# MEDICATION SAFETY Curriculum Guide

World Health Organization 2019

March 2019

Disclaimer

	Table	e of	conte	nts
--	-------	------	-------	-----

List of abbreviations0		
Glossary and definitions1		
Introduction	<u>42</u>	
1. Background	<u>6</u> 2	
1.1. Medication-related harm	<u>6</u> 3	
1.2. Global burden of medication-related harm	<u>7</u> 4	
1.3. WHO Global Patient Safety Challenge: Medication Without Harm		
2. Aims and learning outcomes	<u>14</u> 12	
2.1. Aims	<u>14<del>12</del></u>	
2.2. Learning outcomes		
2.2.1. Knowledge	<u>14</u> 12	
2.2.2. Performance	<u>14<del>12</del></u>	
3. The Medication Use Process	<u>15</u> 13	
3.1 Introduction		
3.2. Procurement		
3.3. Storage		
3.4. Prescribing	<u>16</u> 14	
3.5. Dispensing	<u>17</u> <del>15</del>	
3.6. Preparation	<u>17</u> <del>15</del>	
3.7. Administration	<u>17</u> <del>15</del>	
3.8. Monitoring	<u>18</u> 16	
3.9. Destruction	<u>18</u> <del>16</del>	
4. Priority areas		
4.1 Polypharmacy	 	
4.2 Transitions of care		
4.3. High-risk situations		
Medication factors	<u>22</u> 20	
Provider and patient factors		
Systems and environmental factors	<u>25<del>23</del></u>	
5. Contributing factors and examples of interventions	<u>28</u> <del>27</del>	
5.1. Patients and the public	<u>28<del>27</del></u>	
5.2. Health care professionals	<u>29</u> 28	
5.3. Medication design and characteristics	<u>37</u> <del>36</del>	
5.4. Systems and practices	<u>38</u> 37	

6	Medication sfaety: broader context and link to other initiatives	<u>43</u> 42
	6.1 Universal health coverage	<u>43</u> 42
	6.2 Antimicrobial resistance	<u>45</u> 44
	6.3 Pharmacovigilance and adverse drug reactions	<u>45</u> 44
	6.4 Essential Medicines List	<u>47</u> 44
	6.5 Protocols, checklists and standard treatment guidelines	<u>47</u> 45
7	. Teaching and training students to improve medication safety	<u>49</u> 47
	7.1 What to teach	4947
	7.1.1 Technical skills	<u>49</u> 47
	7.1.2 Non-technical skills	<u>52</u> 50
	7.2 How to teach	<u>5351</u>
	7.2.1 Interactive lectures and/or group discussion	<u>53</u> 51
	7.2.2 Case-based learning	<u>53<del>52</del></u>
	7.2.3. Practical workshops	<u>54</u> 52
	7.2.4 Simulation	<u>54</u> 52
	7.2.5 Project work	<u>5452</u>
	7.2.6 Group discussions	<u>55</u> 53
	7.2.7 Case / incident analysis	<u>55</u> 53
	7.2.8 E-learning	<u>55</u> 53
	7.2.9 Role-playing exercises	<u>55</u> 53
	7.3 Training for capacity	<u>55</u> 54
	7.4 Assessment methods	<u>56</u> 54
~		
8	Case stories on medication-related narm	<u>5/</u> <del>55</del>

# List of abbreviations

AMR	Antimicrobial resistance
GP	General practitioner
LASA	Look-alike sound-alike
NGO	Non-governmental organization
NSAID	Non-steroidal anti-inflammatory drug
SDG	Sustainable development goals
STGs	Standard treatment guidelines
UHC	Universal health coverage
WHO	World Health Organization

# Glossary and definitions

#### Adherence

The degree to which a person's behaviour corresponds with the agreed recommendations from a health care professional (sometimes previously referred to as compliance)

#### Adverse drug event

Any injury resulting from medical interventions related to a drug (medication). This includes both adverse drug reactions in which no error occurred, and harm resulting from medication errors

#### Adverse drug reaction

A response to a drug (medication) that is noxious and unintended and that occurs at doses used in humans for prophylaxis, diagnosis or therapy of diseases, or for the modification of physiological function

#### Antimicrobial resistance

Antimicrobial resistance refers to the ability of a microorganism to stop antimicrobials from working against it; it is a broad term encompassing resistance to antibacterial, antiviral, antiparasitic and antifungal drugs.

#### Anaphylaxis

A severe, life-threatening systemic hypersensitivity reaction characterized by being rapid in onset with potentially life-threatening airway, breathing, or circulatory problems and usually, although not always, associated with skin and mucosal changes

#### Comorbidity

Comorbidity refers to more than one disease or condition being present in the same person at the same time. Conditions described as comorbidities are often chronic or long-term conditions

#### Deprescribing

Deprescribing refers to the stepwise reduction of unnecessary or potentially inappropriate medications <u>supervised by a healthcare professional</u>, after consideration of therapeutic goals, benefits and risks, and medical ethics

#### Essential medicines

Essential medicines are those that satisfy the priority health care needs of a given population

#### Health care professional

A health care professional is a person who is appropriately qualified and permitted by the relevant authorities to provide a health care service to a patient

#### Health care worker

Health care workers are people engaged in actions where the primary intent is to enhance health; this includes health care professionals but is a much wider term.

#### High-alert (in some cases referred to as high-risk) medications

These are drugs (medications) that bear a heightened risk of causing significant patient harm. Although mistakes may or may not be more common with these medications, the consequences of an error are likely to be more serious

#### Inappropriate mediation use

The use of medications that pose more risk than benefit<u>to the individual</u>, particularly where safer alternatives exist

#### Inter-professional education

Occurs when students from two or more professions learn about, from and with each other to enable effective collaboration and improve health outcomes

#### **Medication error**

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, carer or consumer

#### Medication reconciliation

The formal process in which health care professionals partner with patients to ensure accurate and complete medication information transfer at interfaces of care

#### Medication-related harm

Patient harm related to medication. This includes preventable adverse drug events (e.g. due to a medication error) and non-preventable adverse drug events (e.g. an adverse drug reaction). This term is sometimes used interchangeably with adverse drug event, but is sometimes considered to be a broader term encompassing non-adherence, and both accidental and intentional misuse of medication

#### **Medication safety**

Freedom from accidental injury during the course of medication use, or those activities to avoid, prevent, or correct medication-related harm

#### Medication regimen simplification

The process of reducing medication complexity through strategies such as administering medications at the same time, standardizing routes of administration, using long-acting formulations in preference to shorter-acting agents, and switching from multiple single-ingredient preparations to a combination formulation where possible

#### Medication use process

The multistep process involved in the use of medications by or for patients, including: procurement, storage, prescribing, dispensing, preparation, administration, monitoring and destruction

#### Multimorbidity

The presence of two or more long-term health conditions, which can include (a) defined physical and mental health conditions such as diabetes or schizophrenia; (b) ongoing conditions such as learning disability; (c) symptom complexes such as frailty or chronic pain; (d) sensory impairment such as sight or hearing loss; and (e) alcohol and substance misuse

#### Multi-professional education

The process by which students of one profession learn alongside those of another profession for certain periods of their education

#### Near-miss

This may be used to refer to a patient safety incident that did not reach the patient, or to a patient safety incident that reached the patient but did not result in harm

#### Patient safety

The absence of preventable harm to a patient and reduction of risk of harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of current knowledge, the resources available and the context in which care is delivered, balanced against the risk of non-treatment or other treatment

#### Polypharmacy

Polypharmacy is the concurrent use of multiple medications. Although there is no standard definition, polypharmacy is sometimes defined in community settings as the routine use of five or more medications. This includes over-the-counter, prescription and complementary medicines. Polypharmacy may be appropriate or inappropriate

#### Prescription

A prescription is a patient-specific written or electronic order to take (or supply) a specific medication.

#### Risk

The probability that an incident will occur

#### Safety

The reduction of risk of unnecessary harm to an acceptable minimum

#### Side-effect

A known effect, other than that primarily intended, related to the pharmacological properties of a drug (medication)

#### Transitions of care

The points where a patient moves to, or returns from, a particular physical location or makes contact with a health care professional for the purposes of receiving health care

# Introduction

The Medication Safety Curriculum Guide aims to support implementation of the Third WHO Global Patient Safety Challenge: *Medication Without Harm*, launched in 2017 with the goal to reduce severe avoidable medication-related harm by 50%, globally in the next five years. Only through comprehensive, integrated health system strengthening approaches and with commitment of key stakeholders, including national governments, patients and the public, professional associations, academic institutions and civil society organizations, achievements in reducing the harm associated with medication use can be gained and sustained.

One of the prerequisites for the health system to effectively and efficiently perform and address the current and emerging challenges is availability of a competent and well-performing health professionals. Addressing educational agenda grounded in competency-based learning that will allow health professionals to be equipped with knowledge and skills for collaborative work in inter-professional teams is critical and applicable in different technical areas, including medication safety.

This Medication Safety Curriculum Guide is designed to provide an overview of those aspects of medication safety that should be taught to undergraduate and postgraduate health care students and practicing health professionals, and to encourage a culture of ongoing interprofessional learning and practice in relation to medication safety. The intended audience is undergraduate and postgraduate health care students, practicing health professionals, their educators, and relevant professional bodies.

In keeping with the importance of an inter-professional approach to medication safety, it has been designed to support inter-professional learning where possible, in which students or qualified staff from different professional groups learn together and from each other to enable effective collaboration and improve health outcomes. However, the same material can also be used in single profession or multi-professional contexts where needed, with the latter referring to different professions learning in parallel but without specific opportunities to also learn from each other.

The Medication Safety Curriculum Guide replaces Improving Medication Safety topic of the Patient Safety Curriculum Guide: Multi-professional Edition (2011)<sup>1</sup> and it is recommended to link the use of this guide with the Part A (Teacher's Guide) of 2011 edition.

This guide was developed through consultative process in close collaboration with International Pharmaceutical Federation (FIP), International Council of Nurses (ICN), World Dental Federation (FDI), World Federation of Medical Education (WFME), University College London, UK and University of Colombo, Sri-Lanka[y1].

The Medication Safety Curriculum Guide provides links to several resources on medication safety and is supported by some ready-to-teach materials. It is designed for flexible use: it can be reproduced, adopted and/or translated.

Reproduction

<sup>&</sup>lt;sup>1</sup> WHO. <u>https://www.who.int/patientsafety/education/mp\_curriculum\_guide/en/</u>

The Medication Safety Curriculum Guide can be reproduced in its entirety without any modifications to layout or wording. This includes the organizational logos as they appear as an integral part of the material. Co-use of an institutional logo in non-adapted material is not permitted. To acknowledge the original source, the following sentence should be used: "Reproduced from: Medication Safety Curriculum Guide. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO."

#### Adaptation

The Medication Safety Curriculum Guide can be adapted, to meet the specific needs of the country and/or entity, based on local context, specific setting and available resources. If the curriculum guide is adapted in any way, including as a whole and its separate sections, the organisational logos cannot be used, however. To acknowledge the original source, the following sentence should be used: "This is an adaptation of an original work: Medication Safety Curriculum Guide. Geneva: World Health Organization (WHO); 2019. Licence: CC BY-NC-SA 3.0 IGO. This adaptation was not created by WHO. WHO is not responsible for the content or accuracy of this adaptation. The original edition shall be the binding and authentic edition".

#### **T**ranslation

The Medication Safety Curriculum Guide can be translated into local languages. If it is translated, the organizational logos cannot be used, however. To acknowledge the original source, the following sentence should be used: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. Original edition: Medication Safety Curriculum Guide. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO shall be the binding and authentic edition".

For more information on publishing translations of WHO materials please visit:

http://www.who.int/about/licensing/translations/en/index.html

# 1. Background

A great many medical conditions can now be treated or prevented with medication, resulting in a dramatic increase in medication use over the last few decades. People are also living longer, partly due to advances in medical knowledge, which means that many are living with multiple co-morbidities and/or taking multiple medications. Health care professionals will therefore be looking after patients who take medications prescribed by other clinicians (whether in primary care or hospital care) and may not have personal expertise in all the medications a patient is taking. The use of medication has also become increasingly complex. There has been a dramatic increase in the number of medications available, the same active medication may be given via many different routes of delivery and/or formulations (such as long-acting or short-acting), and indications for existing medications have expanded. Sometimes the same formulation of a particular medication is also available as more than one brand name. Unfortunately, these changes collectively increase the likelihood of medication errors and adverse drug events.

The process of providing medications to patients usually involves a wide range of health care professionals and health care workers as well as patients, their family members and other informal caregivers. Health care professionals who may be involved with medication use in different settings include medical staff, nursing staff, pharmacy staff, paramedics, midwives, physiotherapists or respiratory therapists, dentists and anaesthetists. Other health care workers may also play a role in supporting patients or health care professionals in different aspects of medication use, as will patients' families and other caregivers. Communication failures among any of these people can result in increased risk of patient harm. An approach to medication safety based on teamwork and inter-professional working is therefore essential, together with a culture of ongoing learning and its integration with practice.

# 1.1. Medication-related harm

Medication-related harm is a broad term used to describe any harm associated with medication use or its omission. It includes both potentially avoidable adverse drug events (for example, due to a medication error, accidental misuse or non-adherence) and non-preventable adverse drug events (for example, an unanticipated adverse drug reaction). While there is some variation in how these terms are used in different contexts, Figure 1 summarises the relationship between medication errors and adverse drug events as most commonly understood.

A medication error may result in any of the following:

- an adverse drug event, in which a patient is harmed;
- a near miss, in which a patient could have been harmed but this was prevented;
- no harm.



#### Figure 2. Relationship between medication errors and adverse drug events

Source: Adapted, with the permission of the publisher, from Miller et al. (6).

Figure 1. Relationship between medication errors and adverse drug events[ $y_2$ ] Source: Adapted with the permission<sup>2</sup>.

# 1.2. Global burden of medication-related harm

Studies from the USA, Australia and UK in the late 1990s suggested a considerable number of patients were being harmed by unsafe medical care, leading to an international focus on addressing this problem. For example, it was estimated that between 44,000 and 100,000 US patients die every year as a result of medical care<sup>3</sup>. Medication error is a common cause of preventable patient harm, with an estimated one medication error per hospitalized patient per day in the USA [3], resulting in 1.5 million preventable adverse drug events per year [3], and 7,000 deaths [4]. In England, medication errors have been estimated to cause 712 deaths per year and contribute to a further 1,708 deaths<sup>4</sup>.

