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Medication Error, Medical Negligence And Therapeutic Misadventure: A Legal and Comparative Study

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Abstract : *Medication errors, therapeutic misadventures and medical negligence are significant concerns in the healthcare system as they directly affect patient safety, medical ethics and professional accountability. Although these concepts are closely related, they differ in their nature, causes and legal consequences. Medication errors refer to unintended mistakes in prescribing, dispensing or administering medicines, whereas therapeutic misadventures involve unexpected adverse outcomes arising during or after medical treatment, even when reasonable care has been exercised. Medical negligence, on the other hand, involves the failure of a medical professional or healthcare institution to maintain the required standard of care, resulting in harm to the patient. This study comparatively examines these three concepts, focusing on their meaning, causes, essential features, distinguishing factors and legal implications. It also analyses the responsibilities of healthcare professionals, the importance of informed consent, patient rights and the legal remedies available under the Indian legal framework. The study highlights the need for effective medication-management practices, proper medical documentation, professional training and institutional accountability. It emphasises that every medication error or adverse treatment outcome does not automatically constitute medical negligence. The ultimate objective is to promote patient safety, protect patients' rights and establish a balanced approach towards medical accountability and professional responsibility.*

Keywords: Medication Error, Therapeutic Misadventure, Medical Negligence, Patient Safety, Informed Consent, Medical Ethics, Patient Rights, Healthcare Accountability.

I. INTRODUCTION

Healthcare plays a vital role in protecting human life and maintaining public health. Patients depend on doctors, nurses, hospitals and other healthcare professionals for safe and effective medical treatment. However, mistakes during medication, unexpected treatment complications and failures in professional care remain significant challenges in the healthcare system. Medication errors, therapeutic misadventures and medical negligence are three important concepts that directly influence patient safety, medical ethics and legal accountability.

A medication error refers to an unintended mistake in prescribing, dispensing, preparing or administering medicines that may cause harm to a patient[1]. Therapeutic misadventure refers to an unexpected adverse outcome arising during or following medical treatment, which may occur even when reasonable care has been exercised. Medical negligence, on the other hand, involves the failure of a medical professional or healthcare institution to maintain the reasonable standard of care expected under similar circumstances, resulting in injury or harm to the patient.

[1] World Health Organization, *Medication Without Harm: WHO Global Patient Safety Challenge on Medication Safety* (WHO, Geneva, 2017).

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Although these concepts are closely connected, they are not legally or medically identical. A medication error does not automatically amount to medical negligence, and an adverse outcome during treatment does not necessarily establish professional misconduct. The circumstances, nature of the mistake, standard of medical care, causal relationship and injury suffered by the patient must be carefully examined to determine responsibility. Understanding these differences is essential to distinguish preventable medical mistakes from unavoidable treatment complications and legally actionable negligence.

In India, the protection of patients and accountability of healthcare professionals are addressed through various legal mechanisms, including the Consumer Protection Act, 2019, the Bharatiya Nyaya Sanhita, 2023, the law of torts and applicable professional medical regulations. These legal frameworks provide different remedies and standards of responsibility depending on the nature of the incident.

Therefore, this study comparatively examines medication errors, therapeutic misadventures and medical negligence, focusing on their meaning, causes, distinguishing features, patient consequences and legal implications[2]. It also highlights the importance of informed consent, professional responsibility, proper medical documentation and effective patient-safety measures. The ultimate objective is to promote a balanced healthcare system that protects patients' rights while ensuring fairness and accountability for medical professionals.

1. MEDICATION ERROR

A medication error is any preventable event that may lead to inappropriate medication use or patient harm while a medicine is under the control of a healthcare professional, patient, or consumer. Errors can occur during prescribing, dispensing, administration, or monitoring.

Which includes giving the wrong medicine, the wrong dose, or a medicine to the wrong patient. A medication error does not always cause harm—it may be identified and corrected before reaching the patien[3]t.

1.1. Origin of the word

Medical comes through French médical from Late Latin medicalis, meaning “of a physician.” Its roots include Latin medicus, meaning “physician,” and medeor, meaning “to heal or cure.”

Error comes through Old French error from Latin error, meaning “wandering,” “straying,” or “mistake.” It derives from errare, meaning “to wander” or “to go astray.”

1.2. Definition of Medical error

A medical error is “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim,” according to the Institute of Medicine. In simple terms, it means carrying out the right plan incorrectly or choosing an incorrect plan during healthcare[4]. An error may or may not cause patient harm.

1.3. Types of Medication errors

Medication errors can occur during prescribing, recording, dispensing, preparing, administering, or monitoring medicines. They may be classified by the stage at which they occur or by the specific mistake made, so some categories overlap

[2] National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), *About Medication Errors*, United States.

[3] World Health Organization, *Patient Safety: Global Action Plan 2021–2030* (WHO, Geneva, 2021).

[4] Institute of Medicine, *Preventing Medication Errors* (National Academies Press, Washington, D.C., 2007).

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i. Prescribing errors

These occur when a doctor selects an incorrect drug, dose, dosage form, quantity, route, concentration, rate of administration, frequency, or duration of therapy. Examples include prescribing an excessive dose, selecting a drug to which the patient is allergic, or continuing a medicine longer than necessary.

ii. Transcription errors

These occur when a prescription or medication order is incorrectly copied into a medical record, medication chart, or nursing chart. Errors may involve the wrong drug name, dose, formulation, route, frequency, omission of a medicine, or inclusion of an unordered medicine.

iii Dispensing errors

These occur when a pharmacist dispenses a medicine that differs from the prescribed medicine. Examples include dispensing the wrong drug, wrong strength, wrong dosage form, wrong quantity, or wrong labelling.

iv Administration errors

These occur when a nurse or other healthcare worker gives the medicine incorrectly to the patient. Common types include:

- **Wrong drug**: Giving a medicine other than the one prescribed.
- **Wrong dose**: Giving more or less than the prescribed dose, including an extra dose.
- **Wrong route**: Giving a medicine orally instead of intravenously, or by another incorrect route.
- **Wrong time**: Giving the medicine outside the scheduled time interval.
- **Wrong patient:** Giving the medicine to the wrong patient due to failure to verify identity.
- **Omission error**: Failing to give an ordered dose before the next scheduled dose.
- **Wrong rate**: Administering an infusion too quickly or too slowly.
- **Wrong technique**: Incorrect preparation or administration method, such as crushing a tablet that should not be crushed.
- **Unauthorised drug**: Giving a medicine without a valid prescriber's order.

v Preparation and compounding errors

These occur before administration, during the preparation or reconstitution of a medicine. Examples include adding too much or too little diluent, preparing the wrong concentration, or incorrectly mixing two medicines.

vi Monitoring errors

These occur when a healthcare professional fails to review or monitor drug therapy appropriately. Examples include failure to monitor blood glucose for insulin, INR for warfarin, renal function for nephrotoxic drugs, drug levels for narrow-therapeutic-index medicines, or failure to act on abnormal test results.

vii Patient-use errors

These occur when a patient takes a medicine incorrectly, such as taking the wrong dose, missing doses, taking a medicine at the wrong time, stopping treatment early, or using an expired or deteriorated medicine.

