



Review

Forensic pharmacovigilance: Newer dimension of pharmacovigilance



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ABSTRACT

Drug safety for the patients is of paramount importance for a medical professional. Pharmacovigilance attempts to ensure the safety of patients by keeping a close vigil on the pattern of adverse events secondary to drug use. Number of medicolegal cases is at rise since last few years. Forensic sciences and pharmacovigilance need to work hand in hand to unlock the mystery of many criminal and civil proceedings. Pharmacovigilance offers its wide scope in forensic sciences by putting forward its expertise on adverse profile of drugs which may be instrumental in solving the cases and bringing the justice forth. It may range from as simple affairs as defining the adverse drug reaction on one hand to putting expert advice in critical criminal cases on the other one. Pharmacovigilance experts have to abide by the ethics of the practice while executing their duties as expert else it may tarnish the justice and loosen its dependability. As a budding discipline of science, it is confronted with several hurdles and challenges which include reluctance of medical professionals for being involved in court proceedings, extrapolations of facts and data and variations in law across the globe etc. These challenges and hurdles call the medical fraternity come forward to work towards the momentous application of pharmacovigilance in the forensic sciences. Evidence based practice e.g. testing the biological samples for the presence of drugs may prove to be pivotal in the success of this collaboration of sciences.

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1. Introduction

Pharmacovigilance has witnessed an exponential growth in last few decades owing to the increasing awareness amongst healthcare professionals. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.¹ The various components of pharmacovigilance ranging from detection to prevention of adverse drug reactions (ADR's) lay a strong foundation for the solution of medicolegal cases. A medicolegal case is where a person is injured or harmed in any way and needs medical attention for it. Medicolegal cases comprise of detection and collection of evidences in accidents, suicides and homicides. In this contemporary world of medicine, medicolegal issues are emerging out at an alarming rate.² This is worthwhile to mention that law and medical professionals need to work hand in hand for the sake of betterment and rehabilitation of the victims of medicolegal cases.³ Forensic sciences and pharmacovigilance offer collaborative services to each

other for the benefit of stakeholders. They can exchange the knowledge with each other to complement the information. This symbiotic relationship of two vital components of healthcare system gives birth to a new discipline known as "Forensic Pharmacovigilance".

2. Scope of pharmacovigilance in forensic medicine

2.1. Illicit drug use

Illicit drug use cases seek the expert opinion on drugs and their possible adverse events. The illegal drugs use is on rise since few decades. The number of intentional and unintentional deaths from prescription drugs overdose is now greater than the deaths from heroin and cocaine combined. A large part of the problem is the use of pain-killers without a prescription, or misusing a prescribed drug to get "high." Improving the way prescription painkillers are prescribed can reduce the number of people who misuse, abuse or overdose these drugs, while making sure patients have access to safe and effective treatment. In 2011, legislation to create a Prescription Drug Monitoring Program was passed in Maryland to make comprehensive information on prescribed and dispensed Controlled Dangerous Substances available to doctors, pharmacists and other healthcare providers.⁴

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2.2. Role in solving civil or criminal cases

During the criminal proceedings, involvement of drugs in a case may seek the expert advice of pharmacovigilance to solve the case.⁵ Examples of such cases include death due to overdose toxicity of drugs like sedatives being used for sleep disorders or opiates used for pain management. Under few circumstances, apart from the involvement of toxicological effects of drugs; there are certain adverse drug reactions which can be attributed responsible for occurrence of the legal case. The fact that suicidal tendencies secondary to the use of antidepressants are the known adverse effects of these drugs may be useful in mining/unleashing the cause of

death of a person treated by these drugs and who commits a suicide leaving a mystery behind.⁶

Table 1 enlists the examples of drugs and their forensic significance which illustrates the relevance of drugs' knowledge in forensic concerns.

2.3. Differentiation between adverse drug reaction and adverse event

Any untoward medical occurrence that may appear during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment is called

Table 1
Examples of drugs explain their possible ADR's of forensic significance.

