosing may confuse the strengths if they are accustomed to seeing the "Jr" designation.

Simulation products look real. Medications used for educating healthcare practitioners during simulation exercises, also known as demo medications, often appear

continued on page 2—SAFETY briefs >


All Reports
2000 - 2004
2012 - 2016
Number of Reports
0
1,000
3,000
5,000
7,000
816
603
3,275
5,603
Name-Related Confusion
Other Types of Events
Type of Reports


Types of Name-Related Reports
2000 - 2004
2012 - 2016
Number of Reports
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100
200
300
400
500
600
507
183
91
51
218
369
Brand-Brand
Brand-Generic
Generic-Generic
Type of Reports

June 2, 2022 ■ Volume 27 Issue 11

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Educating the Healthcare Community About Safe Medication Practices

Adopt strategies to manage look-alike and/or sound-alike medication name mix-ups

ISMP has long advocated for increased awareness of look-alike and/or sound-alike medication name mix-ups and the implementation of safeguards to prevent them. To support this advocacy, ISMP maintains and periodically updates a comprehensive ***List of Confused Drug Names*** (www.ismp.org/node/102) that have been reported to us and published in our newsletters, many of which are look-alike and/or sound-alike medication names. Referencing this list, along with your internal medication error data, you can identify and update a much more manageable list of error-prone medications with look-alike and/or sound-alike names that require safeguards in your organization. To assist with the prioritization and optimization of safeguards in your organization, we have compiled certain risk-reduction strategies previously published in this newsletter during the past 10 years. The risk-reduction strategies span all phases of the medication-use process as well as general categories such as medication storage and patient education.

Phases of the Medication-Use Process

Procurement

- When possible, avoid purchasing medications in which the manufacturer's trademark symbol or corporate logo is larger than the name of the product because more attention will be drawn to the logo than the name of the product.
- *Before* new products are added to the formulary and/or inventory, use failure mode and effects analysis (FMEA) to ensure that all new medication product names are evaluated by practitioners who may use them. This process will help determine if the new products may be confused with another medication name.
- When new products (including products procured to manage drug shortages) are first received in the pharmacy, conduct an additional review to identify any unanticipated look-alike and/or sound-alike drug name concerns that may have been missed.
- Determine if the risk of a mix-up will be reduced if medications with look-alike names are purchased from different manufacturers. If so, purchase them from different manufacturers.
- When possible, purchase and stock different strengths/concentrations of drugs with potentially confusing, problematic drug names (e.g., morphine 2 mg/mL and **HYDRO**morphone 1 mg/mL).

Prescribing

- When prescribing (or communicating) medication orders, avoid drug name abbreviations (e.g., tPA, TXA), stemmed names (e.g., "statin"), or other shortened names (e.g., "nitro," "pit"). Communicate the full generic name and/or the current brand name.
- Prescribe all medications electronically (rather than handwritten), or use preprinted order sets as much as possible if electronic prescribing is not available.

continued on page 2 — Adopt strategies >

SAFETY briefs

Paxlovid drug interaction. A physician prescribed PAXLOVID (nirmatrelvir and ritonavir) for a 34-year-old patient with flu-like symptoms who tested positive for coronavirus disease 2019 (COVID-19). On day 3 of treatment, the patient presented with signs and symptoms of fatigue and bradycardia, with a heart rate below 40 beats per minute. The physician referred the patient to the emergency department (ED) for further evaluation, where it was discovered that the patient had been taking ivabradine for premature ventricular contractions. Ivabradine is metabolized by the cytochrome P450 3A4 (CYP3A4) enzyme, and the ritonavir component of Paxlovid is a strong CYP3A4 inhibitor. Thus, concomitant use of Paxlovid and ivabradine is contraindicated due to the risk of

continued on page 2 — SAFETY briefs >

Just Culture scholarships

In December 2021, The Just Culture Company announced that three scholarships will be awarded each year to honor Judy Smetzer, BSN, RN, FISMP, former vice president at the Institute for Safe Medication Practices (ISMP). For years, Judy has been an unfaltering advocate of a more fair and just response to medication errors. The three recipients of the ***Judy Smetzer Just Culture Champion Scholarship***, selected by ISMP each year, will be able to enroll in a live-hosted or online Just Culture Certification Course, after which they will be eligible to sit for the Just Culture Certification Exam. Award recipients will also receive membership in the Just Culture Community of Learners (with live-hosted webinars) and a 2-year software license for the Just Culture Algorithm and supplemental learning materials. Applications must be submitted by **July 31, 2022**. Details can be found on **page 6**, and are also available on the ISMP (www.ismp.org/node/30840) and The Just Culture Company (www.justculture.com) websites.

[Adopt Strategies to Manage Look-Alike and/or Sound-Alike Medication Name Mix-Ups | Institute For Safe Medication Practices (ismp.org)]

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ISMP List of *Confused* Drug Names

This list of confused drug names, which includes look-alike and sound-alike name pairs, consists of those name pairs that have been published in the ***ISMP Medication Safety Alert!® Acute Care***, the ***ISMP Medication Safety Alert!® Community/Ambulatory Care***, and the ***FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters***. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as: using both the brand and generic names on prescriptions and labels; including the purpose of the medication on prescriptions; configuring computer systems to require a minimum of the first five letters of a drug name during product searches to limit similar names from appearing together on the same screen; and changing the appearance of look-alike product names to draw attention to their differences. Both the US Food and Drug Administration (FDA)-approved and the ISMP-recommended tall man (mixed case) letters have been included in this list.

Updated through February 2023

Drug Name	Confused Drug Name
Abelcet	amphotericin B
Accupril	Aciphex
acetaminophen	acetaZOLAMIDE
acetaZOLAMIDE	acetaminophen
acetaZOLAMIDE	acetoHEXAMIDE
acetic acid for irrigation	glacial acetic acid
acetoHEXAMIDE	acetaZOLAMIDE
Aciphex	Accupril
Aciphex	Aricept
Activase	Cathflo Activase
Activase	TNKase
Actonel	Actos
Actos	Actonel
Adacel (Tdap)	Daptacel (DTaP)
Adderall	Adderall XR
Adderall	Inderal
Adderall XR	Adderall
ado-trastuzumab emtansine	trastuzumab
Advair	Advicor
Advicor	Advair
Advicor	Altocor
Afrin (oxymetazoline)	Afrin (saline)
Afrin (saline)	Afrin (oxymetazoline)
Aggrastat	argatroban
Aldara	Alora
ALfentanil*	fentaNYL*

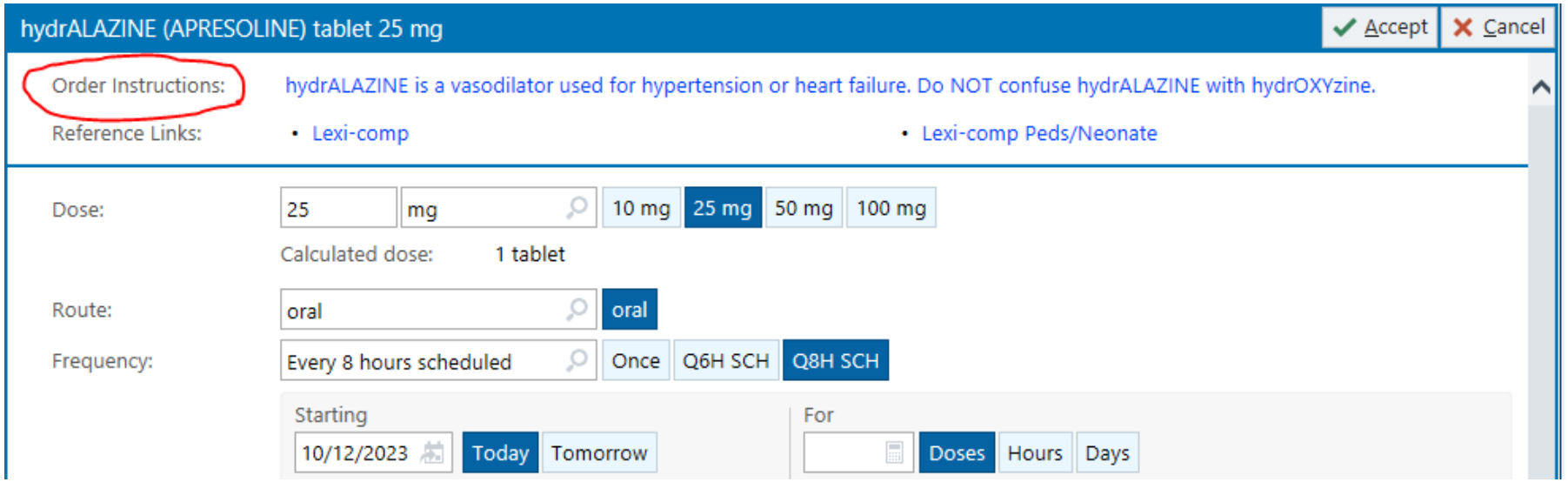
Drug Name	Confused Drug Name
ALfentanil*	SUFentanil*
Alkeran	Leukeran
Alkeran	Myleran
Allegra	Viagra
Allegra (fexofenadine)	Allegra Anti-Itch Cream (diphenhydrAMINE/allantoin)
Allegra Anti-Itch Cream (diphenhydrAMINE/allantoin)	Allegra (fexofenadine)
Alora	Aldara
ALPRAZolam	clonazePAM
ALPRAZolam	LORazepam
Altocor	Advicor
amantadine	amiodarone
Amaryl	Reminyl
Ambien*	ambrisentan*
Ambisome	amphotericin B
ambrisentan*	Ambien*
Amicar	Omacor
Amikin	Kineret
aMILoride	amLODIPine
amiodarone	amantadine
amLODIPine	aMILoride
amphotericin B	Abelcet
amphotericin B	Ambisome
amphotericin B	amphotericin B liposomal
amphotericin B liposomal	amphotericin B

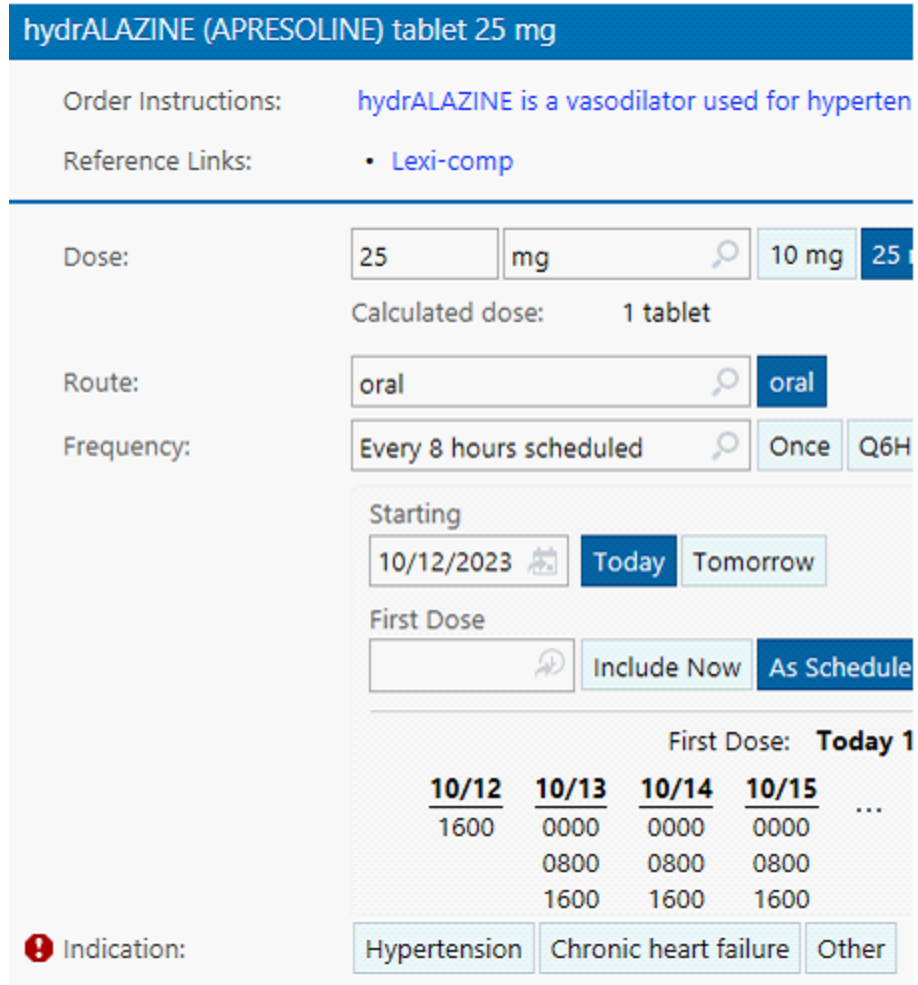
Note: Brand names start with uppercase letter. Some brand names incorporate tall man letters in inititial characters and may not be readily recognized as brand names. Brand names appear in black; generic names/other products appear in red. Name pairs marked with an asterisk (*) are newly added.

ISMP_ConfusedDrugNames_2023.pdf

Interventions that improve drug name safety

- Avoidance of handwritten prescriptions (electronic prescribing, preprinted order sets, etc.)
- Listing both brand name and generic name during computer screen selection
- Read back during oral communication between prescriber and nurse, pharmacist or other healthcare professional
- Error-reporting programs and alerts to the field about LASA drug names; ISMP maintains list of LASA medications
  - List is used to incorporate computer alerts for LASA during prescribing, dispensing, administering medications




hydrALAZINE (APRESOLINE) tablet 25 mg
Order Instructions:
hydrALAZINE is a vasodilator used for hyperten
Reference Links:
• Lexi-comp
Dose:
25
mg
10 mg
25
Calculated dose:
1 tablet
Route:
oral
oral
Frequency:
Every 8 hours scheduled
Once
Q6H
Starting
10/12/2023
Today
Tomorrow
First Dose
Include Now
As Schedule
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1600
10/15
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1600
...
Indication:
Hypertension
Chronic heart failure
Other

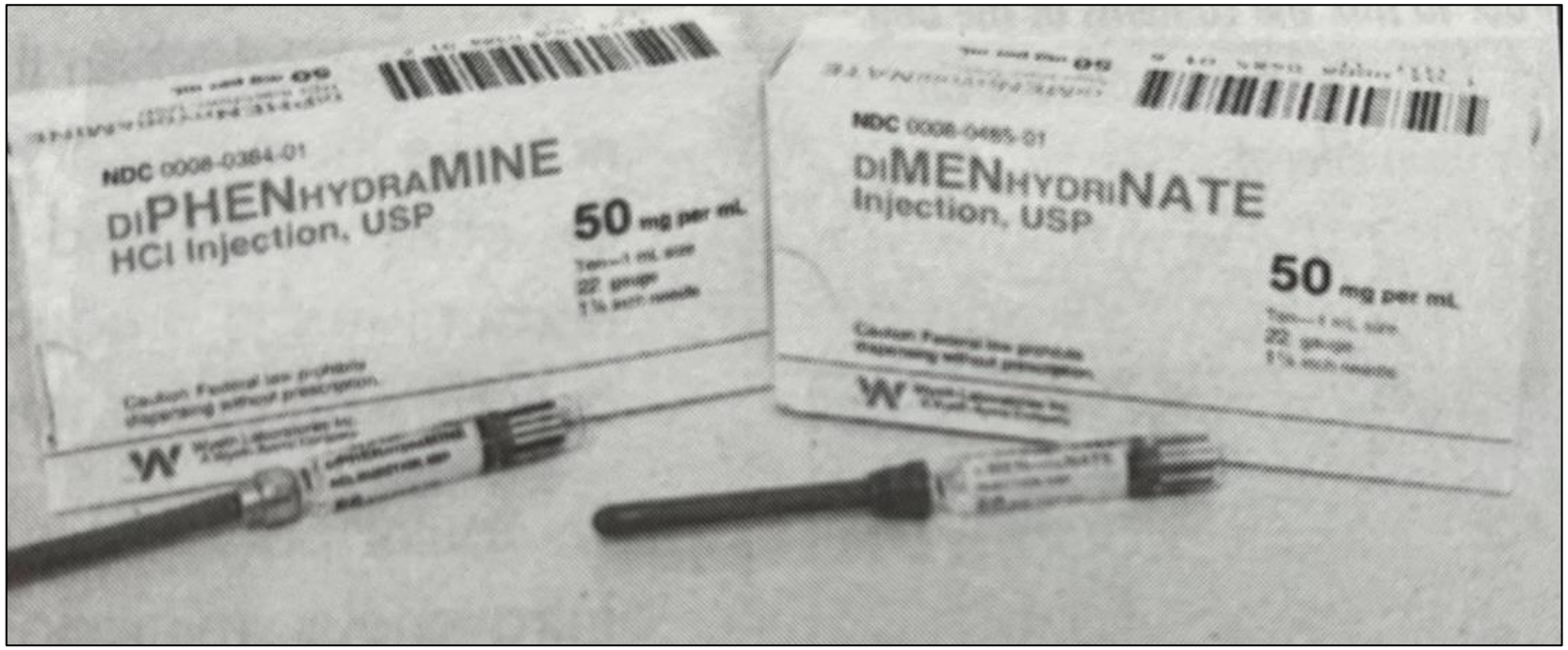
Interventions that improve drug name safety

- Indication-based prescribing and/or order sets to reduce or eliminate drug selection from computer screen
- Barcode scanning of product label in pharmacies, at automated dispensing cabinet, at bedside, etc.
  - Question unsuccessful barcode scans (order for medication in hand may not exist!)
- Require minimum # of letter characters when selecting medications from on-screen (metformin 500 mg or metronidazole 500 mg?)
- Patient involvement at the pharmacy (educate patients so they know names of their medications and what to expect)
- Drug storage practices to limit look-alike access

Interventions to improve drug name safety

- In the USA, FDA has a focus on preventing name confusion
  - Part of drug approval process for new drugs
- Industry field testing of brand names
- FDA phonetic and orthographic computer analysis (POCA) software tool
- Incorporating mixed case (tall man) letters in look-alike drug names
  - FDA funded project with Northwestern University (Chicago)

Use of mixed case lettering to reduce drug name mix-ups



ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man (Mixed Case) Letters

Since 2008, ISMP has maintained a list of drug name pairs or larger groupings with recommended, uppercase and bolded tall man (mixed case) letters to help draw attention to the dissimilarities in look-alike drug names. The list includes mostly generic-generic drug name pairs, although a few brand-brand or brand-generic name pairs are also included. The US Food and Drug Administration (FDA) list of drug names with recommended tall man letters was initiated in 2001 with the agency's Name Differentiation Project (www.ismp.org/ext/1072).

While numerous studies between 2000 and 2021 have demonstrated the ability of tall man letters alone or in conjunction with other text enhancements to improve the accuracy of drug name perception and reduce errors due to drug name similarity,[1-12] some studies have suggested that the evidence is conflicting or the strategy is ineffective.[13-16] The evidence has been mixed due in large part to methodological differences and significant study limitations. However, because gaps still exist in our full understanding of the role of tall man lettering in the clinical setting, ISMP is participating in a 4-year Northwestern University (Chicago) research project, led by Bruce L. Lambert, PhD, and funded by FDA, to assess the comparative effectiveness of various methods of drug name text enhancements and the ability of tall man lettering to reduce errors during drug selection. Meanwhile, there is sufficient evidence to suggest that the simple and straightforward technique of using tall man letters is worth implementing as one among numerous strategies to mitigate the risk of errors due to similar drug names.

To await irrefutable, scientific proof of effectiveness minimizes and undervalues the study findings and anecdotal evidence available today[17] that support this important risk-reduction strategy. As such, the use of tall man letters has been endorsed by ISMP, The Joint Commission (TJC) (recommended but not required), FDA (as part of its Name Differentiation Project), as well as other national and international organizations, including the World Health Organization (WHO) and the International Medication Safety Network (IMSN).[18]

Table 1 (page 2) provides an alphabetized list of FDA-approved established drug names with recommended tall man letters.

Table 2 (starting on page 3) provides an alphabetized list of additional drug names with recommendations from ISMP regarding the use and placement of tall man letters. This is not an official list approved by FDA. It is intended for voluntary use by healthcare practitioners, drug information vendors, and medication technology vendors. Any product label changes by manufacturers require FDA approval.

To promote standardization regarding which letters to present in uppercase/bold, ISMP follows a tested methodology whenever possible called the CD3 rule.[19] The methodology suggests working from the left of the drug name first by capitalizing all the characters to the right once 2 or more dissimilar letters are encountered, and then, working from the right, returning 2 or more letters common to both words to lowercase letters. When the rule cannot be applied because there are no common letters on the right side of the name, the methodology suggests capitalizing the central part of the word only. When application of this rule fails to lead to the best tall man lettering option (e.g., makes names appear too similar, makes names hard to read based on pronunciation), an alternative option is considered.

