Research Article

INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
www.irjponline.com
ISSN 2230-8407 [LINKING]

To study the preventability of adverse drug reactions in Tertiary Care Hospital in Assam

Dr. Binita Teron[1], Dr. Karabi Adak[2], Dr. Gunamani Rabha[3]*, Dr. Baneswar Baro[4]

[1]Associate Professor, Department of Dermatology, Diphu Medical College, Diphu, Assam, India.
[2]Medical Advisor, Wockhardt Ltd. Mumbai, India.
[3]Associate Professor (DACP), Department of Anatomy, Diphu Medical College, Diphu, Assam, India.
[4]Professor (DACP), Department of Anatomy, Diphu Medical College, Diphu, Assam, India.

How to cite: Dr. Binita Teron, Dr. Karabi Adak, Dr. Gunamani Rabha, Dr. Baneswar Baro. **To study the preventability of adverse drug reactions in Tertiary Care Hospital in Assam**. International Research Journal of Pharmacy, 2025,16:12: 93-92.
Doi: http://doi.org/10.56802/irjp.2025.v16.i12.pp93-103

==========

ABSTRACT

Background

An adverse drug event (ADE) is any untoward medical occurrence in a patient who is administered a medicinal product and which doesn't necessarily have a causal relationship with this treatment. Pharmacological adverse drug reactions (ADRs) happen when the plasma and (or) tissue concentration surpasses the "therapeutic window" or a patient's reactivity to the drug agent increases. Preventability assessment can be done to know if the occurred reaction was inevitable or not. Most ADRs can be prevented on the basis of already known adverse reactions to pharmacological products and procedures.

Methods

This study is a non-interventional, hospital-based, prospective, cross-sectional, observational study conducted at Diphu Medical College & Hospital on patients who presented with adverse reactions to both inpatient and outpatient department during the period of 1st July 2024 to 30th June 2025. A total of 123 reported cases of all age group was taken, out of which 99 cases were enrolled under the study.

Results & Observation

Preventability was assessed using Modified Schumock and Thornton Scale. 36.4% of the ADRs were "preventable", 19.2% were "probably preventable" and 44.4% were "not preventable". Hence most of the ADRs are not preventable. No ADR related mortality was recorded during the study period.

Conclusion
The study of assessment of preventability signifies that it is not always possible to preclude an ADR, but measures can be taken to decrease the occurrence of ADR and mortalities.
Key words: Adverse drug effects, Adverse drug reaction, Preventability, Pharmacovigilance.

INTRODUCTION

An appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product. Adverse effects usually predict hazard which may occur in future due to administration of the same drug.(1) An adverse drug event (ADE) is any untoward medical occurrence in a patient who is administered a medicinal product and which doesn't necessarily have a causal relationship with this treatment. Adverse drug reactions (ADR) are noxious and unintended responses to a medicinal product. A cause-effect relationship can often be established between the ADE and the drug, however, this is not the case with a "reaction", where a causal relationship cannot be ascertained.(2) The term "adverse effect" can be interchanged with other terms such as "toxic effect" or "side effect". Toxic effects are exaggerated dose dependent responses to a drug. It occurs when a drug is administered in supra therapeutic doses. However, at times, toxic effects of drugs may be dose independent, and can occur with normal doses as well. The pathogenesis for this peculiar finding, however, remains unclear.(3)

It is important to note that although the expressions "adverse drug event" and "adverse drug response" are sometimes applied synonymously, they have varied meanings. Both adverse effect and adverse reaction have unique markers that can be used to identify them. For example, adverse effects are typically found through clinical investigations or laboratory tests. Conversely, adverse reactions are typically found through their presenting signs and symptoms.(4)

Pharmacological adverse drug reactions (ADRs) happen when the plasma and (or) tissue concentration surpasses the "therapeutic window" or a patient's reactivity to the drug agent increases (despite normal doses being administered to overall population). Idiosyncratic ADRs are rare, serious, independent of dose and do not exhibit a clear dose-effect relation for either toxicity or reaction severity.(5)

WHO laid down the definition of pharmacovigilance (PV) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.(4) By offering a mechanism to gather, evaluate, and disseminate drug safety data, PV seeks to improve patient safety with regard to medications and therapeutic procedures used.(5)

Preventability assessment can be done to know if the occurred reaction was inevitable or not. Most ADRs can be prevented on the basis of already known adverse reactions to pharmacological products and procedures. For determining if ADRs are preventable, the Schumock and Thornton criteria were developed. Numerous research have employed this criterion in its modified form. It is divided into three categories: things that can be absolutely or probably prevented, and those that can't be prevented.(6)

