

Iatrogenic Diseases: When Healthcare Causes Harm

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ABSTRACT

Iatrogenic diseases represent an important challenge in modern healthcare, arising as unintended consequences of medical interventions intended to benefit patients. With advances in pharmacotherapy, diagnostic procedures, surgical techniques, and healthcare technologies, the scope of potential healthcare-related harm has also expanded. Although adverse drug reactions remain a major component of iatrogenic disease, the concept encompasses a broader range of conditions, including surgical complications, healthcare-associated infections, diagnostic errors, device-related injuries, and system-related failures. This review provides an overview of the evolution and concept of iatrogenesis, its classification, major clinical examples, contributing factors, and approaches for prevention. Particular emphasis is placed on pharmacovigilance, rational use of medicines, and patient-safety practices aimed at reducing preventable harm while improving the quality of healthcare delivery.

INTRODUCTION: THE PARADOX OF MODERN HEALING

In current patient-safety language, iatrogenic disease overlaps with adverse events, adverse drug events, adverse drug reactions, health care-associated infections, surgical complications, diagnostic errors and device-related injuries. The concept is especially relevant in pharmacology because drug therapy is one of the most common, modifiable and surveillable causes of health-care harm. However, the broader iatrogenic spectrum extends far beyond medicines and includes blood transfusion, ventilation, surgery, radiology, laboratory testing, hospital environment, communication failures and health-system weaknesses. The primary goal of medicine is to relieve suffering and restore health; however, every clinical intervention carries a potential risk of harm. Iatrogenic diseases represent this paradox, where healthcare intended to benefit patients may unintentionally contribute to adverse outcomes. Such harm may result from medications, procedures, diagnostic decisions, preventable errors, or system-related failures. Recognizing iatrogenic disease emphasizes that patient safety is as important as therapeutic effectiveness. [1,2,3]

Iatrogenic diseases include a broad range of healthcare-related harms, such as adverse drug reactions, surgical complications, healthcare-associated infections, diagnostic errors, and device-related injuries. Although medicines are a major contributor, iatrogenesis extends beyond pharmacotherapy to include transfusion, ventilation, surgery, radiology, and failures in healthcare systems. [4,5,6]

Definitions and Conceptual Boundaries

Iatrogenic disease refers to any unintended harmful condition that occurs as a result of medical care and is not related to the natural course of the underlying disease. It may include both preventable and unavoidable harm, as long as the injury is associated with a healthcare intervention. The WHO patient-safety framework emphasizes reducing preventable harm and minimizing unnecessary risks associated with healthcare. [1,4]

It is important to differentiate iatrogenic disease from adverse events and adverse drug reactions (ADRs). An adverse event refers to any unwanted occurrence during healthcare, regardless of whether it is caused by the intervention. An ADR is a harmful and unintended response to a medicine used at normal therapeutic doses. Iatrogenic disease is a broader term: while ADRs caused by treatment are considered iatrogenic, not all iatrogenic

conditions are ADRs. For example, catheter-associated urinary tract infection and surgical-site infection are iatrogenic diseases but not ADRs, whereas penicillin anaphylaxis and NSAID-induced gastric ulcer represent both ADRs and iatrogenic diseases. [1,7]

Term	Meaning	Clinical examples
Iatrogenic disease	Disease or harmful condition resulting from health-care intervention	NSAID-induced ulcer, post-operative infection, contrast nephropathy
Adverse event	Untoward occurrence during care; causality may be uncertain	Fall during hospitalization, rash after a medicine
Adverse drug reaction	Noxious unintended drug response at normal therapeutic doses	Warfarin bleeding, penicillin anaphylaxis
Medical error	Failure of planned action or wrong plan; may or may not cause harm	Wrong dose, wrong patient, wrong procedure
Drug-induced disease	Recognizable disease pattern caused by a medicine	Hydralazine-induced lupus, INH neuropathy

Historical Evolution of Iatrogenic Disease

The history of iatrogenic disease reflects the evolving understanding of healthcare-related harm. The principle of “*First, do no harm*” became increasingly important as medicine advanced from basic clinical care to complex interventions involving drugs, surgery, intensive care, and technology. Over time, isolated observations of medical harm evolved into structured patient-safety systems focused on surveillance, prevention, and improvement of healthcare practices. [1,2,4]

