

Unit 5: Medication Errors and Pharmacovigilance

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5.1 Medication errors: definition

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, the patient or the consumer, in the standard textbook definition associated with the error literature the syllabus cites. Three words do the work. Preventable distinguishes the error from the adverse reaction of Section 5.8, which can occur with flawless practice; an error is by definition something the system could have prevented. Event includes near misses, errors caught before they reached the patient and errors that reached the patient without harm, because all three teach the same lesson and only chance separates them. Inappropriate use or harm states the outcome range honestly: most errors harm no one, some harm seriously, and a safety system studies the whole distribution rather than waiting for its worst member. Errors may occur at any stage the next sections trace: prescribing, transcribing and documenting, dispensing, administering and monitoring.

5.2 Categorization of medication errors

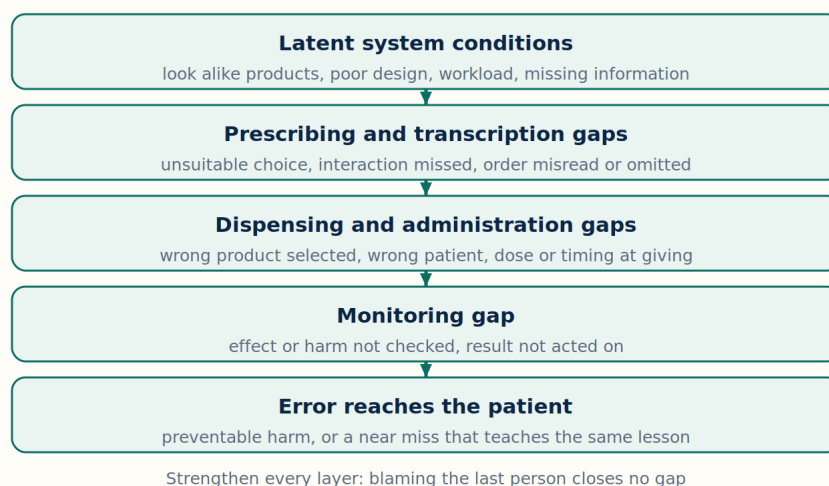
Errors are categorised in several complementary ways, and an examination answer gains by naming the scheme it is using. By stage, errors are prescribing errors, wrong medicine, wrong patient, unsuitable choice, illegible or incomplete order, interaction or allergy missed; transcription and documentation errors, the order changed, omitted or misread as it is copied or entered; dispensing errors, wrong product, strength, form, label or patient at supply; administration errors, wrong patient, medicine, route, time or omission at the point of giving; and monitoring errors, the effect or harm that should have been checked and was not. By outcome, systems grade errors from circumstances with the capacity to cause error, through errors that did not reach the patient, errors that reached the patient without harm, errors requiring monitoring or intervention, to errors contributing to temporary or permanent harm or death, the severity ladder associated with the standard error index teaching. By type of failure, wrong dose in the qualitative sense, wrong medicine and wrong patient remain the classic triad. Categorisation is not bureaucracy: the category decides the countermeasure, because an illegibility problem, a look alike product problem and a knowledge problem have nothing in common except the word error.

Category by stage	Typical failure	First line countermeasure
Prescribing	Unsuitable choice, interaction or allergy missed, incomplete order	Decision support, pharmacist chart review, prescribing guidance
Transcribing and documentation	Order misread, omitted or changed in copying or entry	Direct electronic entry, read back, reconciliation at transfer
Dispensing	Wrong product, form or label, look alike selection	Independent check, separated storage, labelling discipline
Administration	Wrong patient or medicine, omission, wrong timing	Patient identification checks, administration record discipline
Monitoring	Effect or harm not checked, result not acted on	Planned monitoring, result ownership, pharmacist review

