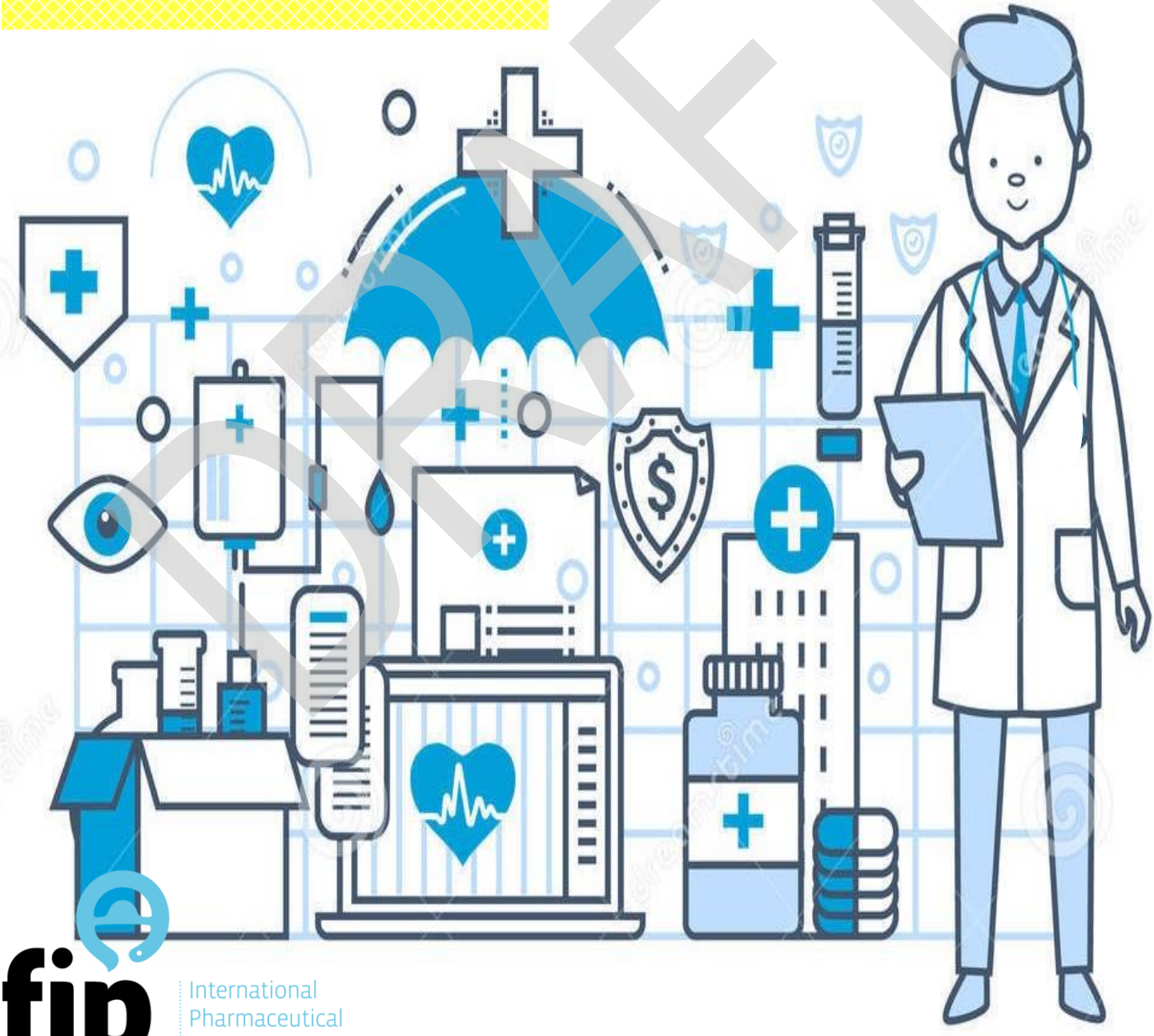
Patient and medication safety

Pharmacists' role in minimising preventable harm to patients

2019



fip International Pharmaceutical Federation

This is the final draft version of the FIP reference document from November 2019. It will be circulated to the Council members and the FIP Board of Pharmaceutical Practice for consultation. Please do not copy or circulate the document further at this stage, it will be published once approved by FIP.

Please follow the instructions and send your comments to Rachel@fip.org before 31 December 2019, please.

Colophon

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Contents

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Executive Summary

The World Health Organization (WHO) reports that one in four patients are harmed by the care they receive in primary and ambulatory care settings. Adverse events are responsible for a large proportion of emergency department visits and hospitalisations. The global costs associated with medication errors has been estimated by the WHO as US $42 billion per year. It is therefore not a surprise that patient safety has become a global emergency and many nations are placing patient safety on their national health priority agenda.

Patient safety is broadly acknowledged as a patient being free from any harm and/or accidental injuries during the course of receiving health care. Medication safety, recognised as a component of patient safety, refers here to preventing and managing medication related errors and consequent harm, in a person's medicating taking journey. Whilst the fallibility of humans and their resultant errors appears to be a contributing factor to medication errors and patient harm, errors often do not have a single cause. Health care organisations and systems, including people that create legislation and policy, people that implement standards and guidelines, and health care professionals who deliver services and provide patient care, are all responsible for ensuring patient safety. A "*culture of blame*" does not prevent nor mitigate harm. Nor does it ensure a positive working environment. However, a collaborative systems approach that fosters a safety culture and promotes effective risk management and continuous quality assurance through building system defences, can ensure patient safety during patients' health care journey.

Pharmacists are an essential health care professional in a patient's health care and medication journey, not only as a professional delivering direct care to the individual patient, but also as a member of a health care team, in health care organisations and systems, delivering care and advocating for a safety culture. In promoting patient safety, pharmacists have a number of roles to play. This reference document on Patient and Medication Safety, Pharmacists' role in Minimising Preventable harm to Patients provides information about what pharmacists can do at an individual patient level, from the beginning of their medication journey, to their role as patient advocates and members of health care teams and organisations. This reference document is supported by evidence of the positive impact of pharmacists on patient and medication safety.

In drawing parallels with other "*safe*" industries, notably the aviation industry, this reference document highlights what pharmacists can do to create a safe culture and ensure patient and medication safety wherever they work. Case examples have been provided from a range of countries as examples of pharmacists' roles in patient and medication safety which can act as a guide for implementation of strategies in other countries and contexts.

A whole-of-system shift is required - there is a need to change health care systems and practices to ensure patient safety and reduce the burden of errors. Currently, with the global drive towards health care and medications without harm to patients, we have a window of opportunity to ensure a change is implemented. There are three essential components: problem recognition, generation of policy proposals, and political events. In creating this change, we need to consider designing and redesigning systems or services collaboratively between all healthcare professionals and key stakeholders, including patients, their carers, policy makers, and educators.

This reference document can serve as a platform to inform policy and practice development of patient safety initiatives in your practice or country context. At the same time, it was the intention to keep it very practical, so that it can serve as a tool for practicing pharmacists to ignite further discussion at national level and to stimulate implementation of services that help preventing patient safety events and reducing risk of unnecessary harm associated with health care to a minimum.

1 Background

Pharmacotherapy is one of the most common interventions used in health care to cure and prevent diseases and mitigate symptoms. Medicines are used by the very young to the very old, as inpatients and in outpatient settings, and predominantly in the home setting where patients are responsible for their own self-management either alone or with the help of their carers and family members. In addition to medicines prescribed, there is a wide range of symptoms and conditions that can be managed by using non-prescription medicines without consulting any health care provider, or if consulted, with the advice of a community pharmacist.

Although effective, pharmacotherapies are often challenging to manage and use appropriately. This is due to a number of factors, such as increasingly complex pharmacotherapies, polypharmacy, ageing populations with multiple diseases, and limited, or not-well coordinated resources in health care systems.[1, 2]

Even though access to safe health care is the fundamental right for patients across the world, recent estimates by the World Health Organization (WHO) indicate that as many as one in four patients are harmed by the care received in primary and ambulatory care settings[1]. Approximately 6% of hospitalised patients experience an adverse drug event (ADE) during their hospital stay.[3] It is estimated that in England alone, there are around 237 million medication errors annually.[4] In hospitals in the United States, over 700,000 emergency department visits and 120,000 hospitalisations result from adverse drug events (ADEs). These visits translate to an estimated financial impact of up to $3.5 billion USD in extra medical costs annually. This estimate may not completely account for costs associated with re-admissions, malpractice and litigation, or other injuries to patients as a result of ADEs.

These error rates are comparable with those in other EU countries and in the USA.[4] Thus, the clinical, humanistic, and economic burden of medication errors is vast at the individual, organisational, national, and global level. Globally, WHO has estimated that the cost associated with medication errors is US$42 billion each year.[5] Patients in low-income countries lose twice as many disability-adjusted life-years due to medication-related harm compared to those in high-income countries.[5] Growing evidence on patient safety risks related to medications in health systems all over the world has created a need to develop new strategies to manage these risks.

Given the importance of patient safety, the FIP Board of Pharmaceutical Practice set up the "*FIP working group on Patient Safety*" in March 2018. The objectives of the working group are to support FIP in providing technical expertise on the topic of patient safety and explore possibilities of increasing the visibility of pharmacists in patient safety, particularly their contribution to the implementation of the WHO Medication Safety Challenge. Furthermore, the group was tasked to produce an inventory of systematic reviews of pharmacists' contributions to medication safety (Annex 1), emphasise pharmacists' key roles in assuring medication safety, outline the importance of safety culture and medication risk management and to identify some of the available resources that pharmacists can use in their practice to improve patient and medication safety. These are included in this FIP reference document on patient safety.

1.1 Medication safety as part of patient safety

Patient safety consists of the identification, analysis, and management of patient-related risks and incidents, also called adverse events or medical errors, in order to make patient care safer and minimise harm to patients.[6, 7] One of the most widely used definitions of patient safety is "*freedom from accidental injuries during the course of medical care, activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of health care*".[6, 8, 9]

Unsafe medication practices contributing to medication errors (MEs) is the most important preventable single factor jeopardising patient safety.[5] Up to 50% of all reported patient safety incidents are estimated to be related to medications. A ME is defined as "*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, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use*".[10]

Safe pharmacotherapy can be divided into drug safety and medication safety (Figure 1).[11-13] Drug safety is related to pharmaceutical products, and usually concentrates on their harm-benefit ratio in terms of adverse drug reactions (ADRs).[11-13] An ADR is a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease or the restoration, correction or modification of physiological function.[6] Medicationsafety refers to preventing and managing MEs, which are unintended mistakes in the medication-use process caused by omissions or commissions (Figure 1).[11-13] A near miss (sometimes also called a close call or a potential adverse drug event), is a medication error that has the potential to cause harm, but did not, either by luck or because it was intercepted and corrected.[6] Near misses are often caused by an adverse drug event (ADE).

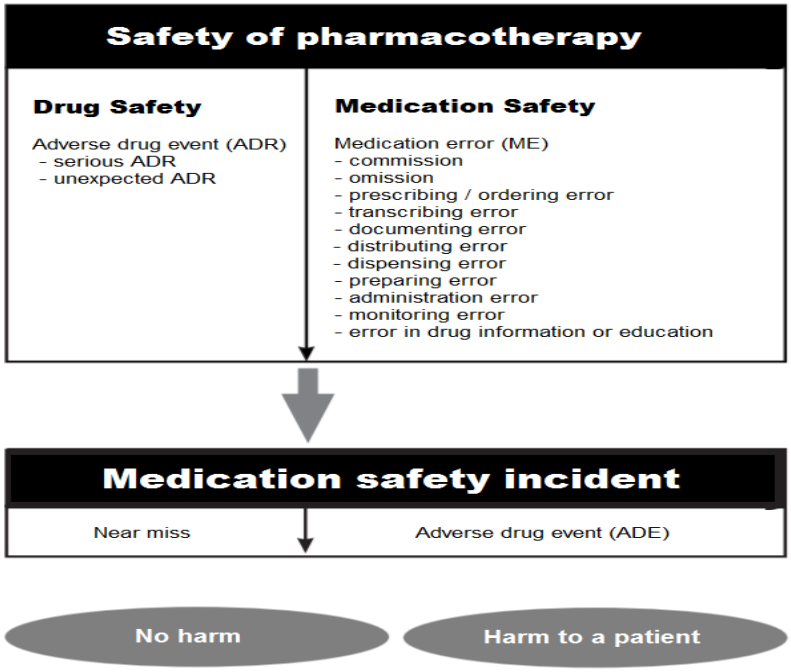


Figure 1. Terms related to safe pharmacotherapy (adapted from Stakes and Rohto 2006, Schepel 2018) [11-13]

Figure 2 illustrates the relationship between MEs, ADEs, and ADRs.[14, 15] An ADE is defined as "*any injury occurring during the patient's medication therapy resulting from either appropriate care, or from unsuitable or suboptimal care*".[6] Thus, the definition includes ADRs and MEs.

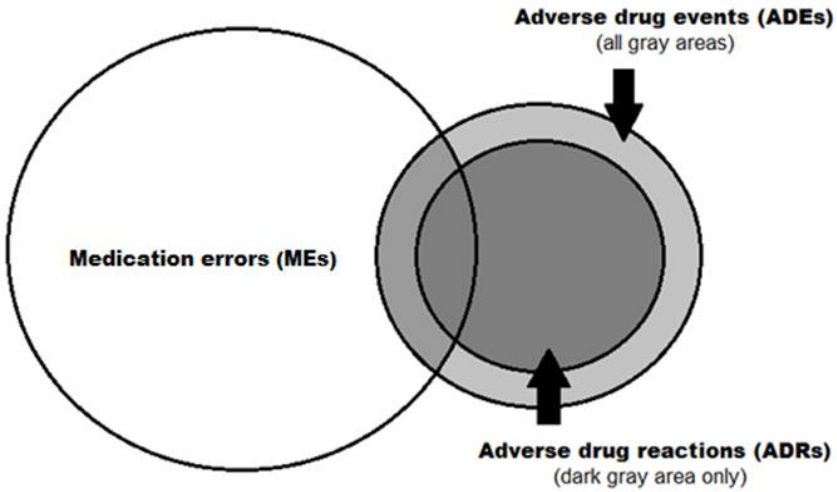


Figure 2. Relationship between medication errors, adverse drug events and adverse drug reactions[13, 14]

In Figure 2 the grey areas represent injuries caused by medication use (ADEs). The dark grey area represents harm caused by a medication (adverse drug reactions, ADRs). Medication errors are significantly more common than ADEs, but they result in harm less than 1% of the time.[16] Conversely, about one quarter of ADEs are due to medication errors.[16]

Pharmacovigilance, i.e., the science and activities related to the detection, assessment, understanding and prevention of the adverse effects of pharmaceutical products has typically been drug- and molecule-oriented[6, 13, 17, 18]. The real-life medication use process, including human error, has not received such degree of attention until the early 2000s when the Institute of Medicine strongly suggested reporting systems as a part of a comprehensive strategy to understand errors and improve patient safety with preventive actions.[8] Since then, local and national medication error reporting systems (MERs) have been launched in many countries.[19] The first national MER system was established in the United States in 1987.[20] The shift to expand the scope of pharmacovigilance to also include MEs can be seen, e.g., in the European Union regulations.[18]

1.1.1 Evolution of patient and medication safety

The landmark report "*To Err Is Human: Building a Safer Health System*" by the US Institute of Medicine started an open discussion about safety concerns in health care and designing processes of care where patients are safe from accidental injury.[8] This report started global system-based patient and medication safety work and created a new, rapidly growing research area.[8] The report stated that the complex problem required multifaceted responses and recommended the following actions:

1) Leadership and knowledge: a national focal point to set the national goals for patient safety and develop knowledge and understanding of errors with patient safety research.

2) Identifying and learning from errors: to create an environment that encourages organisations to identify errors, evaluate causes and take actions to improve performance; and design and implement nationwide, mandatory and voluntary incident reporting systems.

3) Setting performance standards and expectations for safety for health care organisations through regulatory and related mechanism, such as licensing, certification and accreditation. Professional societies should establish a permanent committee dedicated to safety improvement.

4) Implementing safety systems in health care organisations, with patient safety programmes with defined executive responsibility and proven safety practices.

Following the IOM report,[8] international and national working/expert groups were established in order to assess the local situation and to set recommendations for improving patient and medication safety. For example, in Europe, the Council of Europe (CoE) was among the first international organisations to set recommendations on patient and medication safety for its members countries at the Ministerial level.[17, 21] The CoE stated that medication errors are poorly managed in Europe and suggested European health care organisations to.[17]

1) Take steps to establish medication error reporting systems;
2) Establish and use a common terminology concerning harm to patients caused by medications;
3) Create a culture of safety; and
4) Set up a nationally recognised focal point for safe medication practices.

The recommendations and guidelines set by numerous organisations and stakeholders in different countries and continents over the years have emphasised the importance of quite the same actions to prevent medication errors. In addition to above mentioned actions, the recommendations have emphasised a multidisciplinary approach to developing medication safety and extending pharmacists' involvement in patient care, e.g., by conducting medication reconciliation and reviews. Furthermore, there has been a recommendation to implement electronic prescribing systems with clinical decision support incorporating up-to-date patient and medicines information and therapeutic guidelines.[17] The legislative framework-related recommendations have particularly addressed safe labelling and packaging to avoid look-alike and sound-alike (LASA) errors that are common all over the world.

The most recent initiatives and recommendations have continued to emphasise the importance of a safety culture and implementing reporting systems. However, they have also promoted development of training to foster competences in patient and medication safety among all health care providers, transfer of safe and effective practices between health care organisations and countries, patient safety in cross-border health care, development of indicators for health care quality and patient safety, as well as promoting use of information technology and digitalisation in making patient care safer. The importance of allocating funding for research and development of patient and medication safety has also been recognised.

1.2 WHO as a global coordinator of patient and medication safety

At the global level, the World Health Organization has had an important coordinating role in patient safety development since the early 2000s. WHO, with its stakeholder organisations, has demonstrated substantial efforts to improving safety of care globally in all care settings. An important part of these efforts has been creating awareness of a safety culture based on a systems approach, that is, an emphasis on understanding how care processes work and therefore how these processes can be made safer to minimise error and prevent harm to patients.

The WHO has identified high-risk areas in patient safety and developed global programmes to gain commitment to addressing these challenges. The first Global Patient Safety Challenge focused on reducing health care infections through improved hand hygiene ("*Clean Care is Safer Care*" in 2004). The second Challenge addressed the risks associated with surgery ("*Safe Surgery Saves Lives*" in 2008).[22, 23]

The WHO released the third, most current Global Patient Safety Challenge which focuses on medication safety, in 2017.[5] The goal of the programme "*Medication Without Harm*" is to reduce the global level of severe avoidable

medication-related harm by 50% over 5 years. In 2019, WHO released 3 technical reports focused on the key areas of the challenge: 1) high-risk situations, 2) polypharmacy and 3) transitions of care (Figure 3).

1) High-risk situations include high-risk settings (e.g., hospital settings with more serious clinical conditions and the use of more complex medications), high-risk patients (e.g., young children, older adults, patients with concomitant kidney or liver disease), and high-alert medications associated with a high risk of severe harm if used incorrectly. High-risk situations are more often associated with significant harm due to unsafe medication practices or medication errors. WHO report outlines three main factors contributing to high-risk situations: i) medications, particularly high-risk (high-alert) medications, ii) provider/ patient factors, and iii) systems factors (work environment). One or more of these factors, acting alone or in combination may trigger unsafe medication practices or medication errors. The report also outlines how a range of sustainable strategies of proven efficacy can be developed and implemented in conjunction to reduce the risk of harm associated with high risk situations.[24]
2) Polypharmacy has become a growing risk due to the increase in concomitant use of multiple medications as populations live longer ad with more chronic health conditions. Polypharmacy will lead to increased likelihood of adverse effects, interactions, and other clinically significant medication-related problems. More complex medication regimens make self-management of medications more challenging, and can negatively influence adherence. The WHO report highlights importance of leadership in nurturing a culture that prioritises safety and quality of prescribing, provides guidance on prioritising patients for medication review, the role of the patient and the importance of a multi-professional team across the health and care system, including policy makers. Included in the report, there are tools and case studies which illustrate a systematic approach that can be followed by all health care professionals and the patient, across the health and care system to ensure that patients are integral to the decisions about their medications and feel supported to do so.[25]
3) Transitions of care pose an increased risk of communication errors which can lead to serious medication errors. Medication discrepancies impact almost every patient that moves across transitions of care, e.g. admission to or discharge from hospital. The WHO report outlines why improving medication safety in transitions of care is a priority and outlines what has been done to date and what needs to be done. The key elements of leadership and improvement programmes, including formal structured processes, workforce capacity and capability, partnering with patients and families, improving information quality and availability and measurement are outlined.[26]

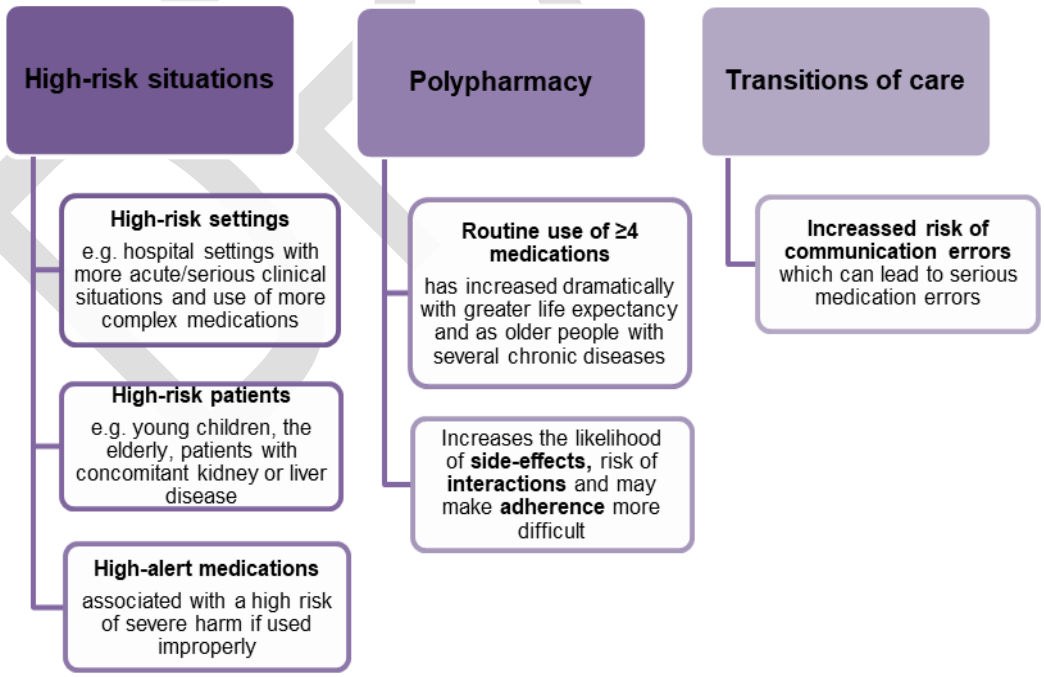


Figure 3. Key areas of the WHO Global Patient Safety Challenge on Medication Safety (WHO 2017, adopted from Schepel 2018).

The Challenge stimulates action to create new policies, practices, and services at national and international levels in four areas: patients, medicines, health care professionals and health systems, and practices of medication. The Challenge reads: "*Preventing errors and the harm that results requires putting systems and procedures in place to ensure the right patient receives the right medication at the right dose via the right route at the right time. […] The Challenge aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring and use. [5] WHO aims to provide guidance and develop strategies, plans and tools to ensure that the medication process has the safety of patients at its core, in all health care facilities*." [5]

WHO has already made available a wide range of practical tools to support implementation of the medication safety challenge. WHO has also encouraged and supported researchers to create evidence on medication safety risks in various health care settings and identify areas where future research is needed.[27, 28]

Training of health care professionals plays a crucial role in ensuring patient and medication safety. During the last ten years, WHO has actively promoted incorporation of patient and medication safety in the curricula of all health care professionals. WHO launched the first multiprofessional Patient Safety Curriculum Guide in 2011 which has a chapter on medication safety.[29] The goal of the Curriculum Guide is to create shared understanding of key concepts, principles, and actions that lay the foundation for safe care processes and their further development. It encourages learning from our own systems and learning from the best practices of others. It recommends that competencies required in safe medication practices are incorporated in the curricula of all health care professionals, preferably in close collaboration between training units of different professionals. It further recommends that various international, national, and local stakeholders should promote and support this incorporation into curricula and share their experiences of pedagogical innovations in education curricula.

The Curriculum Guide is a tool to use to promote patient and medication safety. WHO is working to update and extend the medication safety part of the Curriculum Guide to support the implementation of the Third Patient Safety Challenge on Medication Safety. In addition, there is also a global need to develop patient and medication safety programmes for delivery as continuing professional education to practicing health care professionals.[30]

1.3 FIP as a global coordinator of patient and medication safety initiatives within the pharmacy profession

Since the landmark article by Hepler and Strand on pharmaceutical care in 1990,[31] FIP has taken a global coordinating role in implementing the philosophy of pharmaceutical care internationally among its member organisations and countries. According to the principles of pharmaceutical care, pharmacists are expected to ensure the quality and safety of medication therapies in patient care, through collaborative care and patient interaction. Thus, pharmaceutical care introduced the principles of prospective risk management to medicine use.

FIP has been closely collaborating with WHO regarding implementing pharmaceutical care into practice. WHO released a document called Tokyo Declaration 1993 on the role of pharmacists in the health care system during the FIP Congress in Tokyo in 1993 in order to guide the development of pharmaceutical care practice internationally. The Tokyo Declaration was based on the FIP drafted document "*Guidelines for Good Pharmacy Practice*" (GPP) which was intended to be a standard for every practicing pharmacist in order to ensure worldwide appropriate quality of pharmacotherapy for every patient.[32] In 1997, FIP released jointly with WHO the "*FIP statement of professional standards*" in order to ensure the quality of information provided by the pharmacist to the patient through the relationship between the pharmacist and the patient to promote safe and effective use of medications.[33] This GPP statement was again updated in 2010 and approved by WHO General Assembly in May 2011.[32] Within the FIP, the Board of Pharmaceutical Practice has been the key coordinator of implementation of the GPP through the national member organisations who are able to set local pharmacy practice guidelines, taking into account local health systems and other circumstances.

According to the 2011 FIP/WHO GPP guidelines,[32] the aim of pharmacy practice is to "*contribute to health improvement and to help patients with health problems to make the best use of their medicines*." With this guideline referenced, FIP and WHO encourage pharmacists globally to ensure that their daily practice conduct is in line with GPP. In terms of patient safety, three specific actions are included in these Guidelines that could minimise potential medication errors:

1. Pharmacists should assess and evaluate all paper or electronic prescriptions received. Pharmacists should also consider the therapeutic, social, economic and legal aspects of the prescribed indication(s) before supplying medical products to the patient. Where possible, generic substitution is recommended;
2. Pharmacists should document necessary clinical and patient data to assess and monitor medication therapy and to track patients' therapeutic outcomes; and
3. Pharmacists should provide enough health-, disease- and medicine-specific information to patients for their participation in the decision-making process regarding a comprehensive care management plan. This information should aim at supporting adherence to treatment and empowerment of the patient.

Even though pharmaceutical care and patient-centred clinical pharmacy services have been shown to improve quality, safety and efficiency of care and reduce its costs, their diffusion to many health care systems has been slow.

1.4 FIP's advocacy and collaboration on global level

FIP has a long history of working in close collaboration with the World Health Organization (WHO) and its patient safety programme. Patient safety was identified to be the high-priority topic for FIP in interactions with the WHO even prior to the launch of the Medication Without Harm Programme in 2017. Since then, patient and medication safety have become an even more important area of collaboration. One of the most remarkable contributions by FIP before the launch of the Global Patient Safety Challenge was co-authoring the WHO Patient Safety Curriculum Guide, multi-professional edition, launched in 2011.[29] FIP is currently collaborating with WHO on the update of the Curriculum Guide and the extension of the medication safety chapter.

In 2014, FIP took part in the WHO brainstorming meeting, helping to develop what is now the WHO Medication Safety Challenge. In 2016, FIP contributed to the preparatory work around this challenge, including discussions of the next steps needed to strengthen the whole medicines use process and to reduce medication errors, for example, via interprofessional collaborative practice, and implementation of new services and tools. This is in line with all the important roles that pharmacists are recommended to play as presented in the above mentioned GPP document.[34] FIP was present at the Second Global Ministerial Summit on Patient Safety in Bonn, Germany, where the Medication Safety Challenge was launched in 2017. The Summit was co-organised by the WHO, the Organisation for Economic Co-operation and Development and the Government of Germany. FIP was one of the 300 experts from 40 countries present at the event.

FIP also provides technical expertise to WHO on other topics related to patient and medication safety. The goal is to increase the visibility of pharmacists in patient safety and to advocate for their contributions in the implementation of the WHO Global Patient Safety Challenge on medication safety. Most recently, FIP contributed to the establishment of The Jeddah Declaration on Patient Safety launched in 2019.[35] For that purpose, in 2018, FIP informed health ministers at the Patient Safety Global Ministerial Summit in Tokyo, Japan, about the role pharmacists play in patient safety.[36] Due to FIP's advocacy, The Jeddah Declaration on Patient Safety was founded in March 2019 on the principles that guided the 4th Global Ministerial Patient Safety Summit 2019 in Jeddah, Kingdom of Saudi Arabia.[37] This Summit in turn, sets recommendations for international standards, guidelines, and actions that aim to address patient safety issues of global significance, with a strong emphasis on Low- and Middle-Income Countries (LMIC).[37] Thus, the Summit is establishing patient safety as a crucial principle integrated in the efforts to achieve universal health coverage (UHC).[37]

The Jeddah Declaration on Patient Safety is a call for action on many fronts, and for many actors, at all levels of health care provision and delivery: from frontline, to organisational and policy arenas.[35] The Declaration is founded on the underlying spirit that it is imperative to reflect on the effectiveness of current practices in light of the now mature patient safety evidence base of 20 years; and to collectively move forward with a vision for sustainable and scalable implementation of patient safety solutions known to improve care delivery systems, patient outcomes, and safety culture. FIP endorsed the Jeddah Declaration.[38] Its eigth point specifically refers to promotion of medication safety in community pharmacies. Thus, it promotes the implementation of the Global Medication Safety Challenge in community pharmacies.[38] Such a move would help improve medication safety and strengthen the efforts for patient empowerment and community engagement.