To promote consistency, ISMP suggests following the bolded, tall man lettering schemes provided by FDA and ISMP for the drug name pairs listed in **Tables 1** (page 2) and **2** (starting on page 3).

Table 1. FDA-Approved List of Generic Drug Names with Tall Man (Mixed Case) Letters

Drug Name With Tall Man Letters	Confused With
aceta**ZOLAMIDE**	aceto**HEXAMIDE***
aceto**HEXAMIDE***	aceta**ZOLAMIDE**
bu**PROP**ion	bus**PIR**one
bus**PIR**one	bu**PROP**ion
CARBOplatin	**CIS**platin
chlorpro**MAZINE**	chlorpro**PAMIDE**
chlorpro**PAMIDE**	chlorpro**MAZINE**
CISplatin	**CARBO**platin
clomi**PHENE**	clomi**PRAMINE**
clomi**PRAMINE**	clomi**PHENE**
cyclo**SERINE**	cyclo**SPORINE**
cyclo**SPORINE**	cyclo**SERINE**
DAUNOrubicin	**DOXO**rubicin
dimenhy**DRINATE**	diphenhydr**AMINE**
diphenhydr**AMINE**	dimenhy**DRINATE**
DOBUTamine	**DOP**amine
DOPamine	**DOBUT**amine
DOXOrubicin	**DAUNO**rubicin
glipi**ZIDE**	gly**BURIDE**
gly**BURIDE**	glipi**ZIDE**
hydr**ALAZINE**	**HYDRO**morphone — hydr**OXY**zine
HYDROmorphone	hydr**ALAZINE** — hydr**OXY**zine
hydr**OXY**zine	hydr**ALAZINE** — **HYDRO**morphone
medroxy**PROGESTER**one	methyl**PREDNIS**olone — methyl**TESTOSTER**one
methyl**PREDNIS**olone	medroxy**PROGESTER**one — methyl**TESTOSTER**one
methyl**TESTOSTER**one	methyl**PREDNIS**olone — medroxy**PROGESTER**one
mig**ALA**stat	mig**LU**stat
mig**LU**stat	mig**ALA**stat
mito**XANTRONE**	Not specified
ni**CAR**dipine	**NIFE**dipine
NIFEdipine	ni**CAR**dipine
predniso**LONE**	predni**SONE**
predni**SONE**	predniso**LONE**
risperi**DONE**	r**OPINIR**ole
r**OPINIR**ole	risperi**DONE**
sulf**ADIAZINE**	sulfi**SOXAZOLE***
sulfi**SOXAZOLE***	sulf**ADIAZINE**
TOLAZamide	**TOLBUT**amide*
TOLBUTamide*	**TOLAZ**amide
tra**MAD**ol	tra**ZOD**one
tra**ZOD**one	tra**MAD**ol
vin**BLAS**tine	vin**CRIS**tine
vin**CRIS**tine	vin**BLAS**tine

* These drugs have been discontinued and are not marketed in the United States.

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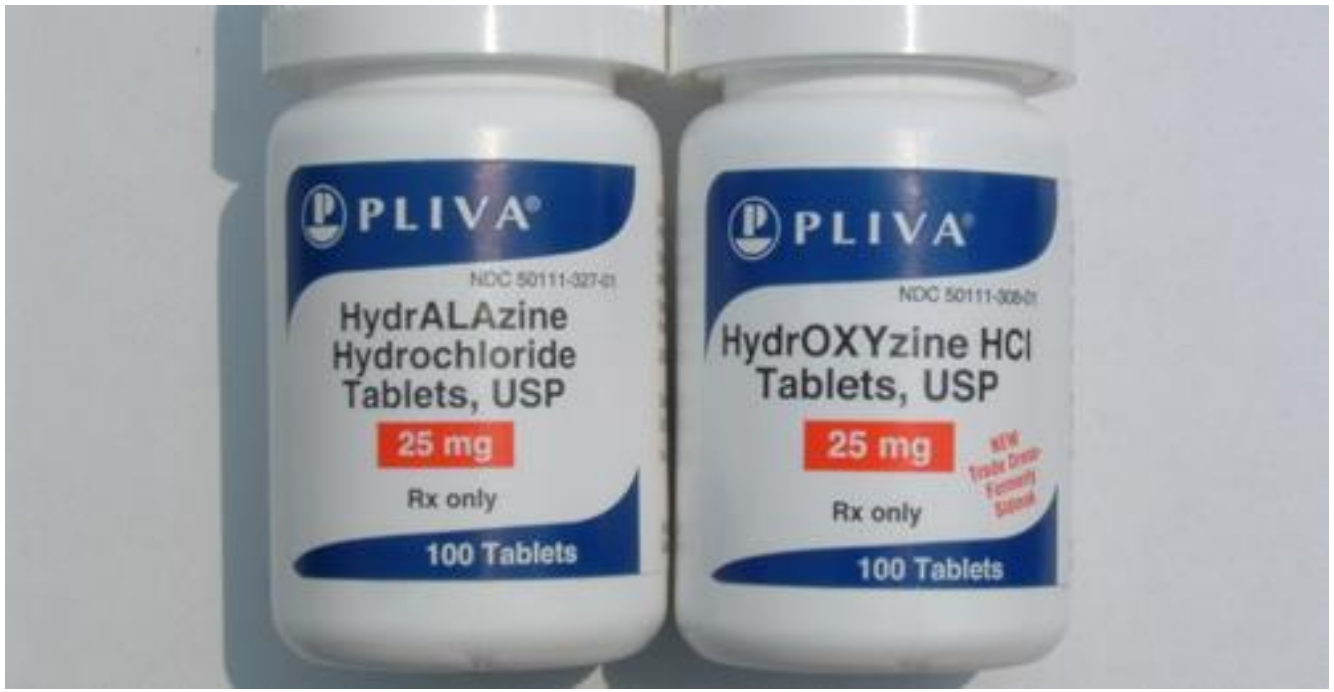
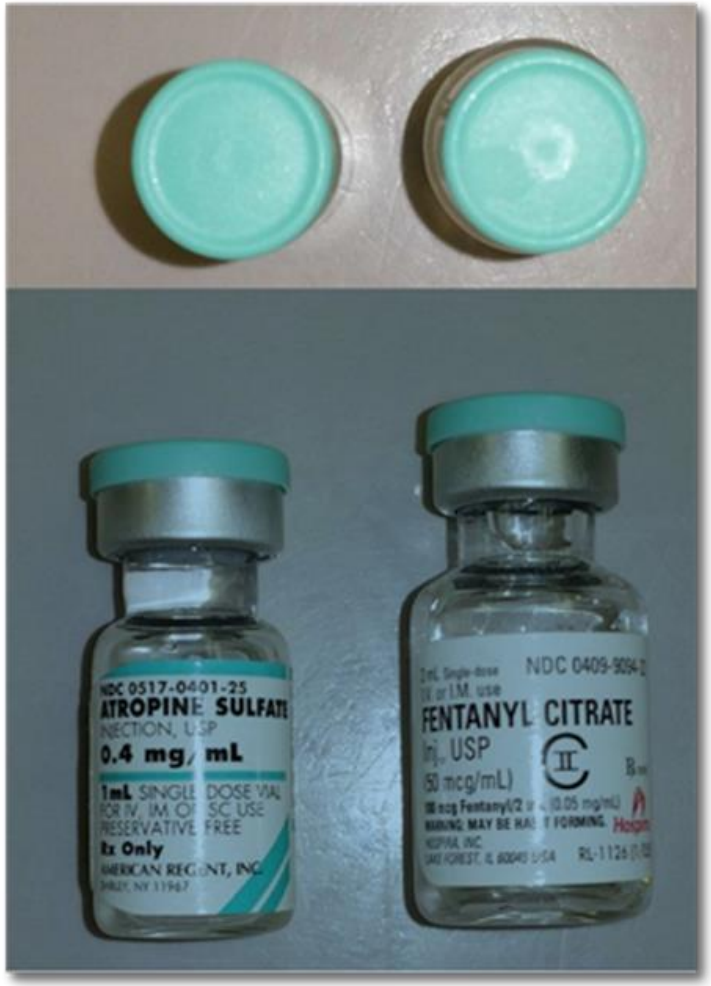

PLIVA
NDC 50111-327-01
HydrALAzine
Hydrochloride
Tablets, USP
25 mg
Rx only
100 Tablets
PLIVA
NDC 50111-308-01
HydrOXYzine HCl
Tablets, USP
25 mg
Rx only
100 Tablets


MAJOR
PHARMACEUTICALS
NDC 0904-6442-61
Unit Dose
HydrALAZINE
HYDROCHLORIDE
TABLETS, USP
50 mg
Each tablet contains:
Hydralazine Hydrochloride, USP ..... 50 mg
USUAL DOSAGE: See product insert for prescribing information, precautions and warnings.
SEE INSERT FOUND AT
WWW.MAJORPHARMACEUTICALS.COM
Store at 20°-25°C (68°-77°F); [See USP Controlled Room Temperature].
Dispense in a tight, light-resistant container as defined in the USP.
Keep this and all medication out of the reach of children. This Unit Dose package is not child resistant and is Intended for Institutional Use Only.
Rev. 04/17
Manufactured for:
Heritage Pharmaceuticals Inc.
Eatontown, NJ 07724
Distributed by:
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152 USA
3 09046 44261 5
MAJOR
PHARMACEUTICALS
NDC 0904-6618-61
Unit Dose
HydrOXYzine
HYDROCHLORIDE
TABLETS, USP
50 mg
Each film-coated tablet contains:
Hydroxyzine Hydrochloride, USP..... 50 mg
USUAL DOSAGE: See product insert for complete prescribing information, precautions and warnings.
SEE INSERT FOUND AT
WWW.MAJORPHARMACEUTICALS.COM
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Dispense contents in a tight, light-resistant container as defined in the USP, with a child-resistant closure, as required.
Keep this and all medication out of the reach of children. This Unit Dose package is not child resistant and is Intended for Institutional Use Only.
L302115
Rev. 07/17
Manufactured by:
Epic Pharma, LLC
Laurelton, NY 11413
Méd. in USA
Distributed by:
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152 USA
3 09046 61861 4


Mountaintop Pharma
NDC 1234-567-89
hydrOXYzine Hydrochloride Tablets, USP
50 mg
100 Tablets
Rx only
Mountaintop Pharma
NDC 1234-567-89
hydrALAZINE Hydrochloride Tablets, USP
50 mg
100 Tablets
Rx only
Mountaintop Pharma
NDC 1234-567-89
hydrOXYzine Hydrochloride Tablets, USP
50 mg
100 Tablets
Rx only
Mountaintop Pharma
NDC 1234-567-89
hydrALAZINE Hydrochloride Tablets, USP
50 mg
100 Tablets
Rx only
Mountaintop Pharma
NDC 1234-567-89
hydrOXYzine Hydrochloride Tablets, USP
50 mg
100 Tablets
Rx only
Mountaintop Pharma
NDC 1234-567-89
hydrALAZINE Hydrochloride Tablets, USP
50 mg
100 Tablets
Rx only
Mountaintop Pharma
NDC 1234-567-89
hydroxyzine Hydrochloride Tablets, USP
50 mg
100 Tablets
Rx only
Mountaintop Pharma
NDC 1234-567-89
hydralazine Hydrochloride Tablets, USP
50 mg
100 Tablets
Rx only

Look-alike Vials Due to the Same Cap Color



Look-alike Labels

ISMP Medication Safety Alert! 2019;18(11):3-4. *ISMP Medication Safety Alert!* 2017;16(1):2-3.
ISMP Medication Safety Alert! 2019;24(17):1-2. *ISMP Medication Safety Alert!* 2020;25(2):4.

[Global Meeting on Drug Product Labelling and Packaging Safety – Cascais, Portugal | International Medication Safety Network (intmedsafe.net)]

Attendees at Labeling and Packaging Summit

- Brazilian Health Regulatory Agency (ANVISA)
- Mexico Federal Commission for the Protection against Sanitary Risks (COFEPRIS)
- European Medicines Agency (EMA – European Union)
- Health Canada
- Portugal National Authority of Medicines and Health Products (INFARMED)
- Netherlands Medicines Evaluation Board (MEB)
- United Kingdom Medicines & Healthcare products Regulatory Agency (MHRA)
- Saudi Food and Drug Authority (SFDA)
- US Food and Drug Administration (FDA)

Labeling and packaging summit

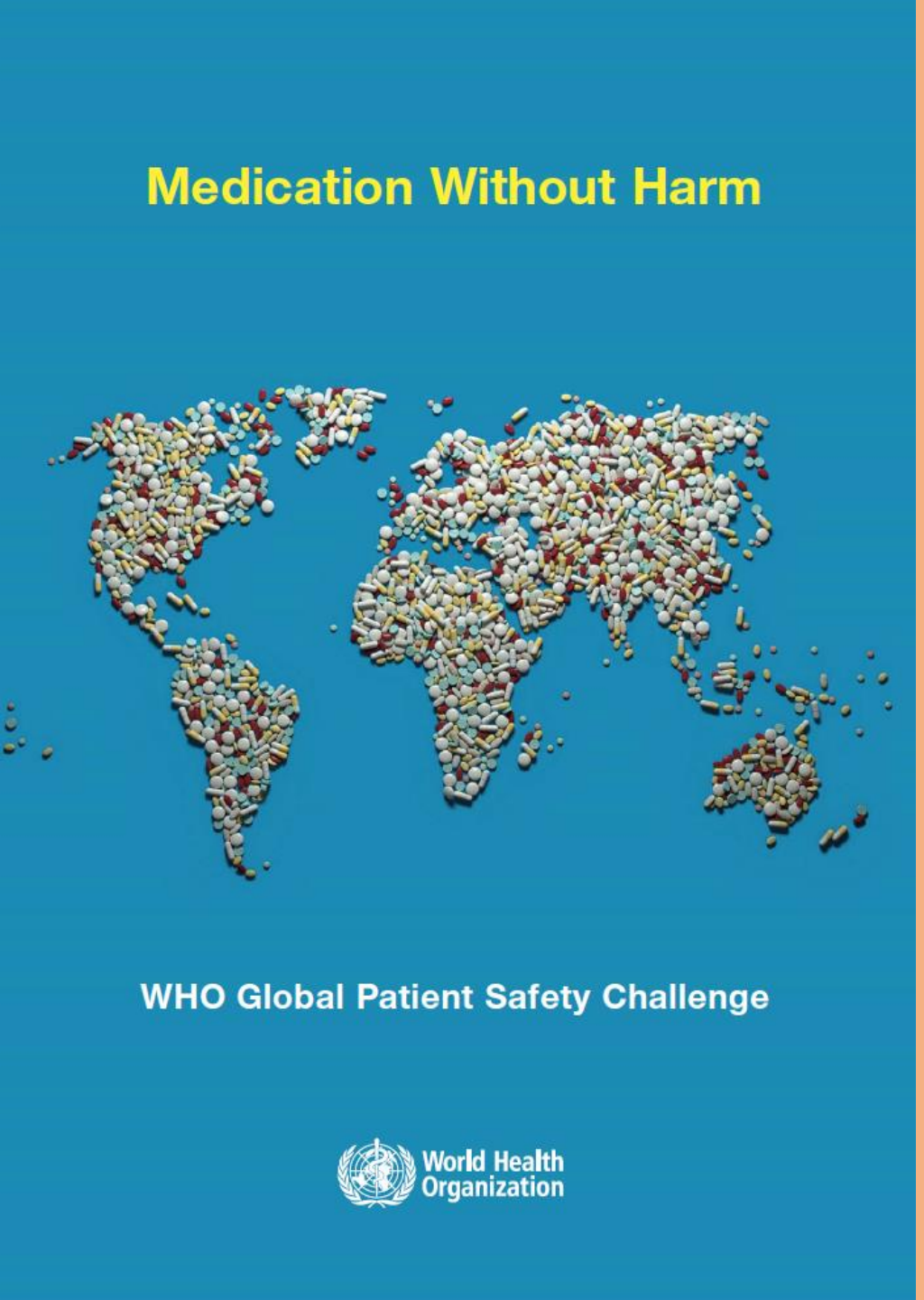
- Participants agreed on the following best practices:
- Include both the per mL and the per container quantity, not the per mL quantity alone, when presenting the concentration for injectable; with prominence given to total content per container
- Use metric units for products and eliminate ratio expressions
- Eliminate potentially error-prone abbreviations and dose designations on labels, such as U for units, IU for international units, and trailing zeros (e.g., 1.0) to express strength
- Prominently display cautionary statements on the carton and immediate container labels of NMBs, KCL concentrate injection, methotrexate, and other selected error-prone medications

Global Meeting on Drug Product Labelling and Packaging Safety – Cascais, Portugal | International Medication Safety Network (intmedsafe.net)

Labeling and packaging summit

- Use contrasting label backgrounds for printing on glass ampules and recommended font size and label orientation to improve readability
- Physically link or integrate "special" diluents for "specific drugs" with their powder component
- Increase the adoption of RTU/ready-to-administer syringes, premixed IV solutions, unit-dose packaging, and other more efficient, safer packaging, while considering the overall cost of implementation
- Develop product-specific world safety standards; for example, standard packaging for non-oncologic methotrexate to prevent accidental daily use and overdose
- Include barcodes on primary packages so they can be scanned at the bedside or other locations where medications are dispensed and administered by healthcare practitioners
- Mention prominently international non-proprietary names (INN) on labels

Global Meeting on Drug Product Labelling and Packaging Safety – Cascais, Portugal | International Medication Safety Network (intmedsafe.net)



