



## Colophon

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# Contents

<b>Acknowledgements</b> .....	<b>4</b>
<b>Executive summary</b> .....	<b>5</b>
<b>1 Background</b> .....	<b>6</b>
1.1 Medication safety as part of patient safety .....	6
1.1.1 Evolution of patient and medication safety .....	8
1.2 The WHO as a global coordinator of patient and medication safety .....	9
1.3 FIP as a global coordinator of patient and medication safety initiatives within the pharmacy profession .....	11
1.4 FIP's advocacy and collaboration on a global level .....	11
<b>2 Definition of key terms</b> .....	<b>13</b>
<b>3 Creation of safety culture: systems approach and the theory of human error</b> .....	<b>14</b>
3.1 Human error theory as a theoretical framework in systems-based risk management .....	15
3.2 Creation of safety culture in medicines use management .....	19
3.3 Measurement of safety culture .....	20
3.4 Role of leadership for safety culture change and implementation.....	21
3.5 The need to improve safety culture in pharmacies .....	22
<b>4 Pharmacists' roles and contributions to patient and medication safety</b> .....	<b>23</b>
4.1 Roles and contributions .....	24
4.2 Medicines use process .....	25
<b>5 Patient safety in the medicines use process</b> .....	<b>28</b>
5.1 Access to medicines .....	28
5.2 Dispensing and supply of medicines .....	28
5.2.1 Common dispensing errors .....	28
5.2.2 Automation .....	29
5.2.3 Unit dose dispensing .....	30
5.2.4 Barcode use and scanning.....	30
5.2.5 Patient counselling.....	30
5.2.6 Self-medication .....	31
5.2.7 Safe disposal of medicines .....	32
5.3 Medication history taking and reconciliation.....	32
5.4 Monitoring medicines use.....	32
5.4.1 Medication history access.....	32
5.4.2 Monitoring of prescribed medication .....	32
5.4.3 Therapeutic drug monitoring .....	33
5.4.4 Polypharmacy and deprescribing.....	33
5.4.5 Pharmacovigilance .....	33
<b>6 Pharmacists' value in collaborative healthcare teams</b> .....	<b>35</b>
6.1 Advocate for the profession.....	35
<b>7 Medicines regulation and patient safety</b> .....	<b>36</b>
7.1 National agencies .....	36
7.2 Packaging and labelling of medicines (including package inserts/medication information) .....	36
7.3 Medicine names .....	37
<b>8 Learning from other industries</b> .....	<b>38</b>
8.1 Lessons from the aviation industry .....	38
8.1.1 Checklists and technology.....	38
8.1.2 Situational training.....	38
8.1.3 Working environment .....	38

8.1.4 Error reporting and learning .....	39
<b>9 Education and competencies .....</b>	<b>40</b>
9.1 Quality assurance .....	41
<b>10 Conclusions.....</b>	<b>42</b>
<b>11 Case studies and snapshots of best practice .....</b>	<b>45</b>
11.1 South Africa: Patient safety programmes .....	45
11.1.1 Dispensing procedures .....	45
11.1.2 Medicine management in hospital settings .....	46
11.1.3 Pharmacist-initiated therapy .....	46
11.1.4 Medicines selection.....	46
11.1.5 Conclusions .....	46
11.2 USA: Patient safety programmes .....	47
11.2.1 Introduction .....	47
11.2.2 Health system supporting patient safety .....	47
11.2.3 Pharmacists' role in patient safety.....	47
11.2.4 Interprofessional collaboration.....	48
11.2.5 New services or innovations to improve patient safety.....	48
11.2.6 Education and patient safety .....	49
11.2.7 Conclusions .....	49
11.3 Canada: Patient safety programmes.....	49
11.3.1 Introduction .....	49
11.3.2 Health system supporting patient safety .....	49
11.3.3 Pharmacists' role in patient safety in different settings .....	50
11.3.4 Interprofessional collaboration.....	52
11.3.5 New services or innovations to improve patient safety.....	52
11.3.6 Education around patient safety.....	52
11.3.7 Conclusions .....	52
11.4 Australia: Patient safety programmes.....	53
11.4.1 Introduction .....	53
11.4.2 Australia's health system .....	53
11.4.3 Pharmacy organisations and patient safety .....	54
11.4.4 Pharmacists' role in patient safety.....	54
11.4.5 Interprofessional collaboration.....	55
11.4.6 New services or innovations to improve patient safety.....	55
11.4.7 Education around patient safety.....	56
11.4.8 Conclusions .....	56
11.5 India: A case study on the role of the pharmacist in patient and medication safety .....	56
11.5.1 Background .....	56
11.5.2 Introduction to Indian healthcare system.....	56
11.5.3 Pharmacists' role in patient safety.....	57
11.5.4 Pharmacy Council of India (PCI) .....	59
11.5.5 Patient counselling .....	61
11.5.6 Public and community health .....	61
11.5.7 Indian Pharmaceutical Association's (IPA) contribution to patient and medication safety.....	62
11.5.8 Future improvements .....	64
11.6 Oman: Role of the pharmacist in patient safety .....	64

11.6.1 Introduction .....	64
11.6.2 Health system supporting patient safety .....	64
11.6.3 Pharmacists' role in patient safety in different settings .....	66
11.6.4 Interprofessional collaboration.....	67
11.6.5 New services or innovations to improve patient safety.....	67
11.6.6 Conclusions .....	68
<b>11.7 Saudi Arabia: Patient safety programmes.....</b>	<b>68</b>
11.7.1 Introduction .....	68
11.7.2 Health system supporting patient safety .....	68
11.7.3 Pharmacists' role in patient safety in different settings .....	69
11.7.4 Interprofessional collaboration.....	69
11.7.5 New services or innovations to improve patient safety.....	69
11.7.6 Education around patient safety (including. leadership, training, continuous education) .....	70
11.7.7 Conclusions .....	70
<b>11.8 Europe: Improving polypharmacy.....</b>	<b>70</b>
11.8.1 Economic benefits of implementing good practice .....	71
11.8.2 Politics and policy.....	72
11.8.3 Conclusions .....	80
<b>11.9 Finland: patient and medication safety work .....</b>	<b>80</b>
11.9.1 Background .....	80
11.9.2 Evolution of the systems-based patient safety work in Finland: Early steps .....	80
11.9.3 Early medication safety initiatives .....	80
11.9.4 Most recent initiatives .....	81
11.9.5 Medication safety research.....	82
11.9.6 Medication safety initiatives by community pharmacies .....	83
11.9.7 The Safe Medication Support Service; A service provided by Finnish community pharmacies to home care and assisted living facilities of older adults.....	84
<b>11.10 The Netherlands: Medication monitoring and reviews .....</b>	<b>84</b>
11.10.1 Clinical risk management on medicines use .....	85
11.10.2 Medication review .....	85
11.10.3 Reporting medication errors.....	85
<b>12 Annex .....</b>	<b>87</b>
Annex 1. Evidence of pharmacists' contribution to patient and medication safety .....	87
<b>13 References .....</b>	<b>94</b>

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## Executive summary

The World Health Organization (WHO) reports that one in four patients is 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. Specifically, the global cost associated with medication errors has been estimated by the WHO as USD 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 agendas.

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 medicines-taking/using journey. While 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. Healthcare organisations and systems, including people who create legislation and policy, people who implement standards and guidelines, and healthcare professionals who deliver services and provide patient care, are all responsible for ensuring patient safety. To make healthcare systems safer, a shift towards a collaborative systems approach that fosters a safety culture and promotes effective prospective risk management and continuous quality assurance through building system defences, is needed. A "culture of blame" neither prevents nor mitigates harm, nor does it enable a positive working environment.

Pharmacists are essential healthcare professionals and are critical members of the whole healthcare team. Pharmacists work in varied settings such as community and hospital, industry and regulatory affairs. Regardless of where pharmacists work, and whether their roles provide direct or indirect patient care, all pharmacists contribute to safe and quality health care. In promoting patient safety and advocating a safety culture, pharmacists have a number of roles to play. This reference document, entitled "Patient safety — Pharmacists' role in 'Medication without harm'", provides information about what pharmacists can do to promote patient safety at an individual patient level, as well as at organisational and in policy development levels (which may be local/organisational through to national and international). This document encourages each of us to take new steps and make initiatives towards safer care at our workplace. We all are advocates of patient safety. As pharmacists, we are particular advocates of medication safety.

This reference document is supported by evidence of the positive impact of pharmacists on patient and medication safety internationally. In drawing parallels with other "safe" industries, notably the aviation industry, this reference document highlights what pharmacists can do to create a safety 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 and these can act as a guide for implementation of strategies in other countries and contexts.

This reference document can serve as a platform to inform policy and practice development of patient and medication safety initiatives in your practice or country context. At the same time, it is the intention to keep it very practical so that it can serve as a tool for pharmacists to ignite further discussions and to support implementation of services (at the organisational, and even national level) that have been shown to prevent adverse events and reduce the risk of unnecessary harm associated with healthcare provision.

# 1 Background

Medicines are 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, in inpatient and 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 prescribed medicines, there is a wide range of symptoms and conditions that can be managed by using non-prescription medicines (including herbal and complementary medicines) without consulting any healthcare professional or, if consulted, with the advice of a community pharmacist.

Although effective, medicines 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 inadequately coordinated resources in healthcare systems.<sup>1,2</sup>

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

These error rates are comparable to those in other EU countries and in the USA.<sup>4</sup> Thus, the clinical, humanistic, and economic burden of medication errors is immense at the individual, organisational, national, and global levels. Globally, the WHO has estimated that the cost associated with medication errors is USD 42 billion each year.<sup>5</sup> Patients in low-income countries lose twice as many disability-adjusted life-years due to medication-related harm compared with those in high-income countries.<sup>5</sup> Growing evidence of patient safety risks related to medication 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 “Third WHO global patient safety challenge: Medication without harm”.<sup>5</sup> Furthermore, the group was tasked to produce an inventory of systematic literature reviews of pharmacists’ contributions to medication safety (Annex 1), to emphasise pharmacists’ key roles in assuring medication safety, to 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.

## 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.<sup>6,7</sup> One of the most widely used definitions of patient safety is “freedom from accidental injuries during the course of medical care,” and “activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of health care”.<sup>6,8,9</sup>

Safe pharmacotherapy can be divided into drug safety and medication safety.<sup>10-12</sup> Drug safety is related to pharmaceutical products, and usually concentrates on their harm-benefit ratio in terms of adverse drug reactions (ADRs).<sup>10-12</sup> 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.<sup>6</sup> Medication safety refers to preventing and managing medication errors (MEs), which are unintended mistakes in the medicines-use process caused by omissions or commissions, as well as other errors (Figure 1).<sup>10-12</sup> 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 has not, either by luck or because it was intercepted and corrected.<sup>6</sup> Near misses are an indication of systemic issues that could lead to an adverse drug event (ADE).



## Examples of medication errors

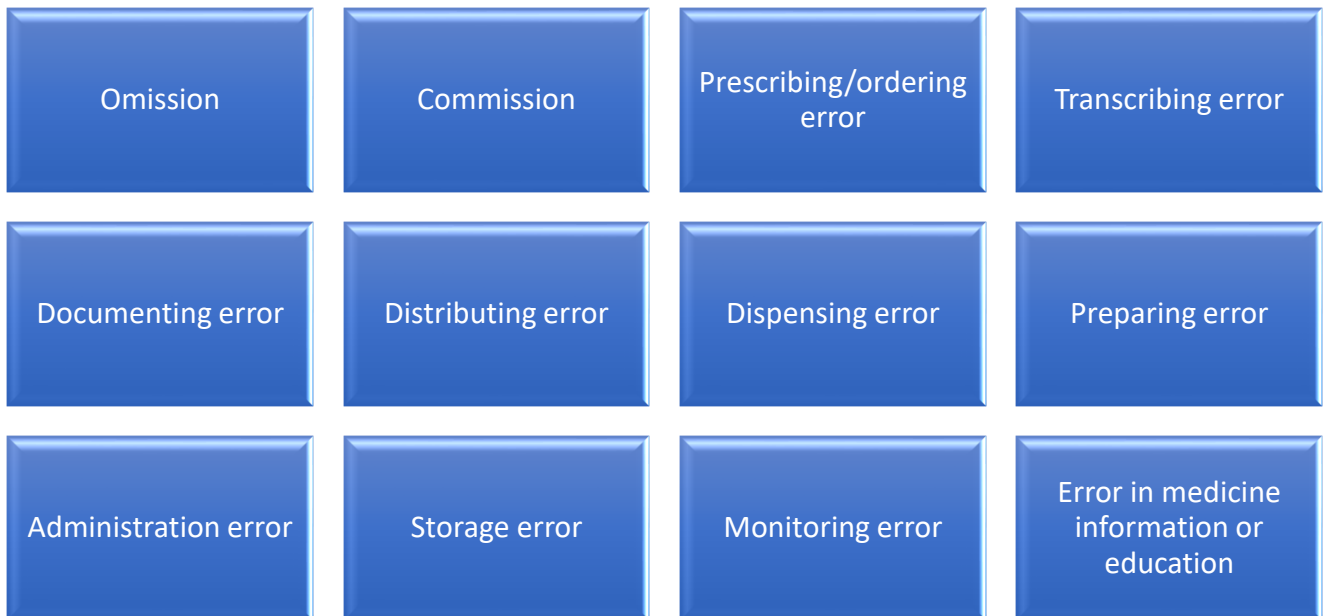


Figure 1: Examples of medication errors.<sup>10-12</sup>

Figure 2 illustrates the relationship between MEs, ADEs, and ADRs.<sup>13,14</sup> 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”.<sup>6</sup> Thus, the definition includes ADRs and MEs.

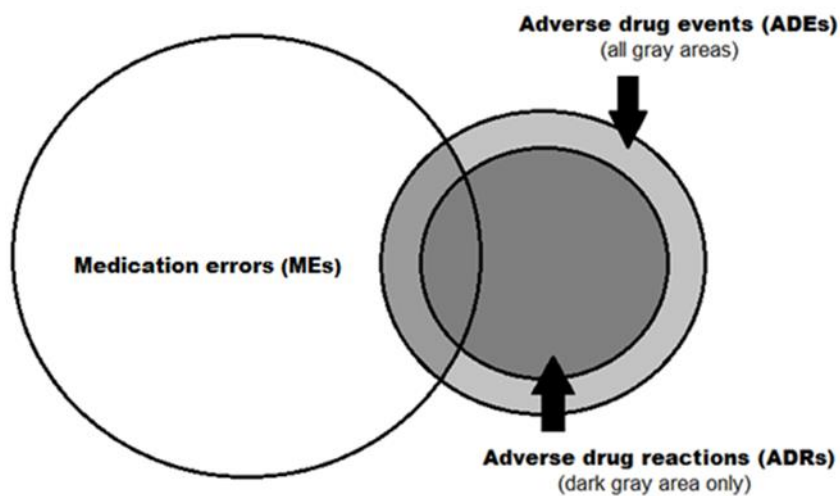


Figure 2: Relationship between medication errors, adverse drug events and adverse drug reactions.<sup>12, 13</sup>

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.<sup>6, 12, 15, 16</sup> The real-life medicines use process, including human error, did not receive such a degree of attention until the early 2000s when the US Institute of Medicine strongly suggested that reporting systems be a part of a comprehensive strategy to understand errors and improve patient safety with preventive actions.<sup>8</sup> Since then, local and national medication error reporting systems have been launched in many countries.<sup>17</sup> The first national medication error reporting system was established in the United States in 1987.<sup>18</sup> The shift to expand the scope of pharmacovigilance to also include MEs can be seen, for example, in the European Union regulations.<sup>16</sup>

Unsafe medication practices contributing to MEs is the single most important preventable factor jeopardising patient safety.<sup>5</sup> Up to 50% of all reported patient safety incidents are estimated to be related to medication. An 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 healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labelling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”<sup>19</sup>

MEs can include ADEs (which include, by definition, ADRs), but ADEs are not always MEs (Figure 2). MEs result in harm in nearly 1% of the error cases.<sup>20</sup> Conversely, about one quarter of ADEs are due to medication errors.<sup>20</sup>

### 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.<sup>8</sup> This report started global system-based patient and medication safety work and created a new, rapidly growing research area.<sup>8</sup> The report stated that the complex problem of patient safety required multifaceted responses and recommended the following actions:

- 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.
- 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. Sharing of lessons learned, i.e., timely dissemination and feedback to individuals and organisations (using incident reporting systems to make healthcare professionals aware of similar medication incidents or ADEs occurring at nearby facilities).
- Setting performance standards and expectations for safety for healthcare organisations through regulatory and related mechanisms, such as licensing, certification and accreditation. Professional societies should establish a permanent committee dedicated to safety improvement.
- Implementing safety systems in healthcare organisations, with patient safety programmes with defined executive responsibilities and proven safety practices.

Following the IOM report,<sup>8</sup> international and national working/expert groups were established in order to evaluate local situations 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 at the ministerial level.<sup>15, 21</sup> The CoE stated that medication errors are poorly managed in Europe and suggested European healthcare organisations should:<sup>15</sup>

- Take steps to establish medication error reporting systems;
- Establish and use common terminology concerning harm to patients caused by medications;
- Create a culture of safety; and
- 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 the 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 medication information and therapeutic guidelines.<sup>15</sup> 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.<sup>22</sup> However, they have also promoted development of training to foster competencies in patient and medication safety among all healthcare providers, transfer of safe and effective practices between healthcare organisations and countries, patient safety in cross-border healthcare, development of indicators for healthcare quality and patient safety, as well as promoting use of information technology and digitalisation in making patient care safer. Patients and consumers need to be engaged through informed and partnered decision making and adequate health literacy, as they or their carers are the last line of defence for medication errors/ADEs. The importance of allocating funding for research and development of patient and medication safety has also been recognised.<sup>23</sup>

## 1.2 The WHO as a global coordinator of patient and medication safety

At the global level, the WHO has had an important coordinating role in patient safety development since the early 2000s. The WHO, with its stakeholder organisations, has demonstrated substantial efforts to improve 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 means an emphasis on understanding how care processes work and how they 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 healthcare 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).<sup>24, 25</sup>

The WHO released the third, most current Global Patient Safety Challenge which focuses on medication safety, in 2017.<sup>5</sup> The goal of the programme, "Medication without harm," is to reduce the global level of severe avoidable medication-related harm by 50% over five years. In 2019, the WHO released three 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 medication), high-risk patients (e.g., young children, older adults, patients with complex comorbidities), and high-risk medication 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. The WHO report outlines three main factors contributing to high-risk situations: i) medication, particularly high-risk medication, ii) healthcare 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.<sup>26</sup>
2. Polypharmacy has become a growing risk due to ageing populations and increased comorbid conditions. Polypharmacy will lead to an increased likelihood of adverse effects, interactions and other clinically significant medication-related problems. More complex medication regimens make self-management of medication more challenging and can negatively influence adherence. The WHO report highlights the importance of leadership in nurturing a culture that prioritises safety and quality of (de)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 care system, including policy makers. Included in the report are tools and case studies which illustrate a systematic approach that can be followed by all healthcare professionals and patients, across the healthcare system, to ensure that patients are integral to the decisions about their medication.<sup>27</sup>

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 through 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.<sup>28</sup>

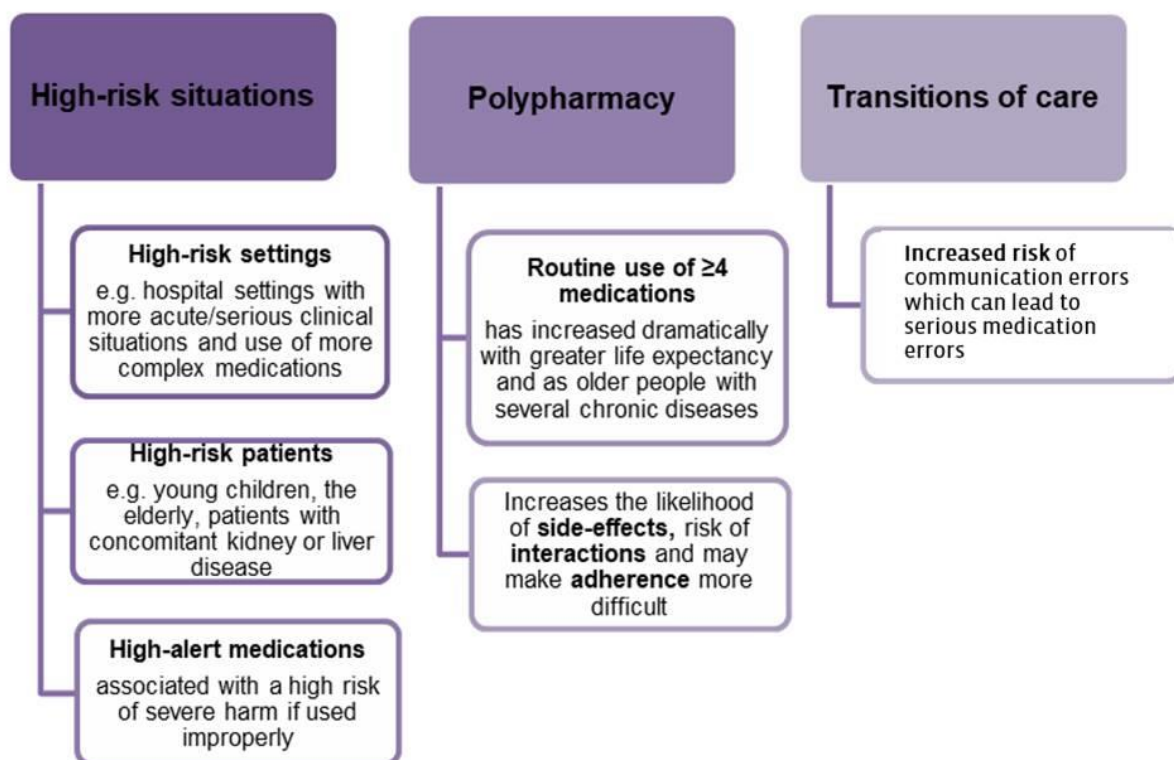


Figure 3: Key areas of the WHO Global Patient Safety Challenge on medication safety (WHO 2017, adopted from Schepel 2018<sup>12</sup>).

The challenge stimulates action to create new policies, practices, and services at national and international levels in four areas: patients; medications; healthcare professionals and health systems; and medication practices (medication management). The challenge says: “Preventing errors and the harm that results require 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. The 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 healthcare facilities.”<sup>5</sup>

The WHO has already made available a wide range of practical tools to support implementation of the medication safety challenge. The WHO has also encouraged and supported researchers to create evidence on medication safety risks in various healthcare settings and identify areas where future research is needed.<sup>23, 29</sup>

Training of healthcare professionals plays a crucial role in ensuring patient and medication safety. During the past 10 years, the WHO has actively promoted incorporation of patient and medication safety in the educational curricula of all healthcare professionals. The WHO launched the first multiprofessional Patient Safety Curriculum Guide, which has a chapter on medication safety, in 2011.<sup>30</sup> 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 from the best practices of others. It recommends that competencies required in safe medication practices are incorporated in the curricula of all healthcare 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 WHO Patient Safety Curriculum Guide is a tool which can be used to promote patient and medication safety. The WHO is working to update and extend the medication safety part of the curriculum guide to support the implementation of its Third Global 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 practising healthcare professionals.<sup>31</sup>

The WHO has also developed practical resources for education of consumers, and these are described in section 4.

### 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,<sup>32</sup> FIP has taken a global coordination 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 in patient care, at all levels of care, through collaborative care and patient interaction. Thus, pharmaceutical care introduced the principles of prospective risk management to medication processes.

FIP has been closely collaborating with the WHO regarding implementing pharmaceutical care into practice. At the FIP Congress in Tokyo in 1993, the WHO released a document, the “Tokyo Declaration 1993”, on the role of pharmacists in the healthcare system in order to guide the development of pharmaceutical care 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 practising pharmacist in order to ensure worldwide appropriate quality of pharmacotherapy for every patient.<sup>33</sup> In 1997, the “FIP Statement of Professional Standards” was published, a joint effort between the FIP and the WHO. The objective of this document was to help ensure the quality of information communicated by a pharmacist to the patient in order to promote safe and effective medication.<sup>34</sup> This GPP statement was again updated in 2010 and approved by the WHO General Assembly in May 2011.<sup>33</sup> Within FIP, the Board of Pharmaceutical Practice has been the key coordinator of the implementation of GPP through the national member organisations, which 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,<sup>33</sup> 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 referenced guideline, the FIP and the WHO encourage pharmacists globally to ensure that their daily practice and 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:

- Pharmacists should assess and evaluate all paper or electronic prescriptions received. Pharmacists should also consider the therapeutic, social, economic and legal aspects of the prescription before supplying medicines to the patient. Where possible, generic substitution is recommended to provide the patient with lower cost medication alternatives;
- Pharmacists should receive and document necessary clinical and patient data to assess and monitor medication and to track patients’ therapeutic outcomes; and
- Pharmacists should provide enough health-, disease- and medication-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 empowering the patient.

Even though pharmaceutical care and patient-centred clinical pharmacy services have been shown to improve the quality, safety and efficiency of care as well as reduce its costs, their incorporation into many healthcare systems has been slow, for various reasons.