To develop a greater knowledge of whether and how safer and sustainable alternatives could be developed, research into the mechanisms of action continues to be a focus. To this purpose, substantial developments in molecular methods and different test species over the past 20 years have offered distinctive ways to evaluate theories about the mechanisms of action of ADRs. Technologies like zebrafish and culture test applying in-vitro technologies have been

utilised to shed light on how some things work.[7] In order to reduce the incidence and prevalence of ADRs, it is prudent that we use the evidence-based preventability assessment tools more frequently. Despite the presence of a large number of studies aiming to assess the incidence of preventable ADRs. Instead of using studies that have methodological differences, it is important that incidence estimates are inferred from those studies that are conducted in a methodologically similar manner keeping in mind the different population characteristics and the idiosyncrasy of the ADRs.[8]

MATERIALS AND METHODS

This study of preventability of ADR is a non-interventional, hospital-based, prospective, cross-sectional, observational study conducted at Diphu Medical College & Hospital on patients who presented with adverse reactions to both inpatient and outpatient department during the period of 1st July 2024 to 30th June 2025. A total of 123 reported cases of all age group was taken, out of which 99 cases were enrolled under the study. The study was conducted using protocol reviewed and approved by the Institutional Human Ethical Committee of the college. The consent form and patient information sheet were provided to enrolled patients or legally acceptable representative (LAR) in vernacular language. They were included for the study only after they read and understood the patient information sheet, signed the consent form willingly and met all parameters of inclusion and exclusion criteria.

Table 1: Inclusion and exclusion criteria of patients enrolled under the study

Inclusion Criteria	Exclusion Criteria
➢ Either sex and of any age group	➢ Intentional or accidental poisoning patients
➢ Admitted to hospital ward as a suspected case of ADE	➢ History of drug abuse
➢ Any hospitalised patients who develop ADR	➢ If not willing to give consent for investigating suspected ADR
➢ Any patients reporting to OPD with suspected ADE	
➢ Any patients developing symptoms during or post blood or blood product transfusion or vaccination	

Medical staff, medical post graduates, nursing staff and patients were educated and encouraged to report any suspected ADR by creating awareness through leaflets, pamphlets, brochures, meetings with the help of AMC (ADR Monitoring Centre) of this hospital. Definitions for ADE, ADR were adopted as given by WHO. Spontaneous reporting method was followed for identifying ADRs. ADR notification forms were made available at nursing station of ward and at reception of OPDs. Any suspected ADR was brought to the notice of concerned physician. The physician would fill the ADR form if the reaction is suspected to be an ADR. The researcher is then notified, who would take further action to collect the ICSR. All relevant data such as demographics, drugs administered, their routes & doses, onset of reaction, batch no.(if available) of the drugs were recorded. A detailed hypersensitivity history of the patients were also collected. In addition, patients' medications as well as supportive therapy given were also noted.

After receiving information about a suspected ADR, investigator would go to the individual patient and gather all required information from the patient or from LAR or both. Patient and his associates were explained the purpose of visit and data collection. Various parameters related to the collected ADRs were assessed according to Wills and Brown classification into nine categories.

Preventability assessment was done using Modified Schumock and Thornton Scale It is grouped categorically as definitely preventable, probably preventable and not preventable. (9)

Modified Schumock and Thornton Scale for PREVENTABILITY assessment

Questions for assessment of preventability
Definitely preventable
1. Was there a history of allergy or previous reactions to the drug?
2. Was the drug involved inappropriate for the patient's clinical condition?
3. Was the dose, route or frequency of administration inappropriate for the patient's age, weight or disease state?
4. Was a toxic serum drug concentration (or laboratory monitoring test) documented?
5. Was there a known treatment for the Adverse Drug Reaction?
Probably preventable
6. Was required Therapeutic drug monitoring or other necessary laboratory tests not performed?
7. Was a drug involved in the ADR?
8. Was poor compliance involved in the ADR?
9. Were preventative measures not prescribed or administered to the patient?
Not preventable
If all above criteria not fulfilled

Statistical Analysis

Microsoft Excel worksheet was used to enter all the collected data. Data was arranged systematically and a master chart was created. The data was analysed and individual parameters such as the demographics of enrolled participants, the drug exposure history and the associated adverse reactions, their types in the study were assessed. Pearson's Chi Square test was used to assess the relationship between management of the adverse drug reaction and its clinical outcome. p-value < 0.05 was considered as statistically significant. Data was analysed using IBM SPSS version 26.0.