The role of healthcare workers in preventing LASA errors

Angela Carrington

Lead Pharmacist for Medication Safety

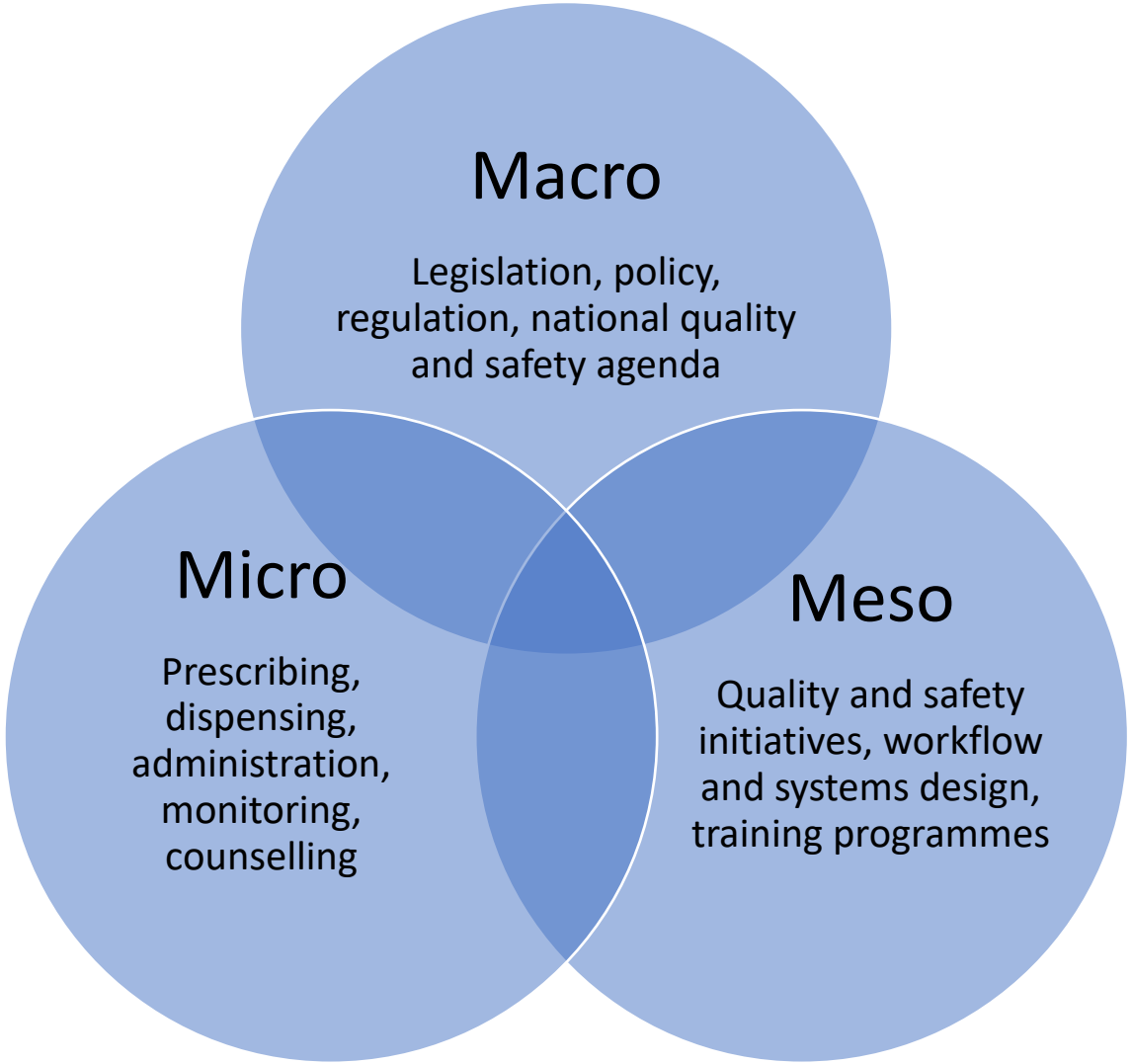
Health and Social Care

Northern Ireland

World Health Organization

MEDICATION WITHOUT HARM
Global Patient Safety Challenge

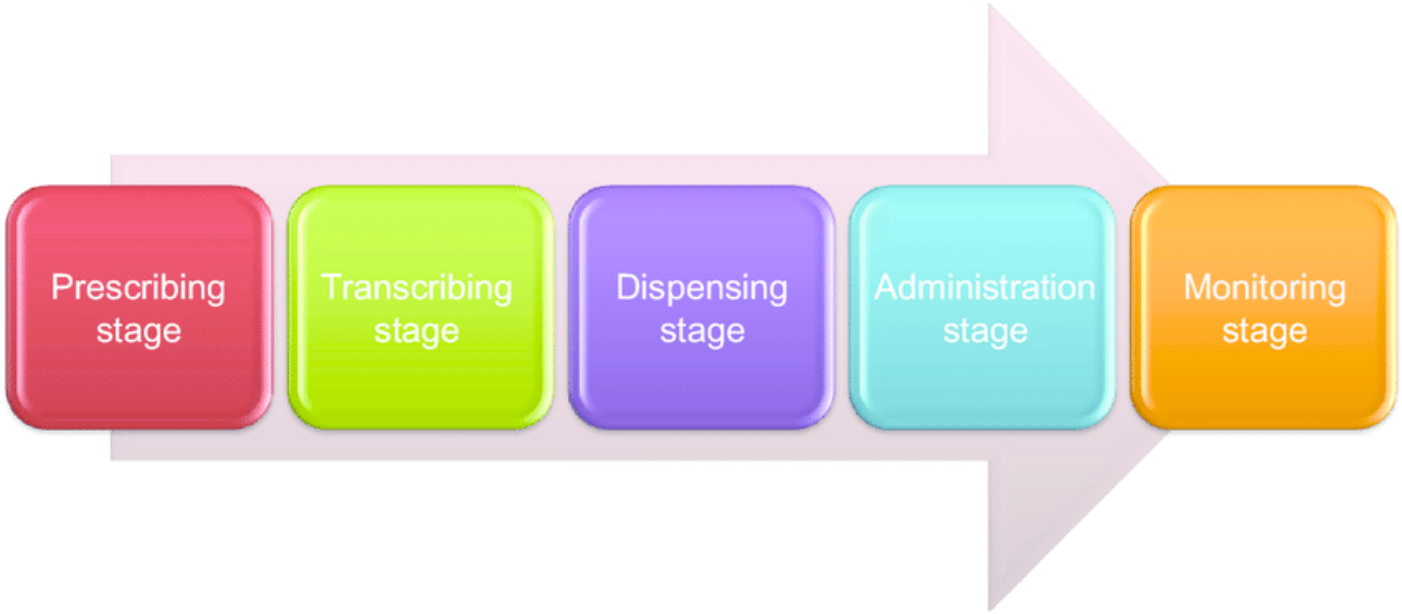
The System Layers of Medication Safety



Everyone at **every** level is **responsible** for medication safety

LASA Errors

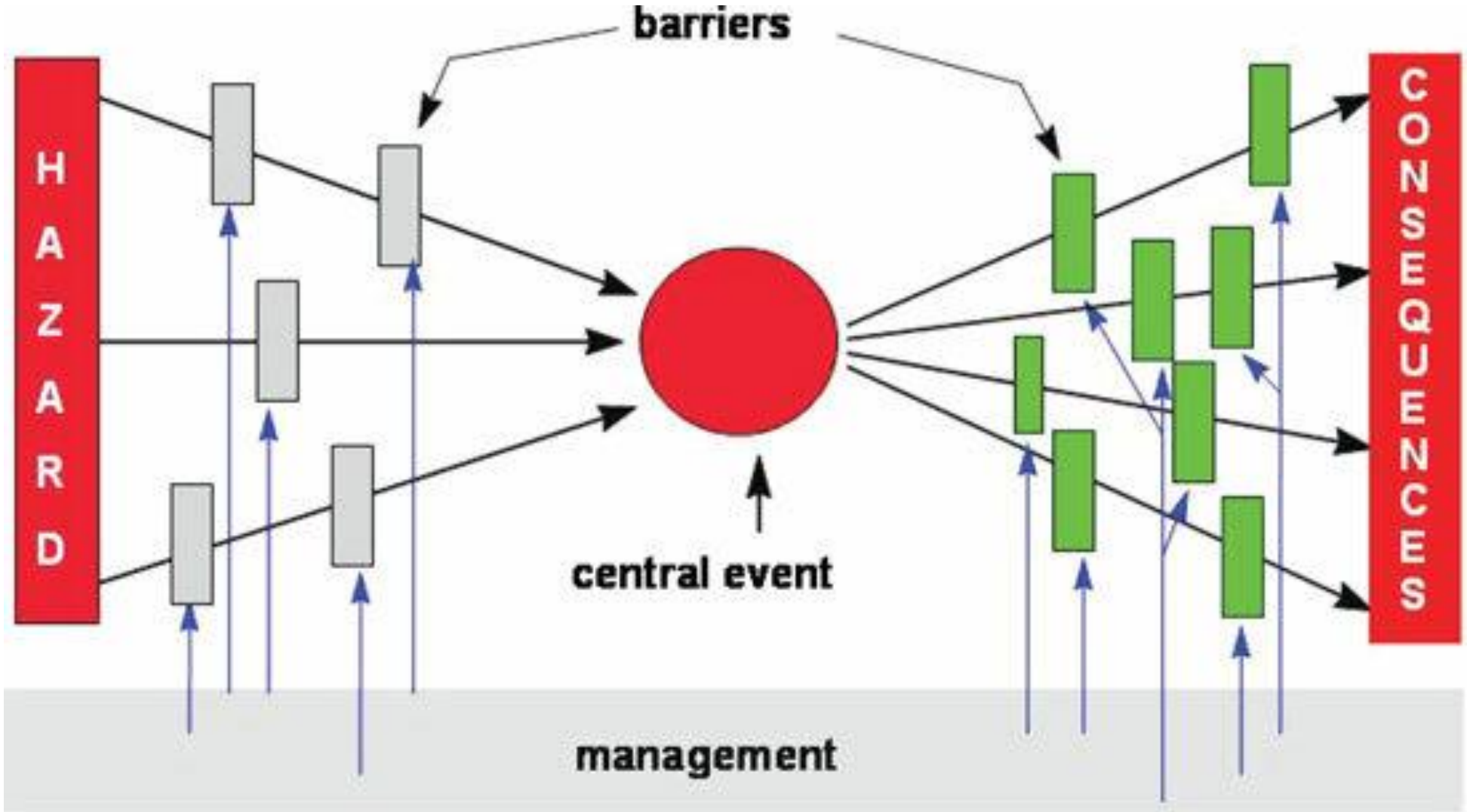
- 6.2% to 14.7% of all medication errors
- Occur at all stages of the medication use process
- Fallibility ‘ liability to error’ is a human trait



“Human beings make mistakes because the systems, tasks and processes they work in are poorly designed.”

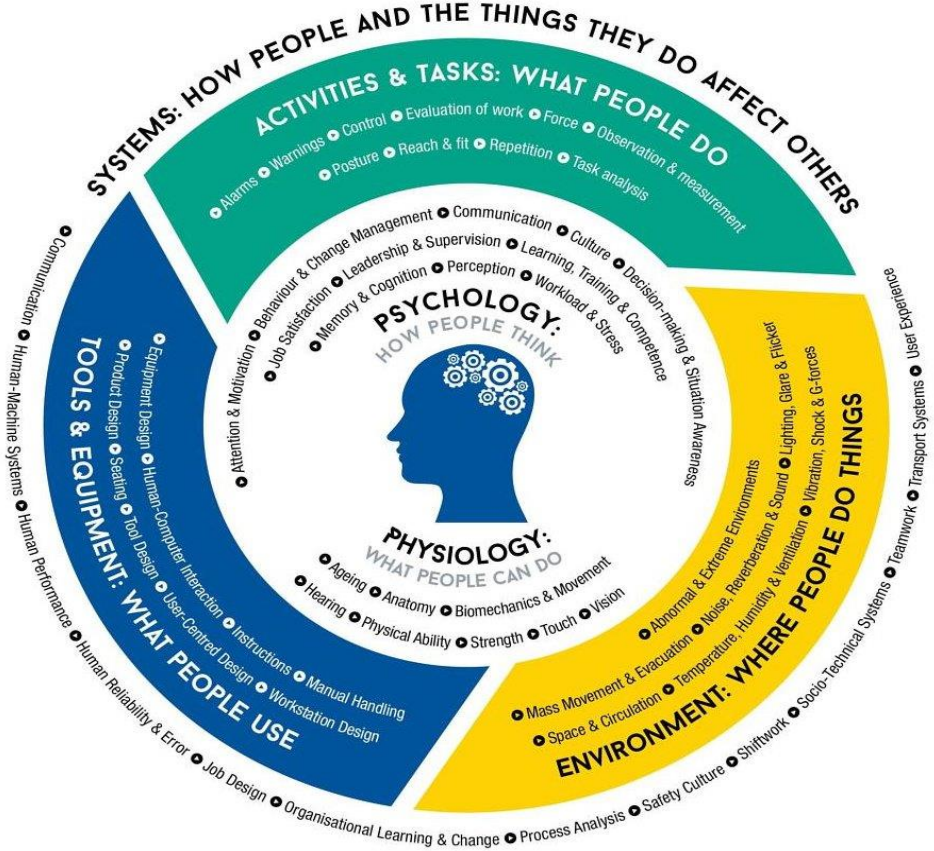
Professor Lucian Leape
Harvard School of Public Health

LASAs as latent hazards



Applying Human Factors/Ergonomics (HFE)

- "Ergonomics (or Human Factors) is…concerned with the **understanding of interactions among humans and other elements of a system…**in order to optimize human **well-being** and overall **system performance**..." (IEA, 2000)

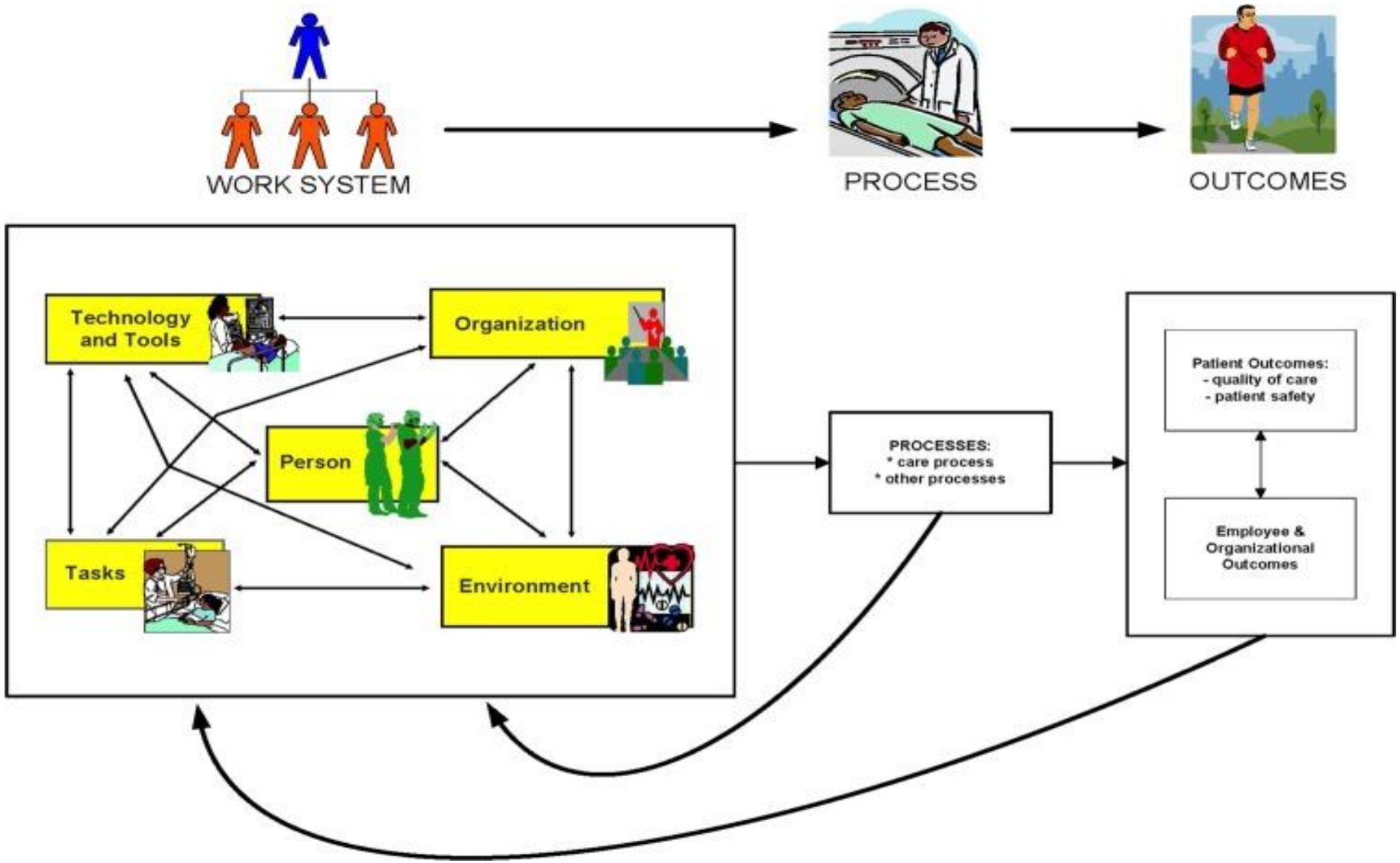


- Applying Human Factors aims to ensures the best possible match between the product (object, environment, system etc) being designed and its users…

In the context of the task that is being performed

- Ergonomics: the science of fitting the job to the worker… the product to the user

SEIPS (Systems Engineering Initiative for Patient Safety)



SEIPS Explained

- SEIPS is the Safety Engineering Initiative for Patient Safety.
- It is based on a Human Factors systems approach to understanding care systems, processes and outcomes to inform better design and improvement.
- SEIPS can be used by anyone as a general systems analysis and problem-solving tool e.g. incident investigation; hazard identification; incident reporting & data collection; simulation design; protocol & checklist development; research design and data analysis..

Guiding Step

1. **As a team, use the worksheet as a prompt to highlight the system-wide factors that contribute to the issue at hand**
2. **Seek to understand how these factors influence processes and interact to produce outcomes (wanted or unwanted)**
3. **Link this new knowledge to making improvement recommendations**

Examples of Performance Influencing Factors (PIFs)

Person Factors

e.g. Physical, psychological capabilities, limitations and impacts (frustration, stress, fatigue, burnout, musculoskeletal, satisfaction, enjoyment, experiences, job control); personality or social issues; cognitive ; competence, skills, knowledge, attitudes; risk perception; training issues; personal needs and preferences; psychological safety; performance variability; personal goals; adaptation to work conditions.
Care team e.g. roles, support, communication, collaboration, supervision, management, leadership
Patient/client e.g. complexity of clinical condition, physical, social, psychological, relationship factors
Others e.g. families and carers, and other health and social services colleagues

Tools & Technology

e.g. design interaction and usability issues; positioning; availability; access; mobility; operational/calibrated; device usability; various IT design issues; electronic records, barcoding.

Task Factors

e.g. level of task complexity; time taken; hazardous nature; capacity and demand match/mismatch; distractions; interruptions; variety of tasks; job content, challenge and utilization of skills; autonomy, job control and participation; job demands (e.g. workload, time pressure, cognitive load, need for attention)

Physical Environment

e.g. Layout; Noise; Lighting; temperature; humidity and air quality; design of immediate workspace or physical environment layout; location; size; clutter; standardisation, aesthetics; crowding

External Influences

e.g. Societal, government, cultural, accreditation and regulatory influences e.g. funding, national policies and targets, professional bodies, regulatory demands, legislation and legal influences, other risks and influences

Organisation of Work Factors

e.g. Coordination, collaboration and communication; organizational culture and safety climate; work schedules and rota design; social relationships; teamwork; supervisory, management and leadership style; performance evaluation, rewards and incentives; organisational strategy, work priorities/targets; conflicting goals; structure and hierarchies; staffing levels; rewards and incentives; risk assessment; **education, training and development environments e.g.** supervision, competence, protected time, professional development, physical and social learning environment

Outcomes

Outcomes – System Performance

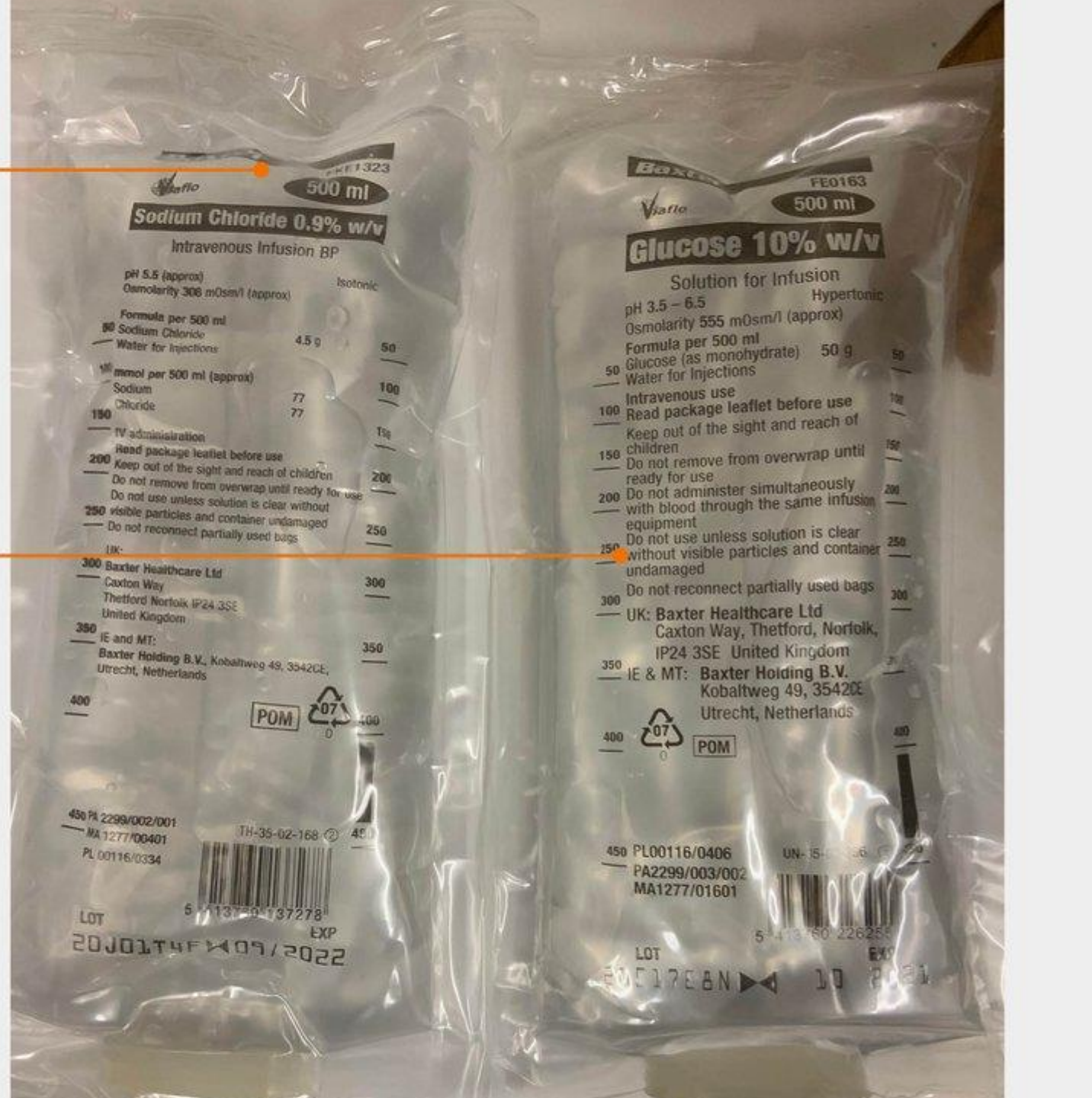
e.g. Safety; productivity; resilience; efficiency; effectiveness; care quality