Although most evidence is from developed nations, there is also growing evidence of harm due to medication errors in low and middle-income countries. A Mexican study revealed that 58% of prescriptions included errors, with dosing errors most common<sup>5</sup>. A systematic review identified 45 studies of medication errors from ten of the fifteen Middle Eastern countries, although many were considered to be of low quality<sup>6</sup>. More recent review of 54 studies from the Gulf Cooperation Council countries revealed prescribing error rates as high as 91% of primary care prescriptions, and adverse drug events in 8.5 to 16.9 per 100 admissions with

<sup>&</sup>lt;sup>2</sup> TBA

<sup>&</sup>lt;sup>3</sup> Kohn, LT, Corrigan, J, Donaldson, M S (2000) To err is human: building a safer health system. Washington, D.C: National Academy Press

<sup>&</sup>lt;sup>4</sup> Elliott R, Camacho E, Campbell F, Jankovic D, Martyn St James M, Kaltenthaler E, Wong R, Sculpher M, Faria R, (2018). Prevalence and Economic Burden of Medication Errors in The NHS in England. Rapid evidence synthesis and economic analysis of the prevalence and burden of medication error in the UK. Policy Research Unit in Economic Evaluation of Health and Care Interventions. Universities of Sheffield and York.

<sup>&</sup>lt;sup>5</sup> Zavaleta-Bustos et al. 2008

<sup>&</sup>lt;sup>6</sup> Alsulami et al. 2013

up to 30% of these preventable<sup>7</sup>. A systematic review of the burden of harm of intravenous drug preparation errors identified studies in Europe, North and South America, Asia and Africa with twelve of 34 studies providing estimates of potentially attributable patient harm<sup>8</sup>.A systematic review of dispensing errors in hospital pharmacy identified research from only four countries, but with four studies from Brazil<sup>9</sup>. A further study from Brazil investigated the relationship between prescribing and dispensing errors in the hospital setting<sup>10</sup>. In community care contexts, a recent systematic review of medication errors and error-related adverse events included studies from Brazil, India and Lebanon<sup>11</sup>. While there is limited evidence in some areas of the world, it is therefore clear that preventable medication-related harm is a global issue[y3].

# 1.3. WHO Global Patient Safety Challenge: Medication Without Harm

Recognizing the scale of avoidable harm linked with unsafe medication practices, WHO launched the third Global Patient Safety Challenge: *Medication Without Harm* (Figure 2) in March 2017, with the goal of reducing severe, avoidable, medication-related harm by 50% over the following five years<sup>12</sup>.

There have been two previous WHO Global Patient Safety Challenges that have addressed critical patient safety topics. The first was *Clean Care is Safer Care*, with the aim to strengthen the commitment of Member States to address health care-associated infection. This goal incorporated multiple areas, including blood safety, immunization safety, safe water, sanitation and waste management. *Safe Surgery Saves Lives* was the second Global Patient Safety Challenge, which focused on improving the safety of surgical care around the world by defining a core set of safety standards that could be applied to all WHO Member States; the WHO Surgical Safety Checklist was a key outcome with many contributors from all WHO regions.

The key idea behind the Global Patient Safety Challenges is to identify a patient safety topic that poses a significant risk to health, call for global action to address the topic, and develop interventions at different levels to be implemented by key stakeholders. Politicians and decision-makers, health care professionals and other health care workers, patients, their families and caregivers therefore all have a role to play.

The key concept behind each Challenge is that errors and adverse events are not inevitable but are often provoked by poor systems and practices. On this basis, strengthening different elements of these systems and practices, including governance, information systems,

<sup>8</sup> Hedlund N, Beer I, Hoppe-Tichy T, et al. Systematic evidence review of rates and burden of harm of intravenous admixture drug preparation errors in health care settings. BMJ Open 2017;7: e015912. doi:10.1136/bmjopen-2017-015912

<sup>&</sup>lt;sup>7</sup> Alsaidan et al <u>https://www.sciencedirect.com/science/article/pii/S1319016418301099</u>

<sup>&</sup>lt;sup>9</sup> Aldhwaihi K, Schifano F Pezzolesi

C Umaru N A systematic review of the nature of dispensing errors in hospital pharmacies Integrated Pharmacy Research and Practice 2016:5 1–10

<sup>&</sup>lt;sup>10</sup> Silva M, Rosa MB, Franklin BD, Reis AM, Anchieta LM, Mota JA. Concomitant prescribing and dispensing errors at a Brazilian hospital: a descriptive study. Clinics (Sao Paulo), 2011;66:1691–1697.

<sup>&</sup>lt;sup>11</sup> <u>https://bmjopen.bmj.com/content/8/5/e019101</u>

<sup>&</sup>lt;sup>12</sup> http://www.who.int/patientsafety/medication-safety/en/

standardisation, education of health care professionals and others, should lead to safer patient care. Specifically, *Medication Without Harm* focuses on four domains:

- 1. Medications are often complex, can be puzzling in their names or packaging, and sometimes lack sufficient or clear information. For example, look-alike or sound-alike medications are a frequent source of error that can be addressed. One of the elements in implementation of the Challenge is therefore to strengthen the regulatory and technical aspects of medication development to ensure availability of safe, effective and user-friendly medications that do not contribute to risks through their design or nomenclature.
- 2. Patients and the public are not always medication-wise. They are too often made to be passive recipients of health care rather than being informed and empowered to play their part in making the medication process safer. Educating, engaging and empowering patients and carers to take active roles in their care, and creating health care systems that value patient input, are therefore critical elements in implementation of *Medication Without Harm*.
- 3. Health care professionals sometimes prescribe, dispense and administer medications in ways and circumstances that increase the risk of harm. Their education, training and skill development through patient-centred and competency-based learning is therefore key to reducing risks related to medication use. Health care professionals have to become well-informed members of inter-disciplinary teams and actively promote and contribute to working environments that support learning from mistakes.
- 4. Systems and practices of medication use are complex and sometimes dysfunctional. These can be made more resilient to risk and harm if they are well understood, designed and managed. Actions are therefore needed in ensuring availability of practical and usable evidence-based policies, strategies and plans (at national, organisational and local levels), supported by legislative and regulatory frameworks, well-functioning reporting and learning systems, good leadership, and stakeholder engagement in all aspects of medication use.



#### Case Scenario 1

Mrs Perera, a 53-year-old woman, was admitted to hospital for investigation of backache of two months duration. Mrs Perera works in her own small grocery shop and has two school-age children. She was on treatment for diabetes and hypertension but did not know the names of medicines she was taking, which were recorded in English in her clinic record book.

In hospital, she was investigated for back pain, but no specific diagnosis was made. An Xray of her spine showed osteopenia and the medical team decided to prescribe calcium and vitamin D tablets for prevention of osteoporosis. The House Officer explained that there was no particular cause identified for her back pain but that she has some thinning of her bones for which calcium and vitamins are given, as well as painkillers for her backache. He wrote the following prescription for her on discharge.

Metformin 500mg bd

Losartan 50mg bd

HCT 50 mg mane

D sodium 50 mg tds

CaCO3 500mg bd

Vitamins A and D 1 tablet EOD [every other day]

She went to the clinic for her medicines, where pharmacists working on four counters dispense medicines to about 400 patients each day. The drugs were dispensed as loose tablets in envelopes, with the name of the medicines, the number of tablets and how often they should be taken handwritten in English on the envelopes. She took the medicines according to these instructions and felt better initially but started feeling lethargic and unwell after about three weeks, with nausea, abdominal pain, loose motions and dizziness. Her husband took her to hospital, by which time she was drowsy and confused. He brought in all her medications. On checking these, the House Officer noted that one drug packet indicated LiCO3. She had tremor, pulse 80, blood pressure 150/90 and nervous system examination showed exaggerated reflexes. Her capillary blood sugar was 160mg/dl, serum creatinine 4.2mg/L, potassium 6.4meq/L, sodium 120meq/L and lithium level was 3.2 meq/L. Chronic lithium toxicity with acute kidney injury, hyponatremia and hyperkalemia was diagnosed. The patient was given insulin with dextrose and calcium gluconate immediately for hyperkalemia, started on hemodialysis and managed in the intensive care unit.

Key medication safety points:

- This patient had been erroneously dispensed lithium carbonate tablets instead of calcium carbonate tablets
- This was due to the pharmacist interpreting CaCO3 as LiCO3 due to the abbreviation used and unclear handwriting, which contributed to the error
- There was no medication reconciliation, or simple cross checking with the patient on dispensing a high-risk medication such as lithium for the first time, which could have prevented the error

• The patient's lack of knowledge about her medications also meant that she did not realize that an error had been made

Mrs Perera recovered with regular dialysis and supportive care. All her neurological symptoms disappeared, and she was conscious and rational. On discharge her serum creatinine was 1.3 mg/dl, sodium 136meq/L and potassium 4.2 meq/L, which were stable more than a week after the last dialysis. Her medication list was revised, and a registrar explained to her that unfortunately she has been issued a wrong medicine (lithium), which resulted in the symptoms she experienced. He further stated that there might have been some degree of renal impairment due to her diabetes, and the painkillers given, which may have also contributed to her developing lithium toxicity.

Further important medication safety points:

- There were several error-prone abbreviations used in the prescription.
  - HCT was used to refer to hydrochlorothiazide, which is common practice in some settings when handwritten prescriptions are issued. When abbreviations such as HCQ are also used to refer to hydroxychloroquine, errors could occur in interpretation of unclear handwritten prescriptions, with serious consequences.
  - 'D sodium' was written instead of diclofenac sodium, which is often mistaken for Dilantin sodium (a brand name for phenytoin sodium), with potential for serious adverse consequences.
  - Using the abbreviation CaCO3 resulted in the serious error highlighted in this case due to a look-alike medicine, LiCO3
- Although writing long names takes time in busy clinics and doctors may want to use abbreviations to save time, serious errors and patient harm can occur.
- Prescribing diclofenac sodium on a regular basis, rather than as needed, can result in adverse effects. Non-steroidal anti-inflammatory drugs (NSAIDs) can result in peptic ulceration, and contribute to renal impairment and hypertension, with the latter two problems occurring in Mrs Perera's case. Paracetamol is a safer analgesic for regular use, with additional doses of a NSAID when required.

#### Case Scenario 2

Mary is a 57-year-old female recently diagnosed with asthma. Today at work she was reporting chest tightness and shortness of breath. Mary said she did not have her inhaler (a short acting beta<sub>2</sub> agonist) with her, and her co-workers called the emergency services. Upon arrival the paramedics assessed Mary and documented the following vital signs – respiratory rate 36 breaths/min, oxygen saturation >92%, pulse 124 beats/min, blood pressure 172/100 and peak expiratory flow < 50%. Using their clinical practice guideline for asthma, they treated Mary for a severe asthma attack with ipratropium bromide 0.5 mg and salbutamol 5 mg via nebuliser, and hydrocortisone 100mg/100 ml sodium chloride (via slow intravenous infusion). When they gave their handover to the nurse in the hospital emergency department, the paramedics communicated that in addition to Mary's present exacerbation of asthma she had several co-morbidities: hypertension, obesity and depression. Based on her pre-hospital emergency care, Mary's initial symptoms of dyspnoea and chest tightness had partially resolved, and her oxygen saturation improved with oxygen delivery to 96%. She received two further treatments of ipratropium 0.5 mg and salbutamol 5 mg, 15 minutes apart, and a peak expiratory flow >75% was recorded.

The nurse caring for Mary learned that she had seen her general practitioner (GP) a few weeks ago for an upper respiratory tract infection and was prescribed an antibiotic. Mary could not recall the specific antibiotic, but she said she had completed the full 7-day course. Mary also had difficulty providing the names of her other medications. She therefore referred her to the clinical pharmacist to establish her medication history, which included contacting her GP to obtain a full list of her prescribed medications. While in the emergency department she had routine blood tests, a chest X-ray and an electrocardiogram; the findings were normal.

The examining medical doctor and nurse jointly shared their concerns with Mary about her understanding and self-management of her asthma and other health conditions together with possible issues of medication adherence. In discussion with Mary it was decided to admit her for observation, additional nebuliser treatments (as above) and start oral prednisolone 40mg/day for 5 days.

Arrangements were also made for the respiratory team to see Mary before discharge from the hospital. When the respiratory consultant saw Mary the next morning it was determined she would be suitable for inhaled corticosteroids (beclometasone), combined with a long-acting beta<sub>2</sub> agonist (formoterol) for long term control of her asthma. The asthma nurse specialist then followed up with Mary providing a detailed teaching session. A symptom-based action plan was seen as a critical treatment goal for helping Mary learn to gradually improve her asthma self-management.

Key points of Mary's action plan were:

- How to self-monitor for asthma control and to recognise when her asthma may be worsening. Symptoms and signs of worsening asthma control were discussed.
- The difference between long term control medications and short-term relief inhalers and Mary's understanding of these medicines
- Peak expiratory flow rate monitoring and recording
- Taking medication appropriately. This included observing Mary's inhaler technique and showing her spacer device techniques.

Mary stated she was worried about the volume of new information she was learning in the session and how she was going to manage when at home. Considering Mary's history of depression and other co-morbidities, it was recognized that a tailored approach for education was needed for achieving better medication adherence.

Mary was discharged from the hospital a day later, with a detailed medication list prepared by the pharmacy technician, clearly labelled supplies of her medication, an easy-to-follow asthma action plan and a copy of the discharge letter emailed to her general practitioner (GP). She was advised to follow up with her GP in the next few days and an appointment was arranged at the respiratory clinic for four weeks' time. Over the next month the practice nurse from the GP's office, referring to the National Clinical Guideline and liaising with the respiratory clinic, worked with Mary to finalise her asthma action plan and reviewed the asthma teaching that had begun in the hospital.

Key medication safety points:

- Inter-professional communication across patient journey (acute care paramedicine, emergency department, specialist team – respiratory consultant, asthma nurse specialist, primary care – general practitioner, practice nurse)
- Importance of documenting response to medication treatment
- Utilisation of research/evidence-based guidelines for asthma management such as pre-hospital emergency care clinical practice guidelines for paramedics and national guidelines for acute care hospital and primary care.
- Identification of and dealing with confounding factors that have the potential to negatively impact treatment planning, patient care and self-management, such as co morbidities, psychosocial factors.