2 Definition of key terms

Currently, FIP defines patient safety as "*freedom from accidental or preventable injuries produced by medical care"* according to the Patient Safety Network (PSNet) glossary.[39] The PSNet is a national web-based resource featuring the latest news and essential resources on patient safety.

The US National Coordinating Council for Medication Error Reporting and Prevention defines medication errors as: *"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, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use".*[40]

The key terms in this document are defined according to the Definitions of Key Concepts from the WHO Patient Safety Curriculum Guide (2011).[29] This document is currently being updated and a new version will be launched in 2019.

The Council of Europe has also published a comprehensive glossary of terms related to patient and medication safety as part of its recommendations in 2006.[6] The glossary was based on the WHO Glossary and other official definitions of patient and medication safety related terms. The goal of the glossary was to promote creation of shared understanding of the key concepts related to patient and medication safety. It should be noted that the glossary was published in 2006 and part of the concepts have been redefined since then. The glossary has been translated and modified to the needs of the national patient and medication safety programmes in part of the Council of Europe member countries (e.g., STAKES and ROHTO 2006 in Finland).

In addition to the internationally recognised glossaries, numerous national glossaries have been established, such as Runciman's paper on preferred terms and definitions for safety and quality concepts in 2006. It was the first paper that aimed to standardise key definitions for patient safety in Australia.[41]

3 Creation of safety culture: systems approach and the theory of human error

We have learnt to trust that it is safe to travel by air, even to take long flights to the other side of the globe. Aviation safety is an outcome of systematic work and quality assurance that covers every detail of the process of a flight. Pilots and other aircraft personnel have learnt to work together to confirm that the passenger leaving from destination A will safely arrive at destination B. Medicine use can be considered to have the same kind of journey for the patient/medicine user. A key component of the journey is communication with the patient and others involved in the care of the patient.

Although this sounds simple, it has turned out to be challenging to ensure patient safety during the medication journey. Consequently, adverse events related to medications are among the most common adverse events in health care throughout the world. Figure 4 below presents early work from the US that demonstrates the dramatic increase in deaths from prescription medicines during a 20-year period from 1979-1998.[42] At the same time, the risks related to common modes of transportation, such as motor vehicle, railway, air and water transport remained stable or even decreased.

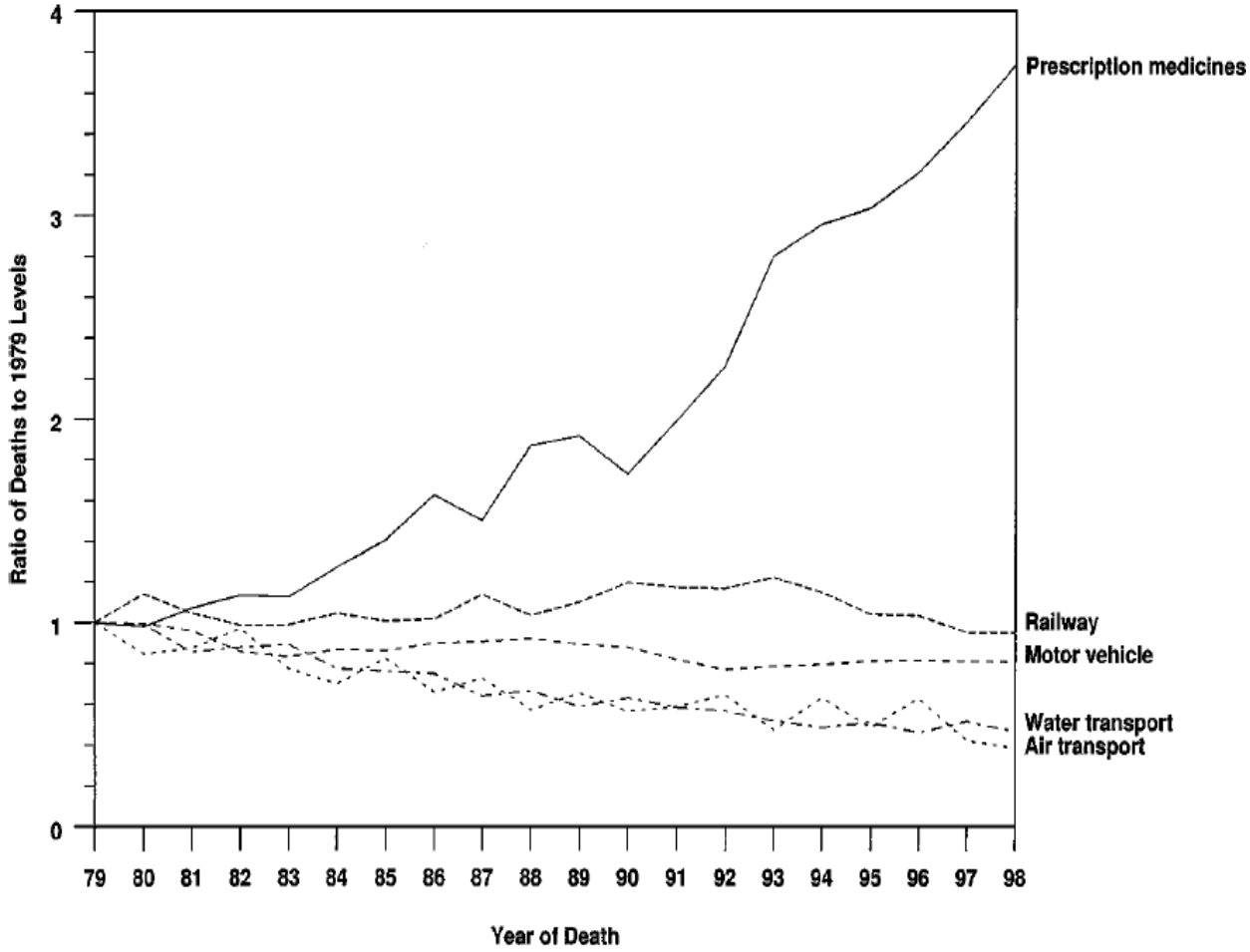


Figure 4. Ratio of deaths to 1979 levels to illustrate mortality from medication errors in the USA during 1979-1998.[43]

A systems approach is crucial to manage errors in health care. When an error occurs, the focus should be on how and why the defences failed, not investigating who made the error. An effective error and risk management strategy relies on a blameless culture and learning from errors and near misses. Health care organisations should identify errors and

near misses, evaluate causes and contributing factors, and take actions to improve patient and medication safety. Pharmacists are in a key position to take a lead on medication safety as part of patient safety in their organisations.[13,15] To be successful, pharmacists should adopt the following key conceptual approaches related to patient and medication safety in clinical practice:

- **Risk management:** Activities or measures taken by an individual or a health care organisation to prevent, remedy or mitigate the occurrence or reoccurrence of a real or potential (patient) safety event.[44]
- **Safety culture:** An integrated pattern of individual and organisational behaviour, based upon shared beliefs and values, that continuously seeks to minimise patient harm which may result from the processes of care delivery.[6, 21]
- **Systems approach:** An approach to safety stating that errors are generally consequences of systemic factors, e.g., weaknesses in organisational processes.[45] Building system defences to reduce and prevent errors is the main method of safety improvement in a systems approach.

3.1 Human error theory as a theoretical framework in systems-based risk management

Reason´s Theory of Human Error has been widely used as a theoretical framework in systems-based patient and medication safety work.[8, 29, 45] To manage errors and risks in organisations and processes, psychologist James Reason (1990, 2000) has explained the challenge of human error with two approaches: the person and the system, which lead to different philosophies of error and risk management. The theory is based on observations and research on cultural characteristics of high-reliability organisations, i.e. systems operating in hazardous conditions but experiencing fewer adverse events and an almost complete absence of catastrophic failures, such as nuclear power plants and air traffic control centers.[45-47]

Traditionally, the person approach to human error has been a dominant approach in health care.[45] It focuses on unsafe acts, errors, and procedural violations of people on the frontline. In this approach, individual health care practitioners (e.g. physicians, nurses, pharmacists) are blamed for errors primarily due to human behaviours such as forgetfulness, inattention, poor motivation, and competence. However, most of the unsafe acts are not intentional.[45] This person approach easily ignores the circumstances where people work which can lead to similar, and repetition of errors, despite the people involved.

The basis of a systems approach is the premise that humans are fallible and errors, caused by omissions or commissions, are to be expected even in the best organisations with the best people.[45] Instead of seeing errors as causes of actions, they are consequences of systemic factors such as complex processes with unclear responsibilities. Because we cannot expect endlessly perfect human performance, the conditions under which humans work must be changed to minimise or avoid errors.

An effective error and risk management strategy relies on a blameless reporting culture and learning from analysis of errors and near misses.[48] A more recent trend has been the shift towards the prospective error and risk management with the development of process defences, barriers, and safeguards to prevent errors and risks.[45] Defences can, for instance, be engineered (e.g. alarms, physical barriers, automatic shutdowns, check and double-check), dependent on people and their competences and routine care processes (e.g. surgeons, anaesthetists, pilots) or dependent on procedures and administrative controls. However, these defensive layers can also have weaknesses. Reason described this with the "*Swiss Cheese*" Model of System Accidents (Figure 5).[45] Defences are illustrated as slices of Swiss cheese (Figure 6). The errors and near misses occur when the holes in many layers momentary line up and permit the passing of an error through different steps of the process.

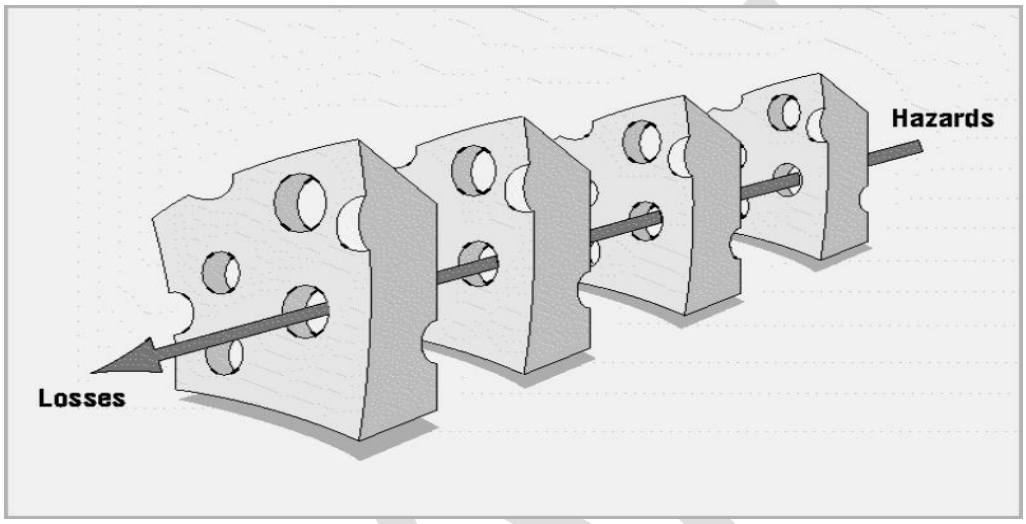


Figure 5. Reason's (2000) Swiss Cheese Model of System Accidents.

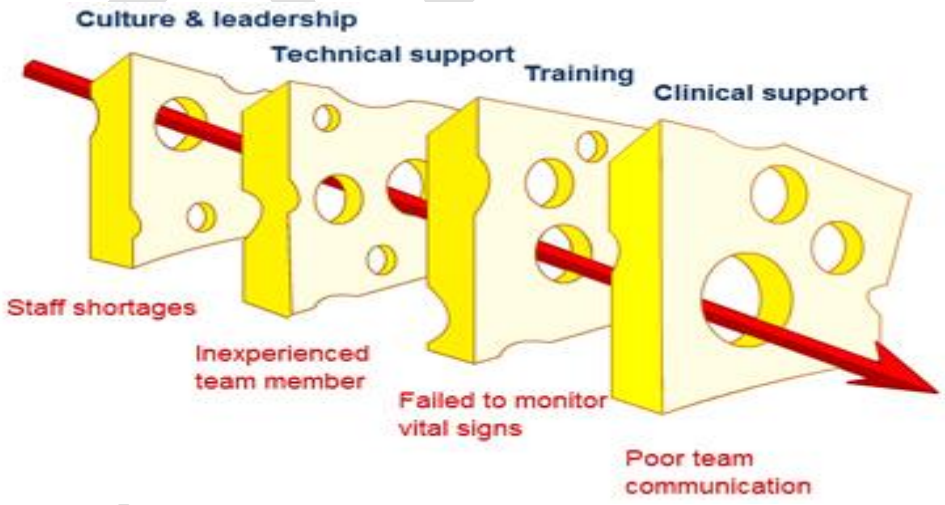


Figure 6. An application of the Swiss Cheese Model (Reason 1990) to identify reasons and contributing factors to medication errors.

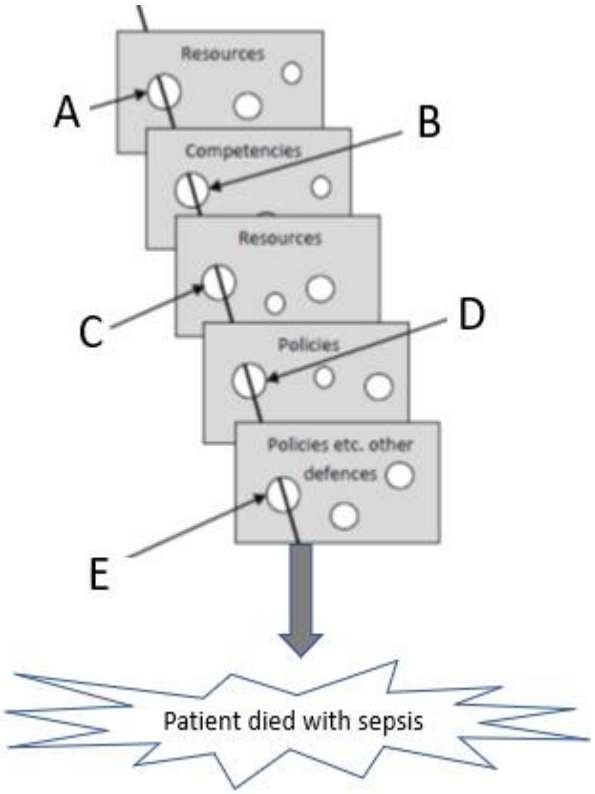
Kettunen (2007) in Figure 7 has described a fatal medication error due to methotrexate overdose in a Finnish central hospital with the Reason's Swiss Cheese Model.[49]

Case description of the fatal medication error due to methotrexate overdose in a Finnish central hospital:

An 86-year old female patient was admitted to a hospital due to a pulmonary embolism. Medication treatment was started immediately. According to a referral, the patient was under treatment for rheumatoid arthritis and was using methotrexate 5 mg on Tuesdays. The dosing was, however, transcribed as 5 mg in the evenings and recorded on the patient's medication list. The patient started to recover from the pulmonary embolism, however, after a week of hospital admission, the patient's condition got worse. The doctors suspected an infection, but instead they diagnosed anaemia and neutropenia. This finding led to checking the medication list of the patient after 12 days of hospital stay. The health care staff discovered that 5 mg of methotrexate had been administered to the patient every day, although the correct dose should have been 5 mg once a week. Despite attempts to save the patient, the patient died of sepsis after 20 days of hospital stay.

Figure 7. Application of Reason's Swiss Cheese Model (2000) to illustrate a fatal system error related to the medication use in a secondary care hospital (Adapted from Holmström 2017, Schepel 2018, original case description Kettunen (2007).[49]

Hazard: Medication with an unconventional dosing → methotrexate 5 mg on Tuesdays transcribed as methotrexate 5 mg in the evenings at the emergency department.



A: The doctor did not check the medication after transcription due to being in a rush and a long queue of patients waiting for treatment.

B: Patient transferred to a hospital ward where there was no experience with methotrexate medication treatment.

C: A substituting doctor did the ward rounds on the next day. The doctor was unfamiliar with the patients. The round was long and exhausting with many patients, and the doctor did not notice the error.

D: Next day, the ward doctor stated that the patient had started to recover. The ward doctor trusted the medication list "checked" by the substituting doctor, because the condition of the patient was better.

E: The medication error was not noticed until 12 days later after the patient's condition became worse.

A: Medication reconciliation, medication reviews, taking part in medical rounds
B: Logistic tasks, e.g. stock control using automated dispensing systems
C: Medication reconciliation, creating instructions, providing medication information, medication reviews
D: Giving medication information to patients
E: Giving medication information to patients, therapeutic monitoring, medication reviews
F: Medication reconciliation, medication reviews, developing medication-use process

Figure 8 below illustrates the evolution of the tasks of clinical hospital pharmacists in Finland by 2016 as reported by the informants from the hospital pharmacies and medicine dispensaries in a national survey.[13, 15]

The figure illustrates the coverage of the clinical pharmacy services in the stages of the medication use process by applying Reason's Swiss Cheese Model.

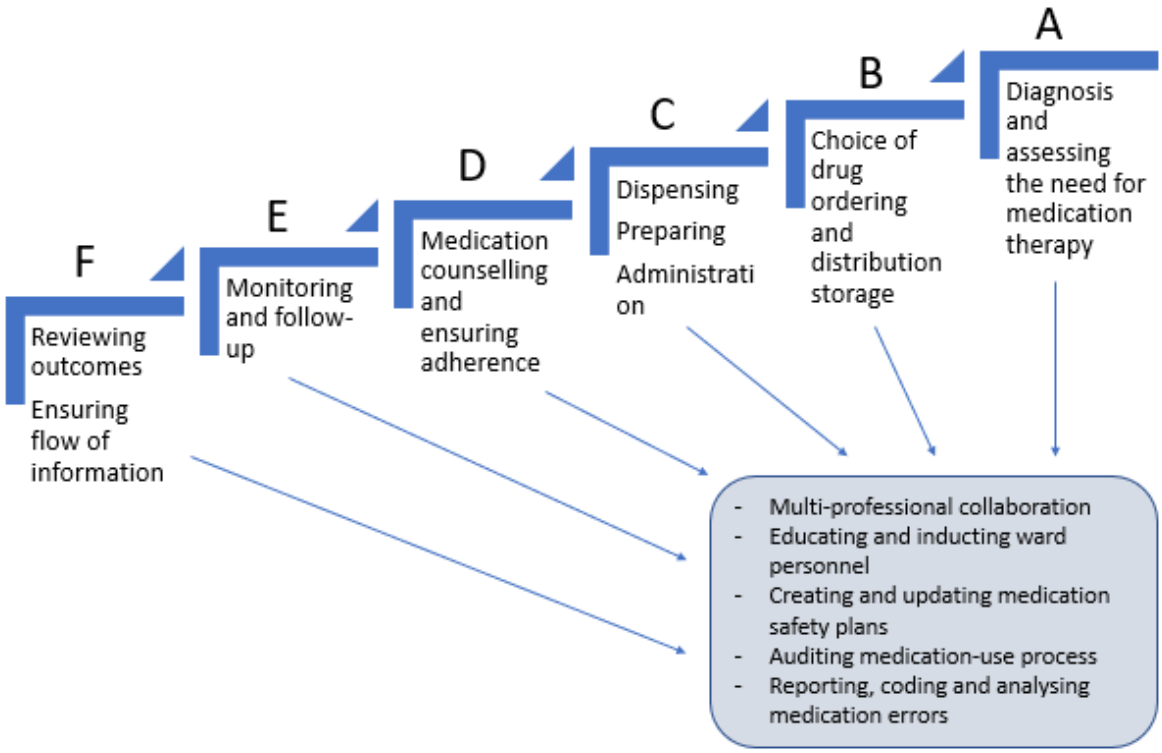


Figure 8. An example of application of the Reason's Swiss Cheese Model to medication safety: evolution of the tasks of clinical hospital pharmacists in Finland

3.2 Creation of safety culture in medication use management

According to the systems approach, active failures and/or latent failures can contribute to adverse events. Active failures are the human mistakes, while latent failures are at-risk situations or phases in the process (i.e., holes in cheese) that have predisposed the system to have active failures that lead to adverse events. These holes in the cheese may be due to imperfect or missing potential defences. Latent failures will always be present in a process. It is important to evaluate the system and processes to identify points of failure and potential contributing factors to the failures in order to reduce or eliminate them. Examples of methods applied to evaluate the safety of the medication use process include:

1. Retrospective methods, such as learning from medication error reports, root cause analysis of contributing factors to severe errors (what happened and why), and analysis of patient records.
2. Prospective methods, such as failure modes and effects analysis.

The systems approach promotes two broad strategies to mitigate or prevent errors. First is to prevent the initial source of the error. However, this is not always possible. The second strategy is to introduce defences to address the system's problems and risks. Examples of risk reduction strategies include: protocols, checklists, medication lists, medication history taking, medication reconciliation and review, enhanced communication among pertinent individuals (e.g., patient, physician, nurse, pharmacist), and increased access to important patient information. These actions can reduce the likelihood that all the holes in the cheese will align, reducing the overall system's potential for harm.[48] Regardless of the solution, continuous risk evaluation needs to be employed to optimise results. It also needs to be kept in mind that not all defences implemented in the system are effective. Thus, their effectiveness needs to be critically evaluated in terms of clinical, humanistic, and economic outcomes. These evaluations form a growing area of health technology assessment.

Although a number of initiatives to improve safety have been implemented by health care organisations, the effectiveness of these interventions has been diminished by a negative safety culture.[50, 51] Poor engagement with the safety interventions of the practitioners, particularly those at the coalface, can be a reflection of the negative safety culture.

The biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm.[52] A number of factors, including cost efficiencies, inability to acknowledge fallibility and the professional norm of perfectionism and hierarchy, combine to create a culture that is considered a potential risk factor and one of the greatest barriers to improving patient safety.[50, 53]

The way "*we do things around here*" influences not only how things are currently done, but also the likelihood that a newly introduced initiative will fail or succeed. Culture can help or hinder the implementation of an innovation like polypharmacy management or counselling patients on their medications. In fact, failure to account for organisational culture is one of the main reasons cited when evaluating why planned change initiatives are not able to overcome barriers. Not only should the culture of the entire health system be considered, but also cultural norms within professions involved.

3.3 Measurement of safety culture

There has been a growing interest for health systems and organisations to evaluate safety culture as part of their efforts to improve patient safety and quality of care. Thus, safety culture assessments have been integrated as part of other evaluation activities. In the literature, the term safety culture is often used interchangeably with the term safety climate. However, safety climate specifically refers to the employees' perceptions of the safety culture of an organisation at a particular point in time.[54, 55] In fact, safety culture of an organisation cannot be directly evaluated, so an alternative approach is to evaluate an organisation's safety climate. Safety climate assessments are often used by health care organisations and institutions for several purposes, including:

- identifying safety issues that require improvement;
- raising patient safety awareness;
- evaluating patient safety interventions;
- performing benchmarking;
- being part of directives or regulatory requirements.[53]

For health systems to evaluate safety culture, a multilevel ethnographic approach is required to understand the elements of safety culture which are not necessarily visible. It is important to pull from a variety of data sources in order to obtain a robust and complete picture of medication safety.[56] Such picture of "*safety climate*" is often used to evaluate the safety culture of an organisation.[57] The purpose of measurement is to learn and improve. Ultimately, measurement serves as a mechanism for feedback and accountability. There are various sources of metrics for determining the relative safety and/or quality of a health care process. Data may include:

1. voluntary error reports submitted through (formal) reporting programmes;
2. automated trigger tools (e.g. using naloxone as a marker for opioid overdose);
3. direct observation of errors;
4. reviewing electronic or manual patient charts;
5. data from technology applications and hardware, including smart pumps, automated dispensing cabinets, and electronic medical records;
6. data from dispensing records

It is important to remember that each of the data sources have their strengths and limitations. This is one of the reasons why multiple measures of safety are necessary to obtain a more accurate assessment of safety in an organisation. Repeated assessments of safety are particularly useful for evaluating changes over time.

Pharmacist involvement is essential in:

- planning the measurement strategy;
- carrying out data collection, analysis and interpretation;
- implementing necessary changes guided by the measures taken.

Pharmacists could perform as responsible managers for these actions, e.g., in the role of medication safety officers. It is also important to involve as wide a range of health professionals as possible in safety work, as their likelihood to report data on errors and events increases if that information is transparent and used for learning purposes to improve practice.[58]

Survey tools are commonly used to measure the safety climate. However, the survey tool needs to be carefully selected, taking into consideration whether the tool has been validated to measure safety climate in the specific population of interest. This is to ensure that the desired outcomes are actually being measured.[59] In the absence of such a validated survey tool, it is recommended to use a survey tool that has been previously used in a population with similar characteristics, rather than developing a new evaluation tool.[55] The following four criteria have been recommended to be used for selecting a tool for a safety climate evaluation.[53]

- the cultural domains or attitudes that are being assessed by the tool;
- the profession that the tool has been previously used;
- the setting for which the tool was developed;
- the validity and reliability analyses that have been conducted on the tool.

In community pharmacies, the organisational structure, for example where there may be a single pharmacist working who owns and runs the practice, needs to be considered in the safety culture evaluations. This is because the same kinds of systems and infrastructure to monitor and manage safe practices may not exist and/or apply that are regarded as a standard in secondary or tertiary care settings. Thus, measures that are valid in large, specialised care units in inpatient care may not be valid in outpatient units and community pharmacies. There have been several specific tools developed to assist community pharmacists in improving the safety culture within their practice (although community pharmacy systems vary a lot by country).[53]

3.4 Role of leadership for safety culture change and implementation

Adapting to the systems-based safety culture must employ a new approach: one that embraces the skills of the members of the health care team, and one that has the leaders of the organisation positioned to improve patient safety. Creating a new safety culture requires a new set of leadership skills integrating principles of systems approach to patient safety with contemporary management principles. Acquiring these leadership competences should be part of the standard curricula of all health care professionals. Also, postgraduate academic and residency programmes should include these leadership competences in medication safety as a separate career pathway to attract pharmacy graduates to a career path focussing on patient and medication safety within organisations.

The toolbox of those working in leadership positions and ensuring patient and medication safety in their organisations must include a wide range of management tools, such as continuous quality improvement, team-building, tracking and assessing progress, communication, and cultivating innovation, to promote transformational changes in safety programmes. The most successful leaders are those who make every decision with the patient in mind and employ change management skills to implement and promote safe practices.

Change management is a skill needed to be employed by pharmacists and other health care professionals around the world to adapt to the change in safety culture, i.e., shifting from a blaming culture to a systems approach. Some changes require methodical and incremental moves while other changes are "*transformational*". Transformational change is the result of a tangible shift in the business culture of an organisation and its underlying strategies and processes. This type of change requires strategic planning, solid leadership, and unwavering support. Instead of methodically implementing new processes, the system may be drastically transformed, altering and expanding the limiting mindset in which the individual or organisation operates. When discussing a mindset, we are referring to attitudes, perspectives, rationales, and logic. An impetus to transform is also required. In other words, if no one thinks the ship is sinking, it is difficult to get people to abandon it. If there is no obvious reason, or impetus, to change, then it is very difficult to motivate change. As part of the transformational change, resources must be allocated to support the organisation goals and a plan to integrate change must cross traditional intra-organisational boundaries. Individual components of change should also be discussed and implemented.

A good leader and manager should involve employees in all phases of the transition to ensure success. Through all types of change, and specifically transformational change, leaders can create organisational environments that are best positioned to support safer use of medications. For example, Kotter's 8 Step Process For Leading Change[60] in combination with strong leadership have been shown to be adaptive to drive change.

In some organisations and health systems, a change towards a safety culture may require a transformational change. This can generate anxieties, since the activities required are different, and there may be a loss of existing roles. Individuals may need to be challenged with the reasons why to break the status quo. Major change often requires the whole organisation to change. Allowing individuals to have a role in a collaborative solution development helps to build momentum, ownership and sustainability. Leadership needs to acknowledge that there will be resistance to change and it is best to anticipate the barriers to the process. Continuous reflection in this aspect of change is important and resolving individual's anxieties is often one of the most challenging aspects of this type of work.

3.5 The need to improve safety culture in pharmacies

There has been a global acknowledgement of the need to improve safe practices within both community and hospital pharmacies. For instance, more than half of the community pharmacists surveyed in Malaysia think patient safety should be improved.[61] There is a need to support staff through appropriate training, such as communication skills for patient counselling. There is also a need to improve communication between shifts to avoid mistakes.[61] Another common theme regarded as a barrier to patient safety is heavy workloads. Community pharmacists complain that they do not have enough time to perform patient safety activities since they are too busy with their dispensing tasks. Their workflow is also constantly interrupted with new tasks that have arisen in the pharmacy. The heavy workloads and constant interruptions in their working environment produce more burnout and are associated with more dispensing errors, which directly endangers patient safety.[62] More importantly, pharmacists' risk management skills need to be addressed. A national survey conducted in Finland among community pharmacists to assess their risk management practices while routinely dispensing revealed a big gap in their medication risk management skills. Some pharmacists stated that they need to be more confident when addressing certain issues regarding patient care. These need to be addressed in order to improve the patient safety environment in outpatient pharmacy settings. Moreover, further studies are needed to identify potential root causes and contributing factors that lie in the system itself.

