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## Case Series

## Indian forensic pharmacovigilance: status quo

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## ABSTRACT

To give the judicial system relevant information, forensic science collects, examines, and applies scientific data. Pharmacy fills a forensic niche. The majority of pharmacists moonlight or work in forensics part-time in their day jobs. A person with expertise in pharmacology has professional knowledge and practical experience in the fields of therapeutics, pharmacokinetics, and toxicology in addition to having been exposed to areas like forensic medicine during medical school. All of these knowledge areas can be used in forensic scenarios and serve as an interface. A forensic pharmacologist's training and experience can be beneficial in a wide range of legal issues. The development and integration of forensic pharmacologists in the Indian legal system are urgently required due to the country's rising frequency of criminal and civil cases. A substantial technological improvement in pharmacology research has allowed it to broaden its use beyond the field of medicines, allowing Indian pharmacologists to study the specialized field of forensic pharmacology.

The many facets of forensic pharmacology include the different pharmacokinetics and pharmacodynamics of drugs in living and dead people, drug interactions, drug abuse, personal injury or death brought on by drug exposure resulting in medico-legal issues, environmental chemical exposure, doping, and forensic pharmacovigilance.<sup>1</sup> Forensic pharmacologists have shown to be invaluable assets in a variety of criminal and civil cases across various nations. They use their pharmacological expertise in civil and legal matters, such as settling disputes, the drug approval process, and the criminal justice system.<sup>2</sup> The role of thorough investigation in determining the cause of death in crime scenes with positive drug screens has been demonstrated via several research papers and case studies.<sup>3</sup> Even the general public is aware of the importance of forensic sciences in the legal system of justice.

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## 1. Introduction

The names "forensic science" and "science" are a combination of two Latin words. The term "forensic" refers to the use of scientific techniques in the investigation of criminal cases that call for a significant court impact, while the term "science" describes a precise method of learning new things.<sup>4</sup> On its whole, forensic science involves the use of technical investigative techniques as well as the practice of gathering, safeguarding, and

examining scientific evidence following ethical standards.<sup>5</sup> The pharmacological science concerned with the gathering, detection, assessment, monitoring, and avoidance of pharmaceutical adverse effects with goods is known as pharmacovigilance, commonly referred to as drug safety. A subfield of pharmacovigilance called forensic pharmacovigilance employs professional knowledge of harmful pharmacological effects associated with illegal substances to answer legal queries or uncover criminal activity. An example of a well-known adverse drug response is bladder cancer, which can develop after long-term usage

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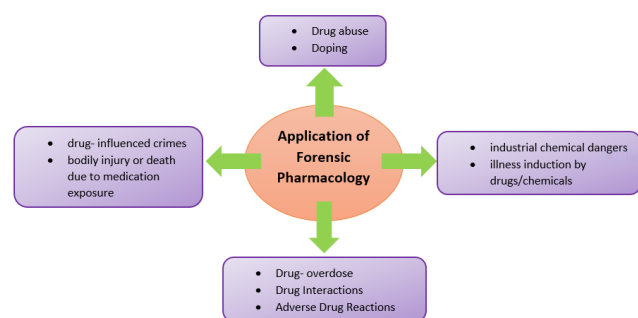
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of the anti-diabetic medication pioglitazone. Following this reported reaction, the medication was outlawed in India. It is distinct from pharmacovigilance since it calls for medical and legal ramifications. Hence, Toxicology, pharmacology, and forensic medicine all come together in forensic pharmacovigilance.<sup>6</sup>

## 2. The State of Forensic Medicine and Pharmacology in India

Clinical forensic medicine with particular medico-legal training is neither well-developed nor well-executed in India, according to experts. Some cities, such as Mumbai, have police surgeon who works both forensically and therapeutically. This, however, falls short of delivering a proper medico-legal examination, precise analysis, and suitable documentation.<sup>7</sup> While forensic medical procedures are widely used in places such as Latin America, Australia, Europe, and many Asian countries, India lags.<sup>8,9</sup>