The global patient-safety movement gained momentum with the WHO resolution WHA55.18 in 2002, followed by the launch of WHO Patient Safety in 2004, the *Safe Surgery Saves Lives* initiative in 2009, and the Global Patient Safety Action Plan 2021–2030, emphasizing reduction of preventable harm in healthcare. [1, 8]

Period / year	Milestone	Patient-safety significance
Ancient ethical roots	The duty to avoid harm became central to medical ethics; the phrase "First, do no harm" summarizes the moral foundation of safe care.	Foundation of clinical prudence
19th century	Hospital-based complications and infection transmission highlighted that care itself could propagate disease.	Basis for asepsis and infection control
1937	Elixir sulfanilamide disaster involving diethylene glycol showed the danger of inadequately tested formulations.	Strengthened drug regulation
1950s-1960s	Therapeutic disasters and drug-induced diseases, including thalidomide embryopathy, oxygen-induced neonatal injury and drug-induced autoimmune or neurologic disease, showed that routine treatments could cause severe long-term harm.	Modern pharmacovigilance and teratogenicity testing
1968	WHO Programme for International Drug Monitoring launched to monitor and improve medicine and vaccine safety.	International pharmacovigilance network
2002	WHA55.18 urged Member States to strengthen patient-safety systems.	Global patient-safety policy begins

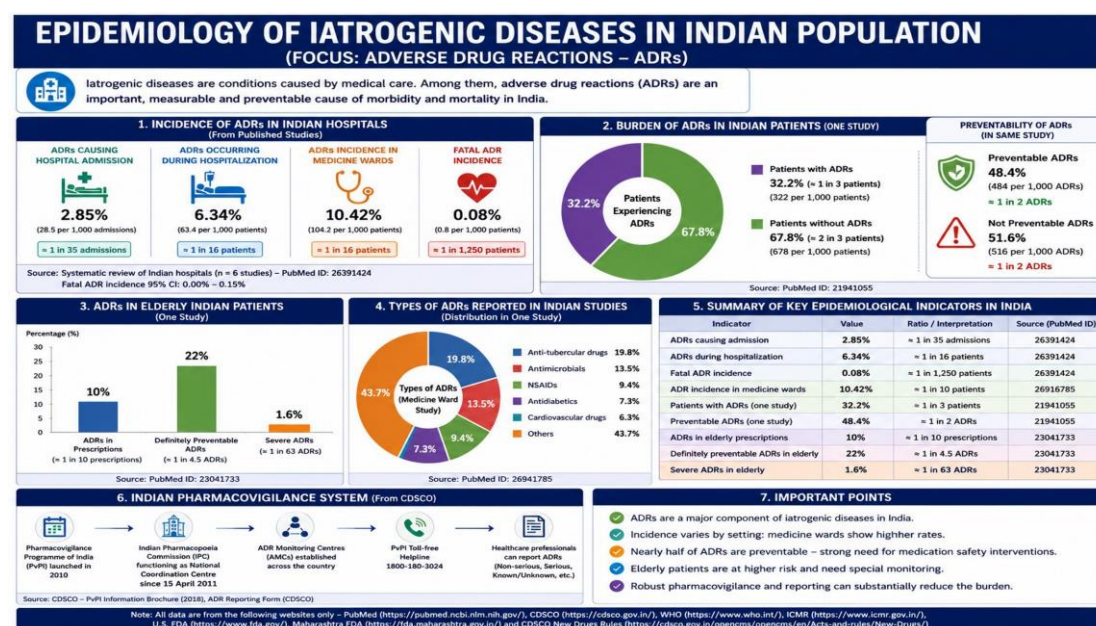
2004	WHO Patient Safety / World Alliance for Patient Safety launched.	International coordination of safety campaigns
2005-2006	First Global Patient Safety Challenge focused on health care-associated infection.	Hand hygiene and infection prevention
2009	WHO Guidelines for Safe Surgery: Safe Surgery Saves Lives published.	Surgical checklist culture
2010	Pharmacovigilance Programme of India launched through CDSCO and later coordinated by IPC.	National ADR surveillance in India
2019	WHA72.6 established global action on patient safety and World Patient Safety Day.	Patient safety recognized as global health priority
2021-2030	Global Patient Safety Action Plan adopted with a vision of safe and respectful care everywhere.	Strategic global roadmap