Other important types

Known-allergy error: Giving a medicine to a patient with a documented allergy or known adverse reaction.

Drug-interaction error: Prescribing or administering medicines that interact dangerously with each other, food, alcohol, or herbal products.

Deteriorated-drug error: Dispensing or administering an expired, contaminated, or physically/chemically damaged medicine.

Duplicate-therapy error: Giving the same therapeutic effect through two medicines unnecessarily, increasing the risk of toxicity.

Medication errors usually result from a combination of human factors and weaknesses in

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1.4 Causes of Medication Errors

Medication errors usually result from a combination of human factors and weaknesses in the healthcare system, rather than a single person's mistake. Common causes include:

- **Poor communication** — unclear verbal orders, incomplete handovers, or misunderstanding between healthcare professionals and patients[5].
- **Illegible or incomplete prescriptions** — unclear handwriting, missing instructions, confusing abbreviations, or incorrect decimal points and units.
- **Inadequate knowledge or training** — unfamiliarity with a medicine's dose, interactions, preparation, or administration requirements.
- **Heavy workload and understaffing** — time pressure and excessive work can lead to rushing and missed safety checks.
- **Fatigue and stress** — tiredness, burnout, and reduced concentration can increase mistakes.
- **Distractions and interruptions** — noise, multitasking, or interruptions during prescribing, dispensing, or administration.
- **Look-alike and sound-alike medicines** — similar drug names, packaging, colours, or strengths can cause confusion.
- **Dose-calculation errors** — mistakes in calculating doses, converting units, or preparing concentrations and dilutions.
- **Incomplete patient information** — lack of accurate information about allergies, current medicines, or recent medication changes.
- **Poor storage and labelling** — confusing labels, similar medicines stored together, or improper storage conditions.[6]
- **Failure to follow safety procedures** — inadequate checking, poor documentation, or failure to follow agreed protocols.
- **Technology-related errors** — selecting the wrong medicine or strength from a computer's drop-down menu.
- **Inadequate patient instructions** — unclear explanations about how much medicine to t Legal Framework for Medication Errors

1.5 Legal Framework in India

✓ **Drugs and Cosmetics Act, 1940**

The Drugs and Cosmetics Act, 1940 is the principal law regulating medicines in India. It governs the manufacture, sale, distribution, import, labelling, and quality of drugs. The Central Drugs Standard Control Organisation (CDSCO) is the national regulatory authority under this framework[7].

- The Act helps prevent medication errors by regulating:
- Licensing of manufacturers, importers, and sellers.
- Quality, purity, and strength of medicines.
- Labelling and packaging requirements.

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[5] World Health Organization, *Medication Without Harm: WHO Global Patient Safety Challenge on Medication Safety* (WHO, Geneva, 2017).

[6] Institute of Medicine, *To Err Is Human: Building a Safer Health System* (National Academy Press, Washington, D.C., 2000).

[7] The Drugs and Cosmetics Act, 1940, particularly the provisions regulating the import, manufacture, distribution and sale of drugs.

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- Prohibition of misbranded, spurious, or adulterated drugs.
- Recall and regulatory action against unsafe medicines.

✓ **Drugs and Cosmetics Rules, 1945**

These Rules provide detailed requirements for drug manufacturing, sale, storage, labelling, record-keeping, and pharmacovigilance. They are important because unclear labels, confusing packaging, wrong strength, or poor storage can directly lead to medication errors[8].

✓ **Pharmacovigilance Programme of India (PvPI)**

The PvPI is India's national system for collecting, analysing, and acting upon reports of adverse drug reactions and medicine-related safety problems. It is coordinated by the Indian Pharmacopoeia Commission (IPC), which functions as the National Coordination Centre, along with Adverse Drug Reaction Monitoring Centres (AMCs[9]).

CDSCO guidance states that adverse events due to lack of efficacy and medication error must also be reported to the national regulatory authority.

✓ **Clinical Trials Framework**

In clinical trials, serious adverse events must be reported quickly. The investigator must report a serious adverse event to CDSCO, the sponsor, and the Ethics Committee within 24 hours of occurrence, followed by a detailed analysis report within 14 days.[10]

This framework is important because medication errors during clinical trials can affect participant safety and must be documented and reported.

✓ **Medical Negligence Law**

If a medication error causes harm because a doctor, nurse, pharmacist, or hospital failed to exercise reasonable care, the patient may claim medical negligence.

The usual elements required to prove negligence are:

1. The professional owed a duty of care to the patient.
   The patient suffered damage or injury.
2. The breach directly caused the injury.

For example, if a nurse gives the wrong dose of insulin despite clear instructions, and the patient suffers serious hypoglycaemia, the hospital or professional may be liable if the act falls below the accepted standard of care.

✓ **Civil Liability**

A patient may file a civil claim for compensation in a civil court or before a consumer commission. Civil liability is based on failure to exercise reasonable care and skill.

✓ **Criminal Liability**

Criminal liability arises only in exceptional cases involving gross negligence or reckless disregard for patient life and safety. Ordinary human error, without gross negligence, usually does not amount to a criminal offence.

✓ **Consumer Protection Act, 2019**

- A patient who suffers harm due to a medication error may approach a consumer commission if the error amounts to deficiency in service. This may include:[11]
- A hospital administering the wrong medicine or wrong dose.
- A pharmacist dispensing the wrong medicine.
- A pharmacy giving unclear or incorrect instructions.

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[8] The Drugs and Cosmetics Rules, 1945.

[9] Indian Pharmacopoeia Commission, *Pharmacovigilance Programme of India (PvPI)*, Ministry of Health and Family Welfare, Government of India.

[10] Central Drugs Standard Control Organisation, *Guidance Document on Periodic Safety Update Reports* (2024)

[11] *Indian Medical Association v. V.P. Shantha*, (1995) 6 SCC 651.

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- A hospital failing to maintain proper medication records.
- A doctor prescribing a medicine without considering known allergies or interactions.
- The consumer commission can order compensation, refund, or other appropriate relief.[12]

✓ **Professional Discipline**

- A medication error may also lead to disciplinary action by professional bodies, including:[13]
- National Medical Commission or State Medical Councils: For doctors.
- Pharmacy Council or State Pharmacy Council: For pharmacists.
- Nursing Council: For nurses.
- Hospital authorities: Through internal disciplinary proceedings.
- Disciplinary action may include warning, suspension, cancellation of registration, or restrictions on practice, depending on the seriousness of the error.