Outcomes – Human Wellbeing

e.g. Health and safety; patient satisfaction and experience; enjoyment; staff turnover; staff welfare; job satisfaction

ine (0.9%
chloride)

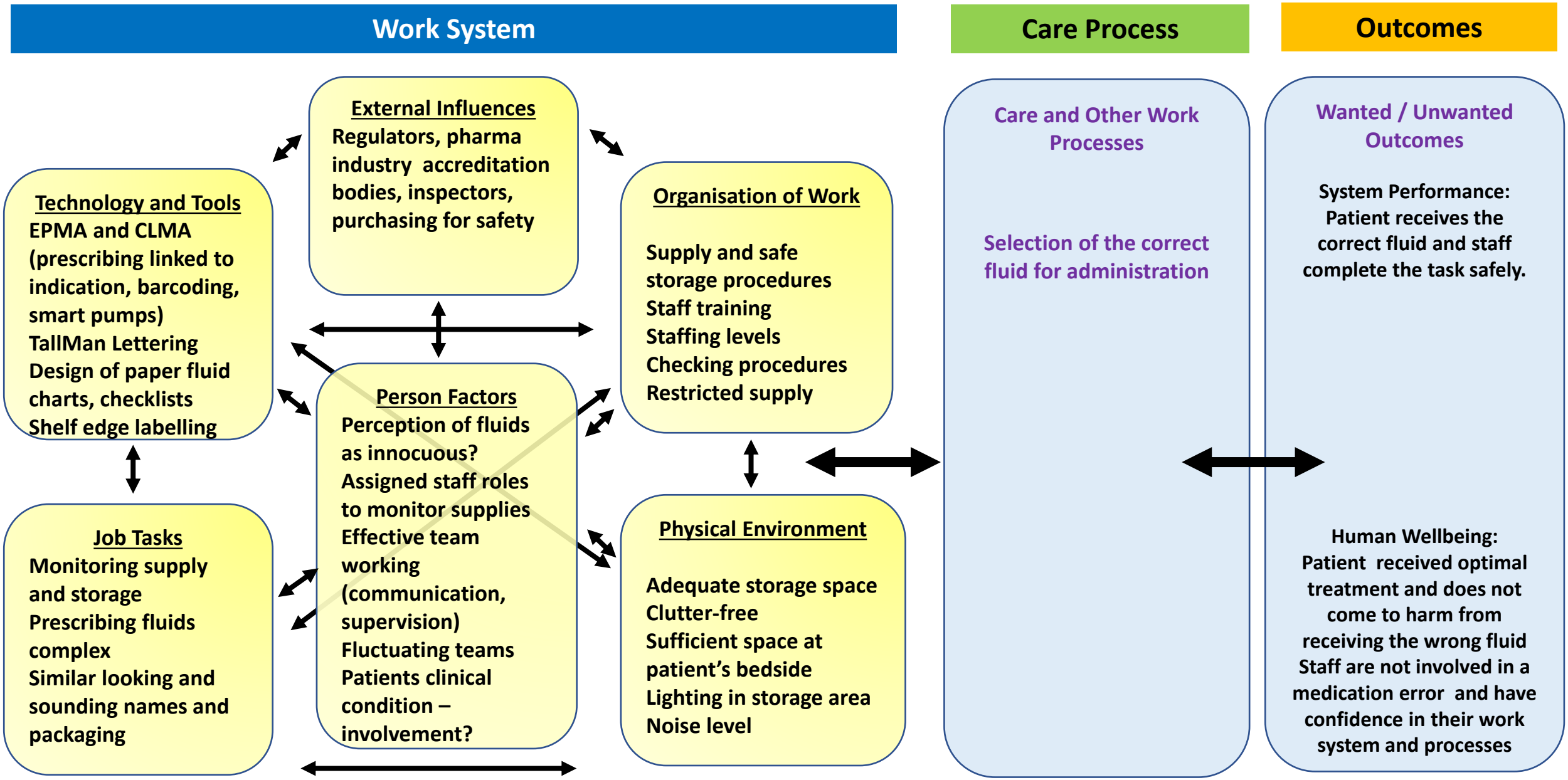
Glucose



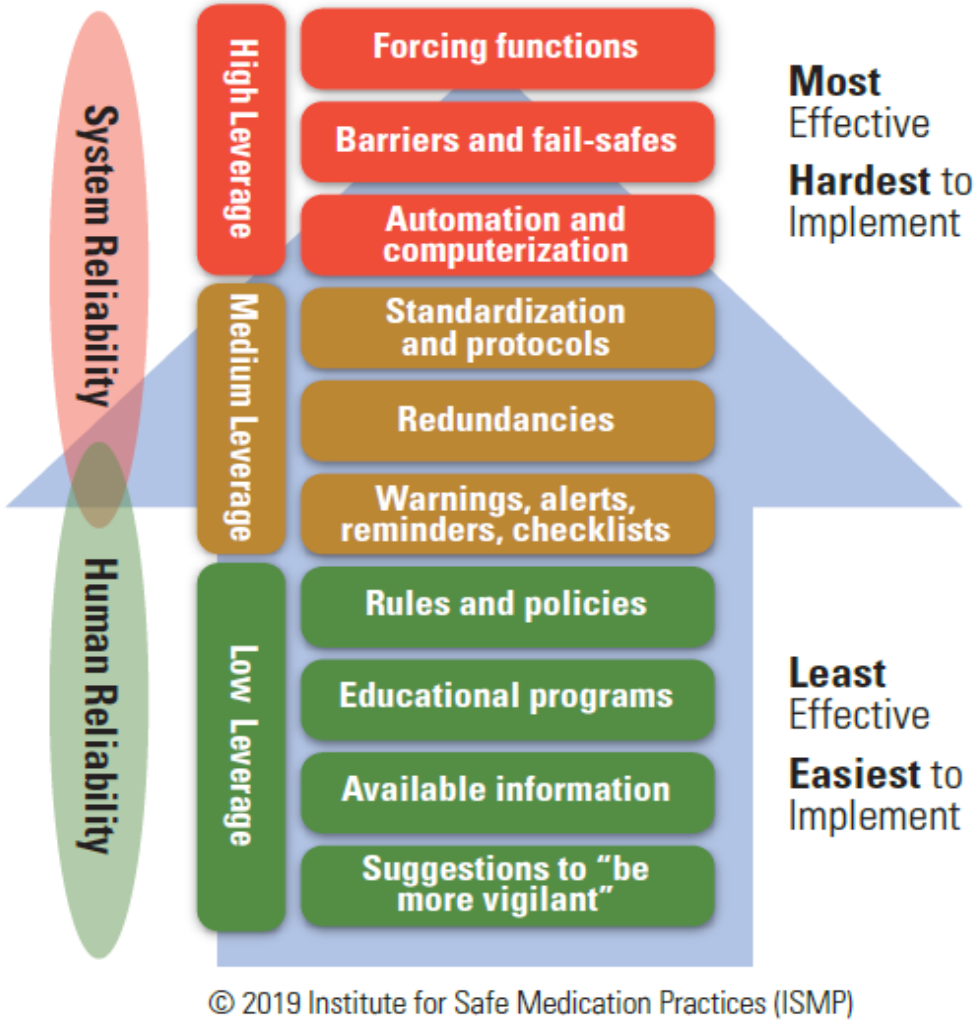

Glucose 5% 100ml
Baxter
B BRAUN
Sodium Chloride 0.9%
500ml
Sodium Chloride 0.9%
250ml

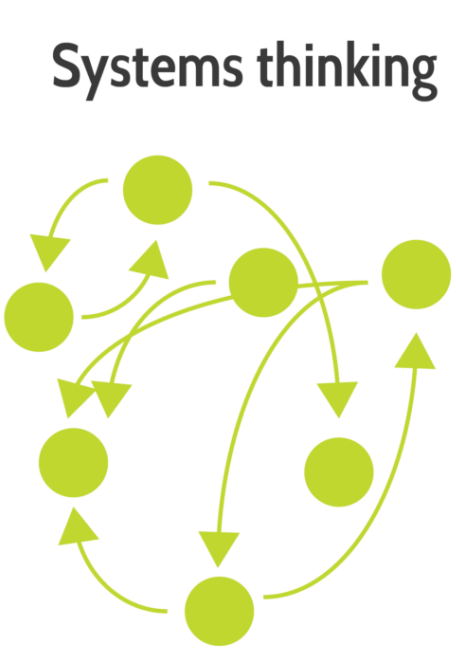

RADC01TB
50%
Sodium Chloride 0.9%
5% w/v Glucose
10 x 1000 ml
Glucose 10% 500ml

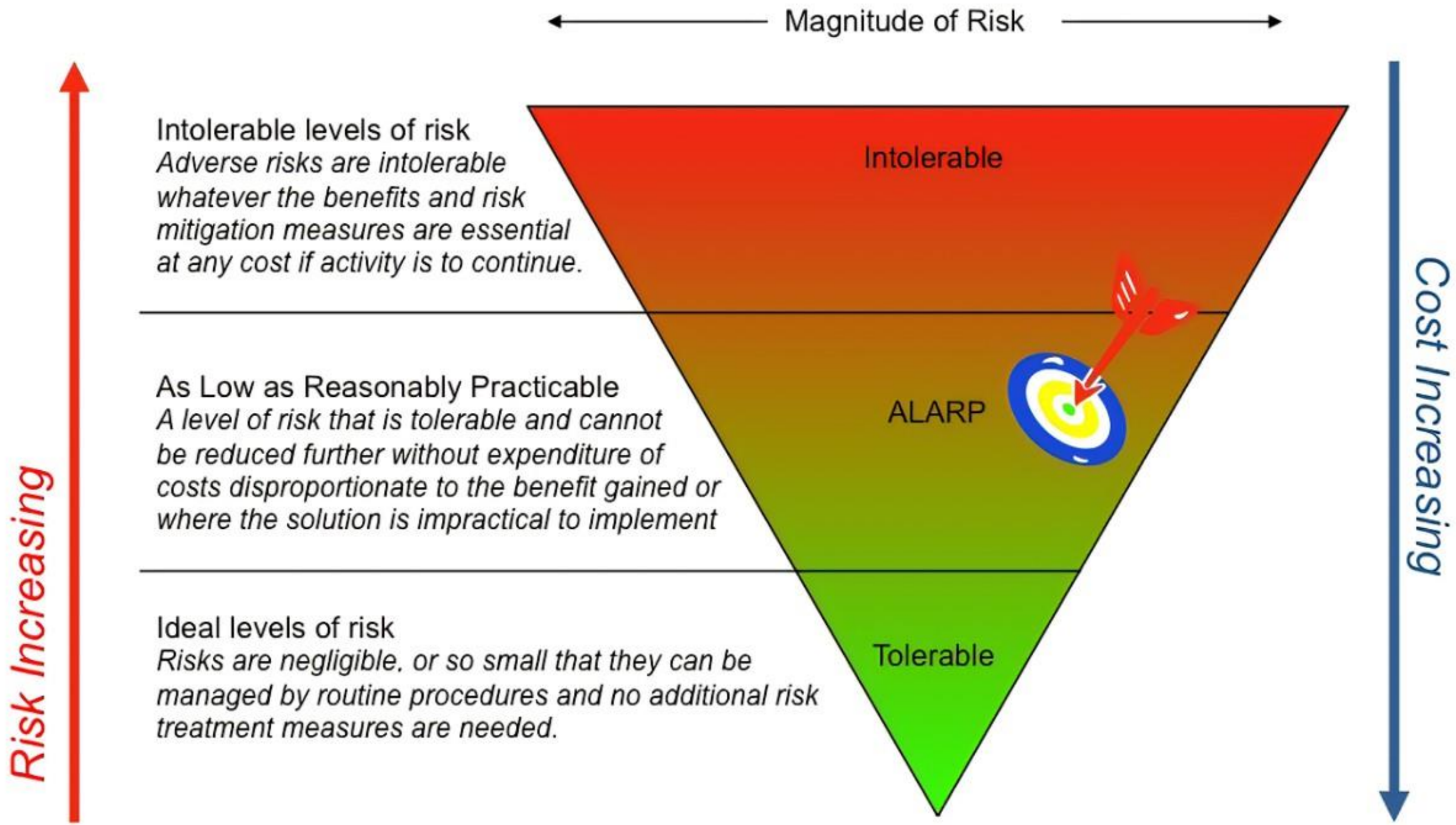
Systems Engineering Initiative for Patient Safety (SEIPS) Worksheet



Hierarchy of Intervention Effectiveness





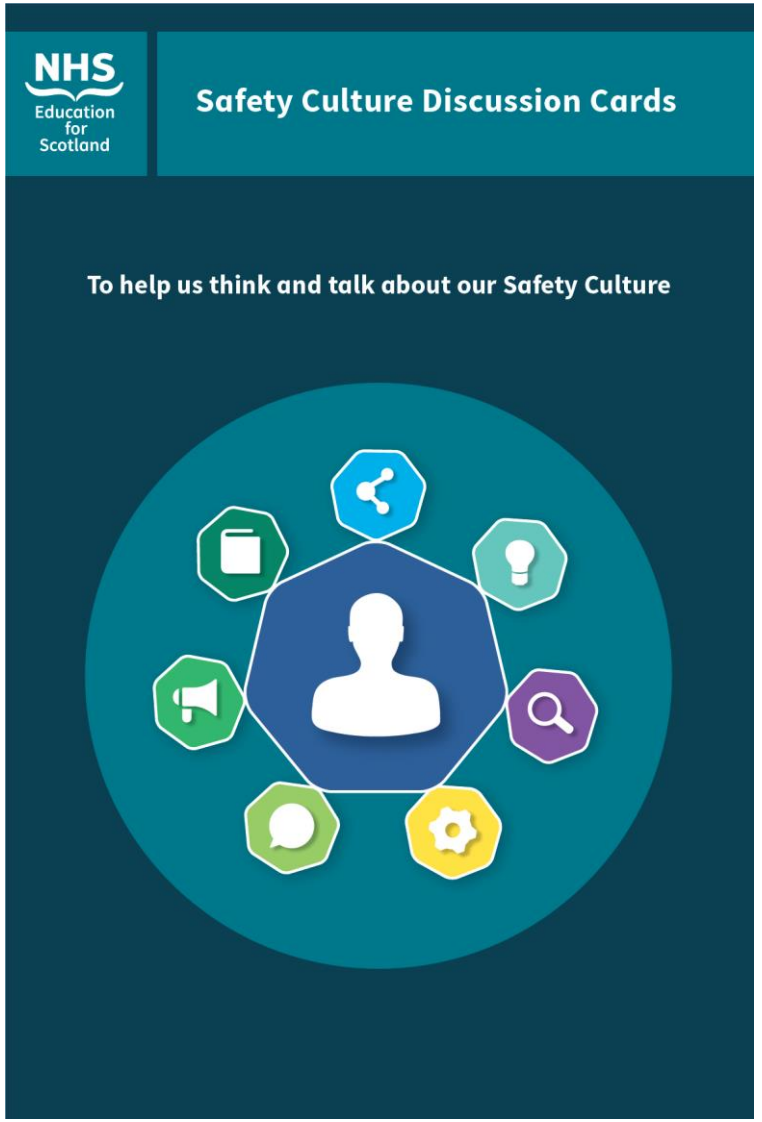

Magnitude of Risk
Risk Increasing
Cost Increasing
Intolerable levels of risk
Adverse risks are intolerable whatever the benefits and risk mitigation measures are essential at any cost if activity is to continue.
As Low as Reasonably Practicable
A level of risk that is tolerable and cannot be reduced further without expenditure of costs disproportionate to the benefit gained or where the solution is impractical to implement
Ideal levels of risk
Risks are negligible, or so small that they can be managed by routine procedures and no additional risk treatment measures are needed.
Intolerable
ALARP
Tolerable

Key actions to prevent LASA errors

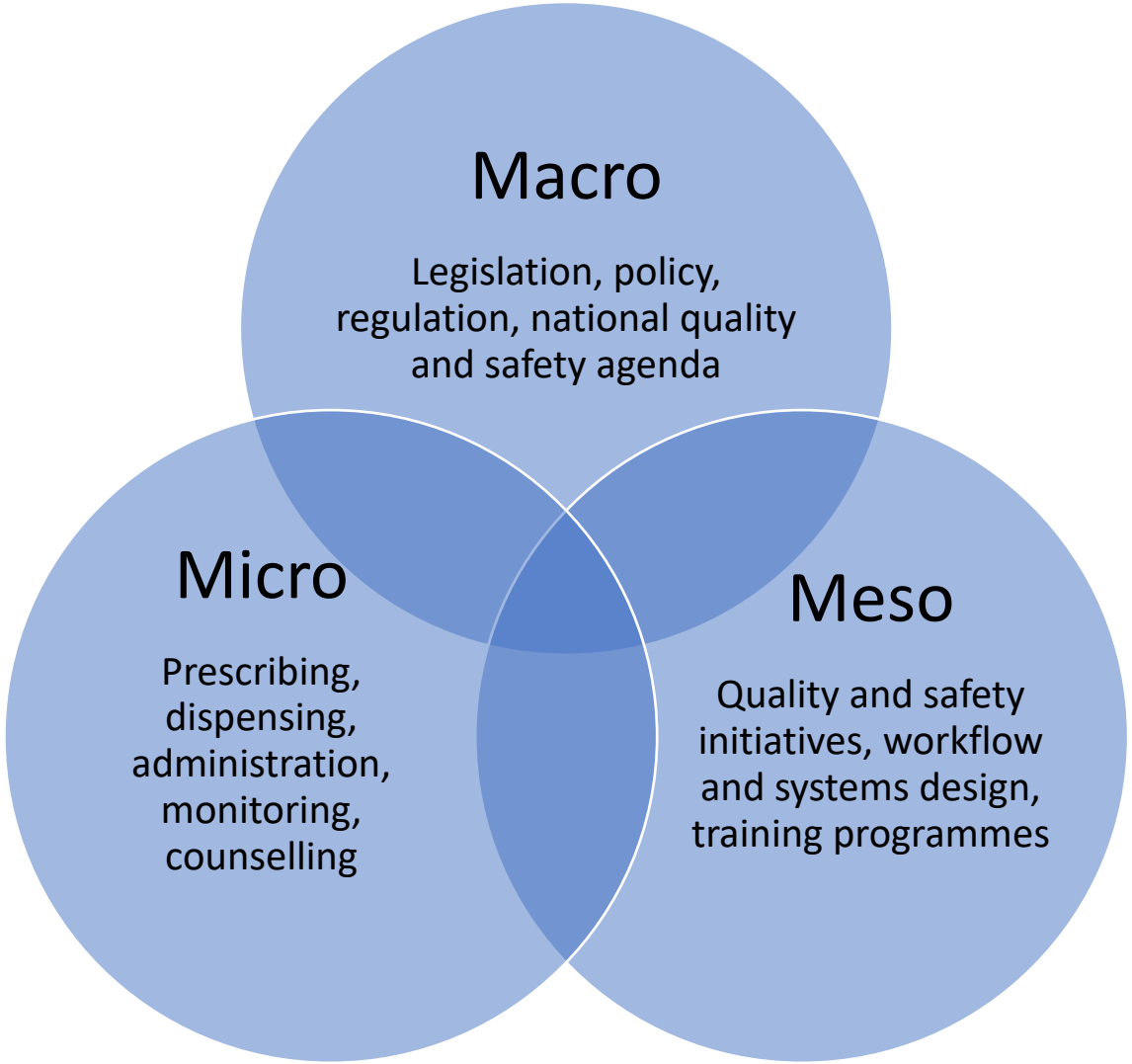
- ✓Identify LASA Hazards in medication use process
- ✓Use a systems based approach
- ✓Consider the barriers and consequences
- ✓Identify strengths and weaknesses
- ✓Risk assess potential of harm
- ✓Understand level of risk acceptance
- ✓Develop and implement strategies –involve those doing the work!
- ✓Purchasing for safety
- ✓Enlist expertise
- ✓Include within medication safety Education and Training
- ✓Undertake ongoing evaluation and improvement
- ✓Continue to report errors