### 1.4 FIP’s advocacy and collaboration on a global level

FIP has a long history of working in close collaboration with the WHO and its patient safety programme. Patient safety was identified to be a high-priority topic for FIP in interactions with the WHO and has contributed to highlighting the

importance and value of medication safety procedures on a global scale. This section serves to highlight these contributions and collaborations.

One of the most remarkable contributions by FIP was co-authoring the WHO Patient Safety Curriculum Guide (multi-professional edition) launched in 2011.<sup>30</sup> FIP continues to collaborate with the WHO on the update of the curriculum guide and the extension of the medication safety chapter.

In 2014, FIP took part in a WHO brainstorming meeting, helping to develop what is now the WHO medication safety challenge. In the years after, FIP contributed to the preparatory work around this challenge, including discussions of the next steps needed to strengthen the whole medication process and to reduce medication errors 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.<sup>35</sup> Additionally, 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 the WHO on other topics related to patient and medication safety with the goal of increasing the visibility of pharmacists in patient safety and advocating for their contributions toward the WHO medication safety challenge. Most recently, FIP contributed to the establishment of the Jeddah Declaration on Patient Safety launched in 2019.<sup>36</sup> Due to FIP's advocacy, this declaration was founded on the principles that guided the 4<sup>th</sup> Global Ministerial Patient Safety Summit in Jeddah, Kingdom of Saudi Arabia, in 2019.<sup>37</sup> This summit, in turn, set 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.<sup>37</sup> The summit aimed to establish patient safety as a crucial principle integrated in the efforts to achieve universal health coverage.<sup>37</sup>

The Jeddah Declaration on Patient Safety is a call for action to reflect on the effectiveness of current practices in light of the now mature patient safety evidence base of 20 years. It calls for sustainable and scalable implementation of patient safety solutions known to improve care delivery systems, patient outcomes and safety culture. It concerns all stakeholders at all levels of healthcare provision and delivery from frontline to organisational and policy arenas.<sup>36</sup> FIP contributed to and endorsed the Jeddah Declaration.<sup>38</sup> Thanks to FIP's advocacy, the declaration's eighth point specifically refers to promotion of medication safety in community pharmacies. It says that "promoting implementation of the 3<sup>rd</sup> Global Patient Safety Challenge: Medication Without Harm, in community pharmacies, would help improve medication safety as well as strengthening efforts of patient empowerment and community engagement." Thus, it promotes the implementation of the global medication safety challenge in community pharmacies.<sup>38</sup>

## 2 Definition of key terms

FIP defines **patient safety** as “freedom from accidental or preventable injuries produced by medical care” based on the Patient Safety Network (PSNet) glossary.<sup>39</sup> The PSNet is a web-based resource in the United States of America, featuring essential resources on patient safety. The WHO defines patient safety as “the prevention of errors and adverse effects to patients associated with health care.”<sup>40</sup>

**Medication safety** is defined as “freedom from preventable harm with medication use”.<sup>41</sup>

The US National Coordinating Council for Medication Error Reporting and Prevention defines a **medication error** 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 healthcare professional, patient or consumer. Such events may be related to professional practice, healthcare products, procedures and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.”<sup>42</sup>

**Safety culture** is “a product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of an organisation’s health and safety management”.<sup>43</sup>

**Just culture** is the concept of identifying system flaws that can be resolved in order to promote patient safety and move away from a culture where failures are punished, covered up or ignored, and individuals who fall short during the patient care process are punished.<sup>44</sup>

Other key terms in this document are defined according to the [Definitions of Key Concepts](#) from the WHO Patient Safety Curriculum Guide (2011).<sup>30</sup> 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.<sup>6</sup> 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 national patient and medication safety programmes in some of the Council of Europe member countries.

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. This was the first paper that aimed to standardise key definitions for patient safety in Australia.<sup>45</sup>

### 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. Medicines 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 can be challenging to ensure patient safety during the medication journey. Consequently, adverse events related to medication are among the most common adverse events in health care throughout the world. Figure 4 presents early work from the US that demonstrates the dramatic increase in deaths from prescription medication-associated errors during a 20-year period from 1979–1998.<sup>46</sup> 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.

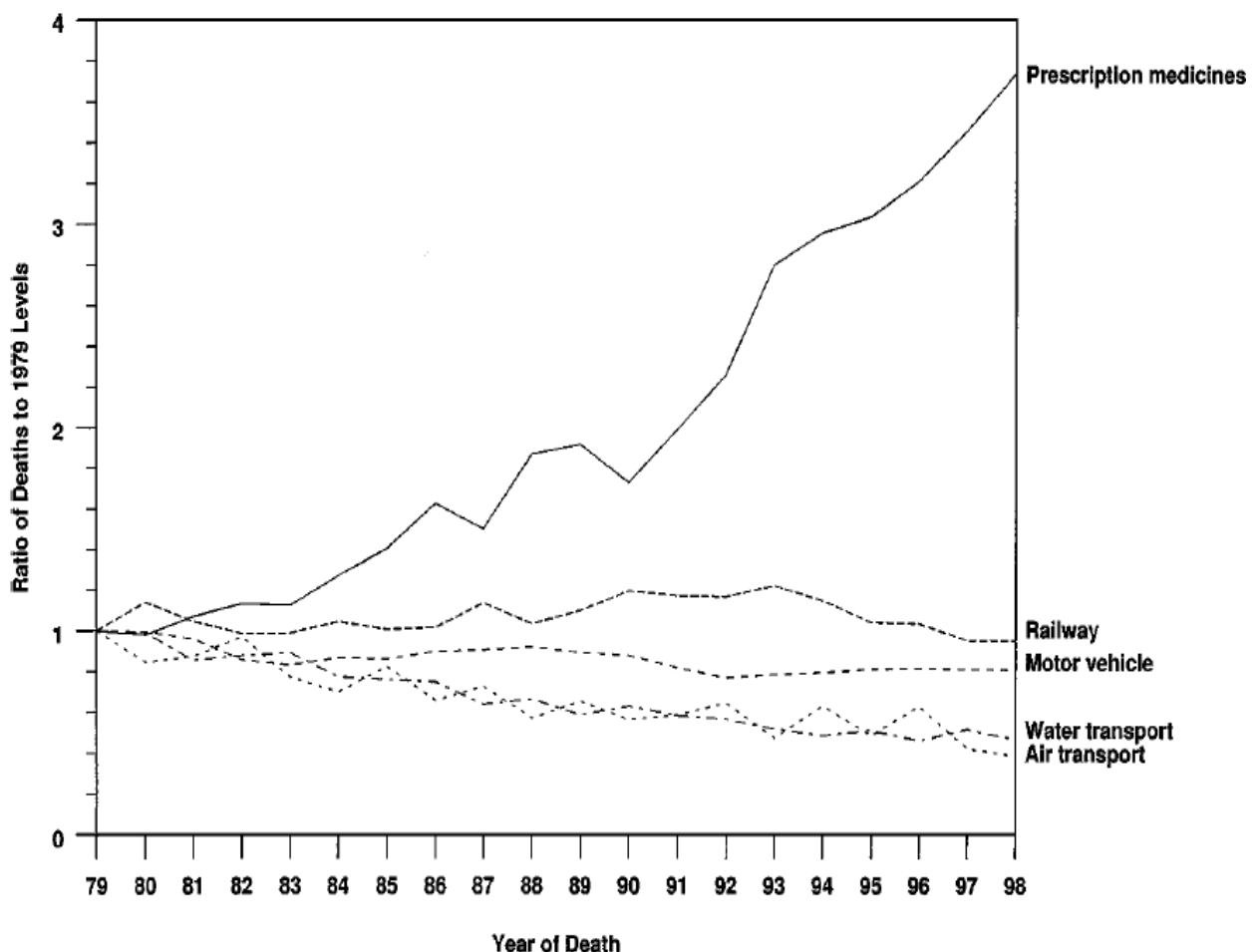


Figure 4: Ratio of deaths to 1979 levels to illustrate mortality from medication errors in the USA during 1979–1998.<sup>47</sup>

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. Healthcare 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.<sup>12,14</sup>



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 healthcare organisation to monitor in order to prevent, remedy or mitigate the occurrence or recurrence of a real or potential (patient) safety event.<sup>48</sup>
- **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.<sup>6, 21</sup>
- **Systems approach:** An approach to safety stating that errors are generally consequences of systemic factors, e.g., weaknesses in organisational processes.<sup>49</sup> 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.<sup>8, 30, 49</sup> To manage errors and risks in organisations and processes, psychologist James Reason 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 centres.<sup>49–51</sup>

Traditionally, the person approach to human error has been a dominant approach in health care.<sup>49</sup> It focuses on unsafe acts, errors and procedural violations by people on the frontline. In this approach, individual healthcare practitioners (e.g., physicians, nurses, pharmacists) are blamed for errors primarily due to human behaviours such as forgetfulness, inattention, poor motivation or incompetence. However, most of the unsafe acts are not intentional.<sup>49</sup> This person approach easily ignores the circumstances where people work, which can lead to similar outcomes 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.<sup>49</sup> 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.<sup>52</sup> 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.<sup>49</sup> Defences can, for instance, be engineered (e.g., alarms, physical barriers, automatic shutdowns, check and double-check), dependent on people and their competencies and routine care processes (e.g., surgeons, anaesthetists, pilots) or dependent on procedures and administrative controls (e.g., quality assurance processes). However, these defensive layers can also have weaknesses. Reason described this as the "Swiss cheese" model of system accidents (Figure 5).<sup>49</sup> Defences are illustrated as slices of Swiss cheese (Figure 6). The errors and near misses occur when the holes in many layers momentarily line up and permit the passing of an error through different steps of the process.

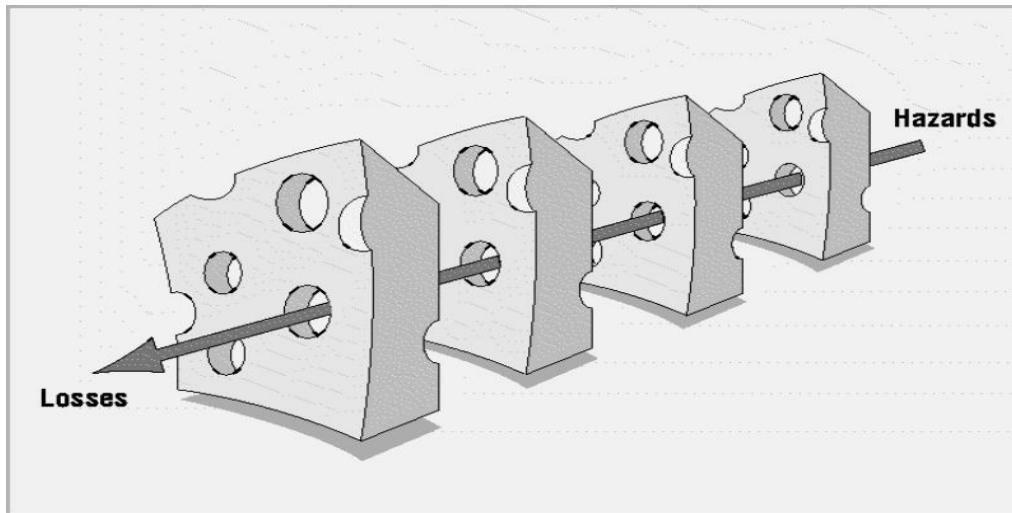


Figure 5: Reason's Swiss cheese model of system accidents.<sup>53</sup>

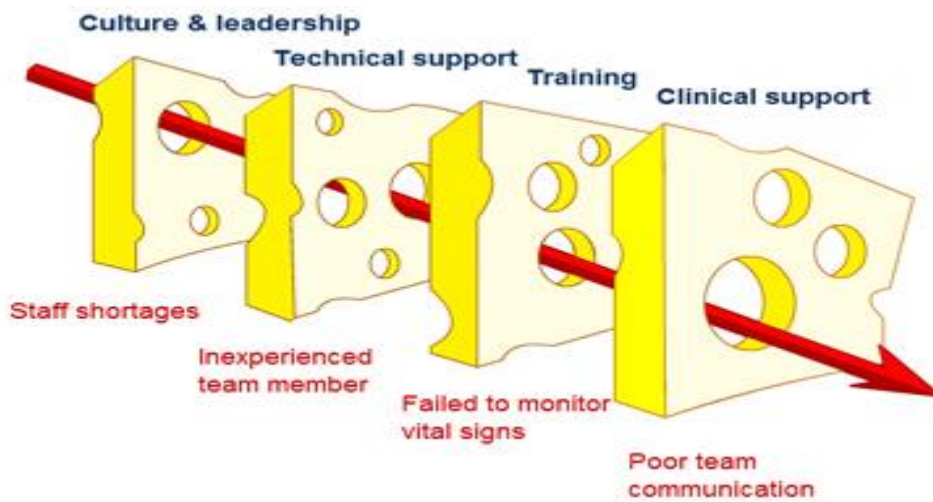


Figure 6: An application of the Swiss cheese model (Reason 1990<sup>53</sup>) to identify reasons and contributing factors to medication errors.

Some illustrative cases are provided below:

**Case description of a 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 was started immediately. According to the referring physician, the patient was under treatment for rheumatoid arthritis and was using methotrexate 5mg on Tuesdays. The dosing was, however, transcribed as 5mg in the evening and recorded on the patient's medication chart. The patient started to recover from the pulmonary embolism, however, after a week of hospital admission, her condition worsened. The doctors suspected an infection, but instead they diagnosed anaemia and neutropenia. This finding led to checking the medication chart of the patient after 12 days of hospital stay. The healthcare staff discovered that 5mg of methotrexate had been administered to the patient every day, although the correct dose should have been 5mg once a week. Despite attempts to save the patient, she died of sepsis after 20 days in hospital.<sup>53</sup>

**Case description of erroneous exchange of asparaginase forms in the treatment of acute lymphoblastic leukemia (ALL) in the Netherlands:**

For the treatment of ALL in children, Dutch paediatric oncologists use the Dutch Childhood Oncology Group ALL 10 protocol. Asparaginase is a medicine used in this disease state and comes in various formulations, each with differing pharmacokinetic parameters: *Escherichia coli* asparaginase, Erwinia asparaginase, and pegylated *E. coli* asparaginase (PEG asparaginase). This report highlights a case of a three-year-old patient with ALL who was erroneously treated with *E. coli* asparaginase instead of PEG asparaginase. Consequently, the patient went undertreated. The error was rectified and by the end of treatment the patient was able to reach complete remission. The full case report identifies the reasons why this error was made and suggests possible preventive measures.<sup>54</sup>

**Trial description of self-reported uptake of recommendations after dissemination of medication incident alerts in the Netherlands:**

In the Netherlands, a Central Medication Incidents Registration (CMR) system is in place to prevent the recurrence of reported medication incidents. The system sends out medication incident alerts with recommendations under the assumption that the healthcare worker will use clinical judgement in the implementation of the recommendations. This cross-sectional study was conducted among 33 Dutch hospital pharmacies from April 2009 to September 2010 with the objective of exploring the degree of self-reported uptake of recommendations. The goal was to identify potential determinants associated with these successful recommendation uptakes. The three alerts that were observed in the study were: 1) administration of methotrexate in a dosage of once a day instead of once a week; 2) administration of glucose 50% potassium-sodium-phosphate concentrate; and 3) administration of glucose 50% instead of 5%. The study concluded that the alerts varied in degrees of self-reported uptake of the recommendations, with the methotrexate alert having the highest degree of uptake. No significant associations with potential determinants were found.<sup>55</sup>

Kettunen has described a fatal medication error due to methotrexate overdose in a Finnish central hospital with Reason's Swiss cheese model (Figure 7).<sup>53</sup>

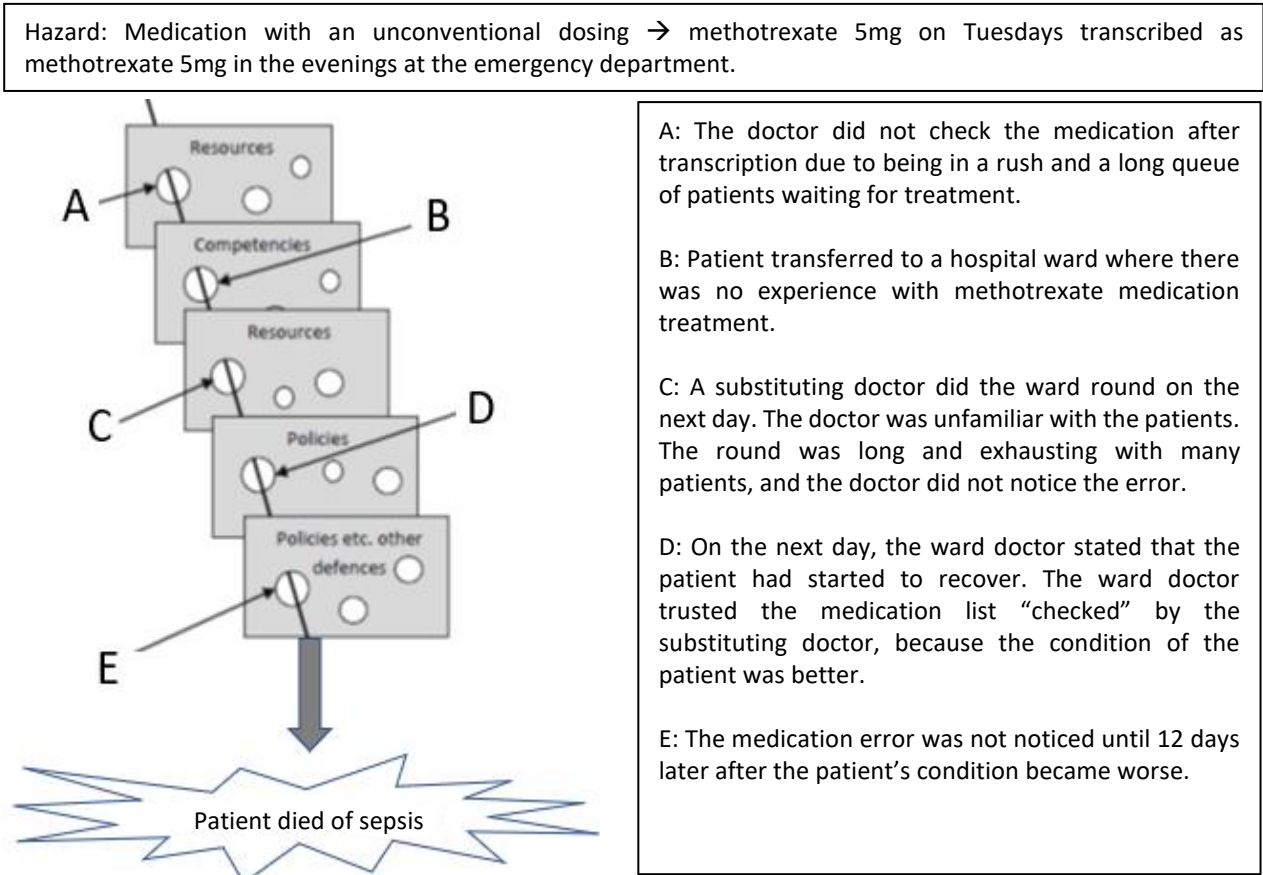
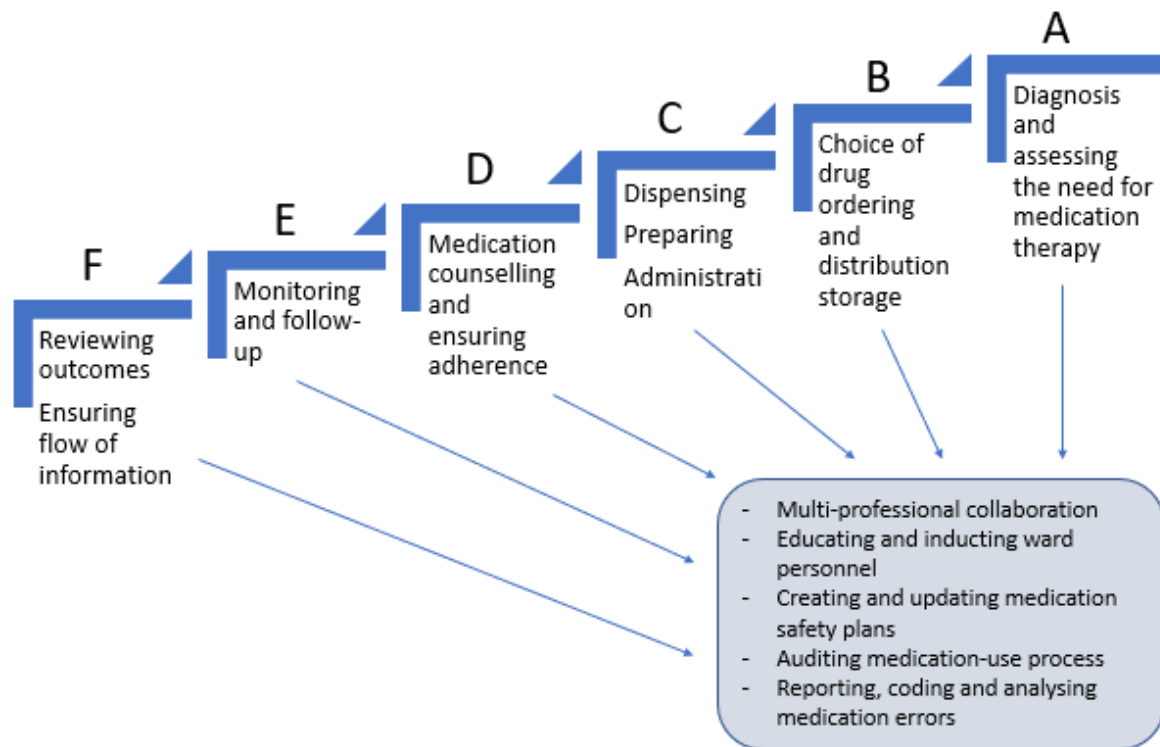


Figure 7: Application of Reason’s Swiss cheese model to illustrate a fatal system error related to medicines use in a secondary care hospital (adapted from Schepel 2018<sup>53</sup>).

Figure 8 illustrates the coverage of the clinical pharmacy services in the stages of the medicines use process by applying Reason’s Swiss cheese model.



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 medicines use process

**Figure 8: An example of application of Reason's Swiss cheese model to medication safety: the role of hospital pharmacists in Finland covers all the steps in the medicines management cycle in order to address potential "holes" in the cheese.**

### 3.2 Creation of safety culture in medicines 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 the 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 or system. It is important to evaluate the system and processes to identify points of potential 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 medicines use process include:

- Retrospective methods, such as learning from medication error reports, root cause analysis of contributing factors of severe errors (what happened and why) and analysis of patient records;
- Prospective methods, such as failure modes and effects analysis; and
- Learning from well-performing practices and processes.

National reporting programmes usually collect and analyse medication error reports from healthcare providers in their own country and only disseminate guidance to healthcare providers within the borders of their country. However, national reporting programmes can benefit from sharing a broad range of alerts and newsletters about medication errors that enhance learning between countries.<sup>56</sup>

The systems approach utilises two broad strategies to mitigate or prevent errors. The 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 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 of all the holes in the cheese aligning, thereby reducing the overall system's potential for harm.<sup>52</sup> Regardless of the solution, continuous risk evaluation needs to be employed to optimise results (reduced harm). 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 healthcare organisations, the effectiveness of these interventions has been diminished by not adhering to safety culture.<sup>57, 58</sup> Poor engagement with the safety interventions by practitioners, particularly those at the frontline, can be a reflection of a negative safety culture.

The biggest challenge to moving towards 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.<sup>59</sup> 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.<sup>57, 60</sup>

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 medication. 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 the 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.<sup>61, 62</sup> In fact, the 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 healthcare organisations and institutions for several purposes, including:

- Identifying safety issues that require improvement;
- Raising patient safety awareness;
- Evaluating patient safety interventions;
- Performing benchmarking; and
- Being part of directives or regulatory requirements.<sup>60</sup>

For health systems to evaluate safety culture, a multilevel ethnographic approach is required to understand the elements of safety culture that 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.<sup>63</sup> Such a picture of the safety climate is often used to evaluate the safety culture of an organisation.<sup>64</sup> 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 healthcare organisation or specific process. Data may include:

- Voluntary error reports submitted through (formal) reporting programmes;
- Automated trigger tools (e.g., using naloxone as a marker for opioid overdose);

- Direct observation of errors;
- Reviewing patient charts;
- Data from technology applications and hardware, including smart pumps, automated dispensing cabinets and electronic medical records; and
- Data from dispensing records.

It is important to remember that each of the data sources has its 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; and
- Implementing the 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.<sup>65</sup>

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.<sup>66</sup> 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.<sup>62</sup> The following four criteria have been recommended to be used for selecting a tool for a safety climate evaluation:<sup>60</sup>

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

In community pharmacies, the organisational structure, e.g., 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 greatly by country).<sup>60</sup>

### 3.4 Role of leadership for safety culture change and implementation

Adapting to a systems-based safety culture requires a new approach: one that embraces the skills of the members of the healthcare team, and 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 across different organisations. Acquiring these leadership competencies should be part of the standard educational curricula of all healthcare professionals. Also, postgraduate academic and residency programmes should include these leadership competencies in medication safety to attract pharmacy graduates to a career path focusing on patient and medication safety within organisations.