Epidemiology and Burden of Iatrogenic Disease

Iatrogenic harm is a significant healthcare challenge. WHO estimates suggest that approximately one in ten patients experiences harm during healthcare, with unsafe care contributing to millions of deaths annually. A substantial proportion of this harm is preventable, with medication-related problems being a major contributor. [1]

The burden extends beyond clinical outcomes and includes considerable economic consequences. Surgical complications, diagnostic errors, healthcare-associated infections, unsafe transfusions, medication errors, and device-related problems remain important sources of preventable harm. [9]

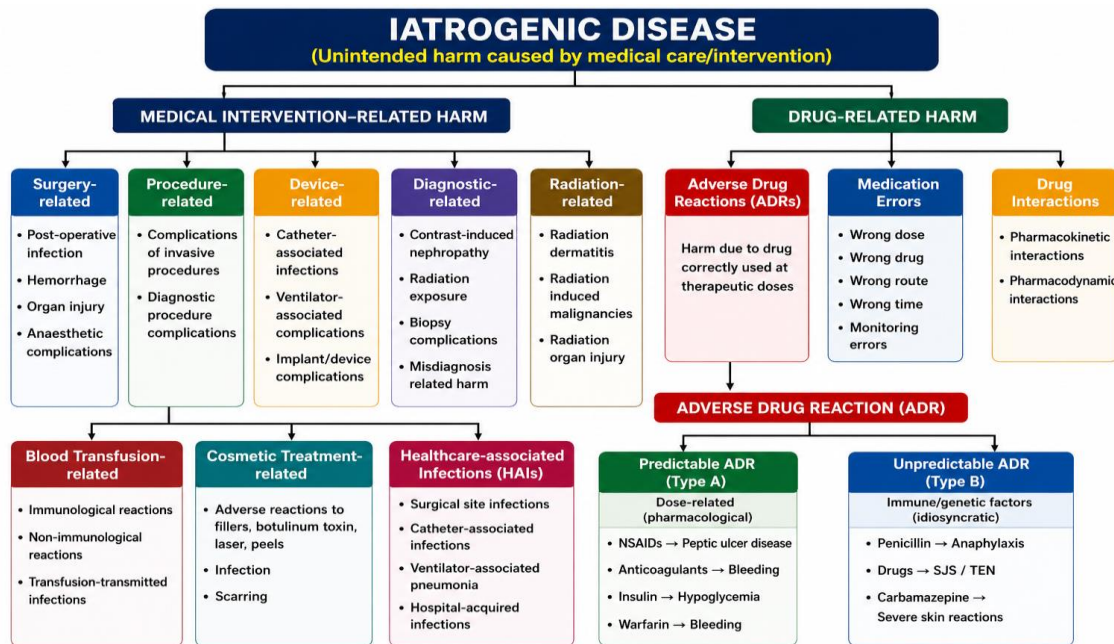
In India, the risk of iatrogenic disease is influenced by factors such as high patient load, polypharmacy, antimicrobial use, self-medication, over-the-counter drug availability, and variations in healthcare resources. Although the Pharmacovigilance Programme of India provides a framework for ADR reporting and signal detection, under-reporting continues to be a major challenge in clinical practice. [10]



Classification of Iatrogenic Diseases

No single classification captures the whole spectrum of iatrogenic disease. For clinical work, it is useful to

classify harm by source, preventability, timing, severity and mechanism. This approach helps clinicians decide whether the condition requires immediate treatment, drug withdrawal, procedural correction, infection-control action, reporting to pharmacovigilance or institutional root-cause analysis. [11,12]



Adverse Drug Reactions and Drug-Induced Diseases

Drug therapy represents one of the most common and well-recognized contributors to iatrogenic disease. An adverse drug reaction (ADR) refers to a harmful and unintended response to a medicine used at normal therapeutic doses. It is important to differentiate ADRs from the broader category of adverse drug effects, which may also include overdose-related toxicity, minor unwanted effects, and treatment failure. [5]

The Rawlins–Thompson classification provides a useful framework for understanding ADRs. Type A reactions are predictable and dose-related, whereas Type B reactions are unpredictable and often related to immune or idiosyncratic mechanisms. Type C reactions occur with prolonged use, Type D reactions are delayed, Type E reactions occur after withdrawal of therapy, and Type F reactions are associated with treatment failure. All these reactions may contribute to iatrogenic disease when they result in clinically significant harm. [5]