LASA Management – Safety Culture

- Reporting and learning
- Involvement of staff in decision making
- Systems thinking mindset
- Safety first
- Getting it right the first time



The System Layers of Medication Safety



Everyone at **every** level is **responsible** for medication safety

Challenges of implementing safety solutions for LASA medicines in low-and middle-income countries

Dr. Priyadarshani Galappatthy

WHO consultant

Professor of Pharmacology

Faculty of Medicine

University of Colombo

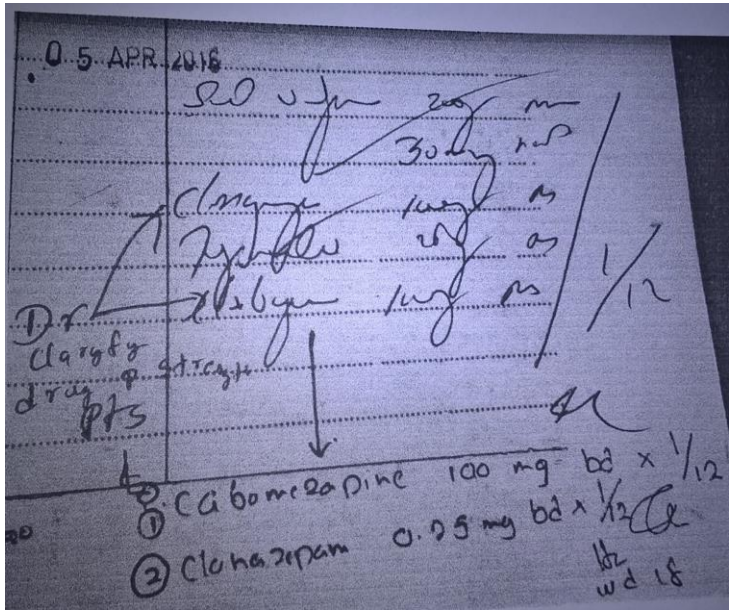
Sri Lanka

World Health Organization

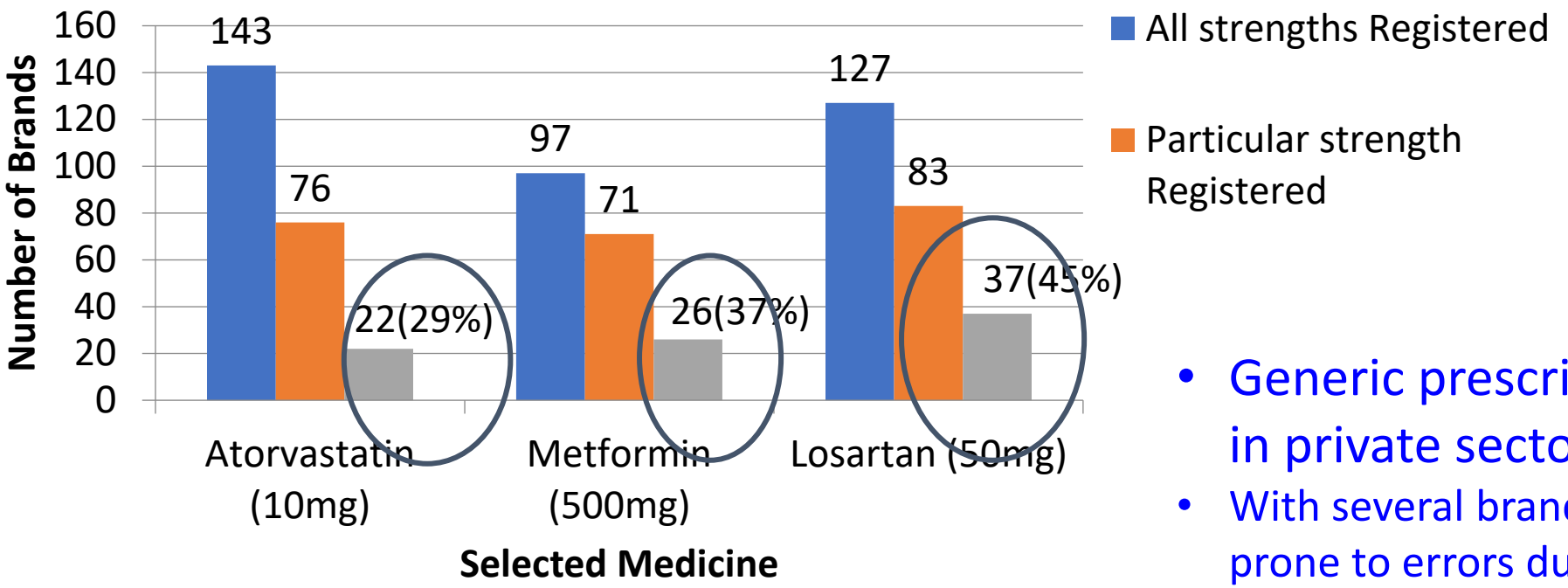
MEDICATION WITHOUT HARM
Global Patient Safety Challenge

Many challenges in LMIC to overcome LASA errors

- Absence of a LASA medicines list
- Lack of awareness of LASA medicines
- Poorly legible handwriting
- Availability of large number of brands
- Prescribing using brand names in private sector
- Lack of proper labelling
- Patient load to dispense medicines
- Staff shortages
- Lack of clinical pharmacists in wards
- Poor medication literacy of patients



Availability of large number of different brands of the same medicine

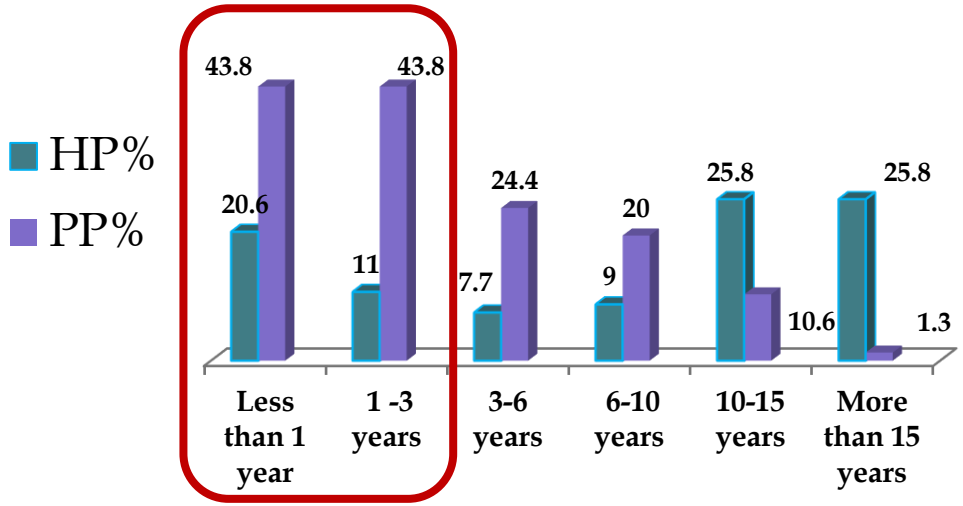


- **The NMRA Act was revised with a 'need' clause added to limit number registered.**

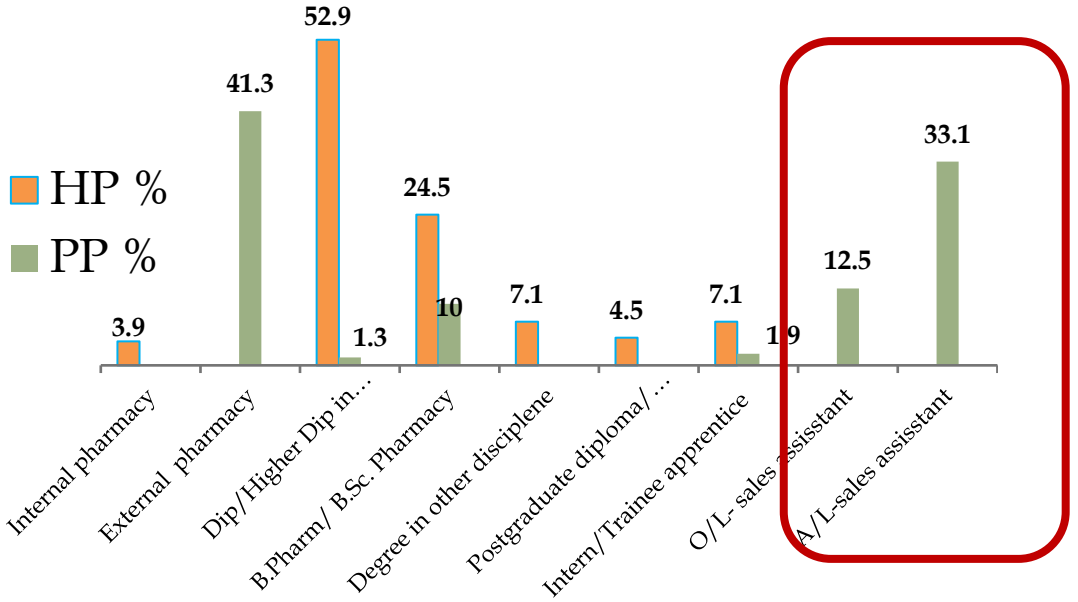
- Generic prescribing – 36 % in private sector
- With several brands - more prone to errors due to high-risk LASA medicines
- Eg. Navane (thiothixene, an antipsychotic) dispensed for Norvasc (amlodipine)

A project to identify a LASA medicines list for Sri Lanka and implement practices to prevent errors

- Study in two major Teaching hospitals – all hospital pharmacists (HP = 155) and pharmacists in 80 private sector pharmacies in the area (PP = 160)



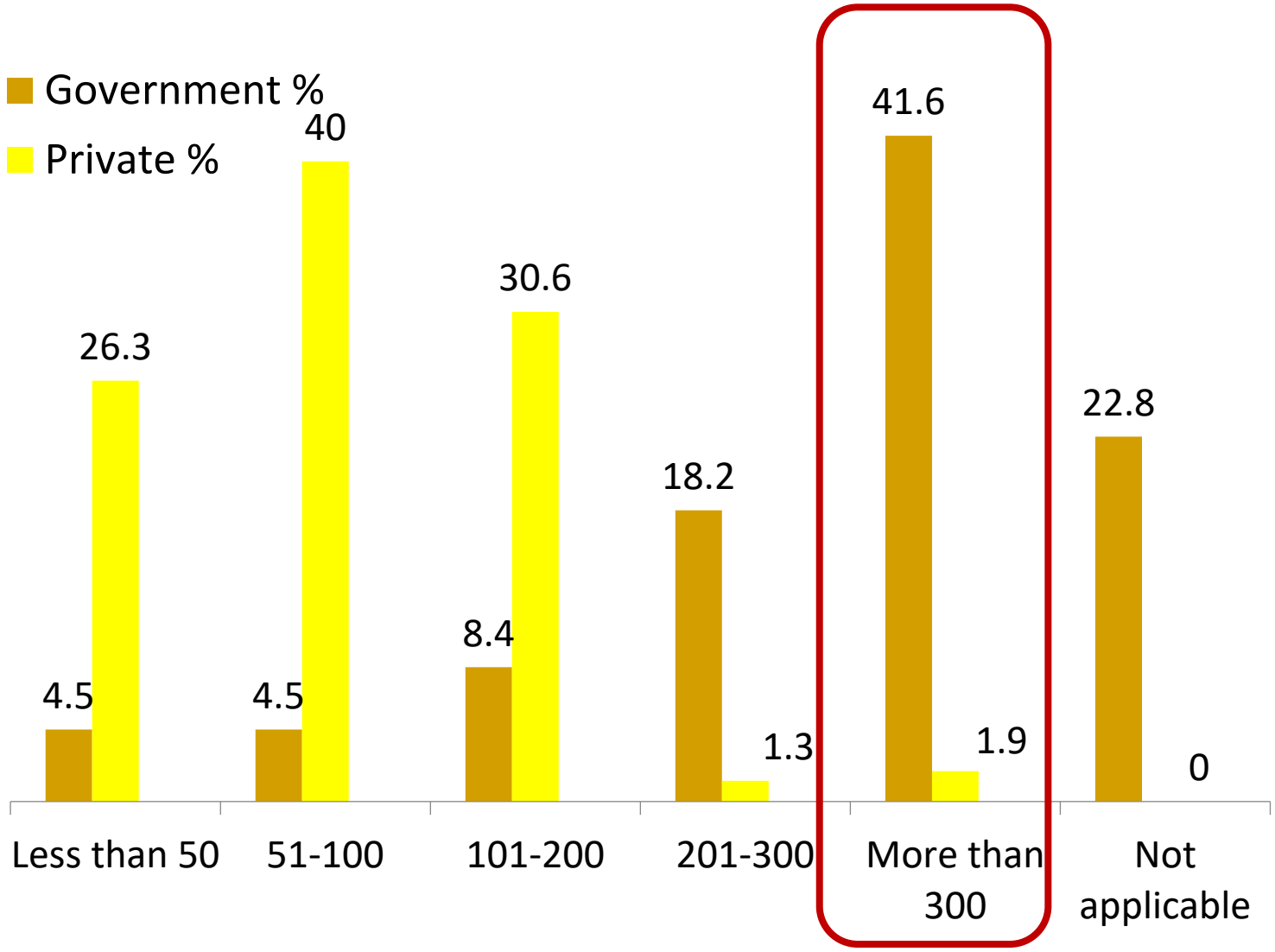
Service experience



Highest education level

A patient prescribed metformin 500mg bd was dispensed methotrexate 5mg bd – developed low counts, sepsis and patient died

Average number of prescriptions issued per day by a pharmacist (n=315)



- Extremely high Patient load to dispense medicines due to lack of referral system and staff shortages
- Lack of time for patient advice and engagement

Important practices on LASA medicines by hospital and private sector pharmacists (n=315)

Aspects that were assessed on LASA medicines	**Hospital % n=155**	**Private % n=160**	**P value**
Availability of a LASA list	0	0	
Labelled with large font	10.4	0	<0.001
Labelled with Tall-Man-Lettering	2	0	<0.001
Used label enhancements/colour coding	7.2	0.6	<0.001
Alerted staff members when two different medicine packages were having similar packages/labels	22.5	0	<0.001
Segregated storage LASA medicines to avoid mix-up	9.8	0	<0.001
Stored separately the same medicine with different strengths and routes	24.2	6.9	<0.001

- Safety practices in both sectors were poor with significant difference in practices between the two settings and some key practices were absent in private sector pharmacies.

NATIONAL ACTION PLAN ON MEDICATION SAFETY FOR SRI LANKA

Ministry of Health
Sri Lanka

Officially launched on the World Patient Safety Day -2021

Domain	Proposed activity	Time frame	Sub activities	Key Performance Indicators (KPIs)	Stakeholders/ Persons/Institutions /Organizations responsible	Responsibility for implementation
2. Medicines	2.1 Activities to identify look alike sound alike (LASA) medicines and take steps to prevent mix ups; i. Use Tall man lettering to identify LASA drugs ii. Storing separately iii. Scrutinize during registration of medicines by the NMRA	2021 - 2024	1. Developing a list of Look Alike Sound Alike (LASA) drugs used in the Sri Lankan settings and recommend tall man lettering for those. 2. Distribution of the list of identified LASA drugs to hospitals through DHQS. 3. Sending a request to hospitals to store LASA medicines separately. 4.Establishing a mechanism to prevent allocating "Sound alike" brand names at the point of registration of medicines by the NMRA. 5.Establishing a mechanism at NMRA; to prevent registering critical medicines (such as warfarin tablets) with same color for different strengths; registering drugs (Eg:	1. Number of hospitals practicing "Tall man lettering" for LASA drugs. 2. Number of hospitals storing LASA medicines separately. 3. Number of incidents identified and prevented from allocating sound alike brand names at the point of registration by the NMRA. 4.Number of similar looking medicines	Government Pharmacists, PSSL, DHQS, NMRA, SLMA, SLDA, CCP, Other professional colleges	Academics, researchers and other healthcare workers involved in work in these areas

Examples of LASA medicine pairs in government and private sector

Clonazepam	Clobazam (5)
Carbamazepine	Carbimazole (4)
Glibenclamide	Gliclazide (3)
Flunnarazine	Fluoxetine (2)
Phenobarbitone	Phenytoin (2)
Atorvastatin	Atenolol (2)
Clonazepam	Clozapine (2)
Cyclophosphamide	Cyclosporine (2)
Amlodipine	Amitriptyline (2)
Chlorpromazine	Clomipramine (2)
Olanzapine	Omeprazole (2)
Theophylline	Thyroxine (2)
Chlorpheniramine	Chlorpromazine (1)
Amiodarone	amlodipine (1)
Mefenamic acid	Metformin (1)
Atenolol	Aldactone (1)
Hydrocortisone	Hydroxyurea (1)
Atenolol	Atorvastatin (1)

Alphapril (enalapril)	Amaryil (glimepiride)
Aldactone (spironolactone)	Aldomat (methyldopa)
Allegra (fexofenadine)	Viagra (sildenafil)
Arlin (linezolid)	Arnil (diclofenac sodium)
Asta (paracetamol)	Evista (raloxifene)
Azopt (brinzolamide)	Atropt (atropine)
Avanza (mirtazapine)	Avandia (rosiglitazone)
Betaloc (metoprolol)	Noklot (clopidogrel)
Brethin (terbutaline)	Brexin (piroxicam B)
Celepram (citalopram)	Celebrex (celecoxib)
Claritec (clarithromycin)	Clarityne (loratadine)
Diabeta (metformin)	Diamox (acetazolamide)
Dianben (metformin)	Diovan (valsartan)

A national LASA list identified for Sri Lanka

- Consultation with all relevant professional college to develop a national list
- A priority list identified
- Standard operating procedure being developed (E.g., Tall man lettering, segregating storage, labelling in local language
- A circular to be issued by the Director General Health Services requesting all hospitals

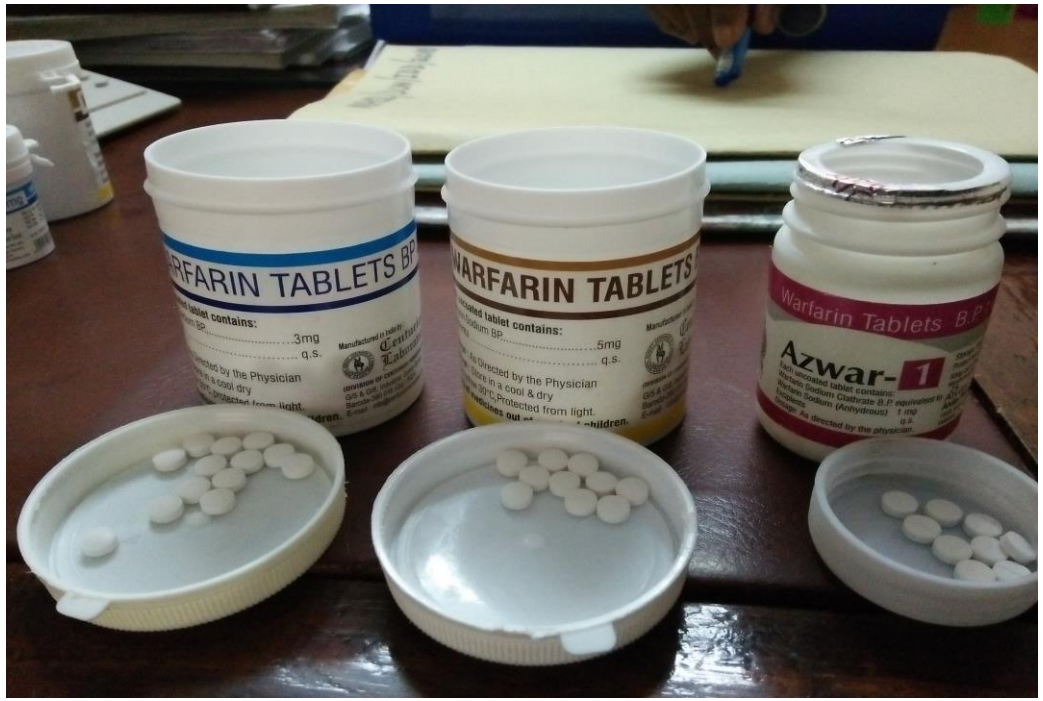
Sound-alike list

- Generic –Generic- 134
- Generic –Brand - 10
- Brand –Brand - 27

Look-alike list

- Generic –Generic - 26
- Generic –Brand - 05
- Brand –Brand - 08

Actions by Regulatory Authorities



Warfarin 1mg, 3mg and 5mg tablets of same color registered and available in government pharmacies

Patient admitted with bleeding and INR of 14

Manufacturers were requested by NMRA to change to blister packs

Some LASA interventions by LMIC

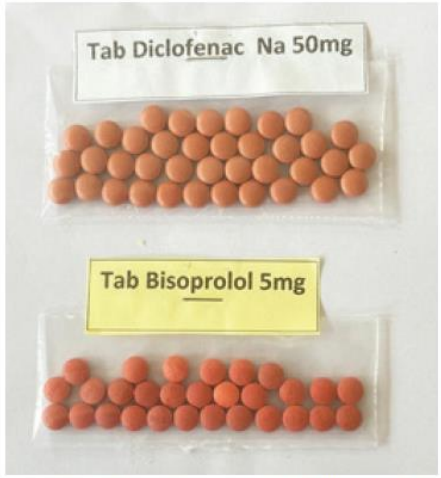
Figure 3: Labelling for LASA medicines in which "tall-man" lettering cannot be applied

CAUTION!
LOOK ALIKE
SOUND ALIKE DRUGS

Auxiliary labelling

Colour coded labelling

Figure 1b: Examples of tablets of LASA medicines identified from LMIC settings

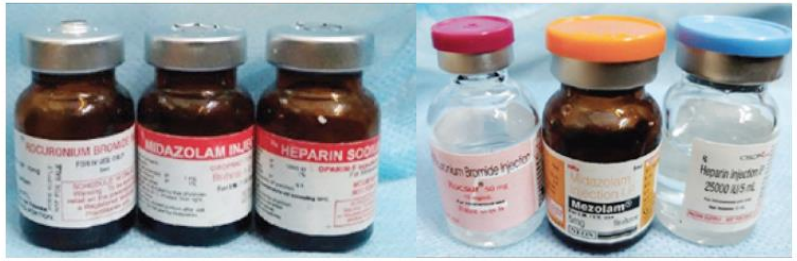


Diclofenac sodium 50 mg (nonsteroidal anti-inflammatory drug used for pain relief) and bisoprolol 5 mg (beta-blocker used for cardiac failure and hypertension)

Gliclazide 80mg (anti diabetic medicine) and enalapril 5 mg (used for hypertension and heart failure) These medicines are re-packed from the original bulk packaging and kept for dispensing

Prepacking with coloured labels

Figure 5: Revision of labelling and appearance of LASA medicines to minimize the risk of potential serious errors



Panel A Panel B

Source: Gangakhedkar et al. *(56)*.

