INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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**Review Article**

# Addiction-Induced Epigenetic Alteration A Pharmacovigilance: Abuse and Misuse of Pharmaceutical Drug

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ARTICLE INFO

Published: 13 Feb. 2025
Keywords:
Drug Abuse, Drug misuse, Technique for detection, Impact on public health, Future Challenges, Treatment.
DOI:
10.5281/zenodo.14863117

## ABSTRACT

Pharmacovigilance is a critical discipline aimed at identifying, evaluating, and preventing adverse drug reactions (ADRs) and drug-related issues, pharmaceutical products can be made safer and more effective. Pharmacovigilance, focusing on its objectives, methodologies, and the vital roles played by various stakeholders, including expert teams, medical representatives, drug safety associates, and medical advisers. It emphasizes the importance of effective communication in enhancing patient safety and care, while also addressing the growing concern of drug abuse and misuse, which has necessitated an expansion of pharmacovigilance efforts. The drug misuse on public health, highlighting its impact on youth, families, mental health, and societal issues, as well as the biological and psychological factors contributing to substance abuse. Furthermore, it explores advanced data analysis techniques in pharmacovigilance for detecting patterns of misuse, and the importance of education and community involvement in addressing drug-related challenges. The findings underscore the need for a collaborative approach among healthcare professionals and regulatory bodies to safeguard public health and promote rational medication use.

## INTRODUCTION

Pharmacovigilance has broadened its focus to include the identification of drug abuse and misuse, which have become increasingly pressing global issues. Advanced data analysis methods, robust monitoring systems, and cooperation between regulatory agencies and medical experts are necessary for effective pharmacovigilance. Pharmacovigilance have a role in detecting prescription drug diversion, identifying cases of misuse, and preventing the negative consequences of drug abuse. Social, psychological, and biological factors contribute to substance abuse, including peer pressure, psychological factors, and genetic predisposition. Drug abuse and misuse have a significant impact on public health,

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**Relevant conflicts of interest/financial disclosures**: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

affecting academic performance, education, and future prospects, particularly among the younger population. Comprehensive drug abuse education in various settings, such as educational institutions, homes, and workplaces, is essential in combating this public health issue.

**Pharmacovigilance:**

"The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem" is how the World Health Organisation (WHO) defines pharmacovigilance. [1]

**Scope:**


**Fig no 1: Scope of Pharmacovigilance**

**Objective:**

- Encouraging the safe, efficient, and logical use of pharmaceuticals.
- Promoting knowledge among patients and the general populace about the sensible application of medications via effective communication methods.
- Improving patient safety and care in the context of medication use.
- Acknowledging the dangers associated with medication use.
- Involvement in the comparative analysis of the advantageous and detrimental effects of pharmaceuticals aimed at enhancing their effective use.
- Identifying and documenting potential adverse drug reactions (ADRs) is essential for patient safety.
    - Contribute to assessing the quality of drug benefits, risks, effectiveness, and drug hazards.
    - Encourage the safe, rational, and more cost-effective use of medication. [2]

**Branches & Regulatory:**

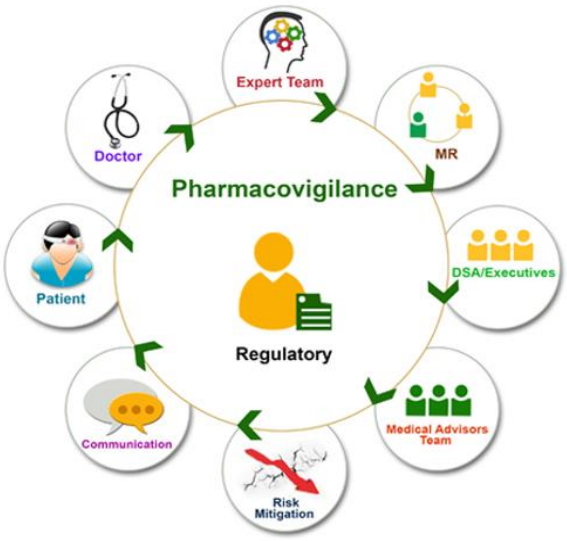


**Fig no 2: Branches and Regulatory of Pharmacovigilance regulatory**

**1. Expert team:**

The expert team specializes in managing pharmacovigilance regulations and provides information on detecting, assessing, and evaluating adverse drug effects. Thorough drug testing is conducted to identify and gain a better understanding of the risks associated with the drug being studied. The presence of the risk of negative side effects is always considered during the drug development stage.