1.6 International Legal and Regulatory Framework

✓ **World Health Organization**

WHO's Medication Without Harm initiative is the leading global framework for reducing avoidable medication-related harm. It is not a binding law, but it guides countries in strengthening medication-safety systems, reporting, training, and patient involvement[14].

Its focus areas include high-risk medicines, polypharmacy, and transitions of care, where medication errors are especially common.

✓ **8.2 ICH Guidelines**

The International Council for Harmonisation (ICH) provides globally accepted standards for pharmacovigilance.

i. ICH E2D: Covers post-approval safety data, including definitions and standards for reporting medication errors, misuse, abuse, and overdose[15].

ii. ICH E2B(R3): Provides the standard electronic format for transmitting individual case safety reports to regulators and safety databases[16].

These guidelines help countries collect medication-error data in a uniform manner and take regulatory action where necessary.[17]

✓ **United States Framework**

In the United States, the FDA regulates drug safety under the Federal Food, Drug, and Cosmetic Act. Its MedWatch programme allows healthcare professionals and the public to report serious adverse reactions, product-quality problems, therapeutic failure, and medication-use errors[18].

Medication-error reporting to FDA's Adverse Event Reporting System is generally voluntary, but the FDA uses such reports to identify safety risks and may require labelling changes, risk-management measures, or recalls[19].

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[12] Consumer Protection Act, 2019, Sections 2(11) and 2(42).

[13] *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1

[14] World Health Organization, *Medication Without Harm: WHO Global Patient Safety Challenge on Medication Safety* (WHO, Geneva, 2017)

[15] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), *ICH E2D: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting* (2003).

[16] International Council for Harmonisation, *ICH E2B(R3): Electronic Transmission of Individual Case Safety Reports*

[17] U.S. Food and Drug Administration, *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*.

[18] United States, Federal Food, Drug, and Cosmetic Act, 1938, 21 U.S.C. §§ 301–399i.

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✓ **European Union Framework**

The European Union has a harmonised pharmacovigilance system under Directive 2001/83/EC and Regulation (EC) No 726/2004. Marketing authorisation holders[20], healthcare professionals, and national authorities must monitor and report safety issues, including medication errors that reveal risks connected with a medicine's name, label, packaging, or instructions[21]

✓ **Legal Consequences of Medication Errors**

A medication error may result in:
Compensation: Payment for medical expenses, disability, pain, suffering, or loss of income.
Disciplinary action: Suspension or cancellation of professional registration.
Regulatory action: Drug recall, licence suspension, warning, inspection, or labelling changes.
Criminal prosecution: Only in cases of gross negligence or reckless disregard for life.
System correction: Improved protocols, staff training, electronic prescribing, barcode verification, and safer packaging.

✓ **Preventive Legal Standards**

Effective legal frameworks encourage healthcare institutions to adopt safety measures such as:
Clear prescription writing and electronic prescribing.
Barcode verification before administration.
Separate storage and clear labelling of look-alike and sound-alike medicines.
Double-checking high-risk medicines such as insulin, anticoagulants, opioids, and concentrated electrolytes.
Medication reconciliation during patient transfer between wards, hospitals, or home care.
Confidential reporting systems for errors and near misses.
Root cause analysis to identify system failures rather than only blaming individuals.ake, when to take it, or how to use it.

1.7 Case laws

1. Indian Medical Association v. V.P. Shantha - Held that medical services rendered for payment are "services" under the Consumer Protection Act, so patients can seek compensation for negligent prescribing, dispensing, or administration[22].

2. Jacob Mathew v. State of Punjab - The leading Indian negligence case: a professional must show the reasonable competence and care expected of an ordinarily skilled practitioner. A mere error of judgment or accident is not automatically negligence; criminal liability requires gross negligence or reckless disregard for life[23].

3. Norton v. Argonaut Insurance Co., 144 SO. 2D 249 (LA. APP. 1962) - A nurse gave the injectable form of Lanoxin when the physician intended oral liquid; the court held the nurse should have questioned an ambiguous order that specified volume but not route or milligram strength[24].

4. Fuhs v. Barber, 36 P.2d 962 (Kan. 1934) - A pharmacist who knew of a dangerous drug interaction but failed to warn the patient was liable for the resulting injury[25].

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[19] U.S. Food and Drug Administration, *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*.
[20] Directive 2001/83/EC of the European Parliament and of the Council on the Community Code Relating to Medicinal Products for Human Use.
[21] Regulation (EC) No. 726/2004 of the European Parliament and of the Council.

[22] I*ndian Medical Association v. V.P. Shantha*, (1995) 6 SCC 651.
[23] *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1.
[24] *Norton v. Argonaut Insurance Co.*, 144 So. 2d 249 (La. App. 1962).

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5. Lovec chio v. Rosenthal - A physician prescribed amiodarone 1,200 mg three times daily—far above the usual 400 mg dose—and the pharmacist dispensed it without questioning it. The jury apportioned liability between doctor and pharmacist

6. Brooks v. Wal-Mart Stores, Inc. - A pharmacist was held liable for filling an unsafe, excessive prednisone prescription; pharmacists have a duty to ensure a dispensed dose is safe.

7. Anonymous v. Miller Pharmacy - Pharmacy dispensed 10 mg methadone tablets instead of the prescribed 5 mg tablets; the technician's entry error and pharmacist's failure to catch it led to a settlement.

II. MEDICAL NEGLIGENCE

Medical negligence means the failure of a doctor, nurse, hospital or other healthcare professional to provide the reasonable care and attention expected from them, resulting in injury or harm to a patient.

In simple words, when a medical professional fails to do what a reasonably careful medical professional should do, and that failure causes harm to the patient, it may amount to Medical negligence[26].

Example:

A patient informs a doctor that they are allergic to a particular medicine. However, the doctor ignores this information and prescribes the same medicine. As a result, the patient suffers a serious allergic reaction. This may amount to medical negligence.

2.1 Meaning and definition of Medical Negligence

Medical negligence refers to the failure of a medical professional or healthcare institution to exercise the reasonable degree of care, skill and attention expected from an ordinarily competent professional under similar circumstances, resulting in injury or harm to a patient.

In simple terms, when a doctor or hospital fails to provide the standard of care reasonably expected in the circumstances and that failure causes harm to the patient, it may amount to medical negligence.

Negligence may occur in two ways:

i. **Act of Commission:** Performing an act that a reasonably careful medical professional would not have performed.

ii. **Act of Omission:** Failing to perform an act that a reasonably careful medical professional would have performed.

For example, administering the wrong medicine may constitute an act of commission, whereas failing to conduct necessary medical investigations may constitute an act of omission[27].