RESULTS

A total 123 cases of suspected ADRs were enrolled for this study and 99 were studied as others dropped out due to various reasons.

Of the enrolled participants, 34% were admitted to the in-patient wards, and the remainder 65% had attended the out-patient departments which is indicated in table 02.

Table 02: Place of patient care		
Place	**Frequency**	**Percent**
In-patient	34	34.3
Out-patient	65	65.7
Total	99	100.0

Tables 3 & 4 depict various drugs causing the ADRs. They are classified and tabulated according to their pharmacological category and individual names. Amongst them, it was noted that corticosteroids caused maximum (31.3%) of the ADRs, followed by antibiotics (23.3%). Amongst the antibiotics, ceftriaxone caused the maximum number (11.11%) of ADRs noted in the study period.

Table 03: Group of implicated drug		
	Frequency	**Percent(%)**
Corticosteroid	31	31.3
Antibiotic	23	23.2
Antipsychotic	7	7.1
Antacid	6	6.1
Antiretroviral therapy	5	5.1
Anti-convulsant	4	4.0
NSAID	4	4.0
Hematinic	4	4.0
Anti-tubercular therapy	3	3.0
Antifungal	3	3.0
Complementary & Alternative Medication	3	3.0
Others	3	3.0
Diuretic	2	2.0
Antihypertensive	1	1.0
Total	99	100.0

Table 04: Name of Drug causing ADR		
	Frequency	**Percent**
OTC Topical Corticosteroid	31	31.31
Ceftriaxone	11	11.11
Sucralfate	6	6.0
Zidovudine/ Lamivudine/ Nevirapine	4	4.04
Azithromycin	4	4.0
Cotrimoxazole	4	4.0
Iron Sucrose	4	4.0

Amoxicillin	3	3.0
Complementary and Alternative Medication	3	3.0
NSAID	3	3.0
Olanzapine	3	3.0
Phenytoin	3	3.0
Dithranol	2	2.0
Piperacillin	2	2.0
Amisulpride	1	1.0
Amlodipine	1	1.0
Aripripazole	1	1.0
ATT	1	1.0
Ciprofloxacin	1	1.0
Dapsone	1	1.0
Doxorubicin	1	1.0
Haloperidol	1	1.0
Hydrochlorothiazide	1	1.0
Indomethacin	1	1.0
Nevirapine	1	1.0
Ofloxacin/ Ornidazole	1	1.0
Pyrazinamide	1	1.0
Risperidone	1	1.0
Topiramate	1	1.0
Torsemide	1	1.0
Unidentified NSAID	1	1.0
Total	99	100.0

Table 05 indicates the frequency and percentage of ADRs occurring with different routes of drug administration. Oral route of drug administration caused the most (48.5%) ADRs, while topical route caused 33.3% and intravenous route caused 18.2% of the ADRs.

Table 05: Route of administration of the offending drug		
	Frequency	**Percent**
Intravenous	18	18.2
Oral	48	48.5
Topical	33	33.3
Total	99	100.0

The preventability of the ADRs recorded were assessed using Modified Schumock and Thornton Scale. It was found that 36.4% of the ADRs were Preventable, 19.2% were Probably preventable and 44.4% were not preventable.

Table 06: Preventability of ADRs		
	Frequency	**Percent**
Preventable	36	36.4
Probably Preventable	19	19.2

Non preventable	44	44.4
Total	99	100.0

Table 07 shows the association between management and outcome of ADRs. P-value was found using Pearson Chi Square test and it was found to be a significant (p-value=0.049) association.

Table 7: Cross tabulation between management and outcome of the ADR

Management / Outcome	Continued same treatment (%)	Drug Substituted (%)	Drug withheld (%)	p-value
Improved	12 (14.0)	20 (23.3)	54 (62.8)	0.049
Not improved	2 (66.7)	0 (0.0)	1 (33.3)	
Loss to follow up	3 (30.0)	4 (40.0)	3 (30.0)	

Tables 07 & 08 indicate that most of (58.6%) the ADRs needed the offending drug to be withheld and that the majority (78.8%) of the patients recovered. The association between withholding the offending drug and clinical improvement was noted and was statistically significant (p=0.049).