**2. MR (Medical Representative):**

It works for a pharmaceutical company and ensure that healthcare professionals are informed about new medical products. Medical representatives (MR) play a crucial role in pharmacovigilance by keeping doctors and healthcare professionals updated on new medical products. It's essential to stay current with the latest innovations in the healthcare sector.

**3. DSA (Drug Safety Associate):**

This aspect is vital to the pharmaceutical industry and clinical research organizations. Drug Safety Associates (DSAs) are engaged in the oversight and documentation of adverse drug reactions (ADR), ensuring that regulatory standards are met, and promoting the safe use of pharmaceutical products

**4. Medical Adviser Team:**

They offer insights about the medication and the sector to healthcare professionals while also relaying clinician feedback back to the industry.

**5. Risk mitigation:**

Pharmacovigilance includes the process of detecting, evaluating, and minimizing the risks associated with pharmaceutical products during their entire lifecycle. Examples of measures to mitigate risks include:

•Altering the labeling or packaging of the drug

•Offering extra training or information to healthcare providers

•Creating a risk management strategy

•Employing signal detection to pinpoint possible safety concerns

**6. Communication:**

Effective communication is essential in pharmacovigilance to guarantee the safety of medications and vaccines while enhancing public health.

• Increase awareness
• Enhance patient care
• Foster transparency
• Ensure proper action
• Deliver information to regulators
• Train healthcare professionals

**7. Patient:**

Patients possess direct experience with the advantages and drawbacks of a medication or device and can communicate adverse drug reactions (ADRs) more promptly than healthcare providers can. Patient reports can assist in:

• Enhancing the identification of ADR signals
• Discovering ADRs in particular populations or types of medications

• Advocating for patient rights and their participation in healthcare management

**8. Doctor:**

Evaluating safety information remains essential even after clinical research has concluded. They offer assistance, direction, and reassurance to patients and their families, aiding them in managing difficult medical circumstances.[19]

**Abuse and Misuse of Pharmaceutical Drug:**

The discipline of pharmacovigilance, which centers on the ongoing assessment and monitoring of the safety and effectiveness of medications, is crucial for the protection of public health. Historically centered on identifying Adverse Drug Reactions (ADRs), pharmacovigilance has broadened its scope to include the identification of drug abuse and misuse, which have become increasingly pressing global issues. This article underscores the importance of pharmacovigilance in recognizing drug abuse, highlighting the necessity of strong surveillance systems, advanced data analysis methods, and collaborative efforts among healthcare professionals and regulatory bodies. By adopting an integrated approach, pharmacovigilance can play a crucial role in pinpointing and tackling drug abuse challenges, thereby promoting safer medication practices. For many years, pharmacovigilance has been essential in maintaining the safety of pharmaceutical products. Beyond its original focus on detecting adverse events, it has progressed to include uncovering new trends in drug abuse. The abuse of both legal and illegal substances presents significant dangers to both individuals and society. The inappropriate utilization of prescribed drugs, over-the-counter products, and illegal narcotics has prompted the need for pharmacovigilance to broaden its scope and actively confront this significant public health challenge. Healthcare professionals must recognize potential prescription drug diversion, identify cases of misuse, contemplate the possibility of polydrug misuse, and strive to prevent it when possible. The role of pharmacists is vital in addressing and reducing drug abuse, necessitating their involvement in evidence-based methods to recognize, analyze, and prevent practices of drug diversion, along with the harmful consequences of drug misuse.

