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Review on Adverse Drug Reaction Reporting

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Abstract: *Adverse drug reactions (ADRs) are one of the main reasons for illness and death.It is estimated that about 10% of hospital visits are because of ADRs, and around 5 to 20% of patients who are in the hospital experience a serious ADR[1]. Reporting ADRs has become a key part of hospital monitoring and evaluation efforts. These reporting programs help keep track of ADRs, encourage people to report them, and teach healthcare workers about possible side effects of drugs. This article looks at ADR reporting and monitoring, including how to classify ADRs, the difference between adverse effects and adverse reactions, and the methods used to monitor ADRs[2,3]*

Keywords: Adverse drug reaction reporting; Pharmacovigilance; Drug monitoring; Uppsala monitoring center, Bizarre, Augmented, Karch and Lasagna, Predictable, Unpredictable

I. INTRODUCTION

Medicines are used for their therapeutic effects of pathological conditions or modify ictal functions[4]. Use of medicines always associated with an intended or unwanted risk leading as adverse drug reactions.The World Health Organization (WHO) defines an ADE as "any unexpected medical event that may happen while someone is taking a medicine, but it does not always mean the medicine caused it" (Wagg 2005). WHO defines an ADR as; ug which is noxious and unintended ang which occurs at doses normally used in person lee used in portion for prophylaxis, diagnosis, or therapy o disease or for the modification of physiologic function". Adverse Drug Reactions (ADRs) unwanted or undesirable effects of a medication caused by normal therapeutic doses that occurs during usual clinical use[5,6]. Adverse drug reactions occur almost daily in health can sector can adze sector and can adversely affect a patient's quality of life, often causing considerable morbidity and mortality. The incidence of adverse drug reactions is difficult to estuarian Du cadence adverse drug reactions is difficult to establish but of acute admissions to hospitals from a reaction to drugs given in general practice[7]. In hospitals, up to 20% of patients experience an adverse drug reaction an although these ADR are rarely life-threatening, they account for 05-196 of hospital in-patient these ADR are deaths.

Every occasion that a patient is exposed to newd to new medicinal product is a unique situationand it can never be accurately estimated the extent of c the lee estimated the extent of damage to the patientHowever, past experience with the same medicines and similar health conditions can help estimate adverse drug reactions[8]. A lot of focus has been placed on finding out which patient groups are most at risk, which drugs are most often to blame, and the possible reasons behind these reactions. Sometimes, bad reactions to medication can make patients feel unsure or upset about their treatment. This can lead them to have negative feelings towards their doctors and might make them try to treat themselves instead. This self-treatment can then result in more bad reactions happening[9].

The classification proposed by Rawlins and Thompson (1977) divides reactions into type
A and type B.

Example of different types Of ADR

Types	Example	Toxicity	Mechanism
Pharmacodynamic	Indomethacin	Left ventricular failure	Water and sodium retention
Pharmacokinetic (due to absorption, distribution,	Digoxin	Digoxin toxicity (nausea, arrhythmias etc.)	Decreased elimination if renewal function is

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metabolism and excretion)			inspired.
Pharmaceutical	Phenytoin	Phenytoin toxicity (ataxia, nystagmus; etc.)	Decreased elimination if renewal function is inspired.
Genetic	Nortriptyline	Confusion	Reduce hepatic elimination as a result of deficiency Off CYP2D6
Drug drug interaction (due to any of the above processes)	Lithium non-steroidal at the inflammatory drugs	Lithium toxicity	Inhibition of excretion of lithium

Classification of ADRs

Type A reactions, are predictable and are caused by an excess of the drug's primary pharmacological effect. (e.g., bleeding from warfarin) or a low therapeutic index (e.g., nausea from digoxin). Type A reactions constitute approximately 80% of adverse drug reactions. Dose-related adverse drug reactions occur most often with drugs that have a steep dose- response curve and/or small difference between therapeutic and toxic doses (i.e., a low therapeutic index = toxic dose/therapeutic dose).

These reactions can be very dangerous, even deadly, like intracranial bleeding with warfarin. Drugs that are commonly used but have a low therapeutic index include anticoagulants, hypoglycemic drugs, digoxin, antiarrhythmics, aminoglycosides, xanthine's, cytotoxic drugs, and immunosuppressive drugs. These reactions usually happen when the dose is not right, especially if the body isn't eliminating the drug properly. The term 'side effects' is often used for minor type A reactions[10].