Overwhelming workload and inadequate time have been identified as common contributing factors to negative patient safety cultures.[63-67] Hospital pharmacists are so overwhelmed by administrative tasks that they do not have time or energy to address patient safety issues. Inadequate knowledge and training are another common theme.[63, 66] The lack of expertise prevents hospital pharmacists from providing suitable recommendations in situations where patient safety is endangered. Hospital pharmacists also report negative attitudes from doctors and nurses due to personal ego, conflicts between different professionals, and difference in hierarchical status and authority.[68] Moreover, the lack of a good error reporting system also acts as a barrier to a positive safety culture.[19, 63, 69, 70] Therefore, better protocols when facing patient safety issues, appropriate training and education, and reasonable work responsibilities for pharmacists are needed in order to improve patient safety cultures for hospital pharmacists. It is also proposed that medication errors identified and addressed by pharmacists should be documented and assessed to identify pharmacists' contribution in each case. This will help justify pharmacists' participation in addressing patient safety and raise the awareness of other health care professionals and policy makers on the value of pharmacists in a multidisciplinary team.[63, 69]

4 Pharmacists' roles and contributions to patient and medication safety

"The ultimate goal of the services of pharmacy must be the safe use of medicines by the public." Donald Brodie[71]

Pharmacists are in a unique position to address the challenges related to medication use. They are well-positioned to minimise safety risks related to the entire medication use process. They have key roles in:

1. ensuring the appropriateness of prescription at initiation of treatment;
2. ensuring safety in transitions of care between hospitals/other health care units and the community;
3. ensuring the accurate supply of medicines;
4. ensuring patients are using their medicines in the correct way; and
5. identifying and resolving clinically significant, potentially harmful medication-related problems.

Thus, pharmacists can focus their expertise and apply their knowledge and skills in medication optimisation and adherence, prevention of illness and safety incidents, adoption of best practices, patient self-management and monitoring, and collaborative health care to improving patient safety in both the outpatient and inpatient settings, pharmaceutical industry, and regulatory and policy sectors (Figure 9). This chapter will give a brief overview of pharmacists' roles in different settings and following chapters will provide more specific examples of pharmacists' contribution to ensuring patient safety and what could be done to improve patient safety by pharmacists.

Examples of pharmacists' contribution to improved patient safety:

- Ensuring access to safe and effective medications
- Supplying medication information
- Medication review
- Improving medication adherence
- Providing health and wellness services
- Optimising medication use
- Delivering medication management services
- Assessing patients' health status
- Preventing illness
- Supporting self-care and self-management
- Monitoring impact of therapy
- Implementing collaborative health care
- Reporting and investigating medication incidents
- Contributing to policies and procedures around safe medication use

Figure 9. Common pharmacists' activities for improving patient safety

Outpatient pharmacists consist of both community pharmacists who work in the retail setting, and ambulatory pharmacists who work in outpatient clinics or health care facilities. They play a key role in managing patient and medication safety in the primary care setting, and have the greatest opportunity compared to other health care professionals to improve patient and medication safety due to their frequent contact with the public.[72] For example, in Australia there are approximately 449 million individual visits every year to a community pharmacy compared to 140 million to general medical practitioners.[73] This significantly higher number of visits correlates to a larger number of opportunities for community pharmacists to ensure patient and medication safety.

Pharmacists in hospitals and other inpatient settings play a critical role in ensuring patient safety when working alone or as a member of the health care team. The American Society of Health-System Pharmacists (ASHP) published the 2019 update from the Pharmacy Accountability Measures Work Group regarding quality measures that health-system pharmacy can implement to ensure patient safety.[74] This update included measures such as International Normalised Ratio (INR) monitoring for patients on warfarin, venous thromboembolism prophylaxis in the intensive care unit, glycaemic control, and opioid use. Having pharmacists as a full member of the health care team has been proven to substantially reduce adverse drug events caused by prescribing errors.[75, 76]

Patient and medication safety begin at the point of medication development and production. Pharmacists in industry work diligently to develop new medications that are safe and effective. The medication development and approval process plus post-marketing surveillance ensure that medications are safe to use. Pharmacists in pharmaceutical companies also serve as the medical service liaison between the industry and prescribers and educate prescribers on how to use new medication appropriately.[77]

Nowadays, there are technology solutions for error reporting, enabling pharmacies or institutions to record, review, and analyse patient safety incidents quickly and securely. Detailed reporting helps to learn from errors that have occurred and can contribute to continuous improvement. One such platform is Pharmapod (currently available in UK, Ireland, and Canada) that enables pharmacists to systematically record medication-related incidents to derive intelligence and identify risks in practice that contribute to errors and implement mitigation processes for improvement.[78]

4.1 Roles and Contributions

To be safe, pharmacotherapies used in any setting require well-designed care processes both for individual patients and at the organisational level. As medication safety risks have been identified as one of the most important preventable factors jeopardising patient safety, international patient safety initiatives have prioritised strategies and policies to improve safe medication practices. These strategies have emphasised the creation of a safety culture, learning from medication errors through reporting systems, and development of preventive actions for potential risk management. To manage these risks, extending pharmacists' involvement in patient care and patient safety work has been increasingly addressed in patient safety initiatives.

With regards to medication use, the definition of patient safety could be rephrased as the absence of preventable harm or the reduction of risk of unnecessary harm to a patient during the medication use process. The medication use process is a multistep process that consists of (1) prescribing, (2) transcribing and documenting, (3) dispensing, (4) administering, and (5) monitoring. The process is interprofessional in nature, and even though the process differs in inpatient and outpatient care, physicians usually prescribe and make the treatment decisions, pharmacists usually dispense the medications and provide patient counselling, support self-management and adherence, and monitor effectiveness of the therapies. Nurses' tasks are also related to counselling, self-management and adherence support, and monitoring the effects of treatments.

Traditionally, pharmacists' contributions to avoiding errors in the medication use process have primarily focused on the medicine supply chain such as ensuring proper storage and preparation. During the last decade, the pharmacist's role has extended towards patient care-oriented tasks. Pharmacists' current routine tasks include, ensuring the proper prescribing of medicines with appropriate dose regimens and dosage forms; clarifying instructions on medication use; preventing potential medicine-medicine and/or medicine-food interactions; avoiding known and predictable adverse drug reactions; minimising unnecessary treatment and considering the cost of medicines.

Annex 1 provides evidence of the effectiveness/outcomes of pharmacists' contributions to patient and medication safety as demonstrated via recent systematic reviews (2013-May 2018). Five major databases (PubMed, Web of Science, BioMed Central, Ovid, and International Pharmaceutical Abstracts) were searched in May 2018 for recent systematic reviews and meta-analyses that have involved pharmacists or pharmacy services regarding patient and medication safety, and which were published between 2013-2018. The review was conducted by Dr Claudia Martin, University of Florida, USA, Oraj Ozbek and Aksun Talu, Yeditepe University, Turkey, Eveliina Määttänen and Prof. Marja Airaksinen, University of Helsinki, Finland.

A total of 18 systematic reviews and meta-analyses were identified published in the period 2013-May 2018 (Figure 10). Of these, eight were related to pharmacists' contributions to patient and medication safety in hospitals and/or in transitions of care, six in community pharmacy setting, and two in outpatient clinics.

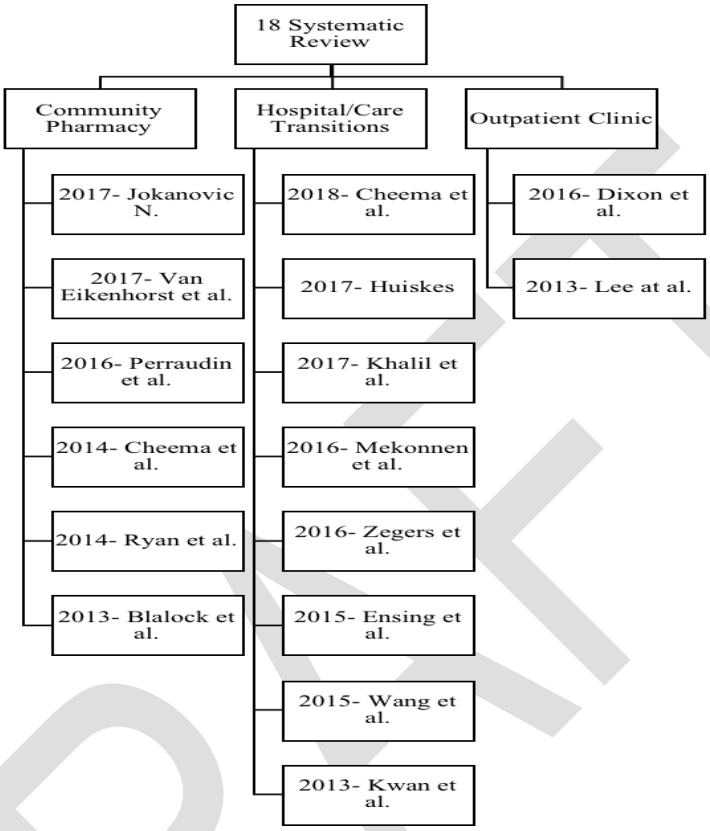


Figure 10. Systematic reviews (n=18) on pharmacists' contributions to patient and medication safety in different settings included in the inventory from the period 2013- May 2018.

4.2 Medication use process

Pharmacists are the ultimate experts in medicines and their use. Therefore, they need to ensure patient safety throughout the medication use process. The medication use process is defined as a combination of interdependent steps that share the common goal of safe, effective, appropriate, and efficient provision of pharmacotherapy to patients. Key stages of the medication use process are: selecting and procuring; storage, prescribing; transcribing and verifying/reviewing; preparing and dispensing; administering and monitoring,[6] with the order and details of these stages likely to vary between countries and settings.

The US Institute for Safe Medication Practices (ISMP) has developed a comprehensive description of the Key Elements of the Medication Use System™ for Hospitals and Community Pharmacies.[79] These key elements include medication prescribing, order processing, dispensing, administration, and effects monitoring. These elements have served as important tools for hospital pharmacists for internal audits and can also serve as a checklist for pharmacists when they are performing their daily duties. They are a very good starting point, but institution-specific data and evidence needs to be collated and used for patient safety outcomes. These key elements are:

1. **Patient information:** Obtain the patient's pertinent sociodemographic information (e.g. age, weight, health literacy level), clinical information (e.g. allergies, lab results), and medication history.

2. **Medication information:** Provide accurate and usable medication information to all health care practitioners, patients and carers involved.

3. **Communication of medication information:** Miscommunication between physicians, pharmacists, and nurses is a common cause of medication errors. Therefore, it is important to ensure effective communication amongst all members of the health care team.

4. **Medication labelling, packaging and nomenclature:** Medication names that look-alike or sound-alike, as well as products that have confusing medication labelling and non-distinct medication packaging can significantly contribute to medication errors. Extra care needs to be taken in double checking and ensuring that effective processes are in place to minimise errors.

5. **Medication storage, stock, standardisation, and distribution:** Standardise medication administration times, medication concentrations, and limit the dose concentration of medications available in patient-care areas. Store medications appropriately and safely.

6. **Medication device acquisition, use, and monitoring:** Appropriate safety assessment of medication delivery devices, such as infusion pumps, should be made both prior to their purchase and during their use.

7. **Environmental factors:** Environmental factors that can often contribute to medication errors include poor lighting, noise, interruptions and a significant workload. This should be minimised and avoided, if possible.

8. **Staff competency and education:** Staff education can be an important error prevention strategy when combined with the other key elements for medication safety. Staff competency should be checked periodically, and further and appropriate training should be provided, if applicable

9. **Patient and public education:** Patients and carers can play a vital role in preventing medication errors when they have been encouraged to ask questions and seek answers about their medications. Increased understanding of medication and its appropriate use can lead to fewer medication errors and adverse drug events. According to WHO, everyone, including patients and health care professionals, has a role to play in ensuring medication safety. WHO has developed a tool to increase public awareness of the safety issues related to medication use and the need for safer medication practices.

   The WHO tool "*KNOW. CHECK. ASK*." encourages and empowers both patients and their caregivers and health care professionals (for example nurses, physicians, pharmacists) to take an active role in ensuring safer medication practices and medication use processes including prescription, preparation, dispensing, administration, and monitoring. Pharmacists are invited to use the posters and all available tools that are freely available on the WHO website.

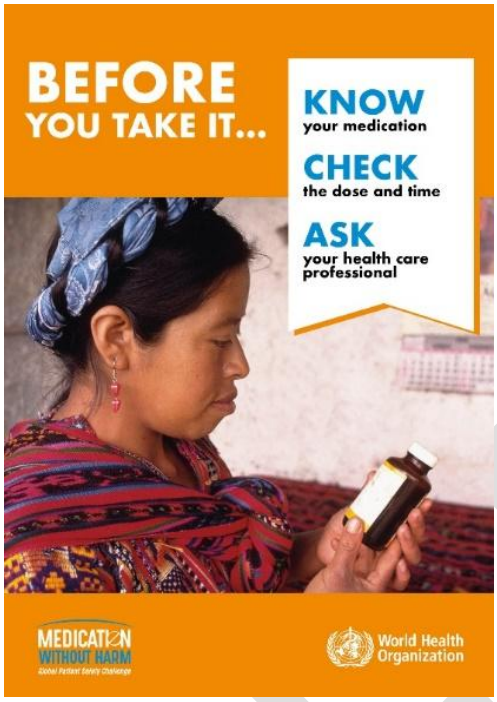


Figure 11. WHO patient empowerment material for improved patient safety: Before you take it… KNOW. CHECK. ASK.[5]

10. **Quality processes and risk management:** The way to prevent errors is to redesign the system using a systems' approach rather than focusing only on correcting the actions of individuals who made the errors.

Effective management of the above key elements by pharmacists and other pharmacy staff can help ensure patient safety throughout the medication use process in the health-system continuum.

5 Patient safety in the medication use process

This section reviews and discusses some of the potential key risks to patient safety during the medication use process. It presents strategies to minimise such risks, specifically how pharmacists can assist in mitigating the risks and ensuring patient and medication safety.

5.1 Access to medications

Access and availability of medications is one of the initial steps to consider when planning for patient and medication safety. However, not everyone is able to access safe and effective medications in a timely manner. Pharmacists play an important role in ensuring that their patients receive their medications in a timely manner. Whilst direct supply by pharmacy staff or by a courier is an effective option, this may not be practical in all circumstances, e.g. to remote communities. For patients on long-term (chronic) medications who have difficulty obtaining medications (e.g. living and working far away from a pharmacy) alternative models of distribution of pre-dispensed medications could assist with increased access and improved adherence to therapy, as medication parcels can be distributed directly to the patient's home or to a facility closer to where a patient lives or works. These pre-dispensed, patient-ready medication parcels need to be correctly received, stored, controlled and supplied, and prescribed by legislation to ensure medicine stability and correct supply chain.[80] To enhance patient safety, qualified pharmaceutical personnel should provide medication instructions and information regarding the correct use of medicine provided or address other health-related concerns of the patient. The facility from which this service is rendered, should be linked to an approved pharmacy, not necessarily the same pharmacy who dispensed the medication parcel.

In order to ensure that the correct medication is being provided to the patient and that the patient is able to take the medication appropriately, the pharmacist must communicate with the patient via telephone to collect relevant patient history and demographic information, and provide medication counselling. As with Remote Automated Dispensing Units, the pharmacist must ensure patient safety when consulting with the patient to ensure complete understanding of therapy.

5.2 Dispensing and supply of medications

The dispensing and supply of medications is at the core of a pharmacist's role in inpatient and outpatient settings. It is also the first step of the medication journey for patients and part of the continuous cycle of medication taking for those on chronic therapy. The process of dispensing, however, has a wider scope than simply labelling and handing out a medication. This section looks at the steps involved in the dispensing and supply of medications, highlighting potential areas where patient safety can be compromised and what pharmacists do, and could do, to minimise errors and harm to patients.

5.2.1 Common dispensing errors

There are many kinds of medication errors that can happen when dispensing medications to patients (Figure 12). Most of the errors take place because the pharmacist has not performed an adequate final product check or failed to perform required patient counselling.[81]

Common errors that can happen in the community pharmacy or outpatient setting:

- Patients receiving the incorrect medication or strength of medication;
- Prescription labels containing incorrect information, or information inconsistent with the original prescription;
- Patients receiving the incorrect quantity of medication;
- Patients receiving an expired medication;
- Patients receiving medications which were incorrectly compounded; and
- Pharmacists not detecting drug interactions or clearly documenting allergy information, resulting in adverse effects for the patient;
- Patients receiving someone else's prescription medication;

- Patients receiving another brand of a medication they already have (e.g. with brand substitution).

Figure 12. Common errors that can happen in the community pharmacy or outpatient setting

It is important to make sure that the right patient is getting the right medication at the right strength and double check that the medication has not expired. Pharmacists should also provide counselling and allow patients to ask questions before receiving the product.[81]

Some medication errors which have occurred in outpatient settings have been prescribing errors such as wrong dose, frequency, or route of administration.[82] Although electronic prescription and electronic prescribing tools can help reduce error compared to the traditional paper prescription, pharmacists should double check each prescription carefully to ensure the selected medication, dose, frequency, and route of administration are appropriate for the patient before dispensing the product.[83] More advanced electronic prescribing systems that include dose and frequency checking tools may help further decrease the rate of prescribing errors if the system is well set up and used.[84]

5.2.2 Patient counselling

Adverse events related to medications are common but many are preventable or ameliorable if they are detected and reported.[85] Community pharmacists, due to their regular contact with patients, are in an ideal position to detect and report any adverse events experienced by their patients. Importantly, community pharmacists, through patient counselling, can educate patients about correct and appropriate medication use, potential medication side effects, interactions between medication and food, and potential allergic reactions, and advise patients about the course of action should they experience any adverse reactions. Patient education and counselling are important strategies for empowering patients to self-manage their medications on a daily basis, and ensure that they are using their medications safely and appropriately.

Hospital pharmacists can also improve patient safety and minimise or prevent adverse drug events by providing patient counselling. During hospital stays and at discharge, it is critical to educate patients on how to take their medication and to provide pertinent information such as drug-drug-interactions and drug-food-interactions in patient-friendly language.[86] In a study of medications for chronic obstructive pulmonary disease (COPD) conducted in Vietnam, pharmacist-driven patient counselling on inhaler technique and adherence improved the quality of life of patients with COPD and prevented worsening clinical outcomes and adverse drug reactions due to non-adherence.[87]

5.2.3 Medication reconciliation

Pharmacists play a key role in medication reconciliation processes, notably, when patients are admitted to or discharged from a hospital or care facility. In an inpatient setting, medication reconciliation reduces discrepancies between a patient's home medication list, how a patient is taking the medications, the inpatient medication list, and the discharge medication list. This helps to ensure that patients are on optimal therapy based on their most up-to-date conditions and to prevent potential adverse drug events.[88] Interventions that a pharmacist can make during the discharge medication reconciliation process which can reduce the number of medication errors, prevent potential adverse drug events, and improve patient safety include, restarting an omitted medication, removing duplicated therapy, adjusting incorrect medication dose or quantity[89], resolving medication discrepancies, and reducing adverse drug reactions.[90, 91] Pharmacist medication reconciliation after discharge can also reduce readmission rates and improve monitoring of pharmacotherapy and the accuracy of the medication history.[92] Medication reconciliation is an effective way of preventing errors in the patient's medication history being compounded after a hospital visit, and ensuring other health care facilities can receive the most accurate and up-to-date medication history when the need arises. This process is particularly important in health care systems that are highly fragmented and where different health care professionals do not readily share information. A good example of a highly fragmented health care system is that in the United States.[93] In many cases, there is little communication between the hospital, outpatient pharmacy, and other health care professionals, which leads to gaps in medication history and inappropriate or duplicated medications.

The positive impact of pharmacists conducting medication reconciliation has been demonstrated in previous studies. A study in Brazil has shown that there are high numbers of unintentional discrepancies between the medication prescribed at admission and patients' home medications. The study concluded that pharmacist-led medication

reconciliation was highly effective in detecting and addressing medication discrepancies before they caused harm to the patient.[68] Similar conclusions were made in another study done in Bogota, Columbia. The study showed that medication reconciliation and medication history review which involve pharmacists during admission reduces the risk of potential adverse drug reactions and prevents clinical deterioration due to medication-related adverse events.[94]

5.2.4 Medication history access

For pharmacists to review the appropriateness of pharmacotherapy, it is imperative that they have access to a patient's complete medication history. Pharmacists can identify potential adverse drug events, drug-drug/food interactions, and duplicate therapy by reviewing the medication history. A study in the Netherlands showed that pharmacist intervention successfully, and statistically significantly, decreased the risk of upper gastrointestinal complications in non-steroidal anti-inflammatory drugs (NSAIDs) use.[95] The interventions included stopping NSAID use or adding a gastroprotective agent after receiving information about their patient's medication history. Another study in Japan revealed that community pharmacists were able to provide recommendations to almost half of the studied population concerning inappropriate (duplicated, contraindicated, etc) medications, interactions, potential adverse drug reactions, and overdose after a complete medication review.[96] This helps to prevent adverse drug events and detect prescribing errors. Both interventions would not be possible if the pharmacist did not have access to patients' medication history. Therefore, it is crucial for pharmacists to have access to their patients' medication history to ensure patient safety.

5.2.5 Prescription medication monitoring

Prescription medication monitoring in institutions and hospitals ensures that patients receive pharmacotherapy as intended by the prescribing clinician or specialist. Pharmacists have a role in prescription medication monitoring to identify medication-related problems, patient and medication risk factors that can compromise patient safety, and opportunities for optimising therapy. Whilst this role can be conducted by the pharmacist alone, working in a multidisciplinary collaborative health care team will facilitate the pharmacist's role and achieve a quicker and optimal outcome for the patient. This multidisciplinary approach has the primary objective of patient safety and optimal medicine use which includes the detection of early stages of adverse drug reactions and medication toxicity.[97]

An example of a pharmacist service delivered to a multidisciplinary team, is the ward pharmacy service. Ward pharmacy service is a patient-orientated, decentralised service which requires the pharmacist to become an integral and indispensable part of the professional health team of the hospital or institution. Ward pharmacists are required to utilise their knowledge and skills in terms of pharmaceutical sciences and product knowledge to ensure and promote safety, efficacy, and economic use of medicine in an advisory capacity to clinicians and nurses, and where needed in specialist care teams.[97]

5.2.6 Self-medication

Pharmacists working in an outpatient setting, especially community pharmacists, act as the last defence between the patient and the public and inappropriate self-medication with over-the-counter or non-prescription products. Self-medication is an important part of self-care. WHO defines self-care as the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a health care provider.[98]

Self-medication can be considered as the medication-related-decision-making of individuals with or without the assistance of health care practitioners. Self-medication can occur at any point, from selection of a medicine to administration of a medicine. For a medicine to be available for self-medication, the medicine must undergo a regulatory procedure to determine that it is safe, appropriate, and in the interest of public health.[99] The WHO's Guidelines for the regulatory assessment of medicinal products for use in self-medication recommends that a medication be available for non-prescription sale if: "*the use of the product has been sufficiently extensive or in high enough volume; the product has been marked on prescription for at least five years (to monitor for adverse events or the need for major changes to product information); and its adverse events give no cause for concern, and their frequency has not increased unduly during the marketing period.*"[99]

Though self-medication can provide wider and easier access to medications, this process is not without risks. The WHO report has identified several risks including:

- Incorrect self-diagnosis;
- Failure to seek appropriate medical advice promptly;
- Incorrect choice of therapy;
- Failure to recognise or self-diagnose contraindications, interactions, warnings and precautions;
- Failure to recognise that the same active substance is already being taken under a different name;
- Failure to recognise or report adverse drug reactions;
- Incorrect route of administration;
- Inadequate or excessive dosage;
- Excessively prolonged use;
- Risk of dependence and abuse;
- Food and drug interactions;
- Storage in incorrect conditions or beyond the recommended shelf life.[99]

As the custodians of medications, pharmacists can play a key role in ensuring safe self-medication.[100] This is particularly important today with patients turning more often towards the Internet for their health information. When presented with a direct product request in the community pharmacy, or with a question regarding a self-medicated product in a clinic visit, it is important that the pharmacist undertake several steps to ensure appropriate self-medication. These may include:

- Taking a detailed patient history to ensure that an appropriate diagnosis has been made and checking for any potential medication-related problems;
- Checking the source and accuracy of the health and medication information from the patient;
- If appropriate, supplying the product requested, providing the patient with clear and appropriate instructions for use, timeframe for use and timeframe to seek further advice from a pharmacist or other health care professionals, especially if there is no improvement in symptoms;
- If not appropriate to supply, considering alternative therapies such as non-pharmacological therapies that may be appropriate as well as referring to other health care professionals that may be able to provide appropriate management.

In addition to these steps, pharmacists should ensure that adverse events and inappropriate use of medications available without a prescription is reported to the appropriate local authorities. This will enable an understanding on a population level of the potential safety issues that may be faced with a product.

5.2.7 Automation

Technological advancement has introduced automation and telepharmacy to aid the medication use process. Many pharmacies nowadays utilise them to increase prescription fill numbers and to reach out to a wider patient population. Examples of automation include the automated dispensing units and remote automated dispensing unit:

- **Automated dispensing units** - also referred to as automated dispensing cabinets, automated dispensing devices, automated dispensing machines, automated pharmacy systems or unit-based cabinets, are mechanical systems that perform operations or activities relating to the storage, picking, packaging, labelling and/or issuing of medicines and medical devices. This may reduce medication selection and preparation errors.[101]
- **Remote Automated Dispensing Unit** may be used to dispense medications and devices for long-term (chronic) therapy in order to improve access to medications. Patient safety must be ensured when using this innovative approach, through audio-visual communication with the patient. More information can be found in the chapter 5.1.

Automation in health care is growing exponentially due to the rapid rate of technological advancements. Although sometimes heralded as a panacea for patient safety, automation is only one approach to eliminate human factors in contributing to medication safety incidents. One of the earliest forms of automation in the medication supply process was using barcode scanners during the dispensing process to check the correct selection of medications. Whilst this practice is mandatory in several developed countries, automation is now occurring in several other places in the medicine supply process. In the hospital setting, ward-based computerised automated dispensing systems have been shown to reduce error rates and costs.[102, 103] However, decentralised automated dispensing systems have been shown to have limited effect in reducing medication errors.[104] During the administration process, the use of electronic

medication records together with barcoded products have also been shown to be beneficial in reducing medication errors.[105] Automation has been implemented in community pharmacy to varying degrees. Automated dispensing systems have reduced the manual dispensing workload and have enabled community pharmacists to undertake greater clinical roles. However, there has been limited evidence to show the reduction of errors in the community setting.[106] Additionally, automation has been used in the repacking of medications into dose administration aids or monitored dosage systems. Studies have shown that there are significant rates of errors that can occur with automation.[107, 108] A number of technological advances have occurred since these studies were conducted, particularly in the automated checking of the repacked medication sachets to ensure a higher accuracy rate. However, automation is not a panacea, and its effect on errors made and therefore patient safety will depend on how well it is introduced and integrated into the routine processes in hospital and community pharmacies as well as other settings. Importantly, pharmacists' role in integrating automation and continuously ensuring quality remains essential.

Pharmacists need to be careful when they are providing services through telepharmacy since this is not the traditional face-to-face contact. It is harder to build rapport or spot an error through a screen or telephone compared to face-to-face interaction. Pharmacists need to make sure that all pertinent information has been collected and that there is no communication error during the interaction. They also need to pay attention to patients' health literacy during the interaction and use appropriate patient-friendly language, so all information is understood by the patients.

5.2.8 Unit dose dispensing

Unit Dose Dispensing (UDD) is useful for a patient who has practical problems in managing their medicines and/or maintaining independent living. UDD dispenses the medications in a single-dose package. The use of original medication packaging is preferred for medication supply to ensure stability. However, by providing a UDD service to patients, the pharmacist must be aware of the risk of removing a medicine from the original packaging and the legal requirements to ensure stability of the product, as well as ensuring that dosing is at the correct intervals, and balance this with improved adherence.

5.3 Monitoring medication use

5.3.1 Therapeutic outcomes monitoring

Therapeutic outcomes monitoring allows for adjustments to doses in order to obtain maximum clinical benefit and limit potential unnecessary toxicity through measurement and close monitoring of plasma concentrations of the medication. Pharmacists have an important role in the interpretation and communication of results from these reports. The reports and documentation become part of the patient's health record,[97] and can therefore be used to monitor progress and ensure patient safety.

Ambulatory care pharmacists are also able to monitor the outcomes of other therapies through direct monitoring, such as, blood pressure therapy, blood glucose therapy, and anticoagulation therapy by taking point-of-care blood pressure, blood glucose, and INR levels, respectively. Pharmacists can also make recommendations to modify existing therapy based on the outcomes of the testing. All these activities help to monitor patient outcomes and symptoms of adverse drug events. Pharmacists therefore can aid physicians and other health care providers by providing feedback on medication use and patient safety issues.

5.3.2 Polypharmacy and deprescribing

As polypharmacy becomes more common due to an ageing population living longer with several chronic medical conditions, pharmacists have an increasing role in identifying inappropriate polypharmacy, and recommending appropriate deprescribing, especially where the risk of harm outweighs any potential benefits.[109] Pharmacists can serve as effective facilitators between prescribers and patients, and support appropriate deprescribing and related patient education to ensure patient safety.

5.3.3 Safe disposal of medicines

Pharmacists also serve as a great resource to educate patients on the safe disposal of unwanted or expired medications and medication return or take-back programmes. This can help prevent medications from posing a harm to the environment, and prevent inappropriate distribution and use of controlled substances and antibiotics.[110, 111]

5.3.4 Pharmacovigilance

Pharmaceutical companies are uniquely placed to monitor the safety of medications through the life of a medication, from development to use by patients. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible medication-related problems.[112, 113] The specific aims of pharmacovigilance are to:[112]

- improve patient care and safety in relation to the use of medications and all medical and paramedical interventions,
- improve public health and safety in relation to the use of medications,
- contribute to the assessment of benefit, harm, and effectiveness of medications, encouraging their safe, rational and more effective (including cost-effective) use, and
- promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

The number of staffs in the pharmaceutical industry involved in pharmacovigilance is growing. This has been in response to the high regulatory standards that have been set at national and international levels and the increasing requirement for post-approval monitoring set by national medication regulatory authorities. Post-marketing surveillance of medications is mainly co-ordinated by government agencies (such as the US Food and Drug Administration) or other national pharmacovigilance centres. They participate in collecting and analysing case reports of ADRs, distinguishing signals from background ‘noise’, making regulatory decisions based on strengthened signals and alerting prescribers, manufacturers and the public to new risks of adverse reactions. Greater integration of pharmacovigilance into clinical practice is still needed. Medication safety should feature in the medical and pharmacy curricula and include pharmacovigilance and/or post-marketing surveillance in the programmes. This document does not specifically discuss all pharmacovigilance issues as it is outside the scope of the report.