ADR type	Clinical Characteristics	Examples
Type A - Augmented	Exaggerated pharmacological effect; dose-related and often predictable	Warfarin bleeding; insulin hypoglycemia; NSAID gastritis
Type B - Bizarre	Unexpected, allergic or idiosyncratic; not usually dose-related	Penicillin anaphylaxis; Stevens-Johnson syndrome
Type C - Chronic	Due to prolonged drug exposure	Steroid-induced osteoporosis; analgesic nephropathy
Type D - Delayed	Appears after a latency period	Drug-induced cancer; teratogenicity
Type E - End-of-use	Withdrawal or rebound after stopping treatment	Steroid withdrawal adrenal crisis; opioid withdrawal
Type F - Failure	Therapeutic failure causing harm	Contraceptive failure with enzyme inducers; antibiotic failure due to resistance

Mechanisms and Risk Factors

Iatrogenic diseases develop through a complex interaction between patient factors, therapeutic interventions, and healthcare processes. The underlying mechanisms vary depending on whether the harm is related to medicines, procedures, or system-related issues. Identifying these contributing factors is essential because many forms of iatrogenic harm can be reduced through careful prescribing, appropriate monitoring, effective communication, and safer healthcare practices. [13,14]

Major mechanisms contributing to iatrogenic diseases

Source of harm	Common mechanisms/examples
Medicines	Excessive drug action, altered drug metabolism due to renal/hepatic dysfunction, genetic variability, drug interactions, cumulative toxicity, medication errors, and inappropriate use
Medical procedures	Tissue injury, bleeding, infection, anesthesia-related complications, thrombosis, and device-associated problems
Healthcare systems	Communication errors, incomplete records, inadequate monitoring, lack of standard protocols, workload-related fatigue, and gaps in reporting systems

Factors increasing the risk of iatrogenic harm

Patient group	Reasons for increased risk
Patient-related factors	Extremes of age, pregnancy, comorbidities, renal/hepatic impairment, allergy history, genetic susceptibility, and frailty
Drug-related factors	Narrow therapeutic index drugs, high-alert medications, complex dosing regimens, drug interactions, prolonged half-life, and look-alike/sound-alike medications
Procedure-related factors	Emergency procedures, poor visualization, anticoagulant use, implants, invasive devices, and inadequate aseptic practices
Healthcare system factors	Understaffing, poor handover, incomplete documentation, unclear prescriptions, lack of protocols, medicine shortages, and healthcare worker fatigue
Technology-related factors	Electronic health record limitations, alert fatigue, infusion pump programming errors, device malfunction, and excessive dependence on automated systems
Social and behavioural	Self-medication, low health literacy, poor follow-up, financial barriers, and non-adherence

Clinical Domains of Iatrogenic Disease

Medication-Related Iatrogenesis

Medication-related harm represents one of the most common forms of iatrogenic disease and may result from either preventable errors or unpredictable adverse drug reactions. Preventable causes include inappropriate drug selection, incorrect dosing, failure to adjust doses in renal impairment, contraindicated use, drug interactions, duplicate therapy, inadequate monitoring, and poor medication reconciliation during transitions of care. Some reactions, such as allergic or idiosyncratic responses, may occur despite appropriate use; however, careful documentation of allergies and pharmacogenomic testing in selected situations may help reduce risk. [9,10,16]

Surgery and Procedural Care

Surgical and procedural interventions, although essential for patient care, may result in complications such as bleeding, infection, organ injury, anesthesia-related events, thromboembolism, retained foreign bodies, pain syndromes, and loss of function. The WHO surgical safety initiative highlighted that reducing such harm requires a team-based approach, with measures such as surgical safety checklists, correct site marking, time-out procedures, antibiotic prophylaxis, instrument counts, and postoperative monitoring to prevent avoidable complications. [16,17]

Diagnostic and Radiological Iatrogenesis

Diagnostic interventions, although essential for accurate clinical decision-making, may themselves become a source of harm. Diagnostic iatrogenesis may result from missed or delayed diagnoses, false-positive findings leading to unnecessary investigations or treatment, overdiagnosis, contrast-associated kidney injury, radiation exposure, invasive biopsies, and cascades triggered by incidental findings. Reducing such harm requires appropriate selection of investigations, interpretation of results in clinical context, effective communication of critical findings, shared decision-making, and reliable follow-up systems. [1]