# 2. Aims and learning outcomes

# 2.1. Aims

This medication safety curriculum guide is designed to provide an overview of those aspects of medication safety that should be taught to undergraduate and postgraduate health care students and practicing health care professionals, and to encourage a culture of ongoing interprofessional learning and practice in relation to medication safety.

The intended audience is undergraduate and postgraduate health care students, practicing health care professionals, their educators, and relevant professional bodies.

# 2.2. Learning outcomes

## 2.2.1. Knowledge

Following completion of material designed in line with this curriculum guide, learners should be able to:

List common types of medication error and where in the process these can occur;

• List key principles associated with safe procurement, storage, prescribing, dispensing, preparation, administration, monitoring and destruction of medication as relevant to professional context;

Describe common high-risk situations;

• Identify ways to make medication use safer in their own areas of practice in each of the four domains of the WHO global challenge (medicines, patients and the public, health care professionals, and systems and practices);

• Give examples of the benefits of an inter-disciplinary approach to medication safety.

## 2.2.2. Performance

A health care professional who understands the issues and risks involved in the use of medication will:

- Use generic names as much as possible;
- Individualise prescribing for each patient;
- Practice taking and documenting thorough medication histories;
- Use appropriate reference sources when needed;
- Communicate clearly;
- Develop safe checking practices;
- Encourage patients to be actively involved in the medication process;
- Report and learn from their own and others' errors;
- Identify high-risk situations in their own area of practice and take action to reduce these risks.

# 3. The Medication Use Process

# 3.1 Introduction

The medication use process comprises a series of steps leading to the use of medications by, or for, a patient. These steps will vary by health care setting but are likely to include some or all of the following: procurement, storage, prescribing, dispensing, preparation, administration, monitoring and destruction. During this process, roles will be played by medical, nursing and pharmacy staff, other health care professionals, other health workers, patients, their family members and caregivers. For example, a nurse in a community clinic may recommend that a patient buys over-the-counter medication, a member of the patient's family buys it from a pharmacy, and then the patient monitors their response to the treatment. In the hospital setting, a doctor may prescribe a medication, a pharmacist adjusts the dose, a pharmacy technician dispenses it and a nurse administer it, with a team approach to monitoring the patient's progress and making decisions about ongoing therapy. Variations in the process and who is responsible for each step will vary across countries and settings. This section outlines some key considerations for safe practice at each of these steps.

# 3.2. Procurement

Medication supplied from a pharmacy or other health care setting will need to be ordered from the manufacturer, wholesaler or other intermediary. Safe processes for medication procurement will need to consider sourcing of appropriate products as well as taking into account the product's shelf life, turnover, and available storage facilities in determining the amount to order. For products such as vaccines that require cold storage, attention is also needed to the integrity of the supply chain to ensure that products are kept cold throughout.

Procurement and maintenance of devices needed to administer medication such as infusion pumps also need to be considered, which may require the skills of biomedical engineers. An inter-disciplinary team is therefore needed to manage the choice, storage, maintenance and disposal of medication-related equipment.

# 3.3. Storage

Storage requires understanding of the legal requirements for medication storage, temperature management, management of stock turnover in relation to expiry dates, and an awareness of practical issues such as additional accessories that may be required for medication administration. Safe storage should consider risks of confusing similar medications, highlighting the differences between similar products where necessary. For example, it may be easier to differentiate "tramadol SOLUBLE tablets 50 mg" and "tramadol CAPSULES 50 mg," in comparison to "tramadol soluble tablets 50 mg" and "tramadol capsules 50 mg."

# 3.4. Prescribing

Prescribing involves both making a clinical decision and communicating this in writing (or electronically) in line with relevant legislation.

In relation to the prescribing decision, WHO recommends six steps in rational prescribing<sup>13</sup>.

- i. Define the patient's problem.
- ii. Specify the objective of therapy.
- iii. Verify the suitability of therapy.
- iv. Start the treatment.
- v. Give information, instructions and warnings.
- vi. Monitor (and stop) treatment as needed.

Performing each of these steps safely requires relevant information, knowledge and skills. For example, verifying the suitability of therapy requires access to the patient's medication history, details of any allergies or previous adverse drug events, the results of relevant laboratory tests and knowledge of how to interpret these, and then skills in weighing up the likely risks and benefits of different courses of action.

Prescribers will need to know how to choose the medications that they are going to prescribe, particularly those used most often. It is generally recommended that prescribers create a list of "P" ("Personal") drugs that is memorised or kept on a readily accessible list. Considerations when selecting a P-drug include adherence to a local formulary or drugs list, the therapeutic indication, safety profile, efficacy, cost, duration, dosage (and insurance coverage, if applicable)<sup>14</sup>.

Once the prescribing decision has been made, the relevant details have to be communicated clearly to those who will dispense and administer the medication, including the patient and their carers where relevant. As a minimum, prescriptions should include the name and contact information of the prescriber, date, generic name of the drug (and the brand, if clinically important), strength, dosage form, dose instructions, amount to be supplied, the patient's name, address and age, and the prescriber's signature and license number if applicable. If possible, the medication's indication should also be included. Requirements will vary depending on country-specific legislation and professional guidance. Well-implemented computerized prescriber order entry or electronic prescribing systems have potentially significant benefits in the quality and safety of prescribing, considered in more detail in section 6.4. Standardization of the format and layout of handwritten prescriptions may also help reduce errors. Where hand-written prescriptions are used, it is essential to use legible handwriting and avoid abbreviations in order to minimise errors. For example, calcium carbonate has been mistaken for lithium carbonate when handwritten as 'CaCO3'. Similarly, diclofenac sodium prescribed as 'D sodium' has been misinterpreted as Dilantin® sodium and the patient administered phenytoin.

<sup>&</sup>lt;sup>13</sup> de Vries T.P.G.M. et al. 1994

<sup>&</sup>lt;sup>14</sup> de Vries R.H. Henning H.V. Hogerzeil D.A. Fresle 1994

The same principles of education around safe prescribing apply to both medical and nonmedical prescribers such as pharmacists and nurses where relevant, and all health care professionals need to be familiar with local and national prescribing regulations and requirements.

# 3.5. Dispensing

In most settings, most of dispensing is done by pharmacy staff. Prior to dispensing, a pharmacist should confirm that the medication is safe and clinically appropriate for the patient and that prescribing documentation meets relevant legal requirements. Pharmacy staff will then need to select the correct drug, strength, formulation and quantity. For medication to be given directly to the patient or their caregivers, patient-specific labels should be used to explain how the medication is to be taken, including any special precautions to be aware of. Any associated additional information (e.g., patient information leaflets) and accessories (e.g., measuring cups) will also need to be supplied. Importantly, patient (or carer) education should also be provided, using techniques such as "teach-back", to ensure that the patient or carer can explain what the medication is for, how to use it, any important side effects to look out for, and what to do if they occur. In some settings, it has been standard practice to issue unlabelled medications, which predisposes to errors as patient may not know how to take their medicines and similar-looking tablets can easily be confused with one another. Dispensed medicines should therefore include the name of the medicine, preferably in the patient's own language, with the strength, dose and frequency of administration also included on the label.

# 3.6. Preparation

Some medications require additional manipulation before use, such as reconstitution or dilution; others may need to be compounded for individual patients. In most countries, there are specific regulations and requirements to support safe compounding. In particular, medications intended for parenteral administration have to be prepared using strict aseptic technique to avoid bacterial contamination leading to potentially life threating infections. For example, a recent outbreak of fatal meningitis was caused by contaminated corticosteroid injections, leading to 64 deaths<sup>15</sup>.

# 3.7. Administration

This involves checking the medication prescribed, preparing and then giving medication to the patient. This is often the last opportunity to detect errors occurring earlier in the process before the dose is administered to the patient.

In patients' homes, patients or family members most commonly administer medication, highlighting an important role for health care professionals and other health care workers in learning how to educate patients and carers in safe medication administration.

In the inpatient setting, the majority of medications are given by nursing staff, giving nurses a crucial role in preventing errors and adverse drug events. Preparing and administering

<sup>&</sup>lt;sup>15</sup> Anon et al.

medications for inpatients may also involve complex calculations and multi-step preparation processes, and so those administering medication must be competent in these areas. Inadequate documentation can also lead to administration errors. For example, if a medication is administered but not recorded as being given, another staff member may give the patient a duplicate dose.

# 3.8. Monitoring

Monitoring involves determining whether the medication is working, is being used correctly and whether there are any adverse events. This may involve observing the patient, requesting tests or investigations, and/or asking for the patient's subjective feedback on their symptoms. Such monitoring may therefore include health care professionals requesting investigations such as laboratory tests or asking patients or their caregivers to look out for, and report, specific events such as evidence of an infection with medication that can cause immunosuppression. Some long-term medications might need regular ongoing monitoring, such as amiodarone requiring thyroid function tests, statins requiring liver function tests, and lithium requiring serum lithium levels.

# 3.9. Destruction

Safe destruction of unwanted medication is important to avoid inadvertent reuse or misuse, particularly for high-risk medications with specific requirements around destruction, such as narcotics and other controlled substances. Destruction will also need to take into account relevant regulations around disposal to minimize contamination of the environment.

# 4. Priority areas

The third WHO Patient Safety Challenge: *Medication Without Harm* calls on countries to prioritize and take early action in key three areas associated with significant patient harm due to unsafe medication practices:

- *Polypharmacy* situations in which patients take multiple medications for the same or different diseases and conditions.
- *Transitions of care* the points at which a patient changes physical location and/or contact with a health care professional for the purposes of receiving health care.
- *High-risk situations* specific circumstances associated with higher risk of medicationrelated harm. These may be related to the medication (e.g. medication with a low therapeutic index), the individual patient or health care professional, or the environment or system (e.g. emergencies, neonatal care).

It is therefore recommended that any teaching and training on medication safety includes the relevant aspects of these three priority areas. The rest of this section gives a brief introduction to each area, highlighting some examples of areas that could be included in inter-professional education.

# 4.1 Polypharmacy

Polypharmacy refers to the concurrent use of multiple medications. There is no standard definition. However, in community settings, polypharmacy is often defined as the use of five or more medications on a daily basis<sup>16</sup>. In aged care homes, a definition of nine or more medications is commonly used<sup>17</sup>.

Polypharmacy is common in older people and/or those who have several comorbidities. It is estimated that 39% of patients aged 65 years or older are prescribed five or more medications and that up to 74% of residents of long-term care facilities use nine or more medications on a regular basis<sup>18</sup>. It is also common that these medications are prescribed by more than one health care professional.

While polypharmacy may be appropriate and necessary, in other cases it is inappropriate and can lead to negative outcomes. Polypharmacy has been associated with greater risk of inappropriate medication use, poor adherence, medication errors and adverse drug events. It is also associated with increased health care costs, and increased risks of hospitalization and mortality<sup>19</sup>. Polypharmacy may be particularly problematic in older people who may have altered pharmacokinetics and pharmacodynamics, with an increased risk of adverse drug events. When faced with multiple medications, some people may not take all those prescribed and selectively take only some. In such situations, some may take non-essential vitamins or

<sup>&</sup>lt;sup>16</sup> Masnoon et al., 2017

<sup>17</sup> https://www.ncbi.nlm.nih.gov/pubmed/25869992

<sup>&</sup>lt;sup>18</sup> Charlesworth et al., 2015; Jokanovic et al., 2015

<sup>&</sup>lt;sup>19</sup> Fried et al., 2014

analgesics while omitting essential antidiabetic or antihypertensive medications. If patients have to pay for their medications, they may also buy only the cheaper ones even if these are the less clinically important, if they are not aware of the indications for each medication.

In many countries, inappropriate polypharmacy is one of the most significant public health challenges of the current age. This burden is set to increase as the population ages with more people suffering from multiple long-term conditions requiring medication. There remains a lack of evidence around treating people with multi-morbidity, as clinical research and health care delivery models tend to focus on single diseases. One study suggests that over 70% of unplanned hospital admissions that are attributable to medication-related harm involve elderly patients on multiple medicines<sup>20</sup>. Students and practicing health care professionals should therefore be aware of the risks of polypharmacy, including drug-drug and drug-disease interactions, and be able to apply approaches to managing these risks in their clinical

#### Strategies to reduce inappropriate polypharmacy

Assessment of a patient's medication regimen requires a clear understanding by the patient and the health care team of the therapeutic aims, and the potential and actual benefits and risks of the patient's medications<sup>21</sup>. These individual goals and priorities will influence the choice to continue, cease or commence medications. An inter-disciplinary approach involving patients, carers, medical practitioners), pharmacists, nurses and other health professionals, is a common feature of successful interventions to reduce polypharmacy<sup>22</sup>. Further relevant areas for intervention include medication review, identifying potentially inappropriate medications, deprescribing and medication regimen simplification, as suggested in section 6.2.

# 4.2 Transitions of care

Transitions of care are the points where a patient moves to, or returns from, a particular physical location and/or contact with a health care professional for the purposes of receiving health care. Unfortunately, however, medication errors associated with transitions of care are common<sup>23</sup>. Common transition points in health care include:

- Admission to hospital or residential care, where patients may be treated by many different health care professionals, and medications may be started, changed or stopped;
- Transfer from one area within a hospital to another, with additional risks if different paper or electronic medication records are used in the different areas, for example emergency department to intensive care unit, operating theatre to ward;
- Discharge from hospital, where a discharge prescription or discharge instructions may be issued;

<sup>&</sup>lt;sup>20</sup> Kongkaew et al. 2013

<sup>&</sup>lt;sup>21</sup> Hilmer et al., 2012

<sup>&</sup>lt;sup>22</sup> Cooper et al., 2015

<sup>&</sup>lt;sup>23</sup> Hospital-Based Medication Reconciliation Practices. A Systematic Review. Stephanie K. Mueller, MD; Kelly Cunningham Sponsler, MD; Sunil Kripalani, MD, MSc; et al Jeffrey L. Schnipper, MD, MPH. Arch Intern Med. 2012;172(14):1057-1069. doi:10.1001/archinternmed.2012.2246

• Transfer from one hospital or residential care setting to another, such as from hospital to a nursing home or rehabilitation facility.