**Effect of drug Misuse and Abuse:**

Dugs are defined as compounds that exert an impact on both the physical and mental states of individuals. Various classifications of drugs elicit distinct effects. It is important to recognize that some outcomes associated with drug use can lead to enduring and irreversible health problems, which may persist long after the cessation of drug intake. . There are several methods through which a person can consume drugs, including injection, inhalation, and ingestion. Each method has distinct physical impacts on the body. For instance, injecting drugs into the bloodstream results in immediate effects, whereas ingestion leads to delayed outcomes. Regardless of the method, all abused drugs impact the brain. These substances provoke an increase in dopamine levels, a neurotransmitter integral to the management of emotions, motivation, and pleasure, thus generating a euphoric sensation. With continued use, drugs can alter the functioning of the brain and hinder decision-making capabilities, resulting in powerful cravings and compulsive actions, which can ultimately result in addiction. Currently, over 7 million individuals are affected by disorders related to illicit drug use, with one in four fatalities linked to such drug consumption. The prevalence of deaths, diseases, and disabilities attributable to substance use disorders surpasses that of any other preventable health issue. Additionally, those who are dependent on drugs and alcohol are more likely to experience accidental injuries, various mishaps, and incidents of domestic violence.[7]

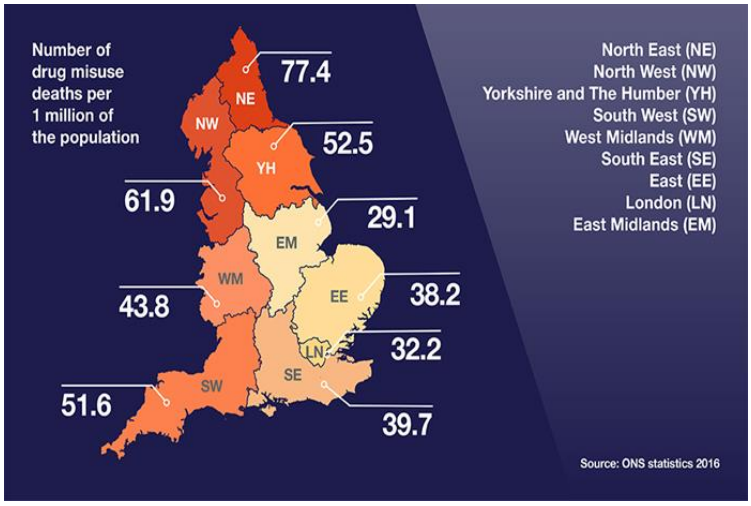


**Fig No 3: Drug Misuse Rate Ratio**


**Fig No 4: Global Drug Abuse Treatment Market**

**Abuse:** The term substance abuse, often synonymous with drug abuse, describes the practice of using certain chemicals to induce pleasurable experiences in the brain.[3]

**Misuse:** The term drug misuse is characterized by the consumption of a substance in ways that are inconsistent with legal or medical protocols (WHO 2006). Such misuse can lead to detrimental effects on health and functioning, and may present as drug dependence or as an element of a larger spectrum of harmful or problematic behaviors.[4]