There is no clear distinction between the specialty's or subspecialty's knowledge, expertise, and hence work.<sup>7</sup> Forensic Pharmacology is at the crossroads of forensic medicine, toxicology, and pharmacology. Figure 1 summarises its broad extent. Despite its importance, it is frequently overlooked by the pharmacologist community in India and is not widely acknowledged or developed in our nation. It is critical to share full information about the use or misuse of drugs/chemicals, as well as their medico-legal repercussions. Several teaching institutions and universities across the world have specialized "Centers for Forensic Pharmacology," such as the American Institute of Pharmaceutical Sciences, which has a dedicated "Center for Forensic Pharmacology."<sup>9</sup> Forensic Pharmacology courses are also available at South Dakota State University and the City University of New York. In India, adding Forensic Pharmacology as a specialization or focusing on the legal issues of drugs while studying pharmacology will undoubtedly benefit medical students.



**Fig. 1:** Application of forensic pharmacology

Currently, a medical student pursuing an MBBS degree in India studies a variety of courses. These include pharmacology, which studies diverse substances and their

therapeutic effects and applications, and forensic medicine, which studies the legal implications of conduct, damage, and sickness. As part of internal medicine, the student also learns about the clinical implications of medications. There is, however, no integrated program that specializes in Forensic Pharmacology as a specialty in today's world, Forensic Pharmacology must be created as a specialism to pave the path for high-quality, fast-paced medico-legal services in India. A deficit that must be identified and corrected in India is the lack of proper specialization in Forensic Pharmacology.<sup>7</sup>

To effectively document and analyse the victim's drug or chemical-related injuries and body fluid samples, an advanced system of Forensic Pharmacology is required. It has the potential to reduce common forensic errors that occur in emergency rooms and hospitals. Errors in recognising, collecting, or maintaining evidence material,<sup>8–10</sup> inaccurate interpretations, and a lack of knowledge of policing or investigation processes can all be remedied with specialist personnel.<sup>10,11</sup>

## 3. Need for Forensic Pharmacovigilance

Both law and medicine require making important judgments that have long-term repercussions based on information that is inconsistent and frequently insufficient. The scientific disciplines that support the observations provided by both professionals and laypeople are represented in the evidence used in court. There are several ways that pharmacovigilance as a medical field is applied in forensic situations. The major questions addressed are: Could this medicine (or chemical) have caused this person's (these people's) negative consequence, and did it do so "beyond all reasonable doubt"? The pharmacovigilance expert must assist the court in comprehending the many types of scientific evidence that are available and inform the court of the relative importance of each type of evidence. The pharmacovigilance expert must also take into account the evidentiary standard that the Court will use and be ready to assist the Court in connecting the case's evidence—which has varying degrees of probative weight—to the standard that the Court will use. The majority of scientists and medical professionals run into trouble at this stage because the court must assess the evidence not only in light of the evidence itself but also in light of the function it serves and the relative positions of the parties involved in the dispute. A significant problem is to provide the court with a clear, objective distillation of all the facts accessible to the pharmacovigilance expert. The next challenge for the pharmacovigilance expert is frequently to remark on numerous professional behaviours, including what the state of knowledge was, when it should have been applied, and how it should have been applied in the prevention and management of damage.<sup>12</sup>

#### 4. Medication Error and Medical Negligence

The department of pharmacovigilance is crucial in resolving incidents of pharmaceutical mistakes or medical malpractice. Following are a few cases of drug errors that were presented as examples:

##### 5. Case 1

According to the WHO, many occurrences include pharmaceutical errors or medical malpractice. One instance of the case is described as follows: A 10-year-old British leukaemia youngster who required a chemotherapy injection. The youngster died as a result of receiving the incorrect injection. The youngster consumed food that was forbidden before the surgery; as a result, he was taken by a different department than the cancer specialists hours later. He received the incorrect treatment that day owing to a mix-up, and he passed away five days later. The shots were administered in a certain order. The committee cleared the doctor because it determined that the boy's death was caused by a combination of other variables, including the when, where, and how.<sup>13</sup>

##### 6. Case 2

In July 1999, an anaesthetist who had provided anaesthesia in a dentist's office to a 14-year-old child with Goldenhar's syndrome was found guilty of manslaughter and given a six-month jail term. Because the tube was linked incorrectly, the youngster was surgically given nitrous gas instead of oxygen, and the doctor confessed to neglecting to check the equipment. Goldenhar's syndrome-related anomalies, such as mandibular and maxillary hypoplasia and tongue deformity, rendered resuscitation more challenging, but neither the anaesthetist nor the dentist had gotten the patient's medical history. "This offence was one of the most severe carelessness," the court said.