Transfusion, Infection and Device-Related Harm

Blood transfusion, invasive devices, and supportive technologies can also contribute to iatrogenic harm. Transfusion-related complications include allergic reactions, hemolysis, circulatory overload, acute lung injury, and infection risks, highlighting the importance of hemovigilance and monitoring systems. Device-related harm includes catheter-associated infections, ventilator-associated pneumonia, infusion pump errors, implant failures, and device-related user errors.[1,12]

Prevention, Detection and Management

Prevention remains the most effective strategy against iatrogenic disease, supported by early detection and appropriate management. Reducing harm requires a system-based approach that addresses workflow challenges, human factors, and communication gaps. Patient safety is strengthened through standardized practices, teamwork, reporting culture, and active patient involvement. [1]

Phase	Practical safety actions
Before treatment	Confirm diagnosis; review allergies, pregnancy, renal/liver function; check interactions; obtain consent; choose evidence-based therapy
During treatment	Use right patient, right drug, right dose, right route, right time, right documentation; monitor response and toxicity
During procedures	Use time-out, aseptic technique, checklist, antibiotic prophylaxis when indicated, equipment checks and instrument counts
After treatment	Medication reconciliation, discharge counselling, red-flag instructions, follow-up test review, ADR reporting
If harm occurs	Stabilize patient, stop or reverse offending intervention, document clearly, disclose appropriately, report and analyze cause
Long-term system learning	Root-cause analysis, morbidity/mortality review, protocol revision, training, audit-feedback loops

Pharmacovigilance and Patient-Safety Systems

Pharmacovigilance is essential for preventing drug-related iatrogenic harm. WHO defines it as the science and activities involved in detecting, assessing, understanding, and preventing adverse drug effects and other

medicine-related problems. It supports rational drug use and regulatory actions such as safety alerts, label changes, and restrictions. [5,7]

The WHO Programme for International Drug Monitoring, established in 1968 with support from the Uppsala Monitoring Centre, facilitates global drug-safety surveillance. In India, the Pharmacovigilance Programme of India (PvPI) provides a national framework for ADR reporting and monitoring. Effective pharmacovigilance depends on reporting, causality assessment, signal detection, regulatory action, and feedback to healthcare providers. [7,8]

Role of pharmacovigilance components in preventing iatrogenic harm

Component	Role in preventing iatrogenic disease
Spontaneous ADR reporting	Detects rare and serious reactions; depends on clinician and patient participation
Causality assessment	Assesses likelihood that drug caused the event; supports rational decisions
Signal detection	Identifies unusual patterns in national and international databases
Regulatory action	Alerts, label updates, restrictions, risk minimization, withdrawal
Education and feedback	Improves reporting culture and prescribing safety
Active surveillance and real-world evidence	Uses electronic records, registries and cohort methods to quantify risk

Future Directions: Safer Innovation

Future prevention of iatrogenic harm will depend on integrating innovation with patient-safety principles. Technologies such as electronic prescribing, clinical decision support, artificial intelligence, pharmacogenomics, and real-world evidence have the potential to improve healthcare safety. However, they may also introduce new risks, including alert fatigue, automation bias, data-related errors, and over-reliance on technology. Therefore, every new intervention should be assessed for both its benefits and unintended consequences. [1,5,6,16]

A strong safety culture that encourages reporting, learning from adverse events, teamwork, and patient involvement is essential. The goal is not to eliminate all risks associated with healthcare but to minimize preventable harm and ensure that unavoidable risks are identified and managed effectively. [1,3]

Selected Landmark Examples of Iatrogenic Harm

Drug and Excipient Disasters That Changed Regulation [17]