As well as other clinical information, accurate medication-related information needs to be transferred between locations and health care providers as well as to the patient or their caregiver. This should include details of any changes to medication and the reasons for these changes.

Such transition points are frequently associated with changes in the medications that a patient receives, with unintended changes often referred to as medication discrepancies (figure 3). In addition, patients' medications may change due to the patient:

- Starting, changing or stopping non-prescription or over-the-counter medication;
- Starting, changing or stopping herbal, traditional or alternative medicines, either with or without interaction with health care providers;
- Using medication obtained from friends or family;
- Using medication obtained from unsafe sources such as from unregulated online suppliers, which may be counterfeit, contaminated or of unknown content.



Figure 4. Changes in medication during transitions of care between home and hospital

Key strategies for improving medication safety during transitions of care are considered further in sections 6.1 and 6.2, and include:

- Partnering between patients, families, caregivers and health care professionals to agree on treatment plans, ensuring patients are equipped to manage their medication safely, and carry an up-to-date medication list.
- Implementing formal structured processes for medication reconciliation at all transition points of care, including (a) building the best possible medication history by interviewing the patient and verifying with at least one other reliable information source;
   (b) reconciling and updating medication lists; and (c) communicating with the patient

and future health care providers about any changes in medication, with agreed roles and responsibilities, and provision of any training, support and tools required<sup>24</sup>.

- Where necessary, prioritizing patients at highest risk of medication-related harm for medication reconciliation and enhanced support.
- Implementing collaborative medication management between medical, nursing and pharmacy personnel and, where staffing is inadequate, planning and investing to increase workforce capacity and capability.
- Improving the quality and availability of information at care transitions and identifying the most reliable information sources for verifying medication histories at transitions.

While medication reconciliation is the responsibility of all health care professionals, pharmacy staff can have an instrumental role. A meta-analysis of 13 randomized trials, including nearly 3,500 patients, showed that pharmacist involvement improved safety by reducing medication errors after hospital discharge as well as subsequent emergency room visits related to medications<sup>25</sup>. Another study showed pharmacy-led medication reconciliation to result in lower levels of medication discrepancies by up to 66%, with greatest benefits in higher risk transitions<sup>26</sup>. However, in settings where clinical pharmacy services are not available, medical and nursing staff may need to take responsibility for medication reconciliation.

# 4.3. High-risk situations

High-risk situations are those particularly likely to be associated with significant harm due to unsafe medication practices or medication errors. There are three main groups of factors contributing to high-risk situations; these relate to the medication, the individual provider or patient, and the environment or system. Each of these are next briefly described. Education on medication safety should include those factors relevant to learners' specific areas of practice.

## Medication factors

#### High-risk medications

High-risk (or 'high-alert') medications include those with a low therapeutic index, in which a dose that will cause toxicity is not much higher than the dose needed for clinically efficacy, and other drugs for which specific precautions are needed. Oral methotrexate, which is unusual in[y5] being taken once weekly, would be one such example. The development of local high-risk medication lists, regularly updated, helps health care professionals to be aware of particular risks in their own context. For example, the New South Wales Clinical Excellence Commission in Australia uses a mnemonic to help remember some important high-risk medications: "A-PINCH"<sup>27</sup>. This stands for Anti-infectives, Potassium and other electrolytes, Insulin, Narcotics and other sedatives, Chemotherapeutic agents, and Heparin and other

<sup>&</sup>lt;sup>24</sup> Tamasine Grimes, Royal College of Surgeons in Ireland & Authors 2009

<sup>&</sup>lt;sup>25</sup> De Oliveira et al. 2017

<sup>&</sup>lt;sup>26</sup> Mekonnen et al. 2016

<sup>27</sup> Anon n.d

anticoagulants. Such lists should be supported by appropriate risk reduction strategies; merely creating a list of high-risk medications is not sufficient.

Other medication-related risks include products with look-alike or sound-alike names or similar packaging, and medications requiring complex calculations or reconstitution.

#### Substandard and falsified medications

Substandard and falsified medications affect every region of the world and pose an unacceptable but preventable health risk. "Substandard" products fail to meet quality standards or specifications or both and may also be referred to as "out of specification". "Falsified" medications deliberately/fraudulently misrepresent their identity, composition or source<sup>28</sup>. Such medications can harm patients due to poor treatment outcomes, treatment failure or poisoning due to harmful ingredients, and undermine confidence in health care.

The first step towards identifying a substandard or falsified product is visual inspection, including searching for suspicious signs such as improper packaging, labelling and description of dosage. Complaints from patients about abnormalities in colour, taste, solubility or medical response can also highlight a substandard or falsified medication. Use of an undetected substandard or falsified product can lead to a second-line treatment being used unnecessarily based on the poor outcomes of the initial treatment. Pharmacy staff can play an important role by being vigilant in identifying such medicines and reporting to the relevant authorities.

The World Health Professions Alliance has developed a freely available toolkit "Be Aware, Take Action" to help health care professionals detect substandard or falsified products and inform colleagues and patients<sup>29</sup>[y6].

Education and awareness of both health care workers and patients is therefore essential for detection of substandard and falsified medicines and preventing the harm they can cause. Caution is especially needed if a patient acquired his/her medicines through a potentially risky source.

#### Traditional and complementary medicines

Traditional and complementary medicines may be used together with, or instead of, other medications across all health care settings. Both medication errors and adverse drug events can occur with such medications<sup>30</sup>. Traditional and complementary medicines may be

<sup>&</sup>lt;sup>28</sup> <u>http://www.who.int/medicines/regulation/ssffc/definitions/en/</u>

<sup>&</sup>lt;sup>29</sup> (<u>http://www.whpa.org/counterfeit\_campaign\_materials.htm</u>

<sup>&</sup>lt;sup>30</sup> Yutaka Shimada, Makoto Fujimoto, Tatsuya Nogami, Hidetoshi Watari, Hideyuki Kitahara, Hiroki Misawa and Yoshiyuki Kimbara. Patient safety incident reports related to traditional Japanese Kampo medicines: medication errors and adverse drug events in a university hospital for a ten-year period. BMC Complementary and Alternative Medicine. 2017; 17:547.

Jinho Lee, Joon-Shik Shin, Me-riong Kim, Jang-Hoon Byun, Seung-Yeol Lee, Ye-sle Shin. Hyejin Kim, Ki Byung Park, Byung-Cheul Shin, Myeong Soo Lee, In-Hyuk Ha. Liver enzyme abnormalities in taking traditional herbal medicine in Korea: A retrospective large sample cohort study of musculoskeletal disorder patients. Journal of Ethnopharmacology. 2015 Jul 1; 169:407 – 412.

prescribed by the relevant practitioners or purchased by patients themselves. Self-care using traditional and complementary medications is increasing for various health conditions. For example, one study revealed that 39.6% of respondents reported use of complementary medicine to support cancer care, of whom 87.9% relied on herbal medicines<sup>31</sup>.

Many of the problems associated with use of traditional and complementary medications arise from insufficient registration requirements for these products. Depending on national regulations in different countries, same single medicinal plant could be regulated as a food ingredient, a functional food, a dietary supplement, an over-the-counter medicine, or a herbal drug. These differences can lead to inconsistencies in monitoring and reporting of patient safety incidents, and in communication between patients and health professionals relating to whether products are included in the discussions about medication. There may also be limited communication between patients and their health professionals about use of traditional and complementary medicines. Studies show that more than half of patients do not disclose their use of complementary and alternative medicine to their physician or pharmacist<sup>32</sup>. The WHO guidelines on developing consumer information promoting proper use of traditional, complementary and alternative medicines may be helpful in supporting their safe use across the continuum of care<sup>33</sup>.

## Provider and patient factors

These may be related to the individual health professional providing patient care or to the patient being treated.

Health care professional factors include their skills and training, being tired or unwell, or working outside their area of expertise. Health care professionals therefore need to be aware of situations in which they may be working at higher risk and be able to consider how to reduce these risks, such as by requesting a second check from a colleague.

Patient-related factors include:

- multi-morbidity and/or polypharmacy
- poor renal or liver function
- extremes of age (children, and older people)
- frailty[s7], limited dexterity, poor vision

Hyeun-Kyoo Shin, Soo-Jin Jeong, Myeong Soo Lee, Edzard Ernst. Adverse events attributed to traditional Korean medical practices: 1999 – 2010. Bull World Health Organ. 2013; 91:569 – 575

<sup>&</sup>lt;sup>31</sup> E. Ben-Arye, E. Massalha, G. Bar-Sela, M. Silbermann, A. Agbarya, B. Saad, E. Lev & E. Schiff. Stepping from traditional to integrative medicine: perspectives of Israeli-Arab patients on complementary medicine's role in cancer care. Annals of Oncology. 2014; 25:476 - 480

<sup>&</sup>lt;sup>32</sup> Syed Shahzad Hasan, Syed Imran Ahmed, Nadeem Irfan Bukhari, William Cheah Wei Loon. Use of complementary and alternative medicine among patient with chronic diseases at outpatient clinics. Complementary Therapies in Clinical Practice. 2009; 15: 152 – 157.

Brian M. Shelley, Andrew L. Sussman, Roberts L. Williams, Alissa R. Segal, Benjamin F. Crabtree. They don't ask me so I don't tell them: patient-clinician communication about traditional, complementary, and alternative medicine. Annals of family medicine. 2009; 7(2): 139 – 147

<sup>&</sup>lt;sup>33</sup> Guidelines on developing consumer information on proper use of traditional, complementary and alternative medicine. World Health Organization. 2004

- low health literacy
- pregnancy and lactation
- communication difficulties (for example due to health professionals not speaking the same language as patients, cognitive impairment, medication affecting the central nervous system, or being under the influence of alcohol).
- Affordability (for example, some people may not be able to afford the medication prescribed for them)

Patients who are taking multiple medications prescribed by more than one health care professional or patients who do not take an active interest in their own health may be additionally at risk. Infants and children have an increased risk of error due to the dose calculations required, with an additional issue being that they have to rely on another person (parents or guardians) to care for them.

Health care professionals therefore need to be aware of the specific clinical considerations for each of these higher risk groups.

#### Patients with liver and renal impairment

Patients with renal and liver impairment are at high risk of developing medication related harm as medications may not be metabolized and/or not eliminated as expected. <u>This occurs with normal ageing, as well as many disease states.</u> In many cases, this leads to accumulation of the medication or its active metabolites, which can lead to harm. In other cases, impaired liver function may lead to non-activation of the medications (such as for pro-drugs such as enalapril and clopidogrel which require conversion to the active form), which can lead to lack of intended therapeutic effect. Chronic liver disease can also change the systemic availability of high extraction drugs, thereby affecting plasma concentrations<sup>34</sup>. Examples of high extraction drugs include morphine, propranolol, calcium channel blockers and levodopa.

For patients with renal impairment, some drugs need to be avoided completely and others need dosing to take into account the degree of renal function. Reference to peer reviewed and ready-to-access information can help reduce medication related harm<sup>35</sup>.

## Systems and environmental factors

These include higher-risk areas within health care settings (e.g. specific risks associated with perioperative or neonatal care), and the working environment in general, such as interruptions and distractions, inadequate information resources and the nature of teamwork and communication.

Considering that medication errors are often caused by a combination of medication, individual and environmental factors, health care professionals need to be aware of what they can do in their own area of practice to address risks in each of these areas.

<sup>&</sup>lt;sup>34</sup> Sloss, A., & Kubler, P. (2009). Prescribing in liver disease. Australian Prescriber, 32(2), 32-5.

<sup>&</sup>lt;sup>35</sup> Aronoff, G. R. (2007). Drug prescribing in renal failure. ACP Press

#### Medication safety in emergencies

Emergency situations impact the lives and well-being of a large number of people or significant percentage of a population and require substantial multi-sectoral assistance<sup>36</sup>. Emergencies put huge burden on health systems and are challenging for all health professionals from different perspectives, including the ability to manage and use medications safely. Scarce resources, changing and unstable conditions, harsh environments, disruptions to communication, fuel, electricity and infrastructure, multifactorial complications and other issues can impact the availability, quality and safety of medications. In addition to this, many factors specific to emergency situations may amplify the frequency of medication errors, including traumatized and/or fatigued health professionals, language barriers, the need for substitution of medications, potential disruption of the supply of medicinal products as well as economic and/or political sanctions.

Medication safety is important at all stages of emergency, including preparedness, response, recovery and mitigation. Health professionals working and providing care to others at any point on this continuum need to be mindful of their role in the safe use and administration of medications, while recognising constraints imposed during these situations.

In preparedness phase, health professionals need to be educated and trained about general principles of safe use of medication as well as be aware of inter-agency emergency health kit and its composition<sup>37</sup>. In addition to that, all health professionals should be aware of national and local government emergency management strategies and plans as well as their specific roles and responsibilities during different phases of emergencies.

In response phase, there may be limited supplies of essential medicines for emerging health concerns such as diarrhoea, hepatitis or cholera, as well as for handling the ongoing treatment of long term chronic medical conditions, including mental health conditions, diabetes, cardio-vascular and oncological diseases, haemodialysis and other. Another concern might be related to the availability of substandard medications that require due vigilance about potential adverse reactions and the need for the reporting of these through the respective channels. Issues may arise in shifting from kit delivery of medicines to single item supply chains. Also, there might be issues of registration and documentation of treatment courses for patients, and in general, patients' records. Moreover, considering multiplicity of stakeholders involved in response phase, one of the critical considerations for health professionals will be to handle clinical handovers effectively and efficiently to address issues related to transitions of care and continuity.

In recovery/mitigation phase the focus needs to be on the 3 R's – Recovery, Reconstruction and Rehabilitation. During this phase, medication safety will continue to be an important issue with health professionals still being required to provide ongoing health services and at the same time to make transitions to the routine service delivery systems. The development or exacerbation of mental health conditions, especially related to stress or trauma induced because of an emergency, can significantly affect individuals at this time, leading to issues of

<sup>&</sup>lt;sup>36</sup> WHO. <u>https://www.who.int/hac/about/erf/en/</u>

<sup>37</sup> https://www.who.int/emergencies/kits/iehk/en/

adherence, and the worsening of current health issues. It should also be remembered that health professionals may also be significantly affected by the critical situation, which, in turn, could potentially contribute to medication safety concerns, such as fatigue related medication errors, or difficulty of work environment and access of workplace during security compromised situations, curfew and other.