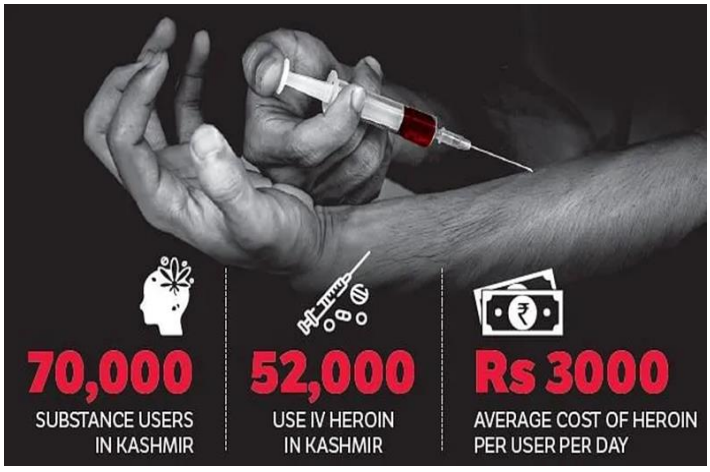


**Fig No 5: Misuse of drug**

**Sign and symptoms of Drug Abuse and Misuse**
**[20]**

| Drug Name | Sign & Symptoms | Adverse drug reaction |
|---|---|---|
| **Opioids** | • Constipation<br>• Nausea<br>• Feeling high<br>• Slowed breathing rate<br>• Drowsiness<br>• Confusion<br>• Poor coordination<br>• Increased dose needed for pain relief | • Nausea<br>• Constipation<br>• dependence<br>• respiratory depression<br>• dependence |
| **Anti-anxiety medicines and sedatives** | • Drowsiness<br>• Confusion<br>• Unsteady walking<br>• Slurred speech<br>• Poor concentration<br>• Dizziness<br>• Problems with memory<br>• Slowed breathing | • Rashes and other skin reactions<br>• Bradycardia (slow heart rate) after a person stops taking the drug<br>• Increased risk of anaesthesia complications<br>• Low blood pressure<br>• Gastrointestinal problems, such as diarrhoea and nausea |
| **Stimulants** | • Increased alertness<br>• Feeling high<br>• Irregular heartbeat<br>• High blood pressure<br>• High body temperature<br>• Reduced appetite<br>• Insomnia<br>• Agitation<br>• Anxiety | • Decreased appetite<br>• Anxiety<br>• Headaches<br>• Weight loss<br>• Insomnia<br>• Psychosis<br>• Pruritus<br>• Paranoia<br>• Sweating<br>• Palpitations<br>• Shortness of breath<br>• Chest pain<br>• Hypertension<br>• Tachycardia<br>• Seizures |

**Causes of Substances Abuse**

**1. Social factors:**

The engagement with and potential abuse of drugs presents various social and ethical issues. These concerns are particularly nuanced, reflecting the complexities of drug use within contemporary societal frameworks. Values can be shaped by various influences, including social, religious, and individual perspectives. Within a single community, differing values can lead to conflicts regarding numerous matters related to drug abuse and misuse. Since the 1960s, the topic of drug abuse has gained significant attention in public discourse. This increased awareness of drugs and their effects has largely stemmed from initiatives and campaigns aimed at educating the community

about the risks associated with drug abuse and misuse.

- Peer pressure (One of the primary causes)
- Role modelling/imitation
- Easy accessibility
- Conflicts (often within families)
- Cultural/Religious influences
- Absence of social or familial support
- Societal attitudes
- Celebratory events
- Rapid urban development

**2. Psychological Factors:**

Psychological methods for treating drug misuse have been extensively studied and debated throughout the years. These methods differ according to the theoretical frameworks that support them but generally rely on the dynamic between the therapist and the client to inspire changes in the client's behaviour, such as engagement in substance use, together with relevant dimensions including cognitive abilities and emotional experiences. Psychological strategies are employed to assist individuals with substance issues in their attempts to modify their drug-using behaviours. The past few years have witnessed a growing emphasis on the formulation and assessment of psychological interventions for the treatment of drug misuse. This includes a range of methodologies such as cognitive-behavioural therapy (CBT), motivational strategies, contingency management techniques, and treatments that involve family participation.

•Interest
•As a new experience
•Social defiance (nonconformity)
•Beginning use early
•Poor self-regulation
•Sensation-seeking (pursuit of euphoria)
•Low self-worth (anomie)
•Inadequate stress coping
•Experiencing childhood loss or trauma
•As an escape from exhaustion or monotony
•To flee from reality
•Lack of interest in traditional goals.
•Psychological suffering

**3. Biological Factors:**

The biological factors primarily influence drug abuse and misuse; for instance, an individual with a family history may experience genetic diseases or disorders. Many genetic disorders are inherited from earlier generations and passed down to subsequent ones. Some individuals may have a sensitivity to certain medications that can lead to medical issues.

- Family background, genetic tendencies
- Existing psychiatric or personality disorders, or other medical conditions
- The reinforcing impacts of substances
- Withdrawal symptoms and cravings
- Biochemical factors:

Various determinants contribute to an individual's propensity for substance use and the development of related disorders. These determinants include genetic factors and biological characteristics, the onset age of substance use, psychological influences derived from personal experiences and individual temperament, and environmental conditions. The latter includes the accessibility of drugs, dynamics within family and peer groups, financial circumstances, cultural influences, exposure to stressors, and the availability of social support. While some of these determinants may elevate the risk of substance use and its associated disorders, others may act as mitigating factors that reduce such risks.