6 Pharmacists' value in collaborative health care teams

As medication experts, pharmacists can contribute to patient safety and therapeutic outcomes in a variety of health care settings, as reported in Section 5. Including pharmacists as a member of multidisciplinary health care professional teams will be an evidence-based approach to improve medication adherence, prevent adverse drug events and, subsequently, ensure patient safety.[86, 114]

Pharmacists do not work alone in the pharmacy. Pharmacy support personnel are critical in ensuring that patient safety remains a priority throughout the medication use process. Many organisations have successfully explored expanding roles for pharmacy support personnel, including pharmacy technicians. As pharmacists' scope of practice continues to expand, pharmacy support personnel become increasingly important, not only in relieving pharmacists of more technical roles, but also supporting pharmacists in more advanced and complex patient centred service delivery. With expanding roles, comes the need to engage in additional training. Therefore, pharmacists must strongly support the development of uniform education, training, registration, certification, and recertification of pharmacy technicians. Standardisation will be required at all levels of pharmacy technician practice.[115] Specific example of the expanded roles of pharmacy support personnel in different countries can be found in the FIP report: Technicians and pharmacy support workforce cadres working with pharmacists: An introductory global descriptive study.[116]

With the most extensive knowledge on medications, pharmacists can assist the interdisciplinary team by eliminating unnecessary, duplicative, or excessive pharmacotherapy during the medication-selection process. They can also help in identifying and resolving drug therapy problems, drug-drug/food interactions, and potential adherence barriers.[117] Researchers have shown that having pharmacists in interdisciplinary teams is associated with lower adverse drug events related to prescribing errors, reduced hospitalisation, and lower mortality rates.[118-120] However, there is a need to increase awareness of the value of pharmacists in health care teams, and implement appropriate policy changes to optimise the use of highly trained pharmacists to improve the quality of health care.[69, 117]

6.1 Advocate for the profession

It is also important for pharmacists to engage in advocacy initiatives for pharmacists to be more recognised as an integral part of the health care team that works to ensure patient safety.[121] Pharmacists are not yet recognised as primary care providers in many countries and many other health care professionals are not aware of how pharmacists can contribute to an interdisciplinary team. This can impede their work in patient safety in many ways.[117] Because of the differences in status, pharmacists can receive unfavourable attitudes from colleagues. Patients may not recognise the expertise of pharmacists which can therefore prevent them from trusting pharmacists and accessing high quality care. Therefore, documentation of interventions made by pharmacists to prevent patient harm and optimise patient care should be part of the routine practice of pharmacists. Furthermore, evidence needs to be collected to support the key role that pharmacist play in health care teams, in particular, of their contributions to patient safety.[66] It is critical to raise awareness so pharmacists can be better incorporated into activities related to patient care.

7 Medication regulation and patient safety

Patient and medication safety not only rely on the safe practice of individual health care professionals and effective health systems, but also on international and national legislation, guidelines and standards which underpin and provide the foundations for safe practice.

7.1 National agencies

Around the world, regulators of the pharmacy profession are constituted under national legislation such as Pharmacy Acts in the case of India or the Health Professionals Regulatory Act in the case of Ghana.[122, 123] Although different organisational terminology is used such as Board (e.g. Pharmacy Board of Australia) or Council (e.g. Pharmacy Council of Pakistan), they all have the same primary purpose, to protect the public by regulating the practice of pharmacy in their country.[124] It is predominantly mandatory for all those who are authorised to practice in any setting of pharmacy, as a pharmacist, in a specific country, to register with this regulatory body.[124] The activities of these regulators include keeping a register of individual pharmacists, facilities, and training providers; setting minimum standards and guidelines for licensure, practice, discipline, and education; and upholding professional standards through inspections and disciplinary processes. These minimum standards or practice guidelines not only provide a mechanism to standardise pharmacy practice and services to patients, but also to ensure patient safety and associated medication safety practices.

7.2 Package inserts and medication information

According to the US Food and Drug Administration (FDA), many medication errors can be avoided at the design stage by drawing on lessons learned from past medication errors and by conducting proactive risk assessments before marketing.[125] The pharmaceutical industry can contribute to reduced medication errors by adhering to global or local standards for the design of medication packaging and labelling that will maximise safety in use.[8] Labelling and packaging issues can cause up to 33 percent of medication errors.[126]

In some countries, e.g., in all EU countries, package inserts and patient information leaflets are compulsory for each product when pharmaceutical companies want to register their products. The purpose of patient information leaflets (PILs) is to improve patients' knowledge about the medication as well as adherence to the treatment.[127] However, patient safety can be compromised when the PIL does not reach the patient. Patients may not receive PILs when there is dispensing of smaller quantities from bulk supplies e.g. 20 or 30 capsules from a larger pack of 100 capsules containing a PIL; or when PILs are available electronically and not printed for patients by health care professionals (e.g. in Australia). Patient safety could be further compromised with a slow turnaround time at the medicine's regulatory authority when changes to the PIL and package inserts are requested, notably when changes are made to the list of the medication's side effects. Importantly, patient safety can be impacted when the PIL contains information that the patient cannot understand or act on, that is, where information has been written at a high level for the patient's health literacy, and the patient is unable to find the relevant information in the PIL, or understand the information provided.

Pharmacists can play several roles in this area. Firstly, they can advocate for the availability of user-friendly, quality patient information leaflets for all medications. Secondly, they can ensure that patients in all settings have access to, and receive, user-friendly patient information leaflets. Thirdly, they can ensure that patients understand all the important information listed on the package insert and patient information leaflets by effectively communicating with patients using patient-friendly language.

7.3 Medication names

Medicine names pose a risk to patient safety through look-alike and sound-alike (LASA) confusion, specifically for prescribers and dispensers. Pharmaceutical companies should be required to test proposed medicine names to identify and remedy potential LASA confusion with existing medicine names.[8] LASA confusion should be assessed during the registration of medicines, and companies should be discouraged from using names that look-alike or

sound-alike existing products. The European Medicines Agency suggests that authorities should ensure that the proposed name of a medicine does not sound similar to the name of another medicine; the labelling of a medicine does not look similar to the labelling of other medicines; and the instructions in the product information on the use of the medicine are clear so as not lead to medication errors.[128] Contributing to the LASA confusion is illegible handwriting, incomplete knowledge of medicine names, newly available products, similar packaging or labelling, similar clinical use, similar strengths, similar dosage forms, similar frequency of administration, and the failure of manufacturers and regulatory authorities to recognise the potential for error and to conduct rigorous risk assessments, both for non-proprietary and brand names, prior to approving new product names.[129, 130] Some examples include:

- Sound-alike brand names: Lasix® (furosemide – diuretic) and Losec® (omeprazole – proton pump inhibitor)[131] – to avoid confusion, brand name for omeprazole has been changed to Prilosec in the USA.
- Look-alike brand names: Eltroxin® 0.01µg and Eltroxin® 0.005µg
- Look-alike and sound-alike brand names: Pulmicort® Turbohaler (budesonide – oral inhalation) and Rhinocort® (budesonide – nasal inhalation).[131]
- Look-alike and sound-alike generic names: hydroxyzine and hydralazine
- Look-alike and sound-alike generic names: tramadol and trazodone

The WHO's International Non-proprietary Names Expert Group works to develop international non-proprietary names for pharmaceutical medicinal substances for acceptance worldwide. However, brand names are developed by the product's sponsor and often differ significantly between countries. It is therefore advised that pharmacists actively identify and manage the risks associated with LASA medications by annually reviewing the LASA medications used in their pharmacy and develop clinical guidelines on how to manage this in the pharmacy e.g. storing look-alike medicines away from each other on shelves and checking indication of sound-alike medicines.[132]

8 Learning from other industries

Many industries have incorporated safety measures in their everyday practice. High-risk industries, such as, aviation, railway transportation or nuclear plants, have developed safety models that could be adapted for health care.

8.1 Lessons from the aviation industry

The aviation industry is widely cited as a great role model for the health care industry regarding safety. The number of daily flights have doubled in the past two decades, however, the number of fatal accidents have decreased considerably.[133] The health care industry on the other hand, has a much higher number of fatalities due to preventable safety incidences and medication errors. It has been estimated that the annual number of preventable fatalities in health care is equivalent to 3 plane crashes every day. Pharmacists need to learn from the experiences of the aviation industry in order to improve patient safety.[133]

The aviation industry and health care industry have different priorities. The aviation industry focuses on safety and has introduced a blame-free culture and a robust error reporting system. In contrast, the health care industry has competing interests such as financial and economic factors and reputation of the institution that impact patient safety. For instance, patients may not be given the most appropriate medication due to their insurance coverage. Safety is an obligation to airline companies while it is only a priority to some members of the health care industry.[133] One of the most important steps pharmacists need to take is to increase awareness of safety issues in clinical settings and be conscious about patient safety when making clinical decisions.[133]

8.1.1 Checklists and technology

The human brain is subject to three cognitive limitations when executing a procedure. We may not remember to perform one of the steps, remember but for some reason do not perform the step, or execute the action incorrectly. Therefore, the aviation industry extensively utilises checklists to avoid solely focusing on the memory of pilots. Checklists are not as common in the health care industry. Pharmacists rely on their memory and experience to execute procedures every day. There is a need for checklists and electronic reminder systems to make sure no step is missed during a procedure and no mistake is made during the process. The importance of technology during the dispensing process has been shown in a study in the United States. In a hospital with more than 200 beds, the use of technology-assisted workflow in the IV room, a place for the sterile preparation of medications, was associated with detection of 14 times more errors compared to non-technology-assisted workflow.[134] Therefore, it is important for pharmacists to learn not to rely solely on memory and experience but to effectively utilise checklists and technologies such as electronic reminder systems to aid their work.[133]

8.1.2 Situational training

Simulators and situational training are used in pilots' training. Pilots undergo proficiency revalidation every few months to assess their continuous ability to perform all necessary tasks. The aviation industry also ensures that pilots have the necessary non-technical skills to handle safety issues, emergency situations, and avoid mistakes. Pharmacists on the other hand, are revalidated every few years and simulator/situational training are limited during their training. It is common for pharmacists to graduate from pharmacy schools and not know how to handle a situation when a medication error or safety issue arises. It is important to introduce situational training into the pharmacy curriculum, so pharmacists know what to do in the real clinical setting, when a patient's life is at stake. The protocol on how to avoid and handle medication errors should become a habit, an instinct. It is also very important to teach the non-technical skills such as leadership, team-work, decision making, situational awareness, stress management, and how to manage fatigue, in order to avoid medication errors in the first place.[133]

8.1.3 Working environment

Working environments for pilots and pharmacists are very different. Pilots carry out their day-to-day duties in what they call a "*sterile cockpit*", a distraction-free zone in which they can focus on the procedure they are performing. The cockpit is sealed off from the outside and there are strict rules and regulations on who can enter the cockpit during

the entire flight. Pharmacists, on the other hand, work in an environment full of distractions. Pharmacists' workflow is constantly interrupted by incoming calls, questions from the pharmacy team, emergencies that arise in other departments, etc. These interruptions negatively impact the procedures that are being performed by pharmacists, creating chaos and stress into the work environment, which increases the chance of error. There is a higher chance of making mistakes when a pharmacist must switch between tasks. These interruptions can lead to mixing up of patients' details, errors in calculations, failure to delete inappropriate medication use, or errors in prescribing, as well as potentially other mistakes. Therefore, a distraction-free work environment is very important to ensure patient safety[133].

8.1.4 Error reporting and learning

A plane is considered one of the safest modes of travel and the aviation industry has a highly successful Aviation Safety Reporting System. Charles Billings, the architect of this system, concluded that people do not report adverse events due to two major reasons: fear of embarrassment, punishment, litigation; and lack of belief that reporting will lead to improvement. These ideas sprouted from the "*blame culture*" in the health care industry in which individuals who are responsible for an error are blamed for the consequences. This encourages people to cover up errors for fear of retribution instead of reporting them for future improvements in the safety culture[135]. It is crucial for pharmacists to adapt the concept of "*just culture*" that focuses on identifying system flaws that can be resolved to promote patient safety, and move away from a "*pathological culture*", where failures are punished, covered up, or ignored and individuals who fall short during the patient care process be punished.[133]

9 Education and competencies

Pharmacy educators have a responsibility to educate future pharmacists on the key concepts outlined in this document. It is also important for practicing pharmacists to keep up-to-date with the current concepts regarding patient safety through Continuing Education and Life-Long Learning. Introduction and re-enforcement of the systems approach to process improvement must occur early in pharmacy training. Emphasising strategic process planning, data collection, analysis, and action throughout a student's education will help shift the international pharmacy paradigm from a culture of blame and inefficiency to one of synergy and coordination. Repeated interventions may be required to change and improve student pharmacists' attitudes towards patient safety and safety culture.[136] Teamwork between health care professionals and other stakeholders in the patient care process is essential for this model to be adopted successfully around the world.

Teamwork is best learned when students work within a team that is cooperating, communicating and collaborating. By learning together early in professional development, students have an opportunity to first be themselves, expose their vulnerabilities, and share a mutual excitement for learning before they take on their discipline-based professional persona.[137] Case-based learning in this context can be an effective strategy to help students understand and apply critical patient safety concepts. Case-based learning encourages shared problem-solving where team members have equal access to information, while experiencing a common (and shared) situational awareness. Educators are encouraged to use new models of teaching to explore and test knowledge in patient safety. Traditional teaching methods may need to give way to greater problem-based learning and role playing. Simulations provide opportunities for students to see the same or slightly modified scenarios over and over until they achieve competency with every procedure that involves risk to the patient. Through team-based models of training, we can better prepare the future workforce to provide the safest possible care to patients.

As health care professional become more and more aware of patient safety, research is needed to identify systematic approaches and methodologies that will help deliver patient care more safely. The WHO identified a set of core competencies regarding conducting patient safety research in 2008. In 2012, the WHO published *Patient Safety Research – A guide for developing training programmes* on how to develop these competencies through tailored training programmes.[138] The guide provides examples of learning objectives and steps for course development and educators can choose which competency to teach and how to teach the students according to their specific needs.

Ultimately, additional didactic and practice-based opportunities must be developed to sufficiently train the next generation of pharmacists in foundational and emerging patient safety methods. The "*WHO Multi-professional Patient Safety Curriculum Guide*" may help ensure pharmacists across the world have enough exposure to these critical principles.[29] The WHO previously developed a Patient Safety Curriculum Guide with a section on medication safety. As part of the WHO's Global Challenge "*Medication without Harm*", the medication-safety-related sections of this Curriculum Guide are being updated and will be made available as a standalone Curriculum Guide during 2019. Recognising the importance of teamwork in the context of medication safety, together with a culture of ongoing learning, the revised curriculum guide takes an inter-disciplinary perspective. It is designed to provide an overview of those aspects of medication safety that should be taught to undergraduate and postgraduate health care students as well as to practicing health care professionals. It also aims to encourage a culture of ongoing inter-professional learning and practice in relation to medication safety. The intended audiences are undergraduate and postgraduate health care students, practicing health care professionals, their educators, and relevant professional bodies. It is being designed to support inter-professional learning where possible, in which students or qualified professionals from different professional groups learn together and from each other to enable effective collaboration and improve health outcomes. Much of the material is structured around the four domains (medications, patients and the public, health care professionals, and systems and practices) and three priority areas (polypharmacy, transitions of care, and high-risk situations) highlighted by the Global Challenge.[24-26]

FIP published a global competency framework in 2012 which is suitable to use as a mapping tool for the creation of country-specific competency standards.[139] This framework was developed after conducting a comparative study with the aim of identifying common behaviours within existing frameworks used in seven other countries. Data obtained from this study was consolidated into four focus areas or domains:

- pharmaceutical public health (population focus);

- pharmaceutical care (patient focus);
- organisation and management (system focus); and
- professional/personal (practice focus).

Patient safety is a golden thread that runs through everything a pharmacist does every day, whether directly or indirectly. Behaviours positively impacting patient safety should be fostered during undergraduate studies.

Competencies directly impacting patient safety:

- counselling skills, advice, and provision of information;
- determination of appropriate medications for individual patients;
- dispensing skills;
- advising patients on medication storage and correct use;
- monitoring medication therapy and resolving any medication management problems for patients;
- identification of patient health-related problems based on signs and symptoms;
- development and adherence to standard operating procedures (SOPs); and
- promotion of health, wellness, and lifestyle.

Competencies indirectly impacting patient safety:

- effective and efficient supply chain management to ensure availability of essential medicines;
- responsible sourcing of medication;
- continued updating of knowledge and skills through continued professional development (CPD);
- adherence to national legislation, regulatory affairs, practice guidelines, code of conduct, ethics code, and good pharmacy practice guidelines;
- participation in research; and
- effective management of epidemics and/or disaster management.[139]

9.1 Quality assurance

For pharmacists to lead the improvement of hospitals and health-systems, they need to have a functional understanding of quality assurance in health systems. Some useful tools and models include the continuous quality improvement model, Plan-Do-Study-Act cycles, the Lean Production System, and Six Sigma.

10 Conclusions

Medicines are the most commonly used intervention in health care, and have an important role in curing and preventing diseases, and mitigating symptoms. Although effective, medicines can be challenging to manage and use appropriately, and even more so with increasingly complex pharmacotherapies, polypharmacy, ageing populations with multiple diseases, and limited, or not-well coordinated resources in health care systems. Growing evidence on patient harm related to medicines in health systems all over the world has created a need to develop new strategies to manage these harms. Safety culture creation through systems approach is crucial for changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm.

This reference document highlights the importance of ensuring patient safety at all levels - from policies and strategies at the global level, to the roles of practicing pharmacists in different settings. Underlying the actions of pharmacists and other health care professionals must be supportive public policy and law. The reference document provides a brief overview of some of the initiatives and activities of multinational, national, regional and local governments and non-government organisations.

Pharmacists are in a unique position to address the challenges related to medication use. The dispensing and supply of medications is at the core of a pharmacist's role in inpatient and outpatient settings. It is also the first step of the medication journey for patients and part of the continuous cycle of medication taking for those on chronic therapy. The process of dispensing, however, has a wider scope than simply labelling and handing out a medication and has extended towards patient care-oriented tasks. Pharmacists' routine tasks include, ensuring the proper prescribing of medicines with appropriate dose regimens and dosage forms; clarifying instructions on medication use; preventing potential medicine-medicine and/or medicine-food interactions; avoiding known and predictable adverse drug reactions; minimising unnecessary treatment and considering the cost of medicines. Pharmacists are generally expected to ensure the quality and safety of medication therapies in patient care, through collaborative care and patient interaction. This reference document provides many examples of current practices occurring in various parts of the world and is extensively referenced. The examples of pharmacists' roles are depicted in case studies from Europe, the United States, South Africa, India, Oman, Australia and Saudi Arabia.

Introduction and re-enforcement of the systems approach to process improvement must occur early in pharmacy training. It is also important for practicing pharmacists to keep up-to-date with the current concepts regarding patient safety through continuing education and life-long learning. Pharmacy educators have a responsibility to educate future pharmacists on the key concepts outlined in this reference document.

The practical tools are listed together with existing, freely-available resources for pharmacists to use. Many international organisations provide guidance and best practice recommendations. Valuable lessons can be learnt and implemented from other industries, such as use of checklists, technology, errors reporting and adjusting the working environment.

As medication experts, pharmacists play a vital role in ensuring the safe use of medications by patients. They are well-positioned to minimise safety risks throughout the entire medication use process. Therefore, pharmacists are encouraged to work with their local and national governments and regulating bodies to implement jurisdiction-specific patient safety initiatives.

11 Tools and resources

There are a multitude of international professional, regulatory and quality organisations that have a role in patient and medication safety, quality improvement, and regulatory compliance. Pharmacists are encouraged to work with their local and national governments and regulating bodies to implement jurisdiction-specific patient safety initiatives.

To assist pharmacists, there are international organisations that provide guidance and best practice recommendations. Some of these organisations are listed below:

- **World Health Organization:** As part of its core functions, the WHO works on patient safety policies and strategies in its member states. Clear policies, organisational leadership capacity, data to drive safety improvements, skilled health care professionals and effective involvement of patients in their care, are all needed to ensure sustainable and significant improvements in the safety of health care. It not only provides resources for the health care professionals, but also to patients and caregivers. For instance, the WHO published *5 Moments for Medication Safety* to guide patients and caregivers to consider medication safety during the care delivering process. The document identifies 5 key moments (starting a medication, taking a medication, adding a medication, reviewing medications, stopping a medication) and questions people should ask during these moments to ensure medication safety.[140]

    - WHO *5 Moments for Medication Safety* for patients and consumers
      https://www.who.int/patientsafety/medication-safety/5moments/en/

    - WHO Multi-professional Patient Safety Curriculum Guide
      https://www.who.int/patientsafety/education/mp_curriculum_guide/en/

    - WHO Patient Safety Research: A guide for developing training programmes
      https://www.who.int/patientsafety/topics/research/developing_research_training_programmes/en/

- **Institute for Health care Improvement (IHI)**: Founded by Don Berwick, MD, the vision of IHI is that everyone has the best care and health possible. To accomplish this, the mission of IHI is to improve health and health care worldwide. IHI is notable for their continuous quality improvement best practices and various other efforts to improve patient safety.[141] IHI also published the Open School Online Courses which students and junior practitioners can access for free to build competency. This online module is centred on quality improvement, patient safety, and person-centred care.[142]

- **Institute for Safe Medication Practices (ISMP)**: ISMP is one of the oldest and largest organisations which focuses on medication safety. Founded by Michael Cohen in 1994, ISMP's mission is to be the premier independent patient safety organisation that leads efforts to prevent medication errors and ADEs. The organisation works to advance patient safety worldwide by empowering the health care community, including consumers, to prevent medication errors. A few of ISMP's activities include: reviewing medication error reports and recommending improvements, publishing newsletters, and consulting. It defines and annually updates a high-alert medication list that focuses on, for example, antiarrhythmics, anti-thrombotics, opioids, sedatives, concentrated electrolytes. Examples of resources include:

    - Medication Safety Culture Indicator Matrix (MedSCIM)
      https://www.ismp-canada.org/download/hnews/201802-HospitalNews-MedSCIM.pdf

    - ISMP Gap Analysis Tool for Safe IV Push Medication Practices
      https://www.ismp.org/resources/gap-analysis-tool-safe-iv-push-medication-practices

    - ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy
      https://www.ismp.org/assessments/community-ambulatory-pharmacy

    - ISMP Medication Safety Self Assessment for High-Alert Medications
      https://www.ismp.org/assessments/high-alert-medications

- **Accreditation and The Joint Commission (TJC)**: Accreditation is an important concept directly related to the quality of care provided at a health care institution. Specifically, accreditation is a method for ensuring an organisation achieves and maintains high-quality patient care.[143] Patient safety is paramount for all accrediting bodies, and typically the accreditation process is voluntary. The international component of TJC, The Joint Commission International, "works to improve patient safety and quality of health care in the international community."

- **International Medication Safety Network (IMSN)**: The IMSN is an international network of safe medication practice centres that operates medication error reporting programmes and produces guidance to minimise medication errors.[144] An example of their guiding documents is the IMSN Global Targeted Medication Safety Best Practices, which has released in June 2019. The document provides three Targeted Medication Safety Best Practices regarding the safe use of methotrexate, potassium injections, and vinca alkaloids. Specifically, pharmacists are asked to perform extra verification and documentation for methotrexate prescriptions that are more frequent than once a week.[145]

- **Patient Safety Movement Foundation:** The Patient Safety Movement Foundation has developed more than 30 evidence-based solutions to over 17 patient safety challenges facing hospitals today. The solutions are updated every year to ensure their accuracy. The Patient Safety Solutions App provides users access to all Actionable Patient Safety Solutions and allows the user to share content across organisations and health care network.[146]

- **American Society of Health-System Pharmacists (ASHP):** ASHP has recommended quality measures for health-system pharmacy through the 2019 update from the Pharmacy Accountability Measures Work Group: https://doi.org/10.1093/ajhp/zxz069

12 Case studies

12.1 South Africa: Patient safety programmes

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In South Africa, the Pharmacy Council (SAPC) developed rules relating to good pharmacy practice (GPP) since 2004.[97] The core of pharmacy activity, listed as one of the GPP requirements, is the supply and distribution of medicines and other health care products, the provision of appropriate information and advice to the patient, ensuring the correct use of medicine and monitoring the effects of the use of medicines. These activities are known as pharmaceutical care.[97] In this reference, the following rules could minimise medication harm and increase patient safety in the practice setting.

12.1.1 Dispensing procedures

The dispensing of medicine is an integral part of the pharmacist's daily duty when working with patients. It could be to either prevent or treat a disease(s) on an acute or chronic basis. In this context, the dispensing process is divided into three phases, namely interpretation and evaluation of the prescription; preparation and labelling of the prescribed medicine and the provision of safe and effective use of medicine.[97]

From the first phase of dispensing, pharmacists play an important role in ensuring patient safety and reduce the potential harm associated with medication. The following precautions will assist the pharmacist to perform a first phase of patient safety measures[97]:

- Confirmation of the integrity of the communication (prescription) together with clear identification of the patient and prescriber, authenticity of the prescription to rule out drug abuse or misuse and clarify the type of treatment and the prescriber's intentions. Identify the medicine and check the dosage form, strength, dose, method of administration and duration of treatment and to inform the patient of the benefits and implications of generic substitution.

- Assess the prescription to ensure the optimal use of medicine by reviewing therapeutic aspects such as the safety of prescribed/needed medicine, possible contra-indications and medicine-medicine or medicine-disease interaction and potential treatment duplication. Further assess the appropriateness of the treatment for the individual and the indication for which the medication is prescribed, together with other social, legal and economic aspects.

- Pharmacist interventions in this stage includes communication with the prescriber regarding any identified problems from the evaluation process and discuss an acceptable plan of action to address these problems together with the prescriber and patient.

A different approach to patient safety is used during phase two of dispensing when the prescribed medication is being prepared and labelled. The three most common dispensing errors that occur in hospital pharmacies are selecting the incorrect item, strength or dosage form.[147] All dispensing procedures, regardless by whom it is performed, must always be carefully checked for accuracy and completeness.[97] Labelling of dispensed products must be clear, legible and indelible to minimise any potential harm caused by incorrect medication use by the patient. Cautionary/advisory labels assist in pointing out important medicine information out such as "*avoid alcohol*", "*complete the course*", "*may cause drowsiness*", "*take with food*", etc.

Comprehensive patient information and correct understanding thereof are critical in the correct use of medicines to avoid failure of therapy resulting in wasted resources and increased health care cost. When it comes to the provision of information and instructions to the patient to ensure the safe and effective use of medicine (phase 3 of dispensing), information must ideally be structured to meet the needs of the individual patient and must always be done with professional judgement. Administrative errors are the second most common medication error.[148] The pharmacist is

also responsible to assess the patient for signs of compliance, effectiveness, and safety of the therapy. If needed, the pharmacist should identify areas for modification while monitoring the patient outcomes.[97]

The purpose of providing patient information is to empower the individual to make their own decisions about their treatments and to take responsibility for their own health. It further encourages effective use of medicines, which will ultimately result in patient safety.[97]

12.1.2 Medicine management in hospital settings

In a hospital or institutional setting, medicine is dispensed for individual patients on a day-to-day basis. To ensure patient safety, a suitable lockable trolley for patients' medication must be available in the ward to separately store the medication of each patient in the ward. Any unused medication should be returned to the pharmacy after treatment is changed or the patient is discharged from the hospital, to avoid unnecessary medication errors.[97]

12.1.3 Pharmacist-initiated therapy

Patients approach the community pharmacist with a health-related question or concern such as advice on symptoms daily. Enough information must be obtained from the patient regarding their request for advice to ensure the pharmacist can conduct a proper assessment relating to who has the problem, what symptoms are experienced for how long, what actions or medication was taken to date to relieve the problem as well as other current medications used by the patient for known acute and chronic conditions.[97] Appropriate advice must always be given to the patient in the case of minor self-limiting health problems, and only when necessary should medication therapy be recommended.

It might be that the symptoms experienced are not due to a minor ailment but rather associated with a serious condition. When the pharmacist suspects the latter, he/she should refer the patient for immediate medical advice to another appropriate health care professional such as a general practitioner.

12.1.4 Medication selection

With new medication products entering the market almost daily, it could sometimes be difficult to determine the most appropriate medicine treatment out of so many options. To assist pharmacists and health care professionals in selecting optimal treatment which is evidence-based, countries should develop national standard treatment guidelines (STG) containing essential medicines list (EML). The rationale for developing and maintaining an essential medicines list is to provide equal access to medicines, improved supply of the limited items and therefore lower cost of medicines procured.

The WHO describes essential medicines as those that satisfy the priority health care needs of the population. Essential medicines are intended to be available within health systems at all times in adequate quantities, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.[149]

The concept of essential medicines incorporates the need to regularly update medicines selections to:

- reflect new therapeutic options and changing therapeutic needs as new products are registered and/or enter the market;
- ensure medicine quality; and
- ensure continued development of better medicines, medicines for emerging diseases, and medicines to meet changing resistance patterns.

In South Africa, the criteria for the selection of essential medicines were based on the WHO guidelines for drawing up a national Essential Medicines List. Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations. It remains a national responsibility to determine which medicines are regarded as essential.[150] South Africa currently has four STG and EML approved as primary references in the public health sector, namely Primary Health care Level, Hospital Level (Adults), Hospital Level (Paediatrics) and Hospital Level (Tertiary and Quaternary).[151]

12.1.5 Conclusions

Pharmacists in South Africa practice in many different settings under the rules defined by the Pharmacy Council (SAPC) on good pharmacy practice (GPP). Pharmacists are key members of the health care team and are in good position to optimise safety by ensuring optimal evidence-based treatment with minimal harm.