# 5. Contributing factors and examples of interventions

There are many factors that can contribute to preventable medication-related harm, often in combination. Interventions therefore need to be chosen taking into account the most significant factors in a given setting. In line with the Third WHO Global Patient Safety Challenge: *Medications Without Harm*, this section considers interventions around the four key domains:

- patients and the public
- health care professionals
- medication design and characteristics
- systems and practices

Educators will need to consider including those interventions most relevant to a given context, depending on what is already in place and what is likely to be practical in that setting.

## 5.1. Patients and the public

While improving medication safety has traditionally been considered the responsibility of health care professionals, it is now increasingly recognised that patients and carers can and should also play a key role. Patient involvement can take a number of forms and can include encouraging patients and caregivers to contribute to reporting of adverse events. However, there is growing evidence to support patients and caregivers taking much more active roles such as by speaking up if they have any concerns, carrying their own medication lists, and making sure that caregivers check their wristband and ask their name before giving medication in the hospital setting. For example, in the USA, active involvement of patients in their own care was identified as a national patient safety goal by the Patient Safety Network in 2007<sup>38</sup> and resources developed to encourage patients to encourage to do this around medicine use. These include "<u>help avoid mistakes with your medicines</u>"<sup>39</sup>. The following are some specific areas for intervention aimed at patients and the public that can be included in medication safety education.

#### Patient-held records[s8]

Patients should be encouraged to keep a list of their medications, including both generic and brand names. Including the brand name is important if patients have a particular reason for needing a specific brand, such as a previous adverse drug reaction. Patients should be encouraged to bring in such lists if they attend hospital or other health care appointments as this can increase the accuracy of medication reconciliation.

#### Patient empowerment[s9]

Another aspect of patients supporting medication safety requires patients to feel empowered to discuss their concerns about medications with their health care professionals. Patients and

<sup>&</sup>lt;sup>38</sup> The Joint Commission; 2018

<sup>&</sup>lt;sup>39</sup> Check and add

caregivers may be the first to notice a safety issue with medications and studies suggest that, in general, patients' reports of adverse events are accurate. While this can be supported through educational material to encourage patients to report problems and increase their confidence in discussing safety, significant changes may also be required on the part of clinicians. A change in culture is needed such that health care professionals welcome patients' questions without defensiveness, encouraging patients to feel confident in discussing their safety concerns<sup>40</sup>. As well as practical tools to support patient engagement in patient safety around medications, health care professionals therefore need to be proactive in encouraging patients' self-care and involvement in decision-making.

#### Language support

Health care is becoming increasingly complex and medicine is generally practiced in the language spoken by the majority. With changes in migration, affordability, access and insurance provision, patients may not have command of the primary language of their local health care setting and will therefore need assistance in being involved in their care. For example, a US study revealed significant misunderstanding of the medication label and its instructions, particularly among those who were not fluent in English<sup>41</sup>. Improving language with simple clear wording can improve understanding and medication adherence<sup>42</sup>. Transitions of care may be particularly high risk if there are language barriers. For example, in a further US study, nearly half of patients with limited English proficiency were unable to provide information about their appointment type, category of medication prescribed, and the purpose of their medication at hospital discharge.

One of the ways to understand the language competency of a patient is by asking them in what language they would feel comfortable talking about their health care. Instructions should be provided in the language of their preference where possible. Labelling dispensed medicines using the patient's preferred language is also important in helping them to know their medications better. It is helpful to have some sort of credentialing on expertise around medical language to ensure that translations are accurate<sup>43</sup>.

# 5.2. Health care professionals

Staff factors that can contribute to medication error include inexperience, time pressures, multitasking, interruptions and distractions, fatigue, boredom, lack of vigilance and lack of confidence in raising concerns. A lack of consistent checking processes can also lead to errors, as can poor teamwork, poor communication, and reluctance to use memory aids and reference materials when needed. Some examples of interventions aimed at health care professionals follow.

#### Use of generic names

<sup>&</sup>lt;sup>40</sup> Health Foundation 2013

<sup>&</sup>lt;sup>41</sup> Davis et al. 2006

<sup>&</sup>lt;sup>42</sup> Wolf et al. 2007

<sup>&</sup>lt;sup>43</sup> Bailey, Sarkar, et al. 2012

Many medications have both a brand name (trade name) and a non-proprietary generic name (the name of the active ingredient). Sometimes the brand name appears in large letters on the box/bottle and the generic name in smaller print. The same drug may also be produced by different companies, each of which will give it a different brand name, adding further scope for confusion. Generic names are usually (but not always) the same in different countries; brand names are more likely to be different. To minimize confusion and simplify communication, it is helpful if health care professionals always use generic names (ideally the international non-proprietary names<sup>44</sup>. However, patients and caregivers will often use brand names as these are what appear in large print on the packaging. This can be confusing for both staff and patients (see box).

A patient was discharged from hospital with a prescription for their usual medication (salbutamol) but using a brand name (Ventolin). The patient did not realize that the two medications were the same and started taking both following their return home.

It is therefore important for health care professionals to explain to patients and caregivers that some medications may have more than one name and encourage them to check with a health care professional if they are uncertain as to which medications are the same or different.

Prescribers should therefore prescribe drugs by their generic names wherever possible, adding the brand name as well for those drugs or situations where the brand is important for clinical reasons, and pharmacists and nurses should refer to generic names wherever possible.

## Use of standard terminology

Health care professionals should use standardized medication names, dosing units and labelling practices, avoiding abbreviations and ensuring that labelling of prepared medications is in line with local protocols.

When dispensing medicines for patients, directions should be clear and unambiguous. The National Academy of Medicines<sup>45</sup> has recommended that such labels should:

- Involve patients in their design
- Use explicit text to describe the dose and how often the medication should be taken (e.g. "take 1 tablet every morning, and 1 tablet every evening" rather than "One tablet to be taken twice a day")
- Use recognizable visual aids where needed
- Use simple language
- Include the medication's indication
- Pay attention to typeface and font size to ensure that text is readable

<sup>&</sup>lt;sup>44</sup> http://www.who.int/medicines/services/inn/innguidance/en/

<sup>&</sup>lt;sup>45</sup> Institute of Medicine 2008

- Use numeric instead of alphabetic characters for numerical information (e.g. "2 tablets" instead of "two tablets").

#### Obtaining the best possible medication history

Taking a good medication history is likely to require inter-disciplinary involvement from prescribers, pharmacy staff, nurses and other healthcare professionals depending on the setting. Maintaining an accurate medication list during transitions of care is particularly important as these are high-risk times for errors due to misunderstandings, inadequate history taking and poor communication.

To obtain a best possible medication history, the following points should be covered:

- Include the name, formulation, dose, route, frequency and duration for every medication the patient is taking.
- Ask about recently started s10 and recently discontinued medications.
- Ask about over-the-counter medications, dietary supplements, traditional and complementary medicines.
- Ask if there are any medications the patient has been advised to take, but does not do so, and the reasons why these are not taken.
- Make sure what the patient is actually prescribed, and is actually taking, matches the medication list.
- Include a thorough allergy history, as outlined in the next section.
- Documentation and resolution of any unintended discrepancies.

#### Obtaining an allergy history

When taking an allergy history, it is important ask for details of any allergies and reactions, and to be aware of the difference between side-effects, intolerances and allergies, as patients and caregivers may describe all of these as allergies. If a patient has a potentially serious allergy and a condition for which staff may want to prescribe the medication concerned, this is a high-risk situation and it is important to alert the patient and other staff. For example, if a community doctor sends a patient to hospital with suspected appendicitis and the patient has a serious penicillin allergy, it is possible that a penicillin will be considered for that patient. In this situation, it is particularly important to emphasize the allergy in communication with the hospital staff, warn the patient that the usual treatment for appendicitis involves penicillin-based antibiotics and encourage the patient to be alert to what medication he/she is being prescribed and to speak up if someone tries to give him/her penicillin. Taking an allergy history and managing any implications of patients' allergies are therefore important to include in medication safety education.

It is essential that health care professionals ask about allergies before prescribing, dispensing or administering medications. In some situations, desensitization can be used to address allergies so that diseases can be treated with the most effective medications. For example, penicillin is the drug of choice for neurosyphilis and it may be possible to desensitize the patient under specialist supervision so that they can receive penicillin-based therapy. Non-medication related allergies are also important. These include allergies to latex, preservatives or dyes that may be used in health care, as well as to contrast media used in imaging.

#### Clear prescription writing

Where paper prescriptions are used, poor handwriting and/or the use of abbreviations can lead to subsequent transcribing, dispensing and administration errors. Health professionals must therefore write clearly and legibly, avoiding abbreviations, and including their name and contact details. Pharmacy or nursing staff who cannot read a prescription should contact the prescriber to check the details rather than making assumptions about what is intended. Prescribers should also follow best practices in writing prescriptions to avoid fraudulent alterations to medication quantities or durations. Stamped or printed prescriber names can also be helpful.

#### Individualizing prescriptions

Before prescribing a medication, always stop and think, "is there anything about this patient that should alter my usual choice of medication?" Factors to consider include allergies, pregnancy, breastfeeding, co-morbidities, <u>goals of care/prognosis</u>, other medications the patient may be taking (including over-the-counter medications), and the <u>age</u>, size and weight of the patient. Similarly, once the need is over, deprescribing and reducing the pill burden will help improve medication safety, as highlighted later in this section.

A further area relating to individualization of therapy is pharmacogenomic testing. Pharmacogenomics relates to the impact of genetic factors in medication effects. For many drugs, it is increasingly being recognized that there is genetic variation in how patients will respond. For example, antiplatelet drugs and anticoagulants such as warfarin are significantly affected by the patient's genetic profile<sup>46</sup>. A pharmacogenomics test can therefore predict how patients will respond, so that therapy can be personalized accordingly. As pharmacogenomics testing becomes more widely available, patients may be increasingly encouraged to have these tests, which can then be used to guide individualised, rather than population-based, treatment choices. This approach is sometimes referred to as "personalised medicine."

#### Optimizing prescribing

When considering initiating a medication or reviewing a patient's medication regimen, it is important to consider some key principles of medication use<sup>47</sup>. This will help optimize therapy and reduce the potential for inappropriate polypharmacy. These principles include:

- Prioritize the use of non-pharmacological therapy where possible
- Consider that any new symptom may be an adverse drug event and not a symptom of older age or underlying disease. In particular, prescribing cascades should be recognized and avoided. These typically occur when a new medication is prescribed to treat a symptom that is an adverse drug reaction to another medication. The added medication may increase the severity of the initial adverse drug reaction or increase the risk of experiencing a subsequent adverse drug reaction, which may result in further addition of another medication.

<sup>&</sup>lt;sup>46</sup> Beitelshees et al. 2015; Emmerich et al. 2016

<sup>&</sup>lt;sup>47</sup> NPS Medicinewise, 2013

- Ensure each medication prescribed has a documented indication and date for review or cessation
- Use the least number of medications, with the simplest dose regimen, at the lowest effective dose
- Be familiar with the effects of medications in vulnerable groups e.g. older people
- Consider cognitive and functional ability, which may change over time
- Provide verbal and written information to support patient understanding and adherence

#### Medication review

Medication review is "a structured evaluation of a patients' medicines with the aim of optimizing medicines use and improving health outcomes. This entails detecting medication-related problems and recommending interventions<sup>48</sup>". Medication review is an inter-disciplinary intervention involving the patient and their health care team. Medication review should be performed routinely, but in particular after significant transitions such as moving into residential care, hospitalization or receiving a new diagnosis.

There are also certain patient characteristics that may be used to identify groups at risk of medication-related problems. Examples of patients in whom medication review and optimisation may be particularly helpful include:

- Residents of care homes
- Those prescribed a high-risk (high-alert) medication
- Those taking more than nine medications
- Those with two or more comorbidities
- People living with Frailty
- People living with Dementia
- Palliative care

#### Deprescribing

Deprescribing may be defined as "the stepwise reduction of unnecessary or potentially inappropriate medications <u>supervised by a health care professional</u>, after consideration of therapeutic goals, benefits and risks, and

medical ethics." Deprescribing is a positive, patient-centred intervention, with inherent uncertainties, and requires shared decision making, informed patient consent, and close monitoring of effects. Evidence is accumulating to support the value of deprescribing to better align a patient's regimen for their current therapeutic goals.

Deprescribing involves the following 5 steps<sup>49</sup>:

- 1. ascertain all medications the patient is taking, and the reasons for each;
- 2. consider overall risk of medication-induced harm in the individual patient in determining the required intensity of deprescribing;
- 3. assess each medication with regard to its current or future benefit potential compared with current or future harm potential;

<sup>&</sup>lt;sup>48</sup> Pharmaceutical Care Network Europe, 2016

<sup>&</sup>lt;sup>49</sup> Scott et al., 2015

- 4. prioritize medications for discontinuation that have the lowest benefit-harm ratio, and the lowest likelihood of adverse withdrawal reactions or disease rebound syndromes;
- 5. implement a discontinuation regimen and monitor patients closely for improvement in outcomes or onset of adverse events.

Figure X provides a guide for stopping potentially inappropriate medications that may be useful in teaching students on this topic.



Figure XX. Algorithm for deciding order and mode in which drug use could be discontinued <sup>50</sup>.

Deprescribing should be considered where a patient:

- presents with a new symptom or clinical syndrome suggestive of adverse events;
- manifests advanced or end-stage disease, terminal illness, dementia, extreme frailty, or full dependence on others for all care;
- receives high-risk medications or combinations;
- receives preventive medications for scenarios associated with no increased disease risk despite medication cessation.

Deprescribing may appear to go against the patient's expectations, the medical culture of prescribing, organizational constraints, and sometimes financial incentives aligned with overprescribing<sup>51</sup>. Patients and their families should be supported to engage in an open discussion with their health professionals related to whether the patient's current medications are consistent with the patient's therapeutic goals. The shared decision to cease a medication should be based on recognition that the medication may be causing harm or is no longer of benefit, and not because the patient is 'not worth treating'. Close monitoring of, and discussion with, the patient throughout the period of medication change will help determine whether goals are being met, detect any adverse drug events, and demonstrate to the patient that the change is part of an active treatment plan<sup>52</sup>. Medication review, computer alerts, patient and family engagement, and clinician education can all help support the deprescribing process.