Judicial Interpretation

In *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1, the Supreme Court of India explained that negligence generally involves three essential elements: the existence of a duty of care, breach of that duty and resulting damage.

The judgment also clarified that a medical professional must be assessed according to the standard of an ordinarily competent practitioner possessing the relevant skill. An unsuccessful treatment or an unexpected medical complication does not automatically establish negligence.

2.2. Types of Medical Negligence

Medical negligence may occur at different stages of healthcare delivery. The major types are discussed below.

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[25] *Fuhs v. Barber*, 36 P.2d 962 (Kan. 1934).

[26] *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1.

[27] Ratanlal & Dhirajlal, *The Law of Torts*, (LexisNexis, relevant edition).

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i. Diagnostic Negligence

Diagnostic negligence occurs when a medical professional fails to identify or correctly diagnose a patient's medical condition despite having sufficient symptoms, information or medical evidence.

It may include:

- Failure to conduct necessary medical examinations.
- Incorrect interpretation of laboratory reports.
- Failure to identify serious diseases.
- Delayed diagnosis of critical medical conditions.
- Ignoring important symptoms reported by the patient.
- Failure to refer the patient to an appropriate specialist.

Example: A doctor fails to recognise the symptoms of a heart attack and sends the patient home without conducting necessary investigations.

ii Treatment Negligence

Treatment negligence occurs when a medical professional fails to provide appropriate treatment according to accepted medical standards.

It may include:

- Providing an incorrect treatment.
- Prescribing unsuitable medication.
- Failure to provide necessary treatment.
- Ignoring complications during treatment.
- Failure to monitor the patient's medical condition.
- Not taking reasonable precautions during medical procedures.

Example: A doctor continues an unsuitable treatment despite clear signs that the patient's condition is deteriorating.

iii Surgical Negligence

Surgical negligence occurs when a surgeon or surgical team fails to exercise reasonable care and skill before, during or after an operation.[28]

It may include:

- Performing surgery on the wrong patient.
- Operating on the wrong body part.
- Leaving surgical instruments inside the patient's body.
- Failure to follow sterilisation procedures.
- Improper handling of surgical instruments.
- Failure to monitor the patient after surgery.
- Performing an unnecessary surgical procedure.

Example: A surgeon accidentally leaves a surgical instrument inside a patient's body after an operation.

vi Medication Negligence

Medication negligence occurs when a doctor, nurse, pharmacist or other healthcare professional makes an error while prescribing, dispensing or administering medicines.

It may include:

- Prescribing the wrong medicine.
- Administering an incorrect dosage.
- Giving medicine to the wrong patient.

[28] *Kusum Sharma v. Batra Hospital and Medical Research Centre*, (2010) 3 SCC 480

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- Ignoring known drug allergies.
- Failure to identify dangerous drug interactions.
- Providing expired medicines.
- Giving incorrect instructions regarding medication.

Example: A nurse administers a medicine despite the patient's medical record clearly mentioning an allergy to that medicine.

v Anaesthesia Negligence

Anaesthesia negligence occurs when an anaesthetist fails to exercise proper care while administering anaesthesia or monitoring the patient during an operation[29].

It may include:

- Administering an incorrect dose of anaesthesia.
- Failure to examine the patient's medical history.
- Failure to monitor oxygen levels and vital signs.
- Improper management of anaesthesia complications.
- Failure to take necessary precautions before surgery.

Example: An anaesthetist fails to monitor the patient's oxygen level during surgery, resulting in serious complications.

vi Post-operative Negligence

Post-operative negligence occurs when medical professionals fail to provide proper care and monitoring after surgery.

It may include:

- Failure to monitor vital signs.
- Ignoring post-surgical infections.
- Failure to provide prescribed medicines.
- Delayed treatment of complications.
- Premature discharge without proper assessment.
- Failure to provide necessary follow-up care.

Example: A patient develops an infection after surgery, but the hospital fails to identify and treat it promptly.

vii Negligence in Informed Consent

Informed consent refers to the voluntary agreement of a patient to undergo medical treatment or a procedure after receiving relevant information about its nature, risks, benefits and available alternatives.

Negligence relating to informed consent may occur when:

- Surgery is performed without valid consent.
- Material risks are not properly explained.
- Available treatment alternatives are not disclosed.
- The patient is not informed about significant complications.
- Consent is obtained through force, fraud or misrepresentation.

Example: A doctor performs cosmetic surgery without adequately explaining its significant risks and possible complications.

A signed consent form does not automatically protect a medical professional from liability for negligent treatment.

viii Communication Negligence

Communication negligence occurs when healthcare professionals fail to communicate important medical information to patients or other members of the medical team.

It may include:

[29] Dr. *Laxman Balkrishna Joshi v. Dr. Trimbak Bapu Godbole*, AIR 1969 SC 128.

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- Failure to explain the patient's medical condition.
- Failure to communicate important test results.
- Providing incorrect medical instructions.
- Failure to inform patients about serious complications.
- Poor communication during patient transfer between departments.

Example: A hospital fails to communicate critical test results to the treating doctor, resulting in delayed treatment.

ix Hospital or Institutional Negligence

Hospital negligence occurs when a healthcare institution fails to maintain proper facilities, qualified staff, medical equipment or necessary safety standards.

It may include:

- Lack of qualified medical professionals.
- Failure to maintain medical equipment.
- Poor hygiene and sanitation.
- Inadequate infection-control measures.
- Lack of emergency facilities.
- Improper maintenance of medical records.
- Failure to provide adequate nursing care.

Example: A hospital fails to maintain essential emergency equipment, resulting in a delay in providing life-saving treatment.

2.3 Essential elements of Medical Negligence

To establish medical negligence, certain essential legal elements must generally be proved. These elements help determine whether the medical professional or healthcare institution has failed to fulfil its legal responsibility towards the patient.[30]

a) Existence of Duty of Care

The first essential element is the existence of a legal duty of care between the medical professional and the patient.

When a doctor accepts a patient for examination or treatment, the doctor assumes a responsibility to provide reasonable medical care.

The duty of care generally includes:

- Proper examination of the patient.
- Appropriate diagnosis.
- Selection of suitable treatment.
- Careful administration of treatment.
- Proper follow-up and monitoring.

b) **Breach of Duty**

The second essential element is the breach of the duty of care.

A breach occurs when a medical professional fails to meet the standard of care expected from an ordinarily competent practitioner in similar circumstances.

Examples include administering the wrong medicine, ignoring serious symptoms, failing to conduct necessary investigations or performing surgery without reasonable precautions.

However, a doctor cannot automatically be held negligent merely because another doctor might have selected a different method of treatment.

[30] Ratanlal & Dhirajlal, *The Law of Torts*, (LexisNexis, relevant edition).

