Medication Without Harm



WHO Global Patient Safety Challenge









Practical examples - Addressing medication safety in high-risk situations at the national level

Professor Priyadarshani Galappatthy

Senior Professor and Chair Professor of Pharmacology Head Department of Medical Humanities Specialist in General Medicine Faculty of Medicine University of Colombo Sri Lanka



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Medication Safety Webinar Series (Virtual)
WHO Global Patient Safety Challenge: Medication Without Harm
Webinar 4: Medication Safety in High-risk Situations

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Priyadarshani Galappatthy

MBBS, MD, MRCP, DipMedTox(Cardiff),FCCP, FRCP(Lond)
Professor of Pharmacology
Specialist in General Internal Medicine
Faculty of Medicine,
University of Colombo





Overview

How to address high risk situations at national level

- High risk/high alert medications
- High risk situations for errors
- High risk healthcare systems
- High risk patients

With practical examples from a LMIC - Sri Lanka



High risk/alert medicines

- High-risk (high-alert) medications are medicines that bear a heightened risk of causing significant patient harm when they are used in error.
- Although mistakes may or may not be more common with these medications, the consequences of an error are clearly more devastating to patients
 - High-Alert Medications In Community/Ambulatory Settings. In: Institute for Safe Medication Practices [website]. Horsham (PA): Institute for Safe Medication Practices; 2011

Actions at national level

- Identify/update list of key high risk/high alert medicines for the country involving all stake holders
- lists for different settings as medications differ
 - Government hospital settings
 - Identify common medicines involved in serious harm
 - Private sector hospital settings
 - availability of some medicines may be different
 - Community settings dispensaries/pharmacies
 - Availability of different brands to be considered



Actions at national level

To be taken by

- The regulatory Authority
 - e.g., during registration of medicines LASA names
- The Ministry of Health
 - circulars on prescribing, dispensing, reporting and key recommendations etc
- The procurement agencies of medicines
 - State Pharmaceuticals corporation, medicines importers for the private sector can request revisions of labelling
- The Directorate Healthcare quality and safety (HQS)
 - focal point for implementation and monitoring of national action plan on medication safety

Identify reasons for serious errors

- For each setting
 - hospital, community, government and private sector
- Method to identify serious errors
 - medication incident reporting system to be established/strengthened to improve reporting
- Address illegible/Unclear handwriting
 - Electronic prescriptions being introduced
 - Seal to identify prescriber in government hospitals
- Look alike sound alike read alike (LASARA) medicines
 - For each setting
- Error prone abbreviations
- HCP factors
 - e.g., lack of clinical pharmacists, inadequate training of pharmacists in the private sector



Develop/update list of high risk/high alert medicines

- Identify for the country for the different settings
- From incident and learning systems reporting
 - if a system exists and update regularly
- Medicines responsible for the serious errors
 - from patient complains
 - from hospital inquiry processes
 - From research studies survey among pharmacists
 - From student assignments
 - serious medication error heard, and preventive actions taken for the Diploma HQS in SL identified >50 serious errors
 - medicines mostly similar to ISMP list but other drugs too



Medications frequently classified as high-risk medications - APINCH

Therapeutic Group	Some classes of medications/ examples from therapeutic group
Anti-infectives	 Aminoglycosides (e.g. gentamicin, streptomycin) Glycopeptides (e.g. vancomycin) Amphotericin Allergy to antibiotics
Potassium & other salts/ electrolytes for injection	O Potassium, magnesium & calcium salts & hypertonic sodium chloride
nsulins	o All insulins
Narcotics (e.g. opioids) & sedatives	 All opioids (e.g. morphine, diamorphine) Benzodiazepines (e.g. diazepam) Propofol
Chemotherapeutic agents & immunosuppressive agents	 Etoposide Vincristine Methotrexate
Heparin & oral anticoagulants	 Heparins (unfractionated & low molecular weight) Vitamin K antagonists (e.g. warfarin) Newer Oral Anticoagulants [NOACs] (e.g., apixaban, dabigatran, edoxaban & rivaroxaban)

Institute for Safe Medication Practices (ISMP)

ISMP List of High-Alert Medications in Acute Care Settings

Classes/Categories of Medications

adrenergic agonists, IV (e.g., EPINEPHrine, phenylephrine, norepinephrine)

adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)

anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)

antiarrhythmics, IV (e.g., lidocaine, amiodarone)

antithrombotic agents, including:

- anticoagulants (e.g., warfarin, low molecular weight heparin, IV unfractionated heparin)
- Factor Xa inhibitors (e.g., fondaparinux, apixaban, rivaroxaban)
- direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran etexilate)
- thrombolytics (e.g., alteplase, reteplase, tenecteplase)
- glycoprotein Ilb/Illa inhibitors (e.g., eptifibatide)

cardioplegic solutions

chemotherapeutic agents, parenteral and oral

dextrose, hypertonic, 20% or greater

Specific Medications
EPINEPHrine, subcutaneous
epoprostenol (Flolan), IV
insulin U-500 (special emphasis)*
magnesium sulfate injection
methotrexate, oral, non-oncologic use
opium tincture
oxytocin, IV
nitroprusside sodium for injection
potassium chloride for injection concentrate
potassium phosphates injection
promethazine, IV
vasopressin, IV or intraosseous



High risk/alert medicines identified from an assignment on medication incidents in SL

- Antibiotics anaphylaxis with amoxicillin, cloxacillin, co-amoxiclav
- Insulin hypoxic brain damage and death
- Narcotics pethidine for obstetric analgesia and hypoxic brain damage in baby
- Chemotherapeutic and Immunosuppressants Azathioprine, methotrexate, vincristine and patient deaths
- Heparin and Anticoagulants warfarin, enoxaparin causing bleeding
- Narrow therapeutic index medicines lithium, carbamazepine toxicity
- Anti-arrhythmics amiodarone, dofetilide casing serious arrhythmias
- NSAIDs diclofenac sodium given in dengue fever causing bleeding
- Surgical spirit for cleaning injection to a patient in the theatre
- Antipsychotics clozapine, thiothixene
- Ergometrine given to a neonate thinking it was vitamin K baby died
- Muscle relaxant atracurium causing respiratory arrest
- Antihypertensive prazosin instead of piriton and severe hypotension
- Syntocinon wrong dose causing severe hypertension



Labelling high risk/alert medicines for identification













Reasons - Illegible prescriptions

Investigation of Medication Errors: A Prescription Survey from Sri Lanka

Table 1: Percentage occurrence of components of the prescriptions and p values obtained from chi square test for two study locations

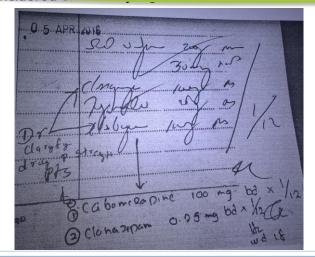
					_nie i
Attribute	Frequency (%)	Aluthgama	Kandy	<i>P-</i> value	
Presence of name of the patient	75 (37.5%)	36	39	0.661	
Presence of age	92 (46%)	49	43	0.395	
Presence of gender	155 (77.5%)	70	85	0.011*	
Presence of name of the prescriber	181 (90.5%)	84	97	0.002*	
Presence of contact details	148 (74%)	64	84	0.001*	
Presence of qualification	170 (85%)	73	97	0.000*	
Presence of registration number	32 (16%)	24	8	0.002*	
Presence of signature	150 (75%)	62	88	0.000*	
Presence of date of consultation	163 (81.5%)	75	88	0.018*	
Presence of non-standard abbreviations	73 (36.5%)	35	38	0.659	
Presence of incomplete units	102 (51%)	53	49	0.572	
Presence or avoidable decimal points	0 (0%)	0	Û		

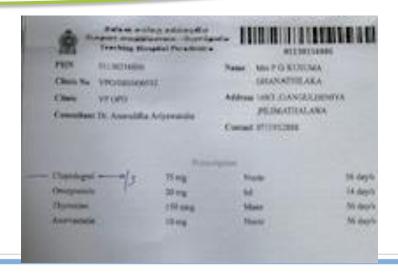
99 (49.5%)

48

*P < 0.00 is considered statistically significant

Legible prescriptions





0.671

51

Identify serious medication errors

A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years (2005–2010)