<sup>&</sup>lt;sup>50</sup> Reeve et al., 2015; Scott et al., 2015

<sup>&</sup>lt;sup>51</sup> Wallis et al., 2017

<sup>&</sup>lt;sup>52</sup> Hilmer et al., 2012

There are various tools that can be used to identify potentially inappropriate medications that may be particularly appropriate to discontinued, as in the following section.

#### Identifying inappropriate medications

Several tools are available to help identify medications that are potentially inappropriate for use in older people<sup>53</sup>. Reducing the use of these medications will help reduce inappropriate polypharmacy and the potential for adverse drug events.

The Beers criteria<sup>54</sup>, the START/STOPP criteria<sup>55</sup> and PRISCUS<sup>56</sup> provide explicit lists of potentially inappropriate medications that should be avoided in older people. Implicit instruments, such as the Medication Appropriateness Index, rely on clinician judgement in assessing the appropriateness of a medication for an individual patient<sup>57</sup>. Tools may also target medications with specific properties such as anticholinergic and sedative effects (Anticholinergic Cognitive Burden Scale and Drug Burden Index<sup>58</sup>), or specific patient groups, such as those with advanced dementia.

Such criteria may be incorporated into clinical decision support systems in electronic medical records to help clinicians identify at risk prescribing. Every clinical situation is different, and criteria should therefore be applied in the individual context of the patient and their therapeutic goals of care.

#### Medication regimen simplification

Medication regimen simplification refers to the process of "reducing medication complexity through strategies such as administering medications at the same time, standardizing routes of administration, using long-acting formulations in preference to shorter-acting agents, and switching from multiple single-ingredient preparations to a combination formulation where possible<sup>59</sup>." Unlike deprescribing, medication regimen simplification does not alter the therapeutic intent of a patient's medication regimen and the number of medications generally does not change. Instead, regimen simplification focuses on reducing the number of administration times and complexity of a patient's medication regimen, with the aim of maximizing patient adherence and quality of life and minimizing caregiver time. Strategies to reduce medication complexity are likely to be important to patients, health care professionals and health care organisations as medication regimen complexity has been associated with undesirable health outcomes in older people such as hospitalisation<sup>60</sup>. The Medication Regimen Simplification Guide for Residential Aged CarE ("MRS GRACE") is five item, implicit tool to guide decision making during the process of medication regimen simplification, which has been validated by pharmacists<sup>61</sup>.

<sup>&</sup>lt;sup>53</sup> Masnoon et al., 2018

<sup>&</sup>lt;sup>54</sup> American Geriatrics Society 2012 Beers Criteria Update Expert Panel 2012

<sup>&</sup>lt;sup>55</sup> O'Mahony et al. 2015

<sup>&</sup>lt;sup>56</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2933536/

<sup>&</sup>lt;sup>57</sup> Masnoon et al., 2018

<sup>&</sup>lt;sup>58</sup> TBA\_Hilmer et al., 2007 PMID: 17452540

<sup>&</sup>lt;sup>59</sup> Sluggett et al., 2018; Tan et al., 2018

<sup>&</sup>lt;sup>60</sup> Wimmer: https://www.ncbi.nlm.nih.gov/pubmed/27991653

<sup>&</sup>lt;sup>61</sup> Chen EYH et al. https://www.dovepress.com/development-and-validation-of-the-medication-regimensimplification-gu-peer-reviewed-article-CIA

#### Clear communication to patients and caregivers

Safe use of medication is a team activity, with the patient and any caregivers also part of the team. Clear, unambiguous communication will help minimize assumptions that can lead to error. What is obvious to the doctor or pharmacist may not be obvious to the patient or nurse, and vice versa. For example, there are numerous reports of patients not removing the cap of metered dose inhalers before using them, a step that was perhaps so obvious to the health care professionals concerned that they did not advise the patient to do this. Using a "teachback" approach, which involves asking the patient to demonstrate how they will use their inhaler, would allow such misunderstandings to be identified.

#### Using a personal safety checklist for dispensing and administration

In many parts of the world, training programmes have emphasized the importance of checklists such as confirming the "*five rights*" before dispensing or administering medication. The five rights are: right drug, right route, right time, right dose and right patient. Some lists include additional points such as the right documentation, the right formulation and the right of a staff member, patient or caregiver to question a medication order<sup>62</sup>. Such lists are also a potentially useful way of remembering important points about a medication that need to be communicated. For example, in an emergency situation, a doctor may need to give a verbal order. Saying "can you give this patient 0.3 mL of 1:1000 epinephrine intramuscularly as soon as possible?" is much better than "quick, get some adrenaline". Another useful communication strategy in this context is to close the loop in confirming what has been heard. This decreases the likelihood of misunderstanding. In our example, the nurse would close the loop by saying, "OK, I will give the patient 0.3 mL of 1:1000 epinephrine intramuscularly as soon as possible".

#### Using medication in children

Multiple initiatives have been shown to improve care for children of all age ranges. For example, weight-based dosing, standardization of concentrations and medication delivery systems (such as only using metric based oral syringes) can help reduce incorrect dosing errors<sup>63</sup>.

#### Using medication in the older people

Older people also have a unique set of challenges due to decline in the hepatic and renal functions that are responsible for metabolism and elimination of medications. Care providers need to be able to appreciate the impact of age-related changes on drug selection and dose. The following high-risk medication groups should be avoided in the elderly where possible, and used with care [s11] where the current indication outweighs the risk for the individual<sup>64</sup>.

<sup>&</sup>lt;sup>62</sup> Edwards S and Axe S. The ten 'R's of safe multidisciplinary drug administration. Nurse Prescribing 2015 Vol 13 No 8

<sup>&</sup>lt;sup>63</sup> Maaskant et al. 2015; Kaufmann et al. 2012

<sup>&</sup>lt;sup>64</sup> Gallagher P., Lavan A., O'Mahony D. (2018) Prescribing for Older Patients. In: Nickel C., Bellou A., Conroy S. (eds) Geriatric Emergency Medicine. Springer, Cham

- Anticholinergics
- Benzodiazepines
- Psychoactive drugs
- Anticoagulants
- Analgesics (both opioid and non-steroidal)
- Oral hypoglycaemic
- Cardiovascular drugs that cause orthostatic hypotension

#### Giving and welcoming feedback

Health care professionals should consider how they can best give feedback to each other about any errors or unsafe practices observed, and how to respond to such feedback. For example, in the context of prescribing errors, it has been suggested that feedback should be as soon as possible after the event, ensure that the person concerned is aware that an error has been made, include possible solutions or relevant resources and be non-judgmental<sup>65</sup>. Similar principles are likely to apply for other types of error. Health care professionals should also practice responding to feedback and questions from colleagues and patients without being defensive, in order to encourage a culture in which both staff and patients feel confident raising any safety concerns.

# 5.3. Medication design and characteristics

Certain medication design factors can increase the risk for medication errors. Some medications can be easily confused, such as tablets or boxes that are similar in appearance and medications that have similar names. For example, the brand names Celebrex, Cerebryx and Celexa are for celecoxib (an anti-inflammatory), fosphenytoin (an anticonvulsant) and citalopram (an antidepressant) respectively. Different preparations or dosages of similar medication may have similar names or packaging. For example, phytomenadione (vitamin K) 1 mg and 10 mg injections look very similar in some countries. Other medication design problems include labelling that is too small or difficult to read, a lack of suitable measuring devices (e.g. spoons or oral syringes for liquid medication used in paediatrics), products without a bar code in settings where barcode medication administration is being used, and medicines requiring partial doses to be administered for children or adults with low bodyweight. Relevant areas for intervention follow.

#### Addressing look alike and sound alike medications

Regulations should focus on avoiding a look-alike and/or sound-alike (LASA) medications. In countries where there may be multiple brand names for the same generic medications, a national registry should be used to ensure that the same brand names are not allowed for different generic drugs (figure X). Including both patients' and health care professionals' input into nomenclature, packaging and labelling may be helpful. Similarly, every health institution should have its own formulary with an associated LASA list to raise awareness of drug name pairs likely to be confused when ordering, dispensing or administering medications. Many major patient safety organizations recommend "tall man" lettering to distinguish similar drug

<sup>&</sup>lt;sup>65</sup> <u>https://qualitysafety.bmj.com/content/26/3/240</u>

names (such as cefOTAXime and cefTAZIDime), although there is no conclusive evidence for the efficacy of such interventions (Zhong et al. 2016). Students should be aware of any local LASA lists or other organisational strategies to prevent errors in medication selection.



Fig XX. Same brand name used for different generic medications

## Modified release formulations

Some modified-release formulations of the same drug may be differentiated with a suffix, although these can also give rise to confusion as there may be many different suffixes in use to imply similar properties, such as slow release, delayed release or long-acting (e.g. LA, XL, XR, CC, CD, ER, SA, CR, XT and SR). It is important to be aware of the release properties of each (such as whether it is intended for daily or twice daily dosing) to ensure that an appropriate product is used.

# 5.4. Systems and practices

Workplace factors that can contribute to error include the absence of a safety culture, which may be evidenced by lack of reporting systems, reluctance to use those in place, fear of reporting, errors being covered up, and/or a failure to learn from previous incidents. Other workplace factors include absence of reference sources or other information on specific medications, lack of access to local policies and guidelines that are fit for purpose, poor or no access to diagnostic or laboratory data, inadequate lighting, and inadequate medication storage facilities that make it difficult to locate the medication required. An increasingly important issue is sufficient access to computer terminals if electronic health records or other electronic resources are required. Other systems-related factors include use of identical connectors for intravenous and intrathecal administration, which can give rise to fatal errors if drugs are given by the wrong route. Similarly, using the same types of syringe for oral and intravenous medication can lead to oral medicines being given intravenously in error.

The following are some areas for intervention in relation to systems and practices.

#### Medication information resources

Access to up to date paper and/or electronic resources for drug information, together with understanding how to use them, is increasingly important as more and more medications become available. With the rapidly increasing number of medications and increasing prevalence of polypharmacy, reference sources or software that can check medication interactions are becoming increasingly important. For example, in a recent study nearly half of prescriptions written without software-based decision support had some sort of drug interaction<sup>66</sup>. Resources should be evidence-based and include details of the authors, publication date and the date on which the document needs to be reviewed and/or updated.

#### Standardisation of practices and procedures

In many cases, standardisation of clinical practice is considered helpful in supporting patient safety so that all involved know what will be done and by whom. Standardisation of practice also allows for this to be documented in local policies and guidelines. Again, these should be evidence-based where relevant, and include details of the authors and both publication and review dates (refer to section 1.4.3).

#### Use of technology at different stages of the medication use process

Technological solutions are increasingly being advocated as patient safety interventions, including electronic prescribing, electronic transmission of prescriptions, use of barcodes, automated dispensing systems and use of 'smart' infusion pumps. However, it is increasingly becoming clear that although technology can at least partially address many problems, it can also introduce new risks. It is therefore important not to assume that technology is safer or that it prevents all problems. Instead, careful consideration is needed to identify any new risks and how to mitigate them.

Electronic prescribing. Prescribing errors affect up to 7% of handwritten inpatient medication orders, 2% of patient days and 50% of hospital admissions<sup>67</sup> and are common in primary care. These safety concerns mean that many health care organisations are transitioning from hand-written orders to electronic prescribing. While it takes a significant amount of time and money to implement these systems, the aim is for safer health care. Not only is there a reduction in errors caused by illegible handwriting, but there is also potential to access the entire medicines formulary and data such as the patient's laboratory data at the point of prescribing through links with the electronic health record. In addition, if the system includes clinical decision support, further safety features such as dose and drug interaction checking can be set up. Systematic reviews confirm that prescribing errors are generally less common with

<sup>&</sup>lt;sup>66</sup> Rathish et al. 2016

<sup>&</sup>lt;sup>67</sup> Lewis et al. 2009

electronic systems<sup>68</sup> <sup>69</sup> <sup>70</sup>. However, errors are not prevented completely, and new types of error can occur. New types of errors include ordering medication for the incorrect patient due to having multiple patient screens open at the same time, selecting the wrong medication from the menus provided, and inappropriately using default doses. Using outdated medication lists can also give rise to medication reconciliation errors at admission and discharge, and the numerous alerts presented through clinical decision support systems can lead to alert fatigue and important alerts being ignored. Electronic prescribing systems therefore need to be planned and implemented considering local working practices and monitoring for and addressing new types of error or other unintended negative consequences. System implementations also vary widely, such that features in place in one health care organisation may not be in place in another, even if the same commercial system is used. It therefore essential that practicing health care professionals know how to use their local system, and that both health care students and practicing professionals are aware of the potential strengths and weaknesses of such systems.

Barcode technology. Use of barcode identification to verify the identity of both medications and patients can improve medication safety<sup>71</sup>, but this requires suitable barcode scanning equipment as well as links to electronic prescribing and administration systems. Such systems may not be affordable or practical in many settings. Workarounds can also occur if the system does not align with workflow or is not reliable<sup>72</sup>. Where such systems are in use, both the type of barcode and its use should ideally be harmonized on a national basis. Barcodes can be incorporated into patients identify wristbands used in the hospital setting, which should be placed on the patient on admission, and can be used to verify the identity of medications dispensed in both hospital and community settings as well as to give unique identifiers for blood products, devices and compounded medications<sup>73</sup>.

