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PHARMACOVIGILANCE - a Need of the Hour to Mitigate the Use of Banned Drugs in the Covid Pandemic

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PHARMACOVIGILANCE- A need of the hour to mitigate the use of banned drugs in the covid pandemic

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ABSTRACT

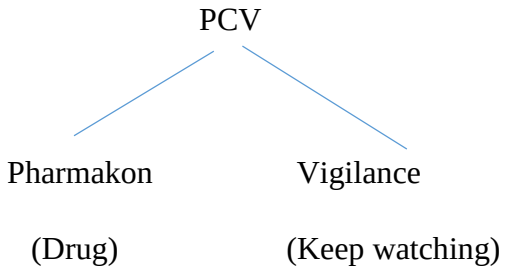
Pharmacovigilance (PCV) supports safe and appropriate use of drugs that cause adverse effect on an individual. Spontaneous reporting of adverse drugs reactions (ADRs) is an essential part of PCV which leads to the early detection of the drugs. Before 1960, the drug safety issue was not taken into consideration and was in shadow. Detection of drugs came into existence after the thalidomide tragedy which happened in 1960. After this incidence the drug safety issues were globalised. Then the world health organisation established a programme related to the drug monitoring in the year 1968 and this paved the way for PCV. Even though the drug monitoring committee was established many years ago but most of the developing countries and under-developing countries are not strictly abiding by the policies and the guidelines. In the present world it is said that the patients getting hospitalised due to ADRs in some countries is about or more than 10%. In the present situation of covid pandemic large amount of drug administration needs to be done and for a new virus like covid for which there is no known vaccine or medicines the chances of adverse drug reactions are at its peak. Correct knowledge of the adverse drug effect i.e. PCV, is the only best way to safeguard the public health. The use of banned drugs should be stopped immediately in order to avoid any further adverse drug reaction to the people using it. This paper mainly speaks about the usage of banned drugs which are still in use especially in developing counties. The main objective of the study is to know the probable usage of banned drugs mainly in developing countries like India and finding out suitable alternative remedy on how the PCV can be enforced in attaining the zero neutrality of banned drugs in circulation among the people and an initiate is also being made in social media and other mass media in implementing PCV.

Keywords: Pharmacovigilance (PCV), Safety, Banned drugs, Adverse drug reactions(ADR), Covid pandemic.

1.0 INTRODUCTION

1.1 Definition: PCV is a science and activity related to the detection, assessment, understanding and prediction or prevention of a drug. The purpose is to reduce the harm to the patients caused by the drugs, or in the other words, to ensure complete safety of the patient. [1]

In a simpler way PCV is divided into two segments



1.2 History: PCV was started in the year 2002 and was initiated by WHO (world health organisation). The drug monitoring system came into existence way back in 1968 when the thalidomide disaster happened in 1960. It is estimated that more than 10,000 babies were born with deformities due to the adverse effect of consuming thalidomide by the pregnant women in the early stage of pregnancy which caused severe effect on the babies after their birth. The programme for saving the patients was started with 10 participating countries in the initial stage and now comprising of 134 member countries. [1]

1.3 How does PCV work:

Initially the protocol is approved which leads to the selection of investigation process. The investigation process is then approved and on the basis of the process the patient recruitment and participation is decided by the committee. The recruitment and participation data received is registered and the statistical analysis of the same is carried out and the report is then presented. The approved presentation report is published and the final data is filled and registration is done. The above said process is explained in figure 1 for easy understanding.