Those working in leadership positions entrusted to and ensuring patient and medication safety in their organisations must use a set of resources that includes a wide range of management tools, such as continuous quality improvement, teambuilding, 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 healthcare professionals around the world to adapt to the changes 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’s goals, and a plan to integrate change must cross traditional intra-organisational boundaries.

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 medicines. For example, Kotter’s “8 steps process for leading change”<sup>67</sup> 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 of individuals and groups are different, and there may be a loss of existing roles. Individuals may need to be challenged about the reasons 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 before they arise. Continuous reflection in this aspect of change is important and resolving individuals’ 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 that patient safety should be improved.<sup>68</sup> 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 (handover) to avoid mistakes.<sup>68</sup>

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.<sup>69</sup> Overwhelming workload and hence inadequate time have been identified as common contributing factors to negative patient safety cultures.<sup>70–74</sup> Hospital pharmacists also report negative attitudes from doctors and nurses due to egos, conflicts between different professionals, and differences in hierarchical status and authority.<sup>75</sup>

Importantly, pharmacists’ risk management skills need to be addressed and appropriate training provided. These skills contribute to improving the patient safety environment in outpatient pharmacy settings. Moreover, the lack of a good error reporting system also acts as a barrier to a positive safety culture.<sup>17, 70, 76, 77</sup> 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.



## 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<sup>78</sup>

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

- Ensuring the appropriateness of prescriptions at initiation of treatment;
- Ensuring safety in transitions of care between hospitals/other healthcare units and the community;
- Ensuring the accurate and appropriate supply of medicines;
- Ensuring patients are using their medicines in the correct way; and
- Identifying and resolving clinically significant, potentially harmful medication-related problems.

Thus, pharmacists can focus their expertise and apply their knowledge and skills to many areas of health care, notably clinical practice, the pharmaceutical industry and regulatory and policy sectors. Some of the more specific areas in clinical practice include:

- Ensuring access to safe and effective medicines;
- Supplying medication information;
- Medication review;
- Medication history taking and reconciliation;
- Improving medication adherence;
- Providing health and wellness services;
- Optimising medicines 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 errors;
- Leading and coordinating safe medication practices; and
- Contributing to policies and procedures around safe medicines use.

This chapter will give a brief overview of a range of pharmacists' roles in different settings and the following chapters will provide more specific examples of pharmacists' contribution to ensuring patient safety. Pharmacists' roles are expanding and evolving. These chapters do not intend to cover all pharmacists' roles in patient safety. Outpatient pharmacists consist of both community pharmacists who work in the retail setting, and ambulatory pharmacists who work in outpatient clinics or healthcare facilities. They play a key role in managing patient and medication safety in the primary care setting and have the greatest opportunity compared with other healthcare professionals to improve patient and medication safety due to their frequent contact with the public.<sup>79</sup> For example, in Australia there are approximately 449 million individual visits every year to a community pharmacy compared with 140 million visits to general medical practitioners.<sup>80</sup> This significantly higher number of visits suggests 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 healthcare team. The American Society of Health-System Pharmacists published the 2019 update from the Pharmacy Accountability Measures Working Group regarding quality measures that health-system pharmacists can implement to ensure patient safety.<sup>81</sup> This update included measures such as international normalised ratio (INR) monitoring for patients taking warfarin, undergoing venous thromboembolism prophylaxis in the intensive

care unit, taking medicines for glycaemic control or using opioids. Having pharmacists as fundamental members of the healthcare team has been proven to substantially reduce ADEs caused by prescribing errors.<sup>82, 83</sup>

Patient and medication safety begin at the point of medication development and production. Pharmacists in industry work diligently to develop new medicines that are safe and effective. The medication development and approval process, plus post-marketing surveillance, ensure that medicines are safe to use. Pharmacists working in pharmaceutical companies often also serve as the medical service liaison between the industry and prescribers, and educate prescribers on how to use/prescribe new medication appropriately.<sup>84</sup>

Nowadays, there are technology solutions for error reporting, enabling pharmacies or institutions to record, review and analyse patient safety incidents quickly and securely.<sup>17</sup> Detailed reporting helps people to learn from errors that have occurred and can contribute to continuous improvement.<sup>85, 86</sup> 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.<sup>87</sup> Another example is HaiPro in Finland, which integrates reporting of MEs with reporting of other medical events.<sup>17, 88</sup> Holmström has published an inventory of medication error reporting systems that provides a comprehensive overview of evolution of MERs and their characteristics.<sup>17</sup>

## 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. Since 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 regard to medicines 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 medicines management cycle or pathway. The medicines management cycle or pathway is a multistep process that can consist of prescribing, transcribing (if electronic prescription not available) and documenting, compounding, when applicable, medication revision and reconciliation, dispensing, administering and monitoring. The process is interprofessional, and even although the process differs in inpatient and outpatient care, physicians usually prescribe and make the treatment decisions, and pharmacists usually review prescriptions/orders and then dispense the medicines and provide patient counselling, support self-management and adherence, and monitor effectiveness of these therapies. Nurses' tasks include administration, but are also related to counselling, self-management, adherence support and monitoring the effects of therapies.

Traditionally, pharmacists' contributions to safety in the medicines use process have primarily focused on the medicine supply chain, such as ensuring proper storage and preparation. During the past decades, the pharmacist's role has extended towards patient care-oriented tasks. Pharmacists' current routine tasks include ensuring the proper prescribing of medication with appropriate dose regimens and dosage forms; clarifying instructions on medicines use, including patient counselling; preventing potential medicine-disease, medicine-medicine and medicine-food interactions; avoiding known and predictable ADRs; minimising unnecessary treatment; and considering the cost of medicines. Pharmacists also hold roles in many specialty areas of a healthcare system including the emergency department, infectious disease, oncology, pain management and anticoagulation management.

Annex 1 provides evidence of the effectiveness/outcomes of pharmacists' contributions to patient and medication safety as demonstrated via recent systematic reviews (Jan 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 and 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, published between January 2013 and May 2018, were identified (Figure 9). Of these, eight were related to pharmacists' contributions to patient and medication safety in hospitals and/or at transitions of care, six in the community pharmacy setting, and two in outpatient clinics.

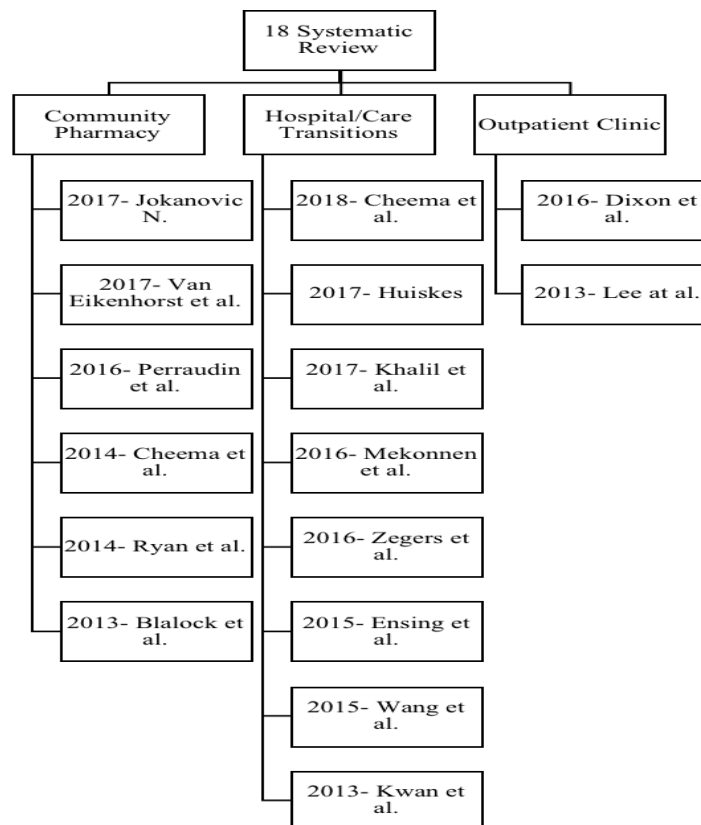


Figure 9: Systematic reviews (n=18) of pharmacists' contributions to patient and medication safety in different settings from the period January 2013–May 2018 (Annex 1).

## 4.2 Medicines use process

Pharmacists are the ultimate experts in medicines and their use. Therefore, they need to ensure patient safety throughout the medicines use process. The medicines 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 medicines use process are: selecting and procuring; storage, prescribing; transcribing and verifying/reviewing; preparing and dispensing; administering and monitoring,<sup>6</sup> with the order and details of these stages likely to vary between countries and settings.

The US Institute for Safe Medication Practices has developed a comprehensive description of the Key Elements of the Medication Use System for Hospitals and Community Pharmacies.<sup>89</sup> 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 need to be collated and used for patient safety outcomes. These key elements are:

- **Patient information:** Obtain the patient's pertinent sociodemographic information (e.g., age, weight, health literacy level), clinical information (e.g., allergies, laboratory results), medication history and comorbidities.
- **Medication information:** Provide accurate and usable medication information to all healthcare practitioners, ensuring that information is accessible and up to date, e.g., information on medicine-medicine interactions, contraindications, dosing control.
- **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 among all members of the healthcare team.

- **Medicines labelling, packaging and nomenclature:** Medicine names that look-alike or sound-alike, as well as products that have confusing labelling and non-distinct 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.
- **Medicines storage, stock, standardisation and distribution:** Standardise medication administration times and medicine concentrations, and limit the dose concentration of medicines available in patient-care areas. Store medicines appropriately and safely.
- **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.
- **Environmental factors:** Environmental factors that can often contribute to medication errors include poor lighting, noise, interruptions and a significant workload. These should be minimised and avoided, if possible.
- **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.
- **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 medicines and be engaged in their self-management. Increased understanding of medication and its appropriate use can lead to fewer medication errors and ADEs. According to the WHO, everyone, including patients and healthcare professionals, has a role to play in ensuring medication safety. The WHO has developed a tool to increase public awareness of the safety issues related to medicines use and the need for safer medication practices.
- **Quality processes and risk management:** Patient safety is part of quality management. Quality improvement is essential to improving patient safety and hence medication safety. Effective responses to previous incidents or near-miss incidents require a positive safety culture, whereby incidents are reported and analysed using a systems approach. A systems approach involves understanding all the different factors that may have contributed to the incident occurring. It is from this analysis that risk minimisation strategies can be developed.

Effective management of the above key elements by pharmacists and other pharmacy staff, in collaboration with other healthcare professionals and patients/consumers, can help ensure patient safety throughout the medicines use process in the health-system journey.

With regard to patient and public education, the WHO tool “Know. Check. Ask.” (Figure 10) encourages and empowers both patients and their caregivers and healthcare professionals (e.g., nurses, physicians, pharmacists) to take an active role in ensuring safer medication practices and medicines use processes including prescription, preparation, dispensing, administration and monitoring. Pharmacists, and all healthcare professionals, are invited to use the posters and all tools that are freely available on the WHO website.



Figure 10: WHO patient empowerment material for improved patient safety.<sup>5</sup>

## 5 Patient safety in the medicines use process

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

### 5.1 Access to medicines

Access and availability of medicines is one of the initial steps to consider in relation to medication safety. However, not every person who needs them is able to access safe and effective medicines in a timely manner. Moreover, from time to time, there are also medicines shortages, which can impact patient safety through lack of medicines availability.

Access to medicines can be compromised by various factors. For example, affordability of medicines can sometimes lead to safety issues (e.g., if patients do not understand how to access specific medicines or if they cannot afford to buy them). Limited access can also present issues, e.g., for vulnerable populations, such as the elderly, or for indigenous populations who access medicines through different channels (e.g., Aboriginal and Torres Strait Island people accessing medicines via Aboriginal Medical Services in Australia).

Medicines shortages can give rise to many patient safety concerns, including use of look-alike, sound-alike packaging, and use of overseas products labelled in foreign languages or using non-standard terminology. Breaches of good manufacturing practice standards can also lead to recall of medicines due to contamination, diversion etc. This then results in limited access to essential medicines.

Pharmacists play an important role in ensuring that their patients receive their medicines in a timely manner. While direct supply by pharmacy staff is an effective option, this may not be practical in all circumstances, e.g., to remote communities. For patients on long-term (chronic) medication who have difficulty obtaining medicines (e.g., those living or working far away from a pharmacy) alternative models of distribution of pre-dispensed medicines could assist with access and improved adherence to therapy. For example, parcels of medicines can be distributed direct to a patient's home or to a facility closer to where the patient lives or works. These pre-dispensed, patient-ready medicines parcels need to be correctly prescribed, and the correct supply chain ensured (from receipt, to storage and delivery) to guarantee that the correct medicine is provided and that medicine stability is not compromised.<sup>90</sup> To enhance patient safety, qualified pharmaceutical personnel should provide medication instructions and information regarding the correct use of medicines provided and address patients' questions or any other health-related concerns. The facility from which this service is rendered should be linked to an approved pharmacy, which may not necessarily be the same pharmacy that dispensed the medicines parcel.

### 5.2 Dispensing and supply of medicines

Dispensing and supply of medicines are at the core of a pharmacist's role in inpatient and outpatient settings. It is also one of the initial steps of the medication journey for patients and part of the continuous cycle of medicine-taking for those on chronic therapy. The process of dispensing, however, starts prior to the patient presenting a prescription. Pharmacists have responsibility in the procurement and storage processes of medicines, and although both may be performed by others, they are under pharmacist guidance and control. If not correctly performed, these two processes might have important safety implications when dispensing occurs. The dispensing process itself involves more than simple labelling and supply of a medicine. The pharmacist has to ensure that the right medicine is being given to the right patient, in the right dosage form, in the right dose, at the right frequency and at the right time. This section considers the steps involved in the dispensing and supply of medicines, 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

Although rates of dispensing errors are generally low, further improvements in pharmacy distribution systems are still important because pharmacies dispense such high volumes of medicines that even a low error rate can translate into a large number of errors.<sup>91</sup> There are many kinds of errors that can happen when dispensing medicines to patients, many of which occur because the pharmacist has not performed an adequate final product check or failed to perform required patient counselling.<sup>92</sup> For example:

- Patients receiving the incorrect medicine, or form or strength of medicine;
- Prescription labels containing incorrect information, or information inconsistent with the original prescription;
- Patients receiving the incorrect quantity of medicines;
- Patients receiving an expired medicine;
- Patients receiving medicines which were incorrectly compounded;
- Pharmacists not detecting drug interactions or clearly documenting allergy information, resulting in adverse effects for the patient;
- Patients receiving someone else's prescription medicine; and
- Patients receiving a different brand of a medicine that they already have (leading to duplication).

It is important to make sure that the right patient is getting the right medicine at the right strength and to ensure that the medicine has not expired. Pharmacists should also provide counselling and encourage patients to ask questions prior to supplying the medicines.<sup>92</sup>

More research is required into dispensing errors, particularly in middle- and low-income countries, and into the underlying causes of dispensing errors.<sup>91</sup>

### 5.2.2 Automation

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

- **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 issuing of medicines and medical devices. This may reduce medicine selection and preparation errors.<sup>93</sup>
- **Remote automated dispensing units** may be used to dispense medicines and devices for long-term (chronic) therapy thereby improving access to medicines. Patient safety must be ensured when using this innovative approach through audio-visual communication with the patient, as outlined in section 4.

Automation in health care is growing 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 and can give rise to new types of error. One of the earliest forms of automation in the medicines supply process was the use of barcode scanners during the dispensing process to check the correct selection of medicines. However, workarounds can occur, increasing the risk of medication errors because the interaction between human and machine plays a pivotal role in technology incidents.<sup>94</sup> While barcode scanning is mandatory in several developed countries, automation is now occurring in several other places in the medicines supply process. In the hospital setting, ward-based computerised automated dispensing systems have been shown to reduce error rates and costs.<sup>95, 96</sup> However, decentralised automated dispensing systems have been shown to have limited effect in reducing medication errors.<sup>97</sup> During the administration process, the use of electronic medication records, together with barcode scanning of products, have also been shown to be beneficial in reducing medication errors.<sup>98</sup>

Automation has been gradually 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 a reduction of errors in the community setting.<sup>99</sup> Additionally, automation has been used in the repacking of medicines into dose administration aids or monitored dosage systems. However, studies have shown that there are significant rates of error that can still occur with automation.<sup>100, 101</sup> A number of technological advances have occurred since these studies were conducted, particularly in the automated checking of the repacked medicine 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' roles in integrating automation and continuously ensuring quality remain essential.

Telepharmacy can present its own challenges in patient care and safety. In order to ensure that the correct medicine is being provided to the correct patient and that the patient is able to take the medicine appropriately, the pharmacist

must communicate with the patient via screen or 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. Pharmacists need to be careful when they are providing services through telepharmacy as cues to potential errors may not be picked up as easily as with traditional face-to-face patient contact. It is harder to build rapport or to identify an error through a screen or telephone compared with 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. Pharmacists also need to pay attention to patients' health literacy during the interaction and use appropriate patient-friendly language, so that all information is understood.

### 5.2.3 Unit dose dispensing

Unit dose dispensing (UDD) can be useful for a patient who has practical problems in managing their medicines and/or maintaining independent living. UDD sees medicines dispensed in a single-dose package. This is a helpful strategy to assist in medication adherence and administration and is often utilised in long-term care facilities, skilled nursing facilities, and even in patients' own homes. In many countries, UDD is also used inside the hospital to reduce the incidence of medication errors related to medicine selection and dose calculation. The use of original medicines packaging is preferred for medicines supply to ensure stability, and to retain important information included in the product packaging, and dispensing label (including ancillary labels). 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.

### 5.2.4 Barcode use and scanning

The use of barcoding has been proven to be a successful patient safety tool both for dispensing and administration. It is important that all primary packages have readable barcodes to enable this best practice technology. For dispensing, scanning of barcodes helps ensure the right product is selected for the patient. In hospitals, barcode medication administration (BCMA) systems are used to reduce medication errors at the point of administration. When administering medicines using BCMA, a health professional scans a barcode on the patient to confirm that the correct patient is to receive the medicine. Then the medicine is scanned to verify that it is the right medicine at the right dose, given at the right time by the right route. BCMA is often used in conjunction with electronic medication administration record (eMAR) systems. An eMAR automatically documents the administration of medicines into an electronic health record (EHR). By linking BCMA with the eMAR, information on medicines administration is electronically captured instantly, reducing documentation burden. BCMA implementation can be remarkably effective in reducing medicines administration errors. A study of BCMA-eMAR implementation in an academic medical centre demonstrated a 41.1% relative reduction in non-timing errors in medicines administration, resulting in a 50.8% relative reduction in potential ADEs due to such errors.<sup>102</sup> BCMA implementation in the emergency department has also shown a relative reduction of 80.7% in medicines administration errors.<sup>103</sup>

### 5.2.5 Patient counselling

Whenever dispensing or reviewing patients' medication, pharmacists should provide written medicines information alongside verbal counselling, as patients may feel overwhelmed by verbal information provided at the time. Written resources must meet the needs of the patient, taking into account literacy in general and health literacy in particular. Every effort should be made to check patient understanding, using techniques such as "teach back" and allowing opportunity for the patient or their carer to ask questions.

Pharmacists can educate patients about correct and appropriate medicines use, potential side effects, medicine-food interactions and potential allergic reactions, and can advise patients about the course of action should they experience any adverse reactions. Patient education and counselling, and the provision of appropriate written information or pictograms are important strategies for empowering patients to self-manage their medication on a daily basis and ensure that they are using their medicines safely and appropriately.

During hospital stays and at discharge, it is critical to educate patients on how to take their medicines and to provide pertinent information on things such as drug-drug-interactions and drug-food-interactions in patient-friendly language.<sup>104</sup> In a study of medication in 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 ADRs due to non-adherence.<sup>105</sup>

### 5.2.6 Self-medication

Pharmacists working in an outpatient setting, especially community pharmacists, act as the last defence between the patient, the public, and inappropriate self-medication with over-the-counter or non-prescription products. Self-medication is an important part of self-care. The 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 healthcare provider.<sup>106</sup>

Self-medication can be considered as the medication-related decision-making of individuals with or without the assistance of healthcare practitioners. Self-medication can occur at any point, from selection of a medicine to its administration. For a medicine to be available for self-medication, it must undergo a regulatory procedure to determine that it is safe, appropriate and in the interest of public health.<sup>107</sup> The WHO's guidelines for the regulatory assessment of medicinal products for use in self-medication recommends that a medicine 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 marketed 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"*.<sup>107</sup>

Although self-medication can provide wider and easier access to medicines, 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 ADRs;
- Incorrect route of administration;
- Inadequate or excessive dosage;
- Excessively prolonged use;
- Risk of dependence and abuse;
- Food and drug interactions; and
- Storage in incorrect conditions or beyond the recommended shelf life.<sup>107</sup>

As the custodians of medicines, pharmacists can play a key role in ensuring safe self-medication.<sup>108</sup> 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 healthcare professionals, especially if there is no improvement in symptoms; and
- If not appropriate to supply, considering evidence-based alternative therapies such as non-pharmacological therapies that may be appropriate as well as referring to other healthcare professionals that may be able to provide appropriate management.

In addition to these steps, pharmacists should ensure that adverse events and inappropriate use of medicines 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 Safe disposal of medicines

Pharmacists also serve as a great resource to educate patients on the safe disposal of unwanted (including unneeded) or expired medicines and medicines return or take-back programmes. This can help prevent medicines from posing a harm to the environment, and prevent inappropriate distribution and use of controlled substances and antibiotics.<sup>109, 110</sup>

## 5.3 Medication history taking and reconciliation

Pharmacists play a key role in medication reconciliation processes, such as 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 (and how they are taking the medicines at home) with 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 ADEs.<sup>111</sup> Pharmacists can identify and resolve medication-related issues to reduce the number of medication errors, prevent potential adverse drug events, and improve patient safety. Some of these errors include restarting an omitted medicine, removing duplicate therapy, adjusting incorrect doses or quantities<sup>112</sup>, resolving medication discrepancies, and reducing ADRs.<sup>113, 114</sup> Pharmacists' involvement in medication reconciliation after discharge can also reduce readmission rates and improve monitoring of pharmacotherapy.<sup>115</sup> Medication reconciliation is an effective way of preventing errors in the patient's medication history being compounded after a hospital visit, and ensuring other healthcare facilities can receive the most accurate and up-to-date medication history when the need arises. This process is particularly important in healthcare systems that are highly fragmented and where patients see different healthcare professionals who do not readily share information. An example of a highly fragmented healthcare system is that in the United States.<sup>116</sup> In many cases, there is little communication between the hospital, outpatient pharmacy, and other healthcare professionals, which leads to gaps in medication history and inappropriate or duplicated medicines.

The positive impact of pharmacists conducting medication reconciliation has been demonstrated.<sup>117</sup> A study in Brazil has shown that there are high numbers of unintentional discrepancies between the medication prescribed at admission and patients' home medicines. The study concluded that pharmacist-led medication reconciliation was highly effective in detecting and addressing medication discrepancies before they caused harm to the patient.<sup>75</sup> Similar conclusions were made in another study done in Bogotá, Colombia. The study showed that medication reconciliation and medication history review which involve pharmacists during admission reduces the risk of potential ADRs and prevents clinical deterioration due to medication-related adverse events.<sup>118</sup>

## 5.4 Monitoring medicines use

### 5.4.1 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 ADEs, drug-drug and 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 drug (NSAID) use.<sup>119</sup> The interventions included stopping NSAID use or adding a gastroprotective agent after receiving information about the 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.) medicines, interactions, potential ADRs and overdose after a complete medication review.<sup>120</sup> This helps prevent ADEs and detect prescribing errors. Both interventions would not be possible if the pharmacist did not have access to patients' medication histories. Therefore, it is crucial for pharmacists to have access to these to ensure patient safety.

### 5.4.2 Monitoring of prescribed medication

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. While this role can be conducted by the pharmacist alone, working in a multidisciplinary collaborative healthcare team will facilitate the pharmacist's role and achieve a timelier, more 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 ADRs and medication toxicity.<sup>121</sup>

An example of a pharmacist service delivered to a multidisciplinary team is the ward pharmacy service. A ward pharmacy service is a patient-oriented, decentralised service that requires the pharmacist to become an integral and indispensable part of the professional healthcare team of a hospital or institution. Ward pharmacists are required to use their knowledge and skills in terms of pharmaceutical sciences and product awareness to ensure and promote safety, efficacy, and economic use of medicines in an advisory capacity to clinicians and nurses, and where needed to specialist care teams.<sup>121</sup>

In outpatient settings, prescribing errors such as incorrect dose, frequency, or route of administration can also occur.<sup>122</sup> Although electronic prescription and electronic prescribing tools can help reduce errors compared with traditional paper prescriptions, pharmacists should check each prescription carefully to ensure the selected medicine, dose, frequency, and route of administration are appropriate for the patient before dispensing the product.<sup>123</sup> 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.<sup>124</sup>

### 5.4.3 Therapeutic drug monitoring

Therapeutic drug 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 administered medicine. 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,<sup>121</sup> 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. Moreover, in some countries, pharmacists are legally allowed to prescribe medicines. All these activities help to monitor patient outcomes and symptoms of ADEs. Pharmacists therefore can aid physicians and other healthcare providers by providing feedback on medicines use and patient safety issues.