5.3 Causes of medication errors

Causes are taught at two levels, the active failure at the sharp end and the latent conditions behind it, because prevention that punishes the last person and changes nothing else guarantees a repetition with a different person. Active failures include slips and lapses, the right intention executed wrongly, a look alike packet picked, a decimal misread, a step omitted under interruption; mistakes, the wrong intention itself, from incomplete knowledge of the medicine, the patient or the interaction; and, rarely, deliberate violations of safe procedure. Latent conditions are the system's contribution: look alike and sound alike names and packaging, poor prescription and system design, excessive workload, fatigue and interruption, inadequate staffing and training, missing information at the moment of decision, patients transferred without reconciled lists, and technology that introduces its own failure modes as Unit 3 described. Human factors teaching summarises the insight in the image of defensive layers with gaps: harm reaches a patient when the gaps in several layers, design, checking, supervision, happen to align. The pharmacist reading an error report therefore asks two questions in order: what happened, and what in our system made it likely.

Medication errors: how harm aligns



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Figure: Harm reaches the patient when gaps align. Strengthen layers and close gaps; blaming the last layer changes neither.

5.4 Detection of medication errors

Detection runs through every checking layer a service builds, and then through the patient's own report. Prescription and chart review by the pharmacist before supply or administration is the highest yield detection point in institutional practice, catching prescribing errors while they are still ink. Double checks at dispensing and administration, independent where the risk justifies them, catch execution errors. Clinical review during therapy catches the error that only declares itself in the patient: the unexpected effect, the missing expected effect, the laboratory result that does not fit. Incident and near miss reporting systems detect what no check caught and, read in aggregate, reveal patterns no single event shows: the ward, the hour, the product pair, the system step where errors concentrate. Trigger based record review, searching records for signals such as antidote use in the generic sense, abrupt stopping or rescue treatment, finds errors and harms that were never reported as such. Patients and carers detect errors too, the tablet that looks different, the instruction that contradicts last month's, and a service that invites those questions respectfully owns a detection layer no technology replaces.

5.5 Prevention of medication errors

Prevention follows from causes, and its measures are strongest when they redesign the system rather than exhort the person. Standardisation removes variation that breeds error: standard order formats and concentrations in the generic sense, standard administration times, formularies that limit look alike duplication. Design and forcing functions make the wrong act difficult: separated storage of look alike products, distinctive labelling, systems that require the allergy field before the order completes, removal of dangerously ambiguous abbreviations from accepted use. Information at the point of decision, interaction and allergy checking inside electronic systems, guidelines inside the workflow, puts knowledge where memory fails. Independent checks are reserved and protected for high risk steps, because a check performed as ritual catches nothing. Education and competency assessment address the knowledge based mistakes, and staffing, workload and interruption management address the conditions in which slips multiply. Finally, the reporting and learning loop of the previous section is itself prevention, because the service that studies its near misses redesigns before the aligned gap produces harm. The pharmacist appears in nearly every measure, as checker, designer, educator and analyst, which prepares the role section below.

5.6 Role of the pharmacist in monitoring and management of medication errors

The pharmacist's role divides into the individual event and the system. For the individual event the duties are immediate and ordered: ensure the patient is safe and the prescriber informed at once where an error has reached a patient, with monitoring and management as the clinical team directs; establish exactly what happened, which medicine, which patient, what was actually given against what was intended, factually and without speculation; document and report through the institution's system fully and promptly; and participate honestly in the review that follows. Concealment is the one unforgivable response, clinically, ethically and in law, because it denies the patient care and the system its lesson. For the system the role is continuing: reviewing error and near miss reports for pattern, leading or serving the medication safety committee work, proposing and evaluating redesigns with the Unit 1 evaluation cycle, educating staff on the error types the data actually show, and feeding serious lessons into formulary, guideline and system decisions. Monitoring in the syllabus phrase therefore means both senses: watching the individual patient's therapy for error, and watching the institution's error pattern over time.