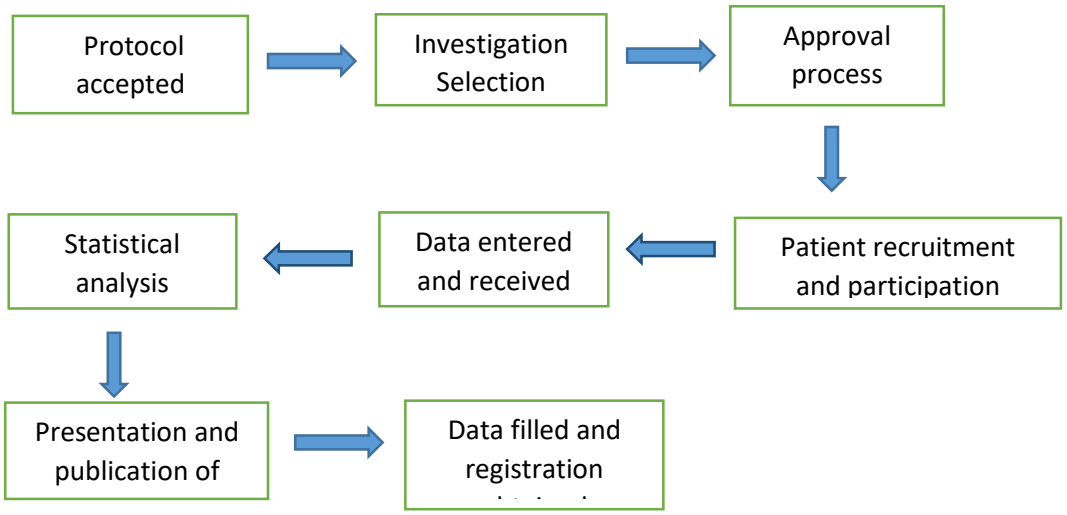


Figure1: The working process of PCV

1.4 Stakeholders: Talking about the key stakeholders who play a vital role in PCV are as follows [2,7]

1) Patient

   Patient are one of the key stakeholders who provide reports which add new information and perspective about ADRs (adverse drug reactions) which in other way are unavailable. This information gathered by the means of patients reports can lead to the strengthening of safety signals and increase the knowledge about ADRs. The different methods used in order to find out more information about the drug given by the patients are systematic literature search, study selection and data abstraction, quality assessment. [2,7]

2) Health care professionals (HCP)

   Healthcare professionals play a very crucial and important role in the area of PCV system because health care professionals having good amount of knowledge about the drugs that are been used in the market for different purposes can easy identity if any adverse reaction is causing for the people that are using and even can recognition any kind of symptoms in early stage of the adverse reaction that happens for the people or even for animals. Adding upon the health care professionals should be educated about the procedure of the adverse drug incidence that can happen for any of the person and even should be educated for taking up the actions immediately if found any. [2,7]

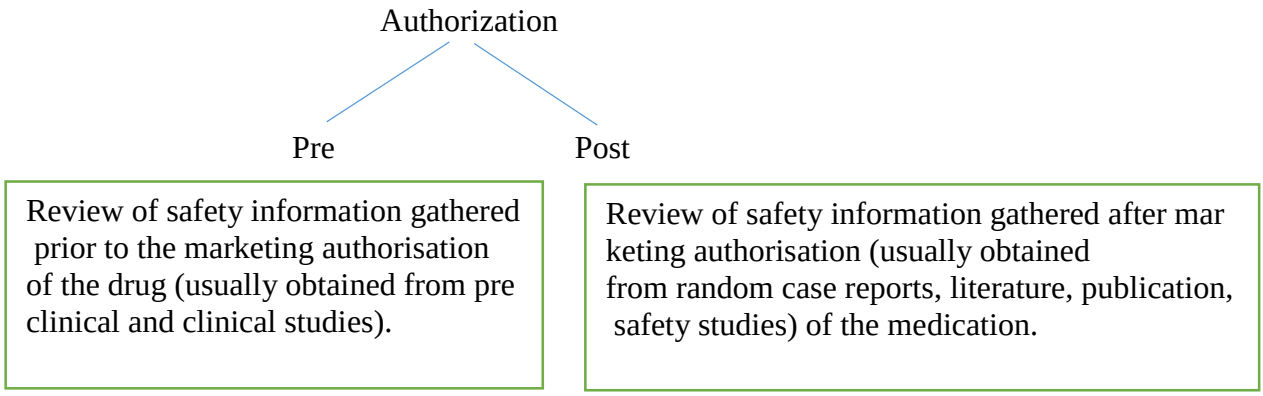
3) Market authorisation holder

The market authorisation holder should keenly and continuously monitor the medicines used in the market by the humans. The authorisation holder should be updated on a day to day basis on the medicines sold in the market whether they are getting positive or negative reviews and if found any negative reviews then immediate action should be taken. [2,7]

4) Regulatory authority organisations

Regulatory authority organisations are the organisation which are mainly responsible for effective drug required for the safety of the human beings. Apart from safety of the drug it also considers the efficiency of the drug, its quality, accuracy and appropriate drug information available in the market for the public to keenly understand the prone and cons of the medicine. [2,7]

1.5 Authorization: There are two authorizations [4,9,10]



The above two authorisations are further divided into 4 phases which clearly explains the whole authorisation process of a drug before releasing in the market to the safety measures.