### 5.4.4 Polypharmacy and deprescribing

As polypharmacy becomes more common due to an ageing population 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.<sup>125</sup> Pharmacists can serve as effective facilitators between prescribers and patients, and support appropriate deprescribing and related patient education to ensure patient safety.

### 5.4.5 Pharmacovigilance

Pharmaceutical companies have the responsibility to monitor safety throughout the life of a medicine, 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.<sup>126, 127</sup> The specific aims of pharmacovigilance are to:<sup>126</sup>

- Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions;
- Improve public health and safety in relation to the use of medicines;
- Contribute to the assessment of benefit, harm and effectiveness of medicines, 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 pharmacists and healthcare professionals working 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 medicines is mainly coordinated 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 routine pharmacy practice is still needed. Medication safety, including pharmacovigilance and post-marketing surveillance, should feature in medical and pharmacy educational curricula.

Adverse events related to medicines are common but many are preventable or can have their effects reduced if they are detected and reported.<sup>128</sup> 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.

It is outside the scope of this document to specifically discuss all pharmacovigilance issues.

## 6 Pharmacists' value in collaborative healthcare teams

As medication experts, pharmacists can contribute to patient safety and therapeutic outcomes in a variety of healthcare settings, as reported in Section 5. Including pharmacists as members of multidisciplinary healthcare professional teams will be an evidence-based approach to improve medication adherence, prevent ADEs and, subsequently, ensure patient safety.<sup>104, 129</sup>

Pharmacists do not work alone in the pharmacy. Pharmacy support personnel are critical in ensuring that patient safety remains a priority throughout the medicines 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 are becoming increasingly important, not only in relieving pharmacists of more traditional roles, but also in 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, in particular. Standardisation will be required at all levels of pharmacy technician practice.<sup>130</sup> A 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".<sup>131</sup>

With the most extensive knowledge of medicines, pharmacists can contribute to the interdisciplinary team by eliminating unnecessary, duplicative or excessive pharmacotherapy during the medication-selection process. They can also help in identifying and resolving medication therapy problems, drug-drug and drug-food interactions, and potential adherence barriers.<sup>132</sup> Researchers have shown that including pharmacists in interdisciplinary teams is associated with lower ADEs related to prescribing errors, reduced hospitalisation, and lower mortality rates.<sup>133–135</sup> However, there is a need to increase awareness of the value of pharmacists in healthcare teams, and implement appropriate policy changes to optimise the use of highly trained pharmacists to improve the quality of health care.<sup>76, 132</sup>

### 6.1 Advocate for the profession

It is also important for pharmacists to engage in advocacy initiatives for pharmacists in order to be more recognised as an integral part of the healthcare team that works to ensure patient safety.<sup>136</sup> Pharmacists are not yet recognised as primary care providers in many countries and many other healthcare professionals are not aware of how pharmacists can contribute to an interdisciplinary team. This can impede their work in patient safety in many ways.<sup>132</sup> 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 pharmacists play in healthcare teams, in particular, of their contributions to patient safety.<sup>73</sup> It is critical to raise awareness so pharmacists can be practising at full scope and contributing to high-value activities related to patient care. Additionally, pharmacists should work on building credibility and trust with other healthcare professionals through building relationships and demonstrating competence.

## 7 Medicines regulation and patient safety

Patient and medication safety not only rely on the safe practice of individual healthcare professionals and effective health systems, but also on international 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.<sup>137, 138</sup> 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, which is to protect the public by regulating the practice of pharmacy in their country.<sup>139</sup> It is predominantly mandatory for all those who are authorised to practise in any setting of pharmacy, as a pharmacist, in a specific country, to register with the relevant regulatory body.<sup>139</sup> 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 Packaging and labelling of medicines (including package inserts/medication information)

According to the US Food and Drug Administration (FDA), many medication errors can be avoided at the design stage of production by drawing on lessons learned from past medication errors and by conducting proactive risk assessments before marketing.<sup>140</sup> Labelling and packaging issues can cause up to 33% of medication errors.<sup>141</sup> The pharmaceutical industry can contribute to reduced medication errors by adhering to global or local standards for the design of medicines packaging and labelling that will maximise safety in use.<sup>8</sup>

In some countries, e.g., in all EU countries, package inserts and patient information leaflets (PILs) are compulsory for each product that a pharmaceutical company wants to register. The purpose of PILs is to improve patients’ knowledge about the medicine and therefore adherence to the treatment.<sup>142</sup> However, patient safety can be compromised when the PIL does not reach the patient. Some PILs may be attached to the manufacturer’s original packaging so a patient may not receive the PIL if they have not been supplied a whole pack, or PILs may be available electronically and not printed for patients by healthcare professionals (e.g., in Australia). Patient safety could be further compromised by 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 medicine’s side effects. Importantly, patient safety can be impacted when the PIL contains information that the patient cannot understand or act on (i.e., where information has been written at a level higher than the average patient’s health literacy) or the patient is unable to find the relevant information in the PIL.

Some agencies have explored ways to mitigate these patient safety issues by regulating the manner in which medicines are labelled and how easily medicines information is to access for both patients and providers. For instance, the FDA has worked with pharmaceutical manufacturers to reformat package inserts for medicines to be more user friendly. Instead of the complex, detailed pamphlet, package inserts have now been formatted with a [‘Highlights of Prescription Information’](#) section which summarises topics such as indication and dosage, warnings and precautions, drug interactions, etc. Additionally, steps to make medicines information more transparent to pharmacists have also been taken, for instance, Dutch pharmacists have easy access to digital medicines information via the Apotheek.nl [website](#).

Pharmacists can play several roles in this area. Firstly, they can advocate for the availability of user-friendly, quality patient information leaflets for all medicines. Secondly, they can ensure that patients in all settings have access to, and receive, user-friendly patient information leaflets. Thirdly, they can orally communicate information to patients using patient-friendly language and by engaging patients in methods such as “teach back” to ensure that patients understand all the important information provided to them. That is, verbal communication is used to complement written information.

## 7.3 Medicine 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.<sup>8</sup> LASA confusion also concerns design of outer packaging and the actual product in unit dose, involving colours, design, layout, font size etc. LASA confusion should be assessed during the registration of medicines, and companies should be discouraged from using names that look like or sound like existing products. The rise of generic medicines manufacturing makes the problem worse. Both the regulators and manufacturers should be held accountable and take this matter seriously. 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 (e.g., package inserts or PILs) on the use of the medicine are clear so as not lead to medication errors,<sup>143</sup> for example where similar looking medicines are intended for different administration routes. 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.<sup>144, 145</sup> Some examples include:

- Sound-alike brand names: Lasix® (furosemide — diuretic) and Losec® (omeprazole — proton pump inhibitor)<sup>146</sup> — to avoid confusion, the brand name for omeprazole has been changed to Prilosec in the USA;
- Look-alike brand strengths: Eltroxin® 0.01µg and Eltroxin® 0.005µg;
- Look-alike and sound-alike brand names: Pulmicort® Turbohaler (budesonide — oral inhalation) and Rhinocort® (budesonide — nasal inhalation);<sup>146</sup> and
- Look-alike and sound-alike generic names: hydroxyzine and hydralazine, or tramadol and trazodone, or cyclosporine/cycloserine.

Also, @EZDrugID on Twitter provides real-life examples of poorly designed ampoules/outer packaging that put clinicians at risk of selection errors.

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 manufacturer or sponsor, and often differ significantly between countries. It is therefore advised that pharmacists actively identify and manage the risks associated with LASA medicines by regularly reviewing those used in their pharmacy and developing protocols on how to manage the risks, e.g., storing look-alike medicines away from each other on shelves and checking the indications of sound-alike medicines.<sup>147</sup>

## 8 Learning from other industries

Many industries have incorporated safety measures in their everyday practice. High-risk industries, such as aviation, railway transportation and 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 of safety for the healthcare industry. The number of daily flights has doubled in the past two decades, however, the number of fatal accidents has decreased considerably.<sup>148</sup> The healthcare 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 three plane crashes every day.<sup>148</sup> Pharmacists need to learn from the experiences of the aviation industry in order to improve patient safety.<sup>148</sup>

The aviation industry and healthcare industry have different priorities. The aviation industry focuses on safety and has established a blame-free culture and a robust error reporting system. In contrast, the healthcare industry has competing interests such as financial and economic factors and reputation of the institution that impact patient safety. For instance, in some countries such as the US, patients may not be given the most appropriate medicine due to their insurance coverage. Safety is an obligation to airline companies whereas it is only a priority to some members of the healthcare industry.<sup>148</sup> One of the most important steps pharmacists need to take is to increase awareness of safety issues in direct patient care settings and be conscious about patient safety when making clinical decisions.<sup>148</sup>

#### 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, we may remember but for some reason not perform the step, or we may 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 healthcare 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 intravenous room (a place for the sterile preparation of medicines) was associated with detection of 14 times more errors compared with non-technology-assisted workflow.<sup>149</sup> Therefore, it is important for pharmacists not to rely solely on memory and experience but to effectively utilise checklists and technologies such as electronic reminder systems or clinical decision support to aid their work.<sup>148</sup>

#### 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 and emergency situations, and avoid mistakes. On the other hand, in many countries, pharmacists are not revalidated or are revalidated every few years, and simulator/situational training is limited during their training (however, this may be slowly changing). 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 clinical setting, when a patient's life may be at stake. A protocol on how to avoid and handle medication errors should become a habit or an instinct. It is also very important to teach non-technical skills such as leadership, team-work, decision making, situational awareness and stress management, and how to manage fatigue, in order to avoid medication errors in the first place.<sup>148</sup>

#### 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 and other healthcare professionals, emergencies that arise in other departments, etc. These interruptions negatively impact the procedures that are being performed by pharmacists, bringing 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 (as can happen when trying to multi-task, e.g., review a patient's medication chart while waiting for another patient's medication history information to be sent through from the community pharmacy). These interruptions can lead to mixing up of patients' details, errors in calculations, failure to detect inappropriate medicines use, or errors in prescribing, as well as other potential mistakes, including dispensing errors. Therefore, a distraction-free work environment is very important to ensure patient safety.<sup>148</sup> The Institute for Safe Medication Practices estimates that pharmacists are distracted and interrupted as often as once every two minutes. To help decrease these distractions, the institute has offered [strategies](#) that are easy to implement, and may dramatically benefit the quality of a pharmacist's work. Some of these strategies include:

- Implementing a “no interruption zone” — a discreet area for critical medication tasks that is cordoned off with visual markers to signify that talking and interruptions are not permitted;
- Checklists — posting a checklist of important points in work areas can help pharmacists to reference where they stopped when a task is interrupted; and
- Alerts, alarms, and noises — reduce the frequency of invalid, insignificant or overly sensitive computer/device alarms to promote the delivery of critical notifications, and minimise the noise of overhead pagers and unnecessary chatter in preparation areas.

#### 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 or litigation; and lack of belief that reporting will lead to improvement. These ideas sprouted from the “blame culture” in the healthcare 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.<sup>150</sup> Lack of reporting in health care in general is a common issue. It is crucial for pharmacists to adopt the concept of “just culture”, which focuses on identifying system flaws that can be resolved in order 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 are punished.<sup>148</sup>



## 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 practising pharmacists, as well as pharmacy support personnel (e.g., pharmacy technicians) to keep up to date with the current concepts regarding patient safety through continuing education and life-long learning. For the purpose of this document, the focus will be primarily on pharmacy students, yet the core principles outlined in this publication are applicable to all learners, including current pharmacists, technicians and interns. Importantly, introduction to 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.<sup>151</sup> Teamwork between healthcare 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 personas.<sup>152</sup> 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 healthcare professionals 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 patient safety while conducting 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.<sup>153</sup> The guide provides examples of learning objectives and steps for course development, allowing educators the ability to 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's "Multi-professional patient safety curriculum guide" may help ensure pharmacists across the world have enough exposure to these critical principles.<sup>30</sup> Recognising the importance of teamwork in the context of medication safety, together with a culture of ongoing learning, the curriculum guide takes an interdisciplinary perspective. It is designed to provide an overview of those aspects of medication safety that should be taught to undergraduate and postgraduate healthcare students as well as to practising healthcare professionals. It also aims to encourage a culture of ongoing interprofessional learning and practice in relation to medication safety. The intended audiences are undergraduate and postgraduate healthcare students, practising healthcare professionals, their educators and relevant professional bodies. It is being designed to support interprofessional 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 (medicines, patients and the public, healthcare professionals, and systems and practices) and the three priority areas (polypharmacy, transitions of care and high-risk situations) highlighted by the Global Patient Safety Challenge.<sup>26–28</sup>

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.<sup>154</sup> This framework was developed after conducting a comparative study with the aim of identifying common behaviours within existing frameworks used in seven 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 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. Further, patient safety should be included as part of life-long learning plans to ensure continued understanding of contemporary strategies and best practices to optimise patient safety. Obtaining certifications and credentials is one way pharmacists can distinguish themselves as patient and medication safety experts. For more information on organisations offering these educational opportunities, refer to the resources section.

Competencies directly impacting patient safety include:

- Identification of patient health-related problems based on signs and symptoms;
- Determination of appropriate medicines for individual patients;
- Dispensing skills;
- Counselling skills, advice and provision of information, including correct use and medicines storage;
- Monitoring medication therapy and resolving any medication management problems for patients; and
- Promotion of health, wellness and lifestyle.

Competencies indirectly impacting patient safety include:

- Effective and efficient supply chain management to ensure availability of essential medicines;
- Responsible sourcing of medicines;
- Continued updating of knowledge and skills through continued professional development;
- Adherence to national legislation, regulatory affairs, practice guidelines, code of conduct, ethics code, and good pharmacy practice guidelines;
- Development and adherence to standard operating procedures;
- Policy development as part of governance of medicines management (at organisational and national levels);
- Participation in research; and
- Effective management of epidemics and/or disaster management.<sup>154</sup>

## 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.

Quality assurance is an important subject. Some universities and institutions offer a curriculum on quality assurance. In the Netherlands, undergraduate pharmacy students follow curricula on pharmaceutical QA about the product (medicines) and the health system (transition between primary and hospital care). The Institute for Healthcare Improvement (IHI Cambridge, Massachusetts, USA) Open School offers courses on quality improvement or tools such as The Plan-Do-Study-Act worksheet for documenting a test of change developed by the institute.

## 10 Conclusions

The global cost associated with medication errors has been estimated by the WHO as USD 42 billion per year. But what does this cost look like for patients and families who have experienced harm due to error? What is the cost to healthcare professionals who are implicated in medication errors, since we know that those who provide care intend to “do no harm”? Patient safety and medication safety is everybody’s business, but particularly that of pharmacists.

Pharmacists contribute to medication safety and drive safer health care wherever they work. Pharmacists use their expertise, working collaboratively with the patient’s healthcare team to optimise the use of medicines for patients. Pharmacists empower patients to manage their medicines safely and effectively to reduce the risk of medication-related harm. Pharmacists advocate for safer work environments for all healthcare staff when handling medicines as part of their job. They do so by leading and supporting safety, quality and the governance of medicines at organisational, national and international levels. Pharmacists work within the medicines industry and regulatory sectors. Pharmacists also work in research and academia to drive evidence-based practice, and to educate and prepare those entering this dynamic and evolving profession. In essence, all pharmacists may consider themselves as medication safety pharmacists — advocates for safety within the healthcare system and for each individual patient.

Pharmacy practice and service delivery may look different across the world, although there are probably more similarities than differences. The common challenges facing pharmacists include increasingly complex medicines and the issue of polypharmacy or inappropriate use of medicines and ensuring optimal transitions of care for our patients in spite of fragmented healthcare systems or models of service delivery. There is also the often-reported issue of being under-resourced and time-poor (and not being able to deliver as much as we would personally and professionally want to). We can learn a lot from each other — for example, through the case examples and snapshots included in this reference paper — to see how effective policy or national agendas, innovative models of care, technology-based advances and so on can benefit patient and medication safety. There are many practical resources and tools (provided in Section 11 of this reference paper) to support best practice.

This reference paper is a personal and professional challenge to all pharmacists, as well as the profession as a whole, to keep patient and medication safety at the forefront of practice and to aim higher for continuous improvement in patient care. We need to collaborate for maximum impact and efficiency, and we need to be innovative to adapt to the natural constraints of the healthcare environment. Lastly, we need to refuse to accept the status quo when we feel something is “not quite right” — for the sake of ourselves, our fellow healthcare professionals, and our patients and their families. What changes can you make to your practice today, and what can you do as an advocate for safer medicines use for tomorrow’s patients?

### Tools and resources

There is 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 healthcare professionals and effective involvement of patients in their care are all needed to ensure sustainable and significant improvements in the safety of health care. The WHO not only provides resources for healthcare professionals, but also for 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 five key moments (starting a medicine, taking a medicine, adding a medicine, reviewing medication, stopping a medicine) and questions people should ask during these moments to ensure medication safety.<sup>155</sup>
  - 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/](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/](https://www.who.int/patientsafety/topics/research/developing_research_training_programmes/en/)
- **Institute for Healthcare Improvement (IHI):** Founded by Don Berwick, MD, the IHI has a vision that everyone has the best care and health possible. To accomplish this, the IHI’s mission is to improve health and health care worldwide. The IHI is notable for its continuous quality improvement best practices and various other efforts to improve patient safety.<sup>156</sup> It 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.<sup>157</sup>
- **Institute for Safe Medication Practices (ISMP):** The ISMP is one of the oldest and largest organisations which focuses on medication safety. Founded by Michael Cohen in 1994, the 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 healthcare community, including consumers, to prevent medication errors. A few of the 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 and 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 (it could also be used for hospital pharmacies)  
<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>
- ISMP Safe Practice Guidelines for Adult Intravenous Push Medications for hospitals  
<https://ismp.org/sites/default/files/attachments/2017-11/ISMP97-Guidelines-071415-3.%20FINAL.pdf>
- **Accreditation and The Joint Commission (TJC):** Accreditation is an important concept directly related to the quality of care provided at a healthcare institution. Specifically, accreditation is a method for ensuring an organisation achieves and maintains high-quality patient care.<sup>158</sup> 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 healthcare 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.<sup>159</sup> An example of its guiding documents is the IMSN [Global Targeted Medication Safety Best Practices](#), which was 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 asking for doses that are more frequent than once a week.<sup>160</sup>
- **Patient Safety Movement Foundation (PSMF):** The PSMF has developed more than 30 evidence-based solutions to over 17 patient safety challenges currently facing hospitals. The solutions are updated every year to ensure their accuracy. The Patient Safety Solutions app provides users with access to all actionable patient safety solutions and allows them to share content across organisations and healthcare networks.<sup>161</sup>

- **American Society of Health-System Pharmacists (ASHP):** The 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>
- **Institute for Healthcare Improvement (IHI):** One of the recognisable global credentials is the Certified Professional in Patient Safety (CPPS) qualification which is managed the IHI: <http://www.ih.org/education/cpps-certified-professional-in-patient-safety/Pages/default.aspx>

# 11 Case studies and snapshots of best practice

## 11.1 South Africa: Patient safety programmes

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In South Africa, the Pharmacy Council has been developing rules relating to good pharmacy practices (GPP) since 2004.<sup>121</sup> The core of pharmacy activity, listed as one of the GPP requirements, is the supply and distribution of medicines and other healthcare products, the provision of appropriate information and advice to patients, ensuring the correct use of medicines and monitoring the effects of the use of medicines. These activities together are known as pharmaceutical care.<sup>121</sup> The following rules could minimise medication harm and increase patient safety in the practice setting.

### 11.1.1 Dispensing procedures

The dispensing of medicines is an integral part of the pharmacist's daily duty when working with patients. It could be to either prevent or treat 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 the medicine.<sup>121</sup>

From the first phase of dispensing, pharmacists play an important role in ensuring patient safety and reducing the potential harm associated with medication. The following precautions will assist the pharmacist to perform the first phase of patient safety measures<sup>121</sup>:

- 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 inform the patient of the benefits and implications of generic substitution, which is allowed in South Africa.
- Assess the prescription to ensure the optimal use of the medicine by reviewing therapeutic aspects such as the safety of the medicine, possible contraindications and medicine-medicine or medicine-disease interactions and potential treatment duplication. Further assess the appropriateness of the treatment for the individual and the indication for which the medicine 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 discussing 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 2 of dispensing when the prescribed medicine is being prepared and labelled. The three most common dispensing errors that occur in hospital pharmacies are selecting the incorrect item, selecting the incorrect strength, and selecting the incorrect dosage form.<sup>162</sup> All dispensing procedures, regardless of who has performed them, must always be carefully checked for accuracy and completeness.<sup>121</sup> Labelling of dispensed products must be clear, legible and indelible to minimise any potential harm caused by incorrect medicine use by the patient. Cautionary/advisory labels assist in highlighting important medicine information 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 healthcare costs. 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 provided with professional judgement. Administrative errors are the second most common medication error.<sup>163</sup> The pharmacist is also responsible for assessing the patient for signs of compliance, effectiveness and safety of therapy. If needed, the pharmacist should identify areas for modification while monitoring the patient outcomes.<sup>121</sup>

The purpose of providing patient information is to empower individuals 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.<sup>121</sup>

### 11.1.2 Medicine management in hospital settings

In a hospital or institutional setting, medicines are dispensed for individual patients on a day-to-day basis. To ensure patient safety, a suitable lockable trolley for patients' medicines must be available in the ward to separately store the medicines of each patient. Any unused medicines should be returned to the pharmacy after treatment is changed or the patient is discharged, to avoid unnecessary medication errors.<sup>121</sup>

### 11.1.3 Pharmacist-initiated therapy

Patients approach the community pharmacist daily with health-related questions or concerns, such as advice on symptoms. 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 and for how long, what actions or medicine was taken to date to relieve the problem as well as other current medicines used by the patient for known acute or chronic conditions.<sup>121</sup> 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, they should refer the patient for immediate medical advice to another appropriate healthcare professional, such as a general practitioner.

### 11.1.4 Medicines selection

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

The WHO describes essential medicines as those that satisfy the priority healthcare 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 individuals and communities can afford.<sup>164</sup>

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 medicines 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 EML. Essential medicines are selected with due regard to disease prevalence, evidence for 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.<sup>165</sup> South Africa currently has four STGs and an EML approved as primary references in the public health sector, namely, primary healthcare level, hospital level (adults), hospital level (paediatrics) and hospital level (tertiary and quaternary).<sup>166</sup>

### 11.1.5 Conclusions

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

## 11.2 USA: Patient safety programmes

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### 11.2.1 Introduction

Pharmacists are an integral part of the healthcare team and are ranked among the most trusted and accessible healthcare professionals.<sup>167</sup> In February 2017, a public opinion poll among nearly 2,000 registered voters found that “69% of voters visit the pharmacy at least once a month, offering many opportunities for pharmacists to counsel and advise on healthcare matters”.<sup>168</sup> In the United States, pharmacists continue to be positioned as the most accessible healthcare professional. Newly licensed pharmacists are required to complete six to eight years of education that is focused on learning disease states and the medicines used to prevent and treat them.<sup>i</sup> As medication experts, pharmacists play a vital role in ensuring the safe use of medicines by patients.

### 11.2.2 Health system supporting patient safety

The healthcare system in the US is complex, as it is delivered and regulated by many stakeholders, including private and public entities at the federal, state, local county and city levels.<sup>169</sup> All professionals in the healthcare system are subject to regulation from multiple government as well as non-government agencies. Major federal regulatory organisations include the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), all of which fall under the US 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) play an important role in advocating for patient safety resources nationally. In the US, pharmaceutical products are primarily regulated at the federal level by the FDA.<sup>169</sup> The Patient Safety and Quality Improvement Act of 2005 (also known as the Patient Safety Act) authorised the creation of patient safety organisations (PSOs).<sup>170</sup> 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 Healthcare Research and Quality (AHRQ) website (<https://www.ahrq.gov/>) provides a list of 93 PSOs that are federally listed.

### 11.2.3 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 medicines to patients is ensuring the right dose of the right medicine reaches the right patient at the right time by the right route. This is known as the “five rights”.<sup>171</sup> However, the number and complexity of medicines continues to increase and “pharmacists’ roles and responsibilities have expanded broadly beyond medication distribution”.<sup>171</sup> Pharmacists provide patient care in almost all healthcare settings.

