Medication Errors & Patient Safety - Part I

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Why Medication Errors Matter More Than We Think?

Medication errors are a significant public health concern, often occurring during various stages of care, whether preventive, diagnostic, therapeutic, or rehabilitative. These errors not only affect patient outcomes but also highlight critical gaps in the safe use of medicinal products. There is a growing need to strengthen risk mitigation strategies and enhance prevention efforts through existing regulatory mechanisms. Beyond the clinical impact, medication-related harm also places a substantial financial burden on healthcare systems globally, with associated costs estimated at around US $42 billion each year.

Medication errors are unintended mistakes that can happen at any stage of the medication process, whether it's during prescribing, storing, dispensing, preparation, or administration. When such errors occur repeatedly, follow a recognizable pattern, or lead to serious patient harm, it becomes critical to investigate the root causes and contributing factors. Understanding the clinical impact of these incidents, along with identifying practical solutions and preventive strategies, is key to ensuring they do not recur.

Stages of Medication Use Process

Storage → Prescribing Stage → Transcribing Stage → Preparation Stage → Dispensing Stage → Administation Stage → Monitoring Stage

What is a Medication Error?

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.

Adverse Event

- GVP Annex I (Rev 3) defines an adverse event as 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.
- An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.
- Medication related adverse events should be distinguished from other adverse events (e.g. fall, surgery on wrong body site etc.).

Adverse Reaction

An adverse reaction (ADR) is a response to a medicinal product which is noxious and unintended (Directive 2001/83/EC, Article 1 (11)). This includes adverse reactions which arise from:

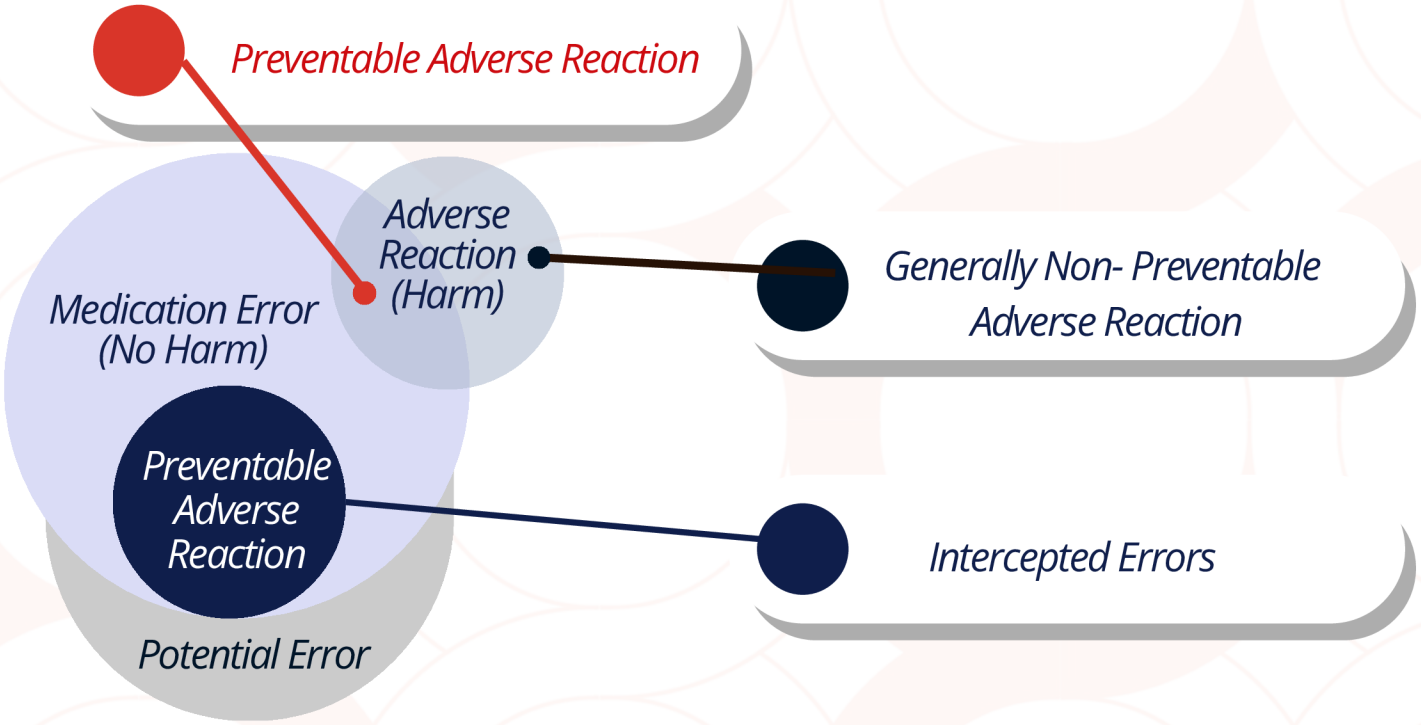
- The use of a medicinal product within the terms of the marketing authorization.
- The use outside the terms of the marketing authorization, including overdose, off-label use, misuse, abuse and medication errors;
- Occupational exposure.

