Medication Without Harm

WHO Global Patient Safety Challenge

World Health Organization

Medication Safety Webinar series

"Global burden of preventable medication-related harm" and

"Policy brief on Medication Without Harm"

Thursday, 07 March 2024

14:00 – 15:30 CET

World Health Organization

Patient Safety

MEDICATION WITHOUT HARM
Global Patient Safety Challenge

WHO Medication Safety Webinar series – initiated for WPSD 2022

Covered many important topics on medication safety

- High risk situations

- Polypharmacy

- Transitions of care

- Medication error reporting and learning

- Patient engagement

- Medication safety for look-alike, sound-alike medicines

"Global burden of preventable medication-related harm" and

"Policy brief on *Medication Without Harm*"

- This session is being recorded and your attendance is consent to be recorded.

Use Q&A feature for questions regarding the topic and presentations
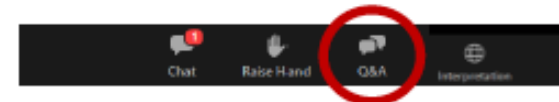
Use Chat feature for questions regarding IT, logistics

Medication Without Harm

WHO Global Patient Safety Challenge
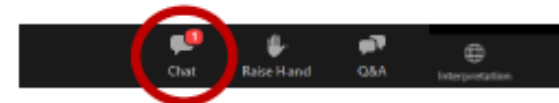
Preamble

- Medical errors are a leading cause of patient harm in healthcare – highlighted from 1999's

- UHC has led to increased access to medicines and, more medication errors and related harm too

- WHO response – A Decade of Patient Safety 2021-2030

  - Key initiative: Global Patient Safety Challenge: *Medication Without Harm*

  - Global Patient Safety Action Plan 2021-2030

Burden of avoidable medication harm

Most patient harm in healthcare is **avoidable**

Medication-related harm accounts for **50% of overall avoidable harm** in medical care

One in 20 patients globally experience preventable medication harm

25% of preventable harm is considered severe or life-threatening
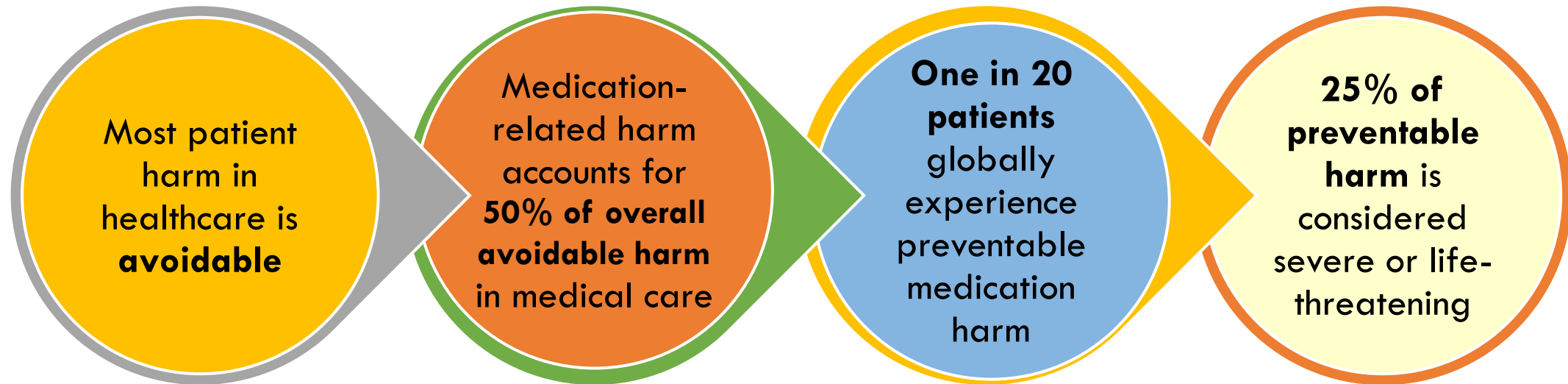
WHO Global Patient Safety Challenge
Medication Without Harm
Global Launch, 29 March 2017

Reduce the level of severe, avoidable harm related to medications by 50% over 5 years, globally

Strategic Framework and Key Action Areas

Domains

- Patients and the public

- Medicines

- Health and care workers

- Systems and practices of medication

Key action areas

- High-risk situations

- Polypharmacy

- Transitions of care

Patient Safety

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SEVENTY-SECOND WORLD HEALTH ASSEMBLY   WHA72.6

Agenda item 12.5   28 May 2019

Global action on patient safety

The Seventy-second World Health Assembly,

Having considered the report by the Director-General on global action on patient safety;[1]

Recalling resolution WHA55.18 (2002), which urged Member States to "pay the closest possible attention to the problem of patient safety; and to establish and strengthen science-based systems, necessary for improving patients' safety and the quality of health care"; recognizing that patient safety is a critical element of, and the foundation for, delivering quality health care; and welcoming the inclusion of the need for patient safety in the Thirteenth General Programme of Work, 2019–2023;

Recognizing that patient safety cannot be ensured without access to: safe infrastructure, technologies and medical devices, and their safe use by patients, who need to be well informed; and a skilled and committed health workforce, in an enabling and safe environment;

Noting that patient safety builds on quality, basic and continued education and training of health professionals that ensures that they have the adequate professional skills and competencies in their respective roles and functions;

Recognizing that access to safe, effective, quality and affordable medicines and other commodities, and their correct administration and use, also contribute to patient safety;

Noting further the importance of hygiene for patient safety and the prevention of health care-associated infections, and for reducing antimicrobial resistance;

Noting that ensuring patient safety is a key priority in providing quality health services and considering that all individuals should receive safe health services, regardless of where they are

...ple of "First do no harm" and recognizing the benefits to be gained and the ...e patient safety across health systems at all levels, sectors and settings ...al health, especially at the level of primary health care, but also including, ...community care, rehabilitation and ambulatory care;

...afety of patients during the provision of health services that are safe and of ...e for strengthening health care systems and making progress towards

¹ Document A72/26.

- ✓ Adopted WHA resolution "Global action on patient safety" (WHA72.6)

- ✓ Recognized Patient Safety as a global health priority

- ✓ Established an annual World Patient Safety Day on 17 September

- ✓ Formulate a Global Patient Safety Action Plan 2021-2030

- URGES Member States to implement the WHO Global Patient Safety Challenge: *Medication Without Harm*

- REQUESTS the Director-General to design, launch and support **Global Patient Safety Challenges**', and to develop and implement strategies, guidance and tools to support Member States in implementing each Challenge, using the best available evidence

Global Patient Safety Action Plan 2021-2030

7x5 matrix includes several strategies to improve medication safety

Framework for Action - The 7x5 Matrix

1	Policies to eliminate avoidable harm in health care	1.1 Patient safety policy, strategy and implementation framework	1.2 Resource mobilization and allocation	1.3 Protective legislative measures	1.4 Safety standards, regulation and accreditation	1.5 World Patient Safety Day and Global Patient Safety Challenges
2	High-reliability systems	2.1 Transparency, openness and No blame culture	2.2 Good governance for the health care system	2.3 Leadership capacity for clinical and managerial functions	2.4 Human factors/ ergonomics for health systems resilience	2.5 Patient safety in emergencies and settings of extreme adversity
3	Safety of clinical processes	3.1 Safety of risk-prone clinical procedures	3.2 Global Patient Safety Challenge: *Medication Without Harm*	3.3 Infection prevention and control & antimicrobial resistance	3.4 Safety of medical devices, medicines, blood and vaccines	3.5 Patient safety in primary care and transitions of care
4	Patient and family engagement	4.1 Co-development of policies and programmes with patients	4.2 Learning from patient experience for safety improvement	4.3 Patient advocates and patient safety champions	4.4 Patient safety incident disclosure to victims	4.5 Information and education to patients and families
5	Health worker education, skills and safety	5.1 Patient safety in professional education and training	5.2 Centres of excellence for patient safety education and training	5.3 Patient safety competencies as regulatory requirements	5.4 Linking patient safety with appraisal system of health workers	5.5 Safe working environment for health workers
6	Information, research and risk management	6.1 Patient safety incident reporting and learning systems	6.2 Patient safety information systems	6.3 Patient safety surveillance systems	6.4 Patient safety research programmes	6.5 Digital technology for patient safety
7	Synergy, partnership and solidarity	7.1 Stakeholders engagement	7.2 Common understanding and shared commitment	7.3 Patient safety networks and collaboration	7.4 Cross geographical and multisectoral initiatives for patient safety	7.5 Alignment with technical programmes and initiatives

GLOBAL PATIENT SAFETY ACTION PLAN 2021–2030

Towards eliminating avoidable harm in health care

Patient Safety

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Implementation of the Global Patient Safety Action Plan 2021–2030

INTERIM REPORT
Based on the *FIRST SURVEY* of patient safety in WHO Member States

APRIL 2023

18%
Percentage of countries that have established their national targets on reducing medication-related harm

World Patient Safety Day 2022
Theme: Medication Safety

Consolidated the work of the
WHO Global Patient Safety Challenge:
Medication Without Harm

Medication Safety Resources

Join us in achieving...
Medication Without Harm

WHO Global Patient Safety Challenge

5 Moments for Medication Safety

Starting a medication
Taking my medication
Adding a medication
Reviewing my medication
Stopping my medication

WHO medsafe

Medication Safety in High-risk situations

Technical Report

Medication Safety in Transitions of Care

Technical Report

Medication Safety in Polypharmacy

Patient Safety — World Health Organization

Medication safety for look-alike, sound-alike medicines

Technical Series on Medication Safety Solutions

BEFORE YOU GIVE IT...
KNOW your medication
CHECK you have the right
☑ patient
☑ medicine
☑ route
☑ dose
☑ time
ASK your patient if they understand

BEFORE YOU TAKE IT...
KNOW your medication
CHECK the dose and time
ASK your health care professional

Medication safety global campaign
KNOW.CHECK.ASK

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Global burden of preventable medication-related harm in health care

A systematic review

MEDICATION WITHOUT HARM
Global Patient Safety Challenge

Patient Safety

World Health Organization

Medication without harm

Policy brief

MEDICATION WITHOUT HARM
Global Patient Safety Challenge

Overview of contents

- Summary

- Background

- Aims of the report

- Methods

- Results

- Discussion

  - Summary of main findings

  - Strengths and limitations

  - Lessons learned and implications for research, policy and practice

  - Recommendations for measuring medication related harm at point of care

- Conclusion

Results

- Studies included, characteristics of studies (total and LMIC-based)

- Characteristics of populations

- Meta-analysis

- Prevalence by LMIC, WHO regions and medical settings

- Severity of preventable medication-related harm, including harm resulting in death

- Stages of medication use process where harm occur

- Main drug classes associated with medication-related harm

- Vulnerable populations, locations and medical settings

Global burden of preventable medication-related harm in health care

A systematic review

Overview of contents

- Executive summary

- Key messages

- Introduction

- Key concepts

- Background

- Errors during the medication use process

- Scale of errors and contributory factors

- Policy options to address medication errors

- The three key action areas of the strategic framework
  - High-risk situations
  - Polypharmacy
  - Transitions of care

- The four domains of the strategic framework
  - Patients and the public
  - Medicines as products
  - Health and care workers
  - Systems and practices

- Summary of the evidence, facts and findings

- A pledge to sign

- Glossary

Background

❑ Reducing medication harm in healthcare delivery is at the forefront of policy and practice

❑ Total medication harm is estimated around 6-13%

➢ Some of this harm is inevitable and some preventable BUT

➢ We do not know the prevalence rates, the core types and severity of preventable harm

❑ Need to focus efforts in reducing preventable harm

➢ Better understanding of the prevalence and nature of preventable harm could help policy makers to devise more efficient and reliable plans to deal with preventable medication harm

Medication Without Harm

*"On March 2017, the World Health Organisation launched a global initiative to look at ways to reduce severe, preventable medication associated harm in all countries by **50%** over the **next 5 years"***

3 early priority actions:

- Polypharmacy
- High risk situations
- Transfers of care

Third Global Patient Safety Challenge

World Health Organization

Relationship between medication errors and ADEs (Definitions)

Medication Error (ME): "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use".

Adverse Drug Event (ADE): "Any injury resulting from medical interventions related to a drug. This includes both adverse drug reactions in which no error occurred and complications resulting from medication errors. In the pharmacovigilance field referred as Adverse Events (AE)".

Medication-related harm: "The harm caused by medication if taken incorrectly, monitored insufficiently or as the result of an error, accident or communication problem".

