

**The Role of Community Pharmacists in Preventing Medication
Errors in Armenia**

Master of Public Health Integrating Experience Project

Problem Solving Framework

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List of abbreviations

ACPE	Accreditation Council for Pharmacy Education
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
ASHP	American Society of Health-System Pharmacist
CIS	Commonwealth of Independent States
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
FIP	International Pharmaceutical Federation
GPs	General Practitioners
GPP	Good Pharmacy Practice
HLIB	Health and Labor Inspection Body
HIC	High-Income Countries
IPE	Inter-Professional Education
IOM	Institute of Medicine
KAP	Knowledge, Attitude and Practice
LASA	Look-Alike/Sound-Alike
LMIC	Low-and-Middle Income Countries
ME	Medication Errors
MOH	Ministry of Health
MD	Doctor of Medicine

NAPLEX	North American Pharmacist Licensure Examination
NIH	National Institute of Health
OTC	Over-the-Counter
Pharm D	Doctor of Pharmacy
PPE	Pharmacy Practice Experiences
PIC/S	Pharmaceutical Inspection Co-operation Scheme
RA	Republic of Armenia
RAU	Russian-Armenian University
RCT	Randomized Clinical Trial
SOP	Standard Operational Procedures
TIC	Toxicological Information Center
USA	United States of America
UK	United Kingdom
UMC	Uppsala Monitoring Center
YSMU	Yerevan State Medical University
YSU	Yerevan State University
WHO	World Health Organization

Executive summary

Patient safety is one of the most alarming public health issues globally. Medication errors (MEs) are in the top three leading threats to patient safety. MEs can cause Adverse Drug Reactions (ADRs) and lead to increased mortality, morbidity, hospital admissions and poor quality of life. It was estimated that MEs cause one of 131 outpatient and one of 854 inpatient deaths in the USA. One in 20 hospital admissions are attributed to MEs in the USA. In Armenia no studies have been conducted to assess patient safety from the context of MEs in community pharmacies. This project aims to disclose the issue related to the lack of MEs' recording, coding, reporting and assessment in Armenia and identify strategies to ensure only high-quality pharmaceutical care is provided to patients.

The root cause analysis showed that the main determinants of MEs in Armenia include lack of standardized protocols and procedures, low level of education and trainings of community pharmacy staff, undifferentiated roles and lack of licensing of community pharmacists and pharmacy technicians, as well as lack of computerized systems, distractions and interruptions during dispensing and preparing medications at community pharmacies. Such factors as patient' age, complexity of clinical case, labelling and packaging of drugs, "look-alike/ sound alike" drugs also need special attention. Proposed interventions are built on the aforementioned key determinants and aim to reduce MEs in Armenia. All strategies were analysed against their advantages, disadvantages, cost, feasibility, political will and stakeholder support. Based on the analysis, the following interventions were prioritized: to require medication error reporting system, to define the roles of community pharmacists and pharmacy technicians, and to fully implement the e-Health system. To evaluate the effectiveness of proposed interventions a cluster randomized controlled clinical trial is suggested

Statement and magnitude of the problem

Patient safety is a top healthcare priority worldwide. It is a person-centered health care discipline that aims to reduce the potential harm that occur to patients during the provision of medical care.¹ The basis of the discipline is the prevention of medical errors. Poor-quality and unsafe health care result in millions of injuries and deaths.² Patient safety can be compromised at any time for various reasons, and one of these reasons is a medication error (ME), which constitutes the majority of medical errors.³

According to the European Medicines Agency (EMA) “a medication error is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient.”⁴ MEs include any error in the drug name, dose, administration route, dosage form, and intervals of administration.⁵ MEs can cause an adverse drug reaction (ADR), which is a “noxious and unintended response to a medicinal product. A causal relationship between a medicinal product and an ADR is at least a reasonable possibility.”⁴ By contrast, an adverse drug event (ADE) is “any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.”⁴

However, not all MEs result in harm to the patient. According to their correlation with harm, MEs can be categorized as a) MEs with ADR, b) MEs without harm, c) intercepted MEs or “near misses” and d) potential MEs (see Figures 1-2).⁴ The majority of MEs do not result in ADRs but, if they do, such disastrous consequences as poor quality of life, increased hospital admissions and mortality are being registered.⁶ Injuries, that appear as a result of ADRs, may include physical and/or mental harm as well as loss of function.⁷ According to Bates et al., the total number of MEs exceeds the number of ADRs by almost 100 times.⁸ MEs do not necessarily result in ADRs, but may have other concerns, such as inappropriate and ineffective use of resources resulting in economic/financial harm.⁴ An

intercepted ME or “near miss” is defined as an error that has occurred but was recognized and corrected by a healthcare provider before the medicine reaches the patient.⁴ “A potential error is the recognition of circumstances that could lead to a medication error, and may or may not involve a patient.”⁴ Potential MEs can also be important for regulatory bodies if, for instance, Look Alike/Sound Alike (LASA) medications or some abbreviations, which could be misinterpreted, are being identified and reported.

According to the EMA, all ADRs should be divided to preventable and non-preventable ADRs.⁴ Those ADRs that result from a ME are termed preventable and constitute approximately one-third of all ADRs, whereas the remaining two-thirds of ADRs are non-preventable.⁴ A non-preventable ADR is “an undesirable effect of a medicine, i.e. for which the probability of harm to the patient is known and accepted and will likely occur depending on the frequency of the adverse reaction and on other circumstances such as co-medication.”⁴ According to the IOM, at least 1.5 million preventable ADRs are detected annually in the USA.⁷ Preventable ADRs were estimated by the IOM to be the 8th leading cause of death in the USA.⁷

According to the WHO, low- and middle-income countries (LMIC) face MEs at least twice as often as high- income countries (HIC).⁵ Likewise, patients living in LMIC are twice as likely to lose disability-adjusted years because of the harm caused by medications than in HIC.⁵ The study on patient safety, published by the WHO, proclaims that two-thirds of all adverse events occur in LMIC, out of which 83% could be prevented.⁹ Several studies showed that the rates of ADRs among outpatient adults are four times higher compared to inpatients (27.4% and 6.5%, respectively).^{10,11,12} However, due to differences in definitions, classifications, identification technique and reporting of MEs, comparisons between HIC and LMIC countries are often impracticable.¹³

MEs are considered an important public health problem regardless of whether an ADR occurred or not.⁸ In 2000, The Institute of Medicine (IOM) report estimated that MEs cause one of 131 outpatient and one of 854 inpatient deaths in the USA.⁷ MEs resulted in approximately 7,000 deaths in 1993 in the USA.¹⁴ Williams et al. found that one in 20 hospital admissions are attributed to MEs in the USA.¹⁴ MEs are also associated with a significant increase in healthcare costs.⁷ According to the IOM, the cost of drug-related morbidity and mortality in outpatient care setting in the USA was estimated to be \$177.4 billion in 2000.⁷

The World Health Organization (WHO) has initiated the Global Patient Safety Challenges program to focus on the most concerning issues posing a significant risk on patients' health.⁵ The medication safety program was among the first three priorities announced by the WHO.⁵ MEs have been considered leading threats to patient safety and one of the most alarming public health problems all over the world.^{5,15,16}

A ME can occur at any step along the provision of drug therapy by a healthcare provider to a patient.¹⁷ The most common classification of MEs is based on the sequence of the medication use process, including 1) prescribing, 2) transcribing, 3) dispensing and 4) administration errors.¹⁸

Prescribing errors made by physicians constitute the majority of MEs.¹⁹ According to the EMA, "a clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice."⁴ Transcribing errors happen when a prescription is correct, but a pharmacy worker misinterprets it, for example, not accurately interpreted handwriting or misheard information.¹⁸ Dispensing errors are responsible approximately for 20% of total MEs and include errors in name, dose, labeling, as well as

errors when serving a patient at the pharmacy.²⁰ Administration errors occur when the drug is used incorrectly by a patient.¹⁸ MEs could be prevented at any level from prescribing and dispensing to administering the medicine.¹⁶