Patient Safety Incident

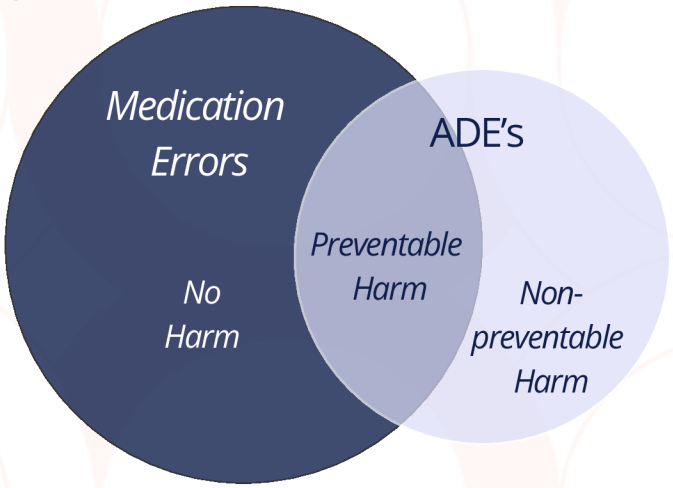
WHO's Conceptual Framework for International Classification for Patient Safety (WHO ICPS) defines a patient safety incident as an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. The scope of patient safety incidents covers the entire health care process whereas the scope of (suspected) adverse reactions in pharmacovigilance is limited to the use of medicines by a consumer or healthcare professional.

Correlation Among Medication Errors, Preventable and Non-Preventable Adverse Reactions, and Intercepted Errors

The diagram is provided for illustrative purposes only to support understanding of medication errors in the context of patient safety, and is not intended to inform or replace pharmacovigilance reporting obligations.



Reference: European Medicines Agency Good practice guide on recording, coding, reporting and assessment of medication errors. EMA/762563/2014



Reference: Contemporary View of Medication–Related Harm. A New Paradigm. NCC MERP and Medication Errors. www.nccmerp.org