**Technique for detection of Drug Misuse and Abuse:**

**1.Data analysis techniques:**

The application of advanced data analysis techniques is essential for obtaining valuable insights from pharmacovigilance information. Methods including signal detection algorithms, disproportionality assessments, and Bayesian data

mining are used to reveal associations between drugs and possible cases of abuse. Network analysis aids in visualizing intricate relationships among drugs, users, and adverse events, revealing concealed patterns of misuse.

**2.Pharmacovigilance in detecting drug abuse and misuse:**

The function of pharmacovigilance in recognizing patterns of drug abuse goes further than just addressing urgent public health issues. By spotting possible indicators of drug misuse, pharmacovigilance can aid in stopping prescription medications from being diverted into illegal markets. Additionally, regulatory bodies can act quickly to limit access to high-risk drugs, thereby safeguarding both individuals and communities.[10][11]

**Impact of Drug misuse and abuse on Public Health**

Declining academic performance, increased absenteeism from school or college, and a higher likelihood of dropping out are issues linked to substance abuse among youth. A significant portion of the younger population struggles with drug addiction and misuse, which adversely affects their education and future prospects while exacerbating various problems. Education serves as a key method for combating drug abuse. Beyond educational institutions, other environments play crucial roles in facilitating learning and social development. Homes, workplaces, and religious organizations, for instance, contribute significantly to the education of both young and older individuals. A significant number of officials support the extensive inclusion of drug abuse education in both public and private sectors, whether they are religious or secular. The application of a cost-effectiveness analysis is instrumental in identifying the most effective strategies to combat drug abuse. Regrettably, there is often insufficient data available regarding the financial implications and outcomes of different educational interventions for drug abuse. In the absence of such data, alternative educational approaches may be examined based on their costs and other relevant factors to determine their viability for program implementation. [12]

- **Health and Safety**

Psychoactive substances impact the central nervous system and influence an individual's emotions, thoughts, and actions. They work by directly interacting with the brain or the central nervous system (CNS), resulting in a range of complications along with health and behavioral issues. Substance abuse among adolescents can lead to a range of health-related issues, including injuries from accidents, such as automobile accidents, the emergence of physical disabilities and illnesses, and the serious risks associated with overdosing.[15]

- **Mental health**

Issues related to mental health, including depression, developmental delays, apathy, social withdrawal, and various psychosocial challenges, are often associated with substance abuse in young people. Adolescents who engage in substance abuse face a greater likelihood of experiencing mental health issues compared to their non-using peers, such as depression, behavioral problems, personality disorders, suicidal thoughts, attempts at suicide, and completed suicide.

- **Families**

In addition to individual challenges, young people's abuse of alcohol and drugs can lead to family crises and threaten various facets of family life, sometimes causing dysfunction within the family. Rapid changes in society, economy, and technology can, in certain situations, diminish familial bonds and lessen the feeling of connection to others, groups, and locations. The stability of relationships, environmental contexts, and expectations is vital for individuals as they navigate their lives, particularly for children and young adults. Extensive research has explored the

relationship between substance abuse, including alcohol misuse, and mental health issues within families. It is well recognized that individuals with family members who struggle with alcoholism are at an increased risk of facing similar challenges. Additionally, families with a history of psychological and social problems may be more susceptible to developing alcohol-related issues. The degree to which these factors affect the use of other substances is not as well understood. Those who are heavy users of alcohol or other drugs may also experience psychiatric symptoms, such as depression.[14]