Community pharmacy is a healthcare setting that provides the local public with access to medications and health advice. The staff of a community pharmacy usually includes pharmacists and pharmacy technicians or pharmacy assistants. According to the International Pharmaceutical Federation (FIP), a community pharmacist “is a scientifically trained graduate health care professional who is an expert in all aspects of the supply and use of medicines. Pharmacists assure access to safe, cost-effective and quality medicines and their responsible use by individual patients and health care systems.”²¹ Pharmacy technicians have vocational level education (associate diploma) and usually work under the direct supervision of a registered pharmacist.²² Community pharmacy staff plays a major role in ensuring patient safety. Flynn et al. estimated that of 3 billion prescriptions, dispensed by community pharmacies in the USA within a year, more than 50 million contained errors.²³ In the meantime, another study conducted in Denmark showed that the prevalence of dispensing errors in community pharmacies was only 0.01%.²⁴ A study conducted in the UK demonstrates that errors in the dispensing process occur in 0.3-0.6% of cases.²⁴ The literature suggests that most of MEs (66%) occurring in community pharmacies were detected by community pharmacists.²⁵ In half of these cases, pharmacists made some corrections or clarifications in the order, in 14% of cases they offered better alternatives, in 4% of cases they detected drug-drug interactions, and identified allergies to prescribed medications in 2% of cases.²⁵

MEs are happening also in the Republic of Armenia (RA). However, no studies have been conducted to understand the magnitude of MEs in Armenia and explore patient safety issues in the republic.²⁶ Since there are no estimates on MEs in Armenia, ADR reports were

used to provide an approximate estimate of MEs' rate. The ADR reports were collected and analyzed by the Scientific Center of Drug and Medical Technology Expertise to assess the impact of irrational pharmacotherapy on patients' health.²⁷ Overall, 1,465 reports were analyzed from 2005 to 2015 in Armenia.²⁷ According to the Scientific Center of Drug and Medical Technology Expertise, the number of ADR reports increased significantly over the years from eight reports in 2007 to 459 reports in 2015²⁷ (see Figure 3). However, they are still underreported in Armenia.²⁷ Dosage errors were the most typical MEs observed in Armenia.²⁷ The reports demonstrate that 31.5% of ADRs were unexpected and 11.2% of cases were rated as serious, causing such adverse health outcomes as anaphylactic shock or other disorders resulted in hospital admissions or death.²⁷ The most common ADRs were caused by the use of antimicrobial drugs, drugs used for central nervous system and gastrointestinal tract.²⁷ Comparative analysis of ADRs by organ systems demonstrated a major difference between ADRs reported in Armenia and the largest database of ADRs in the world VigiBase, the WHO safety database.²⁷ For instance, allergic reactions in Armenia constituted 22% of total ADRs, which is 5.5 times higher compared to 4% reported by the WHO.²⁷ Gastrointestinal disorders and visual impairments detected in the RA exceeded the numbers reported by the WHO by 2.3 and 1.5 times, respectively.²⁷

This project focuses on MEs that occur in pharmacies and the role of community pharmacists in their prevention. MEs can be reduced by clearly defining the roles of community pharmacists and pharmacy technicians, and by requiring a licensed pharmacist to be present at pharmacies throughout the working day, who will be responsible for each dispensed medicine.²⁸ A multicomponent analysis of key determinants will provide better understanding of recommended strategies and interventions for prevention of MEs.

Objectives

The aim of the project is to improve patient safety by improving community pharmacy practices and preventing MEs in Armenia.

In particular, the project objectives are to: 1) identify the roles of community pharmacists and pharmacy technicians in reducing MEs in Armenia, 2) find the gaps in the legislation and regulation of community pharmacies' functions and staff, and identify strategies to fix the gaps to ensure the provision of only high-quality pharmaceutical care in Armenia, and 3) introduce the transformation of pharmacy practice with focus on patient-centered care in Armenia.

The recommended strategies should be evaluated according to their effectiveness, feasibility, cost and political acceptability criteria.

Key determinants

There are many factors that affect patients' safety, which together may have a multiplicative effect on the likelihood of MEs. The factors that affect MEs in Armenia can be categorized as follows: a) factors associated with healthcare providers, b) factors associated with the healthcare system or/and working environment), c) factors associated with patients, and d) factors associated with medicine itself.⁵ This is a complex issue; therefore, the implementation of several strategies will be required to achieve effectiveness in ensuring patient safety at the community pharmacy level. Potential recommendations/strategies will be discussed in the section below. Key determinants can be classified into four groups.⁵

a) Factors associated with healthcare providers

Prescribing errors by physicians

The majority of MEs occur at the prescribing phase.²⁹ Prescribing errors make up 18.9-58.4% of MEs in adults and 68-75% in children.^{7,29} Prescribing errors include any unintended error which occurs in the prescribing (decision-making) or prescription writing process that may lead to harming patients, such as the identity of the drug, dose, administration route, time and duration of administration. In the RA, only physicians and dentists are entitled to prescribe medications to patients.³⁰

In 2020, a survey was conducted among General Practitioners (GPs) in Yerevan, Armenia to examine their Knowledge, Attitude and Practice (KAP) regarding the antibiotic resistance.³¹ The study results demonstrate that the vast majority of GPs, selected from the biggest polyclinics, have had low scores of knowledge, attitude and prescribing practice.³¹ For instance, 43% out of 291 participants chose wrong antibiotic when they were asked to select a safe antibiotic for pregnant women and more than 60% of selected GPs gave an incorrect answer to the question “which is the best preparation against anaerobes”.³¹ Lack of knowledge and training of GPs and improper prescribing practices, documented in the aforementioned study, testify to regular unintended failure in the decision-making process when prescribing medications.³¹ No studies aiming to identify the magnitude of prescribing errors were conducted in Armenia.

Community pharmacists may partially address errors noticed in the medical prescription.¹⁸ Pharmacists' roles in identification of prescribing errors include: 1) checking for errors when getting prescriptions and refer to the prescriber for clarifications before dispensing medication, 2) ensuring that newly prescribed medications can be safely used with chronically consumed ones, and 3) contacting prescribers to provide additional information

about individual patients (such as results of monitoring of a patient, drug allergies, etc.).¹⁹ Improper dosage is the most common prescribing error identified by pharmacists during the provision of pharmaceutical care, which proves that pharmacists can play crucial role in intercepting prescribing errors if they are trained and educated properly.¹⁹ The majority of studies on MEs have been conducted in primary or secondary healthcare settings, since conducting a study in community pharmacies requires more resources and time. However, a few studies found that community pharmacists also may have valuable contribution in identifying and preventing prescribing errors.³² A study conducted in the USA demonstrated that out of 623 identified prescribing errors, 28% could result in injuries for patients if not prevented by community pharmacists.³² Each of the prevented cases was estimated to save 123 USD on average, resulting in notable healthcare savings if extrapolated to the whole system.³² However, more research is required to show the effectiveness of medication review by community pharmacists in reducing prescribing errors.