- Best way incident reporting
- Effective reporting and learning systems are lacking in most LMIC
- In SL did not have a reporting system
- Developed a dedicated form and discussed at a consultative meeting of stakeholders
- Decided to have two step process with two forms
 - one a short form giving only basic information by reporter
 - Healthcare quality and safety (HQS) unit of the hospital to fill the detailed form
- Reluctance for reporting a problem
- Included medication incident reporting as one of the clinical indicators of quality of hospitals by Directorate HQS



HCP/Consumer reporting and learning from errors

Pharmaceutical Services Division Reporters Ministry of Health Malaysia informat www.pharmacy.gov.my	do not neces	ERROR (ME) REPORT FOR sarily have to provide any individual identifiable health names of practitioners, names of patients, names of calitiles, or dates of birth (age is acceptable)		BPF/104/ME/01		Mo	alaysia			
1 Date of event: dd/mm/yy Time of event: hh/mm (24 hr)	Туре о	f Facility: * Government/ Private Location of spital ☐ Clinic ☐ Pharmacy ☐ Ward	☐ A&E ☐ C	Clinic Pharmacy			,			
2 Please describe the error. Include description/s (e.g. change of shift, short staffing, during peak attach a separate page.		Jawaharlal I Please tick the appropriate box		Medication (A b	on Error lame free	Reporting reporting tool)		R)	
patient? NO Was the incorrect medication, dose or dosage YES	4.2 Pleasi NO EF	1. Date of event:		2. Location	of even		macy Others_			
form administered to or taken by the patient? 4.1 Describe the direct result on the patient (e.g. death, type of harm, additional patient monitoring).	ERRO B C		Dispensing Others (spe	ecify)	4. P		DICINES SIDE EFFECT REPORTII औषधि दुष्प्रमाव सूचना फॉर्म ceia Commission, National Coordination Centre- Phan पारतीय भेषण संविद्या आर्थित, राष्ट्रीय सम्मय स्थे	(उपमोक्ताओं व macovigilance Programme nt of India. इ. — भारतीय फार्माकोविर्ग	हे लिए) e of India, Ministry of He	
India		5. Description of the event:	: (how did	I the event o	ccur a	b. Medicines Advised by/ বৰ Self (Past disease experience	Gender/ लिंग (V): Male/ पुरुष Unber/ अन्य Unber/ अन्य Unber/ अन्य Unber/ अन्य Unber/ अन्य पाक्रिक प्रतिकृति प्रति प्रतिकृति प्रति प्रतिकृति प्रतिकृति प्रतिकृति प्रतिकृति प्रतिकृति प्रतिकृति प्रति प्रतिकृति प्रति प्रतिकृति प्रतिकृति प्रति प्रतिकृति प्रतिकृति प्रतिकृति प्रति प	Female/ स्त्री	आयु (वर्ष :	ves/ मित्र / रिश्तेदार 🔲
		Th	ailar	nd		Telephone No/ टेलीफोन मं: 4. Details of Medicine Takin Name of Medicines/ दवाइयों के नाम	e/Taken/ ती जा रही है / ती जा पुरू दर्शा Quantity of Medicines taken (e.g. 250 mg, Two times a day) ती गई दर्शाई की मात्रा (उदाहरण के लिए 250 मिग्रा, एक दिन में दो बार)	Expiry Date of Medicines/ दवा के निष्क्रिय होने की तिथि	Date of Start of Medicines/ दवाइयां आरंग करने की तिथि dd/mm/yy dd/mm/yy	Date of Stop of Medicines/ दवाइयां रोकने की तिथि dd/mm/yy dd/mm/yy
						Dosage form/खुराक का स्वस तरल If Others (Please	न्प(v) : Tablet/ गोली (टेबलेट) Capsule :Specify/यदि अन्य (कृपया निर्दिष्ट करें	/ कैप्सूल Injecti)	ion/ इंजेक्शन 🔲	Oral Liquids/ मौखिक