Preventable medication-related harm: "Medication-related harm was considered preventable when (i) it occurred as a result of an identifiable, modifiable cause and (ii) future recurrence of medication-related harm could be prevented with reasonable adaptation to a process and adherence to guidelines".
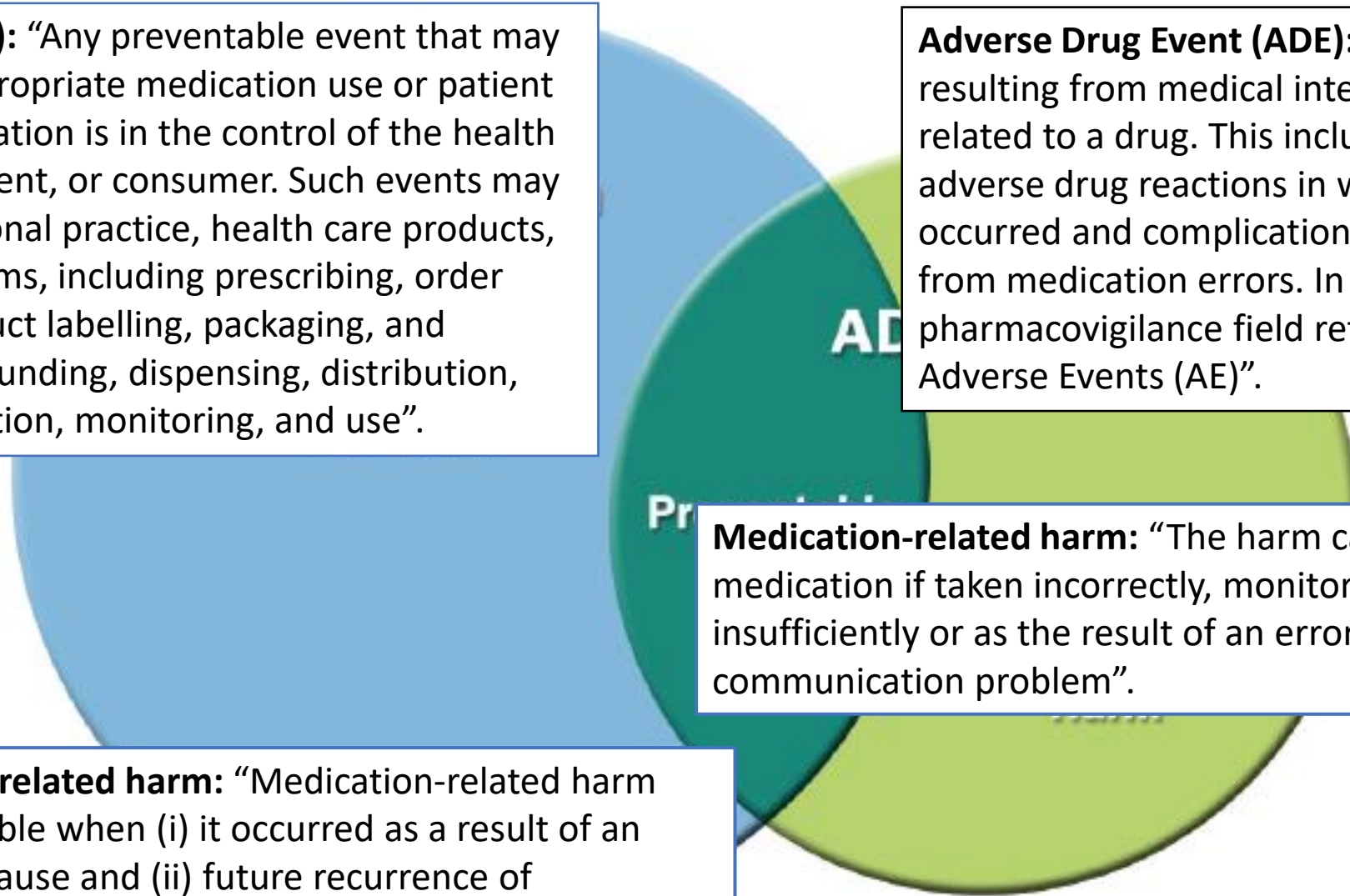
Aims of WHO Commissioned Work

❑ Provide the most up-to-date estimates of the prevalence, nature and severity of preventable medication harm globally

❑ Describe the prevalence, nature and severity of preventable medication harm in low to middle income countries (LMICs)

❑ Describe variations in the methods used to measure and report medication harm and assess the impact of these variations on the prevalence of preventable medication harm

Methodology

❑ 5 electronic databases searched

❑ Meta-analyses:

➢ Prevalence of preventable medication harm
➢ LMIC vs. HICs
➢ Proportions by severity
➢ Prevalence by medical care setting

❑ Data extracted from studies and transformed into a common metric to allow for prevalence calculation

Hierarchy of Evidence

Strength of Evidence

Systematic Reviews

Randomized Controlled Trials

Cohort Studies

Case Reports

Expert Opinion

Adopted from: Sackett DL, Straus SE, Richardson WS, et al. *Evidence-based medicine: how to practice and teach EBM.* 2nd ed. Edinburgh: Churchill Livingstone, 2000

Previous studies

Identification

Studies included in previous version of review (n = 81)

Identification of new studies via databases and registers

Records identified from*:
Databases (n = 2321)

Records removed *before screening*:
Duplicate records removed (n =334)

Identification of studies set in LMIC excl from previous review

Records from previous review (n = 325)

Records removed *before screening*:
Duplicate records removed (n = 8)

Screening

Records screened (n = 1987)

Records excluded (n = 1934)

Records screened (n = 317)

Records excluded (n = 292)

Reports sought for retrieval (n =53)

Reports not retrieved (n = 0)

Reports sought for retrieval (n = 25)

Reports not retrieved (n = 0)

Reports assessed for eligibility (n =53)

Reports excluded:
Adverse events 1 (n = 7)
Disease specific populations (n = 13)
No useable prevent data (n = 13)
Other (5)

Reports assessed for eligibility (n = 25)

Reports excluded:
Adverse events (n = 11)
Disease specific populations (n = 2)
No useable prevent data (n= 5)
Other (n = 3)

Included

Studies included from latest searches (n = 15)
-Studies excluded from previous review now eligible (n= 4)

Total studies included in review (n = 100)

Preventable Medication-related Harms: Findings (1)

❑ 100 studies involving 487,162 patients (30 from LMICs & 70 High income countries (HICs))
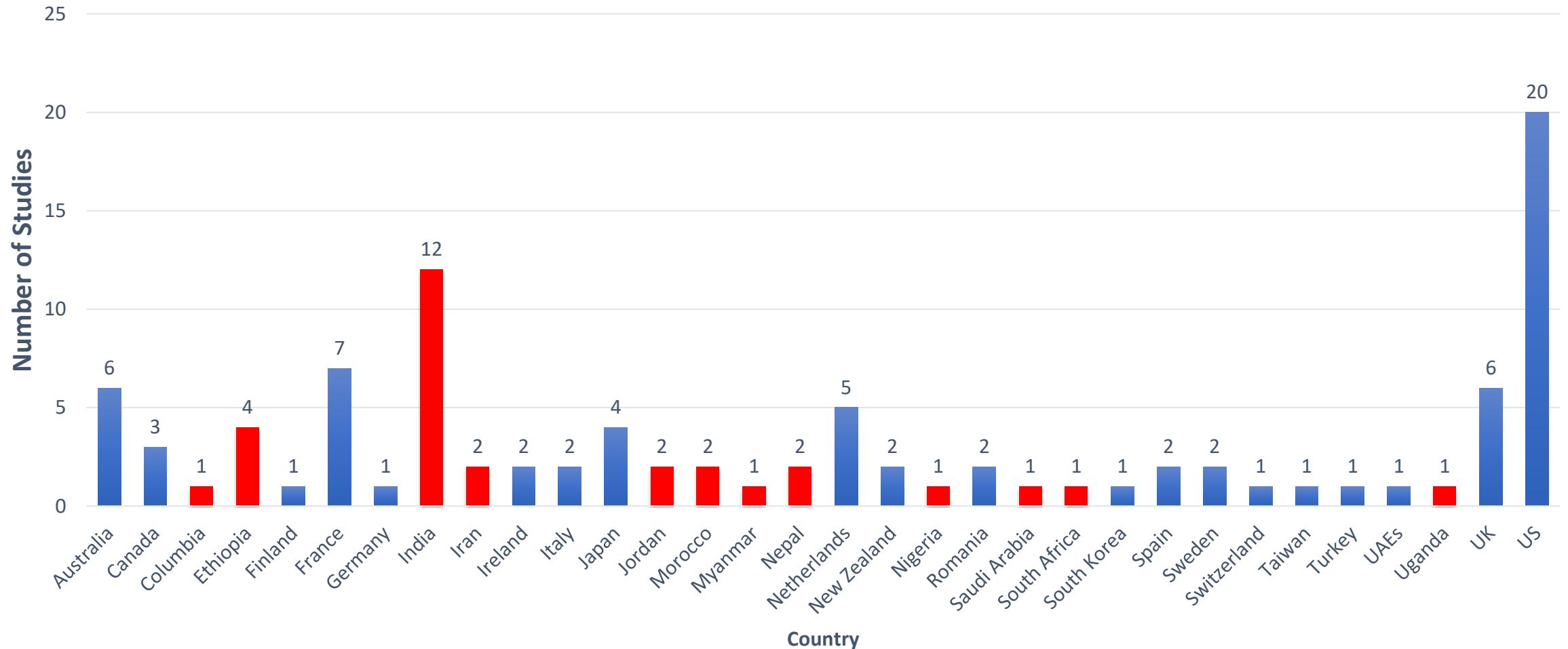
Preventable Medication-related Harms: Findings (2)

Healthcare Setting
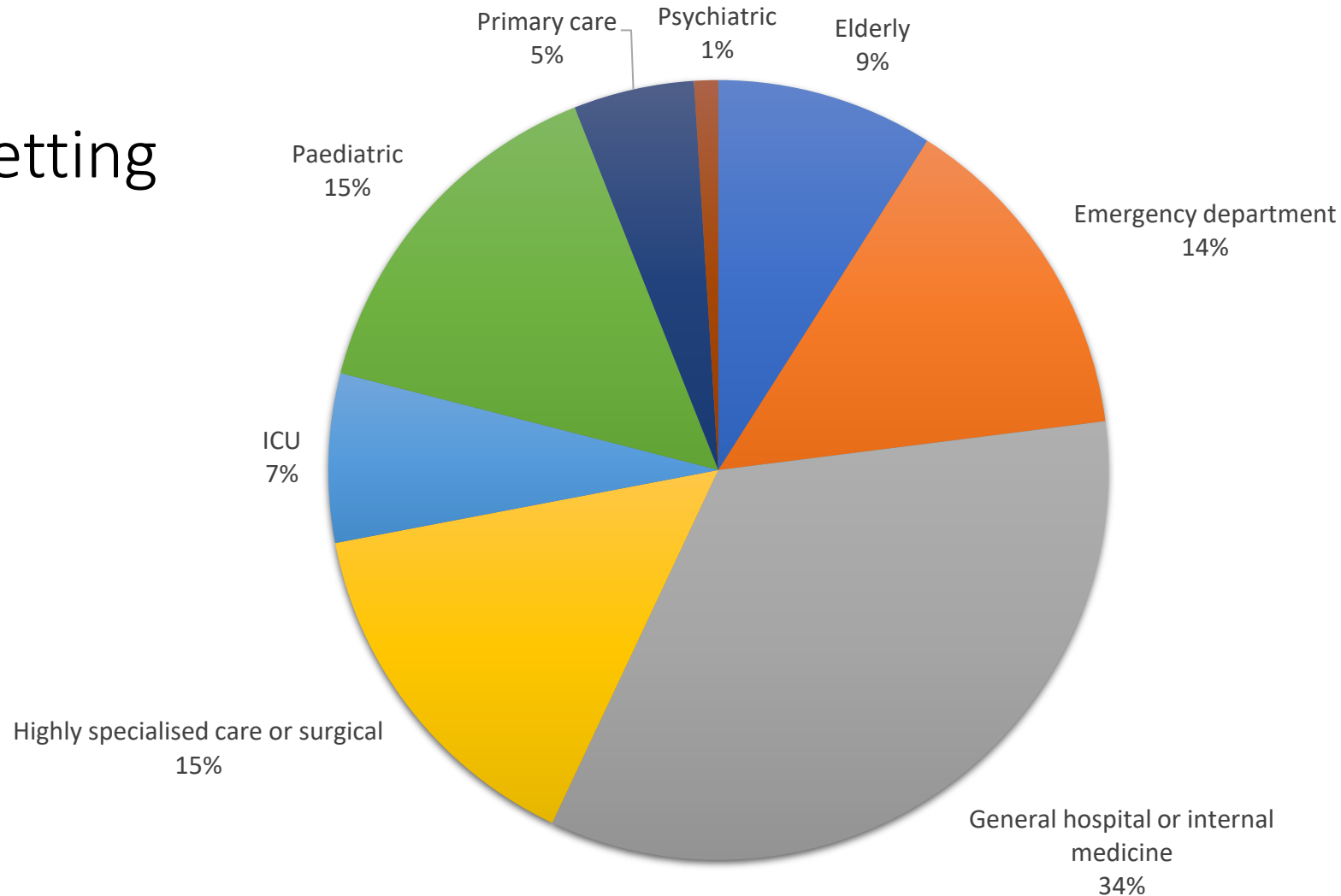
Preventable Medication-related Harms: Findings (3)

Characteristics of the studies:

❏ 45 studies were set in publicly funded healthcare systems, 28 were privately funded healthcare systems and 9 mixed

❏ 70 assessed medication harms by reviewing observations as report in medical records

❏ 60 studies used a standard preventability assessment method (Schumock & Thorton, Hallas criteria, Bates and WHO)

❏ Hartwig & Siegal most common severity assessment method used (k=22)

Preventable Medication-related Harms: Findings (4)

Overall - Meta-Analysis:

- ❑ **1 in 20 (Prevalence ~5%)** patients experience a preventable medication harm

- ❑ Almost **2 in 25 (~7%)** patients in LMICs experience preventable harm compared with **1 in 25 (~4%)** in HICs

- ❑ Higher rates seen in **elderly patient care units (~17%)**, highly specialised/surgical care (~9%), ICU (~7%), emergency departments (~6%)

- ❑ Lower rates observed in paediatric care (~2%), primary care (~2%), general hospitals/internal medicine (~3%)

Preventable Medication-related Harms: Findings (5)

Preventable Medication-related Harms: Findings (6)

Chart data by severity:

	Preventable Medication Harm	Overall Medication Harms	Preventable Medication Harm (LMIC)	Overall Medication Harms (LMIC)
Mild	38%	47%	24%	40%
Moderate	44%	42%	60%	42%
Severe/Life-threatening	23%	15%	14%	17%
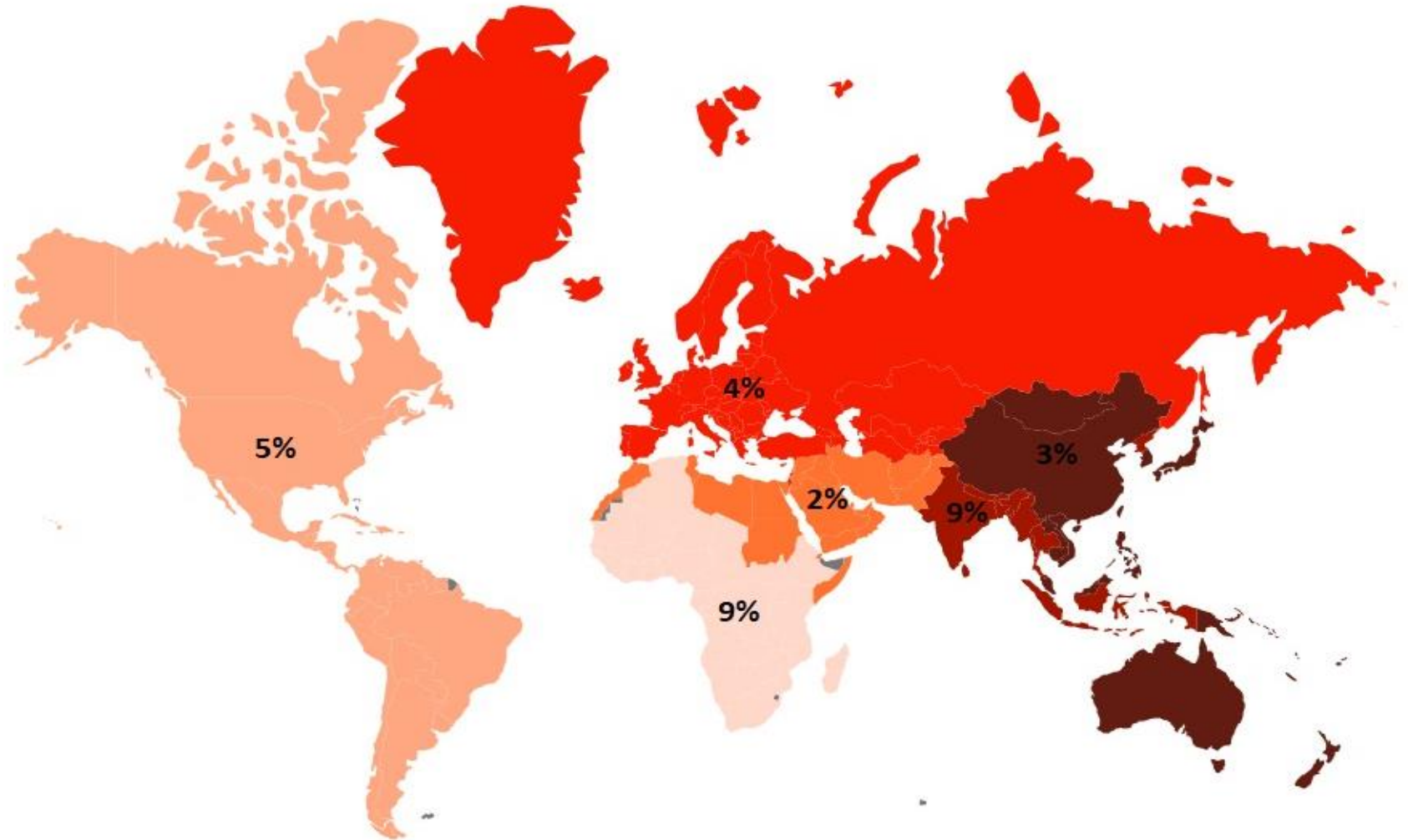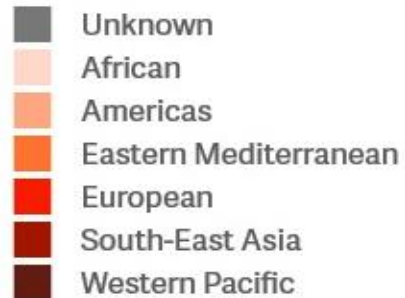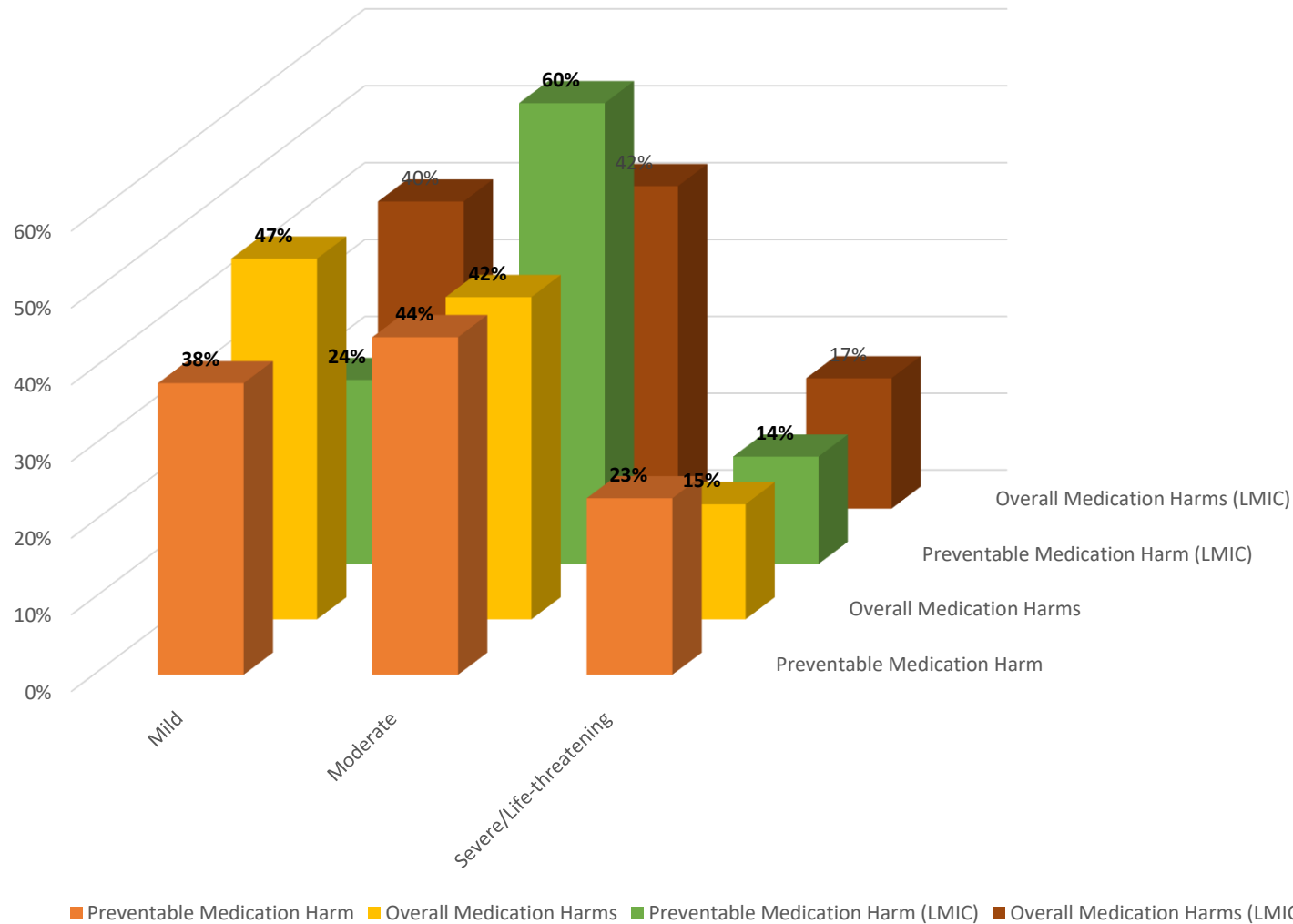
Severity

Mortality rate due to medication harms:
- LMICs: 4.3 per 1,000 population
- HICs: 0.12 per 1,000 population

Preventable Medication-related Harms: Findings (7)

Pathway of care: according to the US's Pharmacopeia 5 major steps

Stages of Medication Use
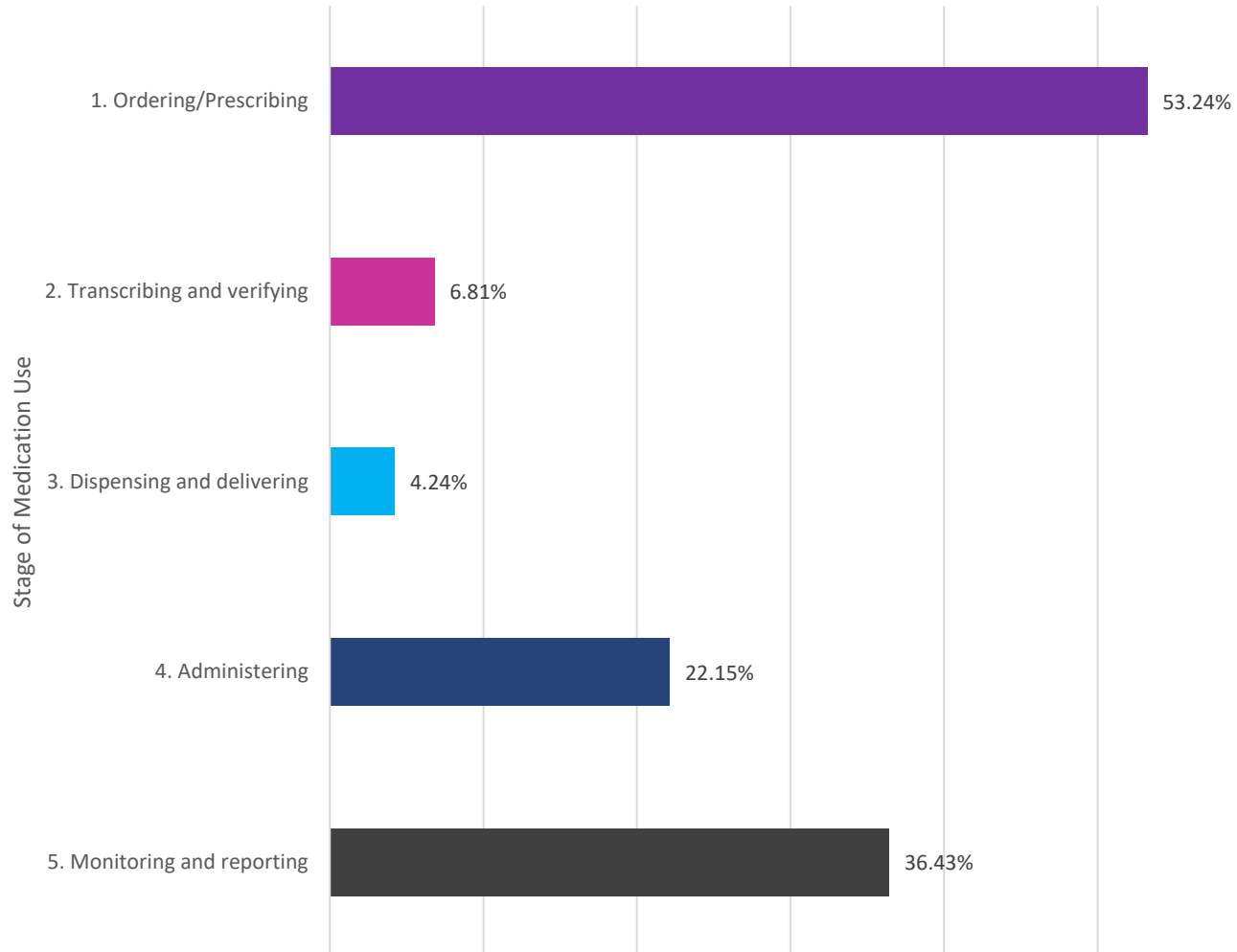
The widespread use of electronic health records has helped avert preventable harm at the **ordering/prescribing** and **transcribing** stages

But these results show that preventable harm persist across all pathways of care!