##### 7. Case 3

A deputizing general practitioner treated a 41-year-old lady with a severe migraine and gave her prochlorperazine and diazepam. She stopped vomiting, but these medications did not make her feel any better. The general practitioner went to get an injection of pethidine from a nearby drugstore after his wife's spouse, a consultant surgeon, advised it. The doctor grabbed a 100 mg diamorphine ampoule because the pharmacy did not have any pethidine and gave the entire amount intramuscularly. For pethidine, the dosage was appropriate, but for diamorphine, it was ten times excessive. After falling asleep, the woman passed away one hour later. Because "administering that amount of medicine amounted to gross carelessness," the doctor was charged with manslaughter. He was found guilty and given a sentence of 12 months imprisonment, suspended for two

years.

##### 8. Case 4

When a 30-year-old lady with asthma started having palpitations, she went to visit her doctor. He recommended an antagonist of the adrenoceptor. A few hours after taking the first medication, she passed away. The general practitioner then attempted to remove any references to asthma from the patient's records and the office computer, but they were unable to since the computer's memory still had evidence. The doctor was accused of manslaughter and attempting to tamper with the legal system. He was found not guilty on the first charge but found guilty on the second one.<sup>14</sup>

##### 9. Case 5

A specialist registrar in pediatric hematology had ordered intrathecal methotrexate and intravenous vincristine for a 12-year-old kid with T-cell non-lymphoma. Hodgkin's youngster was admitted to a regular pediatric unit because the pediatric cancer department was overcrowded. He was supposed to have a lumbar puncture while under anesthesia throughout the day, but because he ate a biscuit, the procedure had to be moved until the evening. A pediatric anesthesia specialist was then brought in to do the surgery. Although the registrar had never administered intrathecal cytotoxic therapy previously, he had spoken with his hematological colleague about it over the phone. Unaware of the hospital policy that said vincristine should never be brought into the operating room, a nurse gave the anesthetist two syringes, one of which contained vincristine and was marked "only for IV use." Because the anesthetist did not read the label, vincristine was given intrathecally. Only two days after the incident, the youngster started to experience growing amounts of discomfort from arachnoiditis, and he eventually passed away. Both registrars were committed for trial on a manslaughter allegation after the prosecution's expert first claimed that the physicians' actions had "seriously and considerably" fallen below the expected level. The expert realized that "major system failings inside the hospital administration" were crucial factors in the boy's death, but the crown provided no proof, and this was before the case went to trial in the crown court. The physicians were exonerated.

##### 10. Case 6

Srinivasa Raghavan et al. reported a medical negligence case report, which is given as "At 10:50 PM, a 49-year-old patient was taken to the casualty and admitted to the ward with an alleged history of a road traffic collision. According to the medical record, there was no clinical indication of pelvic, long bone, or spinal bone damage. A neurosurgeon's opinion was solicited, and a CT brain

scan was recommended. The patient had not been relocated for the CT brain study as he became hemodynamically unstable, with progressive drops in blood pressure (80/60) and tachycardia (120/min). The dopamine drip and IV fluids began. Later, about 11:50 p.m., the patient went into cardiac and respiratory arrest and had to be revived. He was placed on mechanical ventilation. The patient experienced a second episode of cardiopulmonary arrest. Death had been pronounced. "Severe brain damage as a result of a road traffic accident," according to the clinical cause of death. Because it was a medico-legal matter, the body was sent for an autopsy to determine the cause of death. On the morning of April 21, 2011, an autopsy was performed on the deceased's corpse. The death was caused by cardiopulmonary arrest, according to the postmortem report.<sup>15</sup>