#### 11.2.3.1 Outpatient community

In the outpatient community setting, pharmacists’ patient safety actions include ensuring the “five rights”; checking for medicine-medicine/medicine-disease/medicine-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.<sup>84</sup> 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 <https://www.ismp.org/>).<sup>172</sup>

#### 11.2.3.2 Outpatient ambulatory

The ASHP has a guideline that outlines the minimum standard for ambulatory care pharmacists.<sup>173</sup> The 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.<sup>173</sup>

### **11.2.3.3 Hospital**

Pharmacists play a crucial role in both the planning and leading of medication safety programmes and improvement initiatives within healthcare organisations.<sup>174</sup> Examples of initiatives include: developing risk-specific protocols for high-alert medicines; 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.<sup>174</sup> Clinical trials of investigational drugs are another area in which pharmacists have a fundamental position.<sup>174</sup> Pharmacists have the potential to serve as consultants during protocol development, become members on research committees, integrate information technology into the medicines use process, develop order sets for providers, create targeted alerts, and educate the medical team.<sup>175</sup> Pharmacists are also becoming increasingly involved in transitions of care programmes to reduce errors and improve care.<sup>176</sup>

### **11.2.3.4 Regulatory**

As mentioned above, the FDA is the major regulatory agency that oversees drugs in the US. However, other agencies such as the CDC, CMS, and the AHRQ are also highly focused on reducing medication errors and improving patient safety.<sup>177</sup> Pharmacists who 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.<sup>178</sup> 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 medicine’s benefits outweigh the risks and the Bad Ad Programme to ensure that prescription medicine advertising is not misleading.<sup>109</sup>

### **11.2.3.5 Industry**

Pharmacists working in industry have a focus on patient safety as well. They can be involved in the development of new medicines that are both safe and effective, and may serve as medical science liaisons, which help prescribers learn how to appropriately prescribe new medicines.<sup>179</sup> Pharmaceutical companies also have departments dedicated to patient safety, such as pharmacovigilance and global patient safety. 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.”<sup>127</sup> 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.

## **11.2.4 Interprofessional collaboration**

As health care is becoming increasingly complex and the number of medicines available is rising at a rapid rate, it is essential to utilise the skills and expertise of all members of the healthcare team. One way that pharmacists can significantly improve the quality of patient care is by working collaboratively with other healthcare professionals (e.g., physicians, public health professionals, nurses, etc.) and the best way to emphasise their significance is to collaborate and communicate.<sup>180</sup> The impact of collaboration on patient safety has been studied in various contexts. Several studies have identified a reduction in medical 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”.<sup>181</sup> 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.<sup>182</sup>

## **11.2.5 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 to assist in the preparation, verification, tracking and documentation of compounded sterile products.<sup>183</sup> 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, 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”.<sup>184</sup> 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.<sup>185</sup> The use of simulations is also emerging as a way to shape the perception of pharmacy students regarding medication errors and patient safety.<sup>186</sup>

### 11.2.6 Education and patient safety

In the US, the education of pharmacists, physicians, nurses and other healthcare practitioners is rapidly evolving to incorporate interprofessional education as a central component of the respective academic degrees.<sup>187</sup> Several US institutions offer patient safety courses to healthcare providers.<sup>188</sup> For example, the National Patient Safety Foundation has its own patient safety curriculum with continuing medical education modules. The AHRQ provides a wealth of information, tools and resources for training in patient safety. Also, the Institute for Healthcare Improvement has free online courses on quality improvement topics and patient safety.<sup>188</sup> Many organisations have also taken on initiatives to educate patients and prescribers about how medication safety can be improved.<sup>189</sup> Finally, postgraduate training programmes such as residencies and fellowships that specialise in medication safety are also available.

### 11.2.7 Conclusions

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

## 11.3 Canada: Patient safety programmes

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### 11.3.1 Introduction

In Canada, momentum is building with efforts under way 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 across healthcare organisations. Pharmacists are often involved in ensuring standards relating to patient and medication safety are met.<sup>190</sup>

Pharmacists have unique training and skills to act as medication safety stewards through drug therapy management and analysis of medicines use processes to mitigate medication-related outcomes that can cause harm.<sup>191</sup> Furthermore, community pharmacies in Canada fill on average over 600 million prescriptions each year, which situates pharmacists as ideal healthcare providers to be involved in medication safety and error reduction initiatives.<sup>191</sup>

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

### 11.3.2 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 medicines 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.<sup>1</sup>

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 ADRs 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 the CMIRPS 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 healthcare services.

In certain provinces, there are provincial regulations that mandate medication incident reporting in healthcare 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. The CIHI administers a National System for Incident Reporting ([NSIR system](#)), which is a web-based application used by Canadian healthcare institutions to securely and anonymously share, analyse 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 the NSIR. A critical incident is defined in the Public Hospitals Act.<sup>192</sup>

In British Columbia, the BC Patient Safety and 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 Alberta Health System 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 programmes. Each programme is grounded in the principles of a safety culture with medication incident data to be used for quality improvement, non-punitive purposes.

### 11.3.3 Pharmacists' role in patient safety in different settings

#### 11.3.3.1 Outpatient setting

##### 11.3.3.1.1 Community

The role of the community pharmacist has changed significantly over the past few years, particularly with many provinces adopting expanded scope practices that enable pharmacists to focus more on the clinical aspects of direct patient care.<sup>193</sup>

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:

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<sup>1</sup> 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 ability to apply therapeutic substitution in provinces such as Alberta, British Columbia and Nova Scotia; and
- The ability to administer injections, including influenza vaccine, across many Canadian jurisdictions.<sup>193</sup>

Community pharmacists also act as the liaison between prescriber and patient, allowing for the opportunity to review patient profiles for allergies, interactions or other issues 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 (CQI) programmes, as well as provincially mandated CQI programmes that allow pharmacies to perform root-cause analysis and learn from incidents.

#### **11.3.3.1.2 Ambulatory — family health teams**

Pharmacists in family health teams (FHTs) are uniquely situated within a team of healthcare providers such as nurses, registered dietitians, respiratory therapists, occupational and physiotherapists as well as prescribers. This allows for the ability to not just communicate with other healthcare providers, but also to actively collaborate on patient care in a multidisciplinary approach. FHTs in Ontario, for example, often provide seven-day per week access to care, are supported by electronic medical records and provide a broad range of services that are team-based.<sup>194, 195</sup> 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 medication 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.<sup>194</sup> 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.

#### **11.3.3.2 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 apparent from laboratory or vital signs testing 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, and act as mentors, collaborators and scholars.<sup>196, 197</sup>

Pharmacists are also often involved into interprofessional committees such as drugs and therapeutics, medication safety and different quality improvement initiatives. A background and prospective paper conducted in 2006 by the Canadian Society of Hospital Pharmacists addressed a multitude of pharmacy services and programmes that positively impact patient safety.<sup>198</sup> The paper refers to practices such as direct patient care, formulary systems, standardised medicines administration policies and procedures, pharmacist review of medicines orders, application of electronic medical records and computer technologies, medication incident reporting and review and pharmacist provision of education to patients and healthcare providers alike.<sup>198</sup>

#### **11.3.3.3 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, practising in Canada must hold professional competency, including patient care, drug information, drug distribution, management and education.<sup>193</sup> General standards include expertise in medicines and medication therapy, ability to collaborate and communicate effectively, knowledge of safety and quality assurance that has a primary focus on patient safety and responding to safety risks, professionalism and upholding ethical standards.<sup>193</sup>

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 programme, SafetyNet-Rx, in community pharmacy was instituted by the Nova Scotia College of Pharmacists.<sup>199</sup> SafetyNet-Rx involves tracking and analysing medication incidents and near misses in community pharmacy as part of a continuous quality assurance programme.<sup>200</sup> A study conducted analysing medication incidents and near misses over a seven-year period in Nova Scotia community pharmacy found that pharmacists and pharmacy personnel identify at least 82% of medication errors before they reach the patient.<sup>191</sup>

In Ontario, the mandatory Assurance and Improvement in Medication Safety ([AIMS](#)) Programme 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 programmes in community pharmacy that aim to focus a continuous quality improvement lens on medication incidents and near misses. British Columbia will also be moving forward with implementing a similar programme.

#### **11.3.3.4 Industry**

Industrial pharmacists 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 medication 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.

#### **11.3.4 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 healthcare professionals to optimise medication therapy to maximise health outcomes. Interprofessional teams often review incidents to collaboratively identify actionable insights on how to improve the medicines use system and how to design systems with integrated safeguards. Many healthcare settings have interprofessional committees that regularly review medication incidents and trends to identify systemic factors and reduce incident recurrence.

#### **11.3.5 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 autumn. 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.

#### **11.3.6 Education around patient safety**

There are many resources and tools to support continuous education in patient safety. The [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 five questions to ask your healthcare provider about medicines, and other resources are geared towards healthcare providers, e.g., the Opioid Stewardship recommendations.

The Canadian Pharmacists Association has a variety of [resources](#) to support professional development in patient safety including practice tools, pharmacy practice research, and conferences and webinar presentations.

#### **11.3.7 Conclusions**

The involvement of pharmacists in patient safety in Canada spans a myriad of different areas, and pharmacists practising in different settings have a host of expertise to provide optimised patient care. Canada's changing landscape, which 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.

## 11.4 Australia: Patient safety programmes

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### 11.4.1 Introduction

Australia's National Medicines Policy<sup>201</sup> 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, healthcare 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:<sup>201</sup>

- 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

The NMP therefore sets the context and impetus for patient and medication safety at all levels of the healthcare 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:<sup>202</sup>

- Selecting appropriate treatment and management options for patients and consumers, which may include pharmacological and non-pharmacological therapy;
- Where pharmacological therapy is required, choosing the right medication for the right person, and giving the medicine at the right dose, in the right formulation and strength, and at the right time; and
- 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 healthcare practice, and in particular, the practice of pharmacists, it is therefore not surprising that the Pharmaceutical Society of Australia recently launched a report on "Medicine safety: Take care".<sup>203</sup> 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 medication safety. While some alarming facts about medication-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 medication-related harm is preventable, providing significant opportunities for improvement in the healthcare system and practice of healthcare professionals. As such, in December 2019, medication safety became Australia's 10<sup>th</sup> National Health Priority.

### 11.4.2 Australia's health system

Australia's health system consists of public and private sectors, and is funded through government (local, state and territory, federal) and non-government agencies, private health insurers and consumers. Because there are three levels of government which share the responsibilities of the national healthcare 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 programmes. 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;
- Messages are aligned and delivered concurrently across the levels;
- Clinical governance structures vary across the different states and territories,

- Effective implementation strategies are delivered at the patient or consumer interface (e.g., primary care) and are supported by the healthcare system at the appropriate level; and
- There is an effective feedback mechanism and process where the needs of patients and consumers with regard 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 injections ampoules were traditionally all part of ward stock in hospitals. All three ampoules 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 preventive strategy recommendations, including the replacement of potassium chloride ampoules with premixed solution bags.<sup>204, 205</sup>

In 2006, the Council of Australian Governments established the Australian Commission on Safety and Quality in Healthcare, with the purpose of contributing to Australian patients' and consumers' better health outcomes, and ensuring that they receive safe and quality healthcare through leading and coordinating national developments and advancements in safe and quality healthcare. The commission has developed eight National Safety and Quality Health Service Standards<sup>206</sup> 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 the eight is the Medication Safety Standard, which strives for patient safety by healthcare professionals through the medication journey, from prescribing to dispensing, administration and monitoring the use of medicines.

#### 11.4.3 Pharmacy organisations and patient safety

The Pharmaceutical Society of Australia (PSA) has placed medication safety as the top action for Australian pharmacists in their recently published report about the future of pharmacy.<sup>207</sup> 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.<sup>207</sup> These are:

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

The Society of Hospital Pharmacists of Australia (SHPA) promote medication safety as the priority of pharmacists working in acute settings. Guided by expert members covering areas of specialty and generalist treatment, the SHPA produces policy, practice and education materials to support members to provide optimal medicines management in hospitals and across transitions of care. Current medication safety priority areas include reducing opioid harm, improving digital health systems, optimising hospital pharmacy capacity and reducing the impact of medicines shortages.<sup>208</sup>

#### 11.4.4 Pharmacists' role in patient safety

Medication and, therefore, patient safety is in the DNA of pharmacists and extends deeply into all professional activities.<sup>207</sup> The Pharmacy Board of Australia defines professional practice thus: "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."<sup>209</sup> 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 case study 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<sup>210</sup>) and supporting patients to use their medicines safely and appropriately, such as through providing medicines in instalments<sup>211</sup> or through educating patients how to use their devices optimally. Pharmacists may also gain accreditation to undertake more comprehensive medication reviews in patients' homes or in residential aged care facilities.<sup>212</sup> Similarly, pharmacists in a hospital setting conduct medication reconciliation, medicines use reviews including recommendations to optimise positive outcomes and minimise harm related to medicines (e.g., antimicrobial stewardship, deprescribing, therapeutic drug monitoring), as well as educate patients, carers and other healthcare practitioners about optimal medicines use.<sup>213</sup>

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 ADEs. 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 Defence Ltd) 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.

#### 11.4.5 Interprofessional collaboration

While 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. While 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 away from hospitals, 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 healthcare professionals, usually including a pharmacist, collaborate in a community setting to develop management plans for a particular patient. While 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 allows pharmacists to have a greater access to other primary care professionals involved in an individual's care and to optimise their medicines use, including prescribing, medicines use review, medication monitoring and medicine/medicinal device education.<sup>214, 215</sup>

#### 11.4.6 New services or innovations to improve patient safety

As the roles of pharmacists in Australia continuously evolve, so too does their role in improving patient safety. As mentioned above, trialling co-location of pharmacists in general practice clinics has resulted not only in pharmacists' increased collaboration with the various health professionals involved in a patient's care but also in better health outcomes for the patient.<sup>214</sup> Similarly, trials are currently under way to demonstrate the benefits of pharmacists being co-located in residential aged care facilities. There, they are not being used only for medicines preparation and supply but, similar to GP practices, also to aid visiting medical practitioners in prescribing, conducting medicines use reviews, and assisting nursing staff in monitoring and medicine/medicinal device education. Although these initiatives improve patient outcomes, the financial viability of running these services requires ongoing evaluation.

In addition to this, pharmacists in the community have been encouraged to regularly perform medication 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.<sup>216</sup> While 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.



#### 11.4.7 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 practise safely and competently as pharmacy interns and pharmacists of the future. Pharmacy curricula are accredited by the Australian Pharmacy Council (APC), which ensures that the programme meets the accreditation standards, including those that pertain to safe practice. The APC has recently reviewed its accreditation standards, and the 2020 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.”<sup>217</sup> The 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.

#### 11.4.8 Conclusions

Patient and therefore medication safety are at the heart of the Australian healthcare system, as seen with the National Medicines Policy and as a recently announced National Health Priority Area. Key stakeholders 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 healthcare and medicines use journey. There are, however, many opportunities for further improvements to ensure that no patient experiences harm that was avoidable.

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

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#### 11.5.1 Background

The 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 patient safety and the quality of health care, including the monitoring of medicines, medical equipment and technology.<sup>218</sup> This case study on the role of pharmacists in patient and medication safety in India is intended to help readers understand how pharmacists are making efforts to improve patient and medication safety. This case study is developed based on the Siva Prasada Reddy Maddirala Venkata’s 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.<sup>219</sup>

#### 11.5.2 Introduction to Indian healthcare system

India is made up of 29 states and seven union territories with a population of over 1.3 billion.<sup>220</sup> India’s healthcare 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, including remote and rural populations.<sup>221</sup> The healthcare system in India, at present, has a three-tier structure to provide healthcare services to its people.<sup>222</sup> Networks of healthcare facilities at the primary, secondary and tertiary level are mainly run by state governments, and provide free or very low cost medical services. There is also an extensive private healthcare sector covering the entire spectrum from individual doctors and their clinics, to general hospitals and super specialty hospitals. The Indian government has promoted traditional and alternative medicine systems and has been taking quality and safety measures to protect patients.

India’s health workforce is made up of a range of health workers who offer healthcare services in different specialties of medicine. These personnel consists of: allopathic doctors (31%) with bachelor degrees; nurses and midwives (30%); pharmacists (11%) with diplomas, bachelor, master and PharmD (doctorate) degrees; practitioners of Ayurveda, yoga,

naturopathy, unnailed, siddha and homoeopathy (9%), with university degrees or specialisations; and others (9%). "Others" comprise: technicians and allied health workers; community health workers, including health educators and health assistants; accredited social health activists; registered medical practitioners with little or no formal training; traditional medicine practitioners; and faith healers.<sup>223</sup>

### 11.5.3 Pharmacists' role in patient safety

Patient safety measures are taken at different levels (institutional, regulatory, association, population) to avoid harm during the treatment process. Due to the vast number of pharmacists and diversity in the demographics seen in a healthcare team, regulatory authorities are utilising different bodies to protect population health. To ensure patient and medication safety, different regulatory authorities under the ministry of health and family welfare are working together. This case study will describe the patient safety measures taken by different authorities involving pharmacists and pharmacies working in various facets of the pharmacy profession.

In the past, pharmacists were responsible only for dispensing medicines. Slowly, the traditional role of pharmacists has been expanding and now pharmacists are playing a role as a vital team member in the direct care of patients, especially the new generation of pharmacists who have a PharmD. Pharmacists play a major role in providing healthcare services by means of community pharmacy services in rural areas where physicians are not available or where physician services are too costly to meet the healthcare requirements of the community.<sup>224</sup> To ensure patient and medication safety, pharmacies and pharmacists' organisations undertook the following initiatives, and authorities in India are playing a key role:

- Central Drugs Standard Control Organisation
- Indian Pharmacopoeia Commission
- 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 contribution to patient and medication safety
- Accreditation of alternative therapies

#### 11.5.3.1 Central Drugs Standard Control Organisation (CDSCO)

The national medicines regulatory authority in India is the CDSCO, which sits under the Directorate General of Health Services, Ministry of Health and Family Welfare in India. The Drugs and Cosmetics Act of 1940 has entrusted various responsibilities to central and state regulators for regulation of medicines and cosmetics. The CDSCO oversees uniform implementation of the provisions of the Act and Rules made under it for ensuring the safety, rights and wellbeing of patients by regulating medicines and cosmetics. The CDSCO is constantly striving 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 medicines, conduct of clinical trials, laying down the standards for medicines, control over the quality of imported medicines in the country and coordination of the activities of State Drug Control Organisations by providing expert advice with a view to bring about uniformity in the enforcement of the Act.

#### 11.5.3.2 Indian Pharmacopoeia Commission (IPC)

The IPC is an Autonomous Institution of the Ministry of Health and Family Welfare, Government of India. It was created to set standards of medication management in the country. The IPC's vision is to promote the highest standards in medicines for use in humans and animals within practical limits of the technologies available for manufacturing and analysis. The IPC's mission is to promote public health and animal health in India by providing authoritative and officially accepted standards for quality of medicines, including active pharmaceutical ingredients, dosage forms and excipients. The IPC is internationally cooperating with the WHO, European Directorate for Quality of Medicines (EDQM), Japanese Pharmacopoeia and US Pharmacopoeia. It has strengthened its efforts to work with other international pharmacopoeias, industry, academia, regulators and other stakeholders to develop harmonised global standards.

The mandate of the IPC is to publish the Indian Pharmacopoeia (IP) and its addendums, publish the National Formulary of India, certify IP Reference Standards, run the National Coordination Centre for Pharmacovigilance Programme of

India, organise educational and skill development and research initiatives, and establish working relations with other similarly placed institutions at a national and international level.

### **11.5.3.3 Indian Pharmacopoeia**

IP 2018 with its 2019 addendum is the most up-to-date version and contains 2,756 monographs. The 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”, the 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 four volumes, incorporating 220 new monographs (170 chemicals monographs, 15 herbal monographs, 10 blood and blood-related products monographs, two vaccines and immunosera for human use monographs, three radiopharmaceuticals monographs, six biotechnology derived therapeutic products monographs, and 14 veterinary monographs), 366 revised monographs and seven omissions. The IP Addendum 2019 to IP 2018 contains 66 new monographs including 61 chemicals monographs, three herbal monographs and two radiopharmaceuticals monographs.

### **11.5.3.4 The Pharmacovigilance Programme of India (PvPI) for patient safety reporting**

India now has a stable and robust pharmacovigilance system which enables the nation to ensure the safety of medicines.<sup>225</sup> The PvPI has progressed considerably in the past few years. It was approved by the Ministry of Health and Family Welfare in July 2010 with the primary objective of creating a nation-wide system for patient safety reporting. Within a span of five years the PvPI has become a formidable force at the international level with the best pharmacovigilance practices including ADRs reporting and providing skill development. Individual case safety reports are collated in a scientific way and analysed to facilitate appropriate decisions at the CDSCO. There are 250 functioning adverse drug monitoring centres in the country (in medical colleges and corporate hospitals) as part of the PvPI. The programme is striving to build trust between physicians and patients, thereby increasing patient safety and the confidence of people in the country's health system. In addition, the PvPI detects 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.<sup>226</sup> The vision of the PvPI is to improve patient safety and welfare in Indian populations by monitoring medication safety and thereby reducing the risk associated with use of medicines.

The mission of the PvPI is to safeguard the health of the Indian population by ensuring that the benefits of medicines use outweigh the associated risks. Since there exists considerable social and economic consequences of ADRs and the positive benefit/cost ratio of implementing appropriate risk management, there is a need to engage healthcare professionals and the public at large in a well-structured programme to build synergies for monitoring ADRs in the country.

The objectives of the programme are: to create a nation-wide system for patient safety reporting; to identify and analyse reported cases; to analyse the benefit/risk ratio of marketed medicines; to generate evidence-based information on medication safety; to support regulatory agencies in the decision-making process on use of medicines; to communicate the safety information on use of medicines to various stakeholders in order 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 the globe; and to promote the rational use of medicines.

### **11.5.3.5 The Hemovigilance Programme of India (HvPI)**

The HvPI comprises 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. The intention is to collect and assess information about 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 the country. The programme was initiated in 60 medical colleges in the country that were already enrolled under the PvPI.

### **11.5.3.6 The Materiovigilance Programme of India (MvPI)**

In order to foster the habit of reporting, the MvPI encourages reporting of all types of adverse events related to medical devices irrespective of whether they are known or unknown, serious or non-serious, frequent or rare. Materiovigilance is primarily concerned with adverse events associated with medical devices used in India.<sup>227</sup> The 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 a 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.<sup>226</sup>

#### 11.5.4 Pharmacy Council of India (PCI)

The Pharmacy Council of India (PCI) is a statutory body of the Government of India. Its purpose is to regulate and implement education regulations, set a minimum standard of education and play a key role in improving the standards of the pharmacy profession. In the past decade, the PCI has taken on the following initiatives:

##### 11.5.4.1 Patient safety through pharmacy education

Pharmacists represent the third largest healthcare professional group in the world.<sup>228</sup> There are about one million registered pharmacists in India working in various positions, applying their unique knowledge and skills, and contributing to the healthcare system.<sup>229</sup> 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.<sup>230</sup> In India, there are over 1,700 institutions that offer different pharmacy programmes with an intake of over 100,000 students per academic year in DPharm (two years), BPharm (four years) and PharmD (five years).<sup>231, 232</sup>

Delivery of health care is error-prone and errors occurs in around 10% of hospital admissions.<sup>30</sup> The education and training of dentists, doctors, midwives, nurses, pharmacists and other health-care professionals has long been the foundation of safe, high quality healthcare. The 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.<sup>30</sup> Pharmacists' educational quality and standards play an important role in improving patient safety. During the past decade, the pharmacy profession has expanded significantly in implementation of needs-based educational programmes and professional practice.<sup>233</sup>

##### 11.5.4.1.1 PharmD regulations in India, 2008

Before the launch of the PharmD regulations, the role of a pharmacist in India was mostly considered to be dispensing, manufacturing and marketing of medicines.<sup>234</sup> This case study reviews the evolving role expected of clinical pharmacists as the primary custodian of medication management and medication safety processes. As more hospitals in India aspire to become accredited by the National Accreditation Board for Hospitals & Healthcare Providers, it is expected that the role of pharmacists will be understood better and will be essential to ensure proper and safe medication management systems.<sup>235</sup> Pharmacists with higher education (PharmD) have similar roles at accredited hospitals.

##### 11.5.4.1.2 Bachelor of Pharmacy (Practice)

A Bachelor of Pharmacy is a degree that certifies the completion of a course of study and the successful passing of a board examination, both qualifications required to practise as a licensed pharmacist.<sup>236</sup> The new regulations will help upgrade the qualification of practising pharmacists with a Diploma in Pharmacy.

##### 11.5.4.1.3 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 postgraduate education.<sup>237</sup>

##### 11.5.4.2 Patient safety through pharmacy practice regulations

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

##### 11.5.4.2.1 Pharmacy Practice Regulations

India has enacted the Pharmacy Practice Regulations 2015 to ensure best practices in implementing the code of pharmacy ethics, duties and responsibilities of pharmacists; inspections of pharmacies, maintaining GPP and continuing

education programmes, and implementing other laws related to the Drugs and Cosmetics Act. Today, the pharmacy profession is striving hard to realise its vision and mission to achieve best practices and to provide the best pharmaceutical care services to patients. In this process, regulatory authorities are doing their best to implement Pharmacy Practice Regulations 2015 to harmonise the practice of pharmacy throughout the country. Some of the salient features of the regulations are:

- The duties of registered pharmacists are described in detail, including their duties to patients, to each other, to the public and to the profession;
- Actions for professional misconduct have been set out and pharmacists have been made subject to appropriate disciplinary action;
- Details of the job responsibilities, knowledge and skills of hospital pharmacists, community pharmacists and drug information pharmacists have been listed;
- Displaying the registered pharmacist's identity in the pharmacy has been made mandatory, and their dress code is also described; and
- Continuing education programmes for renewal of registration have been made mandatory.

#### **11.5.4.2.2 Duties of registered pharmacists to their patients — obligations to the sick**

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 their care depend on their skill and attention.

Registered pharmacists having any incapacity detrimental to the patient or which can affect their performance vis-à-vis the patient shall not be permitted to practise their profession.