Undifferentiated roles of community pharmacists and pharmacy technicians

The role of community pharmacists has now been significantly expanded and shifted from the traditional product-oriented functions, including dispensing and distribution of medicines, to a more patient-oriented approach.³³ Modern community pharmacy services in HIC include not only supply of drugs and provision of appropriate drug information and advice for patients, but also the optimization of drug therapy, as well as prevention and detection of drug-related problems.³³ Community pharmacies also provide preventive care services, such as monitoring chronic diseases, screening for some diseases (e.g., diabetes, hypertension), health promotion and organization of campaigns and programs (e.g., smoking cessation, family planning), and promotion of rational prescribing and proper use of medicines.³³

Community pharmacy staff is uniquely positioned at the forefront of the healthcare system, which allow them to facilitate self-care and shape patients' decisions.³⁴ Many authority organizations, including the WHO, have highlighted that the ability of pharmacists to communicate with patients and facilitate self-care can reduce MEs and improve adherence to treatment.⁵ Nonetheless, due to the shortage of pharmacists, spread of self-medication and lack of regulations in LMIC, pharmacy technicians very often replace pharmacists and start to play an important role in the health of people by providing drug consultation and advising patients.^{35,36} According to the National Institute of Health of the Republic of Armenia (NIH RA), the total number of pharmacists graduating from both state and private medical universities from 2000 to 2017 amounted to 1,333 with an average of 73 graduates per year, while the mean number of pharmacy technicians graduating from medical colleges was 575 per year (see Figure 4).³⁷ Thus, the average number of pharmacy technicians exceeds the number pharmacists by seven times a year. In contrast, in Soviet Armenia, where the roles of pharmacists and pharmacy technicians were differentiated, the number of pharmacists was greater than the total number of pharmacy technicians by several times.³⁸ This data was also proved by the largest pharmaceutical chains in Armenia, namely Alfa pharm and Natali pharm, with the total number of employees over 1,000, where pharmacy technicians comprise the vast majority of pharmacy workers and are responsible for health-related outcomes of the community members. However, it has been demonstrated that the pharmaceutical care provided by pharmacy technicians is inferior in quality compared to that of pharmacists.^{39,40,41} Numerous studies have shown that pharmacy technicians are more likely to make errors in drug names, provide incorrect strength of a drug or wrong formulation of a drug compared to pharmacists.^{42,28} In more than 50% of those cases, pharmacists identified an error during medication review, thereby preventing the error from reaching a patient.²⁸ A cross-sectional study conducted in Iran, estimated the mean score of knowledge and MEs of

101 pharmacy technicians working in Qom city.⁴¹ Study participants were given 1 point for each false answer and 0 point for correct answers. The study showed that the mean knowledge score of the pharmacy technicians was 5.72 out of 11 possible, while the mean score of MEs was 6.68 out of 11.⁴¹ Another study conducted in the UK revealed that pharmacy technicians were more likely to give inappropriate medication advice than pharmacists, leading to dangerous drug-drug interactions.⁴³ Moreover, two-thirds of their consultations were rated unsatisfactory in comparison with a quarter of visits handled by a pharmacist.⁴³ A significant difference in knowledge about pharmaceutical care between pharmacists and pharmacy technician was demonstrated in many studies, which can be critical for the population.^{44,45,46}

It was proved that community pharmacists in the UK detected 85% of MEs before they reached a patient.⁴⁷ Pharmacists in HIC have had significant contribution to the reporting of drug-related problems, such as ADRs and MEs, which are the strongest indicators of quality of care.³³ For instance, 88.3% of all ADR reports in Canada were received from pharmacists, 40.3% of ADR reports came from pharmacists in Australia, 40.2% in the Netherlands, 39% in Japan, 25.9% in Spain, and 23.4% in Portugal.⁴⁸ More than 1,000 ADRs reports were submitted by pharmacists in each of the aforementioned countries within a year.⁴⁸ Many pharmacists in LMIC countries have also shown great success in reporting drug-related problems.^{49,50} According to the Uppsala Monitoring Center (UCM), such countries as Singapore, Taiwan, Malaysia, South Africa and Egypt receive more than 100 pharmacists' reports on ADRs per country per year.⁴⁸ According to the literature, the level of involvement of pharmacists in ADRs reporting is directly linked to the function of pharmacists in the healthcare system.⁴⁸

In the RA, a total of 32 ADR reports were provided by pharmacists and pharmacy technicians over 10 years, making up 2% of the total number of reports on ADRs received by

the state regulatory body, which proves a lack of responsibility among community pharmacy workers for patient safety.²⁷ One of the reasons for insufficient number of reports from community pharmacy staff in Armenia is the lack of legislation explaining the scope of the work of pharmacists and pharmacy technicians. In the RA, the functioning of community pharmacies is regulated by the Armenian “Law on Drugs”, “Law on licensing”, Civil Code and Law on State Duty. Unfortunately, none of these laws define the roles of pharmacists and pharmacy technicians. Thus, community pharmacy workers do not have a clear understanding of their rights and responsibilities, which leads to the failure of the optimal functioning of the pharmaceutical and healthcare systems in Armenia.

Low level of education and lack of trainings of community pharmacy staff

Pharmaceutical education plays a vital role in creating highly professional workforce, represented by skilled and trained pharmacists and pharmacy technicians, which is one of the key elements for ensuring patient safety at community pharmacies.

According to the information collected from the websites of three most respected state universities in Armenia, namely Yerevan State Medical University (YSMU), Yerevan State University (YSU) and Russian-Armenian University (RAU), the main focus of both undergraduate and graduate programs still remains product/drug oriented.^{51,52,53} The curriculum of these programs consists of different branches of chemistry, toxicology, pharmacology, pharmacokinetics, pharmacognosy, clinical pharmacy and other product-oriented disciplines, whereas no patient-oriented disciplines, such as patient safety, pharmacovigilance, pharmaceutical care, inter-professional collaboration, pharmacy law were included in the curriculum.^{51,52,53,54} It has been proven that patient-focused education prepares healthcare providers to provide better pharmaceutical care and be more responsible for patient safety.⁵⁵

Moreover, information provided to the students, is built mainly on Soviet or Russian sources, which are sometimes outdated and inapplicable in modern, dynamically developing pharmaceutical world.⁵⁴ Since the materials are not being updated regularly, the latest information on the potential harm versus benefits of drugs is not presented to students. As a result, some toxic drugs, which were withdrawn from pharmaceutical markets because of the severity of ADRs, are still being taught in the universities as preferable examples of treatment.

There is a huge gap between pharmaceutical education and pharmacy practice in Armenia.³⁸ When graduates of pharmaceutical programs come to practice, it becomes obvious that a very small part of their knowledge is applicable to practice, and certain important knowledge and skills are missing.³⁸ The survey conducted among last-year students and fresh graduates of YSMU and YSU showed that more than 80% of study participants rated the knowledge provided by their university as moderate and mentioned that they need additional professional training.³⁸ The graduates demonstrated a lack of knowledge on essential medications, pharmaceutical formularies and list of prescription drugs, classifying antimicrobial drugs and steroids as over-the-counter (OTC) drugs.³⁸ As a rule, fresh graduates with a lack of knowledge and experience are more likely to make errors, thereby threaten patient' health.

Life-long learning is an important part of the pharmaceutical profession. Since pharmaceutical market is dynamically developing, specialists must be aware of all recent studies regarding effectiveness and safety of medications. According to the Good Pharmacy Practice (GPP) standards and the Law of the RA on the Provision of Medical Aid, specific number of trainings should be filled by pharmacists and pharmacy technicians every five years.^{30,56} However, since community pharmacy workers have the right to choose which trainings they should attend, such important topics as drug safety, standards of pharmacy

practice, and pharmacy law might be overlooked. According to the National Institute of Health of the RA (NIH), the number of pharmacists participated in trainings in recent years decreased by 10 times.⁵⁷ Training series on pharmacovigilance were organized by the Scientific Center for Drugs in collaboration with the WHO regional office to improve knowledge of healthcare providers about drug-related problems, ADRs, and the reporting systems. However, the vast majority of pharmacists and pharmacy technicians refused to participate in the trainings.²⁷

To ensure only high-quality continuous professional trainings are provided to specialists, different stakeholders should be engaged in the learning processes.

b) Factors associated with the working environment/health system

Lack of standardized protocols and procedures

A standardized method for providing pharmaceutical care is essential for ensuring quality of care.⁵⁸ The American Society of Health-System Pharmacists (ASHP) has developed guidelines on a Standardized Method for Pharmaceutical Care, which emphasize the importance of having consistent form for collecting information about each patient, identifying drug-related problems and having a standard monitoring plan.⁵⁸ The International Pharmaceutical Federation (FIP), in collaboration with the WHO, has developed standards for services provided in pharmacies - Good Pharmacy Practice (GPP).⁵⁹ National standards of 37 countries have been modified based on GPP requirements, and consultations were provided to more than 120 Member Countries.⁵⁹ GPP standards ensure only high quality pharmaceutical care is provided to patients.⁵⁶ Appropriate drug consultations, health promotion, preventive services and patient treatment monitoring are described. Moreover, according to GPP standards, “a system should exist that enables pharmacists to report and to obtain feedback about adverse events, drug-related problems, MEs, misuse or drug abuse,

defects in product quality or detection of counterfeit products.”⁶⁰ Standard Operating Procedures (SOPs) make it clear what steps should be implemented by each community pharmacy worker to ensure that GPP is followed.⁶⁰ However, despite the fact that the rest types of Good Practices (GMP, GDP) developed by the WHO for improving pharmaceutical sector have been implemented in Armenia, the GPP standards have not been adopted by the Government of Armenia yet.