### 11. Is it Beneficial to Prosecute Doctors?

Doctors who are wicked or who abuse alcohol or drugs and murder people as a result should face criminal charges. However, the criminal law is inadequate for the majority of mistakes. Convicting physicians for manslaughter may fulfil a need for vengeance, but it discourages thorough examination of methods to avoid catastrophes from occurring. Police inquiry has three advantages: it is professional, unbiased, and taken seriously. An independent investigative body, perhaps affiliated with the Commission for Health Improvement, that can investigate fatal medical errors and make its findings public would have those benefits, as well as the ability to examine issues of system failure and make informed recommendations on prevention strategies. It would augment the work of coroners, who would be in a good position to recommend cases to it.

The expert group of the Department of Health recommends a unified mechanism for reporting and analysing errors in medical care, a "more open culture in which errors or service failures can be reported and discussed," and a "much wider appreciation of the value of the systems approach in preventing, analysing, and learning from errors." This is entirely reasonable, but we also need an independent investigative body whose mission is to protect patients and which can marshal the resources. Patients and physicians would be safer if an impartial investigation were ensured, and criminal prosecution should be reserved for doctors who demonstrate "such contempt for life and safety as to amount to a crime against the state."

### 12. Future Challenges

The legal profession is accessible to everyone and has a solid foundation of well-defined regulations, whereas the medical profession is private to the general public and depends on the specialists' subjective judgement. For the forensic pharmacovigilance programme to be

successful, both areas must collaborate.<sup>5</sup> However, there are several difficulties as pharmacovigilance advances its use in forensic sciences, including:

1. Globalization and the rise in drug use
2. An exponential increase in the volume of drugs used
3. Polypharmacy

These issues make pharmacovigilance complicated. Given these difficulties, pharmacovigilance should now be considered as more than just disclosing hazards; rather, it should be a rigorous risk-benefit analysis. To provide a precise link between the drug concentration in the body and the corresponding postmortem report, forensic pharmacologists are accountable. Once more, the specialist is unrestricted in providing an objective evaluation. The European Medicine Agency (EMA) published good pharmacovigilance practises (GVP) guidelines in 2012 to establish the industry's benchmarks for excellence.<sup>16</sup> (Guideline GVP) When establishing pharmacovigilance in forensic domains, it is imperative to abide by these rules. So it is important to create a code of ethics for these specialists to maintain the gold standard for ethics in forensic sciences.<sup>17</sup>

### 13. Conclusion

It is challenging for a judicial to provide a radical explanation when there is no way to validate the relationship between the usage of a drug and a particular connected outcome. A forensic pharmacologist can be helpful in these situations by using his or her understanding of drug-related issues and pharmacology to provide pertinent results and data that will help the judicial system make the best judgement possible. Forensic pharmacology has to be developed as a specialisation in Indian medical education. Due to the rise in medicolegal cases, there is a critical need for drug experts to contribute to the resolution of criminal and civil cases that involve drugs at some point. By distinguishing between major and less serious responses, pharmacovigilance can meet the demands of the legal framework to mine the instances involving medications. It may also prove the causal link between the drug and the adverse event.

A newer branch of science known as forensic pharmacovigilance, which offers a wide range of scope and application and necessitates a cautious execution of this exercise lest it deviates from the intended use, was born as a result of the expanding role of pharmacovigilance that has now spread over the field of legal medicine. Expertise in medicines is needed since medico-legal problems are always on the rise. The expert must be able to distinguish between serious and less serious adverse drug reactions to establish a causal link between the drug and the adverse event. They should also be able to resolve criminal and civil cases at various stages, understand pharmacokinetics and

pharmacodynamics of drugs, etc. and generate information that will enable the judicial system to draw conclusions and come to the best choice. As a result, the development of a distinct subfield of forensic pharmacovigilance is essential for Indian medical education.

#### 14. Source of Funding

None.


#### 15. Conflict of Interest

None.

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