Pre authorization

Phase 1: Includes animal studies such as toxicology, carcinogenicity etc.

Phase 2: Involves drug testing in smaller group (example 100-300) of subjects which are usually patients.

Phase 3: Involves drug testing in large group (Ranging from 100 to 1000) of patients.

Post authorization

Phase 4: Safety studies conducted to evaluate safety after the authorization of the drug. Provide additional safety and efficacy information in a large population can be conducted to assess a specific safety concern. [4,9,10]

1.6 PCV status in developed and developing countries

All the countries around the globe are working really hard to make sure that the PCV system work accordingly which helps the countries to identity the adverse drug reaction that can be caused. Taking into consideration both the developed and developing countries, developed countries have more of a sophisticated system of the PCV but the developing countries lack behind because of no proper infrastructure and facilities provided to them which cause the reaction of the drug to spread in a very fast manner. [3,13,14]

Many studies have also reported and stated that a very huge impact of poor quality product of the medicines can cause a serious adverse drug reactions (ADRs) and medication errors can also cause a very great impact on the people using it that usually happens in the under developing or developing countries because of no proper system of detecting the problem of the drug that is been used because of lacking medical system. [3,16,14]

Looking at the different parameters around the world it is evident that the high income countries have better facility and lives but looking around the developing and under developed countries the situation is worse because of no proper health system infrastructure and even the quality of medicines and education and awareness of health staff people is also very less. [3,13,14]

1.7 Regulatory bodies all across the world:

Every country has their own regulatory body which helps to maintain a record on the drugs that are released in the market and drugs that are already publishes in the market. These bodies are the key organisation which helps to track the adverse drug reaction that can be caused by any drug and will help to regulate the adverse reaction. United states have food and drug administration (FDA), European medicines agency (EMEA) in the European union, in Germany federal institute for drugs and medical devices (B.FARM) is established and India has Drug controller general in India (DCGI). [5,16]

1.8 Drug Safety Plans in developed countries

1.8.1 United Kingdom (UK)

The responsibility of patients and public health workers in the United Kingdom is the responsibility of the British Government Department of Health. The medicines related health products regulatory agency (MHRA) is a federal agency acting on behalf of the UK governments department of health. MHRA will ensure the safety, effectiveness and quality of medicines just like health products. MHRA adopts the theme of prescription event monitoring (PEM) that is MHRA establishes and monitors the main 10000 patients. WHO accepted new drugs in the market for any adverse drug events. [17]

General practitioner (GP) prescribes a newly introduced drug, which patients take to pharmacists for dispensing. The prescription information received by the pharmacist will be passed to the prescription pricing authority (PPA). The PPA then sends electronic copy of the study drug prescription to the Drug Safety Research Unit (DSRU). This process helps to collect patient exposure data and continues until about 20 000 to 30 000 patients are collected. From 3 to 12 months after the prescription, a green form will be sent to the prescriber. The form requires detailed information about any events that may have occurred since the patient's prescription is written. [17,19,20]

The form is anonymized to maintain patient confidentiality. The event information on the form provides the result data. Then analyse the detailed information of the event and its occurrence rate, and may lead to the generation of signals, hypotheses or the beginning of subsequent research. Therefore, PEM in the UK can help PCV agencies evaluate new drugs in terms of uncontrolled clinical outcomes and adverse events in the clinical environment and real world. [17,19,20]

1.8.2 United States

The US Food and Drug Administration (FDA) is a federal public health agency that is responsible for ensuring the safety of all marketed medical products, including drugs (drugs and biological agents). The availability of safe and effective medicines depends on the reports of all interested parties (i.e., consumers or patients, healthcare providers and medicine manufacturers) to ADR. Manufactures must report ADR mandatorily. [6,22,39]