Note: Three high-risk medicines – rocuronium (muscle relaxant used in anaesthesia), midazolam (sedative) and heparin (anticoagulant) – in similar bottles, (Panel A) with their appearances changed by differences in labelling and having caps of different colours after recognition of their similarity and the ensuing risks (Panel B).

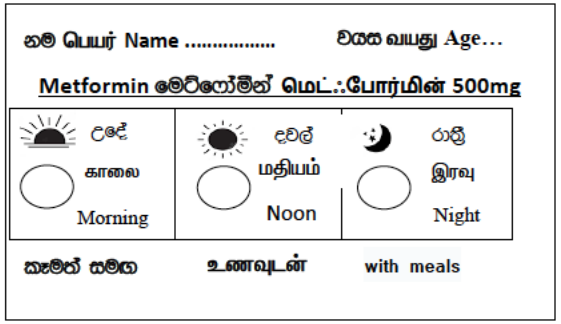
Revising the appearance of products

Figure 4: Storage of LASA medicine pairs separately

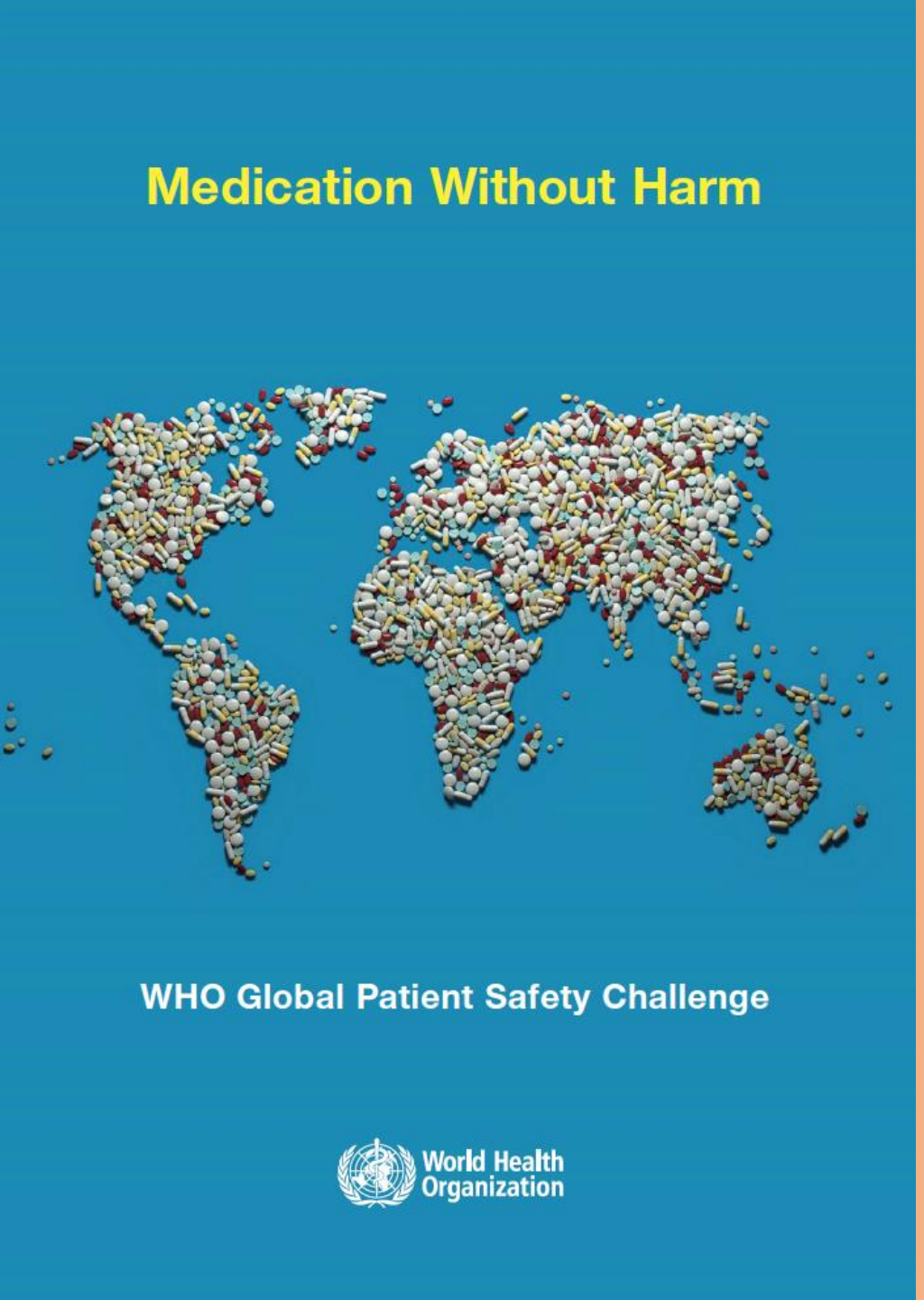
Source: Pharmaceutical Services Division, Ministry of Health, Malaysia *(27)*

Note: Whenever possible, avoid storing LASA medicines close together.

Segregating storage



Naming medicines in local languages in dispensing labels



Regulators and Manufacturers' Roles In Preventing Errors due to Look-alike, Sound-alike Medicines

LCDR Chi-ming (Alice) Tu

Deputy Director, Division of Medication Error Prevention & Analysis II (DMEPA II)
USFDA/CDER/OSE/OMEPRM

United States Food and Drug Administration (US FDA)

United States

World Health Organization

MEDICATION WITHOUT HARM
Global Patient Safety Challenge

What's in a drug name?

- New Drug Application (NDA):

  Proprietary Name (active ingredient) dosage form

  Established Name

- Biologic License Application (BLA):

  Proprietary Name (Core name - suffix) dosage form

  Proper Name

- Both established name and proper name are nonproprietary names

US Food and Drug Administration (FDA)

- FDA Name Differentiation Project*
- Use Tall man lettering (TML) to help differentiate similar established names.

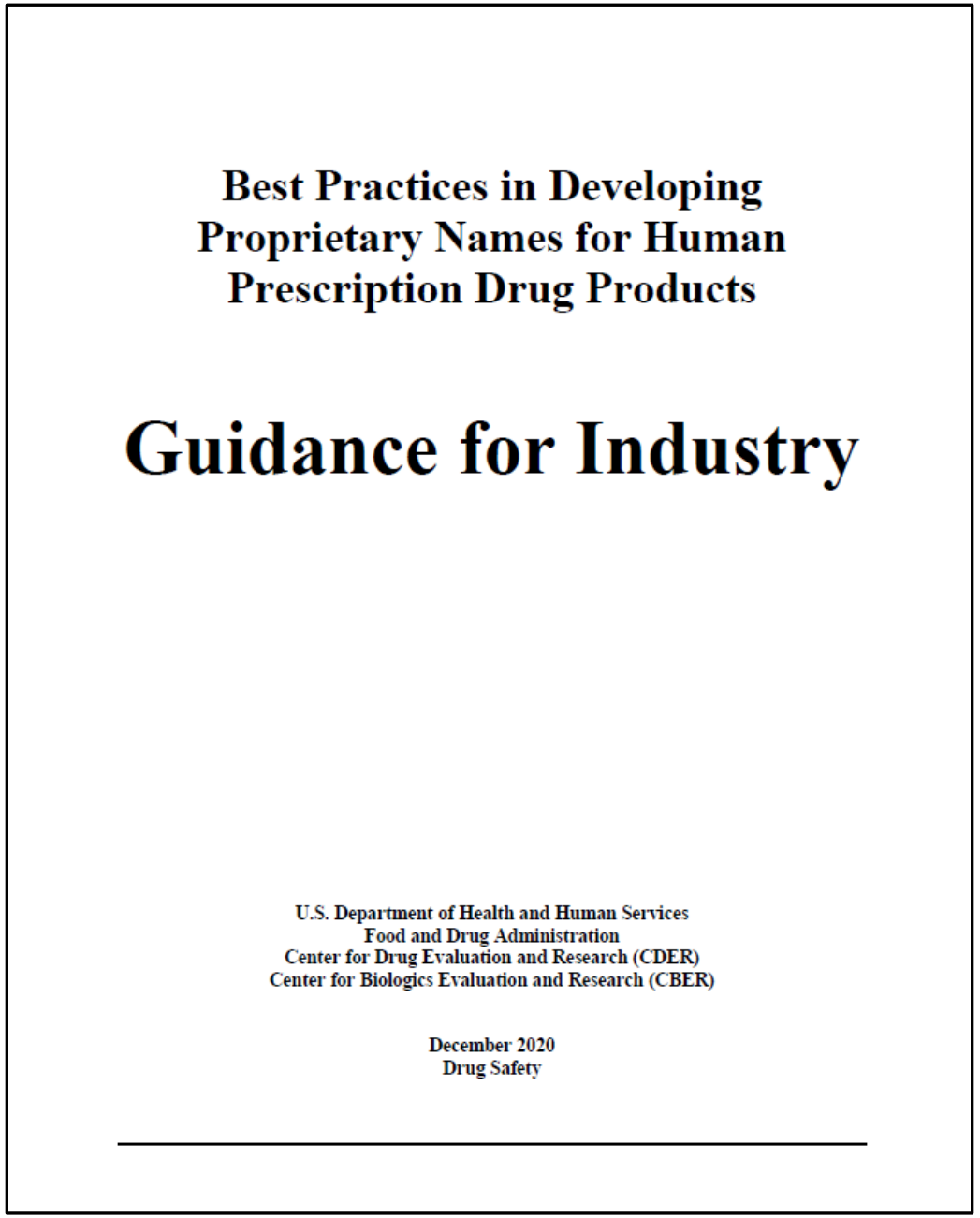
The following is a list of the established drug names recommended to use tall man lettering:

Established Name	Recommended Name
Acetohexamide Acetazolamide	acetoHEXAMIDE acetaZOLAMIDE
Bupropion Buspirone	buPROPion busPIRone
Chlorpromazine Chlorpropamide	chlorproMAZINE chlorproPAMIDE
Cisplatin Carboplatin	CISplatin CARBOplatin
Clomiphene Clomipramine	clomiPHENE clomiPRAMINE
Cyclosporine	cycloSPORINE

*https://www.fda.gov/drugs/medication-errors-related-cder-regulated-drug-products/fda-name-differentiation-project

US Food and Drug Administration (FDA)

- The Divisions of Medication Error Prevention & Analysis I & II (DMEPA I & DMEPA II)
  - Evaluate the acceptability of proposed proprietary names to minimize medication errors associated with product name confusion.
  - Determine the suffix designated in the proper name of biologic products to facilitate pharmacovigilance, accurate identification, and help minimize inadvertent substitution of biological products.
  - Review proposed labels and labeling, packaging, and product design to minimize or eliminate hazards that can contribute to medication errors.
    - Labels and labeling includes container labels, carton labeling, Prescribing Information, Instructions for Use, Medication Guides.



- **Final Guidance for Industry (Dec 2020)**: *Best Practices in Developing Proprietary Names for Human Prescription Drug Products*

- **Draft Guidance for Industry (Dec 2020)**: *Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products*

- **Final Guidance for Industry (Apr 2016)**: *Contents of a Complete Submission for the Evaluation of Proprietary Names*

Proprietary Name Review – Misbranding Assessment

Misbranding Assessment is conducted by the Office of Prescription Drug Promotion (OPDP) for prescription products, and by the Office of Nonprescription Drugs (ONPD) for nonprescription products.

DMEPA will **object** a proposed name if it may **misbrand the product** for the following reasons:

- The proprietary name suggests that the drug is safer or more effective than has been demonstrated by scientific evidence.
- The proprietary name is “fanciful” and suggests that it has some unique effectiveness or composition when it does not. (21 CFR 201.10(c)(3)).

Proprietary Name Review – Misbranding Assessment

- Mock example:
  - Product proposed for the treatment of mild ABC
  - Proposed proprietary name = Cureabcy

  - Cureabcy evokes “cure” and “ABC”
  - Misleadingly suggests that after treatment with Cureabcy, patients can expect to be cured from mild ABC 100% of the time, as well as be cured from all forms of ABC (mild to severe).
  - We object to “Cureabcy” because it creates a misleading impression regarding the efficacy of the drug.

Proprietary Name Review – Safety Assessment

- Comments from other review disciplines (e.g., clinical, chemistry, etc.)
- Preliminary Screening Assessment
- Phonetic Orthographic Computerized Analysis (POCA)
- FDA Name Simulation Studies

Proprietary Name Review – Safety Assessment

Preliminary Screening Assessment

1. **Does your proposed proprietary name have a USAN stem?**
2. **Are there any obvious similarities in spelling and pronunciation to proprietary names, established names, or ingredients of other products?**
3. **Is there a medical abbreviation, symbol, or dose designation incorporated in the name?**
4. **Does the name contain any reference to an inert or inactive ingredient?**
5. **Does the name include or suggest the name of one or more, but not all, of its active ingredients?**
6. **Is this name being reused after discontinuation of another product?**
7. **Is this the same proprietary name as another product that has completely different active ingredient(s)?**

Proprietary Name Review – Safety Assessment

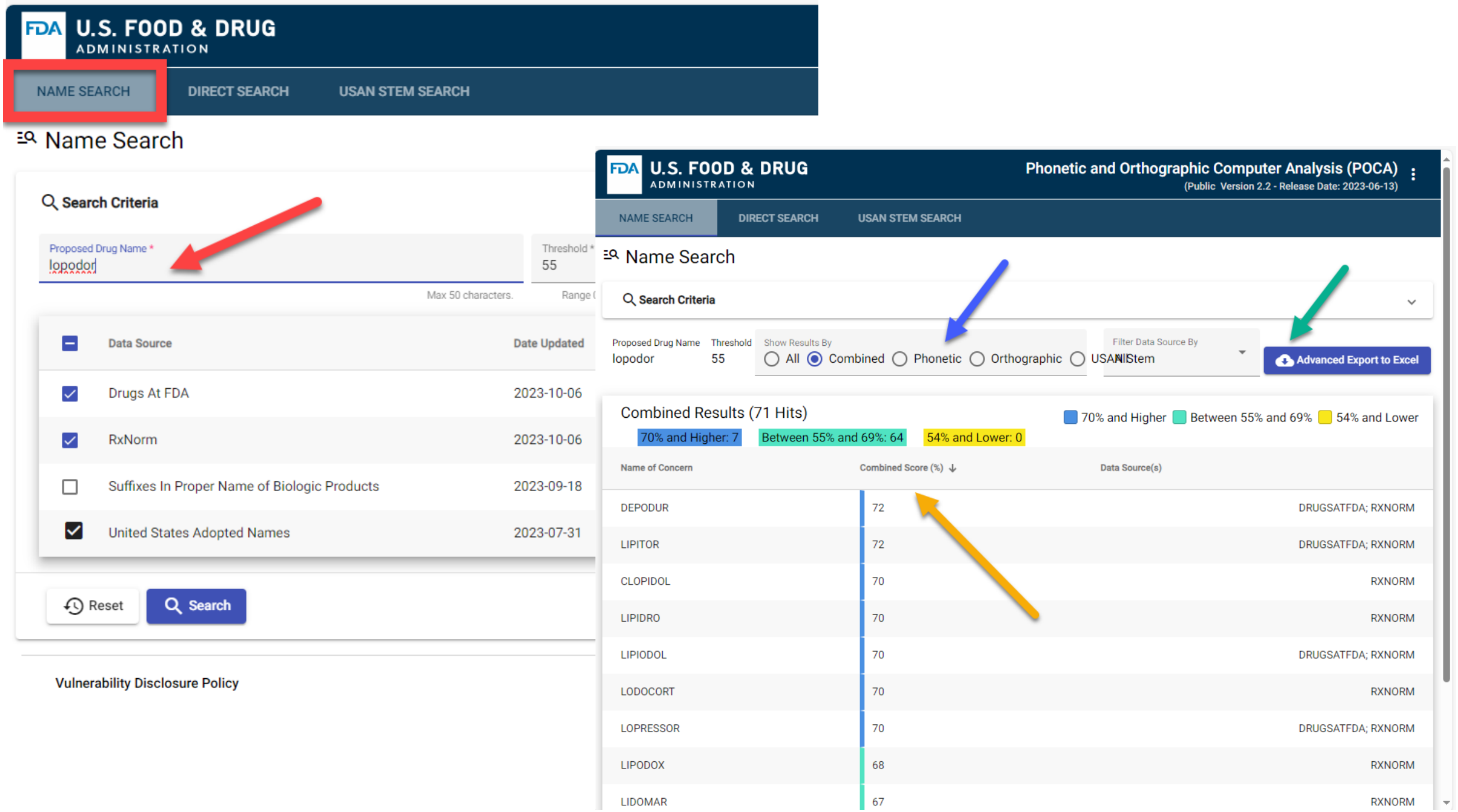
- Phonetic Orthographic Computerized Analysis (POCA) software uses an advanced algorithm to determine the orthographic and phonetic similarity between two drug names

- Since released to the public in 2009, FDA has received feedback regarding difficulties in accessing the program, including difficulties downloading the software

- In September 2020, FDA announced the availability of a cloud-based POCA tool
  - eliminates the complex download processes required with existing POCA version
  - eliminates the need for users to request access and related software from FDA
  - provides the public with a search capability similar to the current public version of POCA.