12.2 The United States: Patient safety programmes

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12.2.1 Introduction

Pharmacists are an integral part of the health care team and are ranked among the most trusted and accessible health care professionals.[152] In February 2017, a public opinion poll among nearly 2,000 registered voters found that "*69 percent of voters visit the pharmacy at least once a month, offering many opportunities for pharmacists to counsel and advise on health care matters*".[153] In the United States (US), pharmacists continue to be positioned as the most accessible health care professional. Newly licensed pharmacists are required to complete six to eight years of education that is focused on learning disease states and the medications used to prevent and treat them.[i] As medication experts, pharmacists play a vital role in ensuring the safe use of medications by patients.

12.2.2 Health system supporting patient safety

The health care system in the U.S. is complex, as it is delivered and regulated by many stakeholders including private or public entities at the federal, state, local county, and city levels.[154] All professionals in the health care system are subject to regulation from multiple government as well as non-government agencies. Major federal regulatory organisations include the Centres for Medicare and Medicaid Services (CMS), the Centres for Disease Control and Prevention (CDC), and the U.S. Food and Drug Administration (FDA), all of which fall under the U.S. Department of Health and Human Services. Furthermore, independent non-government and provider organisations such as the American Pharmacists Association (APhA) and the American Society of Health-System Pharmacists (ASHP) also have a regulatory role. In the U.S., pharmaceutical products are primarily regulated at the federal level by the U.S. FDA.[154] The Patient Safety and Quality Improvement Act of 2005 (also known as the Patient Safety Act) authorised the creation of patient safety organisations (PSOs).[155] The goal of PSOs is to reduce the risks and hazards associated with patient care. They "*serve as independent, external experts who can assist providers in the collection, analysis, and aggregation of patient safety events to develop insights into effective methods to improve quality and safety*". The Agency for Health care Research and Quality (AHRQ) website provides a list of eighty-two PSOs that are federally-listed.

12.2.3 Pharmacists' role in patient safety

The role of pharmacists in patient safety has greatly expanded over time. A core function of pharmacy practice relating to the safe distribution of medication to patients is ensuring the right dose of the right drug reaches the right patient at the right time by the right route. This is known as the "*five rights*".[156] However, the number and complexity of medications continues to increase and "*pharmacists' roles and responsibilities have expanded broadly beyond medication distribution*".[156] Pharmacists provide patient care in almost all health care settings.

12.2.3.1 Outpatient community

In the outpatient community setting, pharmacists' patient safety actions include ensuring the "*five rights*"; checking for drug-drug, drug-disease, and drug-food interactions; documenting allergies; and counselling patients on indication, administration, and possible adverse effects. Pharmacist-provided immunisations and medication therapy management are also vital in helping to keep patients safe.[77] The Institute for Safe Medication Practices' (ISMP) workbook *Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities for Change* is designed to help community pharmacy staff identify potential medication safety risks and prevent errors. Pharmacists and pharmacy personnel are expected to use ISMP's Key Elements of the Medication Use System™ (available on the ISMP website).[157]

12.2.3.2 Outpatient ambulatory

ASHP has a guideline that outlines the minimum standard for ambulatory care pharmacists.[158] ASHP recognises pharmacists as an essential part of the medication safety team. Their roles include:

- Using a systems-based approach to review errors,
- Reviewing near-miss medication errors,
- Analysing the root cause of medication errors, and
- Working with staff to implement systems that include proper checks and balances focused on protecting against human error and mitigating risk.[158]

12.2.3.3 Hospital

Pharmacists play a crucial role in both the planning and leading of medication safety programmes and improvement initiatives within health care organisations.[159] Examples of initiatives include: developing risk-specific protocols for high-alert medications; identifying and evaluating high-risk processes that require special attention; training of staff; evaluating medication error data; evaluating and implementing new medication technologies; and fostering robust error reporting processes.[159] Clinical trials of investigational drugs are another area in which pharmacists have a fundamental position.[159] Pharmacists have the potential to serve as consultants during protocol development, become members on research committees, integrate information technology into the medication-use process, develop order sets for providers, create targeted alerts, and educate the medical team.[160] Pharmacists are also becoming increasingly involved in transitions of care programmes to reduce errors and improve care.[161]

12.2.3.4 Regulatory

As mentioned above, the U.S. FDA is the major regulatory agency that oversees drugs in the U.S. However, other agencies such as the CDC, CMS, and the Agency for Health care Research and Quality (AHRQ) are also highly focused on reducing medication errors and improving patient safety.[162] Pharmacists that work for the FDA support patient safety by performing research on new investigational drugs, evaluating drug proposals submitted by pharmaceutical companies, surveilling post-marketed drugs, and advising on significant new drugs and developments.[163] The FDA also publishes safety-related "*Guidance for Industry*" documents to advise pharmaceutical companies on how to enhance patient safety. Examples of other pharmacovigilance resources include Risk Evaluation and Mitigation Strategies (REMS) to ensure that a drug's benefits outweigh the risks and the Bad Ad Programme to ensure that prescription drug adverting is not misleading.[110]

12.2.3.5 Industry

Pharmacists that work in industry have a focus on patient safety as well. They can be involved in the development of new medications that are both safe and effective and may serve as medical service liaisons, which help prescribers learn how to appropriately prescribe new medications.[164] Pharmaceutical companies also have departments dedicated to patient safety, such as pharmacovigilance. Throughout the life-cycle of a drug (from the start of the drug development process to when it reaches the market), pharmacists engage in pharmacovigilance activities "*relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem*."[113] Furthermore, pharmaceutical companies are expected to adhere to recommendations by regulatory agencies, such as the FDA, that may require them to update the labelling of a specific product.

12.2.4 Interprofessional collaboration

As health care is becoming increasingly complex and the number of drugs available is rising at a rapid rate, it is essential to utilise the skills and expertise of all members of the health care team. One way that pharmacists can significantly improve the quality of patient care is by working collaboratively with other health care professionals (e.g., physicians, public health professionals, nurses, etc.) and the best way to emphasise their significance is to collaborate and communicate.[165] The impact of collaboration on patient safety has been studied in various contexts. Several studies have identified a reduction in medicals errors *"[…] when interprofessional collaboration is strong and teams are trained to work safely, cooperatively, and in a coordinated way to avoid gaps in quality assurance measures."*[166] To promote the interprofessional team in health care, groups that work as a team must train as a team and ongoing professional development is crucial.[167]

12.2.5 New services or innovations to improve patient safety

Advanced technologies offer many opportunities to enhance patient safety. For example, an increasing number of hospitals have implemented pharmacy IV workflow management systems (WFMS) to assist in the preparation, verification, tracking, and documentation of compounded sterile products (CSPs).[168] Some key features of these systems include mandatory barcode scanning of each ingredient, standardised preparation steps, generation of labels, automated calculations, assignment of beyond-use dates (BUD), reduction of drug waste, and creation of a complete electronic audit trail. Some systems also add gravimetric analysis "*to confirm the accuracy of the additives and base solution […].*"[169] Another innovative technology used for the compounding of IV solutions is automated robotic technology which mitigates the potential for human contact and error, supporting a safer and more sterile means of IV preparation.[170] The use of simulations is also emerging as a way to shape the perception of pharmacy students regarding medication errors and patient safety.[171]

12.2.6 Education and patient safety

In the U.S., the education of pharmacists, physicians, nurses, and other health care practitioners is rapidly evolving to incorporate interprofessional education (IPE) as a central component of the respective academic degrees.[172] Several institutions in the U.S. offer patient safety courses to health care providers.[173] For example, the National Patient Safety Foundation (NPSF) has its own patient safety curriculum with Continuing Medical Education (CME) modules. AHRQ provides a wealth of information, tools, and resources for training in patient safety. Also, the Institute for Health care Improvement (IHI) has free online courses on quality improvement topics and patient safety.[173] Many organisations have also taken on initiatives to educate patients and prescribers about how medication safety can be improved.[174] Finally, post-graduate training programmes such as residencies and fellowships that specialise in medication safety are also available.

12.2.7 Conclusions

Pharmacists practice in many different settings and are considered fundamental members of the health care team. With expanding roles, pharmacists have an obligation and duty to reduce harm by optimising safety.

12.3 Canada: Patient safety programmes

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12.3.1 Introduction

In Canada, momentum was building with efforts underway to improve patient safety. The Institute of Safe Medication Practices Canada (ISMP Canada), an independent, not-for-profit organisation with the aim of advancing medication safety in healthcare settings across Canada was established in 2002. ISMP Canada collaborates with regulatory bodies, policy makers, provincial, national and international organisations and the pharmaceutical industry to promote safe medication practices.

In 2003, The Canadian Patient Safety Institute (CPSI) was established by Health Canada with the primary objective to provide quality and safe healthcare to Canadians through providing national leadership and coordinating efforts related to improve patient safety. Standardisation of medication safety initiatives and the institution of Accreditation Canada became a driver for setting medication safety standards cross healthcare organisations. Pharmacists are often involved in ensuring standards relating to patient and medication safety are met.[175]

Pharmacists have unique training and skills to act as medication safety stewards through drug therapy management and analysis of medication utilisation processes to mitigate drug-related outcomes that can cause harm.[176] Furthermore, community pharmacies in Canada fill on average over 600 million prescriptions each year, which situates pharmacists as ideal health care providers to be involved in medication safety and error reduction initiatives.[176]

The presence of pharmacists in primary, acute and long-term care as well as policy and industry settings in Canada creates an opportunity for pharmacists to act as leaders in medication safety.

12.3.2 Health system supporting patient safety

In Canada, both the federal and provincial governments play a role in medication safety. Health Canada, a federal government entity, ensures the availability of safe and effective drugs and health products across the country. In 2014, the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) introduced regulations to improve Health Canada's ability to review and manage therapeutic products and improve transparency related to post-market safety information.[a]

As of December 2019, regulations put in place by Health Canada will require hospitals to report serious adverse drug reactions with the intention of improving the quality and quantity of reported adverse drug reactions to allow for better monitoring by Health Canada and allow for national oversight of a significant component of medication safety.

Health Canada is a partner of the Canadian Medication Incident Reporting and Prevention System (CMIRPS), a pan-Canadian programme which aims to reduce and prevent medication incidents in Canada. Other partners of CMIPRS include ISMP Canada, the Canadian Institute for Health Information (CIHI), the Canadian Patient Safety Institute (CPSI), and Patients for Patient Safety Canada. Specific requirements for mandatory medication incident reporting can vary by province, with provincial governments responsible for administering health care services.

In certain provinces, there are provincial regulations that mandate medication incident reporting in health care institutions. There is a common recognition that reporting incidents is most effective within a safety culture, whereby staff feel safe to report without fear of reprisal. CIHI's administers a National System for Incident Reporting (NSIR) system, which is a web-based application used by Canadian health care institutions to securely and anonymously share, analyze and discuss medication incidents. ISMP Canada publishes regular bulletins capturing key trends and learnings that health care that can be applied broadly. As a few examples, in Ontario, hospitals are required to report all critical incidents related to medication / IV fluids to both their internal incident reporting system and to NSIR. A critical incident is defined in the Public Hospitals Act.[177]

In British Columbia, the BC Patient Safety & Learning System (BCPSLS) is a web-based patient safety event reporting, learning and management tool used by care providers across all healthcare organisations. The information helps to identify problems and learning opportunities with the aim of improving safety.

In Alberta, all hospitals report medication incidents through the Reporting and Learning System for Patient Safety (RLS). The RLS is a system for AHS internal reporting, which is focused on a system approach where patient safety is advanced by learning from clinical adverse events, close calls and hazards for the purpose of improving health care.

Incident reporting in community pharmacies is under the purview of the provincial pharmacy regulatory authorities. Many provinces have either implemented or are developing mandatory medication safety programs. Each programme is grounded in the principles of a safety culture with medication incident data to be used for quality improvement, non-punitive purposes.

12.3.3 Pharmacists' role in patient safety in different settings

12.3.3.1 Outpatient setting

12.3.3.1.1 Community

[a] Health Canada's 'Protecting Canadians from Unsafe Drugs Act' includes new rules that strengthen the regulation of therapeutic products and improve the reporting of adverse reactions by healthcare institutions. It is also called 'Vanessa's law', named after Vanessa Young, daughter of the Member of Parliament. It is available here: https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/questions-answers-regarding-law-protecting-canadians-unsafe-drugs-act-vanessa-law.html

The role of the community pharmacist has changed significantly over the last few years particularly with many provinces adopting expanded scope practices that enable pharmacists to focus more on the clinical aspects of direct patient care.[178]

Some examples of expanded scopes of practice in community pharmacy that can help to foster safer care and provide pharmacists' the ability to exercise the full extent of their knowledge, skills, and judgment include the ability to apply therapeutic substitution in provinces such as Alberta, British Columbia and Nova Scotia, ability to administer injections, including influenza vaccine across many Canadian jurisdictions. [178] Community pharmacists also act as the liaison between prescriber and patient allowing for the opportunity to review patient profiles for allergies, interactions or other queries related to prescribed therapies in order to reduce the risk of harm and improve outcomes. Another important aspect of patient safety in community pharmacy is internal continuing quality improvement programs (CQI) as well as provincially mandated CQI programs that allow pharmacies to perform root-cause analysis and learn from incidents.

12.3.3.1.2 Ambulatory - family health teams

Pharmacists in family health teams (FHTs) are uniquely situated within a team of health care providers such as nursing, registered dieticians, respiratory therapists, occupational and physiotherapists as well as prescribers. This allows for the ability to not just communicate with other health care providers, but actively collaborate on patient care in a multidisciplinary approach. FHTs in Ontario, for example, often provide 7-day per week access to care, are supported by electronic medical records and provide a broad range of services that are team based.[179, 180] In the FHT model, pharmacists are taking on an increasingly prominent role as members of the interdisciplinary team with focused skill sets in pain, diabetes management, anticoagulation and other areas. This role allows for more insight into drug therapy and therefore can play a significant role in patient safety. FHT pharmacists typically carry four core roles including patient care, education, quality improvement and system level projects as well as healthcare system navigation.[179] FHT pharmacists often partner with community and acute care pharmacists in order to help with transitions of care or for communicating medication therapy plans to ensure that all members of the circle of care are aware of any changes.

12.3.3.2 Hospital

The role of the pharmacist in patient safety in the hospital setting is multifactorial and includes attending patient care rounds to understand patient status, care goals and any concerns that may not be visible on labs or vitals, such as pain. Within the hospital setting, most pharmacies follow standards created by Accreditation Canada with a primary focus on creating a culture of quality improvement. Pharmacists in the hospital setting are often medication experts in therapeutic areas such as internal medicine, obstetrics, oncology and infectious disease management. Pharmacists interpret laboratory values, are involved with antimicrobial stewardship as well as act as mentors, collaborators and scholars. [181, 182]

Pharmacists are also often involved in interprofessional committees such as drugs and therapeutics, medication safety and different quality improvement initiatives. A background and perspective paper conducted in 2006 by the Canadian Society of Hospital Pharmacists addressed a multitude of pharmacy services and programs that positively impact patient safety.[183] The paper refers to practices such as direct patient care, formulary systems, standardised medication administration policies and procedures, pharmacist review of drug orders, application of electronic medical records and computer technologies, medication incident reporting and review and pharmacist provision of education to patients and health-care providers alike.[183]

12.3.3.3 Regulatory

Across Canada, the Model Standards of Practice for Canadian Pharmacists prepared by the National Association of Pharmacy Regulatory Authorities (NAPRA) describes a multitude of categories where pharmacists, depending on the role, practicing in Canada must hold professional competency including patient care, drug information, drug distribution, management and education.[178] General standards include expertise in medications and drug therapy, ability to collaborate and communicate effectively, safety and quality assurance which has a primary focus on patient safety and responding to safety risks, professionalism and upholding ethical standards.[178]
Furthermore, beyond the NAPRA standards, pharmacists are regulated by their provincial or territorial regulatory body. The regulatory bodies protect the public by ensuring that pharmacists are meeting standards of practice and providing safe, quality, ethical care. In 2010, the first mandatory medication safety program, SafetyNet-Rx, in community pharmacy was instituted by the Nova Scotia College of Pharmacists.[184] SafetyNet-Rx involves tracking and

analysing medication incidents and near misses in community pharmacy system as part of a continuous quality assurance program.[185] A study conducted analyzing medication incidents and near misses over a 7-year period in Nova Scotia community pharmacy found that pharmacists and pharmacy personnel catch at least 82% of medication errors before they reach the patient.[176]

In Ontario, the Assurance and Improvement in Medication Safety (AIMS) Programme is a mandatory medication safety programme that standardises expectations regarding continuous quality improvement related to medication incidents and near misses involving pharmacies. Other provinces, such as Saskatchewan and Manitoba have since implemented similar mandatory medication safety programs in community pharmacy that aim to impart a continuous quality improvement lens on medication incidents and near misses. British Columbia will also be moving forward with implementing a similar program.

12.3.3.4 Industry

Pharmacists working in the field of industry in Canada can work for drug manufacturing or research companies in specialised areas such as product development, medical affairs and drug compliance. Pharmacists in industry can also take on positions that are more geared towards patient safety such as pharmacovigilance positions whereby the pharmacist is involved with review of adverse drug reports and safety data of marketed products these positions can have a local, national or global focus.

Pharmacists in industry must often be well versed in research methodology in order to conduct literature reviews on different topics, be able to generate recommendations regarding drug therapies or concerns related to marketed or in research products and also act as leader in ensuring compliance with provincial/territorial and national policies and regulations.

12.3.4 Interprofessional collaboration

Pharmacists play an essential role in ensuring that patients receive quality and safe care. Optimising health outcomes and preventing the risk of patient harm requires multi-professional expertise to ensure that all aspects of patient care are working in an integrated fashion. Pharmacists work with other health care professionals to optimise medication therapy to maximise health outcomes. Interprofessional teams often review incidents to collaboratively identify actionable insights on how to improve the medication use system and how to design systems with integrated safeguards. Many health care settings have interprofessional committees that regularly review medication incidents and trends to identify systemic factors to reduce incident recurrence.

12.3.5 5. New services or innovations to improve patient safety

Technological advancements such as electronic patient healthcare records and the use of electronic prescribing are utilised across the country to improve access to medication and medical histories and enhance communication between prescribers and pharmacists. The Canadian Patient Safety Institute (CPSI) oversees the Canadian Patient Safety Week each fall. Multiple events are held during this week such as new episodes of an award-winning PATIENT podcast, a Conquer Silence Webinar, Creating a Safe Space Webinar and a Mandatory Reporting Webinar. On the website there are also many tools to help improve patient care and patient safety.

12.3.6 Education around patient safety

There are many resources and tools to support continuous education in patient safety. CPSI has developed a variety of evidence-based tools and resources with the assistance of experts in patient safety. Some of these tools focus on how to prevent patient safety incidents, by properly designing processes and improving communication and to permit learning from incidents so that prevention strategies can be improved.

ISMP Canada also has many educational resources to support patient safety. Some resources are geared towards the patient such as a poster about 5 questions to ask your healthcare provider about medications and other resources are geared towards healthcare providers such as the Opioid Stewardship recommendations.
The Canadian Pharmacists Association (CPhA) has a variety of resources to support professional development in patient safety including practice tools, pharmacy practice research, and conferences and webinar presentations.

12.3.7 Conclusions

The involvement of the pharmacist in patient safety in Canada spans across a myriad of different areas and pharmacists practicing in different settings have a host of expertise to provide optimised patient care. Canada's changing landscape that focuses more on a culture of safety and less on a culture of blame has created a platform for innovation, creativity, research and implementation to improve outcomes for all patients.

12.4 Australia: Patient safety programmes

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12.4.1 Introduction

Australia's National Medicines Policy[186] launched in late 1999, was one of the first of its kind internationally. It was a policy developed by a cooperative of key stakeholders, including state and federal governments, consumers, health care professionals and organisations, health educators, healthcare providers and suppliers, and the medicines industry. The goal of the National Medicines Policy (NMP) is a healthy consumer. It strives to reach its goal through its four pillars, or objectives:

- *"timely access to the medicines that Australians need, at a cost individuals and the community can afford;*
- *medicines meeting appropriate standards of quality, safety and efficacy;*
- *quality use of medicines; and*
- *maintaining a responsible and viable medicines industry"* [186]

The NMP therefore sets the context and impetus for patient and medication safety at all levels of the health care and medicines industry, with the full support of the government.
Safe, quality and effective medicines, and quality use of medicines (QUM) are the NMP objectives most relevant to patient and medication safety. QUM can be defined based on its components: [187]

- selecting appropriate treatment and management options for patients and consumers, which may include pharmacological and/or non-pharmacological therapy;
- where pharmacological therapy is required, choosing the right medication for the right person, and giving the medication at the right dose, in the right formulation and strength, and at the right time;
- using medicines safely and effectively through patient education, monitoring the impact of the medication, and appropriately acting on any adverse events.

With QUM as a framework underpinning health care practice, and in particular, the practice of pharmacists, it is therefore not surprising that the Pharmaceutical Society of Australia (PSA) recently launched a report on *Medicine Safety: Take care.*[188] This report presents the extent of harm to Australians as a result of medicines use, and identifies opportunities where pharmacists have a key role to play in minimising harm and improving medicine safety. Whilst some alarming facts about medicine-related hospitalisations, emergency department visits, harm post-discharge and harm in residential-aged care settings have been presented, it is noteworthy that 50% of the medicine-related harm is preventable, providing significant opportunities for improvement in the health care system and practice of health care professionals.

12.4.2 Australia's health system

Australia's health system consists of public and private sectors, and is funded through government (local, state and territory, federal), non-government, private health insurers and consumers. As there are three levels of government which share the responsibilities of the national health care system, this can present challenges in ensuring continuity of services and care across the system. For example, the Australian federal government is responsible for setting national policies, the pharmaceutical benefits scheme (medicines subsidies), the national health insurance system (Medicare), regulating private health insurers, and regulating medicines, devices and other medicinal products. At the state and territory level, the governments are responsible for managing public hospitals and public community and primary health services, ambulance services and delivering preventive and public health programs. Local governments play a major role in delivering community and home-based health services, as well as public health and health promotion activities. Some of the challenges in ensuring patient and medication safety are,

- to ensure that there is effective communication and collaboration at all government levels,
- that messages are aligned and delivered concurrently across the levels,
- that clinical governance structures vary across the different states and territories,
- that effective implementation strategies are delivered at the patient or consumer interface (e.g. primary care) and are supported by the health care system at the appropriate level,
- that there is an effective feedback mechanism and process where the needs of patients and consumers, with regards to patient safety, are identified, solutions prepared and strategies planned for implementation and evaluation, and supported by government at all levels.

One example where all systems came together was to prevent the inadvertent use of potassium chloride. Potassium chloride in addition to sodium chloride and water for injection ampules were traditionally all part of imprest ward stock. All three ampules looked very similar and as such were sometimes selected in error when reconstituting medicines for injection on the ward. The sharing of aggregated hospital and state data allowed for a national medication alert to be issued with a number of preventative strategy recommendations, including the replacement of imprest potassium chloride ampules with premixed solution bags.[189, 190]

In 2006, the Council of Australian Governments established the Australian Commission on Safety and Quality in Healthcare (the Commission), with their purpose being to contribute to Australian patients' and consumers' better health outcomes, and ensure that they receive safe and quality healthcare through leading and coordinating national developments and advancements in safe and quality health care. The Commission has developed eight National Safety and Quality Health Service (NSQHS) Standards[191] in collaboration with key stakeholders, such as patients and carers, clinical experts, the Australian Government, and private sector providers. These Standards aim to protect patients and consumers, as well as the general public from harm when accessing health care. Moreover, the Standards also aim to improve the quality of health care that Australians receive. One of these eight, is the Medication Safety Standard, which strives for patient safety by health care professionals through the medication journey, from selection of medication through to prescribing, dispensing, administration and monitoring use of medications.

12.4.3 Pharmacy organisations and patient safety

The PSA has placed Medicine Safety as the top action for Australian pharmacists in their recently published report about the future of pharmacy. [192] The PSA states that pharmacists should be empowered to intervene where necessary to prevent patient harm from medication-related issues, and to address situations and systems which do not support patient safety and could lead to medication-related harm. Furthermore, the PSA has identified four system changes which can ensure patient and medication safety, which should be achievable by 2023: [192]

- *"Recognition of this issue as a National Health Priority Area, empowering pharmacists to proactively identify and resolve medicines-related problems in healthcare*
- *Practice changes that focus pharmacist activities on preventing medicine misadventure, particularly at transitions of care*
- *Workplace reform to enhance and measure the medicine safety contribution of individual pharmacists in all practice settings*
- *Establish a nationally coordinated pharmacovigilance programme which provides feedback on the safe and effective use of medicines"*

The Society of Hospital Pharmacists of Australia (SHPA) have standards of practice for medication safety within hospital and tertiary care settings, which encompass the objectives of a medication safety system and the cores roles of pharmacists within that system, as well as the training and education required by pharmacists. [193]

12.4.4 Pharmacists' role in patient safety

"Medicine [and therefore patient] safety is in the DNA of pharmacists and extends deeply into all professional activities". [192] The Pharmacy Board of Australia defines professional practice as *"Practice as a pharmacist means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist in their profession. For the purpose of [...] registration [...], practice is not restricted to direct patient care. It also includes working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles; and any other roles that impact on safe, effective delivery of services in the professional and/or use of their professional skills."* [194] Every professional role and activity of a pharmacist is underlined by medication and patient safety, and each professional pharmacy organisation has medication and

patient safety as its core goals. This section aims to highlight some key roles that pharmacists play, and is not intended to be an exhaustive list with most of these services having been described as part of the FIP reference document on patient safety.

Pharmacists in primary care play a central role in ensuring patient safety in the community setting. In addition to ensuring the appropriateness of therapy during preparation and supply, community pharmacists undertake a number of clinical roles. These can include performing clinical interventions, conducting instore medicines use reviews (e.g. MedsCheck and Diabetes MedsCheck [195]) and supporting patients to use their medicines safely and appropriately such as through providing medicines through staged supply provisions[196] or through educating patients how to optimally use their devices. Pharmacists may also gain accreditation to undertake more comprehensive medication reviews in patients' homes or in residential aged care facilities.[197] Similarly, pharmacists in a hospital setting conduct medicines reconciliation, medicines use reviews as well as educate patients, carers and other healthcare practitioners about optimal medicine use.[198]

Pharmacists are increasingly becoming more involved in clinical governance roles, such as leading the governance of medication safety committees, implementing medication safety and quality improvement initiatives, and reporting and reviewing errors and adverse drug events. Although this role has been traditionally performed in secondary and tertiary settings, some primary healthcare networks are starting to incorporate pharmacists as part of their clinical governance structures to improve local practices. In addition to this, one of the primary pharmacist insurance agencies (Pharmaceutical Defense Limited) provides governance over issues reported (e.g. errors that have occurred or near misses) to their professional support officers which are reviewed on state and national levels for the development of mitigation strategies and practice warnings.

12.4.5 Interprofessional collaboration

Whilst pharmacists play an integral role in medication safety, interprofessional collaboration is required to ensure safe practices across all levels. In order to do this, pharmacists are usually included as part of various teams to manage medication safety. In hospitals, pharmacists, as part of routine practice, participate in case conferences to develop and evaluate clinical management plans for inpatients. Whilst this has not always existed in the community setting, pharmacists are starting to take more of an expanded team role in the management of community-based patients in a number of ways. As more services are starting to be delivered outside of the hospital, such as palliative care and mental health client management, community-based pharmacists are starting to have an increased role in working with their respective care teams. Care team arrangements can also be instigated by a general medical practitioner whereby selected health care professionals, usually including a pharmacist, collaborate in a community setting to develop management plans for a particular patient. Whilst interprofessional collaboration has been recognised by government bodies as a way to optimise care, and has been incentivised to a degree, the silo like nature of primary care can make this difficult to implement. One strategy that is currently under trial in Australia is the co-location of pharmacists in general medical practices, which allow pharmacists to have a greater access to other primary care professionals involved in an individual's care and to optimise their medicine use, including prescribing, medicines use review, medication monitoring and medicine/medicinal device education.[199, 200]

12.4.6 New services or innovations to improve patient safety

The roles of pharmacists in Australia continuously evolve, so too does their role in improving patient safety. As mentioned above, trialing co-location of pharmacists in general practice clinics has resulted in pharmacists not only increased collaboration between the various health professionals involved in the patient's care more but also resulted in better health outcomes for the patient.[199] Similarly, trials are currently underway to demonstrate the benefits of pharmacists being co-located in residential aged care facilities, not being only used for medication preparation and supply, but similar to GP practices, being used to aid visiting medical practitioners in prescribing, conducting medicines use reviews, assisting nursing staff in monitoring and medicine/medicinal device education. Although these initiatives improve patient outcomes, the financial viability of running these services require ongoing evaluation.

In addition to this, pharmacists in community have been encouraged to regularly perform medicines reconciliation, particularly during transitions in care (e.g. moving into a residential aged care facility or being discharged from hospital) or after a patient has visited a medical practitioner.[201] Whilst this has been part of standard practice for patients who have their medicines repackaged into dose administration aids, it is intended that this will benefit the community at large and minimise confusion and inappropriate use of medicines.

12.4.7 Education around patient safety

Patient safety is a core topic in professional pharmacy curricula throughout Australia. The curricula provide the skills and knowledge that pharmacy graduates need in order to practice safely and competently as pharmacy interns and pharmacists of the future. The pharmacy curricula are accredited by the Australian Pharmacy Council (APC), who ensures that the programme meets the accreditation standards, including those that pertain to safe practice. The APC has been in the process of reviewing its accreditation standards, and the 2019 draft accreditation standards consist of five domains, the first being Safe and Socially Accountable Practice, *"which encompasses the responsibilities and obligations of individuals and organisations to serve society, by seeking both to prevent harm and to promote optimal health outcomes. This represents an innovative approach compared with the Accreditation Standards of the other regulated health professions using this structure, where Domain 1 refers to public safety or safe practice. The use of social accountability focuses attention on a broader approach to the public service aspect of health professions, by acknowledging the importance not only of harm prevention, but of active health promotion and optimisation".* [202] The 2019 draft accreditation standards are more explicit in the pharmacy graduate performance criteria for safe and socially accountable practice. This will more likely ensure that the curricula have explicit learning outcomes and therefore activities and assessments that evaluate, and for the students, demonstrate, the performance criteria.