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When an error is found: the pharmacist's sequence
  Make the patient safe, inform the prescriber at once
    |
    v
  Establish the facts: intended against actual, exactly
    |
    v
  Document and report fully through the safety system
    |
    v
  Review without blame: what in the system allowed it
    |
    v
  Redesign, educate, and check the fix worked
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5.7 Pharmacovigilance: definition, aims and need

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem, in the standard World Health Organization definition. Its aims follow: to detect adverse drug reactions early, especially those not seen before approval; to assess their nature, seriousness and cause in careful relation to the medicine; to understand the factors that predispose to them and the mechanisms by which they occur; and to prevent harm by acting on what is learned, in product information, guidance, restriction or withdrawal, and in

professional and patient education. The need is structural and permanent. Before approval a medicine has been studied in limited numbers, for limited durations, in selected patients who are usually younger, less ill and on fewer other medicines than the patients who will receive it in practice, a limitation the clinical research subject teaches from the trial side. Whole classes of harm are therefore invisible at launch by arithmetic and by selection: rare reactions, long latency reactions, reactions in pregnancy, childhood, old age and organ failure, and interactions with the real world's full medicine lists. Only systematic watching of real use can find them, which is why pharmacovigilance is not suspicion of medicines but the second half of their evidence.

5.8 Adverse drug reactions: types

An adverse drug reaction, shortened to ADR, is a response to a medicine which is noxious and unintended and which occurs at doses normally used in human beings for prophylaxis, diagnosis or therapy, in the classic definition, with dose again understood as the normal therapeutic range and never as figures here. The standard teaching classification divides reactions first by predictability and mechanism. Type A reactions are augmented: extensions of the known pharmacology, predictable in kind, related to the medicine's action and to individual exposure and susceptibility, and they account for the large familiar territory of side effects. Type B reactions are bizarre: not predictable from the known pharmacology, not clearly exposure related, often immunological or idiosyncratic, rarer and frequently more serious. Extended teaching adds further letters in common use: chronic reactions with continued use, delayed reactions appearing after time or after stopping, reactions of withdrawal on ending treatment, and failure of therapy as a reportable outcome where resistance, interaction or quality is in question. A second classification, by seriousness, separates the serious reaction, one that is fatal, life threatening, hospitalising, disabling or otherwise medically important, from the non serious, because seriousness drives the speed and route of reporting and action.

5.9 Predisposing factors and mechanisms of ADRs

Predisposing factors explain why the same medicine harms one patient and serves another. Patient factors include age at both extremes, sex, pregnancy, genetic differences in metabolism and immune response, allergic history, and the disease state itself, especially kidney and liver impairment changing exposure and injured organs tolerating insult poorly. Medicine factors include the drug's inherent toxicity and therapeutic width, its route and duration, and above all its company: polypharmacy multiplies interaction possibilities, and interactions, one medicine altering another's absorption, metabolism, excretion or effect, are among the most preventable of all ADR causes and the pharmacist's daily screening ground. Mechanisms, stated at framework level, divide into pharmacodynamic mechanisms, the medicine acting too much, too long or on an unintended target or tissue; pharmacokinetic mechanisms, exposure raised or lowered by interaction, organ failure or genetics until effect becomes harm; immunological mechanisms, the allergy family, in which the immune system treats the medicine or its product as foreign, with presentations from rash to anaphylaxis; and idiosyncratic mechanisms, rare, genetically or metabolically rooted susceptibilities whose lesson so far is humility and reporting. Predisposition is not blame: its use is prospective, to choose, monitor and counsel better for the next patient.

5.10 Detection, reporting and monitoring of ADRs

Detection begins at the bedside and the counter with a habit of suspicion: any new symptom, sign or laboratory change in a medicated patient is a possible ADR until considered, its timing against starting, changing or stopping medicines examined, and other causes weighed without assuming the medicine innocent or guilty in advance. Reporting converts private suspicion into public knowledge. The core system is spontaneous reporting: a health professional, and in modern systems the patient also, submits a report of

a suspected reaction with the essential elements, an identifiable patient in protected form, the suspect medicine, the reaction and its course, and the reporter, to the national pharmacovigilance programme, in India the Pharmacovigilance Programme of India coordinated through the Indian Pharmacopoeia Commission channel in its standard textbook description, with reports flowing onward into international monitoring. Monitoring completes the work at three levels: the individual patient, watched and followed to outcome; the institution, where ADR committees review reports, feed learning into guidelines and education and close the loop with reporters; and the population, where aggregated reports are examined for signals, patterns of harm not visible in any single report, which regulators assess and act on. Underreporting is the system's known weakness, answered by making reporting easy, thanked and visibly used, and by teaching that a suspicion honestly reported is a contribution, not an accusation to be proved first.