•					
	21 1 44 6				
1.Patient deta Hospital Ward: -	ils and setting of error s Sex: -		Diagnosis		
BHT No: -	Male	Femal	_		
Private hospital	Age:	Tellia			
Pharmacy	Age				
Home					
2. Did the erro	or reach the patient?	Yes	No		
3.Description	of the event (How did tl	he event occur	and how was it	detected)	
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	event occurred			_	
Ward	Theatre Disper	ısary Cl	inic ICU	J Other	
	edicines involved in the			_	
Dosage form	Generic name	Strength	Frequency	Dates of therapy	Diagnosis
	<u> </u>				
The error ar	nd possible contributing	factors for m	edication errors	s (You may tick m	ore than one box)
_	on given to wrong person	ı		h of medication	
_	edicine given	_		administration	
	ke, Sound-Alike medica	tion	Wrong dose of		
	equency of medication		Poor quality o		
	oute of administration		Expired medic		
	beling instructions	<u>ˈ</u>	Poor handwrit	ıng	
			Dose omitted		
7.Patient Outo					
T' 1 (1	Actual	700	1.0	Where No harm	
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	(requiring active treatment) uring monitoring)	IH	Potentially moderate has Potentially mild harm (a	rm (requiring active treatment requiring monitoring)	it)
	n the medication use sys				
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Other (specif	ây):	pensing		Triomicing.	
		<u></u>			
3.Description	of immediate action/int	ervention			
0 D-4					
9.Patient outc		Moderate harm		ild harm	No harm
					No nami
((Permanent harm) (Req	unning active tr	eaunem) (Requ	ming monitoring)	
10.Reporter					
			_		
•			٦.	9	
Medical of	fficer Pharmacist	Nurse	Patient or Fan	nily any other	T



Identify LASARA medicines for the country- especially for high risk/alert medicines

- For the different settings
- Educate the HCP on these
- Tall man/different coloured lettering in labelling and writing
- Separate storage for LASARA medicines especially high risk medicines
 - e.g., atracurium causing respiratory arrest in ICU (Ranitidine vial and Atracurium vial looked similar appearance)





Some LASARA drugs identified from hospital settings Sri Lanka

Clobazam (5)
Carbimazole (4)
Gliclazide (3)
Fluoxetine (2)
Phenytoin (2)
Atenolol (2)
Clozapine (2)
Cyclosporine (2)
Amitriptyline (2)
Clomipramine (2)
Omeprazole (2)
Thyroxine (2)
Chlorpromazine (1)
Penicillin (1)
Metformin (1)
Aldactone (1)
Hydroxyurea (1)
Atorvastatin (1)

Dilantin (1)
Amitriptyline (1)
Dipyridamole (1)
Clopidogrel (1)
Amlodipine (1)
Thyroxine (1)
Diazepam (1)
Lithium carbonate (1)
Olanzapine (1)
Metformin (1)
Thiamine (1)
Lactulose (1)
Cetrimide (1)
Lasix (1)
Atorvastatin (1)
Bisacodyl (1)
Cetrimide (1)
warfarin 5 mg (1)

Regulatory authorities to take steps to prevent mix ups at registration of LASARA medicines

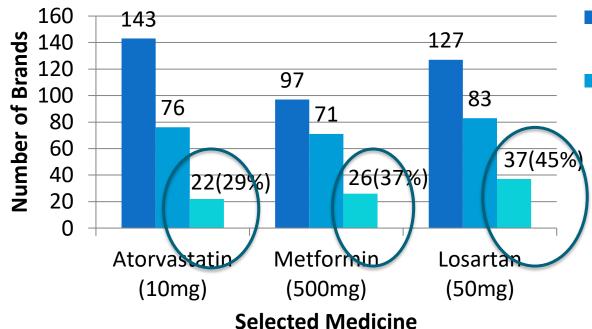


Warfarin 1mg, 3mg and 5mg tablets of same color was available in government pharmacies Patient admitted with bleeding and INR of 14



Changed to blister packs on recommendation by NMRA but again similar packaging for 1mg and 5mg!

Registration status and availability of the most commonly prescribed 3 medicines in private sector in Sri Lanka -2015



- The NMRA Act was revised with a 'need' clause added.
- Now, if > 20 products are registered not granted registration unless justified showing a benefit

- All strengths Registered
- Particular strength Registered
 - Generic prescribing 36 % in private sector
 - With several brands more prone to errors due to highrisk LASARA medicines
 - e.g., Navane (thiothixene, an antipsychotic) dispensed for Norvasc (amlodipine)

Identify error prone abbreviations for errors in the country

Unapproved abbreviations identified from hospital prescriptions in SL – some are High risk/high alert medicines