A standard form for reporting ADRs has been developed in Armenia more than a decade ago. ADRs can be reported through the website, mobile application, hotline or filling the printable forms. However, a ME reporting system has not yet been developed, which is crucial for understanding the magnitude of the problem in Armenia.

The lack of SOPs significantly contribute to MEs.⁶¹ For instance, pharmacists in the RA try to make an assumption about the drug name, the dose or administration route, which is unacceptable and can result in serious errors. To reduce such errors, all the necessary steps for various situations, such as calling the physician if the prescription is not clear, are usually provided in SOPs.⁵⁸

Lack of licensing of pharmacists/pharmacy technicians

The requirements for obtaining a pharmacist’s license differ across countries. In LMIC, due to the shortage of pharmacists, the licensure requirements are minimized to a Pharm D degree obtained from an accredited university.⁶² In contrast, in such HIC as the USA and Canada, pharmacists should complete four-year university studies, followed by at least one-year internship in community pharmacies, pass the North American Pharmacist Licensure Examination (NAPLEX), and pass a pharmacy law exam in order to get a license.⁶³ In most HIC, obtaining a pharmacist’s license requires also language skills, certificate of good health, and absence of criminal records.⁶⁴

The license in the RA is provided only to the institution (community pharmacies in this case), but not to the community pharmacy workers.⁶⁵ There are different types of licensing of community pharmacies in Armenia. The regular license, provided to community pharmacies in the RA, includes the right to sell both OTC and prescription drugs, but does not include the right to distribute narcotic or psychotropic drugs or prepare medications at pharmacies. The license of a community pharmacy is provided outright, which means that it cannot be revoked.⁶⁶ There are no professional requirements for community pharmacy staff, set by the “Law on Licensing”, apart of having a diploma of a pharmacist or pharmacy technician from an institution accredited by the RA.⁶⁶ Armenia is the only country of Commonwealth of Independent States (CIS), where a diploma equals a license.⁶⁷ Thus, immediately after graduation, students coming from different institutions (i.e. colleges, universities etc.) with different level of knowledge automatically receive the right to work in a community pharmacy. Nowadays, there is no standard mechanism in Armenia for verifying their competency in pharmaceutical care and knowledge about their rights and responsibilities. Hence, the lack of licensing of healthcare providers combined with a low level of medical educational standards in the country result in trusting pharmaceutical activity to professionals who might not be able to provide safe pharmaceutical care. Since healthcare providers do not pass state examination on law, such legal issues as mandatory ADR reporting, remain unknown to the providers. Moreover, there is no mechanism to ban a pharmacy worker’s activity in case of violations of the Labor Code of the RA, since the only basis for their activities is a diploma that cannot be revoked. Thus, in case of professional violations causing harm to patients, an administrative penalty or imprisonment (if a patient died) can be applied.⁶⁸ However, after taking the punishment, the healthcare provider can legally continue working in the same position.

Notwithstanding, there are specific requirements for continuous professional development of medical workers in the RA in order to get the right to continue provision of medical care.⁶⁹ According to the Governmental Decree N20 from 26.04.2019, pharmacists should collect 160 credits in a five-year period, whereas pharmacy technicians are obliged to collect 100 credits within the same period every five years as part of continuous professional development requirements.⁶⁹ Credits can be collected either through participation in seminars, conferences and trainings, approved by the MOH, or through publications.⁶⁹

Distractions and interruptions

Distraction is considered one of the major causes of MEs. The vast majority of all MEs can be related to distractions.⁷⁰ Distractions often happen when the attention of a healthcare provider is switched or redirected to another subject/ person. The most common distractions are considered phone calls, as well as distractions from colleagues and patients.⁷¹ Distractions and interruptions play a crucial role in MEs during all stages of the medication use process.⁷¹ All healthcare providers experience performance errors, which occur when a specialist has enough knowledge and skills but can make an error because of inattentiveness.⁷² The negative impact of distractions and interruptions on MEs and patient safety have been studied for decades and proved by different researchers.⁷³ Distractions and interruptions of community pharmacy workers result in an increased number of dispensing errors.

In Armenia, there is no separate space for consultations in community pharmacies; therefore, communication with patients takes place in the main hall of a pharmacy, where other patients might wait for their turn, which makes the pharmacy worker rush. This is especially important for pharmacies with drug preparation department. According to the IOM, drug preparation in a pharmacy is associated with the greatest risk of error since this type of activity is usually performed for children or patients with rare conditions for which

orphan drugs are not available.⁷ Pharmacist's knowledge and skills are required to compound a new form of medication from available chemicals. Therefore, an extreme concentration and attention of a pharmacist during this process are essential, as any distraction and interruption may result in incorrect calculation of the required dose or incorrect labelling.

c) Factors associated with patients

Patient characteristics

Many studies have shown that such patient characteristics as age, complexity of clinical case, multi-morbidity and polypharmacy have significant impact on MEs and ADRs.^{74,75}

Older adults and children are at higher risk for ADRs and medication-related problems than young adults.⁷⁶ According to the study conducted in the Czech Toxicological Information Centre (TIC), up to 88% of severe drug intoxications due to MEs were registered among these two groups of patients.⁷⁷ The retrospective analysis of the toxicological records registered during 2000-2010 years showed that the most widespread MEs amongst older adults and children were dosage errors (60.9%), errors in selecting medication (19.3%) and incorrect route of administration (12.9%).⁷⁷ Despite the fact that seniors make up 13% of the US population, they consume more than 30% of all medications purchased in the country, which increases the risk of MEs and ADRs.²⁴ The reports on ADRs in European Union showed that 30% of all ADRs were registered among people aged 65 and above.⁷⁶

The literature suggests that MEs occur three times more often among children compared to young adults.³ A recent systematic literature review of epidemiology of MEs in pediatric care showed that 5 to 27% of children experience MEs during drug use.⁷⁸ Dosage errors are the most widespread MEs among children since the dose is often calculated individually based on the BMI of a child.³ However, it was proved that better prescriber-

pharmacist communication as well as pharmacist's review of the medication order can significantly reduce MEs in children.⁷⁹

Complexity of clinical cases

Polypharmacy (or taking more than five medications simultaneously) is one of the most common consequences of multi-morbidity (having two or more chronic conditions).⁸⁰ In some cases, polypharmacy is beneficial for patients, however, when multiple drugs are prescribed or used inappropriately, the potential harm of such polypharmacy can outweigh the benefits, thus increasing the likelihood of ADRs and drug-drug interactions irrespective of patients' age.⁸⁰