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. A registered pharmacist shall review the patient record and each prescription presented for supply for the purpose of promoting therapeutic appropriateness by identifying: over- or under-utilisation; therapeutic duplication; medicine-disease interactions; medicine-medicine interactions; incorrect drug dosage or duration of drug treatment; medicine-allergy interactions; correlation of availability of medicines (to avoid artificial shortage of medicines; and clinical abuse or misuse.

#### **11.5.4.2.3 Duties of registered pharmacists — dispensing/supply of medicines**

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

Registered pharmacists shall undertake a pharmaceutical assessment by applying their knowledge to establish safety, quality, efficacy and rational use of medicines in treatments.

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

For all prescriptions handled by the pharmacy, patient details shall be checked and confirmed; pharmaceutical assessment shall be made and proper documentation shall be maintained.

Assessment of a prescription should include but not be limited to assessment of whether: the prescription is legally valid; the prescription includes an appropriate dosage form and appropriate route of administration; the prescription is appropriate to the patient's condition; the duration of treatment is correct; the prescription is appropriate according to the patient's parameters (age, weight, etc.) and previous medication; the prescription is compatible with other medicines; the prescription is consistent with formulary and guidelines, if any; the possibility of side effects or adverse drug reactions exists; the prescribed medicine is contraindicated; the potential for misuse or inappropriate use by the patient of the prescribed medicines exists; and the prescription complies with labelling requirements.

Compounding, dispensing and labelling of medicines should ensure that: the medicine matches the prescription; the medicine has not expired; the medicine is appropriately compounded (if necessary), packed and labelled; the accuracy of dispensing is checked by the registered pharmacist; and proper documentation is made.

### 11.5.5 Patient counselling

Upon receipt of a prescription and following a review of the patient's record, a registered pharmacist shall personally initiate discussion of matters that will enhance or optimise medicines therapy with each patient or care giver. 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: name and description of the medicines; the dosage form, dose, route of administration, and duration of medicines therapy; intended use of the drug and expected action; special directions and precautions for the medicine; common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including how to avoid them, and the action required if they occur; techniques for self-monitoring medicines therapy; advice on proper storage of the drugs; prescription refill information; action to be taken in the event of a missed dose; and how to ensure rational use of the medicines.

#### 11.5.5.1 Counselling requirements:

- Only registered pharmacists are involved in counselling;
- Confidential conversation facilities should be provided;
- Patient information leaflets should be provided;
- Unnecessary counselling should be avoided;
- In every consultation, patient benefit is of foremost importance and all registered pharmacists should be frank with their patients and their attendants; and
- Utmost punctuality should be observed by a registered pharmacist when making themselves available for counselling.

The pharmacist shall maintain records pertaining to medicines administered to patients (medication card) that may be utilised for the evaluation of the medicines therapy. The pharmacist is authorised (as a healthcare professional) to undertake process and outcome research, health promotion and education, including providing health information, and to undertake pharmacoepidemiologic studies.

### 11.5.6 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 pharmacists shall notify constituted public health authorities of every case of communicable disease under their care, in accordance with the laws, rules and regulations. When an epidemic occurs, registered pharmacists shall not abandon their duties for fear of contracting the disease themselves.

#### 11.5.6.1 Patient safety through drug information: Medicines information resources for pharmacists

Indian pharmacists have available several medicines information resources to serve their customers. Official sources of drug information are the Central Drug Research Institute, the National Formulary of India and the several drug information centres run in collaboration with state pharmacy councils, the WHO country office, universities, hospitals and other autonomous bodies. Chauhan et al.<sup>238</sup> has presented an overview of drug information resource centres available in India which is given below:

#### 11.5.6.2 National Information Centre on Drug and Pharmaceuticals (NICDAP)

NICDAP uses the library resources of the Central Drug Research Institute at Government of India a constituent laboratory of Council of Scientific and Industrial Research. Research and development activities in the CDRI are supported by a modern knowledge resource centre which comprises a fully computerised library with a rich collection of relevant books and periodicals, online subscription to many databases and periodicals, and an information centre which provides many services as well as online response to queries.

### **11.5.6.3 National Formulary of India (NFI)**

The NFI is an official tool for pharmacists in India, prepared by the Indian Pharmacopoeia Commission, under the Ministry of Health. It helps in the selection of medicines from a wide range of available medicines in the market. The NFI is the formal drug information resource in India. It is essentially meant to help guide members of the medical profession, including medical students, nurses and pharmacists working in hospitals and in sales establishments. In the preparation of the NFI, the expert opinion of medical practitioners, teachers in medicine, nurses, pharmacists and manufacturers was obtained. The selection of medicine for inclusion in the NFI has been made taking into consideration their relative advantages and disadvantages, the extent of their use in current medical practice and their availability in the country. Thus, the NFI represents a broad consensus of medical, administrative and expert opinions with which to provide the physician with carefully selected therapeutic agents of proved efficacy and which forms the basis of national drug therapy.

### **11.5.6.4 Drug information centres (DICs)**

DICs are regarded as gateways of medicines information. A number of DICs are being opened with the mission of safe healthcare and drug safety which will enhance the role of pharmacists in their service of their communities.<sup>239</sup> There are several DICs established in collaboration with state pharmacy councils, the 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 patients to contact DICs to obtain any information related to medicines. DICs receive queries from health professionals and patients over the telephone, by direct access and during ward rounds if the DIC is located in a hospital.<sup>240</sup> There are 17 independent DICs attached to hospitals with clinical pharmacy services and 14 DICs run by the state pharmacy councils or educational institutions in India.<sup>239</sup>

### **11.5.6.5 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 Healthcare Providers (NABH) is one of the boards of the Quality Council of India, which has been set up to establish and operate accreditation programmes for health-care organisations. The accreditation programme requires complete compliance to safe medication practices as a part of the management of medicines in the hospital.<sup>235</sup>

To reach the quality standards, pharmacists interventions in medication management, prescription auditing, medication safety services such as management of ADRs to minimise medication errors, and the pharmacist's role in clinical research need to be demonstrated. Medication management includes safe, effective and appropriate medicines therapy to patients prescribed by physicians and approved by a clinical pharmacologist. This list needs collective development with inputs from the pharmacist-in-charge, clinical pharmacologist, consultants of various clinical departments,. The NABH-accredited hospitals must monitor certain quality indicators every month which describe the quality of prescribing services in the hospital. Quality indicators includee the number of illegible prescriptions, the number of medication orders with error-prone abbreviations and the number of prescription errors.

## **11.5.7 Indian Pharmaceutical Association's (IPA) contribution to patient and medication safety**

### **11.5.7.1 Good Pharmacy Practice (GPP) — for patient and medication safety**

The IPA community pharmacy (CP) division aims to enhance the role of the pharmacist and raise professional standards of pharmacy practice through its activities, and aims to improve public health through community pharmacists' services. As a part of this, the IPA is striving hard to implement GPP, in this process the CP division, in collaboration with the WHO India office and the CDSCO developed a GPP training manual in 2005, which ws a first document in India on GPP.<sup>241</sup> The CP division also carried out a pilot project on accreditation of pharmacies in2007 in collaboration with the WHO India office. There were 70 pharmacies enrolled, of which 45 (26 from Mumbai and 19 from Goa) were accessed and accredited. The enrolment of pharmacies was purely voluntary and there were no attached criteria or conditions.<sup>242</sup>

### **11.5.7.2 IPA Tuberculosis Fact Card Project**

The participation of pharmacists in the Tuberculosis (TB) Fact Card Project (an initiative of the 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 in the community by dissemination of information and encompassed all aspects of pharmaceutical care by pharmacists. A healthy partnership is being established with physicians through such work. This has become a milestone project leading the placement of 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, in 2014, the RNTCP guidelines mentioned the word "pharmacist", describing them as specialists with expertise in managing multi-drug-resistant TB, which was a step forward.<sup>243</sup> In 2012, a Memorandum of Understanding (MoU) was established between Central TB Division and IPA, PCI, AIOCD and FIP-WHO SEARO Forum of National Pharmaceutical Associations with an objective to engage pharmacists in the RNTCP for TB care and control in India. This MoU was initially valid for one year and was extended until 2017.

### **11.5.7.3 Consumer medicine education initiatives**

Literacy and health literacy 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. The most frequently noted safety issue connected to limited health literacy is the risk of medication errors that result from improper dosing administration.<sup>244</sup> Several studies have found low health literacy to be significantly associated with a poorer understanding of medicine names, indications, and instructions and adherence to treatment regimens.

The IPA's CP division is working consistently for consumer medicine education to improve responsible use of medicines in society. It initiated a "Campaign for awareness on responsible use of medicines" in 2014 and has several posters and leaflets prepared in different languages. The main highlight is a handbook called "Responsible use of medicines: A layman's handbook", which is the first ever publication for educating consumers on basic aspects of medicines usage. The CP division prepares material for National Pharmacy Week and for World Pharmacist Day. The CP division involves pharmacy students in public health activities and conducts competitions for pharmacists during both these events.

### **11.5.7.4 Collaboration with stakeholders**

The IPA's CP division has collaborated with governments, the Pharmacy Council of India, chemists associations, regulators, the corporate sector, non-governmental organisations, academia and IPA's state and local branches for its pharmacists' training programmes and projects for continuing professional development of community pharmacists. The CP division works all across India with the pharma corporate sector, including multinational and Indian companies, to train pharmacists on aspects such as GPP, responsible use of medicines, medication errors, patient counselling and other relevant areas. The CP division also collaborates with several pharmacy institutes across India to increase community-centred activities through pharmacy students.<sup>245</sup>

### **11.5.7.5 Accreditation of alternative therapies**

AYUSH is the acronym for the medical systems that are practised in India, namely, Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy. AYUSH medicines are widely used as a standalone option or as adjunct with biological medicine in chronic diseases. Therefore, the relevance of AYUSH has increased now. Keeping this fact in view, the Government is encouraging a multifarious approach in healthcare where every medical system can grow based on its evident strengths. 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 in AYUSH systems. Yoga is in many countries integrated into the healthcare delivery systems. Similarly, there is great curiosity to understand the principles and practice of Ayurveda, Homoeopathy, Siddha and Unani, especially due to growing challenges for medicine from non-communicable diseases, lifestyle disorders, chronic diseases, multi-drug resistant diseases, emergence of new diseases etc. The NABH has launched an accreditation programme for AYUSH hospitals where quality standards have been established. It consists of accreditation standards and structural standards. Accreditation standards measure the quality and safety aspects of the care delivered to patients.<sup>246</sup>



### 11.5.8 Future improvements

Research concluded that there is a low awareness among health workers of patient safety incidents. There is a need to institute a patient safety incident reporting system with training of all categories of staff in patient safety and quality improvements in a collaborative and sustainable manner.<sup>247</sup>

## 11.6 Oman: Role of the pharmacist in patient safety

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### 11.6.1 Introduction

The pharmacy profession is continually evolving in the Sultanate of Oman. Pharmacists have opportunities to practise 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 of practice in hospitals, with collaborative practice agreements and prescriptive authority within their institutions, which includes counselling, reconciliation, interventions and clinical pharmacy services, and some are managing pharmacist-led clinics which cover non-communicable diseases.

The Directorate General of Pharmacy and Drug Control is the regulatory body in Oman for the licensing of private pharmaceutical establishments (e.g., community pharmacies) and carrying out regulatory activities for drug and medical devices registration and evaluation, Good Manufacturing Practice (cGMP) inspections, customs release, and pharmacovigilance for both medicines and herbals to ensure patient safety.

The Directorate General of Medical Supplies is the regulatory body in Oman for all activities related to pharmaceutical care and the medicines use process from selection and procurement to use by the patient. It is also responsible for training all pharmacy workforces and raises their competency in different areas of pharmacy practice. One of the areas that was the focus of the directorate general is the pharmacist-led medication safety programme. The programme started in 2012 and by 2019 all the Ministry of health units had pharmacists working as medication safety officers who are actively involved in detecting, analysing and reporting medication errors, product quality defects and ADRs. They are also members of their hospital quality teams to discuss and resolve any medication safety issues.

### 11.6.2 Health system supporting patient safety

As per the WHO assessment conducted in May 2017 in collaboration with the Omani Directorate General of Quality Assurance, where pharmacists were members of the evaluating team, four Omani hospitals were scrutinised using the WHO Patient Safety Friendly Hospital Initiative [standards](#). The exercises suggest that the patient safety system in these hospitals is adequate for being consistent with patient safety friendly hospitals. This activity helped in spreading the 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 4 in the WHO Patient Safety Friendly Hospital Initiative standards 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 potential to achieve the targeted core and developmental standards. On the other hand, the pharmaceutical care department at Directorate General of Medical Supplies issued a complete set of policies and procedures which ensures patient safety, such as:

- High alert medicines;
- Look-alike/ sound-alike medicines;
- Medication reconciliation policy;
- Handling patient drug allergy;
- Medicine-food interactions;
- Medicine-medicine interactions;
- Management of ADRs;
- Medication error reporting;

- Medicine quality reporting programme and medical devices quality reporting;
- Medication order review;
- Medicine dispensing guidelines;
- Patient counselling;
- Unit dose dispensing system;
- Emergency crash cart medicines;
- Handling hazardous medicines;
- Floor stock medicine guidelines; and
- Patient's own medicines.

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

#### **11.6.2.1 Electronic prescribing**

Electronic prescribing has been established since 2000. The Ministry of Health in Oman suggests using this and other technology-based solutions to improve patients' adherence to prescription medication. E-Prescribing eliminates handwriting errors/illegibility and gives both physicians and pharmacists access to a patient's prescription history to reduce the chance of the wrong medicine being dispensed (mainly due to mistakes when reading a handwritten prescription) that improve patient safety practices.

A "[Tall man letter](#)" list by ISMP of look-alike, sound-alike (LASA) medicine names based on the Oman national formulary created by the Directorate of Pharmaceutical Care has been approved by the Ministry of Health. The list is integrated in the ministry's Health Information System as additional safeguards to avoid errors with LASA medicines.

Interventions by pharmacists on prescriptions are documented in the progress notes in the electronic health system and accepted and taken into consideration by the prescriber.

#### **11.6.2.2 Drug quality reporting system**

Pharmacists are collecting quality issues reports, clarifying them and forwarding them to the Quality Management and Medication Safety Department at the Directorate General of Medical Supplies, which then analyses these reports and sends feedback to all concerned, including taking any required action with the medicines manufacturers.

#### **11.6.2.3 ADR reporting system**

Pharmacists are collecting ADR reports, clarifying them and forwarding them to the Directorate of Pharmacovigilance and Drug Information, which in turn sends the report to the Uppsala Monitoring Centre for pharmacovigilance using an electronic system of reporting. This electronic reporting system is open to healthcare professionals as well as patients.

#### **11.6.2.4 Medication error reporting system**

Many initiatives have been taken by the Ministry of Health to boost what seems to be under-reporting of medication errors. Pharmacists are collecting the reported medication errors and medication-related problems, clarifying them, conducting root cause analysis and forwarding reports to the Quality Management and Patient Safety Departments in the health units. A copy is sent to the Pharmaceutical Care Department at Directorate General of Medical Supplies to further analyse the reports and set strategies to prevent problems recurring, and to conduct training for healthcare professionals.

#### **11.6.2.5 Quality assurance committees at the hospital level**

Pharmacists participate in quality assurance committees and are well positioned to assist in the improvement of quality care in a healthcare system as they are already established as experts in medication management processes where they resolve medication-related problems and cost-effectiveness issues.

### **11.6.2.6 Selection and procurement**

Selection and procurement of medicines is confined to the list of medicines included in the Oman National Formulary. The formulary is executed through an open bulk tendering process through International and GCC Gulf Joint Purchase to ensure acquisition of supplies with good quality and suitable cost, with a focus on generic and biosimilar procurement in line with WHO guidelines. 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 medicines are analysed by the Central Quality Control Laboratory at the Directorate General of Pharmacy and Drug Control to ensure they meet the required quality and the stated specification standards.

### **11.6.2.7 Central Drug Committee and Drug and Therapeutics Committees**

The Central Drug Committee (CDC) of a health unit/hospital is made up of doctors and pharmacists from different specialties. The CDC is concerned with the selection of medicines in the MOH formulary based on the recommendations of the pharmacy and drug committees at hospitals. The CDC is also involved in the approval of treatment protocols and guidelines for the approved medicines and framing out other policies related to the rational use of medicines.

Pharmacists are active members of Drug and Therapeutics Committees in health units. They are involved in the review of requests for inclusion or removal of medicines from the formulary, and they participate in treatment protocols assessments and drug use utilisation.

## **11.6.3 Pharmacists' role in patient safety in different settings**

### **11.6.3.1 Outpatient settings**

Pharmacists counter check medicines assembled against prescriber orders, counsel patients and follow the approved policies and procedures regarding dispensing, reviewing of medication orders and patient counselling. They also arrange and label the medicines and storage shelves to reduce product selection errors and keep track of any expired medicines, all in an effort to ensure patient safety.

### **11.6.3.2 Community settings**

Pharmacists dispense medicines as per the prescription; except over the counter (OTC) listed items which are freely dispensed. Patients are informed about their five rights — the right medicine to the right patient in the right dose by the right route at the right time — to ensure patient safety.

### **11.6.3.3 Ambulatory settings**

Pharmacists conduct the following in ambulatory settings:

- Medication review;
- Therapeutic drug monitoring for narrow therapeutic index medicines;
- Monitoring of patients for both desired and undesirable therapeutic effects;
- Double checking written prescriptions;
- Verifying product quality and accuracy;
- Labelling products and shelves;
- Counselling patients;
- Monitoring availability of life-saving medicines; and
- Maintaining safety of high alert and look alike and sound alike medicines, and conducting double checks for high alert medicines.

### **11.6.3.4 Hospital settings**

Pharmacists also have a crucial system-level role in planning and leading medication safety programmes and improvement initiatives within healthcare organisations. These initiatives may include: developing risk-specific protocols for high-alert medicines; identifying and evaluating high-risk processes (e.g., total parenteral nutrition,

compounding, paediatric dose preparation) that require special attention, protocols and training; evaluating medication error data; evaluating and implementing new medication technologies; and fostering robust error reporting processes. Pharmacists have a central role in ensuring medication safety across the continuum of care. The complexity of the medicine prescribing and delivery processes can make it difficult to prove the beneficial effect of pharmacists on adverse outcomes directly, but pharmacist involvement has been shown to reduce errors, improve prescribing practices and enhance patient monitoring across all settings.

#### **11.6.3.5 Regulatory settings**

The Directorate General of Pharmacy and Drug Control governs medicines control mainly through:

- A system of medicines, herbals and medical device registration and price control;
- Rules and regulations regarding controlled substances; and
- A pharmacovigilance system.

#### **11.6.3.6 Industry settings**

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

#### **11.6.4 Interprofessional collaboration**

Pharmacists collaborate with other healthcare providers to ensure patient safety by attending ward rounds and providing advice regarding medication, are active members of hospital teams such as risk assessment committees, drug and therapeutics committees and antimicrobial stewardship committees, and take part in warfarin and asthma clinics. Pharmacists who are working as medication safety officers collaborate and educate other healthcare professionals about medication safety issues and disseminate signals and alerts regarding medication safety.

#### **11.6.5 New services or innovations to improve patient safety**

The Ministry of Health implemented the smart pharmacy programme, which is an innovative and competency-based training for pharmacists, under the slogan of “Learn today and apply tomorrow”. In this programme three modules have been carried out and patients are monitored by the pharmacists. These are asthma and chronic obstructive pulmonary disease, and patient care processes to address, hypertension, dyslipidaemia and diabetes. Pharmacists also created classifications for medication-related problems that reflected treatment gaps and emphasised the prescribing issues that compromised the treatment effectiveness. Accordingly, training sessions were conducted for prescribers, and research for tackling the raised issues is planned. In addition, the Ministry of health adopted the WHO’s Patient Safety Friendly Hospital Initiative standards. In these standards, pharmacists were identified as essential members of a healthcare team. Education around patient safety includes leadership, training and continuous education).

Having patient safety at the core of pharmaceutical care, the Ministry of Health trained pharmacists as medication safety officers through a structured accredited course in collaboration with external experts from the United States and Canada (Institute of Safe Medication Practice). The training was extended to include physicians and nurses in 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. It attracts more than 1,200 delegates from different parts of the world and provides 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), the Ministry of Health suggested that the World Patient Safety Day, should be held on 17 September. Each year it focuses on an area suggested by the WHO, including transitions of care, polypharmacy and high-risk situations. The event consists of a one-day symposium for healthcare professionals and another event for public education around patient safety (which is run by pharmacists from different hospitals). During the same year, the Directorate General of Medical Supplies conducted two workshops. One was on medication reconciliation to ensure safe transition of care between different settings by reviewing patients’ medication on admission and discharge. The second was on appropriate polypharmacy to increase pharmacists’ competency to conduct medication reviews and ensure appropriateness of medicines use. Many educational materials have to be created and printed for patients in order to keep them safe through health education. Prior to the month of

Ramadan, a campaign is conducted by pharmacists at a public place and at individual hospitals to educate patients regarding their medication management during Ramadan period. Pharmacists give special consideration to the safety of fasting and address required changes in pharmacotherapy and lifestyle to avoid potential hazards.

### 11.6.6 Conclusions

The Oman Ministry of Health has a well-structured system for medication safety and patient safety in which pharmacists play an important role as experts on medication. More information can be found at: <https://www.moh.gov.om/>

## 11.7 Saudi Arabia: Patient safety programmes

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### 11.7.1 Introduction

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

The pharmacy profession has become an integral part of the Saudi healthcare system and pharmacists play a great role in patient safety. Pharmacists are the most accessible healthcare team professional for patients, and their role is vital to ensure the proper medicines use across the continuum of care.<sup>248, 249</sup>

### 11.7.2 Health system supporting patient safety

Patient safety has been on the national agenda in the Kingdom of Saudi Arabia in the past few years. Notable patient safety measures and support systems have been put in place by the Saudi government and these include the establishment of a national accreditation body (Saudi Central Board of Accreditation for Healthcare Institutions) with a focus on patient safety standards. Accreditation is mandatory for all types of healthcare settings, including hospitals and poly health clinics (private and governmental sectors). Additionally, the Saudi Food and Drug Authority pharmacovigilance system has also been established. This is a service that allows health practitioners, health institutions and individuals to report side effects, pharmacological errors, cosmetic side effects, and any quality defects in pharmaceuticals. They can also report food poisoning and defects in medical devices and supplies.<sup>248</sup>

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 by the Minister of Health as a government initiative in 2017 (implemented through the National Transformation Programme). It is the first of its kind in the region.<sup>249</sup>

The centre aims to initiate a paradigm shift in health service delivery to upgrade performance efficiency, improve clinical quality outcomes, enhance patient experience, establish a culture of patient safety with all healthcare provider organisations, and contribute to the global efforts of eliminating the widespread patient safety problems that all healthcare systems are currently facing.

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 of hosting the 4<sup>th</sup> Global Ministerial Summit on Patient Safety 2019. This is a continuation of the series of the Global Ministerial Patient Safety Summit which has the primary goal of driving 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 the "Jeddah declaration" with its 11 actionable items that are aligned with the 72<sup>nd</sup> World Health Assembly (WHA) resolution on "Global action on patient safety". The summit catalysed collaboration in the implementation of this WHA resolution on "Global action on patient safety". The programme of the summit and the 11 recommendations are to be actioned and implemented by the participating countries.<sup>249</sup>

### 11.7.3 Pharmacists' role in patient safety in different settings

In previous years, the community pharmacy was considered as a point of sale with limited patient counselling scope and access to few over-the-counter medicines. Therefore, the country's focus for patient safety programmes has been on hospital pharmacies, despite the significant number of community pharmacies in the country (approximately 8,000 pharmacies).<sup>249, 250</sup>

While some studies have shown that community pharmacists in Saudi Arabia do provide medication counselling and other patient-centred care services, these services need considerable improvement.<sup>251</sup> One of the newly introduced medication safety initiatives in the kingdom is the Saudi Patient Safety Centre's certification-based programme for community pharmacy (Pharma-Safe) which has a set of medication safety requirements, and aims to standardise community pharmacy practice in Saudi Arabia.<sup>250, 251</sup>

Hospital pharmaceutical care practices in Saudi Arabia are considered to be one of the best and most advanced practices in the Gulf region. Pharmacists play a crucial role in reducing medication-related harm and improving patient safety through transitions of care by helping with: medication reconciliation; verification of orders; unit dose dispensing; preparation of intravenous medicines, total parenteral nutrition, and chemotherapy medicines; and patient counselling and education.