Drug name	Abbreviation
Paracetamol	PCM
Diclofenac sodium	DFS, DN, DS
Norethisterone	NE, NET
Trifluoperazine	TFP
Azathioprine	AZT
Carbamazepine	CBZ
Hydroxychloroquine	HCQ
Hydrocortisone	HCS
Nifedipine sustained release	NSR
Prednisolone	PD
Silver sulfur diazine	SSD
Topiramate	TPM



The Pattern of Abbreviation Use in Prescriptions: A Way Forward in Eliminating Error-Prone Abbreviations and Standardisation of Prescriptions

N.R. Samaranayake*,1,2, P.R.L. Dabare2, C.A. Wanigatunge3 and B.M.Y. Cheung1

Table 3. Error-Prone and Some Other Unapproved Abbreviations Used in the Study Hospital

Abbreviation	Percentage of Usage*
Error-Prone Abbreviations	
d (days/daily)	23.5
μg (microgram)	17.4
n (night)	15.8
m (morning)	4.4
@ sign	4.9
u (units)	1.9
cc (cubic centimeter)	0.2
OD (once a day)	0.2
mcg (microgram)	0.1

 Approximately 69 error-prone abbreviations are used per every 100 drug items prescribed.

Some Frequently Used Unapproved Abbreviations				
pcm/PCM (paracetamol)	5.2			
LA (local application)	2.2			
MS (methyl salicylate)	1.9			
o (oral)	1.5			
syr/sy (syrup)	1.3			
BCo (vitamin B complex)	0.8			
DFS (diclofenac sodium)	0.7			
HCT (hydorchlorothizide)	0.7			
ISMN (isosorbide mononitrate)	0.7			



Reasons for errors in dose of high risk medicines

Reason	Frequency	Percentage
Inappropriate Strength	51	28.7
Additional or less '0'	41	23.0
Mix-up of adult and paediatric doses	27	15.2
Prescription mix-up	26	14.6
Poor handwriting	10	5.6
Dose not written	10	5.6
Look-alike digits	5	2.8
Extra numbers	5	2.8
Oral and IV dose mix up	3	1.7

 Azathioprine 250mg bd prescribed for 25mg bd and same dose dispensed. Patient died of agranulocytosis and sepsis 2 weeks later



A Medication safety practice package for implementation

Started as a PhD project

- Develop a List of High risk/alert medicines
- SOPs for labelling, storage and dispensing of those
- LASA medicines list and tall man lettering for labelling and storage
- Accepted abbreviation list to be identified
- Properly labelled medicines to be dispensed
- Not dispense medicines for unclear prescriptions without double checking

High risk settings for errors

Develop SOPs for handling high risk/alert medicines Identified from incidents

- ICUs
 - muscle relaxants, potassium solutions to be clearly labelled
- Emergency rooms
 - checking for allergies prior to antibiotics
- Operating theatres
 - not to keep unlabeled syringes surgical spirit kept in a syringe injected
- Obstetric delivery units
 - not to mix mothers and baby's medicines ergometrine injected to baby and died
 (Vitamin K vial and ergometrine vial was similar)
- Oncology units
 - not to mix routes eg. oral, IV and intrathecal administration
- Radiology departments
 - check pregnancy, type of contrast medium, sedatives used



High risk health systems A risk for high risk/alert medicines/situations

- Countries with poor systems for patient safety
- Establishment of Directorate of HQS in Sri Lanka in 2012 –
 A major step for improvement
- Lack an effective incident reporting and learning system
- Lack of electronic prescribing in most settings now improving
- Lack of clinical pharmacists for medication reconciliation
- Overcrowding of clinics and hospital dispensaries
- Unqualified pharmacists manning private pharmacies



High risk patients

- Patients with poor medication literacy
 - need to improve knowledge of patients taking high risk medicines
- Oncology patients
 - have SOPs for safe administration of chemotherapeutics
- Patients undergoing surgery
 - have SOPs for safe administration of all anesthetic agents
- Patients with organ dysfunction Renal, hepatic, Cardiac and respiratory
 - To identify and modify drug doses
- Patients with multi morbidity and poly pharmacy
 - Need national guidance on addressing polypharmacy