People aged 65 and above are more likely to have multiple chronic conditions and subsequent polypharmacy. The systematic literature review showed that the prevalence of polypharmacy among older adults living in long-term care facilities varied from 38.1 to 91.2%, globally.⁷⁴ A population-based cross-sectional study conducted in New Zealand in 2005-2013 demonstrated that the prevalence of polypharmacy among older adults aged 65 and above was 29.5%.⁷⁴ According to the WHO, the number of routinely taking medications increases the rates of MEs.⁷⁴ For instance, the risk of MEs among patients taking five medications was 30%, whereas the risk of MEs among patients taking 10 medications was 47%, which clearly demonstrates that the ME rate increased with an increase in the number of taking medications.⁷⁴ Another study conducted in the United Kingdom showed that over two-thirds of older adults in long-term care facilities experienced MEs with the mean number of observed ME per resident equal to 1.9.⁸¹

d) Factors associated with medicines

“Look Alike/Sound Alike” medications

The wide range of drugs and variations in drug names require additional concentration and attention from the pharmacy worker, since many drugs “look alike or/and sound alike.” Similar names of drugs create room for human error. Look Alike/Sound Alike (LASA) drugs account for 25% of all MEs.⁸² LASA medications are a major concern of many authority organizations, such as the WHO, the US Food and Drug Administration (FDA) and others.⁸³ In 2000, the IOM published its first report on MEs “To Err is human”, which had a great influence on the policies of different organizations.⁶ Immediately thereafter, the FDA took specific actions to reduce MEs associated with LASA drugs in the USA.⁸² In particular, approximately one third of new drug names have been rejected by the FDA because of similarities with existing drug names.⁸² Likewise, in order to reduce the probability of human error, unique bar codes were required to be added on all drug packages to make the drugs identifiable by the computerized systems.⁸² However, not all countries, especially LMIC, implemented changes or took serious actions to reduce errors associated with LASA medications. The RA imports drugs not only from Pharmaceutical Inspection Co-operation Scheme (PIC/S) countries with a strict regulatory system (The USA, Canada, EU, Japan, Australia), but also from countries with less developed regulations on drug safety and monitoring. According to the current regulations of the RA, medicines containing different active ingredients, but similar sounding are rejecting in registration. However, those drugs, which were registered before the implementation of the Law on “Drugs” (2016) continue circulating in the Armenian pharmaceutical market. Thus, despite the efforts of local and international organizations to minimize the list of LASA drugs, the Armenian pharmaceutical

sector remains at high risk of MEs, unless appropriate regulatory requirements and changes in the inspection system are implemented.

Poor labeling and packaging

Proper labeling and packaging also play an important role in reducing MEs.⁵ Patients at community pharmacies in HIC are provided with complete information on the purchased medications, particularly “patient name, drug name, dosage, formulation, route, frequency, units, flow rates, duration, reconstitution information.”⁸⁴ However, in the RA there is no standard form for labelling dispensed medication. This may significantly contribute to MEs since drugs are often sold by tablets without the original packaging and proper labeling in Armenia.

A combination of different key determinants can often be observed, which increases the likelihood of MEs and ADRs.⁵ Therefore, multiple strategies need to be implemented to prevent MEs and improve patient safety in Armenia.

Proposed prevention/Intervention strategies

Defining the roles of pharmacists and pharmacy technicians

The main activities of community pharmacists and pharmacy technicians are separated in the European Union (EU), the USA, and in the majority of CIS countries, since the academic background of pharmacy technicians does not allow them to take such responsibilities as providing professional advice to patients, monitoring their treatment, promoting health programs and recording, coding and reporting MEs with or without ADRs.⁸⁵

The WHO determines the role of pharmacists as a “seven star pharmacist who is a care giver, decision maker, communicator, leader, manager, lifelong learner and a teacher.”³⁴

According to the WHO, the role of community pharmacists should include:³⁴

- Providing reliable information to patients on prescribed drugs
- Providing comprehensive data on potential side effects of medicine
- Monitoring effects of treatment
- Ensuring that drug-drug interaction is safe
- Managing long-term conditions
- Supervising pharmacy technicians/assistants
- Educating and training medical graduates at pharmacy level (graduate degrees and residency)
- Providing preventive care services.

The role of a pharmacy technician should include:⁵⁸

- Ordering items
- Dispensing medications
- Selling OTC drugs
- Taking in and handing out prescriptions
- Receiving, loading and unloading medications
- Referring problems to the pharmacist.

According to Dalton et al., medication reviews, handled by a pharmacist were the most successful interventions in reducing MEs and improving medication adherence.⁸⁶ The literature suggests that pharmacist-led consultations can reduce medication-related hospital admissions.⁸⁷ A randomized controlled clinical trial (RCT) conducted in the UK has shown that the pharmacist-led intervention was more effective in reducing MEs than usual care

provided in the control group.⁸⁸ In the intervention group, trained pharmacists spent 10-30 minutes counselling each patient in order to review medications, make some recommendations and changes in the prescription as needed. Pharmacists made recommendations in 75% of cases and the vast majority of those recommendations were accepted by GPs. As a result, MEs (particularly, prescribing and dispensing) were significantly reduced in the pharmacists-led group compared to regular counselling in the control group.⁸⁸

Thus, clear definition of the pharmacist's and pharmacy technician's roles with a mandatory requirement for one pharmacist to be present in a community pharmacy during all working hours may have a crucial impact on improving patient safety in the RA.

Improving pharmaceutical education/trainings

Improving the education of the healthcare providers is an essential component of the improvement of patient safety. The recommended changes in pharmaceutical education are built primarily on the Flexner's report from 1910, which sets a new standard for medical education that has proven to be effective for more than 100 years.⁸⁹ In particular, after four years of university studies at least one year of practice in community pharmacies should be completed to link formal knowledge with clinical experience and ensure that pharmacists are better prepared to take responsibility for patient care. The programs and materials used for pharmaceutical education in Armenia should be updated and revised in accordance with the international standards for pharmaceutical education. Such patient-centered disciplines as patient safety, pharmacovigilance, public health and others should be added to the curriculum.

International accreditation of medical universities should be mandatory in Armenia, since standards and indicators established for international accreditation have been proved to

improve the quality of medical education and ensure that basic requirements for competences of future medical workers are met.⁶⁷

To ensure that only high-quality pharmaceutical care is provided by community pharmacists and pharmacy technicians, new standards can be introduced in education and training programs based on the successful experience of HIC. For instance, in the USA, the medical education has undergone major reforms over the past decades. In particular, pharmacists are required to complete from six to eight years in total to get a Doctor of Pharmacy (Pharm D) degree, which is equivalent to a Doctor of Medicine (MD) degree.⁹⁰ The newest standards for education were set by the Accreditation Council for Pharmacy Education (ACPE) in July 2016 and consist of theoretical and practical components.⁹⁰ In addition to basic theoretical studies, such important disciplines as medication safety, pharmacy law and ethics, biostatistics, epidemiology, innovation, business management, inter-professional education (IPE) and pharmacy practice experiences (PPE). have been added.⁹⁰

The ACPE has also developed specific educational standards for pharmacy technicians in the USA.⁹¹ The standard requirements for pharmacy technicians include the completion of the program, passing the national certification exam, job placement, and proof of continuous quality improvement process.⁹¹ The requirements are very similar in other HIC, such as the EU, Canada, the UK and Australia.

Standards should be established also for building a chain of consistent and sequential trainings on patient safety issues as an integral part of continuous learning process. Trainings organized by the MOH, NIH and Scientific Center for Drugs on patient safety, MEs, ADRs, policy changes, and standardization of pharmacy practice should be mandatory for all community pharmacists and pharmacy technicians in Armenia. Increasing the number of

trainings on patient safety and drug safety monitoring systems is a requirement for all leading organizations worldwide.

Improvement of MEs reporting system in Armenia

All healthcare organizations, including community pharmacies, are strongly encouraged to effectively report MEs and ADRs. In most HIC, ADR reporting is mandatory for all healthcare providers. According to the Article 17 of the RA Law “On Drugs”, “health care institutions, drugstores, institutions and the organizations which are consuming and using medicines, are obliged to inform the authorized governmental body about all cases of development of unknown adverse reactions immediately”.⁹² However, due to the lack of penalties for not reporting and lack of control over drug safety, ADRs are still underreported in Armenia.²⁷ A well-organized and effective system for ME reporting should be adopted in Armenia to collect data on MEs with ADRs, MEs without harm, intercepted MEs and potential MEs, which will be beneficial not only for individual patients, whose safety will be improved, but to the healthcare system of Armenia in general, as it will disclose such an important issue as MEs. Moreover, the data on MEs, registered in Armenia, will contribute to better understanding of MEs globally.