12.4.8 Conclusions

Patient and therefore medication safety are at the heart of the Australian health care system, as seen with the National Medicines Policy. Key stake holders at all levels are developing, implementing and delivering policies, standards and services, and training to ensure patient safety, and prevent harm to the patient and the public during their health care and medication use journey. There are, however, many opportunities for further improvements to ensure that no patient experiences harm that was avoidable.

12.5 India: A case study on the role of the pharmacist in patient and medication safety

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12.5.1 Background

The World Health Organization (WHO) recognised the need to promote patient safety as a fundamental principle of all health systems and urged member states to pay the closest possible attention to the problem of patient safety; and to establish and strengthen science-based systems, necessary for improving patients' safety and the quality of health care, including the monitoring of drugs, medical equipment and technology.[203] This case study on the role of pharmacists in patient and medication safety in India is included in the FIP Reference Document to understand how pharmacists making efforts to improve patient and medication safety. This case study is developed based on Doctoral dissertation: Public Health and Patient Care Aspects in Pharmacy Education and Pharmacists' Role in National Public Health Programmes in India and other recent literature.[204]

12.5.2 Introduction to Indian health care system

India is made up of 29 States and 7 Union Territories with over 1.3 billion population.[205] India's health care system was carefully structured at the time of Independence (1946) to provide primary, preventive, and curative health care within a reasonable distance of the population even in remote, rural areas.[206] The health care system in India, at present, has a three-tier structure to provide health care services to its people.[207] Networks of health care facilities at the primary, secondary and tertiary level, run mainly by State Governments, provide free or very low cost medical services. There is also an extensive private health care sector, covering the entire spectrum from individual doctors and their clinics, to general hospitals and super specialty hospitals. Indian government promoted traditional and alternative medicine systems and the government has been taking quality and safety measures to protect the patients.

India's health workforce is made up of a range of health workers who offer health care services in different specialties of medicine. These personnel consists of allopathic doctors (31%), with bachelor degree or specialists; nurses and midwives (30%); pharmacists (11%) with diploma, bachelor, masters and PharmD (doctorate) degrees; practitioners of Ayurveda, yoga, naturopathy, unnail, siddha, and homoeopathy (9%), with university degree or specialisations; and others (9%) which comprises of technicians and allied health workers; community health workers include health educators and health assistants; accredited social health activists; registered medical practitioners with little or no formal training and traditional medicine practitioners and faith healers.[208]

12.5.3 Pharmacists' role in patient safety

Patient safety measures are taken at different levels; for example, institutional, regulatory, association, population, to avoid harm during the treatment process. Due to the vast demography and huge number of pharmacists and other health care workers managing medicine use and involved in patient treatments, regulatory authorities are utilising different bodies to protect and safeguard population health. To ensure patient and medication safety, different regulatory authorities under ministry of health and family welfare are working. This case study will describe the patient safety measures taken by different authorities involving the pharmacists and pharmacies working in various facets of pharmacy profession.

In the past, pharmacists were responsible for dispensing medications only. Slowly, the traditional role of pharmacists is expanding and now pharmacists are playing a role as a vital team member in the direct care of patients, especially the new generation pharmacists who have PharmD. Pharmacists play a major role in providing health care services by means of community pharmacy services in rural areas where physicians are not available or where physician services are too costly for meeting the health care necessities.[209] To ensure patients and medication safety, pharmacies and pharmacists' organisations took the following important initiatives by authorities in India are playing a key role:

- Central Drugs Standard Control Organisation (CDSCO)
- Indian Pharmacopoeia Commission (IPC)
- ***Pharmacy Council of India***
  - ***Patient safety through pharmacy education regulations***
  - ***Patient safety through practice regulations***
- Patient safety through drug information: Medicines Information Resources for Pharmacists
- Evolving role of clinical pharmacists in accredited hospitals
- Indian Pharmaceutical Association's (IPA) contribution to patient and medication safety
- Accreditation of alternative therapies

12.5.3.1 The Central Drugs Standard Control Organisation (CDSCO)

CDSCO under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. The headquarters is located at FDA Bhawan, New Delhi and has six zonal offices, four sub zonal offices, thirteen Port offices and seven laboratories spread across the country. The Drugs & Cosmetics Act,1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics. It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and wellbeing of the patients by regulating the drugs and cosmetics. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organisations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

12.5.3.2 Indian Pharmacopoeia Commission (IPC)

Indian Pharmacopoeia Commission (IPC) is an Autonomous Institution of the Ministry of Health and Family Welfare, Govt. of India. IPC is created to set standards of drugs in the country. The vision of IPC is to promote the highest standards of drugs for use in humans and animals within practical limits of the technologies available for manufacturing and analysis. IPC mission is to promote public health and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers. IPC is internationally cooperating

with WHO, EDQM, Japanese Pharmacopoeia and USP. IPC strengthen its efforts to work with other international pharmacopoeias, industry academia, regulator and other stakeholder to develop harmonised global standards.

The mandate of IPC is to publish Indian Pharmacopoeia (IP) and its addendums, National Formulary of India, certification of IP Reference Standards, run the National Coordination Centre (NCC) for running Pharmacovigilance Programme of India (PvPI), organising educational and skill development and research initiatives and to establish working relations with other similarly placed institutions at National and International level.

12.5.3.3 Indian Pharmacopoeia

Indian Pharmacopoeia 2019 addendum to IP 2018 is the current version and has developed 2756 monographs. IP has 550 reference standards and 100 impurity standards developed in the Indian Pharmacopoeia Laboratory which is ISO Guide 34: 2009 for "*Reference Material Producer*", WHO Pre-qualified for Quality Control Laboratory and ISO/IEC 17025:2005 Accredited for Chemical and Biological Analysis. IP-2018 has been brought out in 4 Volumes incorporating 220 new monographs (Chemical Monographs (170), Herbal Monographs (15), Blood and Blood related products (10), Vaccines and Immunosera for Human use monographs (02), Radiopharmaceutical monographs (03), Biotechnology Derived Therapeutic Products (06), Veterinary monographs (14)), 366 revised monographs and 7 omissions. The IP Addendum 2019 to IP-2018 contains 66 new Monographs including those of Chemicals (61), Herbs and Herbal Products (03), and Radiopharmaceuticals Preparations (02).

12.5.3.4 The Pharmacovigilance Programme of India (PvPI) for patient safety reporting

India now has a stable and robust pharmacovigilance system; this enables the global community to ensure the safety of medicines.[210] PvPI has progressed considerably in the last few years. The Pharmacovigilance Programme of India (PvPI) was approved by the Ministry of Health and Family Welfare (MOHFW), Government of India (GOI) in July 2010 with the primary objective of the programme to create a nation-wide system for patient safety reporting. Within a span of five years PvPI has become a formidable force at international level the best pharmacovigilance practices including Adverse Drug Reactions (ADRs) reporting and providing skill development. The Individual Case Safety Reports (ICSRs) are collected/collated in a scientific way and analysed to facilitate appropriate decisions at CDSCO. There are 250 functioning Adverse Drug Monitoring centres in the country (in medical colleges and corporate hospitals) as part of the Pharmacovigilance Programme of India. The programme is striving hard to build trust between the physician and the patient, thereby increasing patient safety and the confidence of people in the country's health system, in addition to the detection of substandard medicines and prescribing, dispensing and administration errors. The IPC-PvPI has become a WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services.[211] The vision of PvPI is to improve patient safety and welfare in Indian population by monitoring drug safety and thereby reducing the risk associated with use of medicines. The ultimate safety decisions on medicines may need considerations of comparative benefit/risk evaluations between products for similar indications, so the complexity is great.

The mission of PvPI is to safeguard the health of the Indian population by ensuring that the benefit of use of medicine outweighs the risks associated with its use. Since there exist considerable social and economic consequences of adverse drug reactions and the positive benefit/cost ratio of implementing appropriate risk management - there is a need to engage health care professionals and the public at large, in a well-structured programme to build synergies for monitoring adverse drug reactions in the country.

The objectives of the programme are: to create a nation-wide system for patient safety reporting, identify and analyse new signal from reported cases, to analyse the benefit - risk ratio of marketed medications, to generate evidence-based information on safety of medicines, to support regulatory agencies in the decision-making process on use of medications, to communicate the safety information on use of medicines to various stakeholders to minimise the risk, to collaborate with other national centres for the exchange of information and data management, to provide training and consultancy support to other national pharmacovigilance centres across globe and to promote rational use of medicine.

12.5.3.5 The Hemovigilance Programme of India (HvPI)

Hemovigilance is a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent their occurrence and

recurrence. It is an important tool for improving safe blood transfusion practices in a country. The programme was initiated in 60 medical colleges in the country that were already enrolled under the PvPI. Hemovigilance Programme was launched on in Dec 2012 with 60 Medical College under PvPI as an integral part of Pharmacovigilance Programme of India National Institute of Biologicals is the Coordinating Centre, for BvPI to collate and analyse data with respect to Biologicals and Hemovigilance, and is constantly working toward the advancement of the quality and safety of blood products and the transfusion process to ensure patient care and safety.[212-214]

12.5.3.6 The Materiovigilance Programme of India (MvPI)

In order to foster the habit of reporting MvPI encourages reporting of all types of adverse events related to medical devices- irrespective of whether they are known or unknown, serious and non-serious, frequent or rare. Materiovigilance is primarily concerned with adverse events associated with medical devices used in India.[215] The Materiovigilance Programme of India (MvPI) is responsible for monitoring and reporting adverse events associated with the use of in vitro diagnostics.

To date, about 850 adverse events due to invasive and non-invasive devices have been reported using the Medical Device Adverse Event Reporting Form. These reports were associated with the use of hip implants, intrauterine contraceptive devices, cardiac stents and others. All the reports were analysed for a causal relationship between the device and the events; it was concluded that in most of the cases, devices were not responsible for causing the events. Certain cases were referred back to the reporter to obtain more information.[211]

12.5.4 Pharmacy Council of India (PCI)

Pharmacy Council of India, a statutory body of Government of India to prescribe and implement education regulations, minimum standards of education, is playing a key role in improving the standards of pharmacy profession which will obviously improve the patient safety. As a part of it, PCI has taken the following initiatives in the recent decade:

12.5.4.1 Patient safety through pharmacy education

Pharmacists represent the third largest health care professional group in the world.[216] There are about one million registered pharmacists in India working in various positions, applying their unique, contributing to the health care system in India.[217] The curriculum plays a major role in developing and changing the face of the profession. The PharmD curriculum contains more clinical subjects and patient oriented services than industrial aspects.[218] In India, there are over 1,700 institutions that offer different pharmacy programmes in India with an intake of over 100,000 students per academic year in DPharm (2 years), BPharm (4 years) and PharmD (5 years).[219, 220] PharmD curriculum contains more clinical subjects and patient oriented services than industrial aspects.[204]

Error is routine during the delivery of health care and occurs in around 10% of hospital admissions.[29] The education and training of dentists, doctors, midwives, nurses, pharmacists and other health-care professionals has long been the foundation of safe, high quality health care. WHO has developed a patient safety curriculum guide with a multi-professional perspective, which addresses a variety of ideas and methods for teaching and assessing patient safety more effectively.[29] Pharmacists educational quality and standards plays obviously an important role in improving the patient safety. During past decade, the pharmacy profession has expanded significantly in implementation of need-based educational programmes and professional practice.[221]

12.5.4.2 PharmD regulations in India, 2008:

To focus on clinical pharmacy and patient oriented services.[218] Before launching the role of a pharmacist in the nation was mostly considered to be "*dispensing, manufacturing and marketing of the drugs*".[222] This review discusses the evolving role expected to be performed by clinical pharmacologists as the primary custodian of medication management and medication safety process. As more hospitals in India aspire to become NABH accredited, it is expected that the role of clinical pharmacologists will be understood better and would be required to ensure proper and safe medication management system.[223] Pharmacists with higher education (PharmD) has similar roles at accredited hospitals.

12.5.4.2.1 Bachelor of Pharmacy (Practice):

It consists of a degree certificate of having completed the course of study and passed examination as prescribed in these regulations for the purpose of additional qualification to be entered in the register of pharmacists.[224] These new regulations will help upgrading the qualification of practicing pharmacists with Diploma in Pharmacy.

12.5.4.2.2 Minimum standards of teaching:

The PCI, through an Extraordinary Gazette approved by the government of India on 12, November 2014, made new regulations to maintain the minimum standards of teaching in various departments of a pharmacy college or institution imparting diploma, graduate and post-graduate education shall be as prescribed in the Gazette. [225]

12.5.4.2.3 Patient safety through pharmacy practice regulations

This section describes how pharmacy practice regulations ensure patient and medication safety.

12.5.4.2.4 Pharmacy Practice Regulations:

To ensure best practices to implement Code of pharmacy ethics, duties, responsibilities of pharmacist, inspection of pharmacies, maintain GPP, CEP and implement other laws related to D&C Act, Indian has enacted Pharmacy Practice Regulations, 2015. Today, pharmacy profession is striving hard to realise its vision and mission to achieve best practices and to provide better pharmaceutical care services to the patients. In this process, regulatory authorises are doing their best to implement Pharmacy Practice Regulations (2015) to harmonise practice of pharmacy throughout the country. Some of the salient features of the regulations are:

- Described duties of registered pharmacists in detail, as well as their duties to their patients, to each other, to the public and to the profession.
- Actions for professional misconduct and making pharmacists liable for disciplinary action. Listed out details of job responsibilities, knowledge and skills of various cadres of pharmacists at hospital practice site, at a community pharmacy, and of drug information pharmacists.
- It is mandatory to display Registered pharmacist's identity in the pharmacy and their dress code is also described.
- It is prescribed mandatory CE programmes for renewal of registration.

12.5.4.2.5 Duties of registered pharmacists to their patients - obligations to the sick:

a) pharmacists shall be mindful of the high character of their mission and the responsibility that they discharge in the course of their professional duties. Pharmacists shall never forget that the health and the lives of those entrusted to his care depend on his skill and attention.

(b) Registered pharmacist having any incapacity detrimental to the patient or which can affect his performance vis-àvis the patient, shall not be permitted to practice his profession.

(c) Pharmaceutical care (in addition to the provisions of Drugs and Cosmetics Rules 1945 and Schedule N of the said Rules) the following provisions shall be included. No person other than a Registered Pharmacist shall compound, prepare, mix, dispense or supply of any medicine on the prescription of a Registered Medical Practitioner (Schedule H & X drugs). A Registered Pharmacist shall review the patient record and each prescription presented for supply for the purpose of promoting therapeutic appropriateness by identifying: i) Over utilisation or underutilisation ii) Therapeutic duplication iii) Drug-disease interactions iv) Drug-drug interactions v) Incorrect drug dosage or duration of drug treatment vi) Drug-allergy interactions vii) Correlation of availability of drugs (to avoid artificial shortage of drugs) viii) Clinical abuse/misuse.

12.5.4.2.6 Duties of registered pharmacist - Dispensing/supply of Drugs:

a) Various activities of dispensing like removal of drugs from packing, prescription filling may be performed by a trained person under the supervision of registered pharmacist. However, actual dispensing of drugs shall only be performed by the Registered pharmacist after due verification of work performed by others.

b) Registered pharmacist shall undertake a pharmaceutical assessment by applying pharmacists' knowledge to establish safety, quality, efficacy and rational use of drugs in treatments.

c) Patient confidentiality shall be maintained at all times.

d) Appropriate information shall be provided to the patient or the care giver and, where possible, understanding of this information should be checked.

e) For all prescriptions handled by the pharmacy: (i) Patient details shall be checked and confirmed; (ii) Pharmaceutical assessment shall be made; (iii) Proper documentation shall be maintained.

f) Assessment of the prescription should include but not be limited to assessment of whether: (i) The prescription is legally valid. (ii) The prescription includes an appropriate dosage form and appropriate route of administration. (iii) Prescription is appropriate to the patient's condition. (iv) Duration of treatment is correct. (v) Prescription is appropriate according to patient's para-meters (age, weight etc.) and previous medication. (vi) Prescription is compatible with other medications. (vii) Prescription is consistent with formulary and guidelines, if any. (viii) Possibility of side effects and adverse drug reactions exist. (ix) Contraindicated. (x) Potential for misuse and inappropriate use of the medicines in prescription by patient exists. (xi) Prescription is complying with labelling requirements.

g) Compounding, dispensing and labelling of required drug products should ensure that: (i) The drug product matches the prescription. (ii) The drug product has not expired. (iii) The drug product is appropriately compounded (if necessary), packed and labelled appropriately. (iv) The accuracy of dispensing is checked by Registered Pharmacist. (v) Proper documentation is made.

12.5.5 Patient counselling

Upon receipt of a prescription (prescription drug order) and following a review of the patient's record, a Registered Pharmacist shall personally initiate discussion of matters that will enhance or optimise drug therapy with each patient or care given of such patient. Such discussion shall be in person, whenever practicable or by telephone and shall include appropriate elements of patient counselling. Such elements may include the following: (i) Name and description of the drugs; (ii) The dosage form, dose, route of administration, and duration of drug therapy; (iii) Intended use of the drug and expected action; (iv) Special directions and precautions for the drug; (v) Common severe side effects or adverse effects or interactions and therapeutic contra indications that may be encountered, including their avoidance, and the action required if they occur; (vi) Techniques for self-monitoring drug therapy; (vii) Proper storage of the drugs; (viii) Prescription refill information; (ix) Action to be taken in the event of a missed dose; (x) To ensure rational use of drugs.

12.5.5.1 Pharmacies providing patient counselling shall have regard to the following:

Only Registered pharmacists are involved in counselling. Confidential conversation facilities are provided. Patient information leaflets are provided. Unnecessary counselling should be avoided.

Counselling for patient's benefit: In every consultation, benefit to the patient is of foremost importance. All registered pharmacists engaged in the case should be frank with the patients and their attendants.

Punctuality in counselling: Utmost punctuality should be observed by a registered pharmacist in making themselves available for counselling.

The pharmacist shall maintain the records pertaining to drugs administered to the patients (drug card) that may be utilised for the evaluation of the drug therapy. The pharmacist is authorised (as a Health care professional) to undertake process and outcome research, health promotion and education and provide health information and to undertake pharmacoepidemiologic studies.

12.5.5.1.1 Public and Community Health:

Registered pharmacists, especially those engaged in public health work, shall enlighten the public concerning quarantine regulations and measures for prevention of epidemic and communicable diseases. At all times registered pharmacist shall notify constituted public health authorities of every case of communicable disease under his care, in accordance with the laws, rules and regulations. When an epidemic occurs, registered pharmacist shall not abandon his duty for fear of contacting the disease for himself.

12.5.5.1.2 Patient safety through drug information: Medicines Information Resources for Pharmacists

Indian pharmacists have available several medicines information sources to serve their customers. Official sources of drug information are Central Drug Research Institute (CDRI) and National Formulary of India (NFI) and the several drug information centres run in collaboration with state pharmacy councils, WHO country office, Universities, hospitals and other autonomous bodies. Chauhan et al.[226] has presented an overview of drug information source centres available in India which is given below:

12.5.5.1.3 National Information Centre on Drug and Pharmaceuticals (NICDAP)

NICDAP uses the library resources of Central Drug Research Institute; Government of India a constituent laboratory of Council of Scientific and Industrial Research. R&D activities in CDRI are supported by a modern knowledge Resource Centre which comprises a fully computerised library with a rich collection of relevant books and periodicals, on-line subscription of many databases and periodicals and an Information Centre which provides many services as well as on-line response to queries.

12.5.5.1.4 National Formulary of India (NFI)

NFI is an official tool for pharmacists in India, prepared by the Indian Pharmacopoeia Commission, under the Ministry of Health. It helps in selection of drugs from a wide range of available drugs in the market. NFI is the drug formal information resource in India. The National Formulary of India is essentially meant for the guidance of members of medical profession; medical students, nurses and pharmacists working in hospitals and in sales establishments. In the preparation of NFI, the expert opinion of medical practitioners, teachers in medicine, nurses, pharmacists and manufacturers has been obtained. The selection of drugs for inclusion in the National Formulary has been made taking into consideration the relative advantages and disadvantages of the various drugs used, the extent of their use in current medical practice and their availability in the country. Thus, the National Formulary of India represents a broad consensus of medical opinion in respect of drugs and their formulations and provides the physician with carefully selected therapeutic agents of proved effectiveness which form the basis of national drug therapy. The current version of NFI consists total monographs of 521 medicines, 33 fixed dose combinations, 20 immunological (vaccines) and 12 vitamins.

12.5.5.1.5 Drug information centres (DICs)

Drug Information Centres are regarded as a gateway of drug information. Number of drug information centres are being opened with the prospective of safe health care and drug safety which will surely serve the community and enhanced the role of community pharmacist.[227] There are several drug information centres established in collaboration with state pharmacy councils, WHO Country Office, universities, hospitals and other autonomous bodies. These centres are funded independently by State Pharmacy Councils or in collaboration with any other governmental, private or non-profitable organisations. It is free for pharmacists and/or patients to contact the DCIs to obtain any information related to medicines. Drug information centres receive queries/questions both from health professionals and patients over telephone, direct access and during the ward rounds; if DCI is located in a hospital.[228] There are 17 independent drug information centres attached to the hospitals with clinical pharmacy service and 14 DCIs run by the State Pharmacy Councils and/or educations institutions in India.[227]

12.5.5.2 Evolving role of clinical pharmacists in accredited hospitals

Improving patient safety, medication management, infection prevention and control, quality performance and improvement, and environment of care are the primary objectives of hospitals. The hospitals involved in medical tourism are voluntarily seeking accreditation of their patient safety and service quality standards from accrediting bodies nationally and internationally. In India, the National Accreditation Board for Hospitals and Health care Providers (NABH) is the constituent board of Quality Council of India, which has been set up to establish and operate

accreditation programme for health-care organisations. The accreditation programme requires complete compliance to safe medication practices as a part of the management of medications in the hospital.[223]

In India, the National Accreditation Board for Hospitals and Health care Providers (NABH) is the constituent board of Quality Council of India, which has been set up to establish and operate accreditation programme for health-care organisations. The accreditation programme requires complete compliance to safe medication practices as a part of the management of medications in the hospital. To reach the quality standards, pharmacists and pharmacologists' interventions in Medication Management, Prescription Auditing, Medication safety services such as management of ADRs to minimise medication errors and pharmacist role in clinical research. Medication management includes safe, effective, and appropriate drug therapy to patients prescribed by physicians and approved by a clinical pharmacologist. Patient care is ensured by the various staffs of pharmacy, which needs to be monitored by a clinical pharmacologist and has a very active role in the development of formulary which is an official list of drugs and consumables which are available within a pharmacy. This list needs development by collective inputs from pharmacy-in-charge, clinical pharmacologist, consultants of various clinical departments, and the medical administration team. As a part of quality standards, it is expected to lead the prescription audit services within the hospital. The NABH-accredited hospitals must monitor certain quality indicators every month which describe the quality of prescribing services in the hospital. Some of the quality indicators are: number of illegible prescriptions, number of medication orders with error-prone abbreviations, and number of prescription errors.

12.5.5.3 Indian Pharmaceutical Association's (IPA) contribution to patient and medication safety

12.5.5.3.1 Good Pharmacy Practice (GPP) – to patient and medication safety

IPA Community Pharmacy Division (IPA CPD) aims to enhance the role of a pharmacist and raise professional standards of pharmacy practice through its activities and aims to improve the public health through community pharmacists' services. As a part of this, IPA is striving hard to implement GPP, in this process IPA CPD, in collaboration with WHO India and CDSCO developed Good Pharmacy Practice Training Manual in year 2005 which is a first of its kind of a document in India on GPP.[229] CPD also carried out pilot project on Accreditation of Pharmacies in year 2007 in collaboration with WHO India Office. There were 70 pharmacies enrolled, of which 45 pharmacies (26 from Mumbai and 19 from Goa) were accessed and accredited. This enrolment of pharmacies was on purely voluntary and there were no criteria/ conditions fixed for enrolment.[230]

12.5.5.3.2 IPA Tuberculosis fact card project

Tuberculosis Fact Card Project The participation of pharmacists in TB fact card project (an initiative of Indian Pharmaceutical Association, Commonwealth Pharmaceutical Association and International Pharmaceutical Students Federation) indicates the beginning of a new era in the history of Indian pharmacy practice. The counselling offered treatment monitoring and creation of awareness about TB among the community by dissemination of information and encompasses all the aspects of pharmaceutical care by the pharmacists. There is a healthy partnership which is getting established with physicians through such work. This has become a milestone project leading to put the pharmacists on national programmes. In recent years, pharmacists and professional associations have actively promoted the pharmacist's role in public health. There are examples of pharmacists taking initiatives to be a part of national health programmes such as the Revised National Tuberculosis Control Programme (RNTCP). For the first time 2014, the RNTCP guidelines mentioned the word "*pharmacist*" as specialists with expertise in managing Multi-Drug-Resistant Tuberculosis (MDR-TB) which is a step forward.[231] In 2012, a Memorandum of Understanding (MoU) between Central TB Division and IPA, PCI, AIOCD and FIP-WHO SEARO Forum of National Pharmaceutical Associations with an objective to engage pharmacists in RNTCP for TB care and control in India. This MoU was valid for one year and is extended till 2017.

12.5.5.3.3 Consumer Medicine Education Initiatives

Literacy and health literacy and patient literacy levels play an important role in patient safety and medication errors. Health literacy has increasingly been viewed as a patient safety issue and may contribute to medication errors. Most frequently noted safety issue connected to limited health literacy is the risk of medication errors that result from improper dosing administration.[232] Several studies have found low health literacy to be significantly associated with a poorer understanding of medication names, indications, and instructions and adherence to treatment regimens.

Indian Pharmaceutical Association Community Pharmacy Division (IPA-CPD) working consistently for Consumer Medicine Education to improve responsible use of medicines in the society. CPD initiated a Campaign for Awareness on Responsible Use of medicines (CARUM) since 2014 and has several posters, leaflets prepared under CARUM in different languages. Main highlight is the handbook Responsible Use of Medicines: A Layman's Handbook, which is a first ever publication educating the consumers on basic aspects of medicine usage. CPD prepares material for National Pharmacy Week (NPW) and for World Pharmacist Day. CPD involves pharmacy students in various public health activities and conducts various competitions for pharmacists during WPD or NPW.

12.5.5.3.4 Collaboration with stakeholders

IPA-CPD has collaboration with various stakeholders. IPA-CPD collaborates with governments, Pharmacy Council of India, chemist associations, regulators, corporate Sector, NGOs, academia and IPA's State and local branches for its pharmacists' training programmes and projects for continuing professional development of community pharmacists. IPA CPD works all across India with pharma corporate sector including multinational and Indian companies to train pharmacists on various aspects such as GPP, Responsible Use of Medicines, Medication Errors, patient counselling and other relevant areas. IPA-CPD collaborates with several pharmacy institutes across India to increase community centred activities through pharmacy students.[233]

12.5.5.3.5 Accreditation of Alternative therapies

AYUSH is the acronym of the medical systems that are being practiced in India such as Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy. AYUSH medicines are widely used as a standalone option or as adjunct with Bio medicine in the long-term diseases. Therefore, the relevance of AYUSH has become more now because of this change in health paradigm. Keeping this fact in view the Government is encouraging a pluralistic approach in health care where every medical system can grow based on its evident strength. These systems are based on definite medical philosophies and represent a way of healthy living with established concepts on prevention of diseases and promotion of health. The basic approach of all these systems on health, disease and treatment are holistic. Because of this, there is a resurgence of interest on AYUSH systems. Yoga has now become the icon of global health and many countries have started integrating it in their health care delivery system. Similarly, there is great curiosity to understand the principles and practice of Ayurveda, Homeopathy, Siddha and Unani especially due to growing challenges in medicine in Non-Communicable Diseases (NCDs), Life style disorders, long term diseases, multi drug resistant diseases, emergence of new diseases etc. National Accreditation Board for Hospitals and Health care Providers (NABH) has launched Accreditation Programme for AYUSH Hospitals wherein quality standards for Ayurveda, Homeopathy, Unani, Siddha and Yoga and Naturopathy Hospitals have been established. It consists of two kinds of standards - Accreditation Standards and Structural Standards. Accreditation standards measure the quality and safety aspects of the care delivered to the patients.[234]

12.5.6 Future improvements

A research concluded that there is a low awareness among health workers of patient safety incidents. There is a need to institute a patient safety reporting incident system with training of all categories of staff in patient safety and quality improvements in a collaborative and sustainable manner.[235]

12.6 Oman: Role of the pharmacist in patient safety

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12.6.1 Introduction

The pharmacy profession is continually evolving in Sultanate of Oman. Pharmacists have opportunities to practice in a variety of settings. Omani national pharmacists are predominating in the governmental health institutions and constitute more than 95% of the total number of pharmacists. Those pharmacists have an advanced-level practice in hospitals, with collaborative practice agreements and prescriptive authority within their institutions, which includes counselling, reconciliation, interventions, clinical pharmacy services and some are managing pharmacist-led clinics which cover non-communicable diseases.

The Directorate General of Pharmacy & Drug Control (DGP&DC) is the regulatory body in Oman; it is responsible for licensing of the Pvt. Pharmaceutical establishments and carrying out regulatory activities for drug and medical devices registration and evaluation, Good Manufacturing Practice [cGMP] inspections, customs release, and pharmacovigilance for both medications and herbals to ensure patient safety.

All ministry of health units have pharmacists working as medication safety officers since 2012, they are actively involved in detecting, analysing and reporting medication errors, product quality defects and adverse drug reactions. They are also members of the quality team at the hospitals to discuss and resolve any medication safety issues.