Type B ('idiosyncratic') also called as non-dose related reactions are not predictable from
the drug's main pharmacological action, are not dose-related and are severe, with a considerable mortality. The underlying pathophysiology of type B reactions is poorly if at all understood and often has a genetic or immunological basis. Type B ADR are rare and occur infrequently (1:1000-1:10000 treated subjects being typical).

Type C: This type of ADR is usually due to the long-term use of drugs (e.g., neuroleptic
related tardive dyskinesia or analgesic nephropathy). Type D: This type of ADR is considered as delayed reactions due to the usage of thedrug (e.g., alkylating agents leading to carcinogenesis, or retinoid-associated teratogenesis). Type E: This type of ADR takes place after stopping the use of the drug such as adrenocortical insufficiency follows withdrawal of glucocorticosteroids, or withdrawal syndromes following discontinuation of treatment with benzodiazepines or ß-adrenoceptorantagonists[11].

Types of ADR

Types of ADR	characteristics	Example	Management
Dose related (Augmented)	Due to pharmacological action of drug exaggerated, Pharmacological action of drug dose related most frequent type of ADR predictable low mortality.	Bleeding with warfarin, Digoxin toxicity, Respiratory depression with opioids	Withdrawal or dose reduction.
Non dose related (bizarre)	Rare, unpredictable, Not due to pharmacological action of the drug, idiosyncratic high mortality	Immunological reaction anaphylaxis to penicillin. Idiosyncratic Reaction malignant hyperthermia with general anesthetic	Which world and avoid in future

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Dose related and time related (chronic)	A rare occurred due to cumulative dose of the drug	Hypothalamic petitory adrenal axis suppression by corticosteroid osteoporosis of the jaw with bisphosphonate	Reduce dose or withhold withdrawal may have to be done Hey Cortana
Time related (delayed)	Rare, mostly those related rapidly after withdrawal of the drug	Carcinogenesis, Tardive dyskinesis, Teratogenesis	Often Intractable
Unexpected failure of therapy (Failure)	Frequent Dose related, The result of interactions.	Inadequate dosage of an oral contraceptive when used with an enzyme inducer resistance to antimicrobial agent	Increase dosage, consider effect of incompetent therapy
Withdrawal (end of use)	Rare, mostly dose related sometime only after withdrawal	Withdrawal syndrome with opiates or benzodiazepines (egg, insomnia anxiety)	Reintroduce drug and withdraw slowly.
Genetic	Pharmacokinetics of dynamic	Severe Hemolytic anemia in G6PD- Deficient patient after the ingestion of fava beans and after the use of certain antimalarial drugs or sulfonamides	Those adjustments are withdrawal and avoidance

Pharmacovigilance

Pharmacovigilance, the science, and activities related to the detection, assessment, understanding, and prevention of ADRs, plays a crucial role in monitoring the safety of medications after they are approved for public useTo improve drug safety and patient care, healthcare professionals and patients are encouraged to report any suspected adverse reactions to the appropriate regulatory authorities or healthcare institutions. Reporting ADRs on time and correctly helps keep track of how safe a drug is. This information can lead to changes in how the drug is labeled, how it is used, or even cause the drug to be taken off the market if it's necessary to protect patients[12].

Historical Background

Pharmacovigilance, which is the study and practice of watching for and checking the safety of medicines, has a long history that goes back many years. Here is a summary of the main events in the history of pharmacovigilance**.**

Thalidomide tragedy (Late 1950s-Early 1960s: The thalidomide tragedy happened in the late 1950s to early 1960s and is a major event in the history of drug safety. Thalidomide was a medicine given to pregnant women to help with morning sickness and trouble sleeping. But later, it was found that thalidomide caused serious birth defects, leading to missing or malformed limbs in many babies. This sad event showed how important it is to carefully test and watch drugs to make sure they are safe.

Kefauver-Harris amendment (1962): In response to the thalidomide disaster, the United States passed the Kefauver-Harris Amendment, which strengthened drug regulation and required pharmaceutical companies to demonstrate the efficacy and safety oftheir products before approval. It also established the requirement for post-marketing surveillance to monitor adverse drug reactions after drugs were on the market .