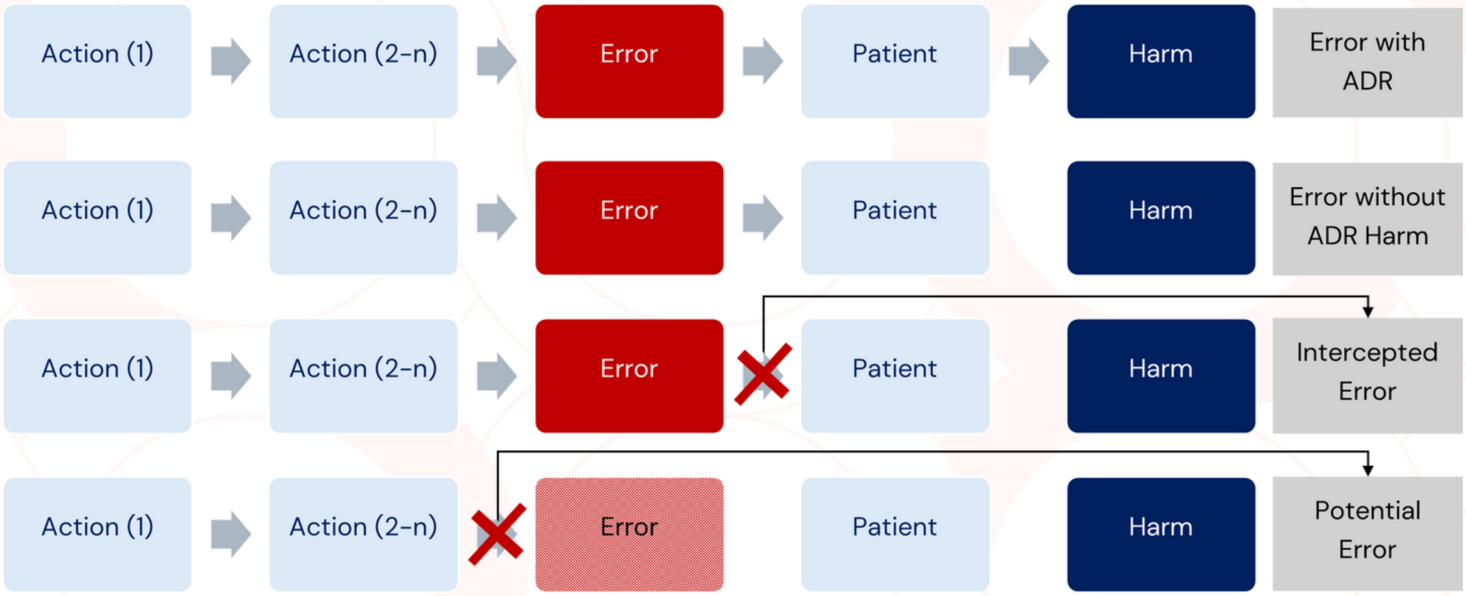
Classification of Medication Errors Reports

To support effective recording, coding, reporting, and assessment, medication errors should be classified based on factual information specific to each case.

It is important to clearly distinguish between:

- Medication errors associated with adverse reaction(s)
- Medication errors without harm
- Intercepted medication errors
- Potential medication errors

The classification depends on where the break occurs in the sequence of events leading to the error and the resulting consequences for the patient, as illustrated below:



Intercepted Medication errors (Near Miss)

An intercepted error indicates that an intervention caused a break in the chain of events in the treatment process before reaching the patient which would have resulted in a 'potential' ADR. The intervention has prevented actual harm being caused to the patient. A near miss from a patient safety perspective is a random break in the chain of events leading up to a potential adverse event which has prevented injury, damage, illness or harm, but the potential for harm was nonetheless very near.

Example: A wrongly prepared medicine is intercepted by a nurse before being administered.

Potential Medication Errors

The recognition of circumstances that could lead to a medication error, and may or may not involve a patient. Refers to all possible mistakes in the prescribing, storing, dispensing, preparation for administration or administration of a medicinal product by all persons who are involved in the medication process and may lead to:

- medication error with harm, but without knowing the actual cause,
- medication error without harm and without knowing the actual cause, or
- medication error without harm, but with the awareness of the actual cause.

Example: Pharmacist noticed that the names of two medicines are similar and could clearly lead to product name confusion in practice, but no patient was actually involved or has taken the medicine. (Scenario c)