All unsolicited reports received by the FDA through voluntary or mandatory channels from healthcare professionals or consumers are called spontaneous reports. Spontaneous reports are

part of clinical observations derived from formal studies. ADR, individual spontaneous reports to drug errors and product quality issues are sent directly to the FDA or manufacturer through the Med watch program, and then indirectly from the manufacturer to the FDA, which combines formal clinical research and medical data and scientific literature to form an after-sales. The main data sources that the monitory depends on.FDA continuously strives to implement updated surveillance technology to detect, report and evaluate adverse events. Another method that FDA may use to detect adverse events is to analyse a claim database with a large sample size. These databases have prescription statements that provide links to the occurrence of adverse events. The FDA issued three separate guidelines in March 2005, including: (1) pre-market risk assessment (2) Formulate and use a risk minimization action plans (Risk MAP) and (3) good PCV measures and Pharmacoepidemiology assessment. According to the "Industry Guidelines", drug safety risk management is defined as an interactive process aimed at optimizing the benefit-risk balance of regulated products, and risk MAP is defined as a strategic safety plan designed to meet the need to minimize known risks. A specific target product that is minimized while retaining its benefits. Risk MAP tools for minimizing risks include physician education and awareness programs and access to reminder systems that can cross-check and provide assistance to healthcare professionals to reduce risks associated with prescription, distribution, receipt and use of products. Some of the measures taken by the FDA guidelines include: identifying drug safety signals, investigating and interpreting risk signals beyond case review, standardizing drug epidemiological research methods for risk assessment, developing diseases and drug registration agencies and conducting patients or health providers Investigate good PCV measures Pharmacoepidemiology assessment. [6,22,39]

Based on the study of PCV several inference has been identified and the outcomes are incorporated and the same remedial measures are discussed below.

2.0 METHODOLOGY

The following methodology was adopted for the research work where initially the problem of PCV was identified by studying about its history and working procedure. Based on the initial study an objective was setup where in the whole concept of PCV was studied. Identified the drugs that are used and banned across the world. For executing the study, the secondary data source mainly from the literatures was taken into consideration. The sequence of the methodology was defined and worked according to the protocol derived. The data was analysed to quantify the output. After the complete data analysis and research a conclusion was made according to the findings and the same has been incorporated in the paper. The below said figure 2 is the research methodology adopted for the study.