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c) Causation

Causation refers to the connection between the negligent act or omission and the injury suffered by the patient.

The patient must establish that the injury was caused by the medical professional's breach of duty and was not merely an unrelated medical complication.

For example, if a doctor negligently administers the wrong medicine and the patient suffers injury because of that medicine, a causal connection may be established.

d) Actual Damage or Injury

The fourth essential element is the existence of legally recognisable damage or injury.

The damage may include:

- Physical injury.
- Mental suffering.
- Permanent disability.[31]
- Additional medical expenses.
- Loss of income.
- Worsening of an existing medical condition.
- Death.

A medical mistake without resulting legally recognisable harm may not be sufficient to establish an actionable negligence claim.

e) Failure to Maintain the Standard of Care

Medical professionals are expected to exercise reasonable skill, knowledge and care according to the accepted standards of their profession.

The law does not demand perfection or extraordinary skill from every medical professional. Instead, it requires the reasonable degree of competence expected from an ordinarily qualified practitioner in similar circumstances.

f) Failure to Obtain Proper Informed Consent

Informed consent is an important element of patient autonomy and medical accountability.

Before conducting a medical procedure, the doctor should explain its nature, material risks, benefits and available alternatives, as appropriate. The patient should be allowed to make a voluntary and informed decision.

Failure to obtain valid consent may give rise to legal consequences, depending on the circumstances.

g) Professional Accountability[32]

Medical professionals must follow applicable professional ethics, medical standards and legal regulations.

Failure to maintain professional standards may result in civil liability, consumer proceedings or disciplinary action, depending on the nature and seriousness of the misconduct.

h) Foreseeability of Harm

A medical professional is expected to recognise reasonably foreseeable risks associated with treatment and take appropriate precautions.

For example, where a patient has a known drug allergy, the doctor must take reasonable steps to avoid prescribing that medicine.

2.4. Important Legal Principles governing Medical Negligence

i) Bolam Test

The Bolam Test originated in the English case *Bolam v. Friern Hospital Management Committee*, [1957] 1 WLR 582[33].

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[31] *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1.

[32] *Indian Medical Association v. V.P. Shantha*, (1995) 6 SCC 651.

[33] *Bolam v. Friern Hospital Management Committee*, [1957] 1 WLR 582

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According to this principle, a medical professional is generally not considered negligent if the professional has acted in accordance with a practice accepted as proper by a responsible body of medical professionals skilled in that particular field.

The Supreme Court of India recognised this principle in *Jacob Mathew v. State of Punjab*.

ii. Res Ipsa Loquitur

The Latin expression *Res Ipsa Loquitur* means "the thing speaks for itself".

This principle may apply when the nature of an accident or injury itself provides evidence of negligence, even where the patient cannot directly explain how the negligence occurred.

For example, where a surgical instrument is found inside a patient's body after an operation, the circumstances may raise an inference of negligence.

However, this principle does not automatically apply to every unsuccessful operation or unexpected medical complication.

iii. Reasonably Competent Medical Practitioner Test

A medical professional is judged according to the standard of an ordinarily competent practitioner possessing the relevant skill and knowledge.

The law does not expect every doctor to possess exceptional expertise. However, every medical professional must exercise reasonable competence, caution and care while treating patients.

2.5 Important Judicial Decisions on Medical Negligence

Indian courts have played an important role in defining medical negligence and establishing the responsibilities of healthcare professionals.

- ✓ **Jacob Mathew v. State of Punjab (2005) 6 SCC 1**

The Supreme Court explained the essential elements of negligence, namely duty of care, breach of duty and resulting damage. It also distinguished ordinary negligence from the higher threshold required to establish criminal medical negligence[34].

- ✓ **Kusum Sharma v. Batra Hospital and Medical Research Centre (2010) 3 SCC 480[35]**

The Supreme Court explained that medical professionals must exercise reasonable skill and care. A doctor cannot be held negligent merely because treatment was unsuccessful or another treatment option was available.

- ✓ **Samira Kohli v. Dr. Prabha Manchanda (2008) 2 SCC 1**

The Supreme Court discussed the importance of informed consent and held that consent for one medical procedure does not automatically authorise a substantially different procedure, except in recognised emergency circumstances[36].

- ✓ **Indian Medical Association v. V.P. Shantha (1995) 6 SCC 651**

The Supreme Court held that medical services provided for consideration generally fall within the scope of consumer protection law, subject to recognised exceptions relating to services provided entirely free of charge.

- ✓ **Maharaja Agrasen Hospital v. Master Rishabh Sharma (2020) 6 SCC 501**

The Supreme Court considered the responsibility of hospitals and medical professionals and discussed the importance of proper medical care, communication and medical records.

- ✓ **M.A. Biviji v. Sunita (2023) 15 SCR 113; (2024) 2 SCC 242**

The Supreme Court reiterated that medical negligence requires proof of duty, breach and resulting injury attributable to the breach. Medical professionals must be judged according to the standard of a reasonably competent practitioner.

[34] *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1.

[35] *Kusum Sharma v. Batra Hospital and Medical Research Centre*, (2010) 3 SCC 480.

[36] *Samira Kohli v. Dr. Prabha Manchanda*, (2008) 2 SCC 1.

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2.6 Legal Framework Governing Medical Negligence in India

Medical negligence in India may result in civil, consumer, criminal or professional disciplinary liability, depending on the facts and applicable legal requirements.

a) Consumer Protection Act, 2019

The Consumer Protection Act, 2019 provides a mechanism for consumers to seek remedies against deficiency in services.[37]

- **Section 2(11):** Defines deficiency in service.
- **Section 2(42):** Defines services.

Medical services provided for consideration generally fall within the scope of consumer protection law, subject to the principles laid down in *Indian Medical Association v. V.P. Shantha*.

b) Bharatiya Nyaya Sanhita, 2023

The Bharatiya Nyaya Sanhita, 2023 contains provisions dealing with criminal liability for negligent acts[38].

- **Section 106(1):** Deals with causing death by a rash or negligent act not amounting to culpable homicide. It contains a special punishment provision for a registered medical practitioner performing a medical procedure.
- **Section 125:** Deals with acts endangering the life or personal safety of others.

Criminal liability must be distinguished from ordinary civil negligence. Every unsuccessful treatment or medical error does not automatically amount to a criminal offence.

c) Law of Torts

Under the law of torts, a medical professional may be held liable for a negligent act or omission that causes legally recognisable injury to a patient. The injured person may seek compensation, subject to proof of the necessary legal elements.

d) Professional Medical Regulations

Medical professionals are also governed by applicable professional conduct and ethical standards. Failure to comply with professional obligations may result in disciplinary proceedings before the competent regulatory authority.