Implementation of the electronic prescribing (e-prescribing) system

The implementation of unified e-health system is one of the main priorities of the Ministry of Health (MOH) of the RA. The e-health system has already been implemented in the primary healthcare facilities in all regions of Armenia and is planned to be introduced in community pharmacies as well. Since all purchased drugs will be recorded by the e-health system, the Health and Labor Inspection Body (HLIB) and other state regulatory bodies can easily detect any unintended error in the drug treatment process.

The literature suggests that MEs were decreased by 48% when the prescription was processed using computer systems.⁸⁷ According to the IOM, “having all pharmacies receive prescriptions electronically would result in fewer errors than occur with current paper or oral approaches”.⁷ Thanks to e-prescriptions, not only errors in the interpretation of handwriting will be eliminated, but also the information presented in the prescription will be more complete. In particular, such fields in an e-prescription as dose, frequency and administration route are required and cannot be overlooked by a physician. Moreover, the e-health system facilitates inter-professional collaboration and provides access to a patient’s medical record, which makes it easier to detect drug-drug interactions and allergies.

Introduction of licensing of pharmacists and pharmacy technicians

Licensing of healthcare professionals is necessary to ensure that an individual meets the required standards to practice. In countries with well-developed pharmaceutical market the need for strict governmental control and structural organization of the licensing bodies has been prioritized more than a century ago. For instance, in the UK, the first Pharmaceutical Society was established in 1841, and the first register of pharmacists was created in 1852 based on the level of education and exams .⁹³

Lack of licensing and registration of healthcare providers is a major issue in the RA. The registration and licensing of pharmacists and pharmacy technicians should be organized by the government agencies of the RA to ensure that minimum standards for protecting patient safety are met and to guarantee only high-quality pharmaceutical care is provided to patients by qualified healthcare professionals. Licensing of healthcare providers serves as a regulatory mechanism to set standards or monitor quality of provided services. For instance, in case of violations of professional standards, a healthcare provider’s license can be suspended or revoked.

Professional associations should be created to ensure continuous professional development, help in solving social and legal problems and negotiate with other stakeholders. Membership in a pharmacy association should be mandatory for all pharmacists and pharmacy technicians, which will allow the association to also fulfill the functions of the national registry of pharmacists and pharmacy technicians in the RA.

Raising public awareness and engagement in reducing medication errors

The IOM states that patient education is vital for positive patient outcomes and is one of the most effective ways in reducing medication administration errors.⁷ When patients better understand the importance of adherence to medication and how to respond to undesirable side effects and ADRs, they become more attentive. Patient engagement tools should be developed, taking into consideration patients' ability to be actively involved in the medicine management process. For instance, patients can be educated to double check the dispensed medicines and check whether any differences exist between prescribed and dispensed drugs. Moreover, patients should be well aware of their right to seek advice from pharmacy, including detailed information about the prescribed drug, its administration route, information on potential side effects, drug-drug interaction, etc.

Improving the safety of drug dispensing

Since labelling is the main source of drug information, state authorities of the RA should develop and implement self-adhesive labels for drugs with fields for the required information and require all pharmacies to use those labels when dispensing drugs in pills to patients. All labels must contain such information as patient name, drug name, dosage, expiry date and administration route. The labels can be filled out electronically or manually by community pharmacy staff. In addition, state authorities should compile a list of LASA medications in Armenia and distribute it to all pharmacies as a list of high-alert medications.

Further research on patient safety issues should be conducted in Armenia to better understand the magnitude of the issue and suggest specific preventive interventions.

Policy and priority setting

To assess the advantages and disadvantages of each suggested recommendation, all the proposed interventions were summarized in Table 1: Policy and priority setting. The cost-effectiveness, feasibility, political will and stakeholder support for each strategy were also analyzed and demonstrated in Table 1.

Specific recommendations

Based on the analysis of advantages, disadvantages, cost-effectiveness, feasibility, political will and stakeholder support of each intervention, the following interventions have been prioritized:

1. Require medication errors reporting
2. Define the roles of community pharmacists and pharmacy technicians
3. Implementation of the e-prescription component of the e-health system

Implementation and practice

Require Medication Error reporting

To evaluate the effectiveness of any intervention aimed to reduce MEs, it is essential to understanding the magnitude, severity and complexity of the problem, which is the first step in the prevention of the problem.⁹⁴ A ME reporting system should be developed based on the experience of other countries since not only MEs with ADRs, but also MEs without harm, intercepted errors and potential MEs that did not reach a patient contain valuable information on causes and frequency of MEs. Both mandatory and voluntary reporting

systems were considered to be effective by the IOM.⁷ Hence, not only legislation should be improved, but also regulatory bodies should consistently monitor compliance the law through regular reminders and checkups for healthcare organizations. Implementing penalties for not reporting MEs is a cornerstone in the improvement of the reporting.⁹⁵ MEs as well as ADRs can be reported using different ways, including mobile application, website, hotline and filling the printable forms. Confidentiality of healthcare providers who report on MEs should be guaranteed, otherwise they will avoid reporting self-errors for fear of punishment. Regular trainings are required to explain the importance of reporting, motivate and teach healthcare providers how to report MEs and ADRs. The only disadvantage of this strategy is the time required to reach the desired level of at least 200 reports per 1 million people per year.⁹⁶ Thus, prioritizing the problem of detecting MEs is vital to succeed in improving patient safety in Armenia.

Define the roles of community pharmacists and pharmacy technicians

The roles and responsibilities of pharmacists and pharmacy technicians should be primarily defined by law. Mandatory presence of a pharmacist in a community pharmacy throughout the working hours should also be established by law. An exception can only be made for pharmacies located in sparsely populated villages, where pharmacists are not available. In order to implement the law painlessly, the managers of the pharmacies should be given enough time to change already formed staff. The estimated time for this intervention is one electoral term.

Implementation of e-prescriptions

One of the most effective ways to reduce MEs is the implementation of e-prescriptions. For this intervention, all pharmacies will need to have a computer and an internet access. As a rule, all pharmacies belonging to pharmaceutical chains as well as most

private pharmacies use computerized systems in their daily work. Nevertheless, some remote pharmacies serving small communities may find it difficult to transition to the e-health system. Apart from setting computerized systems and basic trainings, no additional costs or resources are required for implementing e-Health in community pharmacies.

Evaluation of proposed interventions

Evaluation of the differentiating of the roles of community pharmacists and pharmacy technicians

A randomized controlled clinical trial (RCT) is suggested to evaluate the effectiveness of pharmacist-led approach in the provision of pharmaceutical care and reduction of MEs. Two groups of pharmacies with similar characteristics (such as size, number of pharmacy workers, number of patients' visits etc.) will be selected. In the intervention group, the responsibilities of pharmacists and pharmacy technicians will be clearly defined, the mandatory medication review by trained pharmacists throughout the working hours will be ensured, while the control group will continue to provide usual care. Information about the most common types of MEs and the steps that should be undertaken to prevent MEs will be provided to both groups prior to the study. Pharmacists and pharmacy technicians will record any error detected by them, as well as information on any changes and recommendations made to prescriptions by community pharmacy worker, in a standardized form over a twelve-month period. The study outcome will be the number of recorded MEs, including: a) MEs with ADR, b) MEs without harm, c) intercepted ME and d) potential MEs.