12.6.2 Health system supporting patient safety

As per WHO assessment conducted in May 2017, four Omani hospitals were scrutinised using WHO Patient Safety Friendly Hospital Initiative standards. The exercises suggest that patient safety system in hospitals is adequate for being patient safety friendly hospitals. This activity helped in spreading culture of standards among institutions and facilitated establishing a structure for implementing a national accreditation system in the future. Based on the successful experience each hospital is planning to achieve level four in the next assessment by strengthening its patient safety system through various strategies such as patients and staff empowerment and engagement. Furthermore, these hospitals have the potentials to achieve the targeted core and developmental standards. On the other hand the pharmaceutical care department at Directorate General of Medical Supplies (DGMS) issued a complete set of policies and procedures which ensure patient safety such as high alert medications, look-alike/ sound-alike medications, medication reconciliation policy, handling patient drug allergy, drug - food interactions, drug - drug interactions, management of adverse drug reactions, medication error reporting, drug quality reporting program and medical devices quality reporting, medication order review, medication dispensing guidelines, patient counselling, unit dose dispensing system, emergency crash cart medications, handling hazardous medicines, floor stock medication guidelines, patient's own medications.

Generally, pharmacists are contributing positively with in the health system by accomplishing different roles in the following safety elements:

12.6.2.1 Electronic prescribing

Electronic prescribing has been established since 2000, in MOH Oman this suggest that the use of technology-based solutions can improve patients' adherence to prescription medications. The E-Prescribing eliminates handwriting errors/illegibility and gives both physician and pharmacist access to a patient's prescription history to reduce the chance of the wrong drug being dispensed. Mainly due to mistakes when reading a handwritten prescription that improve patient safety practices.

Tall Man letter list of look alike sound alike (LASA) drug names that approved in MOH is supported by the Health Information System (HIS) as additional safe guards to avoid errors with LASA medications.

Interventions of the pharmacists on prescription are documented in the progress note in the electronic health system and accepted and taken in consideration by the prescriber.

12.6.2.2 Drug Quality reporting system

Pharmacists are collecting quality issues reports clarifying them and forward the same to the Quality Management and Medication Safety Department at Directorate General of Medical supplies (DGMS) to analyses the reports and send feedback to all concerned and take the required action with the drug manufacturers.

12.6.2.3 Adverse drug reactions (ADR) reporting system

Pharmacists are collecting ADRs reports clarifying them and forward the same to the Directorate of Pharmacovigilance and Drug Information in DGP&DC which in turn send the report to the Uppsala Centre using an electron system of reporting. The reporting system is open for healthcare professionals as well as the patients.

12.6.2.4 Medication error reporting system

A lot of efforts and initiatives have been taken by the MOH to boost what is seemed to be as under reporting of the medication errors. The Pharmacists are collecting the reported medication errors and drug related problems, clarifying them, conduct root cause analysis and forward the report to the Quality Management and Patient Safety Departments in the health units with copy to the Pharmaceutical Care Department at (DGMS) and Directorate of Pharmacovigilance and Drug Information in DGP&DC to further analyse the reports and set strategies to prevent them and conduct training for health care professionals.

12.6.2.5 Quality assurance committees at hospital level

Pharmacists participate in quality assurance committees and they are well positioned to assist the healthcare system in improving quality of care, and they are already established as experts in medication management processes, in addition pharmacist review of medication orders for drug-drug interactions, contraindications, precautions, and allergies prior to dispensing.

12.6.2.6 Selection and procurement

Selection and procurement of drugs in MOH is confined to the list of drugs included in MOH formulary and executed through open bulk tendering process through International and GCC Gulf Joint Purchase to ensure acquisition of supplies with good quality and suitable cost with focus on generic and biosimilar procurement in line with WHO guidelines. The pharmacists are playing the main role in analysis of offers and selection of items as per the approved selection criteria.

Random samples from the supplied drugs are analysed by the Central QCL at (DGP&DC) to ensure meeting the quality and the stated specification standards.

12.6.2.7 Central Drug Committee and Drug and Therapeutic Committees

The Central Drug Committee (CDC) is constituted from Key Doctors and Pharmacists from different specialties and it is concerned with selection of drugs in the MOH formulary based on the recommendations of the Pharmacy and Drug committees at hospitals. The CDC is also involved in approval the treatment protocols and guidelines of the approved drugs and framing out other polices related to rational use of drugs.

Pharmacists are active members in Drug and Therapeutic Committees in Health Units, and they are involved in review of requests for inclusion or deletion of medication in the formulary, and they participate positively in treatment protocols assessments, and drug use utilisation.

12.6.3 Pharmacists' role in patient safety in different settings

12.6.3.1 Outpatient settings

Pharmacists counter check drug-assembled against prescriber order and counsel the patient and follow the approved policies and procedures regarding dispensing, reviewing of medication orders and counselling the patients. They also arrange the medications and label the shelves and products to ensure patient safety.

12.6.3.2 Community settings

Pharmacists dispense medication as per the prescription; except OTC listed items which are freely dispensed, and patients informed regarding their rights regarding their medications

12.6.3.3 Ambulatory settings

Pharmacists conduct the following at the ambulatory setting:

- Medication review
- Therapeutic drug monitoring TDM for narrow index medications

- Monitor patient for both desired and undesirable therapeutic effect
- Double checking of prescription
- Labelling of products and shelves
- Counselling of special patient population
- Monitoring availability of life saving
- Maintaining safety of high alert and look alike and sound alike medication double check for high alert medications.

12.6.3.4 Hospital settings

At hospital level besides double checking of prescription and medication review prior dispensing pharmacist practice an advance clinical pharmacy services around patient safety such as medication reconciliation at transition of care. Pharmacists are part of certain programmes and committee such as the antimicrobial stewardship, pharmacy and therapeutic committee, quality assurance committee and they are able to document their intervention in the electronic health system. Pharmacists participate with the physician round and provide pharmaceutical care plan for the patients, provide drug information and provide IV admixture and TPN services as well as Standardising reconstitution of inject able medication and Compounding extemporaneous preparation.

Pharmacists perform Therapeutic drug monitoring TDM for narrow index medications and Monitor patient for both desired and undesirable therapeutic effect to ensure safety.

The unit dose system is implemented by the pharmacists and assistant pharmacists in most of the ministry of health hospitals and in some hospitals the HIV clinic is led by a pharmacist to ensure patient safety by monitoring drug interactions and proving counselling. At secondary level of care pharmacists run asthma clinics to ensure safe use of devices and monitor the patient, while at warfarin led clinics pharmacist monitor the patient and adjust the therapeutic doses according to laboratory investigations.

12.6.3.5 Regulatory settings

The Directorate General of Pharmacy & Drug Control (DGP&DC) emphasising drug control mainly through:

- A system of drugs, herbals and medical device registration and price control.
- Rules and regulations regarding controlled substances.
- Pharmacovigilance system.

12.6.3.6 Industry settings

There are two local pharmaceuticals manufacturers in Oman, they cover most of the needs of the governmental and private health sector for good quality generic drugs at reasonable cost.

12.6.4 Interprofessional collaboration

Pharmacists Interprofessional collaborate with other health care providers to ensure patient safety by attending the rounds and provide advice regarding medications, active members of hospital teams of hospitals such Risk assessment committee, drug and therapeutic committee, antimicrobial stewardship committee and part of warfarin clinic and asthma clinic. Pharmacist who are working as medication safety officers collaborate and educate other health care professionals on medication safety and educate patients on safe use of their medications.

12.6.5 New services or innovations to improve patient safety

Ministry of health implemented the smart pharmacy programme which state that learn today and apply tomorrow which is an innovative and competency-based training for pharmacist. In that three modules have been carried out and patients are monitored by the pharmacists which are, asthma and COPD, patient care process to address, hypertension, dyslipidaemia and diabetes. Pharmacists also created classification of drug related problems for ministry of health hospitals in collaboration with the pharmaceutical care network Europe. Ministry of health adopted

Patient Safety Friendly Hospital Initiative standards which were set by the WHO was pharmacists are essential member in the team.

12.6.6 Education around patient safety (incl. leadership, training, continuous education)

Having patient safety a core of pharmaceutical care, Ministry of health represented by Directorate General of Medical Supplies (DGMS) trained pharmacist as medication safety officers through a structured accredited course in collaboration with external experts from the American and Canadian (ISMP). The training extended to include physicians and nurses during the year 2019.the course provides tools and techniques to ensure patient safety.

The pharmaceutical care conference is an annual event organised by directorate general of medical supplies (ministry of health) to attract more than 1200 delegates from different part of the world and provide a platform for sharing knowledge between different countries on patient safety in general and medication safety in particular.

To meet the WHO Third Global Patient Safety Challenge (medication without harm) ministry of health suggested the national patient safety day which is 17 of September and each year it focuses on one of the areas suggested by WHO that are transition of care, poly pharmacy and high-risk situations. The celebration consists of one day symposium for health care professionals and another event for public education around patient safety which is run by pharmacists from different hospitals. DGMS conducted two workshops on medication recompilation and appropriate poly pharmacy to increase pharmacist's competency to provide safe practice for patients. Many educational materials have to be created and printed for patients in order to keep them safe. Prior the month of Ramadan a campaign is conducted by pharmacists at a public place and at individual hospitals to educate patients regarding their medication during the month of Ramadan to ensure therapeutic outcome and safety.

12.6.7 Conclusions

Oman Ministry of Health has a well-structured system for medication safety and patient safety where pharmacists play an important role as they are the experts on medications. Pharmacy practice in Oman implement patient centred care by providing different services for patients ensuring their safety. More information can be found at: https://www.moh.gov.om/

12.7 Saudi Arabia: Patient safety programmes

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12.7.1 Introduction

Over the recent years, pharmacists' role was limited to outpatient services, including dispensing medication and compounding extemporaneous preparations. Nowadays, this traditional role of the pharmacist has been diversified in such a manner that encompasses the direct care of the patients.

Pharmacy profession became an integral part of Saudi health care system and plays a great role in patient safety. Pharmacists are the most accessible healthcare team to the patients, and their role is vital to ensure the proper medication utilisation across the continuum of care.[236, 237]

12.7.2 Health system supporting patient safety (or not, legal framework)

Patient safety has been on the National agenda in the Kingdom of Saudi Arabia in the last few years. A notable patient safety measures and support systems have been put in place by the Saudi government which include the establishing of a National accreditation body (Saudi Central Board of Accreditation for Healthcare Institutions) with focus on patient safety standards. This accreditation is mandatory for all types of healthcare setting including hospitals, poly health clinics (private and governmental sectors) also establishing The Saudi Food and Drug Authority pharmacovigilance system, a service that allows health practitioners, health institutions and individuals to report side effects, pharmacological errors, cosmetic side effect and any quality defects in pharmaceuticals, reporting food poisoning, reporting a defect in medical devices and supplies.[236]

Since the launch of the Saudi Arabia vision 2030, various patient safety measures have been adopted to enhance patient safety, one of the key reforms was the launch of the Saudi Patient Safety Centre (SPSC), by the Minister of Health as a government initiative in 2017 and is being implemented through the National Transformation Programme. It is the first of its kind in the region.[237]

The Centre aims to initiate a paradigm shift in the health service delivery to upgrade performance efficiency, improve clinical quality outcomes, enhance patient experience and establish a culture of patient safety with all health care provider organisations and contribute to the global efforts of eliminating the endemic patient safety problems that all healthcare system is facing today.

In March 2019, Under the patronage of the Custodian of the Two Holy Mosques, King Salman Bin Abdulaziz, the Kingdom of Saudi Arabia had the honour to host the 4th Global Ministerial Summit on Patient Safety 2019, which is a continuation of the series of the Global Ministerial Patient Safety Summit with the primary goal to drive the global patient safety agenda forward.

The summit has shed light on 12 key patient safety recommendations and announced to the world the launch of "*Jeddah declaration*" with its 11 actionable items that are aligned with the 72nd World Health Assembly (WHA) resolution on "*Global Action on Patient Safety*" and is considered the main catalyst is supporting its implementation.[237]

12.7.3 Pharmacists' role in patient safety in different settings

For the previous years, the community pharmacy was considered as a point of sale with limited scope and few Over-The -Counter (OTC) medication. Therefore, the country's focus was on the hospital pharmacies despite the significant number of community pharmacies in the country (approximately 8,000 pharmacies).[237, 238]

Some studies showed that though community pharmacists in Saudi Arabia do provide medication counselling and other patient ‑ centred care services; however, these services need considerable improvement (Rasheed, Hasan & Babar, 2018). One of the newly introduced Medication Safety initiatives in the kingdom is the Saudi Patient Safety Centres' certification-based programme for community pharmacy (Pharma-Safe) which have a set of medication safety requirements, and it aims to standardise community pharmacy practice in Saudi Arabia.[238, 239]

Hospital pharmaceutical care practices in Saudi Arabia is considered as one of the best and most advanced practices in the region. Pharmacists play a crucial role in reducing medication related harm and improving patient safety through transition of care by helping in doing medication reconciliation, orders verification, unit dose dispensing, Intravenous medication, total parenteral nutrition, chemotherapy preparations and patient counselling and education. Some pharmacists are working as a drug information while others are medication safety officers handling and analysing reported medication errors.[236]

Some pharmacists are working in research centres within the hospitals to handle investigational drugs.[237]

Specialised clinical pharmacists are also practicing in the kingdom hospitals (especially in tertiary care hospitals), and their roles are varied according to the speciality for instance (Critical care, infectious disease and paediatric clinical pharmacists).[237, 238]

According to Ahmed Al-jedai,(2019), Pharmacists not only practice in hospital and community pharmacies but also are involved in non-traditional settings, such as regulatory activities (working within the Saudi Food and Drug Authority for drug evaluation, Good Manufacturing Practice [GMP] inspection, customs release, and pharmacovigilance), the pharmaceutical industry (sales and marketing, scientific office, manufacturing site, or licensing and regulation department), and teaching and academic institutions.[236]

12.7.4 Interprofessional collaboration

Pharmacists are the medication experts and their skills qualify them to play an active role to optimise medication use across healthcare system and to ensure patient safety. In Saudi Arabia pharmacists are integral part of many multidisciplinary collaborations such as the Anti-Microbial Resistance (AMR) taskforce to establish antimicrobial stewardship programmes, develop clinical pathways, Medication Reconciliation, Pain Management, Rapid Response Team and other more multidisciplinary activities (Ismail et al., 2018).[239, 240]

12.7.5 New services or innovations to improve patient safety

Various innovative tools and programmes are newly introduced in the Kingdom. According to Alhawsawi et al., (2019), the human factors engineering is an important aspect of consideration. A very useful strategy to improve Patient Safety is the introduction of 'forcing functions' at the level of the interface. Forcing functions is a feature of the system design that prevents medical errors and/or harm from taking place.[237]

One of the innovative programmes to ensure patient safety in the kingdom is Drug Track and Trace System for pharmaceutical products (RSD) released by Saudi Food & Drug Authority that aims to guarantee the safety of all drugs by knowing their origin starting from manufacturing phase until consumption.[240]

Another important patient safety initiative is The National Reporting and Learning Platform (SAWTAK) launched by Saudi Patient Safety Centre as the consideration of a reporting system in Saudi Arabia is also another factor emphasised upon by Elmonstri (2017), who specifies that healthcare providers are required to comply with policies on reporting. The reporting system helps in the collection of data which in turn helps in tracking the issues that compromise patient safety and hence lessons are learned from failures, and this helps to avoid the occurrence of such cases in the future.[236, 238, 240]

12.7.6 Education around patient safety (incl. leadership, training, continuous education)

"*Invest on Workforce knowledge and safety as the drivers for Patient Safety*" is one of the Jeddah Declaration on Patient Safety Actionable items that highlights the importance of the integration of patient safety curriculum in the undergraduate curriculum for Medical, Nursing, Dental, Pharmacy and Allied Health Sciences (and related) degrees. Some universities started the implementation of patient safety curriculum in their programmes. As a central part in healthcare system, patients are also trained and educated on patient safety, Saudi Patient Safety Centre (SPSC) plays a significant role to promote health literacy by educating patients on patient safety aspects including infection control and medication safety. those educational activities and events conducted in hospitals (Patient Safety Caravan) schools and other public areas.[237]

12.7.7 Conclusions

The pharmacy profession is continually evolving in Saudi Arabia. Pharmacists have opportunities to practice in a variety of settings as a safety net with a primary goal to reduce medication related harm.

12.8 The European Union: Improving polypharmacy

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One of the flagship reports of the third Global Patient safety challenge is the "*how to address appropriate polypharmacy*". This burden is set to increase as the population ages and more people suffer from multiple long-term conditions. There remains a lack of evidence-based solutions, as both medical research and healthcare delivery models have focused on single disease interventions. This challenge, and the limited range of solutions, have significant implications for how healthcare resource is used to address inappropriate polypharmacy. However, with up to 11% of unplanned hospital admissions being attributable to harm from medicines, and over 70% of these being due to elderly patients on multiple medicines there are significant opportunities to reduce this burden by timely and effective interventions.[241]

The Institute of Medicine report, Responsible use of Medicines demonstrates that 0.3% of the global health budget could be saved by managing polypharmacy appropriately. The report identifies key areas of focus which include using risk stratification to identify vulnerable patients and a more collaborative role for pharmacists, physicians and patients.

One way to assess the readiness of the health system is to conduct a baseline assessment of hoe countries have implemented the programme using the change management techniques. The SIMPATHY (Stimulating Innovation in the Management of Polypharmacy and Adherence in the Elderly) project used case studies, benchmarking survey and literature review demonstrate that there are some effective polypharmacy management programmes in the EU, but

that they are too few in number. The project also demonstrates that patients believe inappropriate polypharmacy is an important issue to address.

The SIMPATHY report and the Cabinet Secretary for health for Scotland called for EU countries to work together in a focused way to manage and prevent inappropriate polypharmacy, and improve medicines adherence, through the use of a change management approach that is coordinated and collaborative in order to deliver better patient outcomes through the following six key recommendations. [241]

Adopting these recommendations will help prepare EU countries for the WHO global patient safety challenge to improve medication safety, of which polypharmacy is an essential element:

1. Use a systems approach that has multidisciplinary clinical and policy leadership
2. Nurture a culture that encourages and prioritises the safety and quality of prescribing
3. Ensure that patients are integral to the decisions made about their medicines and are empowered and supported to do so
4. Use data to drive change
5. Adopt an evidenced based approach with a bias towards action
6. Utilise, develop and share tools to support implementation.

Different countries across the project delivered their work in different sectors to address polypharmacy. The approaches could be considered in terms of their political, economic and quality impact on patient safety. Below is set out how countries can start to consider how to implement a polypharmacy programme by using adaptation of Kotter's Change management process and case examples of how different EU countries across the project have addressed some of these areas in order to build programmes to address the patient safety challenge.[241]

Application of the Kotter 8-step in transforming change in polypharmacy management:

1 Establishing a sense of urgency
Communicating to stakeholders the need to change current ways of reviewing medication to benefit patient care, improvement in patient safety and outcomes from medicines. Examining other projects that are developing and whether they pose a threat to the development of the framework. Existing projects may focus on cost efficiencies rather than on patient safety due to budgetary pressures.

2 Forming a powerful guiding coalition
A project group is assembled including both primary and secondary care clinicians made up of doctors, pharmacists and geriatricians and long-term conditions collaborative leads locally and nationally. Have discussions about working together to inform work of medical, pharmacy and public health directors, both locally and nationally.

3 Creating a vision
A vision is created as to what the project might achieve for patient care and for the healthcare provider. Project plan outlines strategies for achieving the vision.

4 Communicating the vision
Share this in written communication and have face to face dialogue with people both locally and nationally.

5 Empowering others to act on the vision
Looking at the obstacles to change, the biggest one will be ownership, so provide feedback and adaptation of the protocol, e.g. link with anticipatory care plans.

6 Planning for and creating short-term wins
To gather data and provide feedback within a relatively short space of time after review framework is piloted. Share data from pilots and use to build the business case. Break the project down into smaller tasks so that results can be seen and shared, e.g. design of guidance for review.

7 Consolidating improvements and producing still more change
Engage with individuals that might influence change in policy to adopt the vision. Transfer of project to other areas to reinvigorate the project, e.g. running project in another locality and other health care providers.

8 Institutionalising new approaches
Sharing of benefits of the new process to the organisation, e.g. reduced admissions and improved patient care. Adoption of project into nationally delivered service development, e.g. sharing outcomes with local and national leads on service development.

Figure 13. Application of the 8 Kotter's steps in transforming change in polypharmacy management

The application of the transformation process is illustrated below in the examples from Sweden and the United Kingdom (Scotland). [241]

12.8.1 Economic benefits of implementing good practice

12.8.1.1 Sweden: Improved quality leading to economic benefits

In a randomised controlled trial in Sweden, clinical pharmacists performed comprehensive medication reviews on elderly hospitalised patients. Patients who received a medication review had 16% fewer hospital visits and 47% fewer visits to the emergency department within a 12-month follow-up period compared to usual care. Medication-related readmissions were even reduced by 80%. After inclusion of the intervention costs, the total hospital-based healthcare costs per patient in the intervention group was approximately 200 euros lower than in the control group. The researchers concluded that, if implemented on a population basis, the addition of clinical pharmacists to healthcare teams would lead to major reductions in morbidity and healthcare costs.[241]

12.8.1.2 Scotland: Economic benefits of implementing good practice

The implementation of the Scottish Polypharmacy Management Programme was underpinned by detailed economic analysis. The data demonstrates notable savings, even when considering the cost of reviews as depicted in the table below.

Table 1: **Range of estimates of savings from polypharmacy reviews:**[241]

Unit cost/saving Scotland	**Age 75+, 10+ medicines, plus high-risk ones**		**75+ group plus all care home residents**
Number of patients with high risk medicines	40,585		64,729
Cost estimates based on savings per case p.a	**GBP**	**GBP M**	**GBP M**
1 Med stopped; 6 repeats; 1 yr; unit cost GBP 9.87	9.87	2.4	3.8
2 Meds stopped; 6 repeats; 1 yr; unit cost GBP 9.87	19.74	4.8	7.7
Lower estimate of value of medications stopped	66	2.7	4.3
Base-case: change medication only	90	3.7	5.8
Upper estimate: change medication + switching to cost effective + cost avoidance measures	155	6.3	10.0

12.8.2 Politics and policy

The politics of policy making is an important aspect to consider. The political case for more effective polypharmacy management is to improve patient outcomes and patient well-being of the citizen as they age. This is set out in the EU led European Innovation Programme on Active and Healthy Aging (EIP AHA, more information at: https://ec.europa.eu/eip/ageing/home_en). This should improve the outcomes for patients by improving quality and patient safety and deliver economic benefits. Innovative models that deliver this care through multiprofessional working can also help address the capacity of the traditional workforce models that are under extra pressure, due to challenges of an aging population with increasing multiple morbidities.[241]

Kingdon suggests that there is usually a window of opportunity for concepts to be accepted and adopted politically which are dependent on three components being essential: problem recognition; generation of policy proposals; and political events. For addressing polypharmacy, the window is open, and policies are being driven that acknowledge the problems, as governments seek to improve the health of their populations with resources that have competing demands.[241]

In addition to establishing integrated care there is a call to look at population care systems that aim to address the wide range of influences affecting health, as many health problems are preventable. For example, although there may be a focus on care of the elderly, in reality, 29% of the people likely to have multiple morbidities and are under 65

years of age, and come from the most deprived communities. Reflecting this, polypharmacy management must be considered for whole populations. Since the publication of Choosing Wisely many policy documents have raised awareness of using resources wisely, and also about the importance of the greater role of the patient in decision making about their healthcare, including, medication.

Whilst awareness of the benefits of polypharmacy management is a growing, there is a need identified through both the SIMPATHY benchmarking and Delphi surveys to increase understanding about the benefits of effective polypharmacy management across the EU. Further change is needed to raise awareness, to share and scale up good practice.[241]

The figure 14 below depicts the vision and strategies of implementation of processes leading to improved polypharmacy.

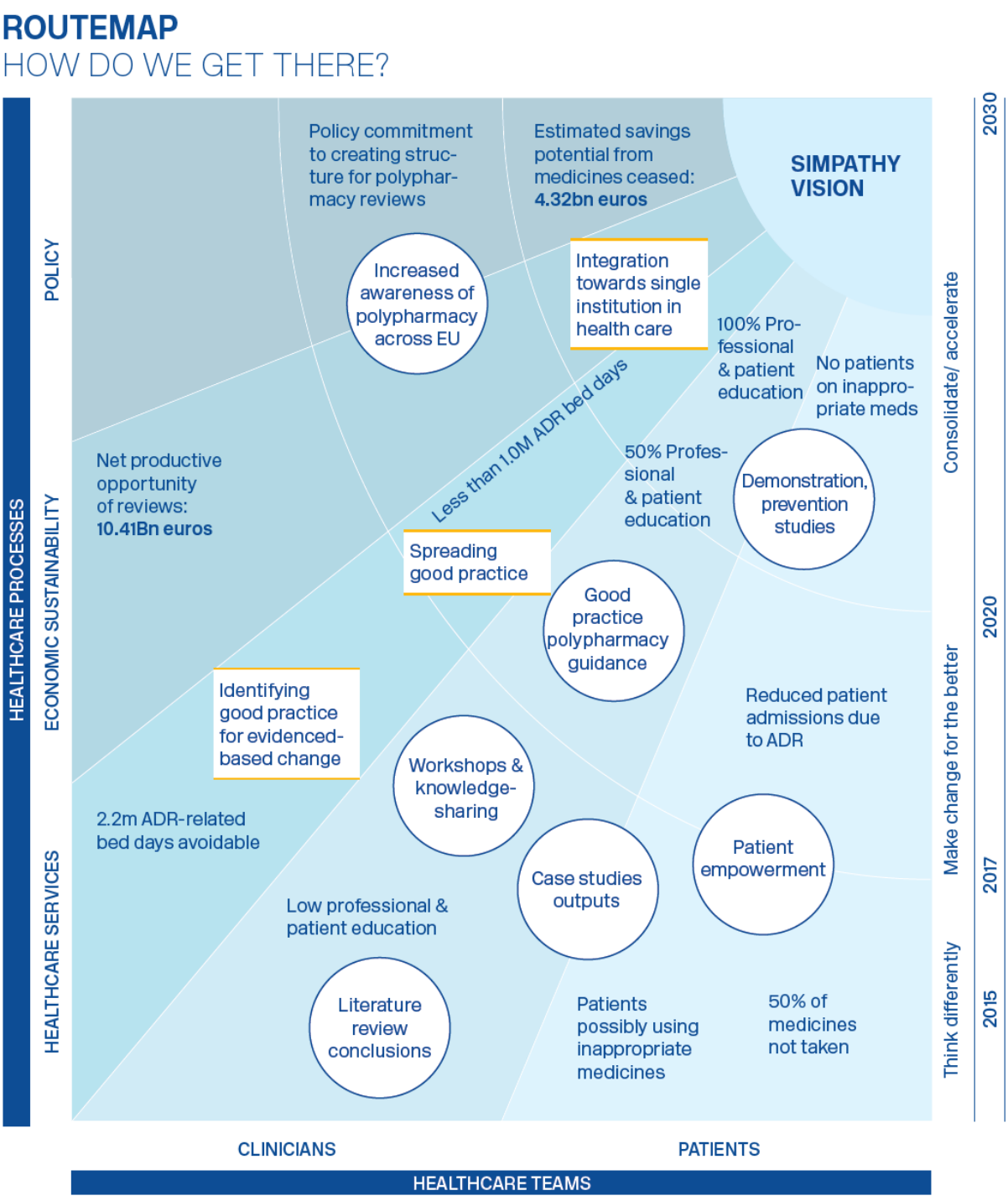

Figure 14.: Routemap of SIMPATHY project on implementing the vision for polypharmacy in selected countries of the European Union[241]

Political support across EU countries can facilitate implementation of effective polypharmacy management to improve health and well-being throughout life and protect independence into older age. The political work is not solely policy-focused. Nurturing deep change in how health professionals, policymakers and patients think about, and practice medication safety in general, and polypharmacy in particular will generate some resistance no matter how compelling the evidentiary-based case is. Everyone involved will have to re-order priorities and adapt to new, unfamiliar and sometimes even uncomfortable ways of interacting with each other. Helping people through that process is a different kind of work than convincing them of the merits of polypharmacy management, but just as essential to

policy and implementation success.[241] SIMPATHY consortium engaged with the expertise of Marty Linsky in addressing political challenges and recordings are offered on the SIMPATHY website (www.simpathy.eu).