Some pharmacists are working as drug information pharmacists, while others are medication safety officers handling and analysing reported medication errors.<sup>248</sup> Yet others work in research centres within the hospitals to handle investigational drugs.<sup>249</sup>

Specialised clinical pharmacists are also practising in hospitals (especially in tertiary care hospitals) and their roles vary according to the specialty (e.g., critical care, infectious disease and paediatric clinical pharmacists).<sup>249, 250</sup>

Pharmacists not only practise in hospital and community pharmacies but are also involved in non-traditional settings, such as regulatory activities (working within the Saudi Food and Drug Authority for drug evaluation, Good Manufacturing Practice 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.<sup>248</sup>

### 11.7.4 Interprofessional collaboration

Pharmacists are the medication experts and their skills qualify them to play an active role in optimising medicines use across the healthcare system and to ensure patient safety. In Saudi Arabia, pharmacists are an integral part of many multidisciplinary collaborations such as: the Anti-Microbial Resistance Taskforce to establish antimicrobial stewardship programmes; developing clinical pathways; medication reconciliation; and pain management. They are also involved in rapid response teams and other multidisciplinary activities.<sup>251, 252</sup>

### 11.7.5 New services or innovations to improve patient safety

Various innovative tools and programmes have been recently introduced in Saudi Arabia. According to Alhawsawi *et al.*, human factors engineering is an important aspect for consideration.<sup>249</sup> A very useful strategy to improve patient safety is the introduction of "forcing functions". Forcing functions is a feature of the systems design that prevents medical errors and/or harm from taking place.<sup>249</sup>

One of the innovative programmes to ensure patient safety in the kingdom is Drug Track and Trace System for pharmaceutical products, released by Saudi Food & Drug Authority, that aims to guarantee the safety of all medicines by tracking their journey, from the manufacturing phase through to consumption.<sup>252</sup>

Another important patient safety initiative is the National Reporting and Learning Platform launched by the Saudi Patient Safety Centre. The aim is to build a reporting system in Saudi Arabia. This reporting system helps in the collection of data which in turn helps in tracking the issues that compromise patient safety. Lessons are learned from failures, and this helps to avoid the occurrence of such cases in the future.<sup>248, 250, 252</sup>

### 11.7.6 Education around patient safety (including leadership, training, continuous education)

“Invest in 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 integrating the patient safety curriculum into the undergraduate curriculum for medical, nursing, dental, pharmaceutical and allied health sciences (and related) degrees. Some universities have done so. As a central part of the healthcare system, patients are also trained and educated on patient safety. The Saudi Patient Safety Centre plays a significant role in promoting health literacy by educating patients on patient safety aspects, including infection control and medication safety. Such educational activities and events are conducted in hospitals (patient safety caravan), schools and other public areas.<sup>249</sup>

### 11.7.7 Conclusions

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

## 11.8 Europe: Improving polypharmacy

### Author:

Alpana Mair, Scottish Government, United Kingdom

One of the flagship reports of the third Global Patient Safety Challenge is “medication safety in 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 resources are 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.<sup>253</sup>

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 health systems is to conduct a baseline assessment of how countries have implemented the programmes to address polypharmacy and adherence using change management techniques. The SIMPATHY (Stimulating Innovation in the Management of Polypharmacy and Adherence in the Elderly) project used case studies, benchmarking surveys and literature review to demonstrate that there are some effective polypharmacy management programmes in the EU, but that they are too few in number. The project also demonstrated 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. This is to be achieved through the following six key recommendations and 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:<sup>253</sup>

- Use a systems approach that has multidisciplinary clinical and policy leadership;
- Nurture a culture that encourages and prioritises the safety and quality of prescribing;
- Ensure that patients are integral to the decisions made about their medicines and are empowered and supported to do so;
- Use data to drive change;
- Adopt an evidenced-based approach with a bias towards action; and

- Utilise, develop and share tools to support implementation.

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.

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. Countries can start to consider how to implement a polypharmacy programme by using an adaptation of Kotter's change management process (Figure 11). Also provided are case examples of how different countries across the project have addressed some of these areas in order to build programmes to address the patient safety challenge.<sup>253</sup>

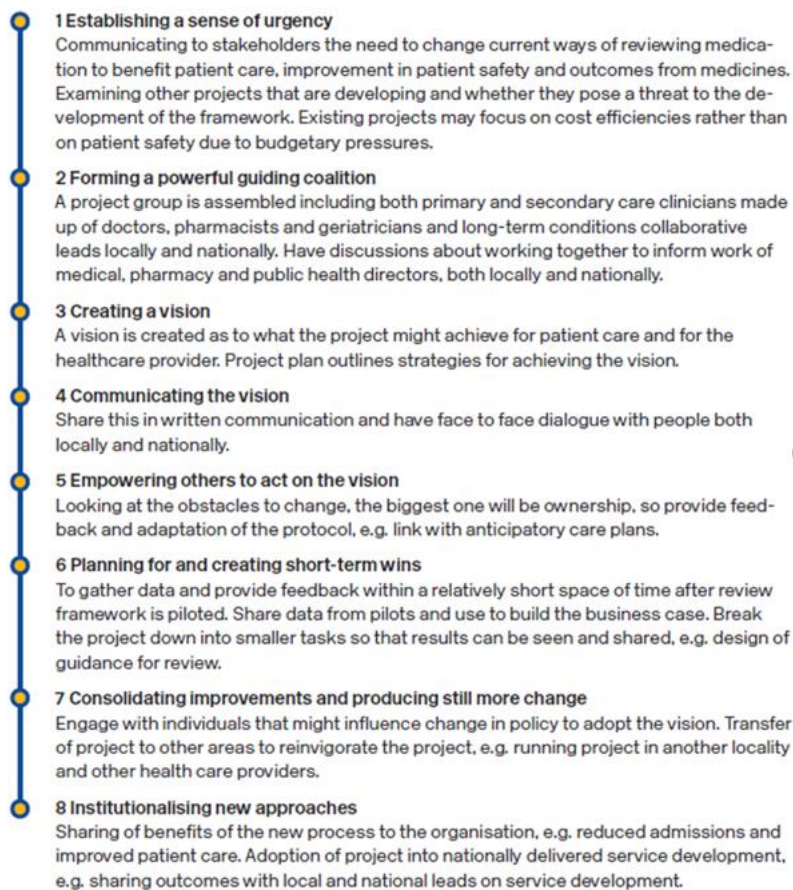


Figure 11: Application of Kotter's 8 steps in transforming change in polypharmacy management.

### 11.8.1 Economic benefits of implementing good practice

#### 11.8.1.1 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 with patients receiving usual care. Medication-related readmissions were reduced by 80%. After inclusion of the intervention costs, the total hospital-based healthcare costs per patient in the intervention group was approximately EUR 200 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.<sup>253</sup>



### 11.8.1.2 Scotland: Economic benefits of implementing good practice

The implementation of the [Scottish Polypharmacy Management Programme](#) was underpinned by detailed economic analysis. The data demonstrate notable savings, even when considering the cost of reviews as depicted in Table 1.

Table 1: Range of estimates of savings from polypharmacy reviews.<sup>253</sup>

Range of estimates of savings from polypharmacy reviews			
	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

### 11.8.2 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 well-being of citizens as they age. This is set out in the EU-led European Innovation Programme on Active and Healthy Ageing (more information at: [https://ec.europa.eu/eip/ageing/home\\_en](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 practice can also help address the capacity of the traditional workforce models that are under extra pressure, due to challenges of an ageing population with increasing multiple morbidities.<sup>253</sup>

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 subject to competing demands.<sup>253</sup>

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 people are likely to have multiple morbidities, be 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”, which is an [initiative](#) of the ABIM Foundation that promotes patient-physician conversations about unnecessary medical tests and procedures, many policy documents have raised awareness of using resources wisely, and also about the importance of the greater role of patients in decision making about their healthcare, including medicines.

While awareness of the benefits of polypharmacy management is growing, there is a need, as identified through both the SIMPATHY benchmarking and Delphi surveys (see below), 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.<sup>253</sup>

Figure 12 depicts the vision and strategies of implementation of processes leading to improved polypharmacy. These views were sought through a Delphi study that examined how the vision to deliver polypharmacy management could be achieved across all the 27 countries in the EU and the UK. It gathered views from clinicians, policy makers, academics and patients. It concluded that full implementation of polypharmacy and adherence programme across the EU would take use at least until 2030 to fully realise all the benefits, but that work was needed to start now to address this. The various steps that the EU countries thought needed to be taken are illustrated in the route map below (Figure 12). For example, it shows the education programmes countries in the SIMPATHY consortium to support the learning of healthcare professionals.<sup>253</sup>

# ROUTEMAP

## HOW DO WE GET THERE?

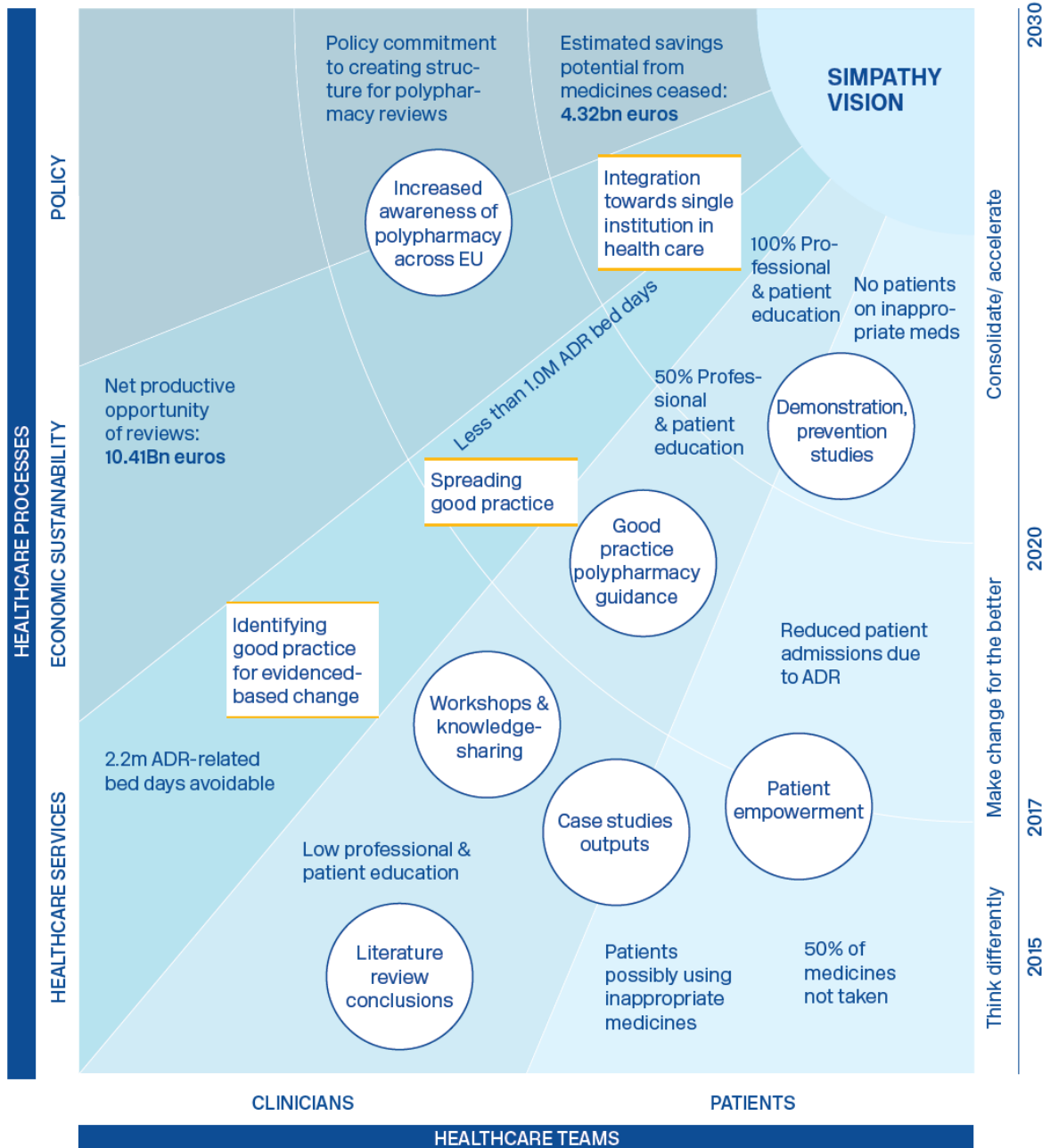


Figure 12: Routemap of SIMPATHY project on implementing the vision for polypharmacy in selected countries of European Union.<sup>253</sup>

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. Political work is not solely policy-focused. Nurturing deep change in how health professionals, policymakers and patients think about and practise medication safety in general. Polypharmacy, in particular, will involve a change in culture and will generate some

resistance from some healthcare professionals no matter how compelling the evidentiary-based case is. Everyone involved will have to reorder priorities and adapt to new, unfamiliar and sometimes 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.<sup>253</sup> The SIMPATHY website ([www.simpathy.eu](http://www.simpathy.eu)) also addresses political challenges and offer recordings.

#### **11.8.2.1 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.<sup>253</sup>

The Campania region is integrated in the national network 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.<sup>253</sup>

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 (a field of research dedicated to understanding and augmenting rehabilitation through the application of robotic devices). For this project, Campania, Liguria, Piedmont and Calabria along with the Ministry of Health co-financed a total budget of EUR 4.2 million.<sup>253</sup>

#### **11.8.2.2 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 (Figure 13).<sup>253</sup>

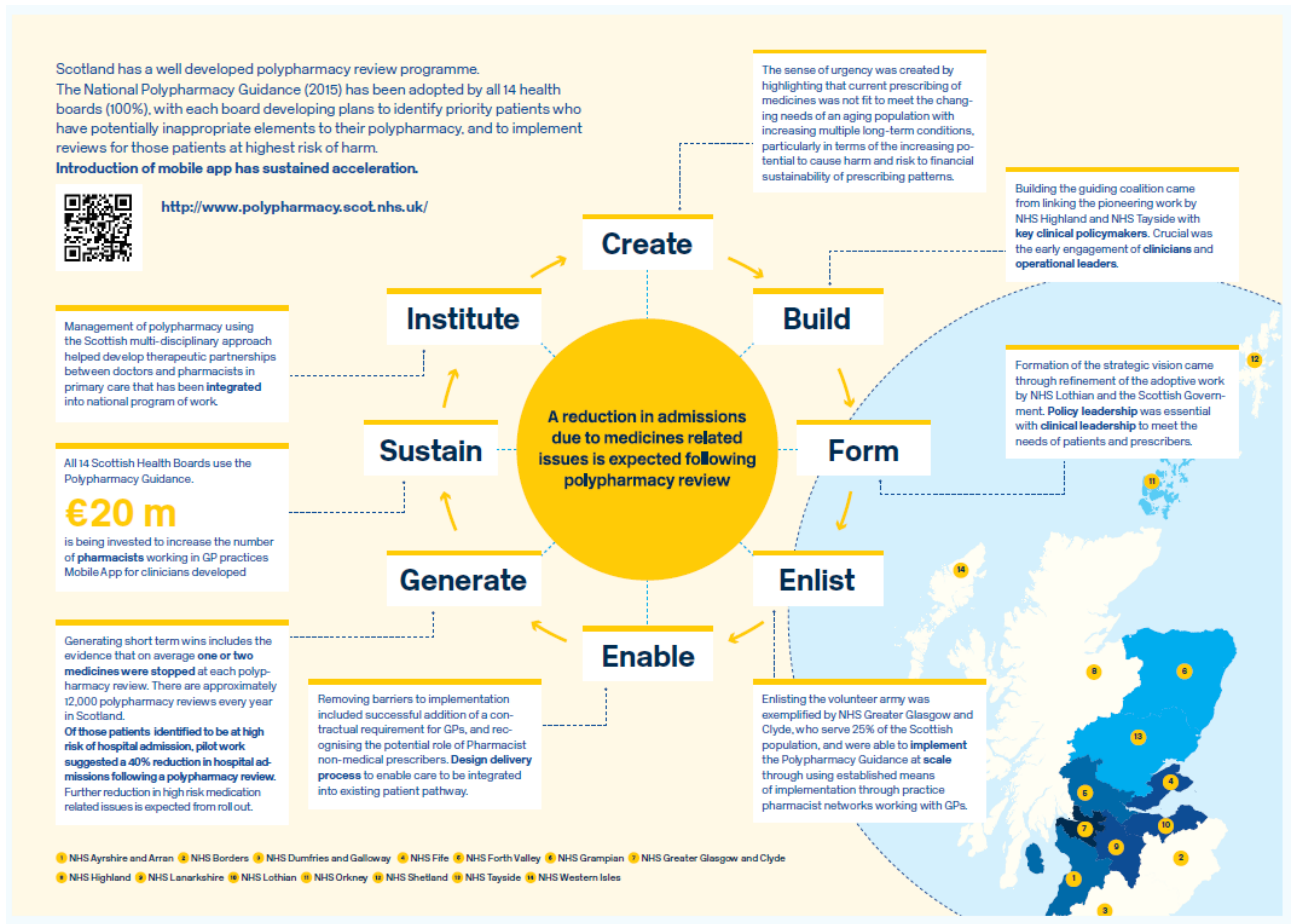


Figure 13: Polypharmacy guidance and programme in Scotland.

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

Figure 14 depicts the process of agreeing specific objectives with the patient in terms of both therapeutic objectives and current life priorities. Step 1 (“What matters?”) sets the context within which all further decisions are made. Next, agreement is reached on which medicine is the right medicine (step 2) and which are unnecessary (step 3), whether therapeutic objectives that matter to the patient (“Effective medicine”) are achieved (step 4), which medicines may be “Harmful medicines”, i.e., are too risky or cause unacceptable adverse effects (step 5), and which medicines are cost effective (step 6). Finally it must be determined whether the patient is willing and able to agree and share the medicine plan (step 7), i.e., manage their medicines in a way that avoids harm and maximises benefit.

## 7 STEPS TO APPROPRIATE POLYPHARMACY



Figure 14: 7 Steps to appropriate polypharmacy.<sup>253</sup>

### 11.8.2.3 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 in August 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.

### 11.8.2.4 Germany: Political influence driving systems change

Since October 2016 a standard medication chart has been introduced for mandatory use by all doctors and pharmacists (Figure 15). Every person taking 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 about medicines. This initiative has been supported and driven by the Federal Ministry of Health and has been agreed by all relevant stakeholders at the federal level. The standard medication chart is part of the e-Health Law and ensures that all prescribed medicines data are documented in this digital format. It can be printed out in doctors' offices during a consultation and handed to the patient.<sup>253</sup>

GPs now receive a small remuneration to incentivise the new practice of standard medication charts or electronic prescribing. The interim solution of using a paper medication chart kept with the patient will be replaced by the electronic health card issued by health insurers.<sup>253</sup>



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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® Penfil®	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	Lai® 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	Vivnox® Sleep Schlaftabletten stark	50 mg	TAB	0	0	0	1	Stck	b. Bed. 30 min vor dem Schlafengehen mit ausreichend Flüssigkeit	Schlafstörungen	

Figure 15: Example of a standard medication chart for polypharmacy patients.

#### 11.8.2.5 Northern Ireland: Policy commitment across the healthcare system

Optimising health benefits from medicines is an important enabler of active and healthy ageing 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.<sup>253</sup>

In addition, there was a formal commitment to implement 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.<sup>253</sup>

Outcomes 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.<sup>253</sup>

#### 11.8.2.6 Catalonia, Spain: Policies leading to polypharmacy and adherence guidelines

In Catalonia in Spain, policies have been developed on polypharmacy from 2010 to 2015. The development started with a new Catalan Health Plan, which guided all health programmes and policies under one strategy.

Patients were put at the centre and, with an ageing society, a strategic work line was created specially for patients with chronic diseases. A working group was set up with the task of meeting the goals outlined in the strategy. One of the tools used was the medication management recommendations for clinical practice, focused on medication reconciliation, deprescribing and adherence to therapy of patients with complex chronic conditions (see Figure 16).

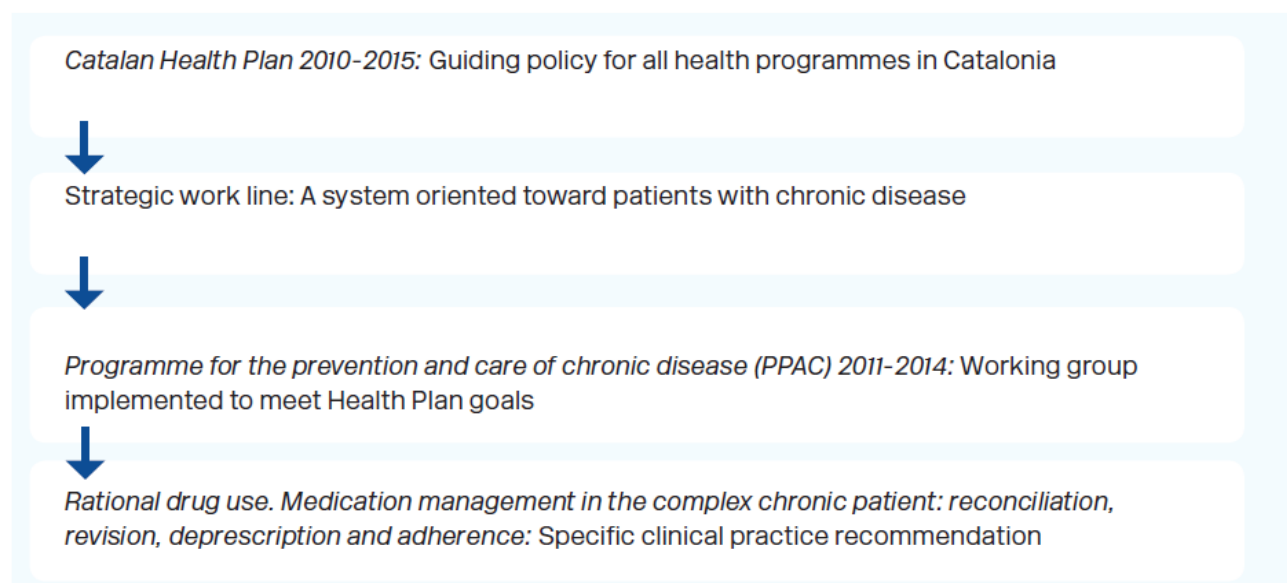


Figure 16: Policies leading to polypharmacy and adherence guidelines.

Table 2 shows the overview of the polypharmacy management educational initiatives for pharmacists in different regions of Europe.

Table 2: Polypharmacy management educational initiatives for pharmacists:<sup>253</sup>

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



### 11.8.3 Conclusions

In order to deliver positive change in the approach to management of medication safety across the EU, countries need to apply the lessons learnt from the SIMPATHY project across eight EU countries, considering policy, quality and the economics of the programme across health and care systems.<sup>253</sup>

## 11.9 Finland: patient and medication safety work

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### 11.9.1 Background

The scope of this case study is health policy-oriented. It demonstrates how pharmacists can be actively and successfully involved in policy making. It describes how international patient and medication safety recommendations have laid the foundation for national patient safety work, and how medication safety has been an integral part of this work since the mid-2000s. Medication safety has also been taken into account in the National Medicines Policy 2020 by the Ministry of Social Affairs and Health which is based on the principle that pharmaceutical services are a part of the social and health services.

More recently, the Ministry of Social Affairs and Health launched a “Rational pharmacotherapy action plan 2018–2022” as part of the government programme. The action plan aims to improve coordination of medicines use processes at the patient, organisational, regional and national levels by improving partnerships between professionals and medicine users, making better use of technology in managing, sharing and reconciling patient information, and prospectively managing clinically significant medication-related risks that could harm patients. Special emphasis has been on the safety of pharmacotherapy in various geriatric care settings, because our population is ageing fast.

### 11.9.2 Evolution of the systems-based patient safety work in Finland: Early steps

Establishing the national patient safety network in 2005 and the patient safety steering group in 2006 by the Ministry of Social Affairs and Health were important for initiating systems-based patient safety work in Finland. The steering group established the first national patient safety strategy, and guidelines for reporting adverse events in health care. The first patient safety strategy 2009–2013 focused on embedding the systemic patient safety culture and work (leadership and responsibilities) in the structures of our health system.

The patient safety strategy was used as a base for incorporating patient safety into our legislation in 2011. The legislation obliged all healthcare organisations in inpatient and outpatient care to develop a local patient safety plan, including a plan for safe medication practices, describing the system, processes, resources and persons in charge of patient safety within the organisation. The legislation has led to nominating patient safety coordinators and steering groups and implementing voluntary, electronic patient safety incident reporting systems. Establishing patient safety incident reporting systems and culture can be seen as crucial milestones in the early phase of patient safety work in Finland.

The National Institute for Health and Welfare was mandated to coordinate the implementation of the patient safety strategy and legislation through a four-year programme launched in 2011. About the same time in 2010, the Finnish Society for Patient Safety was founded with a special section for medication safety. The society has been actively involved in national patient safety work in close cooperation with authorities, healthcare organisations, professional and patient organisations, researchers and healthcare educators.

### 11.9.3 Early medication safety initiatives

Finland was actively involved in the Council of Europe’s (CoE) expert groups on patient and medication safety in 2003–2006. The CoE recommendations inspired the National Centre for Pharmacotherapy Development to establish a

multidisciplinary working group on medication safety in 2004. The working group created the Finnish glossary of terms related to patient and medication safety with systems approach, based on the CoE glossary.

In 2005, the Ministry of Social Affairs and Health launched a guide of safe medication practices (“Safe pharmacotherapy”) in healthcare units. A key element was instructions to create organisation-based plans for safe medication practices, where the medicines in use (local formulary), medicines use process, competences and responsibilities of healthcare providers were described. The safe pharmacotherapy guide emphasised learning from medication errors with a systems approach (e.g., reporting medication errors, root cause analysis).