Preventable Medication-related Harms: Findings (8)

ATC Drug Class
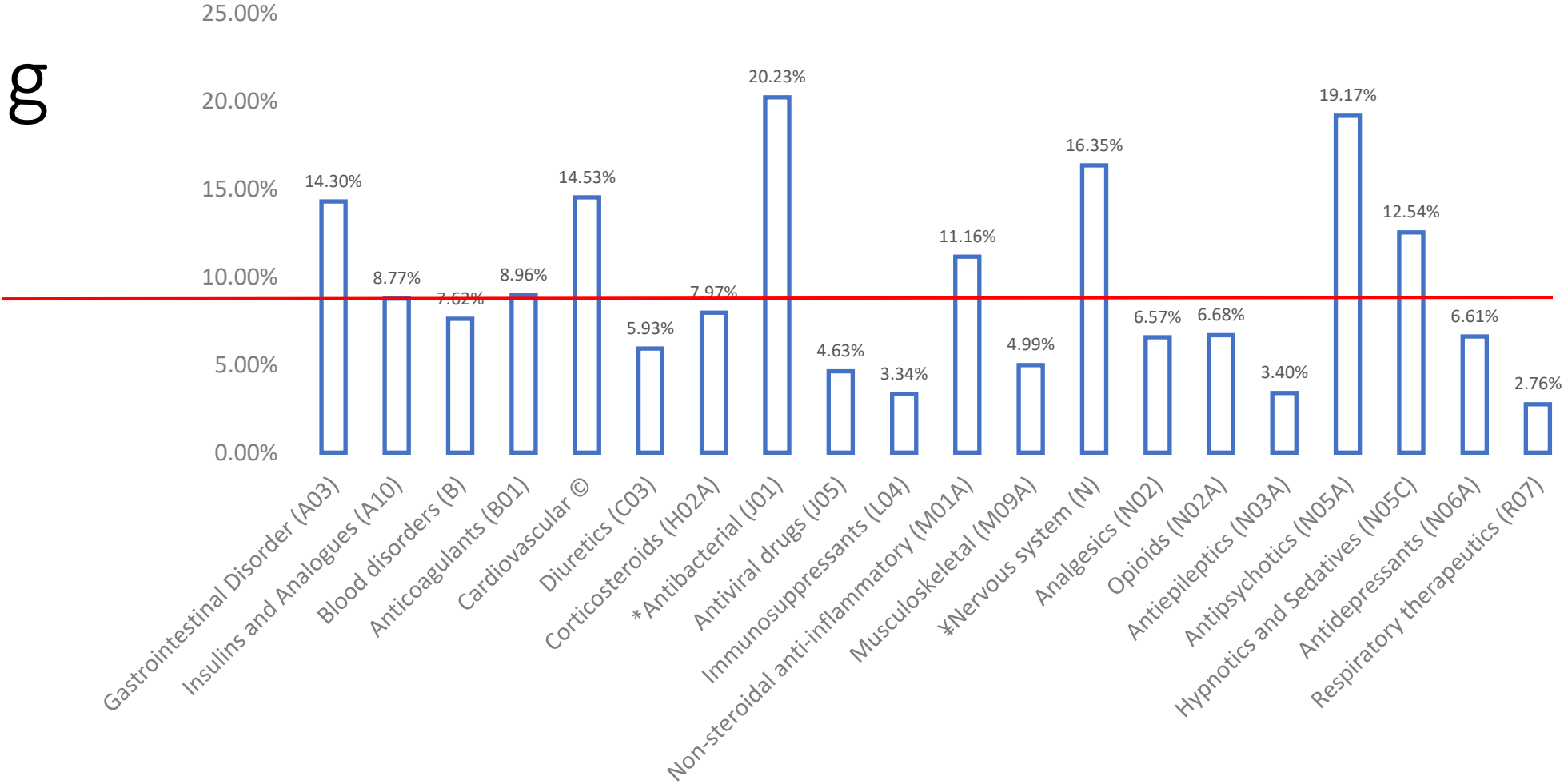
Preventable Medication-related Harms: Findings (9)

Prevalence by Study Time Period:
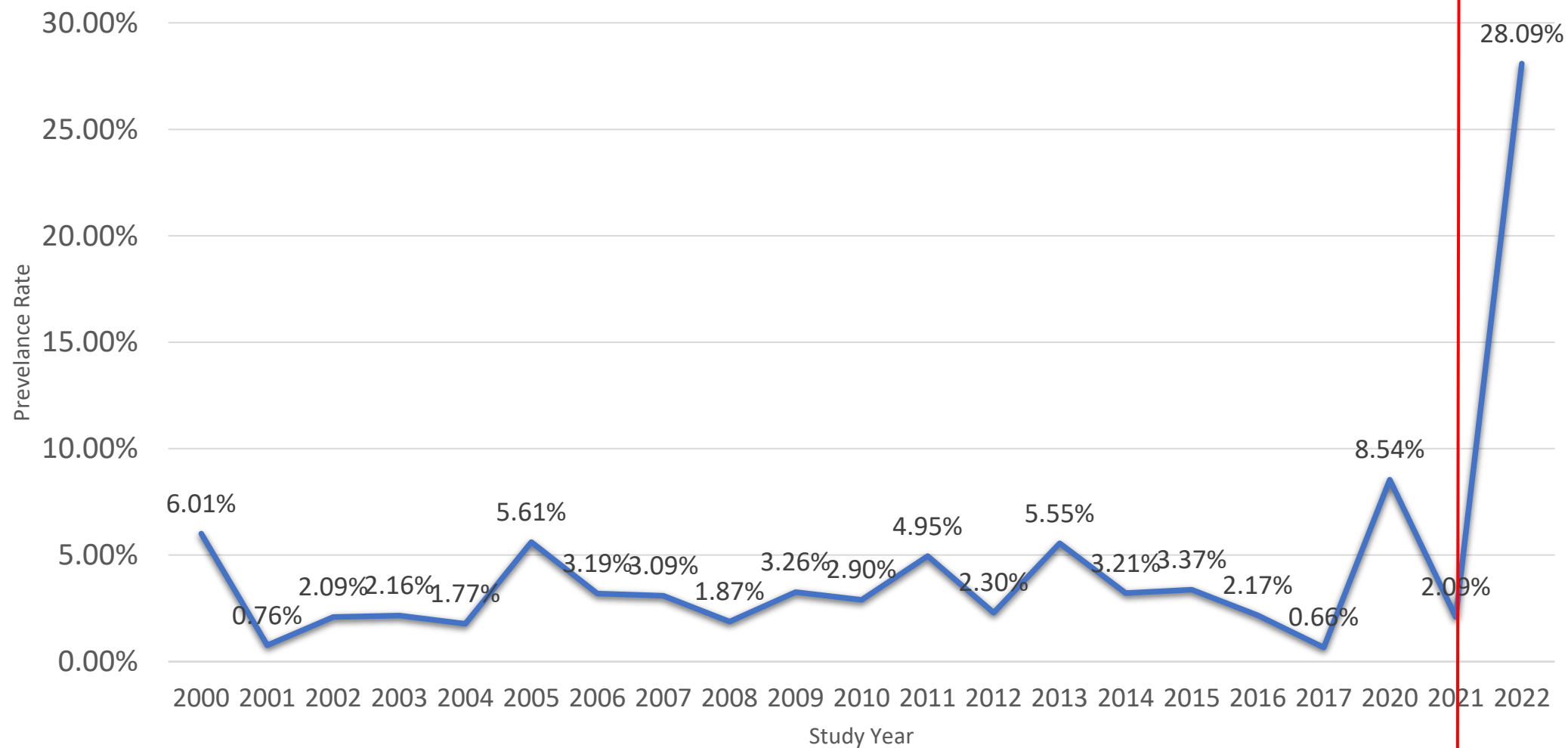
Preventable Medication-related Harms: Findings (10)

Low Middle-Income Countries (LMICs):

❑ Preventable harms greatest in highly specialised/surgical care (~13%) and lowest in paediatric care (~1%)

❑ **14%** of the preventable harms was severe or potentially life threatening

❑ Preventable harms occurred most at the ordering/prescribing stages of medication use (~78%)

❑ High risk drugs: cardiovascular (~13%), antibacterial (~24%), gastrointestinal disorder (~15%), antipsychotics (~17%) and corticosteroids (~20%)

Summary of Key Findings (1)

❑ 5% (or **1 in 20**) patients experience preventable medication harm

❑ **7%** of patients living in LMICs experience preventable mediation harm compared to 4% in HICs

❑ African and South-East regions displayed highest prevalence rates of preventable harm

❑ Almost **one quarter** of preventable harm was **severe** or **life-threatening**

❑ Although preventable medication harm was more common in LMICs than in HICs, it was less likely to be as severe

Summary of Key Findings (2)

❑ Preventable harms are worryingly higher in **elderly/geriatric care setting** and **highly specialized care** (including surgical care) and also higher (but less pronounced) in **intensive care** and **emergency medicine** settings

❑ Antibiotics and antibacterial, antipsychotics, treatment for cardiovascular disease, gastrointestinal and non-steroidal anti-inflammatory drugs accounted for at least **10%** of medication harm

❑ In LMICs, antibiotics and antibacterial, corticosteroids, antipsychotics, gastrointestinal and cardiovascular drugs accounted for the most medication harm

Summary of Key Findings (3)

❑ Approximately half of medication harm occurs at the **prescribing/ordering** stage and approximately one third occurs at the monitoring and reporting stage of medication.

❑ In contrast, medication harm occurs 7% of the time at transcribing and verifying stages, and only 4% in dispensing and delivering stages.

Overall Conclusions (1)

❑ Detailed analysis of the major preventable sources of severe health care harm as well as the stages, the systems and the practitioners involved in the occurrence of preventable harmful incidents is fundamental for designing more efficient strategies to prevent harm in the healthcare process.

❑ Mixed method approaches needed which connect the occurrence of health care harm to the presence of specific contributory factors and we need to engage patients as partners in establishing these connections.

❑ Need to gain better insight into the systemic and cultural circumstances under which preventable patient harm occurs.

Overall Conclusions (2)

❑ Evidence from LMICs although much improved remain suboptimal and of lower quality, as many studies from developing countries failed to provide data on preventability of harm.

❑ There are important concerns in certain specialties such as intensive care whereas there is lack of evidence in other specialties such as psychiatry.

❑ Interventions to reduce medication-related harm are encouraged by these findings, particularly at the stages of prescribing and administration of medication where most preventable harms occur.

❑ Diagnostic errors are also an important source of preventable harm which remains an understudied area of patient safety research.

Collaborators

Core Team:
- Dr Maria Panagioti
- Dr Alexander Hodkinson
- Dr Claire Planner

With thanks to:
- Natasha Tyler
- Ioannis Angelakis

Other Key Collaborators:
- Prof Darren Ashcroft, Prof Antony Avery, Dr Richard Keers

NIHR School for Primary Care Research, Centre for Primary Care, Manchester Academic Health Science Centre, University of Manchester

NIHR Greater Manchester Primary Care Patient Safety Research Collaboration (Greater Manchester PSRC), Manchester Academic Health Science Centre University of Manchester

Division of Primary Care, School of Community Health Sciences, University of Nottingham

National efforts towards measuring medication related harm

31% Indicators on medication-related harm have been defined in the country

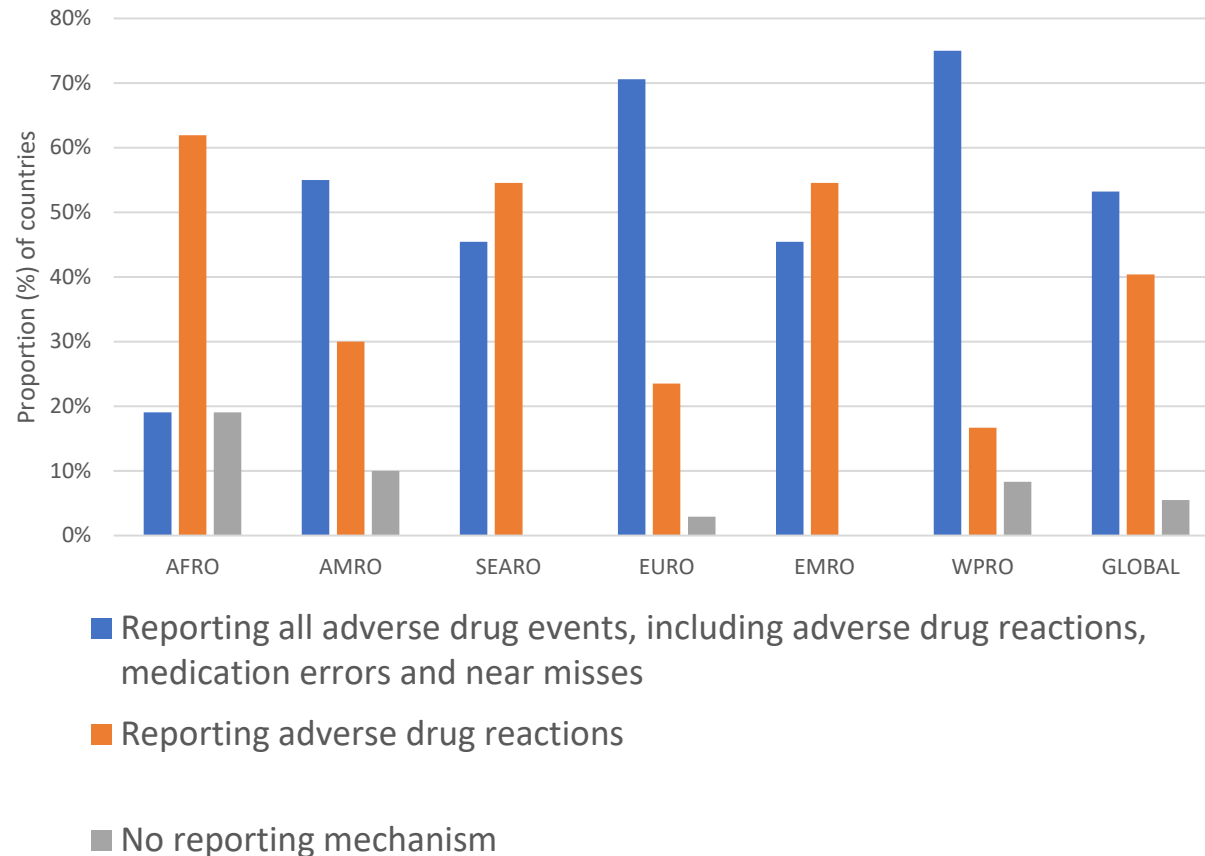**17%** Burden of medication harm estimated recently (≤ 5 years) in the country

21% A national target has been set for the reduction in medication-related harm

Variation in reporting of adverse drug events

WHO Regions
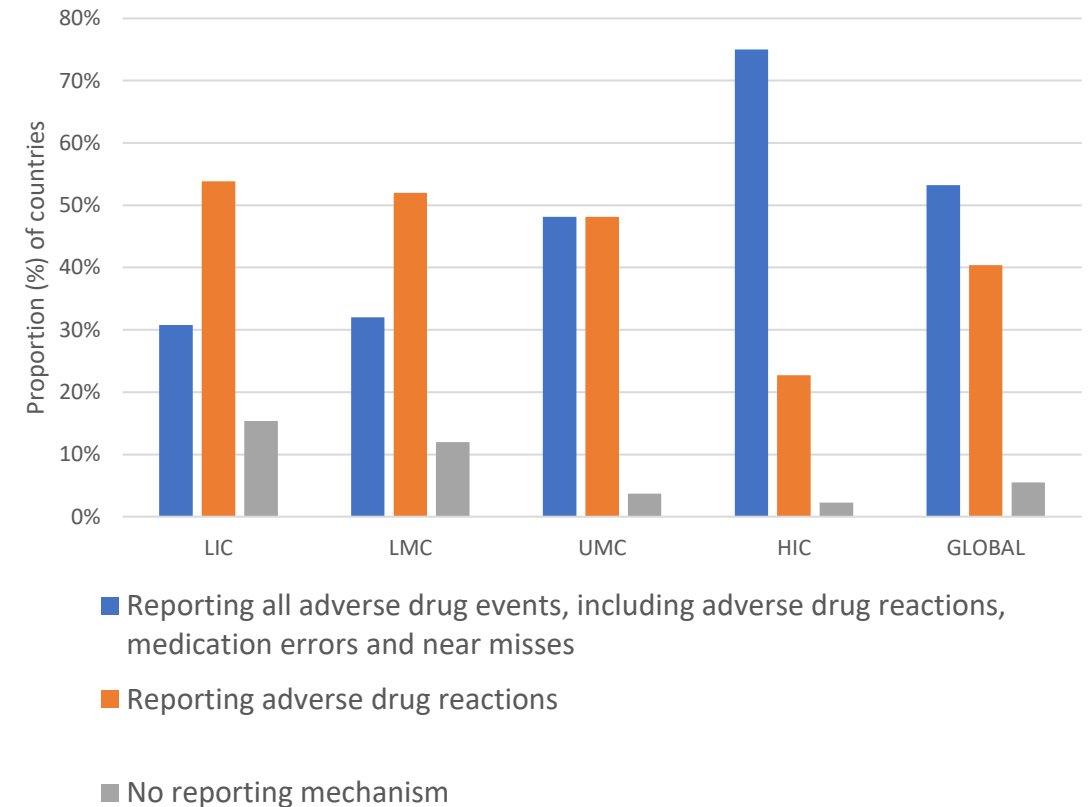
World Bank Income Groups

Member State survey on implementing Global Patient Safety Action Plan 2021-2030

How countries are measuring medication related harm

- **Bhutan**: Uses various KPIs like incorrect medication.