III. THERAPEUTIC MISADVENTURE

Therapeutic misadventure is an unintended injury, adverse reaction, or harmful outcome caused by medical treatment rather than by the patient's underlying disease. It generally refers to an unfortunate but unforeseeable complication that occurs despite the healthcare professional exercising reasonable care and skill.

3.1 Meaning

In medication practice, it may include an unexpected adverse drug reaction, an unpredictable response to anaesthesia, or harm from a diagnostic procedure using contrast dye. The key point is that the treatment was properly intended and administered, but the patient suffered an unexpected bad outcome.

This occurs when harm, injury, or death results from treatment given to a patient.

Examples include:

- A severe or fatal allergic reaction to penicillin, aspirin, or tetracycline.
- An adverse reaction to anaesthesia during surgery.
- Excessive administration of an antidote to a poisoned patient.
- Harm caused by a drug reaction or an unintended complication of therapy.

[37] Consumer Protection Act, 2019, Sections 2(11) and 2(42).
[38] The Bharatiya Nyaya Sanhita, 2023, Sections 106(1) and 125.

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The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 do not define "therapeutic misadventure" or create a separate offence for "medical error." They regulate doctors' professional conduct, record-keeping, consent, disclosure, and disciplinary consequences; errors become relevant when they show a breach of professional duty.

Relevant provisions relating to The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

Regulation 1.1.1–1.1.2: A physician must maintain good medical practice and uphold the dignity of the profession. Repeated or serious medication errors, unsafe prescribing, or failure to follow accepted practice may be examined as professional misconduct[39].

Regulation 1.2: The physician must exercise a reasonable degree of skill and knowledge and use modern scientific methods. This is the core standard used to assess whether an adverse medication event was an unavoidable therapeutic misadventure or negligent care.

Regulation 1.3.1: Maintain indoor-patient medical records for 3 years from the date of commencement of treatment. Prescriptions, drug charts, administration records, allergy history, and adverse-event notes are essential evidence in a medication-error case.

Regulation 1.3.2: Provide medical records to the patient, authorised attendant, or legal authorities within 72 hours of request. Concealment, alteration, or non-production of records after an error can itself amount to professional misconduct.

Regulation 2.1.1: Obtain informed consent before treatment or a procedure. This is relevant where a patient was not warned about material medication risks or possible adverse reactions.

Regulation 7.2: Failure to maintain medical records or refusal to provide them within 72 hours is professional misconduct. This is directly important after a suspected medication error or therapeutic misadventure.

3.2 Nature and characteristics

Therapeutic misadventure may have the following characteristics.

- It occurs in connection with medical treatment.
- The outcome may be unintended.
- Tome may arise even when appropriate care has been taken.
- The patient may experience an unexpected reaction or complication.
- The circumstances must be examined to determine whether the outcome was an unavoidable risk, a medical error, negligence, or a combination of these factors.

3.3 Difference between Therapeutic misadventure and Unavoidable complications

Basis of Comparison	Therapeutic Misadventure	Unavoidable Complications
Meaning	An unexpected adverse outcome arising during or following medical treatment.	A complication that cannot reasonably be prevented despite proper medical care and precautions.
Nature	May arise from an unexpected treatment-related event or adverse response.	An inherent or unforeseen risk associated with a medical procedure or treatment.
Cause	May result from an unexpected reaction, treatment-related event or complication.	May arise due to individual patient conditions, biological responses or inherent procedural risks.
Preventability	May or may not be preventable, depending	Generally cannot be prevented even with reasonable

[39] **The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002**

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Basis of Comparison	Therapeutic Misadventure	Unavoidable Complications
	on the circumstances.	care.
Medical negligence	Does not automatically establish medical negligence; the circumstances must be examined.	Ordinarily does not amount to negligence when reasonable professional care has been exercised.
Standard of care	Must be assessed to determine whether the medical professional followed accepted standards.	The medical professional is expected to have followed accepted medical standards and taken reasonable precautions.
Legal liability	Depends on whether negligence, breach of duty or another legal basis for liability is established.	Generally no negligence-based liability arises where the complication was genuinely unavoidable and reasonable care was exercised.
Example	A patient experiences an unexpected adverse reaction during properly administered treatment.	A patient develops an unavoidable complication after surgery despite proper precautions and monitoring.

An unavoidable complication is an adverse event that cannot reasonably be prevented even when appropriate medical care is provided.

For example, a patient may develop a recognised complication because of the nature of the disease or the patient's individual medical condition.

However, we should not assume that every complication is unavoidable.

Some complications may arise because of inadequate precautions or failures in treatment.

3.4. The Legal provisions in India relating to medication errors, medical negligence, and therapeutic misadventure mainly arise from the Constitution, criminal law, consumer law, contract/tort principles, drug regulation, medical-record rules, and professional-ethics regulations.

a) Constitutional basis

Article 21 of the Constitution of India guarantees the right to life and personal liberty. Courts have interpreted it to include the right to health and protection from medical negligence.

Article 47 directs the State to raise the level of nutrition and standard of living and improve public health, forming part of the Directive Principles of State Policy.

b) Criminal law

Section 106(1), Bharatiya Nyaya Sanhita, 2023 (BNS): This replaced Section 304A of the Indian Penal Code, 1860. It penalises causing death by a rash or negligent act culpable homicide not amounting to murder. The general punishment may extend to five years and fine, but where the act is done by a registered medical practitioner during a medical procedure, imprisonment may extend to two years and fine.

For criminal liability, the prosecution must generally prove gross negligence, rashness, or reckless disregard for patient safety—not merely an unfortunate outcome or a simple error of judgment. This principle was laid down in Jacob Mathew v. State of Punjab (2005).

Sections 336, 337, and 338 of the IPC earlier dealt with rash or negligent acts endangering life or causing hurt; corresponding provisions now exist in the BNS. These may be relevant where a medication error causes injury rather than death.

c) Law of torts: Medical negligence is primarily a civil wrong. The patient must establish duty of care, breach of duty, causation, and damage—often described as the "four Ds": duty, dereliction, direct causation, and damage.

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d) Consumer Protection Act, 2019: Medical services provided for payment fall within the definition of "service." A patient may file a complaint for deficiency in service before the District, State, or National Consumer Disputes Redressal Commission, depending on the value of the claim. This follows the Supreme Court's decision in Indian Medical Association v. V.P. Shantha (1995[40]).