12.8.2.1 Italy: Political support helping spread change

In Italy, the SIMPATHY project stimulated collaboration among the many different stakeholders of the regional health system in the Campania region, raising awareness about the implications of polypharmacy in the Regional Health System.[241]

The Campania region is integrated in the national network for the internationalisation of regional health systems, therefore Campania stakeholders involved in the SIMPATHY project had the opportunity to share their experience. The results of the project were shared with other Italian regions, as well as with the Italian Ministry of Health. This, in turn, has fostered the exchange of good practices and contributed to the national plan for chronic diseases. [241]

Sharing the SIMPATHY experience within the national network facilitated the identification of a shared priority to respond to a research call by the Ministry of Health leading to an inter-regional project on the management of multimorbidity in community-dwelling older adults, with a focus on integrated polypharmacy and rehabilitative robotics. For this project Campania, Liguria, Piemonte and Calabria along with the Ministry of Health co-financed a total budget of 4.2 million euros.[241]

12.8.2.2 Scotland: Using policy to drive polypharmacy management

In Scotland, the existence of clinical leaders with a national policy role meant that effective polypharmacy management developed regionally in some National Health Service boards, could be scaled up through the development of a polypharmacy guidance document that was supported through an official Chief Executive Letter and included in the general practice contract.[241]

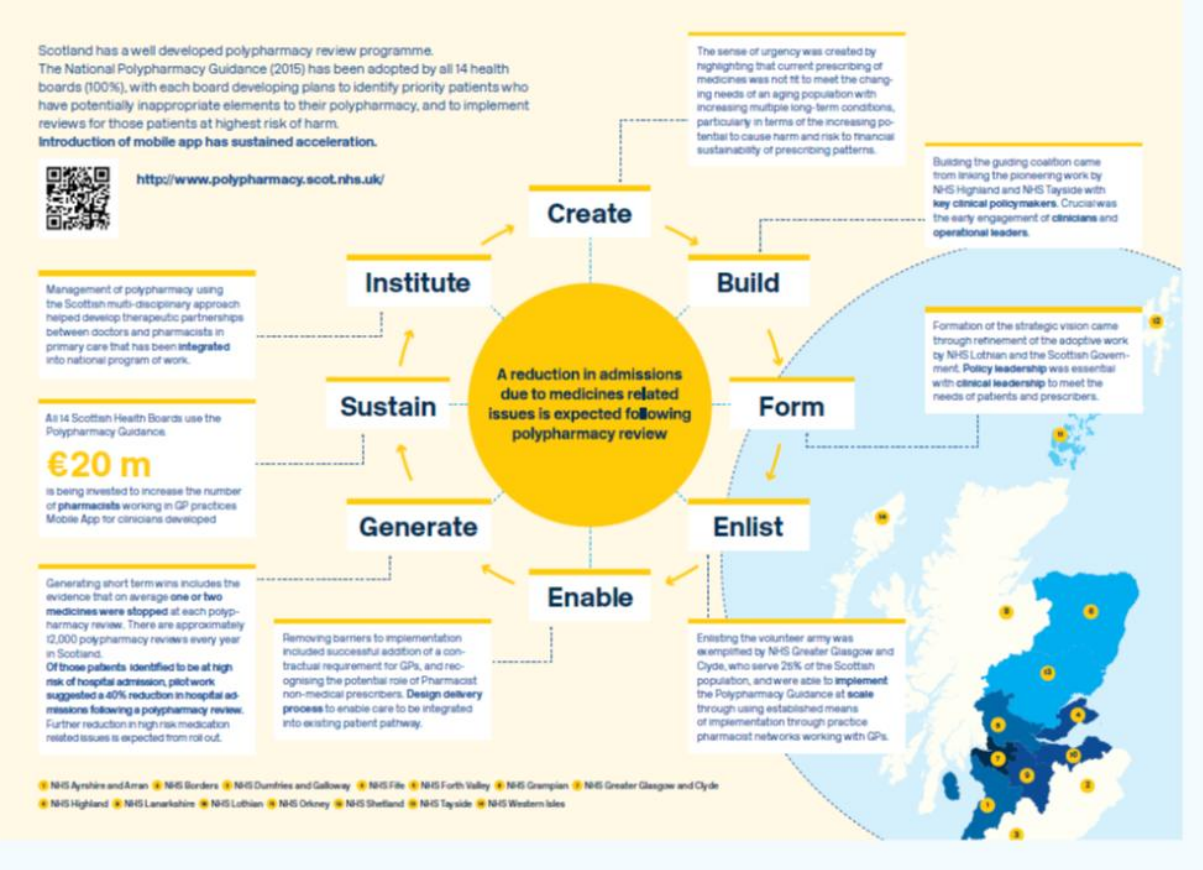

Figure 15: Polypharmacy guidance and programme in Scotland

Scotland is now in its third edition of the polypharmacy guidance and its programme has been supported through a 7-step model that has been designed with a patient centred approach. More information can be found at: http://www.polypharmacy.scot.nhs.uk

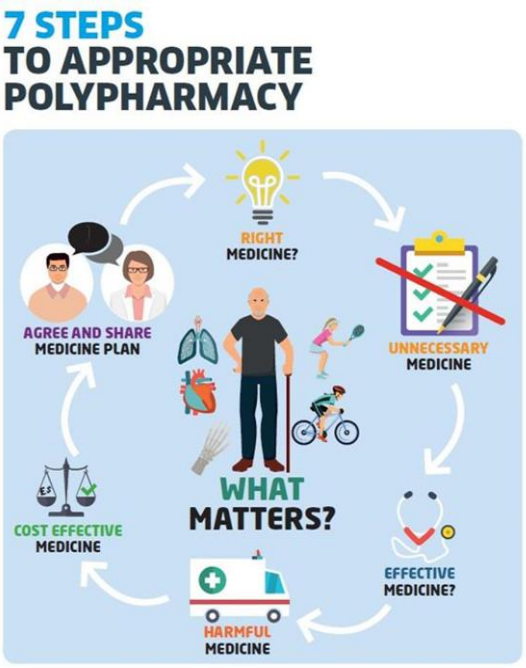

Figure 16: 7 Steps to appropriate polypharmacy[241]

12.8.2.3 Poland: Policy driving change

The Polish Ministry of Health has created a group whose aim is to develop a model and strategy on polypharmacy management in the elderly. The group was established on August 27th, 2015 by the Minister of the Health Directive. It includes representatives of the National Health Fund, the Ministry of Health, pharmacists, lawyers, pharmaceutical inspectors and pharmaceutical societies. The team's task is "*to develop a project of pharmaceutical care which will be supported by public funding*".

12.8.2.4 Germany: Political influence driving systems change

Since October 2016 a uniform standard medication chart has been introduced for mandatory use by all doctors and pharmacists. Every person with three or more medicines is entitled to receive such a medication chart on paper, equipped with a QR-code, so that pharmacists and doctors can digitally read, update and exchange information on medicines. This initiative has been supported and driven by the Federal Ministry of Health and has been agreed by all relevant stakeholders on the federal level. The standard medication chart is part of the e-Health Law and insures that all prescribed medicines data are documented in this digital format. It can be printed out in doctors' offices in the consultation as a paper version for the patient.[241]

The governmental aims are clear, and input is strong in this field considering that Germany has a system of sharing powers between the government, the health insurances as self-regulated non-profit organisations and the health professional entities.[241]

Now GPs receive a small fee for service remuneration to incentivise the new practice. By 2018 the interim solution of using a paper medication chart kept with the patient will be replaced by the electronic health card issued by the health insurances.[241]

Medikationsplan

Seite 1 von 1

AKTIONSPLAN ZUR VERBESSERUNG DER ARZNEIMITTEL THERAPIESICHERHEIT IN DEUTSCHLAND

für: **Armin Müller** geb. am: **19.10.1959**

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Wirkstoff	Handelsname	Stärke	Form	Mo	Mi	Ab	zN	Einheit	Hinweise	Grund
Metoprololsuccinat	Metoprololsuccinat 1A Pharma® 95 mg retard	95 mg	TAB	1	0	0	0	Stck	Mit 1 Glas Wasser	Herz/Blutdruck
Ramipril	Ramipril-ratiopharm®	5 mg	TAB	1	0	0	0	Stck	Mit ausreichend Flüssigkeit	Blutdruck
Clopidogrel	Clopidogrel Zentiva®	75 mg	FTA	0	0	1	0	Stck		Herz
Pantoprazol	Pantoprazol dura®	20 mg	TMR	1	0	0	0	Stck	1 Stunde vor der Mahlzeit	Magen
Insulin aspart	NovoRapid® Penfill®	100 E/ml	PAT	20	0	20	0	I.E.	Wechseln der Injektionsstellen, unmittelbar vor einer Mahlzeit spritzen	Diabetes
Simvastatin	Simva-Aristo®	40 mg	FTA	0	0	1	0	Stck	Mit ausreichend Flüssigkeit	Blutfette
Torasemid	Torsamid Hexal®	5 mg	TAB	1	0	0	0	Stck	Mit etwas Flüssigkeit	Blutdruck
Zeitlich befristete Medikation										
Clarithromycin	Clarithromycin-TEVA®	250 mg	FTA	alle 12 Std. 1				Stck	von 1.4. bis 6.4.	Bronchitis
Selbstmedikation										
Myrtol	GeloMyrtol®	120 mg	KPS	2	2	2	0	Stck	Mind. Halbe Stunde vor dem Essen mit einem großen Glas kaltem Wasser	Bronchitis
Johanniskraut	Laif® Balance	900 mg	FTA	1	0	0	0	Stck	Nach dem Frühstück	Stimmung
Selbstmedikation bei Bedarf										
Magnesium	Magnesium® Verla	121,5 mg	BTA	bei Bedarf 1-2				Stck		Wadenkrämpfe
Diphenhydramin-HCl	Vivinox® Sleep Schlaftabletten stark	50 mg	TAB	0	0	0	1	Stck	b. Bed. 30 min vor dem Schlafengehen mit ausreichend Flüssigkeit	Schlafstörungen

Figure 17: Example of a medication plan for polypharmacy patients

12.8.2.5 Northern Ireland: Policy commitment across the healthcare system

Optimising the health benefits from medicines is an important enabler of active and healthy aging in Northern Ireland. In March 2016 the Minister of Health announced the publication of a new strategy 'The Medicines Optimisation Quality Framework' to help people to gain the best possible outcomes from medicines.[241]

In addition, there was a formal commitment to implementing the Framework through an innovation and change programme which seeks to develop, test and scale up best practices to support a national medicines optimisation model. In the next three years there will be a focus on the needs of older people specifically relating to pharmacy roles, services and smart technologies which support appropriate polypharmacy and better adherence. [241]

Outputs include a national medicines optimisation model to support appropriate polypharmacy and better adherence and a Medicines Optimisation Innovation Centre to support research, service development and knowledge sharing nationally and internationally.[241]

12.8.2.6 Catalonia, Spain: Policies leading to polypharmacy and adherence guidelines

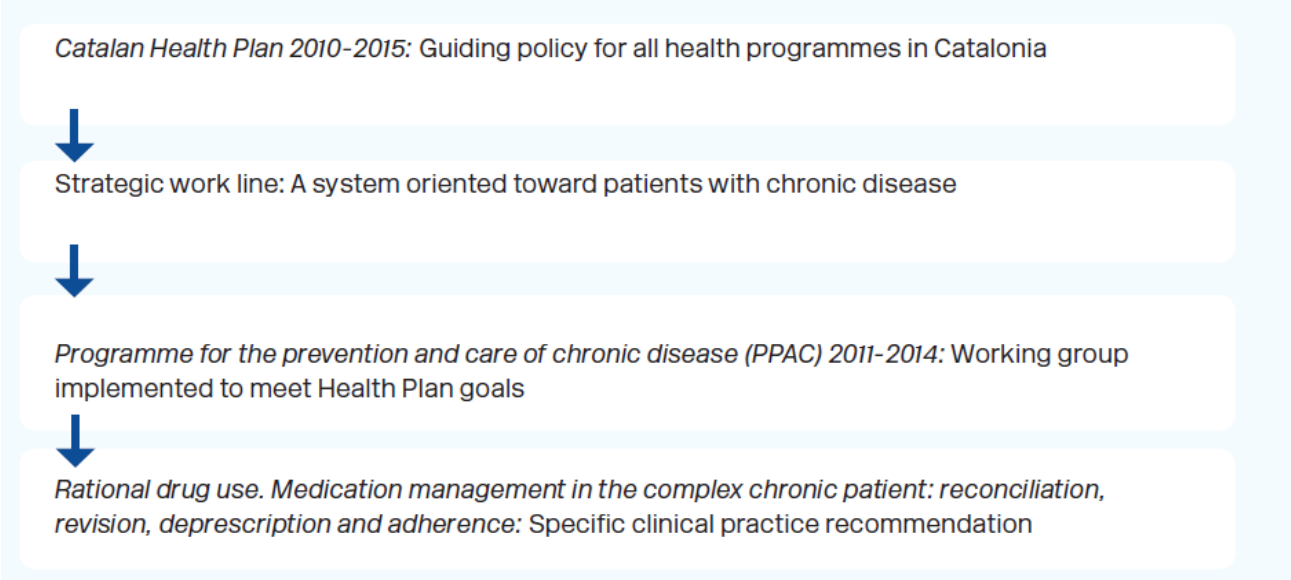

Figure 18. Policies leading to polypharmacy and adherence guidelines

The project also sought views across the EU 28 on how the EU could achieve its vision to deliver polypharmacy management across the EU gathering views from clinicians, policy makers, academics and patients. It concluded that this would take use at least to 2030 to fully realise al the benefits but that work was needed to be now to address this. Some countries had education programmes to support the learning of healthcare professional to support this. [241]

Polypharmacy management educational initiatives for pharmacists

Location	Practice setting, target audience	Sponsoring Institution	Description
Lower Saxony, Germany	Community pharmacy, community pharmacists	Chamber of Pharmacy, Lower Saxony	Two day in person and four month practical training with tutor supervision (ATHINA)
Catalonia, Spain	Primary care	CatSalut (public insurer in Catalonia, Spain)	In person and online case based training in managing patients with complex chronic disease
Uppsala, Sweden	Hospital and primary care	Uppsala University	Master programme in clinical pharmacy for graduated pharmacists
Scotland	Hospital, intermediate care, primary care	NHS Education for Scotland	Multiple courses in advanced pharmacy practice ranging from pre-registration training to independent prescribing
Northern Ireland	Hospital, intermediate care, primary care	Northern Ireland Centre for Pharmacy Learning and Development	Multiple courses in advanced pharmacy practice ranging from pre-registration training to independent prescribing

Figure 19. Polypharmacy management educational initiatives for pharmacists[241]

12.8.3 Conclusions

In order to deliver a change in the approach to manage medication safety across the EU, countries need to apply the lessons learnt from the SIMPATHY project across 8 EU countries, considering policy, quality and the economics of the programme across the health and care system.[241]

12.9 Finland's safe medication support for home care and service accommodation units

Author:
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The population of Finland is aging. At the same time, the aim is to cover the increasing need for service in outpatient care services. Outpatient care is used to treat increasingly debilitated, multi-patient and multi-drug elderly people and they are handled with scarce resources. To ensure safe medication, well-designed operational processes and cross-sectoral cooperation is needed. Community pharmacies mainly supply the medicines with outpatient care, but role and medicines therapy skills should be better utilized as part of outpatient care rational and safe implementation of drug therapy.

The Safe Medication Support Service provides concrete tools for the pharmacy to work with safe medications processes development and management expertise. The aim of the service is to improve medication safety of home care and service accommodation units.

The service is based on four risk management (auditing) tools that help the pharmacy to support the care unit through medications processes safety assessment and development:

- Safe automated unit dose dispensing
- Medication cabinet inspection and safe drug logistics
- Realization of safe medication
- Safe medical qualifications

The aim is to identify, in collaboration with the care unit, the medication safety by utilizing the tools to identify the medication safety of the care unit risk areas and develop development measures. The service includes a follow up meeting after 3-6 months. To evaluate the overall medications processes, it is necessary to evaluate all these areas (tools) during one or two years.

Safe and instructed processes improve medication safety and facilitate the daily life of both the care unit and the pharmacy. Service improves the quality of life of the elderly and makes it possible to stay at home longer. At the same time, the cost of both the customer and the society can be saved.

13 Annexes

Annex 1. Strength of evidence on pharmacists' contributions to patient and medication safety and conclusions by the authors of the systematic reviews/meta-analyses

Table 2: Strength of evidence on pharmacists' contributions to patient and medication safety and conclusions by the authors of the systematic reviews/meta-analyses

Authors and year of publication	Strength of evidence	Conclusion by the authors of the systematic review
Community pharmacy (n=6)		
Article 1[242] Jokanovic et al. 2017	Strong (31 systematic reviews of moderate or high quality)	Moderate and high-quality systematic reviews (n=31) support the value of pharmacist-led medication review for a range of clinical outcomes. The largest overall numbers of unique primary research studies with favourable outcomes were for diabetes control (78% of studies reporting the outcome), blood pressure control (74%), cholesterol (63%), medication adherence (56%) and medication management (47%). Significant reductions in medication and/or health care costs were reported in 35% of primary research studies. Results from the meta-analyses of 12 systematic reviews suggested positive impacts on glycosylated haemoglobin, blood pressure, cholesterol, and number and appropriateness of medications. Conflicting findings were reported in relation to hospitalisation. No meta-analyses reported reduced mortality.
Article 2[243] Van Eikenhorst et al. 2017	Moderate (included only studies conducted within the UK and in countries comparable to the UK on consultations and selling of non-prescription medicines NPMs)	Eighty-three studies were included (quantitative surveys excluded). Thirty-three (44%) of the studies were conducted in the UK. Non-pharmacist staff dealt with a large proportion of the consultations and pharmacists were usually involved in the consultation through referral from non-pharmacist staff member. Counselling was not consistently offered to everyone. Where counselling was provided it was not always of sufficient quality. Consultations were performed much better when symptoms were presented compared to when people made a direct product request. Pharmacists were reported to conduct better consultations than non-pharmacist staff. The evidence suggested that appropriate counselling afforded the person a safe environment to utilise their NPMs.
Article 3[244] Perraudin et al. 2016	Weak (included only studies from European countries)	Of the 21 studies included, 13 were conducted in United-Kingdom. Eleven studies assessed professional pharmacy services (PPS) to improve treatment outcomes of individual patients (such as pharmaceutical care services, medication review, educational and coaching programme, disease support service, medicines management and telephone-based advisory for improving adherence). Findings were contradictory and did not lead to strong conclusion. Screening programmes for different diseases showed robust positive results (n=2) as well as smoking cessation services (n=5) and should be considered to be more widely available in accordance with national context.
Article 4[245]	Strong	This systematic review and meta-analysis confined to 16 randomised controlled trials (3032 patients) provides evidence that community pharmacists can make a clinically important contribution to the

Cheema et al. 2014		management of hypertension in patients with or without associated cardiovascular co-morbidities. Pharmacist-led interventions were patient education on hypertension, management of prescribing and safety problems associated with medication, and advice on lifestyle. These interventions were associated with significant reductions in systolic (11 studies, 2240 patients) and diastolic blood pressure (11 studies, 2246 patients).
Article 5[246] Ryan et al. 2014	Strong	This is an update of a 2011 overview of systematic reviews published on the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects, which synthesises the evidence, irrespective of disease, medicine type, population or setting, on the effectiveness of interventions to improve consumers' medicines use. 75 systematic reviews of varied methodological quality were included. They assessed interventions with diverse aims including support for behaviour change, risk minimisation and skills acquisition. No reviews aimed to promote systems-level consumer participation in medicines-related activities. Medication adherence was the most frequently-reported outcome, but others such as knowledge, clinical and service-use outcomes were also reported. Adverse events were less commonly identified, while those associated with the interventions themselves, or costs, were rarely reported. For most outcomes, medicines self-monitoring and self-management programmes appear generally effective to improve medicines use, adherence, adverse events and clinical outcomes; and to reduce mortality in people self-managing antithrombotic therapy. However, some participants were unable to complete these interventions, suggesting they may not be suitable for everyone. Furthermore, uncertainty still exists about the effectiveness of many interventions, and the evidence on what works remains sparse for several populations, including children and young people, carers, and people with multimorbidity. Promising interventions to improve adherence and other key medicines-use outcomes, which require further investigation to be more certain of their effects, include: · simplified dosing regimens: with positive effects on adherence; · interventions involving pharmacists in medicines management, such as medicines reviews (with positive effects on adherence and use, medicines problems and clinical outcomes) and pharmaceutical care services (consultation between pharmacist and patient to resolve medicines problems, develop a care plan and provide follow-up; with positive effects on adherence and knowledge). Several other strategies showed some positive effects, particularly relating to adherence, and other outcomes, but their effects were less consistent overall and so need further study. These included:

		· delayed antibiotic prescriptions: effective to decrease antibiotic use but with mixed effects on clinical outcomes, adverse effects and satisfaction; · practical strategies like reminders, cues and/or organisers, reminder packaging and material incentives: with positive, although somewhat mixed effects on adherence; · education delivered with self-management skills training, counselling, support, training or enhanced follow-up; information and counselling delivered together; or education/information as part of pharmacist-delivered packages of care: with positive effects on adherence, medicines use, clinical outcomes and knowledge, but with mixed effects in some studies; · financial incentives: with positive, but mixed, effects on adherence.
Article 6[247] Blalock et al. 2013	Moderate (US-focused study)	The authors systematically reviewed the literature on the effectiveness of pharmacist-delivered patient care services in community pharmacy settings in the United States. 21 articles were included in the review. Information concerning 134 outcomes was extracted from the articles. Of these, 50 (37.3%) demonstrated statistically significant, beneficial intervention effects. The percentage of studies reporting favourable findings ranged from 50% for blood pressure to 0% for lipids, safety outcomes, and quality of life. The findings suggest that evidence supporting the effectiveness of pharmacist-provided direct patient care services delivered in the community pharmacy setting is more limited than in other settings. Therefore, the authors highlighted the need for rigorous, systematic research to better understand the patient-level, pharmacist-level, pharmacy-level, and health system–level factors that can affect the effectiveness of direct patient care services provided by community pharmacists. Without understanding the factors that are critical for success, investigators are likely to weaken interventions that have demonstrated effectiveness in other settings when attempting to implement them in the community pharmacy setting. Implementation research is also needed to understand the mechanisms through which pharmacist-provided patient care services may lead to improved patient outcomes. In addition, future research evaluating pharmacist-provided direct patient care services in community pharmacy settings should use adequate research methods to ensure internal validity. Inadequate sample sizes, lack of fidelity to intervention protocols, and insensitive outcome measures may have contributed to the null findings that were observed.
Hospitals/Care transitions (n=8)		
Article 1[248]	Strong	This systematic review updated the previous assessment of pharmacist-led medication reconciliation by restricting the review to randomised controlled trials (RCTs) only (by Dec 2016). The effect of

Cheema et al. 2018		pharmacist-led interventions on medication discrepancies, preventable adverse drug events, potential adverse drug events and health care utilisation were assessed. 18 RCTs (6,038 patients) were included. The quality of the included studies was variable. Pharmacists-led interventions led to an important decrease in medication discrepancy. Reductions in health care utilisation, potential ADEs and preventable ADEs were not considerable.
Article 2[249] Huiskes et al. 2017	Strong	This systematic review assessed the effectiveness of medication review as an isolated short-term intervention, irrespective of the patient population and the outcome measures used. Randomised controlled trials (RCTs) with medication review as isolated short-term intervention (<3 months) were included by September 2015. No restrictions were set to patient characteristics and outcome measures. Thirty-one RCTs were included in this systematic review (55% low risk of bias). An isolated medication review during a short-term intervention period has an effect on most drug-related outcomes (decrease in the number of drug-related problems, more changes in medication, more drugs with dosage decrease and a greater decrease or smaller increase of the number of drugs), minimal effect on clinical outcomes (mortality, hospital admissions/health care use, the number of patients falling, physical and cognitive functioning) and no effect on quality of life. No conclusion can be drawn about the effect on economical outcome measures. If research on the effect of cross-sectional medication review is still continued, high quality studies including high-risk patients and using relevant outcome measures should be conducted to assess if/when medication reviews can contribute to better medication use and subsequent better clinical outcomes. However, more effort should be put in the development and evaluation of other medication improvement strategies, such as more individualised and longitudinal medication therapy management, targeting at specific risk moments of drug treatment and targeting at problems that patients experience themselves.
Article 3[250] Khalil et al. 2017	Weak	This study determined the effectiveness of professional, organisational and structural interventions compared to standard care to reduce preventable medication errors by primary health care professionals that lead to hospital admissions, emergency department visits, and mortality in adults. Randomised trials in which health care professionals provided community-based medical services were included by Oct 2016. Also, interventions in outpatient clinics attached to a hospital were included. All participants, irrespective of age, who were prescribed medication by a primary health care professional were included. 30 studies (169,969 participants) were included in the review: four studies addressed professional interventions to prevent medication errors (8266 participants) and 26 studies described organisational

		interventions (161,703 participants). None of the studies addressed structural interventions. Interventions in primary care for reducing preventable medication errors probably make little or no difference to the number of people admitted to hospital or the number of hospitalisations, emergency department visits, or mortality. Professional interventions make little or no difference: -to the number of hospital admissions -to the number of participants admitted to hospital -to the number of emergency department visits -to mortality Organisational interventions reduce: -the number of hospital admissions Larger studies addressing both professional and organisational interventions are needed before evidence-based recommendations can be made. There is a need for high-quality studies describing the interventions in more detail and testing patient-related outcomes.
Article 4[251] Mekonnen et al. 2016	Strong	This study systematically investigated the effect of pharmacist-led medication reconciliation programmes on clinical outcomes at hospital transitions. 17 studies involving 21 342 adult patients were included. Eight studies were randomised controlled trials (RCTs). Most studies targeted multiple transitions and compared comprehensive medication reconciliation programmes including telephone follow-up/home visit, patient counselling or both, during the first 30 days of follow-up. The pooled relative risks showed a more substantial reduction in adverse drug event-related hospital revisits, emergency department (ED) visits and hospital readmissions in the intervention group than in the usual care group. The pooled data on mortality and composite readmission and/or ED visit did not differ among the groups. Authors concluded that pharmacist-led medication reconciliation programmes are effective at improving post-hospital health care utilisation. This review supports the implementation of pharmacist-led medication reconciliation programmes that decrease ADE-related hospital revisits, all-cause readmissions and ED visits.
Article 5[252] Zegers et al. 2016	Weak	This systematic review of systematic reviews provides an overview of effective interventions aimed at reducing rates of adverse events in hospitals. Systematic reviews of interventions aimed at reducing adverse events in hospitals, including studies with an experimental design and reporting adverse event

		rates, were included (published until October 2015). Sixty systematic reviews with moderate to high quality were included. Statistically significant pooled effect sizes were found for 14 types of interventions, including: (1) multicomponent interventions to prevent delirium; (2) rapid response teams to reduce cardiopulmonary arrest and mortality rates; (3) pharmacist interventions to reduce adverse drug events;(4) exercises and multicomponent interventions to prevent falls; and (5) care bundle interventions, checklists and reminders to reduce infections. Most (82%) of the significant effect sizes were based on 5 or fewer primary studies with an experimental study design. The authors concluded that evidence for patient-safety interventions implemented in hospitals worldwide is weak. The findings address the need to invest in high-quality research standards in order to identify interventions that have a real impact on patient safety. Interventions to prevent delirium, cardiopulmonary arrest and mortality, adverse drug events, infections and falls are most effective and should therefore be prioritised by clinicians.
Article 6[253] Ensing et al. 2015	Strong	This systematic review identified the components of pharmacist intervention that improve clinical outcomes during care transitions. Randomised controlled trials (RCTs) that studied pharmacist intervention with regard to hospitalisation were searched (published until Nov 2014). 30 studies were included. A model was created to categorise cluster components of pharmacist intervention. The average number of components deployed, stages of hospitalisation covered, and intervention targets were equally distributed between effective and ineffective studies. A best evidence synthesis of 15 studies revealed strong evidence for a clinical medication review in multifaceted programmes (5 effective vs. 0 ineffective studies). Conflicting evidence was found for an isolated post discharge intervention, admission medication reconciliation, combining post discharge interventions with in-hospital interventions, and covering of multiple stages. Closely collaborating with other health care providers enhanced the effectiveness. Although there is a need for well-designed and well-reported RCTs, the study heterogeneity enabled a best evidence synthesis to elucidate effective components of pharmacist intervention. In isolated post discharge intervention programmes, evidence tends towards collaborating with nurses and tailoring to individual patient needs. In multifaceted intervention programmes, performing medication reconciliation alone is insufficient in reducing post discharge clinical outcomes and should be combined with active patient counselling and a clinical medication review. Furthermore, close collaboration between pharmacists and physicians is beneficial. Finally, it is important to secure continuity of care by integrating pharmacists in these multifaceted programmes across health care settings. Ultimately, pharmacists need to know patient clinical background and previous hospital experience.
Article 7[254] Wang et al. 2015	Weak/moderate	This systematic review focused on controlled clinical trials evaluating the effect of pharmacist intervention on medication errors (MEs) in intensive care unit (ICU) settings. Four studies were included in the meta-analysis. Results suggest that pharmacist intervention has no significant

		contribution to reducing general MEs, although pharmacist intervention may significantly reduce preventable adverse drug events and prescribing errors. This meta-analysis highlights the need for high-quality studies to examine the effect of the critical care pharmacist.
Article 8[255] Kwan et al. 2013	Strong	The purpose of this systematic review was to summarise evidence about the effectiveness of hospital-based medication reconciliation interventions. Eligible studies evaluated the effects of hospital-based medication reconciliation on unintentional discrepancies with nontrivial risks for harm to patients or 30-day post discharge emergency department visits and readmission. Eighteen studies evaluating 20 interventions were included. Pharmacists performed medication reconciliation in 17 of the 20 interventions. Most unintentional discrepancies identified had no clinical significance. Medication reconciliation alone probably does not reduce post discharge hospital utilisation but may do so when bundled with interventions aimed at improving care transitions. Pharmacists played a major role in most successful interventions. Commonly used criteria for selecting high-risk patients do not consistently improve the effect of medication reconciliation.
Outpatient clinics (n=2)		
Article 1[256] Dixon et al. 2016	Weak/moderate	This qualitative review details the evidence supporting the role of pharmacist-led amiodarone monitoring services (AMS) in improving adherence to amiodarone monitoring guidelines and identifying adverse effects. Five studies were identified. Overall, these programmes had a favourable impact on improving adherence to guideline-recommended monitoring standards for amiodarone. The available evidence is limited by the significant variations in study designs and outcome definitions, lack of patient randomisation, and limited generalisability. Nevertheless, available studies suggest that pharmacist-led AMS may improve adherence to recommended monitoring guidelines and identification of amiodarone-related adverse effects. Further research is needed to demonstrate whether these services impact the overall quality of care provided to patients receiving amiodarone, which may justify broader implementation.
Article 2[257] Lee et al. 2013	Strong (focused on US practices)	This systematic review and meta-analyses examined the effects of pharmacists' care on geriatric patient-oriented health outcomes in the United States (U.S.). 20 studies were included in the final meta-analyses. Study sample size ranged from 36 to 4,218, with mean age of subjects being 65 and older. The studies were most frequently conducted in ambulatory care clinics, followed by inpatient settings; the majority focused on multiple diseases and conditions. Pharmacist activities varied widely, with technical interventions used most often. Favourable results were found in all outcome categories, and meta-analyses conducted for therapeutic, safety,

		hospitalisation, and adherence were significant (P < .001), favouring pharmacist care over comparison. Thus, authors conclude that pharmacists should be involved in team-based care of older adults.

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