#### Addressing interruptions and distractions

Many studies have highlighted the impact of interruptions and distractions for all health care staff involved in medication use. For example, direct observation studies have shown nurses to be interrupted frequently while conducting critical tasks<sup>74</sup>. Most of these interruptions stem from other nursing colleagues, patients, pump alarms, family members, management and pharmacists, with many interruptions being to ask a question or to inform of an alert. A system-

<sup>&</sup>lt;sup>68</sup> Shamliyan TA, Duval S, Du J, Kane RL. Just what the doctor ordered. Review of the evidence of the impact of computerized physician order entry system on medication errors. Health Serv Res. 2008;43(1P1):32–53. doi: 10.1111/j.1475-6773.2007. 00751.x

<sup>&</sup>lt;sup>69</sup> Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U. The effect of electronic prescribing on medication errors and adverse drug events: a systematic review. J Am Med Inform Assoc. 2008;15(5):585–600. doi: 10.1197/jamia.M2667

<sup>&</sup>lt;sup>70</sup> Nuckols TK, Smith-Spangler C, Morton SC, Asch SM, Patel VM, Anderson LJ, et al. The effectiveness of computerized order entry at reducing preventable adverse drug events and medication errors in hospital settings: a systematic review and meta-analysis. Syst Rev. 2014;3(1):56. doi: 10.1186/2046-4053-3-56. <sup>71</sup> Poon et al. 2010; Khammarnia et al. 2015

<sup>&</sup>lt;sup>72</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2442264/

<sup>&</sup>lt;sup>73</sup> Cummings et al. 2005

<sup>&</sup>lt;sup>74</sup> Westbrook JI, Woods A, Rob MI, et al. Association of interruptions with an increased risk and severity of medication administration errors. Arch Intern Med 2010; 170:683–90.

level intervention might help reduce workplace distraction such as providing a quiet medication preparation room<sup>75</sup>. Some organisations ask staff administering medication to wear distinctive aprons highlighting that they should not be interrupted<sup>76</sup>, although the evidence for such interventions is weak<sup>77</sup>. Other approaches may include helping staff consider how to address their queries without interrupting the nurse administering medication, and how to handle interruptions safely when they do occur<sup>78</sup>. Studies have also examined interruptions to medical <sup>79</sup> and pharmacy staff<sup>80</sup> although there has been less research to evaluate interventions to reduce their impact.

#### Using incident reporting and learning systems

An organisation with a good safety culture will invest time and resources in learning from mistakes to make changes to systems and practices, rather than blaming individuals. Reporting of errors and near misses and then learning from them is crucial. Whenever an adverse drug event or near miss occurs, there is an opportunity for learning and improving care. It will be helpful for students if they understand the importance of talking openly about errors and near misses and are aware of the reporting and learning systems in place in the organizations in which they work. As well as reporting incidents, it is helpful for students to be involved in analysing incidents and identifying the system issues involved to identify areas for improvement, as well as considering how lessons learned could be shared more widely.

It has been shown that most medication errors go unreported in nearly all settings of care. There are many reasons for this, including lack of awareness than an error has occurred, lack of knowledge on how to report it, lack of time, fear of the implications of reporting, and lack of feedback about what has happened as a result. Inter-disciplinary team training and sharing knowledge of their workflows can help build trust and understanding, leading to improved reporting and the associated safety culture<sup>81</sup>. For example, pharmacists are more likely to report and explain near-miss errors when prescribers are open to listening to their explanations. A just culture that emphasizes the process and not individuals is therefore essential, as outlined in section 5.2.

#### Disclosure and apology

Disclosing any error to the patient and family early on can help reduce mistrust and anxiety as well as reduce the risk of litigation. It is also a legal requirement in some countries. However, it is still often believed that apologizing for the event is not the right thing to do. Medical care is very complex and there is always a power differential between the patient and the providers. An explanation of what happened, how it happened, why it happened and how the organization will learn from it can be very helpful to the patient or their family. A systematic review of disclosure of patient safety events showed that while there is fear of retaliation and litigation, there were observed benefits in patient satisfaction, the credibility of both the

<sup>&</sup>lt;sup>75</sup> Trbovich et al. 2010

<sup>&</sup>lt;sup>76</sup> https://qualitysafety.bmj.com/content/23/5/414

<sup>77</sup> https://qualitysafety.bmj.com/content/26/9/701

<sup>78</sup> https://qualitysafety.bmj.com/content/26/9/701

<sup>79</sup> https://qualitysafety.bmj.com/content/27/8/655

<sup>&</sup>lt;sup>80</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3583790/

<sup>&</sup>lt;sup>81</sup> Sharma et al. 2016

organisation and the staff and reduction in guilt among the health care professionals involved. As well as creating a work culture that promotes disclosure and apology, it is therefore helpful for health care professionals to receive training in how to disclose medication errors to patients<sup>82</sup>. This could include role play to practice how to do this in an appropriate manner.

<sup>&</sup>lt;sup>82</sup> Ock et al. 2017; Giraldo et al. 2017

# 6 Medication safety: broader context and link to other initiatives

# 6.1 Universal Health Coverage



Patient safety has been recognized as one of the most important components of health care delivery, essential for the achievement of universal health coverage (UHC) and moving towards the United Nations Sustainable Development Goals (SDGs). UHC means that all people and communities can access and use the promotive, preventative, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that use of these services does not expose the user to financial hardship<sup>83</sup>. Progress towards UHC must mean extending safe care, because unsafe care reduces efficiency and directly compromises health outcomes.

The 2030 Agenda for Sustainable Development, including its 17 Sustainable Development Goals and 169 targets was adopted by the 193 Member States of the United Nations in 2015. The adoption of the 2030 Agenda was a landmark achievement, providing for a shared global vision towards sustainable development for all. Universal, inclusive and indivisible, the Agenda calls for action by all countries to improve the lives of people everywhere, leaving no one behind.

<sup>&</sup>lt;sup>83</sup> <u>https://www.un.org/sustainabledevelopment/</u>

# Sustainable Development Goal 3: Ensure healthy lives and promote wellbeing for all at all ages 3.1 By 2030, reduce the global maternal mortality ratio to less than 70 per 100 000 live births.

3.2 By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1000 live births and under-5 mortality to at least as low as 25 per 1000 live births.

3.3 By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, waterborne diseases and other communicable diseases.

3.4 By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.

3.5 Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol.

3.6 By 2020, halve the number of global deaths and injuries from road traffic accidents.

3.7 By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes.

3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

3.9 By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination.

3.a Strengthen the implementation of the WHO Framework Convention on Tobacco Control in all countries, as appropriate.

3.b Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

3.c Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States.

3.d Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks.

Medication safety is important for UHC and the SDGs for several reasons. Firstly, it has been shown that most of the burden of iatrogenic harm is associated with a small number of common adverse events, one of them being medication error (the others include health care associated infections, venous thromboembolism, pressure ulcers and wrong or delayed diagnosis)<sup>84</sup>. Secondly, medication is a common health care intervention, and is a key part of preventative, curative, rehabilitative and palliative health care. Finally, an important component of medication safety is the challenge of antimicrobial resistance (AMR) as presented below, which is particularly relevant in the context of tackling diseases such as tuberculosis, human immunodeficiency virus and malaria within the broader SDG context.

<sup>&</sup>lt;sup>84</sup> OECD 2018

# 6.2 Antimicrobial resistance

Antimicrobial resistance (AMR) refers to the ability of a microorganism to stop antimicrobials from working against it. As a result, standard treatments become ineffective, infections persist and may spread to others<sup>85</sup>. It is becoming a serious threat to global public health that requires immediate action. Without effective antimicrobials, the success of major surgery and cancer chemotherapy will be compromised, medical procedures such as organ transplantation and diabetes management will pose greater risk and the fight against tuberculosis, human immunodeficiency virus and malaria will become even more complicated. AMR also contributes to system inefficiencies, because the cost of health care for patients with resistant infections is higher than care for those with non-resistant infections<sup>86</sup>.

The causes of antimicrobial resistance are complex, but contributing factors include overprescribing of antimicrobials, inadequate choice of antimicrobials, patients not adhering to treatment plans, poor infection control in health care facilities, lack of hygiene and poor sanitation, lack of new antibiotics being developed, and over-use of antibiotics in livestock and fish-farming. Tackling these issues requires a systematic approach that includes education and training of health care staff alongside measures such as the strengthening and enforcement of relevant regulations and guidelines on the safe use of antimicrobials.

The Global Action Plan on AMR<sup>87</sup>, adopted by WHO Member States in 2015, aims to ensure that health workers have an improved awareness and understanding of AMR through effective communication, education and training. Several measures have now been put in place to address health worker needs. These include the WHO competency framework for health workers' education and training on AMR<sup>88</sup>; this provides guidance on AMR competencies such as appropriate use of antimicrobials, safe disposal of medicines, timely and accurate administration, understanding local and international regulations, and identifying and reporting substandard antimicrobials. It is important for health educators to ensure that all health care workers (including those in managerial and leadership roles) are competent to contribute to safe and appropriate use of antimicrobials at all levels of health care delivery.

# 6.3 Pharmacovigilance and adverse drug reactions

WHO defines pharmacovigilance as the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other medication-related problem<sup>89</sup>. For all medications, there is a trade-off between the benefits and the potential for harm. So, another dimension of harm minimization is to ensure that medications are of good quality, safety and efficacy as well as they are used rationally.

<sup>&</sup>lt;sup>85</sup> WHO <u>http://www.who.int/antimicrobial-resistance/en/</u>

<sup>&</sup>lt;sup>86</sup> World Bank. 2017. "Drug-Resistant Infections: A Threat to Our Economic Future." Washington, DC: World Bank. License: Creative Commons Attribution CC BY 3.0 IGO

<sup>&</sup>lt;sup>87</sup> Global action plan on antimicrobial resistance. Geneva: World Health Organization; 2015

 <sup>&</sup>lt;sup>88</sup> WHO competency framework for health workers' education and training on antimicrobial resistance.
 Geneva: World Health Organization; 2018 (WHO/HIS/HWF/AMR/2018.1). Licence: CC BY-NC-SA 3.0 IGO.
 <sup>89</sup> WHO http://apps.who.int/medicinedocs/en/d/Js6164e/1.html

Pharmacovigilance integrates identification of adverse drug reactions, data collection, processing and analysis. All adverse drug reactions should be reported and analyzed to allow the respective actions being taken at different levels and by different stakeholders. For example, regulators should be equipped with the necessary information to amend the recommendations on the use of the medicines periodically, health professionals are educated and trained to understand the effectiveness/risk of medications that they prescribe, and the patients, their families and caregivers are well aware not only about the benefits, but also about the potential risks associated with medication use and are empowered and engaged in shared decision-making.

It is important to differentiate the concepts of adverse drug reactions, adverse drug event, medication error and medication-related harm. The table below provides detailed definitions for each of the concepts.

Adverse drug reaction	A response to a drug (medication) that is noxious and unintended and that occurs at doses used in humans for prophylaxis, diagnosis or therapy of diseases, or for the modification of physiological function.
Adverse drug event	Any injury resulting from medical interventions related to a drug (medication). This includes both adverse drug reactions in which no error occurred, and harm resulting from medication errors.
Medication error	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, carer or consumer.
Medication-related harm	<ul> <li>Patient harm related to medication that includes:</li> <li>preventable adverse drug events (e.g. due to a medication error) and</li> <li>non-preventable adverse drug events (e.g. an adverse drug reaction).</li> <li>This term is sometimes used interchangeably with adverse drug event but is sometimes considered to be a broader term encompassing non-adherence, and both accidental and intentional misuse of medication.</li> </ul>

Pharmacovigilance should be an integral part of any public health programme that implies the use of medications. It will ensure cost savings and optimization in the use of scarce health resources through early recognition and management of the risks.

# 6.4 Essential Medicines List

The Essential Medicines List (EML) is a comprehensive list of medications considered to be the most effective and safe to meet the most important needs in a given health care delivery system. It is divided into a core list and complementary list. The core list outlines a minimum list of medications required by a basic health care system that focuses on efficacy, safety and cost-effectiveness for priority conditions. The complementary list includes additional medications that need more specialized diagnostics and/or input from more specialist health care professionals, such as at a specialist centre<sup>90</sup>.

EMLs are important in the process of development of the STGs to ensure adequate options for pharmaceutical treatment of common health problems experienced by populations in different health care systems. As such, EMLs represent one approach to promoting equitable access to affordable, safe and effective medications. Moreover, EMLs allow standardization of clinical practice that leads to fewer variations in practice and potentially a reduction in errors.

The WHO Model EML is published every two years (ref to the new one TBA). EMLs exist in many countries and are generally adapted based on local needs. Preparing such a list at national level is an inter-disciplinary and stepwise process that needs input from all health care professionals and policy makers.

The WHO Model List of Essential Medicines which serves as a guide for the development of national and institutional essential medicine lists is updated and revised every two years by the WHO Expert Committee on Selection and Use of Medicines. It is frequently used by countries to help develop their own local lists of essential medicine.

The 20th Essential Medicines List, published on 6 June 2017, marks the 40th anniversary of this flagship WHO tool to expand access to medicines. The updated list adds 30 medicines for adults and 25 for children and specifies new uses for 9 already-listed products, bringing the total to 433 drugs deemed essential for addressing the most important public health needs globally.

# 6.5 Protocols, checklists and standard treatment guidelines

Protocols and checklists have often been shown to reduce patient harm through improved standardization and communication (REF). Standardization of practice in complex health care environment nowadays is critical to reduce unwarranted variation in processes that may lead to increased rates of errors. Elimination of variation in medical practice has been successful in various health care disciplines, including anaesthesia, where adverse events have been significantly reduced over the past 25 years through standardization of patient monitoring, dispensing of inhaled gases, and medication administration (REF). Initial data from the WHO Surgical Safety Checklist, for example, demonstrated significant reductions in both morbidity and mortality with checklist implementation. A growing body of literature has identified that while the physical act of "checking the box" may not necessarily prevent all adverse events, the checklist is a scaffold on which attitudes towards teamwork and

<sup>&</sup>lt;sup>90</sup> http://www.who.int/selection\_medicines/list/en/

communication can be encouraged and improved. Recent evidence reinforces that adherence to the checklists is critical for the effects on patient safety to be realized.

Standard treatment guidelines (STGs) articulate the preferred treatments for common health problems experienced by different population groups. As such, they represent an approach to promoting equitable access to affordable, safe and effective medications. STGs can also help to address the issue of AMR. For example, WHO recently updated the treatment guidelines for gonorrhoea to address emerging AMR, no longer recommending quinolones (a class of antibiotic) for the treatment of gonorrhoea due to widespread resistance.

In addition to WHO resources, protocols, checklists and STGs can be developed by international professional organizations and/or adapted by national governments and other relevant organisations.

# 7. Teaching and training students to improve medication safety

Training students and practicing health care professionals to improve medication safety will need to consider knowledge, skills, and attitudes. The skills required include both technical skills (which are often role or profession specific) and more general non-technical skills and are therefore best learned through a combination of classroom-based (didactic) and clinically-based (experiential) activities. Education should ideally be competency-based, such that the learning is linked to roles and responsibilities a given professional will hold and the tasks they will need to perform.