- **Thailand**: Measures high alert drugs and medication error incidents.

- **UAE**: Reports ADRs as a percentage of total monthly transactions.

- **Sri Lanka**: Monitors percentage of medication-related incidents in patients.

- **Malaysia**: Targets zero cases of severe harm/death from medication errors.

- **Colombia**: Assesses adverse drug events in hospitalizations and emergencies.

- **USA**: Utilizes passive reporting through FDA's MedWatch and active surveillance systems.

- **Singapore**: Records medication errors and interventions.

- **Qatar**: Currently reports medication errors, shifting to error rate formula.

- **Spain**: Uses protocols and improvement actions as safety indicators.

- **Australia**: Focuses on clinical risk mitigation for medication complications.

- **New Zealand**: Emphasizes e-Medicine Reconciliation and Opioid QSM.

- **Ireland**: Rates medication incidents per 1,000 bed days.

- **Ghana**: Calculates percentage of medication therapy discrepancies/errors.

- **Türkiye**: Reports medication error notifications per hospitalization days.

- **Indonesia**: Ratios patient safety incidents due to medication errors against total incidents.

Member State survey on implementing Global Patient Safety Action Plan 2021-2030

Various methods of reporting medication harm

- National reporting systems for medication errors and adverse drug events.

- Health department-led online and voluntary reporting platforms.

- Regular data collection through healthcare monitoring agencies.

- Surveys and automated systems for quality and safety indicator reporting.

- Periodic safety updates and incident reporting for continuous oversight.

- Centralized pharmacovigilance databases for adverse event tracking.

- Multi-source data aggregation for comprehensive harm analysis.

- Pharmacovigilance activities, including case reviews and public submissions

- Trigger tools for regular screening of potential medication harm

Member State survey on implementing Global Patient Safety Action Plan 2021-2030

Medication safety terms and how they are interpreted and used by pharmacovigilance centres (PVCs) and patient safety organizations (PSOs) *

Term	Meaning in PVC	Meaning in PSO	Comment
Patient safety incident	Currently not used	Event or circumstance which could have resulted, or did result, in unnecessary harm to a patient	PVCs could adopt this term
Medication incident	Currently not used	Any undesirable experience that has happened to the patient while taking a drug but which may or may not be related to the drug	PVCs could adopt this term
Potential patient safety incident	Currently not used	A patient safety incident without harm	Commonly referred to as "near miss" PVCs could adopt this term
Adverse event	Any untoward medical occurrence temporally associated with the use of a medicinal product, but not necessarily causally related	An injury related to medical management, in contrast to complications of disease	PSO meaning not restricted to medicines
Adverse drug event	Currently not used	Any injury resulting from medical interventions related to a drug	PVCs could adopt this term instead of "adverse event" (see section 4.1)
Potential adverse drug event	Currently not used	No harm occurred even if error occurred or was intercepted	Commonly referred to as "near miss"
Preventable adverse drug event	Currently not used	Injury that is the result of an error at any stage of the medication use process.	= medication error PSOs could replace this term with "medication error" (see below under "medication error")

Reporting and learning systems for medication errors: the role of pharmacovigilance centres. World Health Organization 2014

Challenges:

- Disproportionate concentration of studies on preventable medication-related harm in high-income countries (HICs) versus low- and middle-income countries (LMICs).

- Lower quality and reporting standards in studies conducted in LMICs.

- Inconsistencies in data from LMICs regarding the severity and specifics of medication-related harm.

- Lack of detailed understanding of medication use stages, drug classes, and factors contributing to harm in LMICs.

Global burden of preventable medication-related harm in health care: a systematic review

Opportunities:

- Commissioning high-quality, targeted research in LMICs to better understand the nature and causes of medication-related harm.

- Development of improved data collection and reporting systems in LMICs to accurately assess medication-related harm.

- Formulating strategies for harm prevention, especially in under-researched settings like primary care, mental health, and psychiatry.

- Enhancing medication safety programs by focusing on healthcare specialties where medication harm is prevalent, such as geriatrics, surgical care, ICU, and emergency medicine.

- Raising awareness and educating healthcare providers on the appropriate prescription to reduce preventable harm

Methods for estimating harm in data poor setups

- retrospective record review

- record review of current inpatients

- staff interviews on current inpatients

- direct observation and related interviews

- nominal group meetings

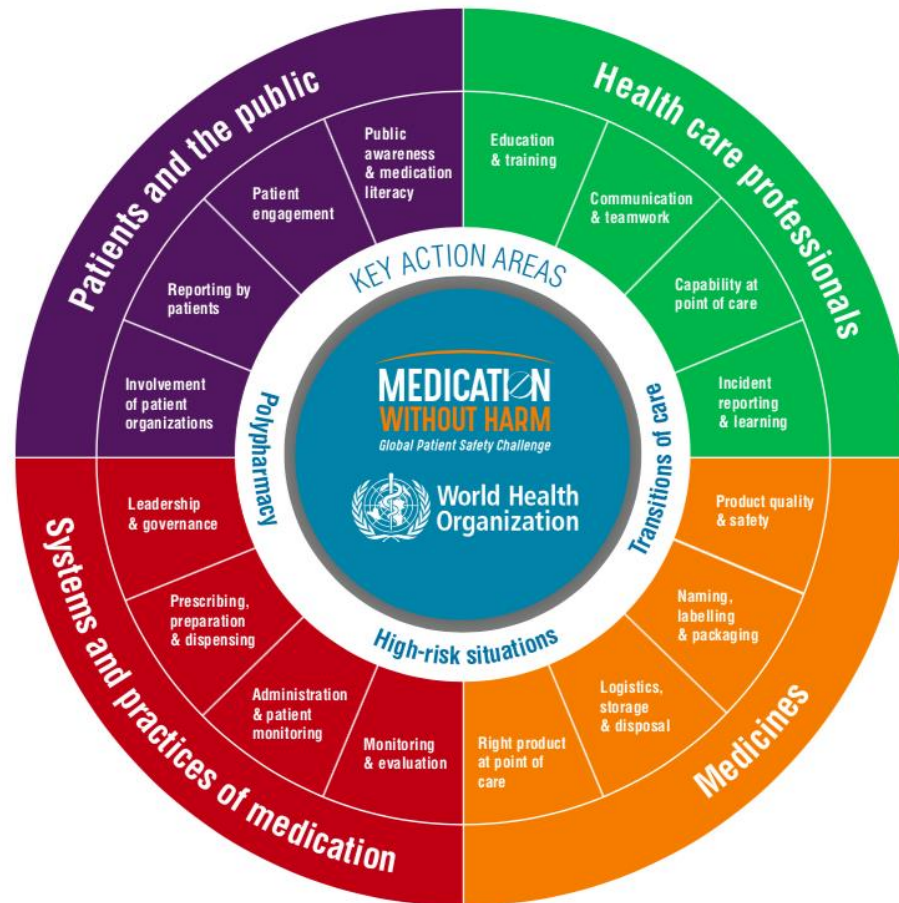World Health Organization | Patient Safety — A World Alliance for Safer Health Care | RESEARCH — Better knowledge for safer care
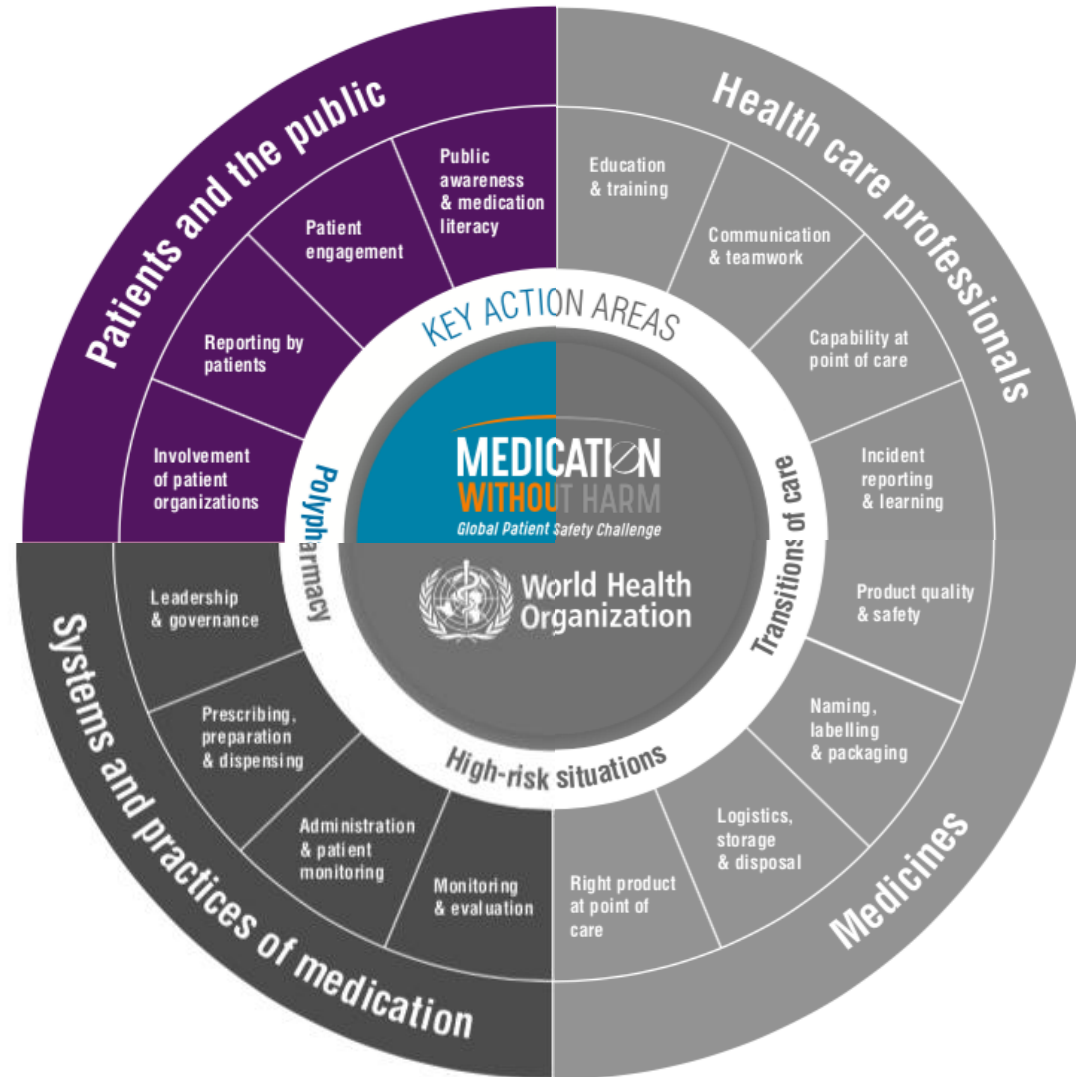
Assessing and tackling patient harm