World Health Organization (WHO) programmed for international drug monitoring (1968) : The World Health Organization created the Programmed for International Drug Monitoring (PIDM) together with the Uppsala Monitoring

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Centre (UMC) in Sweden. PIDM was meant to gather and study information about bad reactions to drugs from different countries, which helped countries work together to make sure medicines are safe.

Development of adverse drug reaction reporting systems (1970s-1980s) : During this time, many countries created their own national systems for reporting bad reactions to medicines and programs to monitor drug safety. These systems let doctors and the public report any suspected side effects, which helped build a larger collection of information about how safe medicines are.

International conference on harmonization of technical requirements for registration of pharmaceuticals for human use (ICH) (1990s The ICH is a worldwide group made up of regulatory agencies and people from the pharmaceutical industry. It was created to make drug development and regulatory rules more consistent around the world. ICH guidelines have covered many areas related to tracking drug side effects and safety reports, helping to make these practices easier and more uniform across different countries.

Strengthening of regulatory oversight (2000s): In the early 2000s, various regulatory agencies around the world, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), intensified their efforts to strengthen pharmacovigilance systems. This included implementing risk management plans, enhancing safety labeling, and improving signal detection methods.

Advancements in Technology (Recent Years): As technology has improved, pharmacovigilance has made big progress in collecting data, finding signals, and analyzing information. Using electronic health records, data mining methods, and artificial intelligence has made it easier and more accurate to track adverse drug reactions.

Application of ADR

- Improve patient safety
- India reporting Sales detect Harmful or unexpected effects of drug early, preventing future harm to patient
- Supports pharmacovigilance programs
- It forms the foundation of national and global pharmacovigilance system like (Indias Poppi OR WHO-UMC), Which monitor drug safety after marketing.
- Detection of new ADRs
- Reporting can help identify previously unknown side effects that not detected during clinical trials
- Helps in regulatory decision
- a regulatory agency like CDSCO, USFDA, or EMA use ADR Data:
- Update drug label and warnings
- A restrict or ban on safe drugs
- Change dosage recommendations
- Promotes rational use of medicine
- By understanding which drugs cause more reactions, healthcare professionals can describe safer and more appropriate medicine.
- Improves clinical practice
- ADR reports guide clinicals in recognizing and managing side effects more effectively in real world settings.

Significance ADR Reporting

Adverse drug reaction (ADRs) Reporting is significant as it is playing a vital role in ensuring drug safety and patient care. It helps in the early that may not appear during clinical trials. By collecting and analyzing these reports, Healthcare authorities can take appropriate action such as updating safety information, restricting use, or even withdrawing harmful drugs from the market[13].

ADR Reporting also promotes a rational and safe use of medicine, Reduce drug related morbidity and mortality, and strengths. Formative vigilance system at national and global levels. Moreover, It increased the awareness among healthcare professionals and patients about the importance of monitoring drug effects, thereby improving the overall quantity of health care[14].

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Objective of ADR Reporting

- To detect unknown, rare, or serious adverse drug reaction early.
- To assess the frequency, severity, pattern of know ADRs.
- To improve patient safety and ensure the safe and of medicines.
- To provide information for uploading for updating labels and warnings.
- To support regulatory authorities in decision-making about drug approval, restriction, or withdrawal.
- To promote rational prescribing and use of medicines.
- To educate healthcare professional about drug safety and encourage reporting culture.
- To strengthen the national and international pharmacovigilance system.

Role of ADR Reporting

The rule of ADR reporting is to monitor, identify Cortana evaluate unwanted effect of medicine to ensure the safety and effective use. It helps in our detecting new rear end series reaction that may not appear during clinical trials. ADR reporting provides essential data to regularly authorities for updating safety information, issuing warnings, or withdrawing unsafe drugs. ADD also guide healthcare professionals in making better prescribing decision and promotes rational drug use. Overall, ADR reporting plays a vital role in improving the patient's safety, enhancing drug quality, strengthening coma pharmacovigilance system worldwide[15].

Advantages of ADR Reporting

- Improve business simply by identifying and preventing harmful drug effects.
- Detect 's New York real side effects not found during clinical trials.
- Health Regulatory Authority update Warnix, dosage, or withdraw unsafe drugs.
- Promotes rational use of medicine and better prescribing practices.
- Supports pharmacovigilance system at national and global levels.
- Enhance healthcare quality and increase awareness among professionals.