Event / period	Clinical features and consequences	Patient-safety learning
Thalidomide tragedy (1957-1961)	Marketed in 1957 as a supposedly safe sedative for morning sickness. It caused severe congenital malformations, including phocomelia, absent limbs, ear and eye defects, cardiac defects and gastrointestinal abnormalities. The slide notes that more than 10,000 babies were affected worldwide and that the drug was sold in more than 46 countries.	Classic example of drug-induced iatrogenic disease. It revolutionized drug-safety regulation, clinical trial protocols, pharmacovigilance systems and teratogenicity testing.
Sulfanilamide disaster (1937)	A liquid preparation called elixir sulfanilamide used toxic diethylene glycol as a solvent. The slide describes cutaneous/systemic findings such as skin rashes, cyanosis and severe dehydration, with more	Demonstrated that inactive ingredients and solvents can be lethal. It strengthened the need for excipient testing, pre-market safety evaluation

	than 100 deaths in the United States.	and stronger drug regulation.
Panama diethylene glycol poisoning epidemic (2006)	Government-produced cough syrup became contaminated with diethylene glycol. The slide identifies acute tubular necrosis, severe acute kidney injury, metabolic acidosis and multi-organ failure; it also notes more than 100 confirmed deaths and many poisoned patients.	A modern supply-chain disaster showing that pharmaceutical-grade labeling is not enough without analytical verification, quality control and traceability of excipients.
Rofecoxib/Vioxx cardiovascular disaster (1999-2004)	Rofecoxib was a COX-2 inhibitor NSAID used for arthritis pain. Later studies linked it with myocardial infarction, stroke and sudden cardiac death. The slide notes 88,000-140,000 excess serious coronary heart disease cases in the United States and global withdrawal in 2004.	Highlighted the importance of post-marketing surveillance, complete safety-data reporting, rapid regulatory response and cardiovascular outcome assessment for high-use medicines.

Drug-Induced Organ and System Toxicities [\[17\]](#)

Event / period	Clinical features and consequences	Patient-safety learning
NSAID-induced gastric ulceration	NSAIDs inhibit COX enzymes and reduce prostaglandin synthesis. Loss of prostaglandin-mediated mucus, bicarbonate and mucosal blood-flow protection leads to erosion and ulceration. The slide highlights the 1988 MUCOSA study in arthritis patients: placebo gastric ulcer occurrence 21.7%, misoprostol 100 micrograms 5.6%, and misoprostol 200 micrograms 1.4%.	Predictable pharmacological toxicity can be reduced by risk stratification, lowest effective dose, gastroprotection and patient counselling.
Analgesic nephropathy epidemic (1950s-1980s)	Long-term overuse of combination painkillers containing phenacetin, aspirin and caffeine caused chronic interstitial nephritis, renal papillary necrosis and progressive kidney failure. The slide emphasizes that common over-the-counter medicines could silently destroy kidneys.	OTC availability does not guarantee safety. Long-term analgesic use requires renal-risk awareness and avoidance of unsafe combinations.
Chloroquine-induced retinopathy (1950s-1970s)	Patients on chronic chloroquine therapy developed blurred vision, reading difficulty, color-vision defects and peripheral vision loss. Chloroquine accumulation in retinal pigment epithelium and photoreceptor cells causes cellular degeneration, macular damage, progressive retinal toxicity and bull-eye maculopathy.	Cumulative-dose toxicity requires baseline and periodic ophthalmic monitoring and careful reassessment of long-term therapy.
Hydralazine-induced systemic lupus erythematosus (1951-1953 onward)	Hydralazine, introduced for severe hypertension and heart failure, can alter immune regulation and trigger ANA and anti-histone antibodies. Slide-listed risk factors include women, slow acetylators, high-dose therapy and long-term use.	Important proof that medicines can induce autoimmune disease; clinicians must suspect drug-induced lupus when symptoms emerge during prolonged therapy.
Isoniazid-induced peripheral neuropathy (1950s-1970s onward)	Isoniazid interferes with vitamin B6/pyridoxine metabolism, leading to pyridoxine deficiency, impaired neurotransmitter synthesis and axonal nerve injury.	Mechanism-based prevention is possible: pyridoxine prophylaxis dramatically reduces neuropathy risk in vulnerable patients.