A methodological guide for data-poor hospitals

Monitoring & Evaluation Framework

Domain 1
Patients & Public

Output / Process Indicators

Subdomain	Global/ Regional (Annually)	National (Half Yearly)	Facilities (Monthly
Public Awareness and Medication Literacy	Percentage of countries that have formally launched a campaign on the medication without harm challenge	Number of visits to Medication Safety Information portal	Percentage of patients provided and counselled for 5 moments of Medication safety
Patient Engagement	Percentage of countries has adopted WHO medication safety patient engagement tool	Percentage of hospitals are using medication passports	Percentage of patient are using medication passport
Reporting by patients	Percentage of countries having patient reporting system on medication	Number of patient reported on Patient Safety reporting portal	Percentage of hospital taking feedback on patient experience
Involvement of patient organizations	Percentage of countries has involved NGO and consumer groups formally in medications safety program	Percentages of district / counties community self medication advocates have been appointed	Availability of collaboration with local patient groups/ NGO for education on Patient Safety
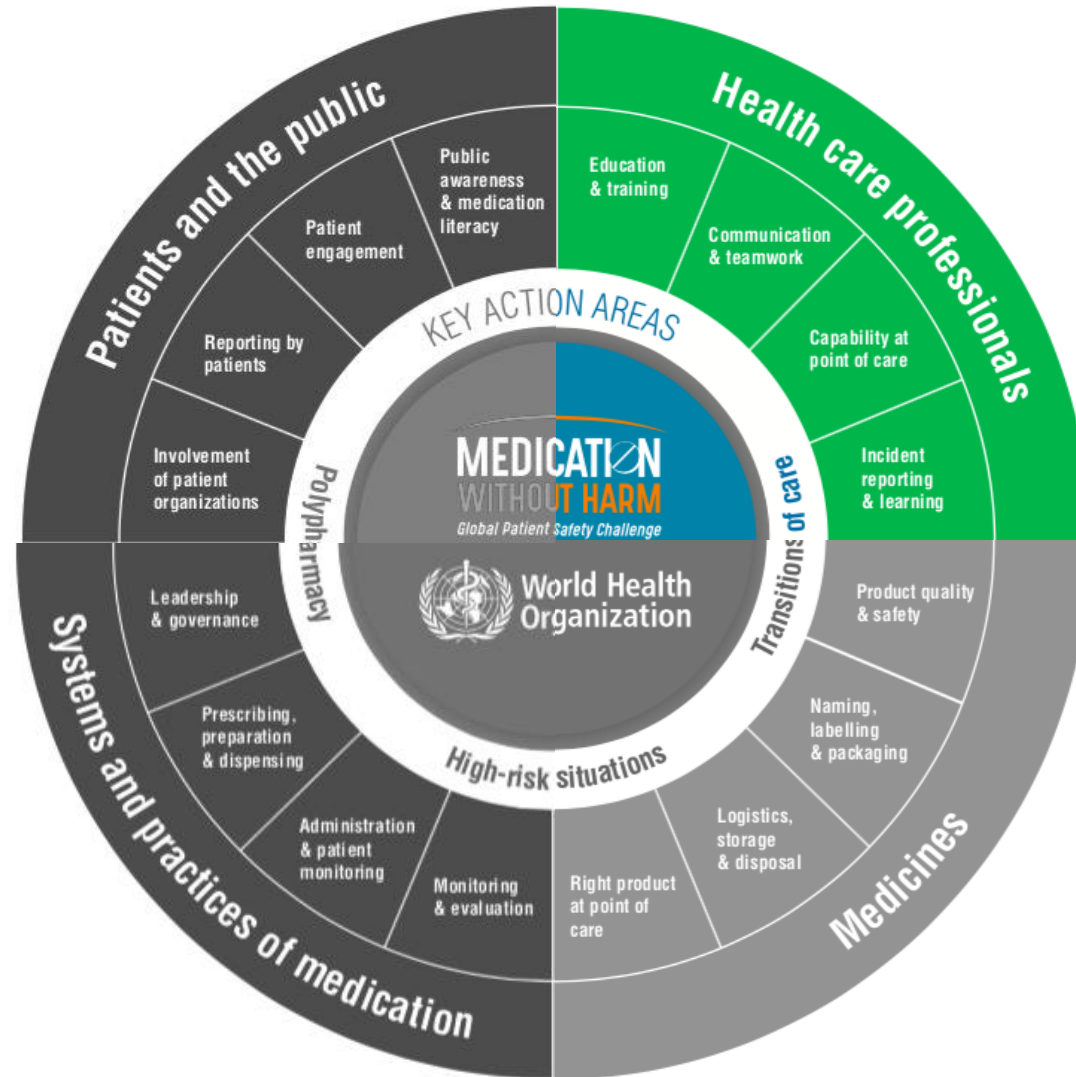
Domain 2
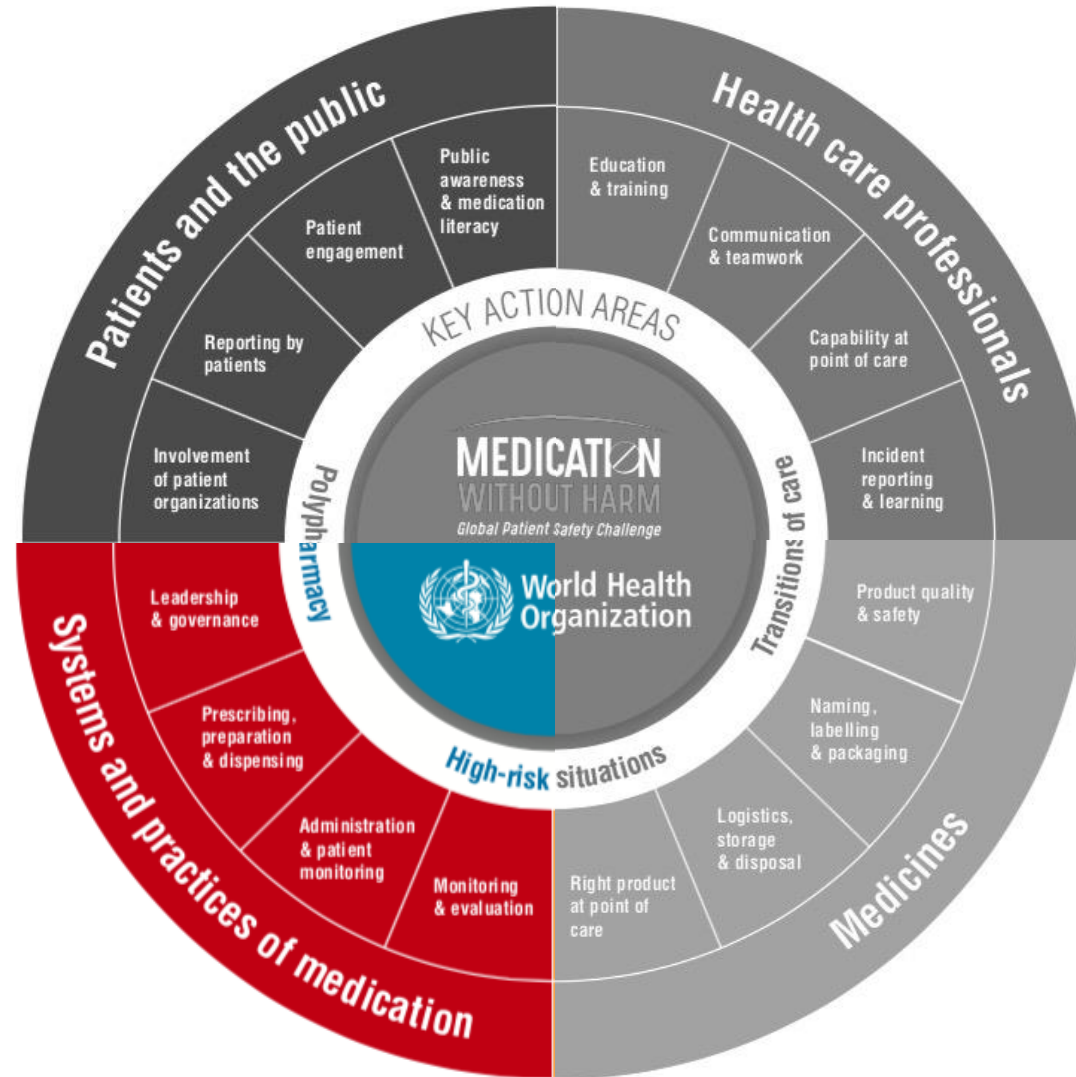Healthcare Professionals

Output / Process Indicators

Subdomain	Global/ Regional (Annually)	National (Half Yearly)	Facilities (Monthly
Education & Training	Percentage of countries has formally included medication safety in teaching curriculum	Percentage of medical /nursing /pharmacy schools has introduced medication safety their curriculum	Percentage of staff trained for medication safety
Communication & Teamwork	Percentage of countries having institutional framework for drug and therapeutic committee	Percentage of hospitals have established patient centered multi- disciplinary	Percentage of medication error identified as communication error Reconcillataion
Capability at point of care	Percentage of countries has issued guidelines/ instructions for medicines reconciliation and medication reviews	Percentage of hospital are having medicines reconciliation and medication reviews as standard practice	Percentage of indoor patient offered medicines reconciliation
Incident Reporting & Learning	Percentage Countries with a operational reporting and learning system (RLS) for medication safety	Percentage of facilities participating in reporting and learning system (RLS) for medication safety	Percentage change in medication error reporting
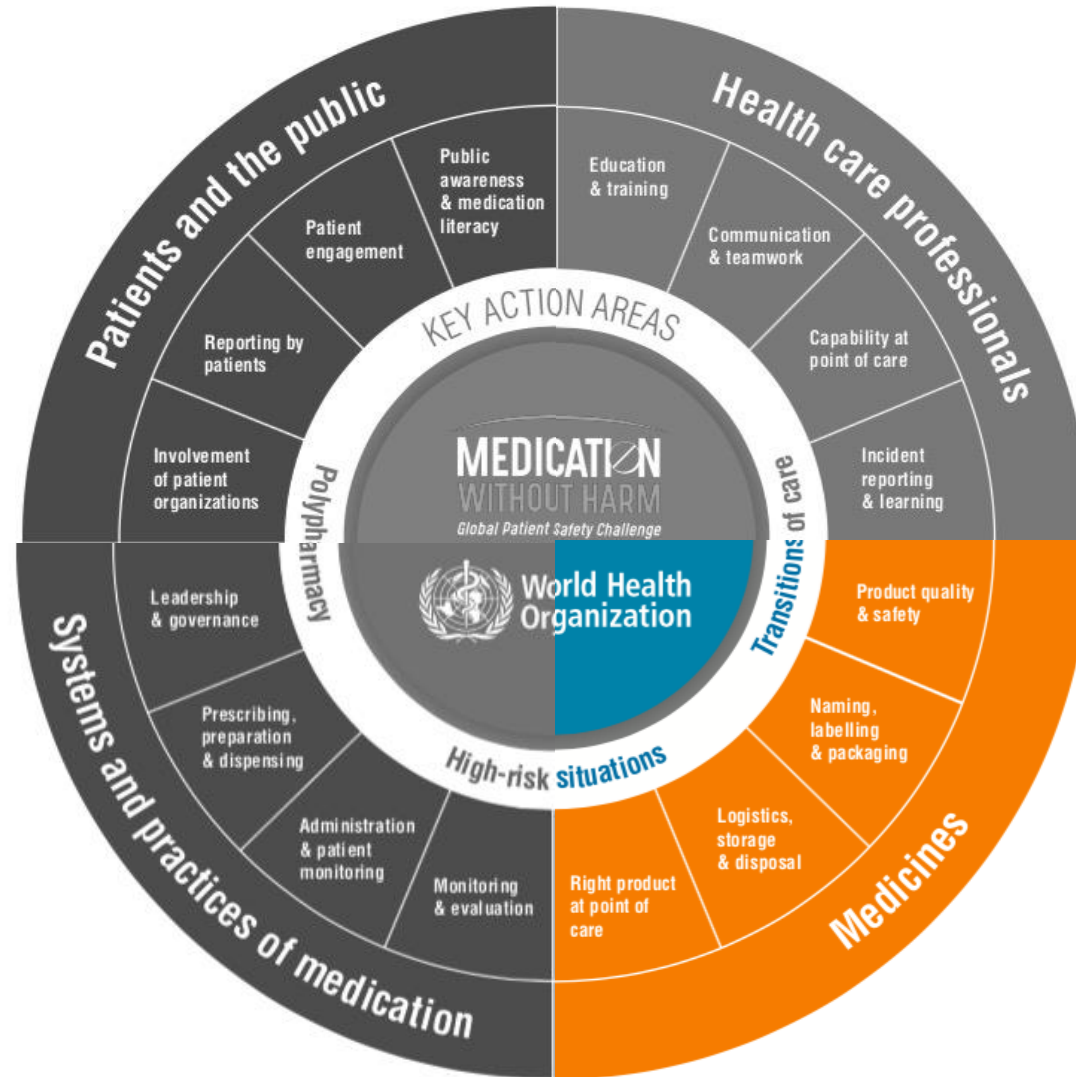
Domain 3
Medicines

Output / Process Indicators

| Subdomain	Global/ Regional (Annually)	National (Half Yearly)	Facilities (Monthly
Naming, Labelling & Packaging	Percentage of countries have established universal guidelines for Naming, Labelling and Packaging of medicines	Percentage of hospitals have implemented policy on Look alike & sound alike medicines	Percentage of dispensing errors because of look alike / sound alike medicines
Product Quality and safety	Percentage of countries national level regulatory authority to control quality of drugs	Percentage of dugs found sub standards/ spurious during the quality control process	Availability of list of High Alert drug in hospital
Logistics, Storage and Disposal	Percentage of countries have guidelines for warehousing, storage and transportation of drugs	Number of supply chain audits done per district	Percentage of drugs discarded because of expiry or deterioration due to wrong storage
Right product at point of care	Percentage of countries have taken initiative for reduction of error prone and concentrated high alert drugs at point of care	Percentage of hospitals has implemented ever and never list of medication	Percentage of adverse drug events due wrong administration of High Alert Drugs

Domain 4
Systems & Practices of Medication

Output / Process Indicators

Subdomain	Global/ Regional (Annually)	National (Half Yearly)	Facilities (Monthly
Leadership & Governance	Percentage of countries that signed the pledge	Percentage of Healthcare Facilities have signed the pledge	Percentage of patient care staff has taken the pledge
Prescription, preparation & Dispensing	Percentage of countries having national prescribing guidelines	Parentage of facilities of hospitals conducting prescription audits	Percentage of Prescription and dispensing errors out of all medication errors
Administration & Patient Monitoring	Percentage of countries having a policy of patient identification	Percentage of facilities where INR values can be monitored for patient on heparin	Percentage of administration and monitoring errors out of all medication errors
Monitoring & Evaluation	Percentage Countries/institution using medication safety assessment tool for evaluation of status of medication safety	Percentage of hospitals using medication safety assessment tool for evaluation of status of medication safety	Score based of Medication safety assessment