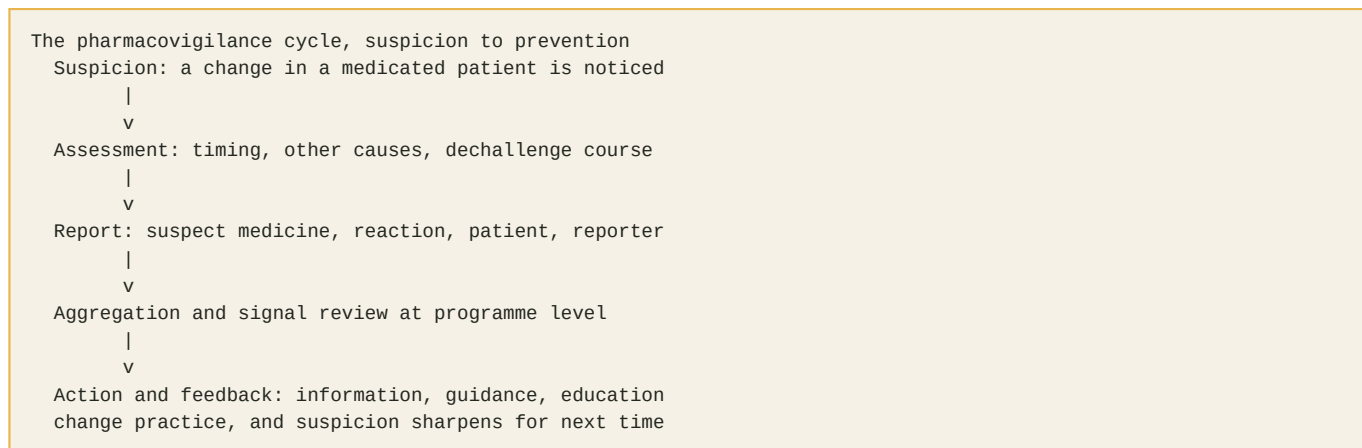
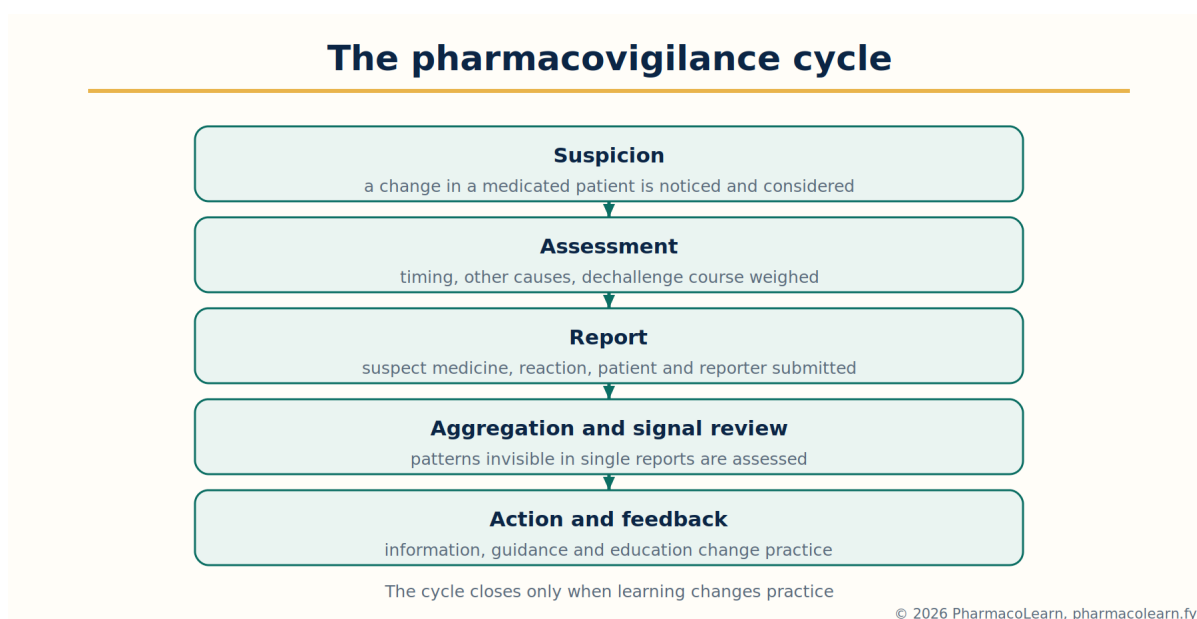