Table 8: Cross tabulation between management and outcome of the ADR

Management / Outcome	Continued same treatment (%)	Drug Substituted (%)	Drug withheld (%)	p-value
Improved	12 (14.0)	20 (23.3)	54 (62.8)	0.049
Not improved	2 (66.7)	0 (0.0)	1 (33.3)	
Loss to follow up	3 (30.0)	4 (40.0)	3 (30.0)	

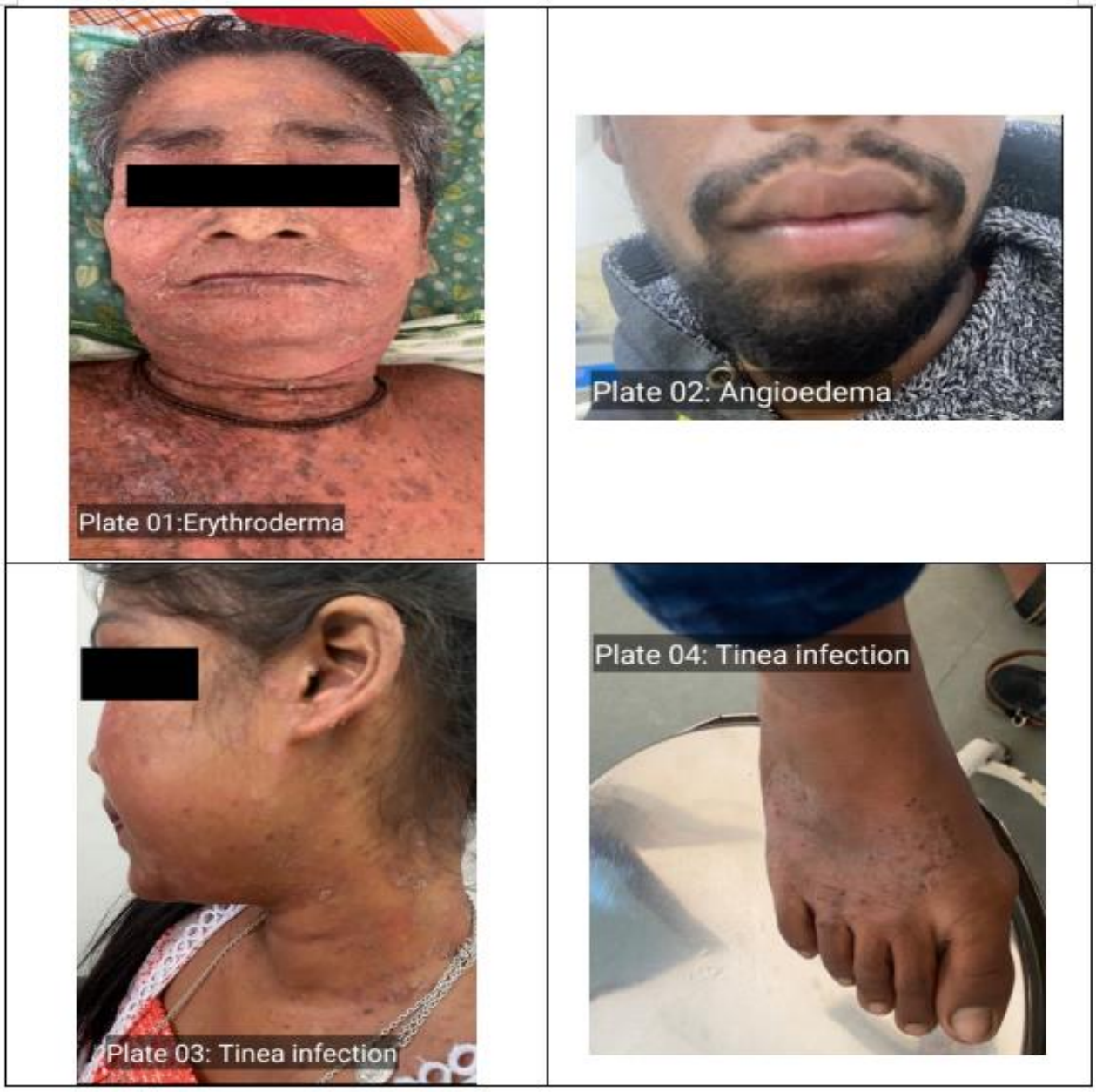
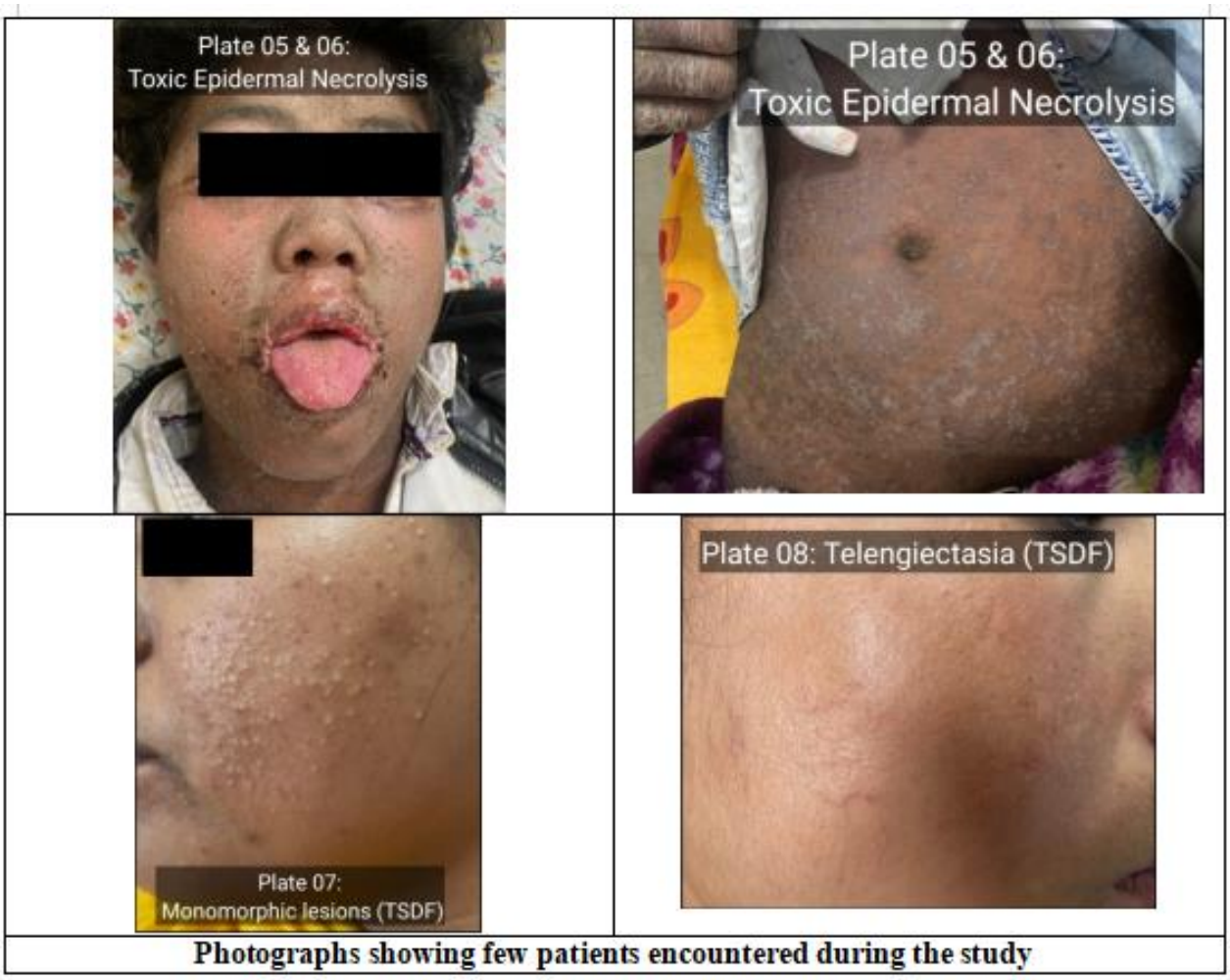