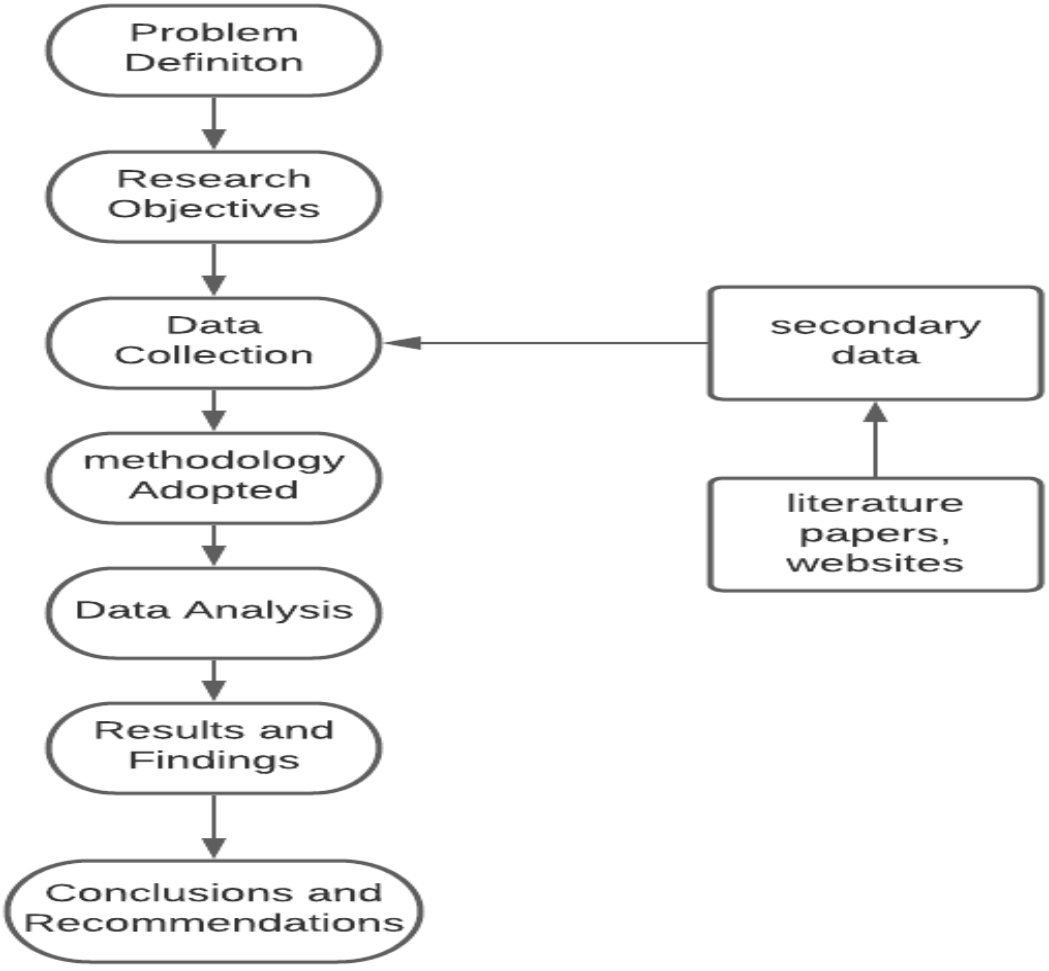


Figure 2: Research Methodology

3.0 RESULTS AND DISCUSSIONS

3.1 The need of PCV in India

According to the 2011 census, India is the second largest population in the world, with a population of more than 1.21 billion people. The Indian pharmaceutical industry is worth US $ 18 billion, and its growth rate is estimated to be 12-14 % per year. Pharmaceutical exports have also grown at a compound annual growth rate (CAGR) at 25% per year. The total export value of medicines reaches 8 billion US dollars, which makes India a global pharmacy for generic drugs, because it is an independent entity that provides high-quality and affordable generic drugs. Globally, India is regarded as an emerging hub for clinical trials, drug discovery, research and development. After years of clinical trials, and with the gradual approval of the drug regulatory authorities, the drug for the treatment of specific diseases has been launched. Before being put on the market, despite several inspections during the drug discovery and development process, certain drugs were withdrawn from the market when ADRs related to them were discovered. Even is the drug is sold on the market for ten years or more, it may be withdrawn. Examples of such drugs are rosiglitazone, rofecoxib, gatifloxacin, rimonabent and especially nimusulide preparations have been 12 years old. Some ADRs can be avoided. Spontaneous reporting by medical professionals is an important step in prevening or reducing ADR. The ADR reporting rate in India is less than 1%, while the global ADR reporting rate is 5%. Given the low incidence in India, one of the reasons may be attributed to the awareness of PCV and ADR monitoring by Indian healthcare providers. In pandemic situations like covid-19 a large amount of drug administration needs to be done, and for a new virus like covid for which there is no known vaccine or medicines the chances of adverse drug reactions are at its peak. In this situations hit and trial policy is adopted on a large number of people to check the effectiveness of the drug. New drugs which do not undergo the long trial methods of testing and approval proves to be a serious threat. In the event of any miss happenings the adverse drug reactions only increase at an exponential rates, in such times the importance of PCV is to be kept in mind. The total number of ADR reports and also the no of females in the report is showed through bar chart in figure3. [21,23,25,40]