Indian Contract Act, 1872: Where there is a doctor–patient agreement, breach of contractual obligations may also give rise to civil liability, though negligence claims are more commonly pursued in tort or consumer law.

e) Drugs and Cosmetics Act, 1940: Regulates the import, manufacture, distribution, and sale of drugs. It is relevant where a medication error involves spurious, adulterated, misbranded, substandard, or improperly labelled medicines.

f) Drugs and Cosmetics Rules, 1945: These rules prescribe standards for manufacture, labelling, sale, storage, and distribution of drugs. They also require reporting of serious adverse drug reactions under Schedule Y and Schedule M requirements.

g) Pharmacovigilance Programme of India (PvPI): Healthcare professionals can report suspected adverse drug reactions to Adverse Drug Reaction Monitoring Centres or the National **Coordination Centre–PvPI**. Serious and unexpected adverse reactions must be reported by.

3.5 Professional Discipline

a) Indian Medical Council Act, 1956 / National Medical Commission Act, 2019: These laws govern registration and professional discipline of medical practitioners. The National Medical Commission now performs the functions previously carried out by the Medical Council of India[41].

b) Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002: These require doctors to maintain proper medical records for three years, provide copies within 72 hours when requested, obtain informed consent, and maintain reasonable skill and care. Failure to maintain or produce records can amount to professional misconduct.[42]

c) Regulation 7.2 of the 2002 Ethics Regulations: Specifically provides that failure to maintain indoor-patient records or refusal to supply them within 72 hours is professional misconduct.

3.6 Hospital and clinical establishment regulation

a) Clinical Establishments (Registration and Regulation) Act, 2010: Provides for registration and regulation of clinical establishments, including maintenance of standards, records, and facilities. It is relevant where hospital systems, staffing, or infrastructure contribute to a medication error.

b) State-level rules: Tamil Nadu and other States may have their own rules and notifications under the Clinical Establishments Act or earlier State legislation, governing licensing, inspection, and standards of clinical establishments

3.7 Related Case Laws

1. Jacob Mathew v. State of Punjab, (2005) 6 SCC 1

This is the leading Supreme Court case on medical negligence in India. The Court held that a professional may be liable only if he lacked the requisite skill he professed to have, or failed to exercise reasonable competence and care in the given case. A doctor is not liable merely because treatment failed or an unfortunate complication occurred.

Relevance: This case provides the test for distinguishing an unavoidable therapeutic misadventure from actionable negligence.

[40] Consumer Protection Act, 2019.

[41] Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Regulations 1.3.1, 1.3.2 and 7.2

[42] The Indian Medical Council Act, 1956.

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2. Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Bapu Godbole, AIR 1969 SC 128

The Supreme Court held that a doctor owes duties of care in deciding whether to undertake the case, deciding what treatment to give, and administering that treatment properly. A breach of these duties may amount to negligence.

Relevance: Consumer forums have relied on this case while finding therapeutic misadventure where the treatment and post-treatment care fell below the required standard.

3. Indian Medical Association v. V.P. Shantha, (1995) 6 SCC 651[43]

The Supreme Court held that medical services rendered for payment are "services" under the Consumer Protection Act. Therefore, a patient alleging negligent treatment or therapeutic misadventure can seek compensation before a consumer commission.

Relevance: This case provides the procedural remedy for patients claiming compensation for harm caused by medical treatment.

4. Achutrao Haribhau Khodwa v. State of Maharashtra, (1996) 2 SCC 634[44]

The Supreme Court held that where a surgical mop was left inside a patient's abdomen, the hospital and doctors were liable. The Court rejected the argument that the incident was merely an unfortunate accident.

Relevance: This is useful to show that some therapeutic mishaps are so clearly avoidable that they amount to negligence rather than genuine misadventure.

5. Dr. (Mrs.) Chanda Rani Akhouri v. Dr. M.A. Methusethupathi, 2022

The Supreme Court reiterated that a doctor cannot be held negligent merely because the patient could not be saved. Liability requires proof that the doctor failed to exercise the skill and care expected of a reasonably competent practitioner.

Relevance: This supports the defence that a poor outcome, complication, or therapeutic misadventure is not automatically negligence.

6. Somraj Sen v. Kothari Medical Centre, 2023

The consumer forum held that a medical practitioner is not liable simply because things went wrong due to mischance, misadventure, or an error of judgment in choosing one reasonable course of treatment over another. The forum found that the decision to perform a laparoscopic dye test was neither wrong nor a therapeutic misadventure.

Relevance: This case shows that courts examine whether the chosen treatment was reasonable and whether the complication was avoidable.

7. New India Assurance Co. Ltd. v. Suraj Bhan Khangwal, NCDRC

The National Consumer Disputes Redressal Commission held that a medical practitioner is not negligent merely because things went wrong from mischance or misadventure. However, where the treatment caused severe pancreatitis and complications due to substandard care, the Commission treated it as therapeutic misadventure committed by the opposite party.

Relevance: This case illustrates that "therapeutic misadventure" may be used where the harm resulted from the treatment itself and the practitioner's conduct fell below the required standard.

8. Appollo Hospitals v. Bhagwan L. Moorjani, 2018

The court found the doctor liable for therapeutic misadventure because he failed to obtain proper informed consent and did not seek an ophthalmologist's opinion before surgery, despite the risk of ophthalmic complications.

Relevance: This case connects therapeutic misadventure with failure to warn, informed consent, and failure to obtain appropriate specialist advice.

[43] *Indian Medical Association v. V.P. Shantha*, (1995) 6 SCC 651.

[44] *Achutrao Haribhau Khodwa v. State of Maharashtra*, (1996) 2 SCC 634

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9. Harishbhai Shamjibhai v. Ramaben Shamjibhai, NCDRC, 2014

The National Consumer Disputes Redressal Commission described the doctor's act as a therapeutic misadventure amounting to medical negligence that caused the patient's death.

Relevance: This shows that consumer forums may use the expression "therapeutic misadventure" when an adverse treatment outcome is linked to negligent care.

10. Failed tooth Extraction Case, NCDRC, 2023

The NCDRC awarded compensation after finding that a failed tooth extraction led to multiple surgeries and amputations. The Commission relied on Dr. Laxman Balkrishna Joshi and held that the doctors were deficient in service; it described the incident as "not even a bona fide mistake, but a therapeutic misadventure."

Relevance: This is a recent example where the Commission used therapeutic misadventure to describe a serious treatment-related adverse outcome.

3.7 Foreign case law

1. Bolam v. Friern Hospital Management Committee, 1 WLR 582[45]

The English court held that a doctor is not negligent if he acts in accordance with a practice accepted as proper by a responsible body of medical opinion skilled in that field, even if another body of professional opinion would prefer a different technique.

Relevance: The Bolam test has strongly influenced Indian medical-negligence law and helps distinguish a reasonable therapeutic choice from negligence.

2. Roe v. Minister of Health, 2 All ER 131

The court held that doctors were not negligent for injury caused by contaminated anaesthetic stored in glass ampoules, because the risk was not known to medical science at the time.