Plate 01:Erythroderma
Plate 02: Angioedema
Plate 03: Tinea infection
Plate 04: Tinea infection



Photographs showing few patients encountered during the study

DISCUSSION

For preventability assessment, Modified Schumock and Thornton Scale was used.[10,11] 44.4% of the ADRs were "non-preventable", 36.4% were "preventable" and 19.2% were "probably preventable". Surendiran et al. in their study also found that majority of their ADR cases were "non-preventable". Most ADRs were not preventable due to poor predictability and poorly understood mechanisms to explain their genesis. Common ADRs, such as nausea and vomiting, can, however, be effectively controlled with adequate pre-medication. This highlights the importance of anticipation and recognition of potential toxicities by the treating physician and the role of patient counselling regarding the same prior to initiating therapy[10]. In a study conducted by Shajahan et al., only 0.3% ADRs were "preventable", 18% were "probably preventable" and 81.7% were "not preventable". The pattern noted in the study by Raut A et al is different, with 34%, 21%, and 45% being "preventable", "probably preventable" and "unpreventable", respectively.[12] The observed differences could be attributed to differences in the types of reactions included and the attitude of health care professionals towards ADR reporting.[13]

The association between ADR management and its outcome was found to be significant

(p-value=0.049). This finding indicates that the management done for the patients presenting with ADR was satisfactory. It also shows that ADR identification in most of the cases were correct and timely management proved to be effective.