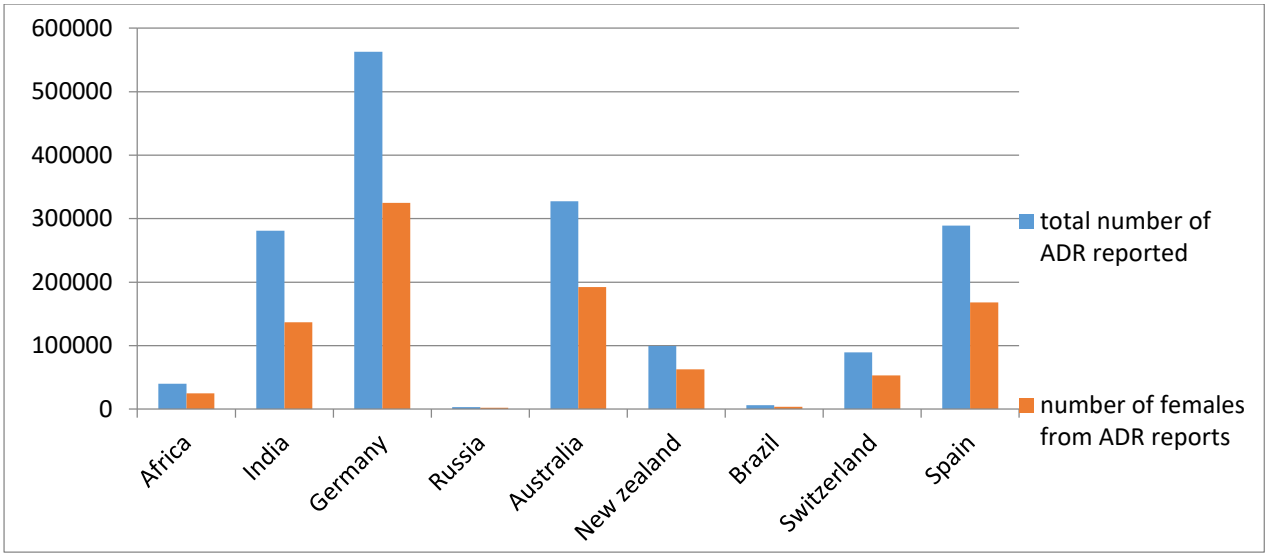


Figure3: Bar chart showing total ADR reports and number of female reports

3.2 Drugs that got banned

Taking into the account of the undesirable effects caused by Adverse drug reactions (ADRs) cause a serious health problem to the patients and ADR sometimes causes the utmost effect to the patient which can even lead it to death. This type of condition many times occurs in the developing or under developed countries where the awareness and treatment are very less due to no proper infrastructure. Developing countries such as India, Argentina, Brazil, Bulgaria, Chile etc. are some countries where the adverse drug reaction causes serious effects on the people. Some of the research studies have explained and monitored that the effects of ADRs mainly by looking at hospital readmissions. After all the studies done it is said that almost 6.7% patients in India are readmission cases. [18,43]

The new form of finding the adverse drug reaction is the detection of yellow card reports, which is a cost-effective way to monitor the safe use of drugs. The use of the yellow card report is helpful in many ways. The yellow card can help you to identify unrecognized adverse drug reactions, the risk factors for ADRs occurring between drugs of different treatment categories, drug safety issues and risk benefits comparisons. [47]

The medicines usually order should go through different test stages, such as pre-clinical and clinical tests, to prove their safety and effectiveness. This step helps to ensure that the medications used are correct and will not harm people of any age, because ensuring that medications are used before use can help to reduce adverse drug reactions. After the drug is put on the market, the process of detecting adverse reactions through regular monitoring is

PCV. In the PCV system, if any drug is found to have any adverse drug reactions, it will be banned by the FDA or voluntarily withdrawn by the production pharmaceutical company. When drugs are used in combination with other drugs and if they cause adverse events, the FDA prohibits the use of the drug combination rather than a single drug. Many single-dose or combination drugs have been discontinued and are available in the Indian market. The single drugs banned in India in the last ten years are as follows. The study aims to review the status of illicit drugs in India. It also studied the PCV programs in the United Kingdom and the United States and provided inspiration for improving PCV in India. Below are some of the medicines that got banned from time to time. These banned drugs are some of the major problems caused in patients' health making it adverse reaction and hence got banned. Some of the drugs got banned from 1983 to 2008 are mentioned below [38,41,42]

(1) 1983: Amidopyrine, Phenacetin, fixed dose combination of Tetracycline with vitamin C, fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers, fixed dose combination of Iron with Strychnine, Arsenic and Yohimbine.

(2) 1994: Dovers powder I.P, dovers powder tablet I.P, Antidiarrhoeal formulations kaolin or pectin or attapulgite or activated charcoal.

(3) 1995: Fixed dose combination of Hydroxyquinoline group of drugs with any other drug except for preparations meant for external use only.

(4) 1996: Fixed dose combination of oxyphenbutazone or phenylbutazone with any other drug.

(5) 1999: Fixed dose combination of centrally acting, antitussive with antihistamine, having atropine like activity in expectorants.