Relevance: This is a classic example of therapeutic misadventure: harm occurred during treatment, but the doctors could not reasonably have foreseen or prevented it

3.8 Difference between Medication error, Medical negligence and Therapeutic Misadventure

Basis of comparison	Medication Error	Medical Negligence	Therapeutic Misadventure
Meaning	An unintended mistake in the medication process.	Failure to exercise the legally required standard of medical care.	An unexpected adverse outcome arising during or after medical treatment.
Nature	Primarily a medication-related safety incident.	A breach of professional duty.	An adverse treatment outcome or complication.
Main cause	Mistake in prescribing, dispensing or administering medicines.	Failure to exercise reasonable care, skill or attention.	Unexpected or unavoidable response to treatment.
Intention	Generally unintentional.	Usually arises from an act or omission falling below the required standard of care.	Generally unintended and may occur despite reasonable care.
Preventability	Often preventable, depending on circumstances.	Generally involves a failure that reasonable care could have prevented.	May be unavoidable despite proper precautions.

[45] *Bolam v. Friern Hospital Management Committee*, [1957] 1 WLR 582.

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Basis of comparison	Medication Error	Medical Negligence	Therapeutic Misadventure
Patient injury	May occur, but is not essential for an error to exist.	Legally recognisable harm must generally be established for an actionable negligence claim.	May involve an unexpected injury or complication.
Legal liability	Does not automatically create legal liability.	May result in civil, consumer or criminal liability, depending on the facts and applicable law.	Does not automatically create liability if reasonable care was exercised.
Example	Administering an incorrect dosage of medicine.	Prescribing an incorrect dosage due to failure to check the patient's medical history.	A patient develops an unpredictable adverse reaction despite correct prescription and administration.
Basis of comparison	Medication Error	Medical Negligence	Therapeutic Misadventure
Meaning	An unintended mistake in the medication process.	Failure to exercise the legally required standard of medical care.	An unexpected adverse outcome arising during or after medical treatment.
Nature	Primarily a medication-related safety incident.	A breach of professional duty.	An adverse treatment outcome or complication.
Main cause	Mistake in prescribing, dispensing or administering medicines.	Failure to exercise reasonable care, skill or attention.	Unexpected or unavoidable response to treatment.
Intention	Generally unintentional.	Usually arises from an act or omission falling below the required standard of care.	Generally unintended and may occur despite reasonable care.
Preventability	Often preventable, depending on circumstances.	Generally involves a failure that reasonable care could have prevented.	May be unavoidable despite proper precautions.
Patient injury	May occur, but is not essential for an error to exist.	Legally recognisable harm must generally be established for an actionable negligence claim.	May involve an unexpected injury or complication.
Legal liability	Does not automatically create legal liability.	May result in civil, consumer or criminal liability, depending on the facts and applicable law.	Does not automatically create liability if reasonable care was exercised.
Example	Administering an incorrect dosage of medicine.	Prescribing an incorrect dosage due to failure to check the patient's medical history.	A patient develops an unpredictable adverse reaction despite correct prescription and administration.

IV. CONCLUSION

Medication errors, therapeutic misadventures and medical negligence are important concerns in healthcare as they directly affect patient safety and medical accountability. Although these concepts are closely related, they differ in their nature and legal consequences. Medication errors involve unintended mistakes in prescribing, dispensing or administering medicines, while therapeutic misadventures refer to unexpected adverse outcomes despite reasonable

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medical care. Medical negligence, on the other hand, involves a failure to maintain the required standard of professional care, resulting in harm to the patient. Therefore, every medication error or unsuccessful treatment cannot automatically be considered medical negligence[46].

A proper understanding of these distinctions is essential to protect patients' rights while preventing unjustified legal liability for medical professionals. Healthcare institutions must strengthen patient-safety measures, maintain accurate medical records, follow standard treatment protocols and ensure valid informed consent. Ultimately, the objective of medical law should be to prevent avoidable errors, promote ethical medical practice and ensure accountability. A balanced legal approach will strengthen public confidence and contribute to a safer and more responsible healthcare system[47].

V. SUGGESTIONS

Strengthen prescription practices: Doctors should write prescriptions clearly, mentioning the drug name, strength, dose, route, frequency, and duration. Standard abbreviations and electronic prescribing can reduce misreading and transcription errors.

Verify allergies and medication history: Before prescribing or dispensing, healthcare professionals should check the patient's allergy history, current medicines, herbal or over-the-counter product use, kidney and liver function, and past adverse drug reactions.

Use clinical decision-support systems: Hospitals should implement computerised physician order entry with allergy alerts, drug-interaction alerts, duplicate-therapy warnings, and dose-range checks.

Encourage pharmacist review: Pharmacists should verify prescriptions for correct drug, dose, route, interactions, contraindications, and high-risk medicines before dispensing.

Adopt barcode medication administration: Barcode verification of the patient, medicine, and dose can reduce wrong-patient, wrong-drug, and wrong-dose errors.

Improve communication during transfers: When patients shift between wards, hospitals, or doctors, a complete medication reconciliation should be carried out to avoid duplication, omission, or incorrect continuation of medicines.

Monitor high-risk medicines closely: Drugs such as insulin, anticoagulants, opioids, chemotherapy drugs, digoxin, lithium, and concentrated electrolytes should be prescribed, stored, administered, and monitored under strict protocols.

Report adverse drug reactions and near-misses: Healthcare professionals should report suspected adverse drug reactions to the Pharmacovigilance Programme of India and report medication near-misses internally, so recurring system failures can be identified and corrected.

Maintain complete medical records: Doctors and hospitals should maintain accurate records of prescriptions, drug administration, allergies, monitoring, consent, and adverse events. This supports patient safety and is also required under the Indian Medical Council Ethics Regulations, 2002.

Provide patient education: Patients should be counselled on the correct dose, timing, route, storage, possible side effects, and what to do if a dose is missed. They should also be advised not to self-medicate or stop prescribed medicines without medical advice.

Ensure adequate staffing and reduce workload pressure: Hospitals should minimise interruptions during medication preparation and administration, ensure adequate staffing, and provide training to reduce fatigue-related errors.

Create a non-punitive safety culture: Hospitals should focus on identifying system failures rather than only blaming individual staff. Open reporting of errors and near-misses helps improve processes and prevents repetition.

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[46] Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.

[47] World Health Organization, *Medication Without Harm: WHO Global Patient Safety Challenge on Medication Safety* (WHO, Geneva, 2017).

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Strengthen legal and ethical compliance: Healthcare providers should follow informed-consent requirements, maintain records for the prescribed period, and comply with the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, the Consumer Protection Act, 2019, and the Drugs and Cosmetics Act, 1940.

Conduct regular audits and training: Hospitals should conduct periodic medication-safety audits, root-cause analyses of serious errors, and continuous training for doctors, nurses, and pharmacists.