Way forward

- Harmonizing the medication safety incident terms

- Process measurement in medication use

- Use of trigger tools and point prevalence methods

- Sharing of information between PVG and PSRLS systems on medication errors

- Investment in medication safety measurement research
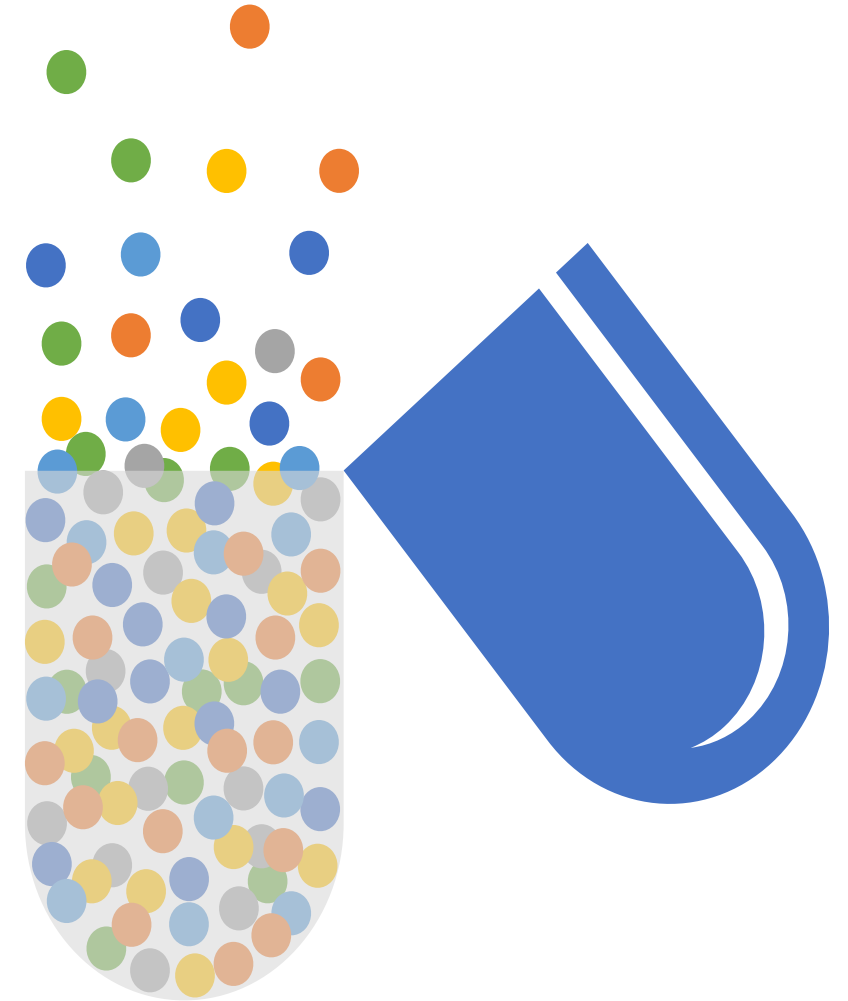
Thank You

WHO definition of pharmacovigilance (PV)

- **Pharmacovigilance** is the science and activities relating to the…
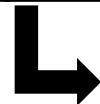

DETECTION
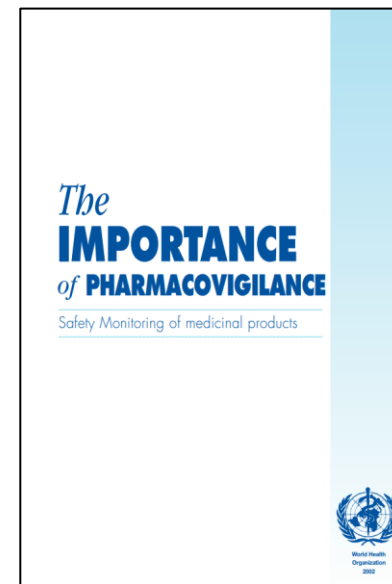
ASSESSMENT

UNDERSTANDING

PREVENTION

…**of adverse effects or <u>any other medicine related problem</u>**

↳ Medication errors

- The Importance of Pharmacovigilance - Safety Monitoring of Medicinal Products, WHO, 2002, Link

WHO publication regarding PV for medication errors

REPORTING AND LEARNING SYSTEMS FOR MEDICATION ERRORS: THE ROLE OF PHARMACOVIGILANCE CENTRES

World Health Organization
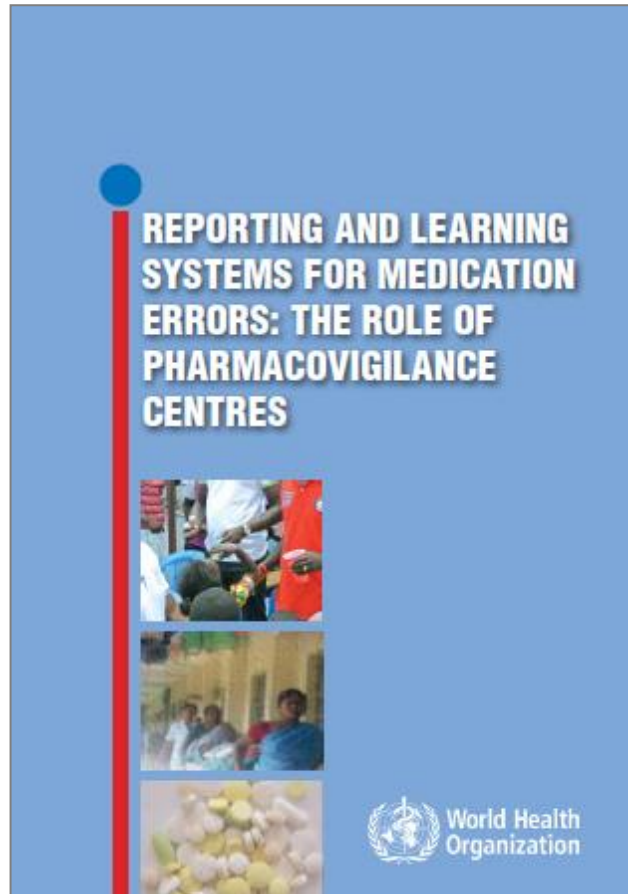
[Key points]
- This publication is intended to strengthen the capacity of national pharmacovigilance centres (PVCs) to identify, analyse and issue guidance to prevent or minimize medication errors that harm patients.
- In addition, it is intended to **stimulate cooperation between national PVCs and patient safety organizations (PSOs)** to work together in order to minimize preventable harms from medicines.
- PVCs should develop their tools and their skills to **identify medication errors from ADR reports** and to investigate their preventability. A model ICSR reporting form with important data fields to support ME detection is attached.
- In all cases, **close collaboration between PSOs and PVCs should be put in place** so that data can be shared.

Reporting and learning systems for medication errors: the role of Pharmacovigilance Centres.
WHO, 2014. https://www.who.int/publications/i/item/9789241507943

Medication Without Harm: policy brief

4.2 Reporting medication errors and learning

- The national reporting systems in countries identify the common errors reported especially those that have caused serious patient harm and learn from those to take preventive actions.
- European Union legislation passed in 2015 requires information on medication errors to be collected and reported through national pharmacovigilance systems for evaluation and assessment.
- A clear distinction is made between adverse drug reactions which are not preventable, medication errors, resulting in preventable adverse events, medication errors that do not cause harm, intercepted medication errors and potential errors.
- **National authorities responsible for pharmacovigilance are requested to collaborate and exchange information on medication errors resulting in patient harm with national patient safety organizations**.

How reports of medication errors reach the WHO database of Individual Case Safety Reports, VigiBase

Medication error

Near miss

Patient harm due to medication error

Individual Case Safety Report (ICSR) on medication error

Submit to National pharmacovigilance centre (PVC)

Medication error is coded by MedDRA

Submit to WHO global database of ICSRs, VigiBase
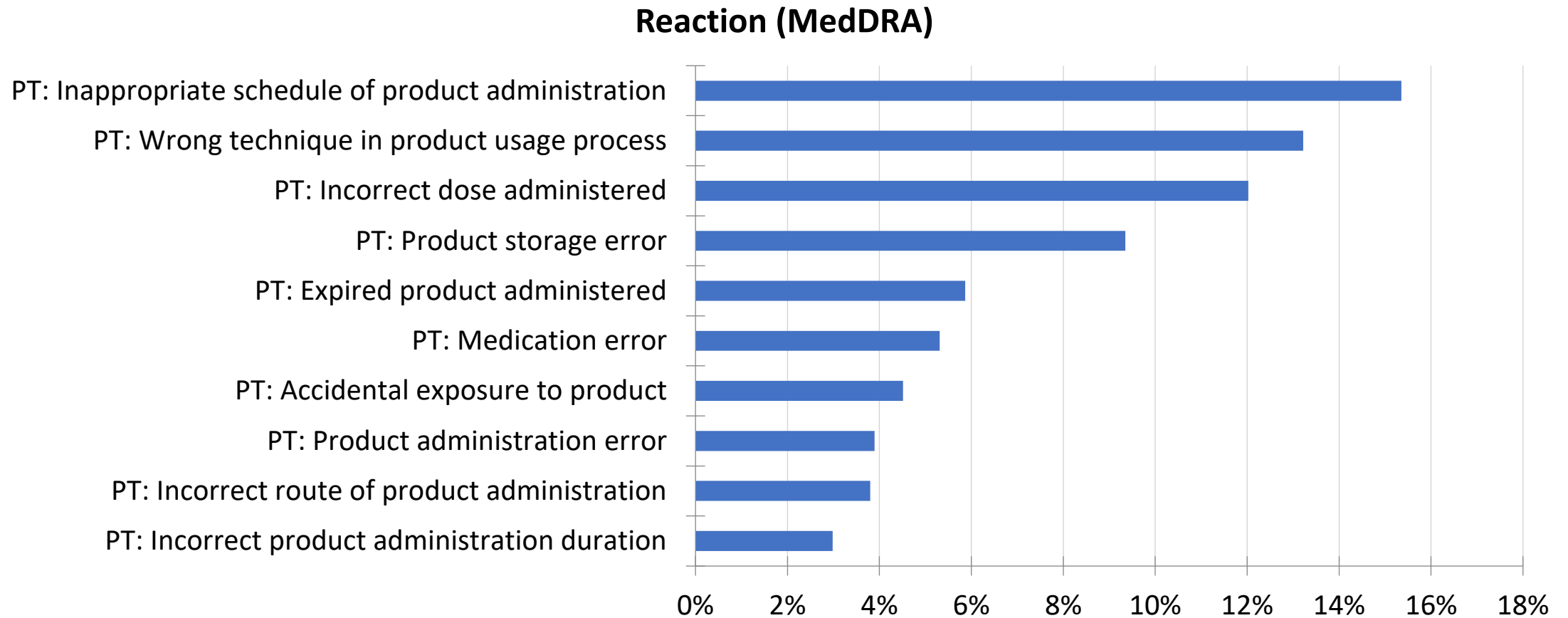
World Health Organization
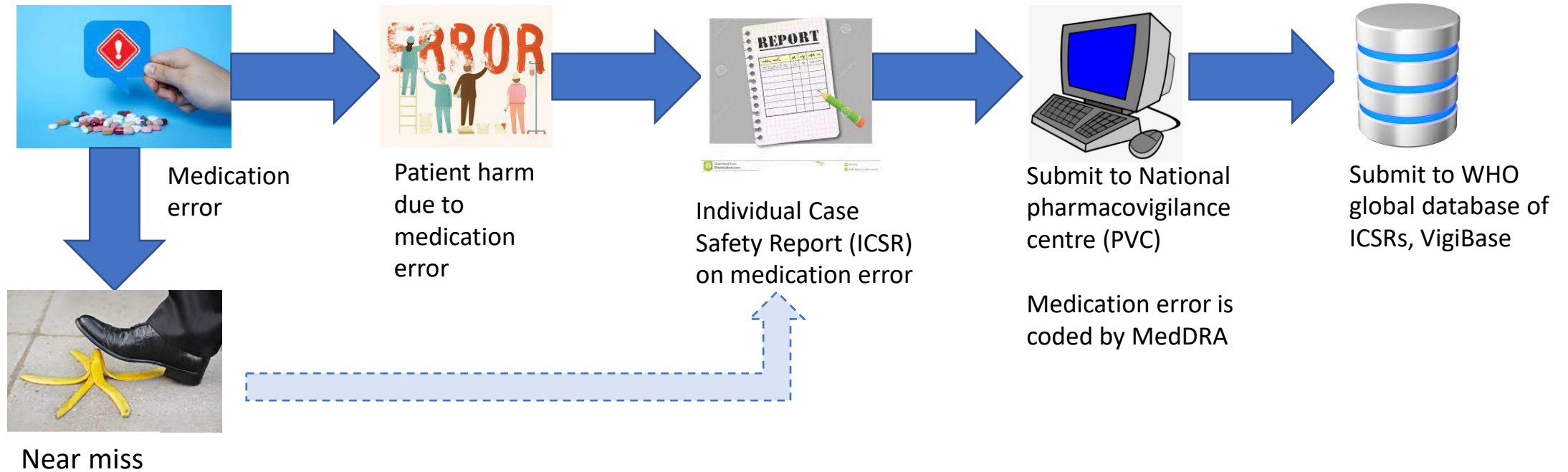
Number of ICSRs with medication error in VigiBase 1994-2024
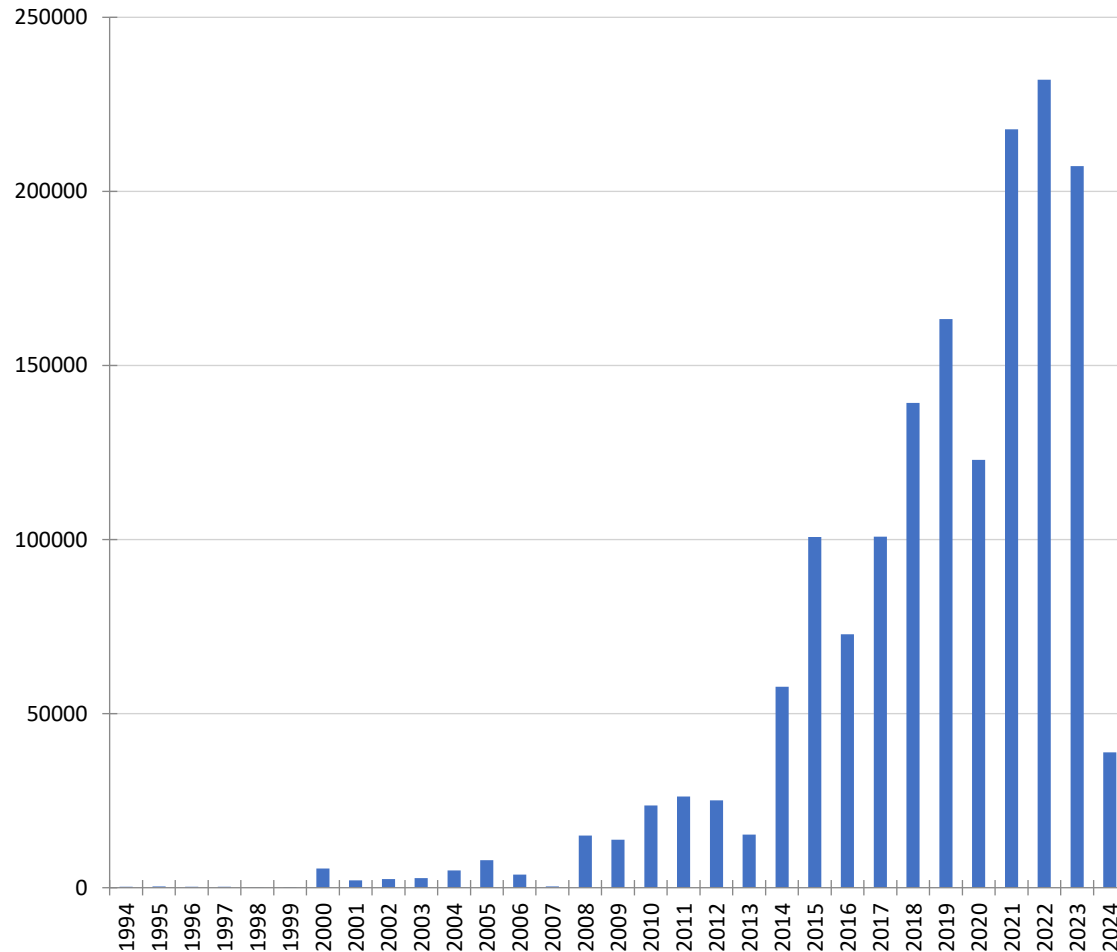
VigiBase accessed on 01.Mar.2024