- **Work place and Employment**

In terms of employment, numerous substance users often missed work, regularly borrowed money from friends and colleagues, displayed low productivity, and encountered a lack of respect from both employers and peers. Many received warnings from their employers regarding their dangerous drinking habits, which led to frequent conflicts with both employers and coworkers, thus undermining their self-worth. [5] It is reported that "approximately 30 percent of the global workforce is not effectively engaged in work. Over 120 million individuals are officially unemployed, while around 700 million are underemployed" Additionally, the gap in income levels between affluent and impoverished nations continues to widen; even though some countries have seen a reduction in poverty rates, the distribution of income has not significantly improved. Younger individuals demonstrate a greater prevalence of substance abuse compared to their older counterparts. The risk factors that contribute to drug use often develop prior to individuals' entry into the labour market. As a result, the substance abuse problems that exist within communities are often reflected in workplace settings. The demographic most affected by drug use typically ranges from 18 to 35 years, although there are notable disparities across different countries.[12]

- **Crime:**

Drugs and crime can be connected in a number of ways, none of which are straightforward. First of all, it may be illegal to produce, manufaur e, distribute, or possess drugs.Second, drugs may make other, nondrugrelated crimes more likely to occur.Thirdly, using drugs to generate income mi ght lead to money laundering.Fourth, there may b e a strong connection betweendrugs and other seri ous issues including terrorism, illegal gun owners hip, and various sorts of violence.Drug misuse, cr iminal behavior, and societal attitudes have all be en discovered to be closely related by researchers. An analysis of existing research on crime and drug use supports three primary conclusions: daily use of opiates correlates with a marked increase in criminal activity; heroin-dependent individuals frequently participate in criminal conduct; and a considerable proportion of those abusing heroin exhibit a lack of interest in obtaining treatment, notwithstanding the fact that drug treatment initiatives have been shown to diminish criminality among participants while they are undergoing therapy. [13]

**Drug misuse and abuse on unborn babies:**

1. **Prescription Drugs**
   When opioids and other narcotics are taken during pregnancy, the infant may have severe withdrawal symptoms. [16]
2. **Alcohol**
   Pregnancy-related alcohol consumption can result in lasting behavioural and physical issues, heart abnormalities, mental retardation, and physical deformities. There is no safe limit on how much alcohol a pregnant woman may consume. [17]
3. **Smoking**

Smoking cigarettes exposes your unborn child to nicotine and other harmful substances. Additionally, smoking raises the chance of a stillbirth or early delivery. [8]

4. **Other drugs:**

Engaging in drug use while pregnant significantly elevates the likelihood of several adverse outcomes, including sudden infant death syndrome (SIDS), impaired fatal development, cognitive and behavioural disorders, miscarriage, premature labour, birth defects, stillbirth, and withdrawal symptoms in infants.

**Addiction-induced epigenetic alteration**

Epigenetic effects are known to be induced by addiction or repetitive exposure to different psychoactive medications. At the epigenetic level, addictive chemicals affect many genes directly or indirectly, causing changes in expression that lead to addiction phenotypes.

The development, health, and disease outcomes of offspring are shaped by various environmental factors, including nutrition, stress levels, exposure to diverse chemicals, and the health status of the parents.[6]

**Epidrugs in addiction treatment**

Today, there are several ways to prevent and lessen the effects of epidrugs, including medicine, psychotherapy, behavioural therapies, exercise, yoga, and dietary supplements. Buprenorphine, methadone, extended-release naltrexone, and lofexidine are common drugs used to treat opioid addiction. Nicotine addiction is treated with bupropion, varenicline, and nicotine replacement therapy. Acamprosate, naltrexone, and disulfiram are used to treat alcohol addiction.

**FDA approved epidrugs and their characteristics [6]**

| Epidrug Type | FDA Approved Epidrug | Disease Approved | Characteristics |
|---|---|---|---|
| DNA Methyltransferases inhibitors (DNMTI) | Decitabine | Myelodysplastic syndrome | Anti-cancer, anti-metabolite drug |
| | Procainamide | Ventricular arrhythmias | Inhibits DNMT1 activity |
| | Hydralazine | Hypertension | Antihypertensive, inhibits DNMT1 activity, adverse immune reactions observed |
| Histone methyltransferase inhibitors | Phenelzine | Depression | Irreversibly inhibits monoamine oxidase. |
| Histone Deacetylase inhibitor (HDACI) | Nicotinamide | Pellagra, As food additives. | Inhibits protein non-competitively, inhibits deacetylation action of sirtuins through reaction with an intermediate |
| | Valproic acid | Neurologic disorders, Antidepressive | Anti-epileptic, anticancer, chemosensitizer, inhibit sodium channels, increases GABA availability in synapse |
| | Carbamazepine | Epilepsy, trigeminal neuralgia | Anti-epileptic, inhibits HDAC3 and HDAC7 |
| Protein arginine deiminase inhibitor (PADI) | streptomycin and methotrexate | Rheumatoid arthritis | inhibition of the binding of interleukin |