The ME rate will be calculated as the total number of detected errors per total number of prescriptions. A greater number of identified MEs will indicate the professionalism of the community pharmacy staff. A similar RCT was conducted in the UK (Pincer trial).⁸⁸ In the intervention group, pharmacists were trained to spend 10-30 minutes counselling each patient

in order to review medications and make some recommendations, whereas in the control group the staff was not trained and provided usual care to the patients.⁸⁸ As a result, pharmacist-led interventions were significantly more effective in preventing MEs compared to the usual care.⁸⁸ Moreover, the Pincer trial demonstrated that the cost per each avoided error resulted in significant healthcare cost saving, which proved also the cost-effectiveness of the pharmacist-led intervention.⁸⁸

Conclusion

MEs are one of the most alarming threats to patient safety all over the world, resulting in increased morbidity and mortality rates, hospital admissions and healthcare costs. Raising the issue of recording, reporting and assessment of MEs in community pharmacies is an integral part of providing high-quality pharmaceutical care and ensuring patient safety. Undifferentiated roles of community pharmacists and pharmacy technicians, low level of education and training of pharmacists /pharmacy technicians, lack of licensing and registration of pharmacists/ pharmacy technicians, and lack of standardized protocols and procedures are some of the main challenges in ensuring patient safety in Armenia.

International experience has shown that tremendous time, efforts, political will and stakeholder support are required for reducing MEs. Nevertheless, the recommended actions include all the main aspects of the call for actions of such authority organizations as the WHO, the IOM, the FDA and others that have proven to be the most effective and efficient strategies in preventing MEs.

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Table 1: Policy and priority setting for existing and potential intervention strategies

RECOMMENDATIONS	ADVANTAGES	DISADVANTAGES	COST	STAKE-HOLDER SUPPORT	POLITICAL WILL	FEASIBILITY
<p>1. DEFINE THE ROLES OF PHARMACISTS AND PHARMACY TECHNICIANS.</p> <p>The main activities of community pharmacists and pharmacy technicians should be separated in Armenia, since the academic background of pharmaceutical technicians does not correspond to such responsibilities as providing professional advice to patients, monitoring their treatment, especially ADRs, and promoting health programs. Pharmacists should be constantly present during all working hours to provide medication review, medication reconciliation and counselling.</p>	<p>The quality of pharmaceutical care will be significantly improved if highly qualified specialists will become responsible for the medication use process. The literature suggests that community pharmacists can detect more than 85% of medication errors before they reach a patient.⁴⁷ Moreover, pharmacist-led interventions have proven to be one of the most cost-effective ways to reduce MEs and improve medication adherence.⁸⁸</p>	<p>Since pharmacists are not available in all regions of the RA, especially in far sparsely populated villages, it will be difficult to implement the recommendation all over Armenia. However, an exception can be made for the regions, where pharmacists are not available. Time will be needed for managers of pharmacies to reconstruct the workforce. Also some pharmacy technicians may become unemployed.</p>	+	++	+++	+++
<p>2. IMPROVE PHARMACEUTICAL EDUCATION.</p> <p>Four-year university studies should be followed by at least one-year of internship in community pharmacies to</p>	<p>Changes in the educational program will create well-trained, competitive and demanded workforce with the necessary knowledge, skills and abilities. The clinical practice at</p>	<p>Systematic supervision of students should be organized in every community pharmacy during practice sessions, which requires the</p>	+++	++	++	++

+ low

++ medium

+++ high

<p>link formal knowledge with clinical experience and to ensure that pharmacists are better prepared to take responsibilities for patient care. The university curriculum used for pharmaceutical education in Armenia should be renewed and revised in accordance with international standards. Such patient-oriented disciplines, as pharmacovigilance, public health and others should be added to the curriculum. International accreditation of medical universities should be required.</p> <p>The MOH, NIH and the Scientific Center for Drugs should ensure an increase in the number of trainings on patient safety, drug safety monitoring systems, policy changes and standardization of pharmacy practice, with mandatory participation of all community pharmacists and pharmacy technicians.</p>	<p>community pharmacies is an integral part of preparing highly qualified workforce. The number of community pharmacies is several times higher than the total number of graduates from pharmacy faculties in Armenia, which allows to effectively organize practical trainings. The maximum number of graduates from both public and private universities was 119, whereas the total number of pharmacies is over 1700. Since pharmaceutical industry is one of the most dynamically and rapidly developing sectors, continuous learning process is essential to ensure that pharmacists and pharmacy technicians are aware of the latest developments in this field.</p>	<p>involvement of human resources and time Educational institutions should organize strict monitoring through progress reports. Moreover, curriculum changes require a long approval process from the Ministry of Education, MOH, as well as faculty staff training, etc. This is one of the most essential, but at the same time costly and time-consuming interventions.</p> <p>Continuous learning process requires constant involvement of all stakeholders and resources.</p>				
<p>3. IMPLEMENT e-PRESCRIPTIONS.</p> <p>Implementation of the unified e-health system was proved to reduce the likelihood of MEs.</p>	<p>Several studies showed that approximately half of MEs can be prevented thanks to the implementation of e-prescriptions.⁸⁷ Transcribing errors will be eliminated. The</p>	<p>All pharmacies, including those located in the regions, are required to have computers and internet access. Basic trainings should be</p>	+	++	+++	+++

+ low

++ medium

+++ high

	detection of undesired drug-drug interaction and drug allergies will be easier with access to the medication history.	organized for community pharmacy workers.				
4. IMPLEMENT LICENSING AND REGISTRATION OF PHARMACISTS AND PHARMACY TECHNICIANS. The registration and licensing of pharmacists and pharmacy technicians should be organized by the governmental organizations of the RA to ensure that minimum standards for protecting patient safety are met and to guarantee only high quality pharmaceutical care is provided to patients by skilled healthcare providers. Specific number of credits, which are required for re-licensure of pharmacists and pharmacy technicians in the RA, should necessarily include credits on patient safety disciplines.	The licensing and registration process aims to ensure the provision of safe pharmaceutical care to patients. The only possible way to ensure that only high-quality specialists work in the pharmaceutical sector in the RA is setting unified standards for licensure for graduates coming from different educational institutions. Professional associations can play a major role in ensuring constant professional development, inter-professional co-operation, solving some social, and legal problems.	Different tests and standards should be developed for pharmacists and pharmacy technicians, which is time and cost consuming. The licensing should be organized step by step. First, new graduates will be required to pass licensing, and then already working specialists must go through this procedure. A governmental body should be developed to be responsible for licensing, re-licensing, national registry and associations, which must be supported by appropriate legislation.	+++	++	++	+
5. REQUIRE REPORTING ON MEDICATION ERRORS WITH OR WITHOUT ADVERSE DRUG REACTIONS	Medication error reporting systems are essential to understand the magnitude of the problem, to identify the most common types of medication	Separate forms for reporting different types of MEs should be developed. Regular trainings of healthcare	+	++	+++	+++

+ low

++ medium

+++ high

<p>Oblige all healthcare organizations including community pharmacies, to effectively record, code, and report medication errors irrespective of adverse drug reactions occurrence.</p>	<p>errors, and develop the most effective strategies to prevent these errors. Appropriate reporting will allow to assess long-term improvements of patient safety.</p>	<p>providers should be organized, which is time- and resource- consuming.</p>				
<p>6. INCREASE PUBLIC AWARENESS AND ENGAGEMENT.</p> <p>Patients can be educated to double check the dispensed medicines and check for any differences between prescribed and dispensed drugs. Moreover, patients should be well aware of their right to request consultation at the pharmacy, including detailed information about the prescribed drug, its administration route, information on potential side effects, drug-drug interaction, etc.</p>	<p>Patients must be aware about the steps they may take to prevent MEs and actions in case of an error. Public awareness raising campaigns can be organized through mass and social media, advertisements, brochures and pamphlets distributed in healthcare centers.</p>	<p>A tailored approach should be developed to target specific population, yet, many patients might not be reached. The public awareness raising campaigns should be regularly revised and updated, which requires resources. Moreover, the effectiveness of this type of intervention is difficult to assess.</p>	<p>++</p>	<p>+++</p>	<p>+++</p>	<p>++</p>
<p>7. MAKE DISPENSING OF DRUGS SAFER.</p> <p>Require all pharmacies to use standardized self-adhesive labels when distributing drugs by pills to the patients, which will necessarily contain information on patient name, drug name, dosage, batch number, expiry</p>	<p>Since there is no health insurance in the RA, many patients cannot afford buying the whole package of medications. Therefore, re-packaging of medication or the process of transferring drugs into smaller packages is used for patients' convenience. Detailed</p>	<p>It is not clear who becomes responsible for the quality of re-packaged medications. Appropriate conditions for re-packaging, such as appropriate light, room air temperature and sanitary</p>	<p>+</p>	<p>+</p>	<p>+</p>	<p>++</p>