Chemotherapy-induced alopecia	Cytotoxic drugs damage actively growing hair follicles, producing anagen effluvium. The slide notes onset within 1-3 weeks, major hair loss by 2-4 weeks, diffuse hair loss, eyebrow/eyelash loss, scalp tenderness and psychological distress. Listed drugs include cyclophosphamide, doxorubicin, docetaxel, paclitaxel, vincristine, etoposide and ifosfamide.	Some harms are not fatal but have major quality-of-life impact. Counselling, scalp cooling where appropriate and supportive measures such as minoxidil or other dermatologic care may reduce distress.
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Neuropsychiatric Iatrogenesis [17]

Event / period	Clinical features and consequences	Patient-safety learning
Reserpine-induced depression and parkinsonism (1950s)	Reserpine irreversibly depletes monoamine neurotransmitters. The depression slide links depletion of serotonin, norepinephrine and dopamine with severe sadness, emotional withdrawal, suicidal thoughts and psychomotor slowing. The parkinsonism slide links dopamine depletion in basal ganglia with tremor, rigidity, bradykinesia and mask-like face.	A landmark example connecting drug action, neurotransmitter biology and psychiatric/movement adverse effects. It influenced the monoamine theory of depression and recognition of drug-induced parkinsonism.
Chlorpromazine-induced parkinsonism and tardive dyskinesia	Chlorpromazine was introduced as the first major antipsychotic and changed psychiatry. Dopamine blockade in basal ganglia produced tremor, rigidity, bradykinesia and mask-like facies. Later, tardive dyskinesia presented with lip smacking, tongue protrusion, facial grimacing and abnormal involuntary movements.	Long-term dopamine-blocking therapy needs dose minimization, monitoring for extrapyramidal symptoms, regular neurological assessment and early action when abnormal movements appear.

Procedure-, Transfusion- and Biological Product-Related Iatrogenesis [17]

Event / period	Clinical features and consequences	Patient-safety learning
Iatrogenic Creutzfeldt-Jakob disease (CJD)	The slide states that more than 500 people worldwide developed iatrogenic CJD from medical procedures and contaminated biological products. Around 226 cases were linked to cadaver-derived human growth hormone and more than 230 cases to contaminated dura mater grafts, especially Lyodura. It highlights long incubation, devastating neurological symptoms and near-universal fatality.	Biological products and surgical materials require strict donor screening, sterilization standards, traceability and avoidance of high-risk human-derived products when safer alternatives exist.
Oxygen therapy-induced bronchopulmonary dysplasia (1960s)	During the 1960s, premature infants received prolonged high-concentration oxygen therapy and mechanical ventilation. Severe chronic lung injury in survivors led to recognition of bronchopulmonary dysplasia. The slide notes that William A. Northway Jr. first described BPD in 1967.	Even oxygen can cause harm when exposure is excessive. Neonatal care requires target oxygen saturation ranges, careful ventilation strategies and continuous monitoring.
Hazards of blood transfusion	The slide divides hazards into immunological reactions, including allergy/anaphylaxis, fever, hemolysis and non-cardiac pulmonary edema, and non-immunological harms, including circulatory overload, thrombophlebitis, embolism, bacterial contamination, transfusion-transmitted infections	Transfusion safety depends on correct identification, compatibility testing, infection screening, hemovigilance and prompt recognition of acute

	and transfusion siderosis. It also reports hemovigilance figures: 8,162 adverse reactions and an overall incidence of 8.4 per 10,000 products.	reactions.
Surgery-induced disease	The slide lists hemorrhage, infections and organ damage as major surgical iatrogenic harms. Hemorrhage may cause anemia or shock; infections include SSI, pneumonia and sepsis; organ injury may result from technical error, poor visibility or anatomical variation. The slide also states that more than 300 million procedures occur yearly and that surgical complications affect about 7 million patients with more than 1 million deaths annually.	Surgical safety requires checklists, time-out, asepsis, antibiotic prophylaxis, careful hemostasis, instrument counts, anatomical awareness and post-operative surveillance.

Across these examples, iatrogenic harm commonly results from predictable toxicity, idiosyncratic reactions, dose-related injury, contamination, and failures in monitoring systems.

They emphasize the need for appropriate drug selection, safe dosing, quality assurance, patient counselling, and effective reporting mechanisms to prevent avoidable harm.

CONCLUSION

Iatrogenic disease remains an important challenge in modern healthcare. It encompasses drug-related harm, surgical complications, diagnostic errors, healthcare-associated infections, transfusion reactions, device-related injuries, and failures in healthcare systems. Lessons from landmark events such as sulfanilamide, thalidomide, Vioxx, iatrogenic CJD, transfusion-related harm, and surgical complications highlight the importance of clinical vigilance, pharmacovigilance, ethical reporting, and system-based prevention. The aim is not to avoid medical interventions but to ensure that every treatment is safer, better monitored, and more accountable.

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