- For more information on POCA, visit the Phonetic and Orthographic Computer Analysis (POCA) Program | FDA*

*https://www.fda.gov/drugs/information-industry-drugs/phonetic-and-orthographic-computer-analysis-poca-program


U.S. FOOD & DRUG ADMINISTRATION
NAME SEARCH
DIRECT SEARCH
USAN STEM SEARCH
Name Search
Search Criteria
Proposed Drug Name *
lopodor
Threshold *
55
Max 50 characters.
Range
Data Source
Date Updated
Drugs At FDA
2023-10-06
RxNorm
2023-10-06
Suffixes In Proper Name of Biologic Products
2023-09-18
United States Adopted Names
2023-07-31
Reset
Search
Vulnerability Disclosure Policy
U.S. FOOD & DRUG ADMINISTRATION
Phonetic and Orthographic Computer Analysis (POCA)
(Public Version 2.2 - Release Date: 2023-06-13)
NAME SEARCH
DIRECT SEARCH
USAN STEM SEARCH
Name Search
Search Criteria
Proposed Drug Name
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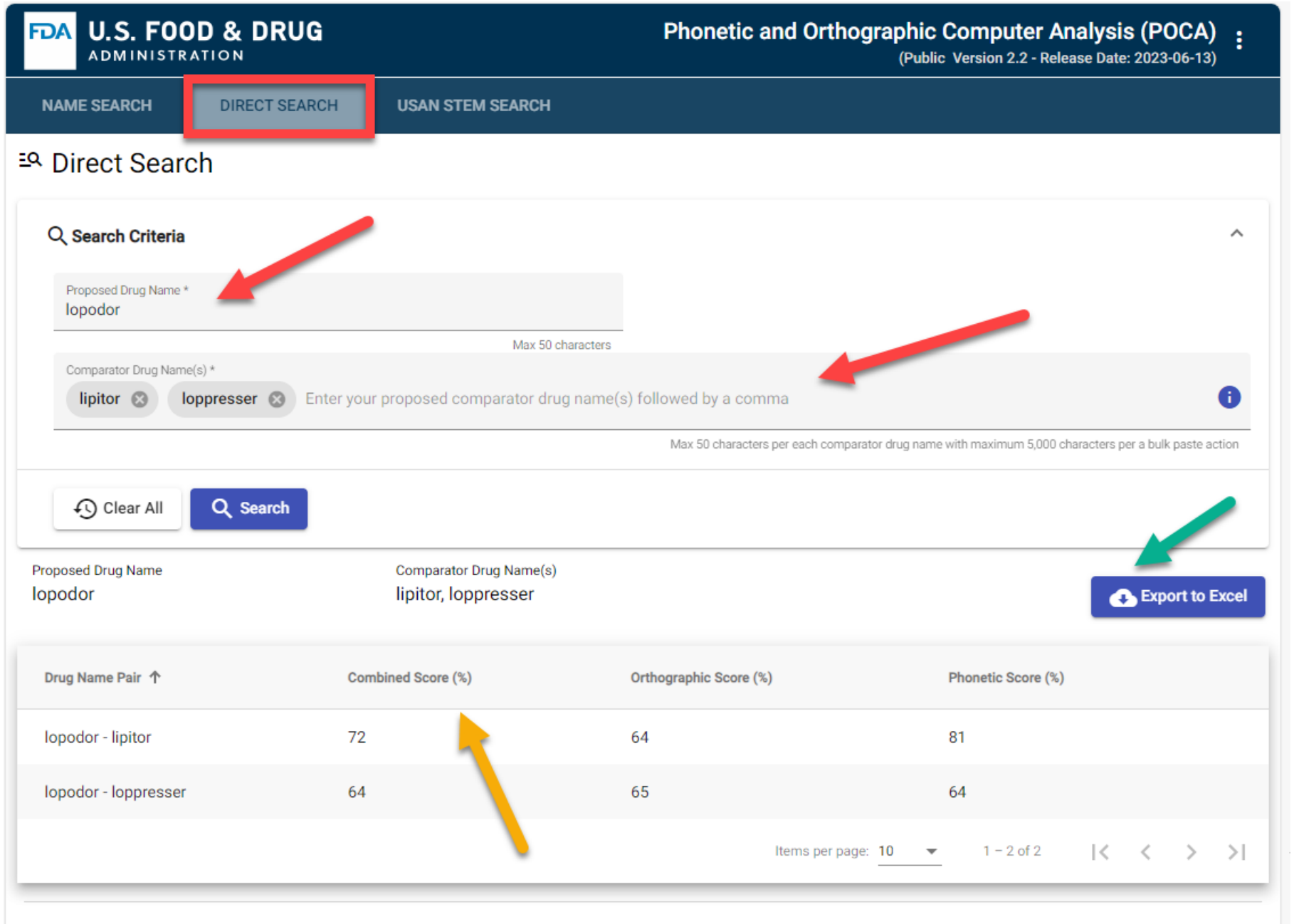
Threshold
55
Show Results By
All
Combined
Phonetic
Orthographic
USAN Stem
Filter Data Source By
Advanced Export to Excel
Combined Results (71 Hits)
70% and Higher
Between 55% and 69%
54% and Lower
70% and Higher: 7
Between 55% and 69%: 64
54% and Lower: 0
Name of Concern
Combined Score (%)
Data Source(s)
DEPODUR 72 DRUGSATFDA; RXNORM
LIPITOR 72 DRUGSATFDA; RXNORM
CLOPIDOL 70 RXNORM
LIPIDRO 70 RXNORM
LIPIODOL 70 DRUGSATFDA; RXNORM
LODOCORT 70 RXNORM
LOPRESSOR 70 DRUGSATFDA; RXNORM
LIPODOX 68 RXNORM
LIDOMAR 67 RXNORM


U.S. FOOD & DRUG ADMINISTRATION
Phonetic and Orthographic Computer Analysis (POCA)
(Public Version 2.2 - Release Date: 2023-06-13)
NAME SEARCH
DIRECT SEARCH
USAN STEM SEARCH
Direct Search
Search Criteria
Proposed Drug Name *
lopodor
Max 50 characters
Comparator Drug Name(s) *
lipitor
loppresser
Enter your proposed comparator drug name(s) followed by a comma
Max 50 characters per each comparator drug name with maximum 5,000 characters per a bulk paste action
Clear All
Search
Proposed Drug Name
lopodor
Comparator Drug Name(s)
lipitor, loppresser
Export to Excel
Drug Name Pair
Combined Score (%)
Orthographic Score (%)
Phonetic Score (%)
lopodor - lipitor
72
64
81
lopodor - loppresser
64
65
64
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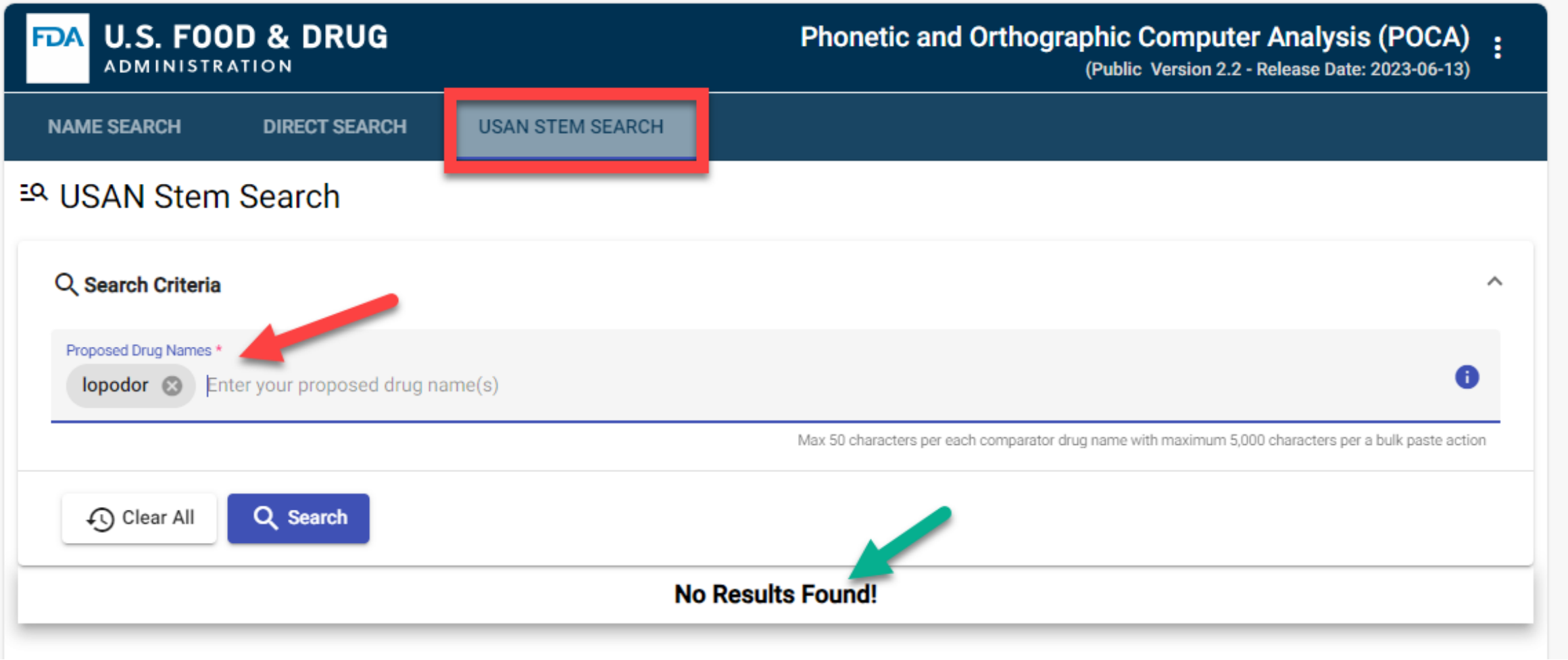
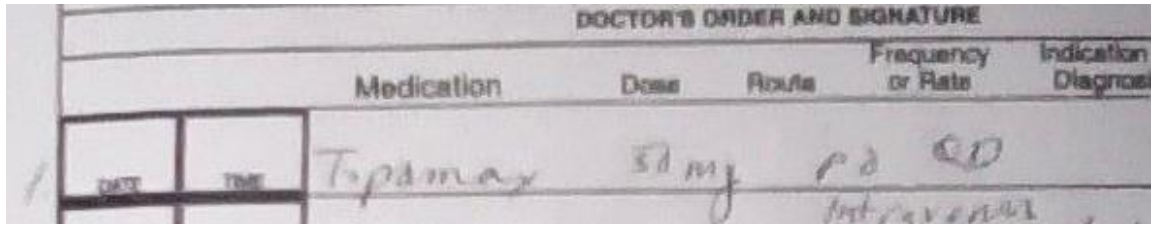
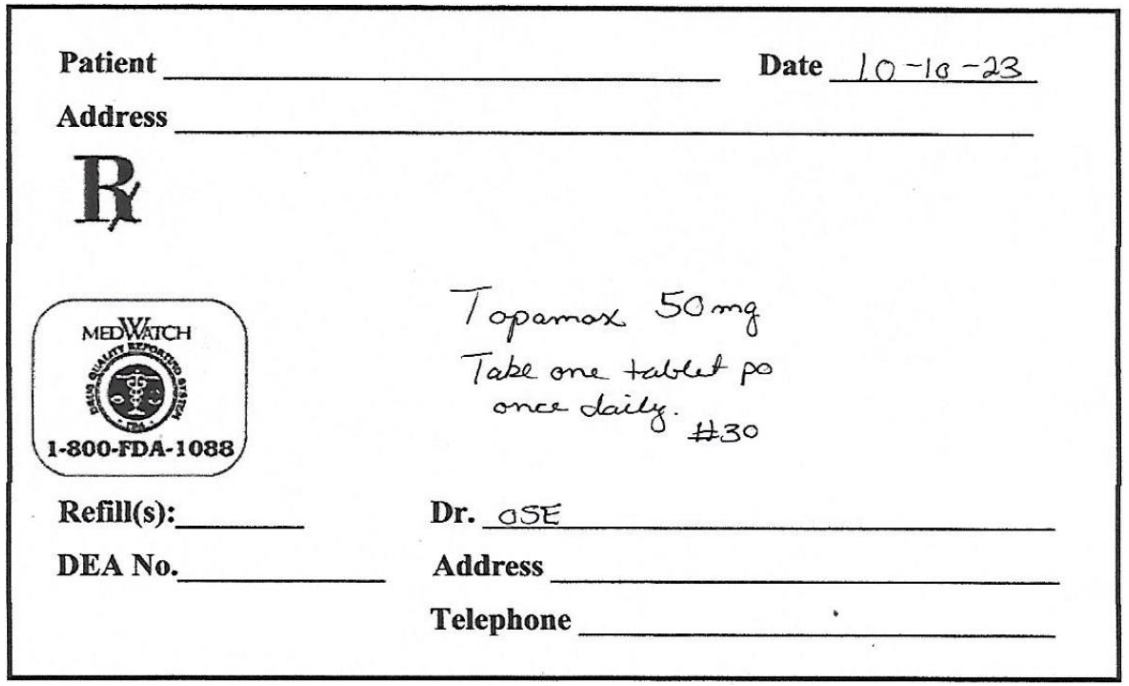
1 – 2 of 2

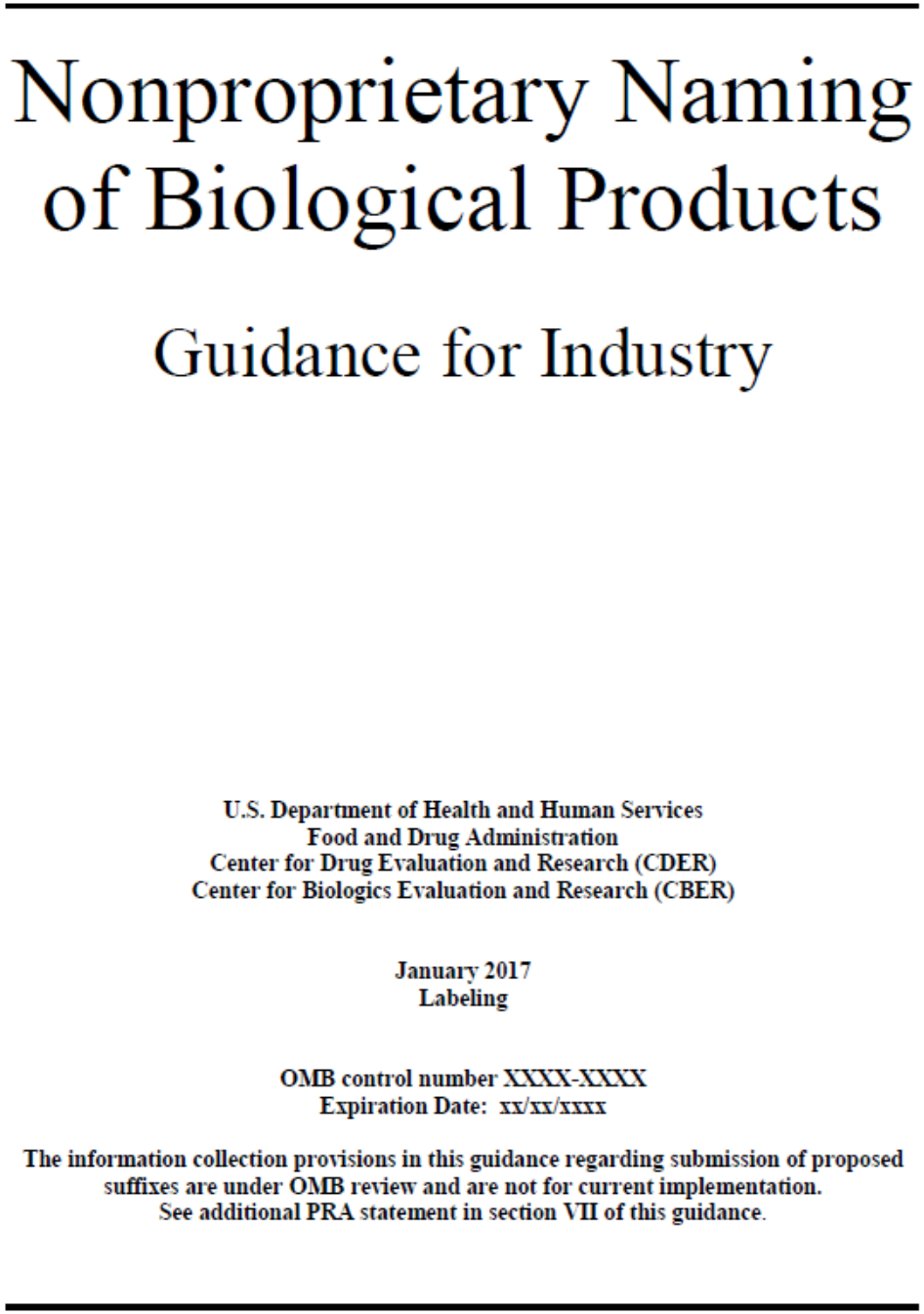

U.S. FOOD & DRUG ADMINISTRATION
Phonetic and Orthographic Computer Analysis (POCA)
(Public Version 2.2 - Release Date: 2023-06-13)
NAME SEARCH
DIRECT SEARCH
USAN STEM SEARCH
USAN Stem Search
Search Criteria
Proposed Drug Names *
lopodor
Enter your proposed drug name(s)
Max 50 characters per each comparator drug name with maximum 5,000 characters per a bulk paste action
Clear All
Search
No Results Found!

Proprietary Name Review – Safety Assessment

- FDA Name Simulation Studies
  - Inpatient written
  - Outpatient written
  - Verbal order
  - Computerized Prescriber Order Enter (CPOE)
- Sample size is small (~20 for inpatient, ~20 for outpatient, etc.)
- Qualitative data







- **Guidance for Industry (Jan 2017)**: *Nonproprietary Naming of Biological Products*

- **Draft Guidance for Industry (Mar 2019)**: *Nonproprietary Naming of Biological Products: Update*

Suffix Review

- The proposed suffix should:
  - Be unique
  - Be devoid of meaning
  - Be 4 lowercase letters of which at least 3 are distinct
  - Be nonproprietary
  - Be attached to the core name with a hyphen
  - Be free of legal barriers that would restrict its usage

Suffix Review

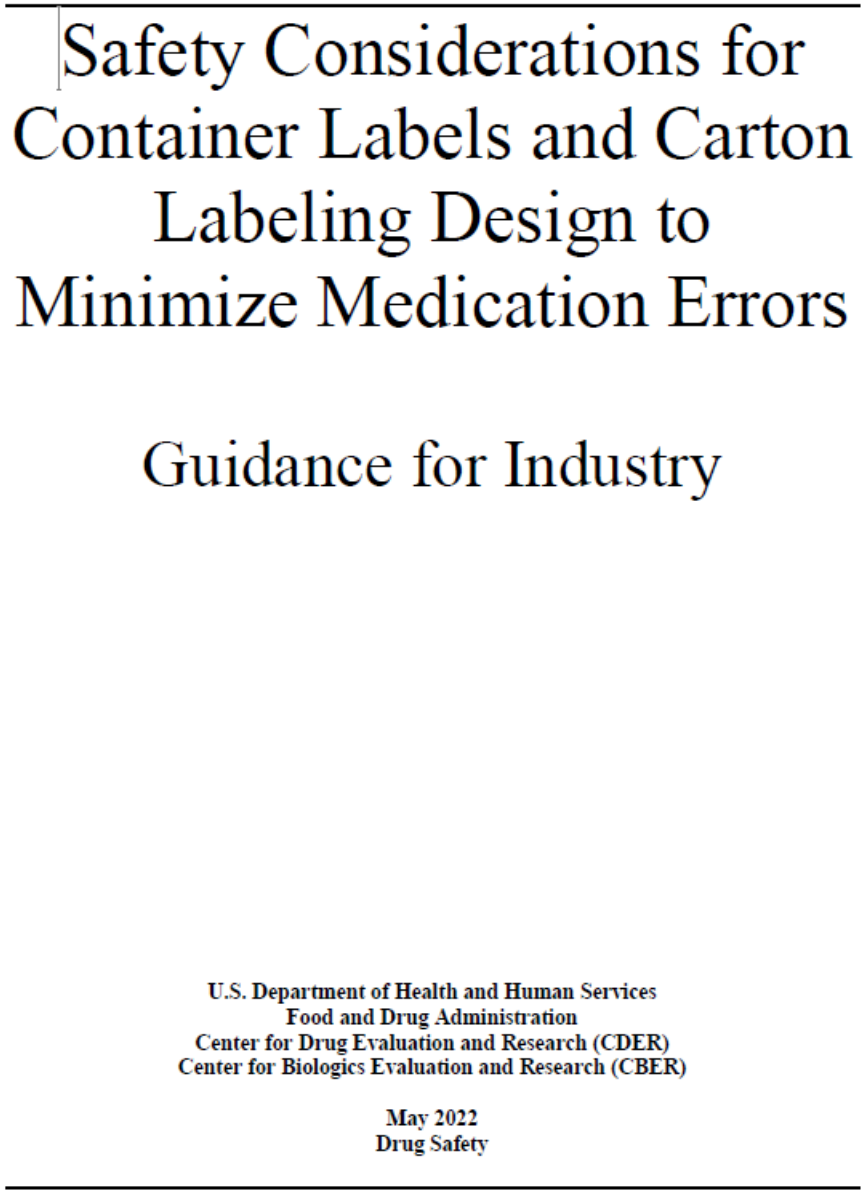
- The proposed suffix should not:
  - Be false or misleading, such as by making misrepresentations with respect to safety or efficacy
  - Include numerals and other symbols aside from the hyphen attaching the suffix to the core name
  - Include abbreviations commonly used in clinical practice in a manner that may lead the suffix to be misinterpreted as another element on the prescription or order
  - Contain or suggest any drug substance name or core name
  - Look similar to or be capable of being mistaken for the name of a currently marketed product (e.g., should not increase the risk of confusion or medical errors with the product and/or other products in the clinical setting)
  - Look similar to or otherwise connote the name of the license holder
  - Be too similar to any other FDA-designated nonproprietary name suffix