The safe pharmacotherapy guide was updated in 2015. The main aim was still to guide the development of local plans for safe medication practices in healthcare units as the plans had proved to be useful for building up locally harmonised practices. The updated guide also emphasised identifying and managing high-alert medicines. Furthermore, availability of up-to-date medication charts/lists with the help of medication reconciliation and reviews was highlighted. Medication safety audits were launched by adopting the US Institute of Safe Medication Practices’ (ISMP) medication safety self-assessment tools for hospitals and community pharmacies. The ISMP tools were validated to assess and audit medicines-use processes in the Finnish healthcare context. The content of the tool for hospitals was structured to assist in the development of the local plan for safe medication practices.

The current national Medicines Policy 2020 was launched in 2011, i.e., almost 10 years ago. It stated that rational pharmacotherapy and medication safety enhance the well-being of the population, improve public health and decrease healthcare costs. It also stated that medication safety is jeopardised because of poor patient involvement in their own care and lack of coordination in managing medication. The document recommended the following actions to improve medication safety: the promoting medication safety through organisation-based plans for safe medication practices, reporting medication errors and adverse events, and using evidence-based databases for enhancing safety.

#### 11.9.4 Most recent initiatives

During the past five years, Finland has been preparing a major healthcare reform. For this purpose, the Ministry of Social Affairs and Health established a Rational Pharmacotherapy Action Plan in 2018. From the medication safety perspective, the aim is to enhance medication management by 2022 with the following actions:

- To establish a patient-specific electronic medication record system incorporated in the national patient data repository (Kanta, it already contains nationally all e-prescriptions);
- To make patient-specific pharmacotherapy plans available as part of treatment plans;
- To ensure availability of up-to-date medication lists by medication reconciliations in all transitions of care;
- To ensure regular medication reviews that can be collaboratively conducted and to identify high-risk patient groups needing medication reviews most;
- To ensure the competence and skills of the healthcare professionals to communicate interactively on medicines to encourage patients to be active partners in their medicines use process; and
- To ensure continuous (closed loop) care pathways that involve medicines use in the transitions of care between different health and social care organisations by coordinating medicines use processes nationally, regionally and locally.

The Foundation for Municipal Development published a research-based review on major medication safety concerns in Finland and suggestions for managing them in the ongoing healthcare reform. The suggested solutions are:

- Improving leadership, management, and coordination of medication safety;
- Establishing a national focal point for promoting and coordinating rational medication therapy and medication safety;
- Ensuring that operation culture, healthcare facilities and information technology systems are supporting safe and rational medication therapy (suggested methods: learning from errors, prospective risk management, plan-do-check-act cycle);

- Ensuring the comprehensive management of patients' medication therapy with well-defined responsibilities, interprofessional collaboration and patient involvement;
- Ensuring competence related to medication therapies and systems approach in medication safety; and
- Systematically increasing and utilising medication safety research.

### 11.9.5 Medication safety research

Patient and medication safety form a new research area that started to evolve as a response to the first reports raising concerns regarding the safety of health systems.<sup>8</sup> During the past few decades, this research area has been rapidly growing. Research has been urgently needed to provide a more detailed picture of patient and medication safety risks in health systems to assess effectiveness of interventions intended to prevent risks and errors.

Medication safety research has grown to become a large research area in Finland that has remarkably contributed to the recent development of medicines use processes, prospective medication risk management, competence development and policy making. Within medication safety research, the safety of pharmacotherapy of older adults has become a major topic as the safety risks are cumulative in this growing population segment.

Finland has had an electronic reporting system for safety incidents in healthcare organisations (HaiPro) since 2007. HaiPro data have laid the foundation for other medication safety research in Finland. The first study focusing on medication errors reported to HaiPro was conducted in 2012. The data consisted of medication errors and near misses reported during 2007–2009 (n=32,592). Almost half of the reported MEs reached patients (51%) and the remainder (49%) were near misses. The most reported ME types were dispensing errors (33%), administration errors (25%) and documenting errors (17%). Other early HaiPro studies have found quite similar results. These findings have accelerated the transition to another type of dispensing, administration and documentation practices in hospitals, e.g., towards electronic cabinets and closed-loop systems to reduce errors.

Research on HaiPro data on medication errors and near misses has extended and diversified over the years. One of the most effective research lines so far has related to use of HaiPro data for identifying high-risk medicines. For example, at Helsinki University Hospital it has led to establishing organisation-based high-risk medication lists and guidelines which have been implemented throughout the hospital. Medical specialties and wards have been encouraged to use their own HaiPro data to customise their high-risk medication practices. Other studies have identified medication errors and risks, e.g., in cancer therapy and paediatric antimicrobial therapy. One of the recent research lines has specialised in investigating systemic risks in intravenous medication and potential systemic defences for preventing these risks.

In addition to the HaiPro data, the documentation gathered by the Finnish authorities has provided insights in medication errors, particularly in severe ones. These studies covering the years 2000–2014 have revealed that patients with older age and polypharmacy have been experiencing severe medication errors more often. The most common error types have found to be wrong procedure or course of action, wrong dose and wrong drug. Errors have been related to commonly used medicines, the most commonly involved high-alert medicines being opioids, oral hypoglycaemic agents, methotrexate, warfarin and heparin. Most of these errors were considered preventable. Another analysis on severe medication errors compensated by the Patient Insurance Centre found that most were related to antithrombotic agents, antibacterials for systemic use and cardiovascular drugs. High-alert medicines were related to about one-third of the errors. The most common error types were omission of medication, wrong dose, wrong medicine and a failure to observe contraindications. All these errors were considered preventable. The most recent follow-up study of compensated medication errors found similar results, with antithrombotic agents and antibacterials for systemic use being the most common medication groups involved. High-alert medicines were involved in 37% of the cases.

Retrospective medication safety research has been instrumental in guiding the shift towards prospective medication risk management in Finland. The research has systematically been based on Reason's risk management theory, the systems approach as illustrated by the Swiss Cheese Model (see Section 3.1). The research has involved academic researchers, students and practitioners, and composing multidisciplinary research teams in various settings such as hospitals, primary care and community pharmacies. This has facilitated implementation of systemic defences for managing medication risks. Among widely researched systemic defences in Finland are collaborative medication reviews in various settings, medication counselling services, automated dose dispensing, development of validated tools for medication-risk assessment in older adults and action research-based studies to enhance care coordination and collaborative practices. The next steps will focus on enhancing the use of electronic databases in prospective medication

risk management. This is because we have a wide range of these tools available throughout the healthcare system, including community pharmacies, but they are still underused.

The recent rational pharmacotherapy action plan by the Ministry of Social Affairs and Health aims at enhancing evidence-informed decision-making in health care. The goal is that research on and development of rational pharmacotherapy are a part of the health and social services system. Research evidence should be used to guide decision-making in the health and social services system and medicines policy. The action plan prioritises the following research areas:

- Structures and operational prerequisites promoting rational pharmacotherapy;
- Processes in the implementation of pharmacotherapy in various social and healthcare contexts; and
- Outcomes and effectiveness of pharmacotherapies.

These research priorities demonstrate the continuous need for medication safety research to guide development of structures and processes of medication management systems. They also demonstrate the multifaceted nature of medication safety research with evolving methodologies.

#### 11.9.6 Medication safety initiatives by community pharmacies

Community pharmacies have a legal mandate to promote safe and appropriate medicines use in primary care. The medication safety risks of outpatients have been well recognised both nationally and internationally. The safety risks are associated with, e.g., polypharmacy, lack of follow-up and support for self-management in long-term therapies, and limited availability and access to medicines information. There are also potential risks associated with self-medication, such as interactions and adverse effects of medicines, or a delay in consulting a physician in a severe health condition. An evolving safety issue is migration, which causes challenges in communication and literacy, as well as in access to care.

During the past decades, Finnish community pharmacies have been actively developing new tools and services to improve medication safety. These include medication counseling services, automated dose dispensing, and medication reviews. The goal of information technology development in community pharmacies has also been to support patient care and safe medication management. In order to make better use of the resources and potential that community pharmacies have in assuring safe medication practices in primary care, community pharmacies have run several long-term national development programmes. One of these was a collaborative contribution of the pharmacy profession to the National Patient Safety Programme (National Institute for Health and Welfare 2011–2014). The national four-year programme for promoting medication safety in Finnish community pharmacies was launched in 2012.

The goals of the four-year programme, called APILA, were two-fold. The first goal was to promote medication safety within community pharmacies by improving their internal systems and processes. The second was to influence medication management systems and processes in primary care so that the actions taken can lead to improved medication safety (see an example of such a service below, Section 12.9.7). The actions of the APILA programme were focused on enhancing medication counseling and medication review services, particularly for the aged, disabled, immigrants and those using self-medication products. Community pharmacies also have tools to assist social service and healthcare units in establishing medication management plans.

In order to ensure safety of their own internal processes and practices, community pharmacies have a special tool for self-assessment of safe medication practices. The Association of Finnish Pharmacies has also established a national reporting system for dispensing and prescribing errors in outpatient care.

As many medication safety tools already exist, the current mission is to improve their implementation and use in routine practice. This has been carried out through undergraduate and continuing education and creating awareness of systems approach to medication safety in the primary care context. Also, development of information technology has supported medication safety (e.g., databases assisting in medication reviews). Another essential element is research to inform progress in medication safety and indicating high-risk practices and processes needing further improvement.

These national community pharmacy development programmes over the years since 2000 have been carried out in collaboration with the following national stakeholders: the Association of Finnish Pharmacies; the Finnish Pharmacists' Association; the Finnish Pharmacists' Society; University of Helsinki; University of Eastern Finland; Åbo Akademi

University; the Pharmaceutical Learning Centre; Education Centre for Training and Development, University of Eastern Finland; and the HY+ Centre for Continuing Education, University of Helsinki.

### 11.9.7 The Safe Medication Support Service; A service provided by Finnish community pharmacies to home care and assisted living facilities of older adults

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Finland has one of the most rapidly ageing populations in the world. The challenge for primary outpatient care is to meet the increasing health services needs of the growing number of older people. With scarce resources, outpatient care units such as home care and assisted living units take care of increasingly fragile older people who often have complicated comorbidities and polypharmacy regimens. To ensure medication safety, these units should have well-designed medication use processes and cross-sectoral cooperation. Community pharmacies mainly deliver medicines to these units. However, they have potential to assist home care and assisted living units in medication management and in organising their medicines use processes in a safe way.

The Safe Medication Support Service, developed by the Association of Finnish Pharmacies, is planned to be provided by individual community pharmacies to their client organisations that want to have support for making their medicines use processes safer. The service package contains concrete tools and instructions for the consultant pharmacists to work with the cooperating unit. It consists of the following four risk assessment (auditing) tools that can help the pharmacist to identify high-risk phases in the medicines use process to be changed:

- Audit tool to assess safety of medicines use process in a unit using automated dose dispensing/ multidose dispensing service for having medicines dispensed for its residents or clients;
- Audit tool for assessing medication cabinets and safety of drug logistics in the unit;
- Audit tool assisting in implementing safe medication practices; and
- Tool for assessing safe medication qualifications.

This case study is primarily based on the following sources:

1. Holmström AR. Learning from medication errors in healthcare: How to make medication error reporting systems work? [Doctoral dissertation]. University of Helsinki; 2017. Available at: <https://helda.helsinki.fi/handle/10138/179230> (accessed 22 June 2020).
2. Keskimäki I, Tynkkynen L-K, Reissell E et al. Finland: Health system review. Health Syst Transit 2019;21(2):1–166.
3. Ministry of Social Affairs and Health, Finland. Rational pharmacotherapy action plan 2018–2022. Final report. Available at: <https://stm.fi/en/rational-pharmacotherapy> (accessed 22 June 2020).
4. Schepel L, Aronpuro K, Kvarnström K, et al. Strategies for improving medication safety in hospitals: Evolution of clinical pharmacy services. Res Soc Admin Pharm 2019;15(7):873–82.
5. Schepel L. Strategies for medication safety: An organization-based approach focusing on high-alert medications and clinical pharmacy services in Helsinki University Hospital [doctoral dissertation]. University of Helsinki; 2018. Available at: <https://helda.helsinki.fi/handle/10138/266766> (accessed 22 June 2020).
6. Toivo T, Dimitrow M, Puustinen J, et al. Coordinating resources for prospective medication risk management of older home care clients in primary care: procedure development and RCT study design for demonstrating its effectiveness. BMC Geriatr 2018;18(1):74.

## 11.10 The Netherlands: Medication monitoring and reviews

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### 11.10.1 Clinical risk management on medicines use

Since the introduction of computers, clinical risk management of medicines use has been developed in the Netherlands over the past 35 years. This has led to a safer use of medicines. Pharmacists have developed clinical risk management skills, with monitoring on dosing, medicine-disease interactions (e.g., chronic diseases, renal functions, etc.), duplicate medicines, medicine-medicine interactions, medicine intolerabilities, etc. The clinical risk management is incorporated in the dispensing process and the pharmacy information system is supporting the pharmacist in this task with alerts. More and more patient data have become available to pharmacists, such as laboratory data/clinical data (e.g., cholesterol, glycosylated haemoglobin, blood pressure, renal function and pharmacogenetic parameters). In recent years, therefore, pharmacists have access to tools as clinical decision support systems with embedded clinical rules to support pharmaceutical care, alongside traditional clinical risk management on medicines use. Clinical rules combine all available patient data, making it possible to identify new risk situations. The pharmacist receives more specific and relevant signals than with traditional clinical risk management and can concentrate on the high-risk alerts, promoting a more personalised pharmaceutical care for every patient.

### 11.10.2 Medication review

In the Netherlands, pharmacists have introduced an annual medication review in collaboration with general practitioners (GPs) and in consultation with the patient (shared decision making). By performing a medication review, pharmacists work together with GPs to optimise the patient's pharmacotherapy and reduce the potential risks of polypharmacy. Pharmacists and GPs (or medical specialists) are jointly responsible for the medication review. These medication reviews are intended for older patients with multimorbidity and polypharmacy to reduce drug-related problems (DRPs) and hospitalisations. In the Netherlands, pharmacists and GPs are expected to perform regular medication reviews in older patients according to the national multiprofessional guideline. A study showed that community pharmacists in the Netherlands identified a median of two DRPs in older patients with polypharmacy by conducting a medication review. Overtreatment and undertreatment accounted for 41.4% of the DRPs identified. When dealing with DRPs, pharmacists proposed a variety of interventions of which 70% were either implemented or led to alternative interventions.<sup>254</sup>

Another study was conducted in 2019 to investigate the effect of medication review to be patient-centred, focused on personal goals, on health-related quality of life (HR-QoL), and on number of health problems. The study showed improvement in older patients' lives and well-being by increasing their quality of life and decreasing the number of health problems that had an impact on daily life.<sup>255</sup>

One way of establishing a patient-centred approach in medication review is to prioritise medication changes by setting and evaluating the attainment of patient-specific health-related goals. Goal-setting can be used as a part of a shared-decision making process to reach optimal therapy for a patient's current situation, and to prioritise the most important problems for the patient with the aim of eventually improving the patient's HR-QoL. An example of an expected health-related goal suggested by a patient during a medication review could be a desire to reduce pain. During the medication review, the patient's pain medication could be optimised to achieve this goal. Another likely goal of older people with polypharmacy could be the wish to use fewer medicines. This could be an excellent opportunity for the pharmacist and GP to address deprescribing — the act of tapering, reducing or stopping a medicine — and thereby balance the benefits of a medicine (e.g., long-term effect) against the disadvantages (e.g., experienced adverse effects). The patient-centred approach of medication review, focusing on the patient's preferences, has the potential to address their health-related complaints and personal goals related to their medicines and their quality of life, and translate into an increased HR-QoL.<sup>256</sup>

### 11.10.3 Reporting medication errors

In the Netherlands, there is a national reporting system to report medication errors made by pharmacists. Many Dutch hospitals and community pharmacies have established internal systems for reporting incidents. In order to learn from incidents that occur in other hospitals and pharmacies, a multicentre, information technology-supported reporting system, named "central medication incidents registration" (CMR), was developed, in which hospitals, community pharmacies, mental healthcare organisations and GPs participate. To prevent recurrence of reported medication incidents, the CMR sends medication incident alerts with recommendations to healthcare providers.

From the start, 90 of all 93 hospitals (96.8%) and 872 of 1,948 community pharmacies (44.8%) participated in the CMR. A study conducted between March 2006 and March 2010 showed that the CMR comprised 15,694 reports of incidents. In the period from March 2010 to March 2011, 1,642 reports were submitted by community pharmacies and 2,517 by hospitals.<sup>254</sup>

## 12 Annex

### Annex 1. Evidence of pharmacists' contribution to patient and medication safety

For illustration purposes, a selected evidence presented in research papers were included with the evidence of pharmacists' contributions to patient and medication safety and conclusions by the authors of the systematic reviews/meta-analyses. The list is presented in Table 2.

Table 2: Strength of evidence of 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)		
<p><b>Article 1<sup>257</sup></b> Jokanovic et al. 2017</p>	<p>Strong (31 systematic reviews of moderate or high quality)</p>	<p>Moderate and high-quality systematic reviews (n=31) support the value of pharmacist-led medication review for a range of clinical outcomes.</p> <p>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 healthcare costs were reported in 35% of primary research studies.</p> <p>Results from the meta-analyses of 12 systematic reviews suggested positive impacts on glycosylated haemoglobin, blood pressure, cholesterol, and number and appropriateness of medicines. Conflicting findings were reported in relation to hospitalisation. No meta-analysis reported reduced mortality.</p>
<p><b>Article 2<sup>258</sup></b> Van Eikenhorst et al. 2017</p>	<p>Moderate (included only studies conducted within the UK and in countries comparable to the UK on consultations and selling of non-prescription medicines [NPMs])</p>	<p>Eighty-three studies were included (quantitative surveys excluded). Thirty-three (44%) 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 members. 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 with when people made a direct product request. Pharmacists were reported to conduct better consultations than non-pharmacist staff. The evidence suggested that appropriate counselling appropriate counselling helped the patient use their NPMs more safely.</p>

<p><b>Article 3<sup>259</sup></b> Perraudin et al. 2016</p>	<p>Weak (included only studies from European countries)</p>	<p>Of the 21 studies included, 13 were conducted in the UK. Eleven studies assessed professional pharmacy services 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 advice for improving adherence). Findings were contradictory and did not lead to a strong conclusion. Screening programmes for different diseases showed robust positive results (n=2) as did smoking cessation services (n=5) and should be considered to be more widely available in accordance with national context.</p>
<p><b>Article 4<sup>260</sup></b> Cheema et al. 2014</p>	<p>Strong</p>	<p>This systematic review and meta-analysis confined to 16 randomised controlled trials (3,032 patients) provides evidence that community pharmacists can make a clinically important contribution to the 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, 2,240 patients) and diastolic blood pressure (11 studies, 2,246 patients).</p>
<p><b>Article 5<sup>261</sup></b> Ryan et al. 2014</p>	<p>Strong</p>	<p>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. Seventy-five 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.</p> <p>For most outcomes, medication 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 multiple morbidities.</p> <p>Promising interventions to improve adherence and other key medicines-use outcomes, which require further investigation to be more certain of their effects, included:</p> <ul style="list-style-type: none"> <li>• Simplified dosing regimens: with positive effects on adherence; and</li> </ul>



		<ul style="list-style-type: none"> <li>• 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, including consultation between pharmacist and patient to resolve medicines problems, develop a care plan and provide follow-up, with positive effects on adherence and knowledge.</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>• Delayed antibiotic prescriptions, which effective to decrease antibiotic use but had mixed effects on clinical outcomes, adverse effects and satisfaction;</li> <li>• Practical strategies like reminders, cues and organisers, reminder packaging and material incentives, with positive, although somewhat mixed effects on adherence;</li> <li>• 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; and</li> <li>• Financial incentives, with positive, but mixed, effects on adherence.</li> </ul>
<p><b>Article 6<sup>262</sup></b> Blalock et al. 2013</p>	<p>Moderate (US-focused study)</p>	<p>The authors systematically reviewed the literature on the effectiveness of pharmacist-delivered patient care services in community pharmacy settings in the United States. Twenty-one 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.</p> <p>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.</p>
<p>Hospitals/care transitions (n=8)</p>		

<p><b>Article 1</b><sup>263</sup></p> <p>Cheema et al. 2018</p>	<p>Strong</p>	<p>This systematic review updated the previous assessment of pharmacist-led medication reconciliation by restricting the review to randomised controlled trials (RCTs) only (by December 2016). The effect of pharmacist-led interventions on medication discrepancies, preventable adverse drug events, potential adverse drug events and healthcare utilisation were assessed.</p> <p>Eighteen RCTs (6,038 patients) were included. The quality of the included studies was variable. Pharmacist-led interventions led to an important decrease in medication discrepancy. Reductions in healthcare utilisation, potential ADEs and preventable ADEs were small in quantity.</p>
<p><b>Article 2</b><sup>264</sup></p> <p>Huiskes et al. 2017</p>	<p>Strong</p>	<p>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. RCTs with medication review as isolated short-term intervention (less than three months) were included by September 2015. No restrictions were set with regard to patient characteristics and outcome measures.</p> <p>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 medication-related outcomes (decrease in the number of medicine-related problems, more changes in medication, more medicines with dosage decrease and a greater decrease or smaller increase of the number of medicines), minimal effect on clinical outcomes (mortality, hospital admissions/healthcare 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.</p> <p>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 and when medication reviews can contribute to better medicines use and subsequent better clinical outcomes. However, more effort should be put into the development and evaluation of other medication improvement strategies, such as more individualised and longitudinal medication therapy management, targeting at specific risk moments of pharmacotherapy and targeting at problems that patients experience themselves.</p>
<p><b>Article 3</b><sup>265</sup></p> <p>Khalil et al. 2017</p>	<p>Weak</p>	<p>This study determined the effectiveness of professional, organisational and structural interventions compared with standard care to reduce preventable medication errors by primary healthcare professionals that lead to hospital admissions, emergency department visits and mortality in adults. Randomised trials in which healthcare professionals provided community-based medical services were included by October 2016. Also, interventions in outpatient clinics attached to a hospital were included. All participants, irrespective of age, who were prescribed medication by a primary healthcare professional were included.</p>

		<p>Thirty studies (169,969 participants) were included in the review: four studies addressed professional interventions to prevent medication errors (8,266 participants) and 26 studies described organisational interventions (161,703 participants). None of the studies addressed structural interventions.</p> <p>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.</p> <p>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 or to mortality. Organisational interventions reduce the number of hospital admissions.</p> <p>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.</p>
<p><b>Article 4<sup>266</sup></b> Mekonnen et al. 2016</p>	<p>Strong</p>	<p>This study systematically investigated the effect of pharmacist-led medication reconciliation programmes on clinical outcomes at hospital transitions. Seventeen studies involving 21,342 adult patients were included. Eight studies were 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 (ADE)-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.</p> <p>The authors concluded that pharmacist-led medication reconciliation programmes are effective at improving post-hospital healthcare utilisation. This review supports the implementation of pharmacist-led medication reconciliation programmes that decrease ADE-related hospital revisits, all-cause readmissions and ED visits.</p>
<p><b>Article 5<sup>267</sup></b> Zegers et al. 2016</p>	<p>Weak</p>	<p>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: multicomponent interventions to prevent delirium; rapid response teams to reduce cardiopulmonary arrest and mortality rates; pharmacist interventions to reduce adverse drug events; exercises and multicomponent interventions to prevent falls; and care bundle interventions, checklists and reminders to reduce infections. Most (82%) of the significant effect sizes were based on five or fewer primary studies with an experimental study design.</p>

		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.
<b>Article 6</b> <sup>268</sup> Ensing et al. 2015	Strong	<p>This systematic review identified the components of pharmacist intervention that improve clinical outcomes during care transitions. RCTs that studied pharmacist intervention with regard to hospitalisation were searched (published until November 2014). Thirty 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 (five effective vs. zero ineffective studies). Conflicting evidence was found for an isolated post discharge intervention, admission medication reconciliation, combining post discharge interventions with in-hospital interventions. Closely collaborating with other healthcare providers enhanced the effectiveness.</p> <p>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 healthcare settings. Ultimately, pharmacists need to know patients' clinical backgrounds and previous hospital experiences in order to make meaningful interventions.</p>
<b>Article 7</b> <sup>269</sup> 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 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.
<b>Article 8</b> <sup>270</sup> 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 non-trivial 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.

		<p>Pharmacists played a major role in most successful interventions.</p> <p>Commonly used criteria for selecting high-risk patients do not consistently improve the effect of medication reconciliation.</p>
<p>Outpatient clinics (n=2)</p>		
<p><b>Article 1</b><sup>271</sup></p> <p>Dixon et al. 2016</p>	<p>Weak/moderate</p>	<p>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.</p>
<p><b>Article 2</b><sup>272</sup></p> <p>Lee et al. 2013</p>	<p>Strong (focused on US practices)</p>	<p>This systematic review and meta-analyses examined the effects of pharmacists' care on geriatric patient-oriented health outcomes in the United States.</p> <p>Twenty studies were included in the final meta-analyses. Study sample size ranged from 36 to 4,218, with mean age of subjects being 65 years and older. The studies were most frequently conducted in ambulatory care clinics, followed by inpatient settings, with 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&lt;0.001), favouring pharmacist care over comparison. Thus, the authors concluded that pharmacists should be involved in the team-based care of older adults.</p>

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