Figure: Reporting is the middle of pharmacovigilance, not the end. The cycle closes only when learning changes practice.

5.11 Causality assessment of ADRs

Causality assessment is the structured judgement of how likely it is that the suspect medicine caused the observed reaction, made because temporal association alone, the reaction followed the medicine, does not establish cause. The assessment weighs a standard set of considerations: the temporal relationship, whether the timing fits the known behaviour of such reactions; previous knowledge, whether the reaction is already recognised for this medicine or its class; dechallenge, what happened when the medicine was stopped, allowing for reactions that resolve slowly or not at all; rechallenge, whether the reaction recurred on re exposure, powerful evidence that is only ever weighed from history and never deliberately sought

where the reaction was serious; alternative causes, the disease, other medicines and other exposures that could explain the event; and the patient's predisposing factors of the previous section. Formal instruments organise this judgement into categories running from certain through probable and possible to unlikely, the World Health Organization Uppsala Monitoring Centre categories in their standard form, and algorithmic scales such as the Naranjo scale in its textbook form score the same considerations into a probability band. The examination point is the reasoning, not the label: a good assessment shows the evidence for each consideration and lands on a category the reasoning supports.

5.12 Management of ADRs

Management begins with the patient, in seriousness order. The immediate duties are to recognise severity, stop or withhold the suspect medicine where the reaction and the clinical situation require it and the prescriber so directs, remembering that some medicines need planned withdrawal rather than abrupt stopping, and to give the supportive and specific treatment the reaction demands under medical direction, with emergency treatment first where the reaction threatens life. The continuing duties are documentation and protection of the future: the reaction, its suspect medicine, its course and its outcome recorded prominently in the record; allergy and intolerance entries made accurately, distinguishing true allergy from intolerance so future choices are guided and not needlessly narrowed; the patient and carers informed in plain language what happened, which medicine is suspected and what to avoid and to declare at every future consultation; and the report of Section 5.10 filed, because an unreported reaction protects no one else. Where the medicine remains necessary and no alternative serves, specialist led decisions, graded re exposure or desensitisation in the settings equipped for them, belong to specialist practice and are named here only to mark their existence and their boundary. Review of the whole event by the institutional committee converts management into prevention, closing the subject where it began, with evaluation.

5.13 Role of the pharmacist in pharmacovigilance

The pharmacist is placed, by position and by knowledge, at the centre of pharmacovigilance practice. At detection, pharmacists review charts and dispensing patterns with ADR suspicion as a standing question, are accessible to patients at the counter where reactions are first mentioned in ordinary language, and pick up the interaction and predisposition patterns other reviewers miss. At reporting, the pharmacist completes, quality checks and submits reports, helps other professionals report by making the process easy and the forms complete, and follows reports to outcome so the record is whole. At assessment, medicine information pharmacists work up causality and literature for the institutional committee. At prevention, the pharmacist turns learning into formulary conditions, alerts and counselling points, allergy documentation standards and education, and counsels the patient who has experienced a reaction so that fear is answered with a plan and future prescribers inherit knowledge rather than rumour. In the national programme the profession staffs and leads much of the monitoring centre work itself. The syllabus phrase role of pharmacist in pharmacovigilance therefore earns a full answer: detector, reporter, assessor, educator and system builder, the same fivefold shape as the medication error role, because the two halves of this unit are one safety profession seen from two sides.