Disadvantages of ADR Reporting

- Under reporting many ADRs are not reported by healthcare professionals.
- Incomplete and inaccurate data can reduce airport quality.
- Difficulty in establishing casualty linking the to the reaction.
- Time consuming process for busy healthcare workers.
- Lack of awareness and training may limit effective reporting.

Importance of ADR for drug safety

- **Finding new side effects:** Reporting side effects helps find uncommon or previously unknown problems that medicines can cause. Finding these early lets doctors act quickly, which can stop more harm to patients.
- **Post-marketing surveillance**: Clinical trials before drug approval may not capture all possible adverse reactions due to limited sample sizes and controlled conditions. ADR reporting enables continuous monitoring of drug safety in real-world settings after drugs are released to the market.
- **Signal detection and risk assessment**: Aggregating ADR reports from various sources helps in identifying patterns or signals that may indicate potential safety concerns. Analyzing these signals aids in assessing the risk-benefit profiles of drugs, leading to appropriate regulatory actions if necessary.
- **Improving drug labeling and usage guidelines:** ADR reports provide valuable data that can lead to updates in drug labeling, including warnings, precautions, and contraindications. This ensures that healthcare professionals and patients are informed about potential risks and appropriate usage.

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- **Enhancing pharmacovigilance practices**: ADR reporting contributes to the overall improvement of pharmacovigilance systems and practices. Regular analysis of ADR data can lead to enhancements in reporting processes and signal detection methodologies.
- **Understanding drug interactions and comorbidities**: ADR reporting helps in assessing the interactions between multiple medications and the influence of underlying medical conditions, providing valuable insights for personalized medicine and treatment plans.
- **Patient empowerment**:Encouraging patients to share information about adverse drug reactions helps them take an active role in their health care. When patients report these reactions themselves, it can help make healthcare safer and lead to better results for patients.
- **Post-approval safety assessment:** ADR reporting helps regulatory agencies keep checking how safe drugs are. It also lets them look again at whether the benefits of a drug are still worth the risks, to make sure the drug remains safe and works well.

Challenges in ADR Reporting

ADR reporting faces several challenges that impact its effectiveness and completeness. Some of the key challenges include:

- **Underreporting**: One of the most significant challenges is the underreporting of adverse drug reactions. Healthcare professionals and patients may not always recognize or report ADRs, leading to a significant gap in the data collected. Underreporting can hinder the detection of rare or long-term adverse reactions, potentially delaying necessary interventions.
- **Reporting bias**: ADR reporting is susceptible to reporting bias, where certain adverse reactions may be over reported or underreported due to various factors such as media attention, public perception, or the drug's popularity. This bias can distort the true safety profile of a medication.
- **Lack of awareness**: Healthcare professionals and patients may have limited awareness and understanding of the importance of ADR reporting. Lack of knowledge about reporting mechanisms, uncertainty about causality, or fear of repercussions can deter reporting .
- **Time constraints and workload**: Healthcare professionals often face time constraints and heavy workloads, which can discourage them from dedicating time to reporting ADRs. Reporting processes may be perceived as time-consuming and cumbersome, reducing participation rates.
- **Difficulty in causality assessment**: Determining the causality between a drug and an adverse reaction can be challenging, especially when patients are taking multiple medications or have underlying health conditions. Establishing a clear cause-and-effect relationship is essential for accurate reporting.
- **Incomplete or inaccurate information**: ADR reports may lack crucial details, such as patient demographics, drug dosage, and concomitant medications, making it difficult to assess the seriousness and validity of the reported adverse reaction.
- **Patient involvement**: Patient reporting of ADRs is gaining recognition, but challenges remain, including patient awareness, the ability to differentiate ADRs from other symptoms, and limited access to reporting channels.

Where to report

Nearest ADR Monitoring Center (AMC) – AIIMS Raipur – Pt. JNMC, Raipur
Directly to NCC, IPC Ghaziabad
pvpi.ipcindia@gmail.com pvpi@ipcindia.net
Toll free no. – 1800 180 3024
ADR Reporting Android app

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What to report?

Serious or Non-serious ADR

Known or Unknown ADR

Frequent or Rare – Related to medicine, vaccine, herbal products

II. CONCLUSION

The results of the studies included in this review showed a promising effects of ADR reporting through mobile applications, as shown by the increase in the number of submitted ADR reports. Furthermore, the current review included onlv several applications adjusted for specific conditions. The development of mobile applications for specific patient populations would enable better signal detection of ADRs and improve patient care.

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