+ low

++ medium

+++ high

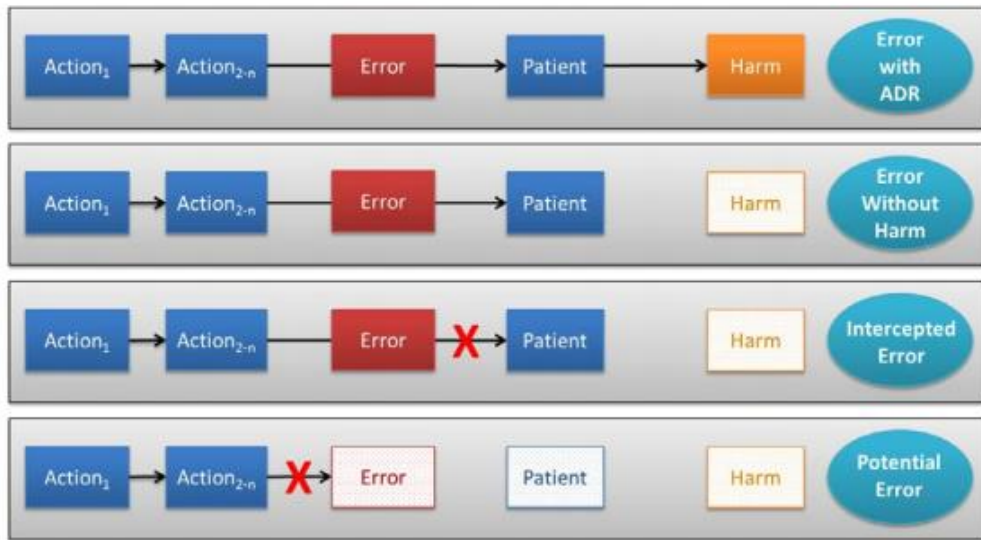
<p>date and administration route. Also, a list of LASA medications should be distributed to all pharmacies in the RA as a list of high-alert medications.</p>	<p>information will be provided to a patient or a caregiver on the labels of dispensed drugs, which will minimize medication administration errors.</p>	<p>standards should be ensured. Also, re-packaging complicates the control over dispensed drugs. It will require more time from community pharmacy staff to fill all the necessary fields on the labels.</p>				
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+ low

++ medium

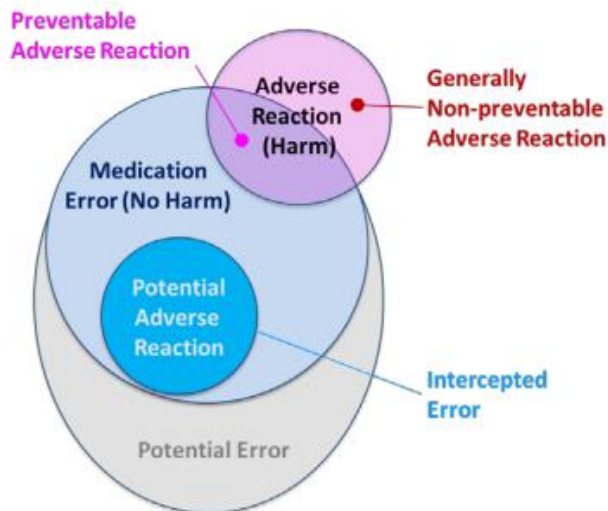
+++ high

Figure 1: Classification of MEs



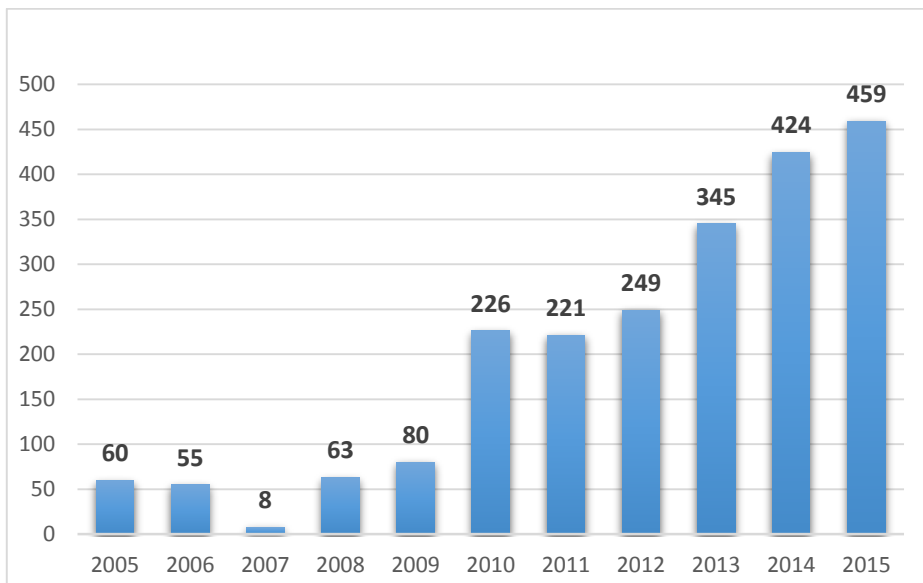
Source: European Medicines Agency. Good practice guide on recording, coding, reporting and assessment of medication errors. Eur Med Agency. 2015;(October):1-42.
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/11/WC500196979.pdf.

Figure 2: The relationship between MEs, preventable and non-preventable ADRs and intercepted errors



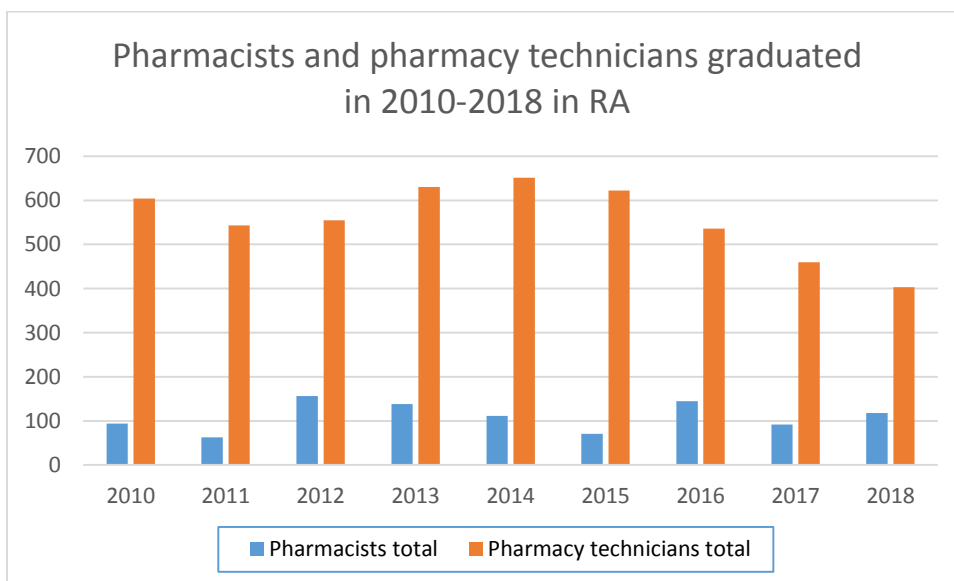
Source: European Medicines Agency. Good practice guide on recording, coding, reporting and assessment of medication errors. Eur Med Agency. 2015;(October):1-42.
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Figure 3: Reports on ADRs by years in the RA



Source: Sahakyan A.E. Romanova N. V. Development of international pharmacovigilance and the situation in Armenia. *Sci Med J.* 2016.

Figure 4: Pharmacists and pharmacy technicians graduated in 2010-2017 in the RA



Source: National Institute of Health, Republic of Armenia