Research suggests that when tasks (e.g., how to elicit medication histories) are taught interprofessionally, there can be gains in both core and inter-professional skills, and that these gains may be transferable to other situations<sup>91</sup>.

# 7.1 What to teach

Although students may not be permitted to prescribe, dispense, or administer medications until after qualification, there are many aspects of medication safety that students can simulate and practice from the very beginning of their training. The following topics represent those that can be introduced early and revisited at multiple stages and with more depth across the journey from novice, through to entry into practice, and then advanced practice.

Each topic on its own could be a stand-alone educational session (e.g., lecture, workshop, tutorial). Combined and connected, the topics could form the basis of a more comprehensive medication safety module. Integrating the topics into various sessions across multiple units (e.g., pharmacology, professional practice) and discussing them in both the didactic and experiential environments would be an even stronger instructional method.

A complete list of all the curricular elements potentially associated with medication safety is beyond the scope of this curriculum guide, but the following examples can be used as a guide that can be adapted and built upon as needed.

## 7.1.1 Technical skills

#### Prescribing

Introducing a prescribing framework is an important step for confirming the set of competencies that should underpin training in prescribing for both medical and non-medical prescribers. From this agreed framework, a tailored curriculum can be built.

One example of an inclusive prescribing framework is the Competency Framework for All Prescribers developed by the Royal Pharmaceutical Society of Great Britain<sup>92</sup>. This framework

<sup>&</sup>lt;sup>91</sup> Saxe J, Balano K, Wamsley M, et al. J Allied Health 2017; 46(2): e35–e37)

<sup>&</sup>lt;sup>92</sup> Royal Pharmaceutical Society, 2016

describes patient-centred prescribing based on ten prescriber competencies over two domains, regardless of the professional background of the prescriber. Prescribing skills should include both making the prescribing decision and communicating this clearly in writing or electronically.

Specific curricular elements associated with a prescribing framework might include:

- How to tailor treatment decisions (including those related to medications, including deciding not to prescribe or to deprescribe) to individual patient and system factors
- How to evaluate the risk-benefit relationships of using specific medications
- How to avoid unnecessary use of medications
- How to collaborate effectively to ensure that when medications are needed, the optimal product is selected

Other relevant areas are included in sections 5.2 and 5.4 of this curriculum guide.

#### Medication administration

Specific curricular elements associated with medication administration might include:

- Strategies for preventing the human, environmental, and systems causes of medication administration errors, such as dealing with interruptions
- Techniques for communicating with others about medication administration

Other relevant areas are included in sections 5.2 and 5.4 of this curriculum guide.

#### Medication calculations

Poor calculation competence and confidence has been identified as a key cause of medication errors. With this in mind, medication calculations should be an assessed element for all disciplines of health professionals.

Specific curricular elements associated with calculations instruction might include:

- Manipulating units, volumes, concentrations, and doses and converting between them
- Calculating weight-based doses
- Tools for improving arithmetic accuracy (e.g., pen and paper, calculator, smartphone apps)
- Performing calculations in high stress and/or high-risk situations
- Communication techniques for cross-checking calculations

#### Documentation

Documentation about prescribing, dispensing, and administration of medications should be clear, legible, and unambiguous. Because of widely acknowledged problems with interpreting handwriting, use of well-designed electronic systems should be encouraged if these are available.

Specific curricular elements associated with documentation might include:

- How to document key elements of information required for medication use: patient name, drug name, dose, formulation, route, time, schedule and duration
- How to document key communication elements for the care team name and contact details of the prescriber, dispenser, administerer, and patient
- How to document the information required at transitions of care, clearly indicating which medications have been started, stopped, changed or continued, and the reasons for any changes
- How to document information required for monitoring the effects of medication such as relevant laboratory tests and symptoms such as pain scores, to allow for monitoring of both efficacy and any adverse effects.
- Documentation of relevant information in suitable language and format for the patient or their carer/

#### Eliciting a medication history

A thorough and accurate medication history is an important precursor to safe medication use. This is a complex skill is it involves eliciting and validating information from multiple sources, and the technique used can affect the accuracy of the medication history obtained. Eliciting a medication history is a skill that all practicing health care professionals will need, and mastery of this skill is likely to need multiple opportunities for practice followed by feedback.

Specific curricular elements associated with medication history instruction might include:

- The advantages and disadvantages of different sources of information that can be used as part of eliciting a thorough and accurate medication history, including prescription, non-prescription, and complementary therapies
- Strategies for questioning patients and their carers that improve the likelihood of obtaining complete information
- Strategies for overcoming the most common mistakes in eliciting a medication history

#### Medication information resources

The complexity of different health care options, in terms of diagnosis, treatment, and care management together with increases the difficulty of the decisions clinicians face. It is no longer possible for a single clinician to know everything about every medication used within even a narrow field of practice. All health professionals involved with medication therefore need very good medication information skills and to maintain awareness of how to access the most up-to-date information as part of their continuing professional development.

Specific curricular elements associated with medication information resource use might include:

- When and how to access relevant and up-to-date information sources such as national and local formularies, national treatment guidelines, databases, websites, and reports by key external bodies.
- How to access, interpret, and communicate medication information from primary, secondary, and tertiary sources.

## 7.1.2 Non-technical skills

#### Teamwork and communication

Safe and effective use of medications is a team responsibility. To work effectively as a team requires an understanding of roles, responsibilities, and practices. Further, respectful and effective communication in teams means listening actively and encouraging the ideas and opinions of others.

Specific curricular elements associated with teamwork and communication might include:

- Strategies for seeking information respectfully from colleagues
- How to communicate openness to hearing feedback or concerns from colleagues
- Strategies for speaking up with questions or concerns
- Techniques for improving transfer of critical information during a clinical handover
- How to check understanding of others to ensure effective communication
- How to use incident reporting systems to report areas of concern and share learning

#### Communication with patients, their families and caregivers

Effective communication with patients and carers is essential in both supporting patients in taking medication safely and in supporting them to ask questions or raise concerns.

Specific curricular elements associated with communication with patients, families and caregivers might include:

- Strategies for seeking information respectfully and sensitively using patient-centric language
- How to communicate openness to hearing questions or concerns from patients and carers
- How to explore the reasons for any non-adherence to medication, and how to work with the patient to develop possible solutions
- How to communicate medication-related information and instructions to patients and carers, including verbal, non-verbal and written communication
- How to check understanding of patients and carers to ensure effective communication

#### Generic communication skills: influencing and rapport

Health care practice also requires skills in obtaining rapport and influencing others, such as in making recommendations for changes to medication.

Specific curricular elements associated with influencing and rapport might include:

- Strategies for establishing and understanding others' perspectives
- Strategies for establishing rapport with others
- Strategies for influencing others, such as in making recommendations for changes in medication
- How to give feedback to others about errors or unsafe practice

# 7.2 How to teach

There is a variety of ways to teach medication safety. Different people have different natural preferences for certain training modalities, e.g. through visual stimuli, oral interactions, and learning by doing. Deep learning of complex topics like medication safety requires active involvement. For this reason, a combination of approaches is likely to be most effective. Ideally, these methods are used in both didactic and experiential training phases. Further, whenever possible, training should be team-based. In some countries, availability of basic training and continuous professional development opportunities is limited. In-service training may fill this gap.

A complete list of all the instructional methods potentially useful for teaching medication safety is beyond the scope of this chapter, but examples of some of the key strategies and formats described below can be used as a guide. A more comprehensive summary, together with advantages and disadvantages of each, is available from Management Sciences for Health <sup>93</sup>.

- Interactive lectures
- Case-based learning
- Practical workshops
- Simulation (using mannequins, actors or other standardized scenarios)
- Project work (including tasks undertaken in the clinical environment)
- Guided reflections
- Group discussions
- Case/incident analysis
- E-learning
- Role-playing exercises

## 7.2.1 Interactive lectures and/or group discussion

The PowerPoint<sup>®</sup> presentations included in this package are designed for use as an introductory lecture on medication safety or as part of a teacher-led small group discussion. It can be readily adjusted to be more or less interactive and you can adapt it for your clinical setting by including local examples, local issues and local systems. Using patients as educators can also be a powerful tool in learning about their experiences and perspectives.

A series of questions are interspersed throughout the presentation to encourage students to engage with the topic. The short cases provided with questions and answers could be embedded in the lecture or distributed to the students as a separate exercise.

## 7.2.2 Case-based learning

Case scenarios can serve to raise issues relevant to medication safety. Cases can be videoor paper-based. One example is the <u>WHO Learning from Error</u> video and booklet. This

<sup>&</sup>lt;sup>93</sup> <u>https://www.msh.org/sites/msh.org/files/mds3-ch52-training-mar2012.pdf</u>

resource includes a dramatized incident of how a series of errors led to the incorrect administration of a medication used to treat cancer. Students can be asked to respond to reflective questions after reading through or watching the case.

#### 7.2.3. Practical workshops

While learning *about* medication safety is an important foundation, it is critical for students to obtain hands-on *practice* implementing the strategies described in this curriculum and that they receive feedback on this practice. Students should have opportunities to practice their skills under time pressure, mimicking real life clinical situations. Role-plays can also be incorporated into practical workshops to allow students to portray patients and different members of the health care team. Potential workshop topics include medication calculations, prescribing, deprescribing, dispensing, and medication administration. Practical workshops are also an excellent opportunity to practice teamwork, communication and other non-technical skills.

#### 7.2.4 Simulation

Simulation of emergencies is a powerful method for preparing practitioners for fast-paced and higher risk environments. There are adult and paediatric mannequins that can be used to simulate scenarios such as overdose or accidental ingestion of medications. These high-fidelity simulators are realistic but are too expensive for use in many environments. Training using less expensive low-fidelity simulation can be just as effective<sup>94</sup>. Scenarios can be used to highlight roles and responsibilities of all team members with regard to technical concepts like doses, types, and administration frequency for reversal agents. Simulation is also an excellent opportunity to practice non-technical skills and to highlight the role of workplace factors such as distractions and interruptions. Scenarios can also be simulated in a standardized patient scenario where learners can practice not only the technical skills but also non-technical skills such as communication within a team.

## 7.2.5 Project work

Student projects can be a powerful method for engaging the learner in constructing their own meaning from medication safety activities. Some potential projects include;

- Interviewing pharmacists to find out what errors they commonly see;
- Accompany a nurse on a drug round to observe the process of transcription, dispensing and administration;
- Interviewing nurses or doctors who administer medications (e.g., anaesthetists) about the strategies they use to minimize errors;
- Researching a medication that has a reputation for being a common cause of adverse events and present the findings to fellow students;
- Reviewing and updating the Wikipedia page about a high-risk medication
- Preparing a personal formulary of medications likely to be commonly prescribed, dispensed or administered in the early postgraduate years;

<sup>&</sup>lt;sup>94</sup> Aggarwal R, Mytton OT, Derbrew M, et al. Training and simulation for patient safety. BMJ Quality & Safety 2010;19:i34-i43

- Performing a thorough medication history on a patient taking multiple medications, then learning more about each of these medications, their potential side-effects, and drug interactions, and considering whether there are any medications that could be ceased and what patient education may be appropriate. Discuss recommendations with a pharmacist or doctor with clinical responsibility for the patient, and share what you have learnt with fellow students;
- Defining the term *medication reconciliation* and talking to hospital staff to find out how this is achieved in a specific facility. Observe and, if possible, participate in the process during admission and discharge of a patient and consider how the process may prevent errors and also whether there are any gaps or problems with the process.

#### 7.2.6 Group discussions

Discussion groups can be used to generate possible solutions to problems, with interdisciplinary groups particularly useful in exploring different perspectives and learning from other professional groups. For example, an inter-disciplinary group could map the process of medication reconciliation, highlighting areas of risk, exploring the roles of each professional group, and developing a shared understanding of how best to work together. Group discussions can also be useful to facilitate sharing of experiences among the group, such as following a practical exercise or project work.

#### 7.2.7 Case / incident analysis

Analysis of a specific case or medication incident can be helpful in understanding why things go wrong in clinical practice, and how defences such as a second check, using a checklist or 'speaking up' can prevent patient harm. This also develops skills in analysing incidents, identifying areas of learning, making appropriate recommendations for practice and providing feedback to the staff member who reported the incident.

# 7.2.8 E-learning

E-learning can be useful in allowing individual study at a time and place most suited to the student concerned, although the limited opportunity to interact with others can be a disadvantage. E-learning can be quite sophisticated, although developing high quality materials and keeping them up to date can also be expensive and time-consuming. Within medication safety, E-learning may be most appropriate for teaching and testing quantitative skills such as calculations rather than communication skills.

#### 7.2.9 Role-playing exercises

Role-playing exercises are another potentially valuable educational tool for teaching students about medication safety, particularly in relation to non-technical skills.

# 7.3 Training for capacity

Training students to work in inter-professional teams to improve medication safety should be a required element of every health care professional curriculum. However, it is important to remember that while knowledge, skills, and attitudes are important precursors for safe medication use, these will not be sufficient without an enabling institutional environment. Systematic capacity building models such as the one depicted below show that individual capacity for skill in using medication safety tools will not lead to improved system performance without a foundation of institutional capacity re: structures, systems, and roles. Building this foundation is more complex and will take more time but is an important goal<sup>95</sup>.

# 7.4 Assessment methods

These should be competency-based where possible, and might include some or all of the following:

- Multiple choice questions
- Assignments
- Objective structured clinical examinations or simulations
- Workplace based assessment
- Portfolios
- Peer feedback
- Short and long essays

<sup>&</sup>lt;sup>95</sup> Potter C and Brough R, Systemic capacity building: a hierarchy of needs. 2004. HEALTH POLICY AND PLANNING; 19(5): 336–34

# 8. Case stories on medication-related harm

The medication safety movement has been deeply affected by the stories patients and health professionals have shared which have identified numerous opportunities for improvements. One example of these is the <u>WHO Medication Without Harm: Real-life stories</u> series. These compelling stories could form the basis of reflective practice activities such as blog postings.

http://www.who.int/patientsafety/medication-safety/photostory/en/

- Patient's Stories
- Health Professionals Stories
- Stories that led to changes