- VigiBase search by MedDRA SMQ: Medication errors (narrow)

- A total of 1,604,129 ICSRs reporting medication errors (4.3% of all ICSRs), originating from 111 countries and regions

- 107,033 (6%) of ICSRs for medication errors originate from LMICs

Top 10 reported medication errors in VigiBase (MedDRA Preferred Term level)

Reaction (MedDRA)

PT: Inappropriate schedule of product administration	
PT: Wrong technique in product usage process	
PT: Incorrect dose administered	
PT: Product storage error	
PT: Expired product administered	
PT: Medication error	
PT: Accidental exposure to product	
PT: Product administration error	
PT: Incorrect route of product administration	
PT: Incorrect product administration duration	

0% 2% 4% 6% 8% 10% 12% 14% 16% 18%

- We know that many ME occur – but all are not reported to the WHO global ICSR database
- Collaboration between PVC and PSO needed to link patient safety and PV databases so that
  - A global repository of MEs to help study:
    - types of medication errors, contributing factors, and root causes
    - products prone to medication errors
    - mitigation strategies that are needed
    - the impact of the strategies: trends over time

Example of collaboration between PVC and PSO

Calcium chloride, calcium gluconate: potential risk of underdosing with calcium gluconate in severe hyperkalaemia, Medicines and Healthcare products Regulatory Agency (MHRA, UK), 27 June 2023

- The MHRA has reviewed available UK data related to inappropriate use of calcium gluconate and identified isolated cases where medication errors have occurred, including **one death**, where 10ml of calcium gluconate was used during cardiopulmonary resuscitation (Yellow Card literature report).

- Reports from the National Reporting Learning System received since the guideline was updated indicate that 6 incidents showed incorrect calcium gluconate administration and monitoring in the context of severe hyperkalaemia and cardiac arrest (**5 fatal**, 1 unknown outcome).

- We have also issued a National Patient Safety Alert following consultation with NHS England and bodies in Scotland, Wales, and Northern Ireland, as well as the UK Kidney Association.

Medicines & Healthcare products Regulatory Agency

NHS England

Tools are continuously developed

MedDRA (Medical Dictionary for Regulatory Activities): a standardised, structured and multilongual medical terminology to facilitate sharing of regulatory information internationally for medical products, developed by International Council for Harmonisation (ICH)

ICD-10 to MedDRA Mapping Now Available *2023-06-27*

- The MSSO is pleased to announce the availability of the ICD-10 to MedDRA mapping. The mapping was developed in a collaboration between WHO and ICH with MSSO supporting.

- WHO and ICH with MSSO supporting, plan to continue their joint activities to develop bi-directional ICD-11 – MedDRA mappings. These mappings will support the interoperability between ICD-10/11 data that provides critical knowledge on the extent, causes and consequences of human disease and death worldwide with MedDRA that facilitates global regulatory decision making on the safety and efficacy of medicinal products.

Summary

- Medication errors are in the scope of pharmacovigilance and adverse event reporting.

- Close collaboration between regulatory authority and patient safety organization should be put in place <u>so that data, analysis and action can be shared and coordinated</u>.

- Reports of medication errors reach the WHO database of Individual Case Safety Reports, VigiBase through national pharmacovigilance centers

- Data link and analysis of both pharmacovigilance and patient safety databases are important. Tools to support these activities are being developed, e.g., ICD-10/11 and MedDRA mapping for large database analysis.

Overview

- Contributory factors for errors
- Policy options to address medication errors
- The three key action areas
- The four domains
- A pledge to sign

Contributory factors for errors

Extremes of age	• More errors occur in very young and older persons- less likely to tolerate ADRs and have severe outcomes
Multimorbidity	• Presence of two or more long-term health conditions and increases with age with more medication use
Polypharmacy	• Use of five or more medicines that include over-the-counter, prescription and/or T&CM products
High-risk (high-alert) medications	• Pose a higher risk of harm when used in error or inappropriately
Antimicrobials and resistance	• In 2019, 4.95 million deaths were associated with AMR • Common cause of allergic reactions, including anaphylaxis and death

Contributory factors for errors -ctd

Palliative care
- Most medical errors in palliative care are related to medicines particularly opioids

Transitions of care
- Discrepancy rate 56% noted and 11–59% are potentially at risk of harm

Medicines as products
- Substandard and falsified medicines
- Look-alike and sound-alike medicines
- Traditional and complementary medicines

Health and care workers
- Fatigue, burnout, distraction and interruption, psychological factors, inexperience, workload and insufficient decision support are reasons for errors

Health care systems
- High-income countries, have many systems to prevent medication errors while in LMICs systems factors such as handwritten prescriptions, overcrowding are more prone to errors

Policy options to address medication errors

Safety culture and managing change

- All workers accept responsibility for the safety
- Prioritize safety over financial and operational goals.
- encourages and rewards the identification, communication and resolution of safety issues.
- organizational learning from accidents.
- appropriate resources, structure and accountability to maintain effective safety systems.

Reporting medication errors and learning

- improve patient safety by learning from failures.
- identify the common errors reported that have caused serious patient harm and learn from those to take preventive actions
- should also allow reporting by patients and include reporting of errors or adverse events related to T&CM product

GLOBAL LAUNCH
GLOBAL PATIENT SAFETY CHALLENGE
ON MEDICATION SAFETY

29 March 2017, Bonn, Germany

The strategic framework

Four key domains and 16 subdomains

- Systems and Practices
- Healthcare professionals
- Medicines
- Patients and the public

Three action areas

- Polypharmacy
- High-risk (high-alert) situations
- Transitions of care

Patients and the public

Public awareness and medication literacy

- Make use of the WHO materials such as "KNOW. CHECK. ASK" campaign
- Correct misconception on traditional products as always 'safe'

Patient engagement

- Use The WHO patient engagement tool, "*5 Moments for Medication Safety*"

Reporting by patients

- Allowing patients to report any concerns about their medicines

Involvement of patient organizations:

- To provide patients' perspectives on improving medication safety

Health and care workers

Education and training

- Use the *WHO Curriculum Guide on Patient Safety*, section on medication safety, and the upcoming Medication safety curriculum guide to develop the skills
- Mentor new team members on safe medication systems and practice.

Communication and teamwork

- Provide clear and full information on medicines
- Read back during verbal orders to prevent errors

Capability at points of care

- Prescribe rationally and check on 5 rights (right patient, drug, dose, route and time) at all stages of medication use process.

Incident reporting and learning

- Share lessons learnt following any error with the healthcare team and with patients, when possible

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Patient Safety Curriculum Guide
Multi-professional Edition

Medicines as products

Product quality and safety

- Implement robust regulatory processes to avoid substandard and falsified medicines.
- Ensure quality control of T&CM products for safety.

Naming, labelling and packaging

- During registration of pharmaceuticals - especially for high-alert medicines and LASA medicines.
- Auxiliary labelling in facilities
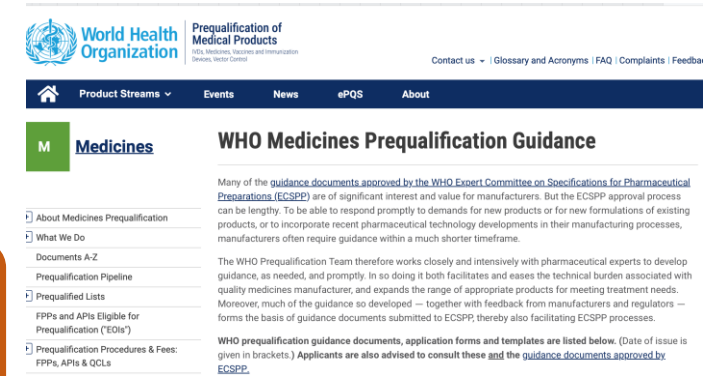
Medicines as products –ctd

Logistics, storage and disposal

- Maintain the cold chain specific to each product.
- Store high-alert and LASA medicines separately
- dispose medicines according to the guidelines.

The right products at points of care

- Prescribe rationally appropriate in the context of multi-morbidity and ageing.
- Empower patients to participate in decision-making

Systems and practices of medication

Leadership and governance

- Review health care systems to identify areas for improving medication safety
- Design and implement medication safety action plans
- Establish medication safety committees and officers.

Prescribing, preparation and dispensing

- Use technology and train staff on use – computerised technology
- Medication reconciliation and pharmacists in medication safety

Systems and practices of medication - ctd

Administration and patient monitoring

- prioritize high alert medicines, perioperative care, emergency departments, care of children and the elderly
- Analyse Medication errors, employ emergency clinical pharmacists, double checking and proactive monitoring

Monitoring and evaluation

- Ensure monitoring and evaluation of progress in medication safety programmes.
- Determine the impact of interventions

The 3 action areas

High risk situations

- Identifying high risk medicines
- Prioritize high risk situations for actions

Transitions of care

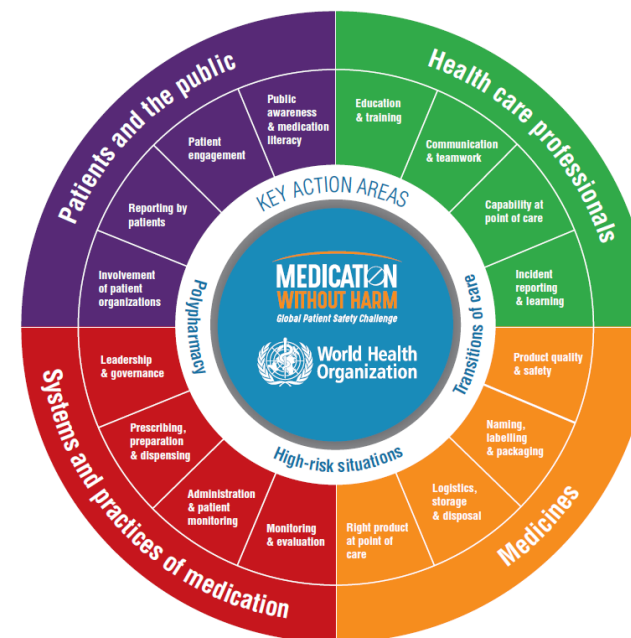- Medication reconciliation

Polypharmacy

- Deprescribing
- Rational prescribing

A pledge to sign

Countries are asked to **sign a pledge** (Annex 2) to support the Challenge and to encourage as many of their health care facilities as possible to also pledge adoption of the Challenge. A five-point plan has been developed to facilitate adoption:

1. Designate a national coordinator of the WHO Global Patient Safety Challenge: *Medication Without Harm*

2. Take early action to protect patients from harm arising from high-risk situations, polypharmacy and transitions of care.

3. Convene national experts, health system leaders and practitioners to develop guidance and action plans for each of the four domains of the strategic framework:

   ▸ patients and the public

   ▸ health and care workers

   ▸ medicines as products

   ▸ systems and practices.

4. Establish mechanisms, including tools and technologies, to enhance patient awareness and knowledge about medicines and medication use process, and their role in managing their own medications safely.

5. Assess progress regularly.

Thank you