Improve patient's knowledge on medicines

Percentage of patients attending a medical clinic knowing

- 1.Name of drugs prescribed 42.4%
- 2.Indication 41.1%
- 3. Dose 22%
- 4. Frequency 57.8%
- 5. Additional details (special instructions/ adverse effects/storage)
- only 6.8%
- All patients given high risk/alert medicines need to be educated about the medicines

Need to address High risk medicines/situation in National action plans

NATIONAL ACTION PLAN ON MEDICATION SAFETY FOR SRI LANKA





Strand	Proposed activity	Time frame		Subactivities	Key	Performance Indicators (KPIs)	Stakeholders/ Persons/Institut ions /Organizations responsible	Responsibility for implementation
1. Systems	1.1		1.	Introduce a separate	1.	Percentage of	Director General of	Director- DHQS
and	Introduce	2021		medication incident		hospitals	Health Services	
practices	medication			reporting form.		having a	(DGHS),	Heads of Institutions
	incident	2023	2.	Integrate the medication		functional Incident	Deputy Director	Medical Officer -
	reporting		۷.	integrate the medication incident reporting in to			General / Medical Services -1	
	system into hospitals and			adverse event reporting		reporting system.	(DDG/MS-1),	Quality Management Units in hospitals
	implement			process in hospitals.		зузсень	DDG/MS - 11,	onic in nospitais
	action plans to			process in nospitals	2.	Number of	DDG/Dental Services,	The Society of
	prevent		3.	Issue a circular from DGHS		medication	Director - Medical	Government
	occurrence of			introducing the medication		safety	Supplies Division	Pharmacists
	similar events.			incident reporting form to		incidents	(MSD),	
				all hospitals including		reported	Directorate of	All Island Private
				private hospitals and			Healthcare Quality	Pharmacy Owners
				encourage reporting with	3.	Number of	and Safety (DHQS),	Association (AIPPOA)
				reporting guidelines, which		sentinel	Quality Management	
				would indicate assessment		events	Units (QMU) in	State Pharmaceutical
				of reports in a no blame culture.		reported	hospitals, Government	Cooperation
					4.	Number of	Pharmacists.	
						near misses	Sri Lanka Medical	
			4.	Use MSMIS electronic		reported	Association (SLMA),	
				system to report in			Sri Lanka Dental	
				hospitals where these			Association (SLDA),	
				facilities are available.			Ceylon College of	
							Physicians (CCP),	
			5.	Reinforce establishment			Sri Lanka College of	
				and function of Drugs and			Pediatricians (SLCP),	
				therapeutic committee in			Sri Lanka College of General Practitioners	
				all hospitals where reported incidents are			(SLGP),	
				reported incidents are			(SLUP),	



Strand	Proposed activity	Time frame	Sub activities	Key Performance Indicators (KPIs)	Stakeholders/ Persons/Institut ions /Organizations responsible	Responsibility for implementation	
2. Medicines	Prepare a list of "high risk medicines" for serious errors. i. Identify through incident reporting. ii. From published literature on high-risk medicines. iii.Educate Health Care Personnel on "high risk medicines" and take preventive actions. (Eg. Individual packaging, Colour cording whenever	2021 - 2024	1. Preparing a List of "highrisk medicines". 2. Preventing use of; same color code for different strengths of products, which can be confusing during registration by NMRA. 3. Develop specifications when calling for tenders; such as color cording, limiting strengths, individual packages etc. whenever possible.	1. Availability of "List of highrisk medicines" at the relevant institutions. 2. No. of Institutions that have been informed about serios errors due to high-risk medicines (to prevent similar errors in the future) 3. Number of medication incidents reported regarding high risk medicines.	Through medication error reporting system - D/HQS CCP, SLCP, SLCP, SLGP, PSSL, SLDA, University academics, NMRA, MSD, AIPPOA.	Academics, researchers and other healthcare workers involved in work in this area	
FACULTY University of Co	possible)						

Take home messages A 'practice package' for High risk/alert medicines

- Develop/update High risk/alert medicines
- SOPs for labelling, storage and dispensing
- LASARA medicines list and tall man lettering for labelling and storage of high alert medicines
- Accepted abbreviation list to be identified
- Properly labelled medicines to be dispensed
- Preventive actions when serious errors occur
- Training of HCP on high risk/alert medicines

Include all above into national action plan on medication safety





Thank you