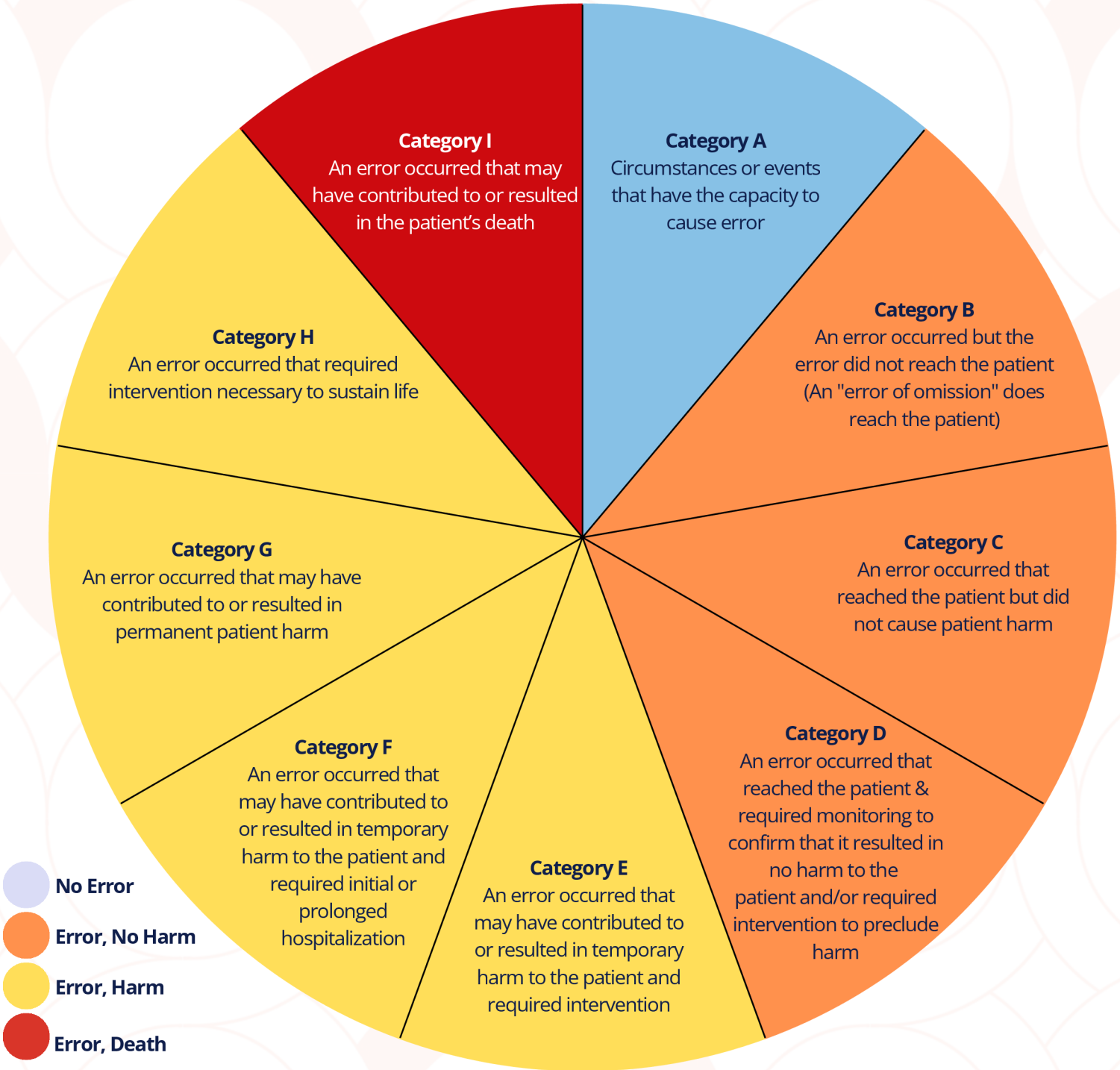
Medication Errors with Harm (Adverse Reactions)

Medication errors that result in harm to the patient, specifically those associated with one or more adverse reactions. These cases also involve preventability.

Example: A patient receives an incorrect dose leading to hypotension and hospitalization.

Medication Errors without harm

NCC MERP Index for Categorizing Medication Errors



Selected References

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6. National Coordinating Council for Medication Error Reporting and Prevention. Available at: www.nccmerp.org.
7. www.fda.com and www.ema.europa.eu

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Dr. Sumit Verma is a medical graduate with specialization in anesthesiology and has more than 15 years of experience in the pharmaceutical industry, clinical medicine, clinical research, and pharmacovigilance. He has built teams that have consistently delivered and exceeded customer expectations across pharmacovigilance domains such as case processing, signal management, risk management, aggregate reports, and clinical safety. He has co-authored two books – one on pharmacovigilance and another on pharmacology.

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