Suffix Review

- Mock example - proposed suffix: aabb → not 3 distinct letters
- Mock example - proposed suffix: love → not devoid of meaning
- Mock example
  - Proposed suffix: gxbm
  - POCA “gxbm”
  - Review POCA results, take core name-suffix into consideration to determine if there’s look-alike risk

Labels and Labeling

- Legible, readable, and understandable
- Color differentiation
- Tall man lettering
- …. and much more



Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

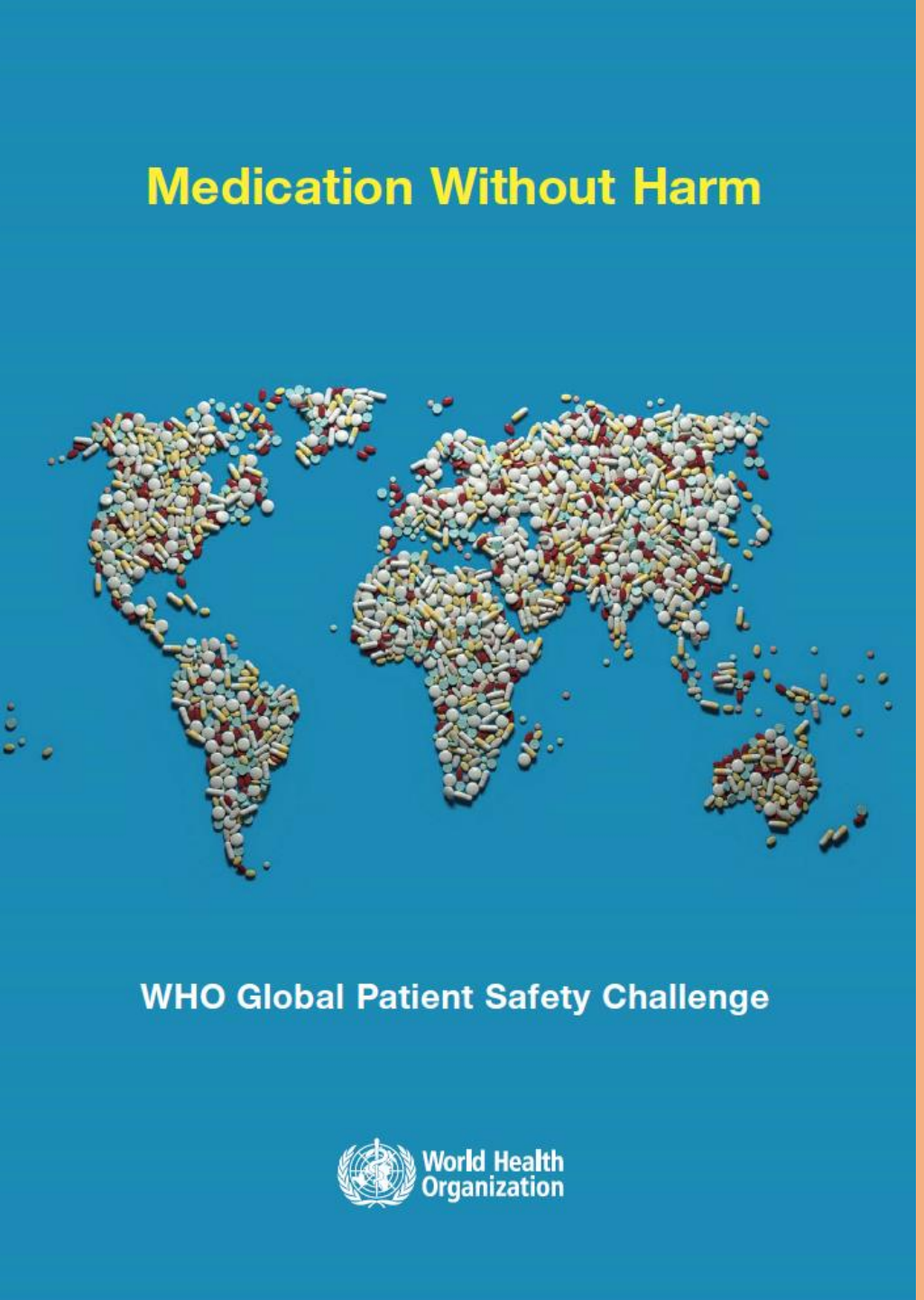
May 2022
Drug Safety

Manufacturer's Role

- Manufacturers or companies who submit a new drug application (NDA) or an investigational new drug (IND) to US FDA are called Applicants or Sponsors, respectively.

- Applicant or Sponsors may include any assessments of the proprietary name as a part of the proposed proprietary name submission to US FDA. This is optional and is not required as a part of submission.

- Typically, we see Applicant/Sponsor's assessments contain name simulation studies, utilize the public POCA, and performs look/sound-alike evaluations.



Pharmacovigilance for medication errors including LASA errors

Fumihito Takanashi, MPH

Technical officer,
Pharmacovigilance Team (PVG)

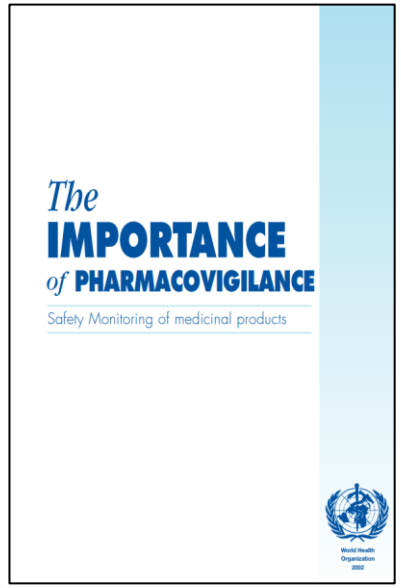
WHO Headquarters

Geneva

World Health Organization

MEDICATION WITHOUT HARM
Global Patient Safety Challenge

WHO definition of Pharmacovigilance (PV)



- **Pharmacovigilance is the science and activities relating to the…**

DETECTION

ASSESSMENT

UNDERSTANDING

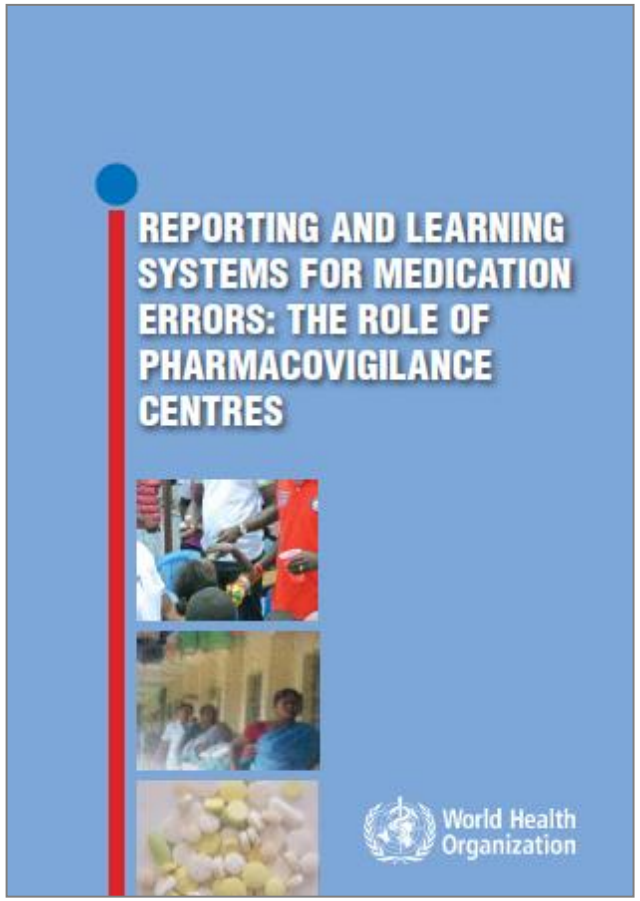
PREVENTION

…of adverse effects or <u>any other medicine related problem</u>

↳ Medication errors including LASA errors

- The Importance of Pharmacovigilance - Safety Monitoring of Medicinal Products, WHO, 2002, https://apps.who.int/medicinedocs/en/d/Js4893e/

WHO publication regarding PV for medication errors



[Key points]

- This publication is intended to strengthen the capacity of national pharmacovigilance centres (PVCs) to identify, analyse and issue guidance to prevent or minimize medication errors that harm patients.
- In addition, it is intended to **stimulate cooperation between national PVCs and patient safety organizations (PSOs)** to work together in order to minimize preventable harms from medicines.
- PVCs should develop their tools and their skills to **identify medication errors from ADR reports** and to investigate their preventability. A model ICSR reporting form with important data fields to support ME detection is attached.
- In all cases, **close collaboration between PSOs and PVCs should be put in place** so that data can be shared.

Reporting and learning systems for medication errors: the role of Pharmacovigilance Centres.
WHO, 2014. https://www.who.int/publications/i/item/9789241507943

Roles of regulatory authority in PV for LASA (from LASA report)

[4.3.2 Roles of regulators, naming bodies and manufacturers]

- Regulators are responsible for monitoring the naming and packaging of new products to avoid LASA medicine errors.
- The medicines regulatory authority in a country can prevent registration of products with the same brand names but that contain different active ingredients or different strengths of medicines having the same appearance.
- Regulators can develop tools and skills to identify medication errors from reports of adverse incidents from health care facilities and investigate their preventability.
- Ensuring a similar appearance of generic products of the same medicine would also aid in identification of the same medicines from different sources.

[4.5 Additional points for consideration by Member States and organizations]

- Advocate for increased emphasis on patient safety in the naming of medicines and for elimination of LASA names by participating in national and international regulatory, standards and advisory boards.
- Collaborate with international regulatory agencies and industries to develop a uniform naming process and safety culture.

Example of WHO PV alert on LASA error

Risk of medication errors with tranexamic acid injection resulting in inadvertent intrathecal injection, WHO, 16 March 2022

- WHO is alerting health care professionals about the risk of administration errors that can potentially occur with tranexamic acid (TXA) injection. There have been reports of TXA being mistaken for obstetric spinal anaesthesia used for caesarean deliveries resulting in inadvertent intrathecal administration.
- TXA is frequently stored in close proximity with other medicines, including injectable local anesthetics indicated for spinal analgesia (e.g., for caesarean section). **The presentation of some of the local anesthetics is similar to the TXA presentation (transparent ampoule containing transparent solution)**, which can erroneously be administer instead of the intended intrathecal anesthetic resulting in serious undesirable adverse effects.
- **Reviewing of existing operating theatre drug handling practice is required** in order to decrease this risk, such as storage of TXA away from the anaesthetic drug trolley, preferably outside the theatre.

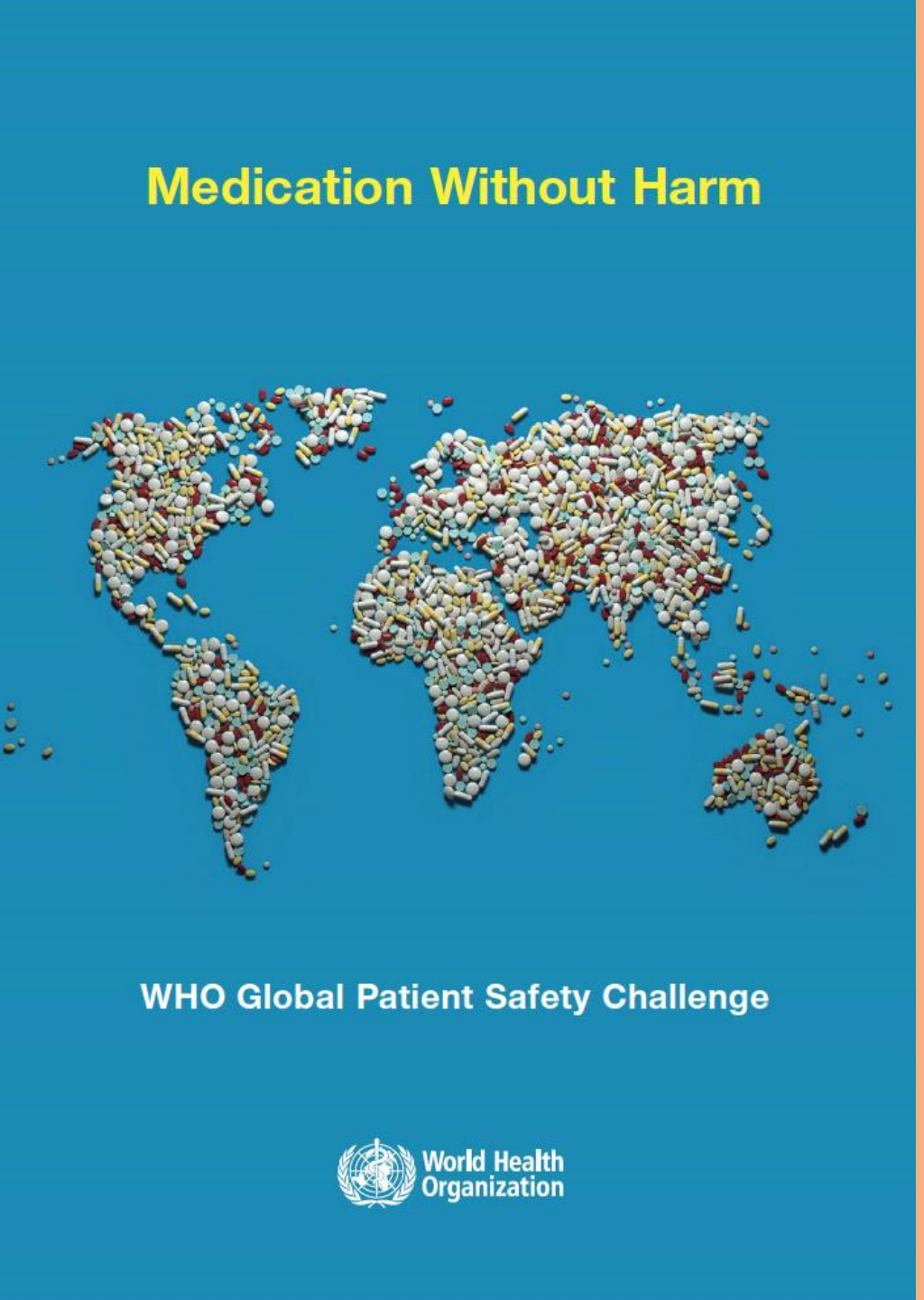
Example of collaboration between PVC and PSO

Calcium chloride, calcium gluconate: potential risk of underdosing with calcium gluconate in severe hyperkalaemia, Medicines and Healthcare products Regulatory Agency (MHRA), 27 June 2023

- The MHRA has reviewed available UK data related to inappropriate use of calcium gluconate and identified isolated cases where medication errors have occurred, including one death, where 10ml of calcium gluconate was used during cardiopulmonary resuscitation (Yellow Card literature report).
- Reports from the National Reporting Learning System received since the guideline was updated indicate that 6 incidents showed incorrect calcium gluconate administration and monitoring in the context of severe hyperkalaemia and cardiac arrest (5 fatal, 1 unknown outcome).
- We have also issued a National Patient Safety Alert following consultation with NHS England and bodies in Scotland, Wales, and Northern Ireland, as well as the UK Kidney Association.

Summary

- Medication errors including LASA errors are in the scope of pharmacovigilance and adverse event reporting.
- Collection and analysis of ICSRs is important for detection of medication and LASA errors by regulatory authority. Regulatory authority should take appropriate regulatory actions for identified risks.
- Close collaboration between regulatory authority and patient safety organization should be put in place so that data, analysis and action can be shared and coordinated.



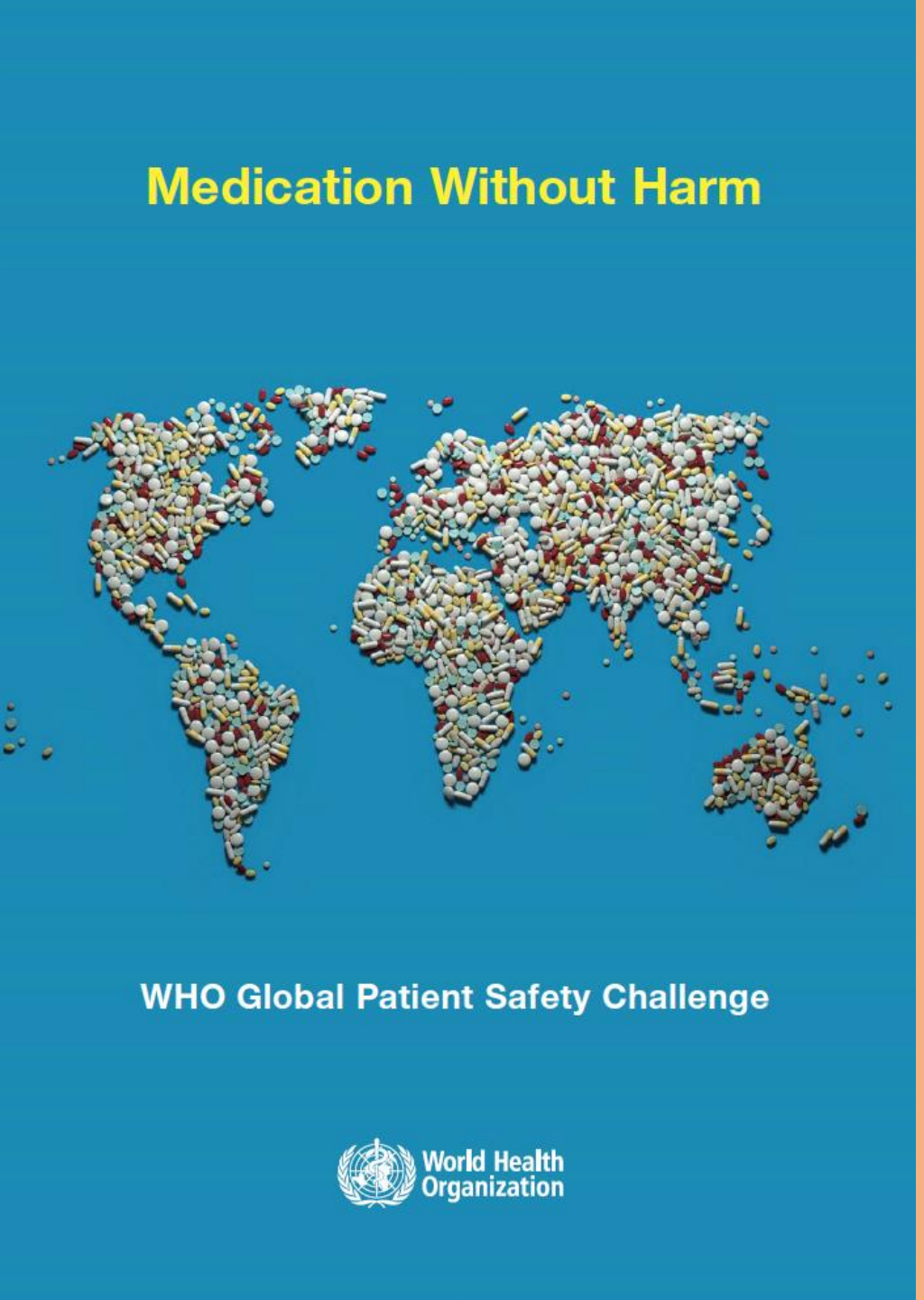
Discussion
Medication safety for Look-alike, sound-alike Medicines

Sir Liam Donaldson

WHO envoy for patient safety

World Health Organization

MEDICATION WITHOUT HARM
Global Patient Safety Challenge



Closing and next steps

Dr Neelam Dhingra

Unit Head
Patient Safety Flagship

WHO headquarters

Geneva

World Health Organization

Patient Safety

MEDICATION WITHOUT HARM
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