| | | | |
|---|---|---|---|
| | | | 1-beta to its cell surface receptor |

**Treatment of Drug Abuse and Drug Misuse:**

Approaches to the clinical management of drug misuse can be divided into three main categories: harm reduction strategies, maintenance-oriented therapies, and abstinence-focused treatments. The overarching goal of these interventions is to prevent or lessen the negative consequences of drug use. Integral to the treatment process are care planning and the role of key workers in facilitating ongoing support.

**1.Harm reduction:**

The primary goal is to prevent or lessen the harmful health outcomes and other societal consequences associated with drug misuse, affecting both the individual user and the broader community. In this framework, a decrease in drug use is not necessarily required, although it can be one of the strategies employed to achieve harm reduction. An illustrative case is the implementation of needle and syringe exchange initiatives, which seek to minimize the spread of blood-borne viruses by promoting safer injecting practices.

**2. Maintenance-oriented treatments**:

In the UK framework, attention is chiefly directed towards the pharmacological treatment of individuals who are dependent on opioids, utilizing prescribed opioid substitutes like methadone or buprenorphine. This intervention seeks to curtail or eradicate their engagement with illegal drugs and the resultant harms.

**3. Abstinence-oriented treatments:**

The primary aim is to decrease the level of drug use among individuals, with the long-term objective of achieving total abstinence. Findings from the National Treatment Outcome Research Study (NTORS) indicated that nearly one-third of participants in treatment maintained abstinence five years post-intervention. However, it is important to note that these treatment approaches may lead to an increased likelihood of overdose-related deaths upon relapse, particularly after a period of abstinence that results in a loss of drug tolerance. As such, it is essential for treatment programs focused on abstinence to include educational components addressing the risks of relapse and overdose following detoxification, as well as to offer extensive psychosocial rehabilitation support..[18]

❖ **Future challenges:**

Drug usage and its numerous associated issues are still on the rise in many parts of the world, and there is no easy solution or single reason. In certain regions of the world, both industrialised and developing, drug addiction is a serious problem. Reports of sickness, accidents, fatalities, crime, decreased production, and other issues are common. When drug usage is not properly regulated, it hinders social and human development and is inextricably linked to endemic issues of The interrelated issues of violence, poverty, unemployment, and illness present significant societal challenges. The patterns of illicit drug consumption and the problems associated with it vary widely from one nation to another, revealing diverse traits. Drugs are often quite profitable to sell and are easily sold as commodities. Additionally, they have strong behavioural and cognitive impacts that affect a variety of human activity. The prevention of drug misuse is influenced by a multitude of factors. Foremost among these is the necessity for individuals, communities, and institutions that are affected to take a proactive role in addressing drug-related challenges. The emphasis should be placed on the people involved, as they represent both the heart of the issue and the starting point for viable solutions. This perspective will manifest

differently in rural versus urban contexts and will be shaped by class distinctions. In rural areas, it is crucial to implement alternative development strategies that are responsive to the specific conditions of the target communities. Conversely, urban drug problems require a tailored assessment and intervention that capitalizes on local strengths, akin to rural approaches. Both urban and rural initiatives demand extensive long-term planning and a range of support systems to ensure their success. Additionally, the backing of the local community and a foundation in public policy are essential for achieving desired outcomes. The profits generated from illicit drug sales are indeed substantial, often overshadowing major international development efforts.[9]

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HOW TO CITE: Patil Sushant *, Patil Shweta, Gaikwad Sipora, Addiction-Induced Epigenetic Alteration A Pharmacovigilance: Abuse and Misuse of Pharmaceutical Drug, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 2, 938-950. https://doi.org/10.5281/zenodo.14863117