Frequently Asked Questions

Q: What is quality use of medicines? A: Quality use of medicines means medicines are used wisely, safely and effectively: the decision to use a medicine and the choice of medicine are judicious and evidence informed, risks are known and managed, and the medicine reaches the right patient in a usable form for long enough to work, with its effect reviewed. It is a property of decisions and systems, not of products.

Q: What are the principles of QUM? A: The principles are primacy of the person, partnership among all who share responsibility for a medicine, consultative and collaborative practice, support for consumer and professional education, evidence informed decision making, and monitoring with accountability. A strong answer illustrates one principle in a named activity, such as partnership operating in a multidisciplinary medication review.

Q: What is evidence based medicine and what are its five steps? A: Evidence based medicine is the conscientious, explicit and judicious use of current best evidence in decisions about individual patients, integrated with clinical expertise and the patient's values. Its five steps are ask an answerable question, acquire the best evidence, appraise it for validity, effect size and applicability, apply it with expertise and patient values, and assess the outcome.

Q: What are essential medicines and why does a country need a list? A: Essential medicines are those that satisfy the priority healthcare needs of the population, selected on disease pattern, evidence of efficacy and safety, quality and comparative cost effectiveness. A limited list concentrates procurement, quality assurance, training and information on the medicines of greatest need, keeps them available and affordable, and anchors formularies and prescribing guidance. In India the instrument is the National List of Essential Medicines in its current revision.

Q: What is rational drug use? A: Rational drug use requires that patients receive medications appropriate to their clinical needs, in doses meeting their individual requirements, for an adequate period of time, and at the lowest cost to them and their community, in the classic World Health Organization formulation. Its opposites include prescribing where no medicine is indicated, too many medicines per encounter, guideline departure without reason and unsafe self medication.

Q: How does QUM differ between hospital, ambulatory and residential care? A: In hospital, QUM runs through committees, formularies and ward based clinical pharmacy, with transitions at admission and discharge as its weak points. In ambulatory care it rests on brief encounters, maintained medicine lists, periodic review and the community pharmacist's checks and counselling. In residential care its centre is structured periodic medication review by prescriber, pharmacist and care team, because residents take many medicines, are administered them by staff and report problems least easily.

Q: What changes in prescribing for children, older people, pregnancy and organ failure? A: Standard adult assumptions about handling and risk do not hold. Children change rapidly in absorption, distribution, metabolism and excretion and need age and weight based checking, suitable formulations and caregiver counselling. Older people accumulate medicines and declining organ function, so whole list review and deprescribing dominate. Pregnancy requires holding maternal benefit and fetal risk together using specialist information sources. Organ failure changes clearance and accumulation, so organ function based guidance and deliberate monitoring govern choices.

Q: What does drug scheduling do for quality use of medicines in India? A: Scheduling under the Drugs and Cosmetics Rules grades the conditions of sale to the risk of unsupervised use: prescription only supply for medicines needing medical supervision, added records and warnings for medicines with dependence or misuse potential, and labelling requirements across supply. The pharmacist at the counter is where scheduling becomes real, by insisting on required prescriptions and keeping required records.

Q: What is a medication error and how is it different from an adverse drug reaction? A: A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a professional, patient or consumer, at prescribing, transcribing, dispensing, administering or monitoring. An adverse drug reaction is a noxious, unintended response at normally used doses and can occur with completely correct practice. Preventability is the dividing line.

Q: What is pharmacovigilance and how is causality of an ADR assessed? A: Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects and other medicine related problems, needed because pre approval studies are too small, short and selected to reveal rare, delayed and population specific harm. Causality assessment weighs timing, previous knowledge of the reaction, dechallenge, any history of rechallenge, alternative causes and predisposing factors, and expresses the judgement in categories from certain to unlikely, as in the World Health Organization Uppsala categories.

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