S. No.	Drug	Class/Use	ADR	Forensic significance	Reference
1	Citalopram	Selective serotonin reuptake inhibitors	QTc interval prolongation	May cause adverse drug reactions of serious outcomes	7,8
2	Dextropropoxyphene	Opioid analgesic	QTc interval prolongation	May cause adverse drug reactions of serious outcomes	9–11
3	Flunitrazepam	Intermediate acting benzodiazepine	QTc interval prolongation	May cause adverse drug reactions of serious outcomes	12
4	Methadone	Opioid analgesic	QT Prolongation Respiratory depression	Respiratory arrest	13,14
5	Varenicline	Nicotinic acetylcholine receptor agonist	Manic episodes induced Suicidal Ideation	Death involving a suspicion of suicide committed by a person taking varenicline	15,16
6	Digoxin	Cardiac glycoside	Arrhythmia	ST depression, Ventricular fibrillation leading to fatal or other serious outcome	17
7	Fentanyl	Opioid analgesic	Respiratory depression	Overdose toxicity may result in death.	18
8	Heroin	Opiate	Mast cell degradation	Cardiac failure which may be an explanation of death	19,20
9	Cefuroxime	Cephalosporin	Disulfiram-like reaction	Unexpected death	21
10	Morphine	Opioid analgesic	Respiratory depression leading to death in severe cases	Intentional or accidental overdose results in death. Medication error or suicidal events should be differentiated.	22
11	Aldicarb	Acetylcholinesterase inhibitor	CNS depression	Death due to an aldicarb acute intoxication.	23,24
12	Trazodone	Antidepressant, anxiolytic, and hypnotic	Suicidal ideation	While mining the evidences in death of such cases suicidal ideation may be considered.	25,26
13	Atracurium	Nondepolarizing skeletal muscle relaxant	Hypertension and tachycardia and hypotension and bradycardia	Overdose toxicity for Suicidal intention	27
14	Cyclizine	Antihistaminic	CNS depression, hypertension	Overdose toxicity may result in death	28,29
15	Zopiclone	Nonbenzodiazepine hypnotic agent	Amnesia, palpitation, hallucination	Suicidal attempt results in fatality	30
16	Fluoxetine	Selective serotonin reuptake inhibitor	Development of akathisia related to the development of suicidal ideation.	Suicidal ideation information may be instrumental in solving mysterious death cases	31
17	Imipramine	Tricyclic antidepressant	Depresses automaticity	Complete atrio-ventricular heart block resulting in sudden death	17
18	Mephedrone	CNS stimulant	Delirium	Impaired judgement may cause accidental death	32
19	Quinidine	Anti arrhythmic	QT prolongation	Rapid ventricular arrhythmia results in death. Reason of death may be explained.	17
20	Clozapine	Atypical antidepressant	Myocarditis	Myocarditis induced death due to overdose	33,34
21	Thioridazine	Antipsychotic	Arrhythmia	Arrhythmogenic sudden cardiac death	35
22	Dextromethorphan	Antitussive	Tachycardia, hypertension, and respiratory depression	Death from respiratory failure	36
23	Acetaminophen	NSAID/Antipyretic	Hepatotoxicity	Fulminant hepatic failure	37
24	Ceftriaxone	Cephalosporin	Auto –immune hemolytic anemia	Hemolytic anemia induced cardio-respiratory arrest, Acute renal failure	38,39
25	Tetracycline	Antibiotic	Jaundice	Hepatotoxicity	40
26	Thyroxine	Congenital hypothyroidism	Progressive bradycardia	Cardiac Arrest	41
27	Azathioprine	Immunosuppressant	Bone marrow suppression, hematological toxicity, pancreatitis	Serious pancytopenia due to the accumulation of cytotoxic metabolites	42–44
28	Doxorubicin	Cytotoxic	Cardiotoxicity	Cardiomyopathy or cardiac failure	45,46
29	Rifampicin/Isoniazide/Ethambutol/Pyrazinamide	Antitubercular FDC	Hepatotoxicity	Acute liver failure due to hepatic encephalopathy	47
30	Enalapril	ACE inhibitor	Hepatotoxicity	Hepatic failure	41
31	Propofol	Anaesthetic	Pulmonary oedema and haemorrhagic pancreatitis, respiratory depression, bronchospasm and chest wall rigidity	Death occurred due to pulmonary oedema as patient did not receive ventilation	48

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