CONCLUSION

It is not always possible to preclude an ADR, but measures can be taken to decrease the occurrence of ADR and mortalities caused by adverse effects can be averted. In day to day practice, few measures can be followed to achieve the same.Attention to patient's old medical history, constitution is vital. Special care should be taken regarding the drug dose, dosage form and route of administration for extremes of age. Drugs should be prescribed after rational choice and judgement taking into consideration their pharmacokinetics, pharmacodynamics and known side-effects. Knowledge and awareness about ADE and ADR reporting should be strengthened and taken seriously. This will add up to the existing evidence regarding the safety of medical products, and in turn avoid or decrease the potential of ADRs.

Updated adverse event data should be published in indexed journals and must be easily available to clinicians, nurses, and other personnel of healthcare. Regular ADR awareness programs for the public should be organised. They must be encouraged to report any kind of suspected adverse event. ADRs pose a potential burden to healthcare costs in addition to causing patient harm, for example cancer, deformity and even death. Healthcare professionals should pay attention to the occurrence of ADEs and ADRs to minimise hazards to public health.

Further research work on ADE and ADR must be undertaken and advocated for better understanding and knowledge of these reactions. Drug-safety monitoring studies should also be done concurrently to add to the data. Patient safety and cost reduction must be our prime concern and any work towards that should be patronised and promoted.

REFERENCES:

1. Coleman JJ, Pontefract SK. Adverse drug reactions. Clin Med Lond Engl. 2016 Oct;16(5):481–5.
2. Kumar DA, Reddenna L, Basha SA. Pharmacovigilance Programme of India. Innov Pharm. 2015;6(1):13.
3. Nambiar I. Analysis of serious adverse event: Writing a narrative. Perspect Clin Res. 2018;9(2):103–6.
4. Maharshi V, Nagar P. Comparison of online reporting systems and their compatibility check with respective adverse drug reaction reporting forms. Indian J Pharmacol. 2017 Oct;49(5):374–82.
5. Kim JH, Scialli AR. Thalidomide: the tragedy of birth defects and the effective treatment of disease. Toxicol Sci Off J Soc Toxicol. 2011 Jul;122(1):1–6.
6. R J, M B. A study to analyze the pattern, causality, severity, predictability, and preventability of adverse drug reactions among patients attending department of obstetrics and gynecology at a tertiary care hospital. Natl J Physiol Pharm Pharmacol. 2018;(0):1.
7. Cassar S, Adatto I, Freeman JL, Gamse JT, Iturria I, Lawrence C, et al. Use of Zebrafish in Drug Discovery Toxicology. Chem Res Toxicol. 2020 Jan 21;33(1):95–118.

8. Wolfe D, Yazdi F, Kanji S, Burry L, Beck A, Butler C, et al. Incidence, causes, and consequences of preventable adverse drug reactions occurring in inpatients: A systematic review of systematic reviews. PLOS ONE. 2018 Oct 11;13(10):e0205426.
9. Hakkarainen KM, Andersson Sundell K, Petzold M, Hägg S. Methods for Assessing the Preventability of Adverse Drug Events: A Systematic Review. Drug Saf. 2012 Feb;35(2):105–26.
10. Surendiran A, Balamurugan N, Gunaseelan K, Akhtar S, Reddy KS, Adithan C. Adverse drug reaction profile of cisplatin-based chemotherapy regimen in a tertiary care hospital in India: An evaluative study. Indian J Pharmacol. 2010 Feb;42(1):40–3.
11. Schumock GT, Thornton JP. Focusing on the preventability of adverse drug reactions. Hosp Pharm. 1992 Jun 1;27(6):538.
12. Raut A et al. Adverse drug reactions in hospitalized patients in tertiary care setting in India. Journal of Clinical and Diagnostic Research. 2015.
13. Shajahan J, Parathoduvil AA, Purushothaman S. An analysis of seriousness, predictability and preventability of adverse drug reactions reported at a tertiary care teaching hospital in Kerala, India: a retrospective observational record based study. Int J Basic Clin Pharmacol. 2018 Nov 24;7(12):2433–8.