(6) 2000: Fixed dose combination of haemoglobin in any form (natural or synthetic).

(7) 2001: Fixed dose combination of diazepam and diphenhydramine hydrochloride.

(8) 2003: Fixed dose combination of rifampicin, isoniazid and pyrazinamide, except those which provide daily adult dose.

(9) 2004: Rofecoxib and its formulations for human use.

(10) 2008: Diclofenac and its formulations for human use.

Although each country has its own list of prohibited drugs it is worrying that there are still some drugs on the Indian market that are banned because other drugs have been proven to have adverse effects. Some of these drugs are available on the counter, and people may take them without realising the risks. Precautions about these drugs can help patients decide whether to take the drug. Some drugs that are banned but still sold in India are mentioned below:[24,26,48]

Sr.No	Banned Drug	Effects
1	Phenylpropanolamine	Phenylpropanolamine is commonly found in cold medicine and cough medications in India. In the United States, it is also used to treat obesity and is found to increase the risk of haemorrhagic stroke (stroke due to cerebral haemorrhage). It may also exacerbate mental illness.
2	Metamizole(Analgin)	A Analgin is a painkiller. Because of the risk agranulocytosis (condition in which the bone marrow does not produce certain types of white blood cells), it has been banned in some countries. India does not prohibit the use of Analgin itself, but prohibits the use of Analgin with any other drug.
3	Oxyphenbutazone	It causes bone marrow suppression and other side effects; it has been banned in many countries. It is prohibited to use it in combination with any other drugs in India.
4	Nimesulide	Nimesulide is an analgesic that was not introduced in the US, UK or Australia market, but is widely used in India. It has been found to cause liver failure, so it is banned in some countries.
5	Cisapride	Cisapride is a drug that increases gastrointestinal motility. It is used to treat acidity and constipation. When used in large doses or in combination with other drugs such as erythromycin and ketoconazole, it may cause arrhythmia, therefore the use of this feature is prohibited in some countries. Its use in India is limited by scanners and it may soon be ban.
6	Cerivastatin	Cerivastatin in a cholesterol-lowering drug similar to atorvastatin. Since it caused several cases of rhabdomyolysis (damage to muscles), the patient subsequently suffered kidney failure, so it was withdrawn. Unfortunately, it is still available in India.

3.3 Reasons Of Availability Of Banned Drugs In India Are

- The long legal bans in developed countries banned the use of many drugs in India, which allowed manufacturers to manufacture these taboo drugs in India for a long time. The commercial interests of pharmaceutical companies, corruption, lack of transparency and accountability are the main reasons for such delays in the 28 ban processes. [44,49]

- Regulators lack enforcement power.

- Due to India's poverty line, these drugs are easily sold at low costs.

- Many private practitioners and doctors know nothing about the ban.

- *Patients prescribe prescription drugs for common diseases and conditions, which leads to patient non-compliance. The patient has a mentality that he is taking medication quickly for common diseases such as Nimesulide, Rofecoxib, Phenylpropanolamine (such as colds, coughs, headaches etc) and they do not know the side effects caused by it.

- Due toself-prescription, many allergies and allergic reactions often occur in India. This can be prevented through a public awareness program about the status, use and side effects of self-prescription drugs,

- Unable to get the right medicines and their high cost.

- Prescribers lack of knowledge and experience

- In some places such as Ludhiana, the department has no provision to notify hospitals and doctors about the status of these illegal drugs except through newspaper.

- *One of the reasons for offering free illegal drugs in the market is the communication gap between DCGI and national drug regulators. The most recent case involved phenformin preparations. After the ban was issued on October1, 2003, the product can still be purchased in the market. A serious problem facing the medical community today is the lack of updating existing and new drug knowledge. [28,30,31]

- The Drug Inspector cannot contact and check every pharmacist/ wholesaler because there are only limited Drug Inspectors.

3.4 Rapidly selling banned drugs in India

Looking above all the banned drugs in the country which are been sold despite being banned is creating a huge problem. The below chart explains the drugs that are been banned and even though getting sold in the market in a very rapid way. Taking into account four drugs namely Rofecoxib, Analgin, Phenylpropanolamine and Nimesulide which are banned in the country but are still sold in the market is shown in figure4. [32,33]

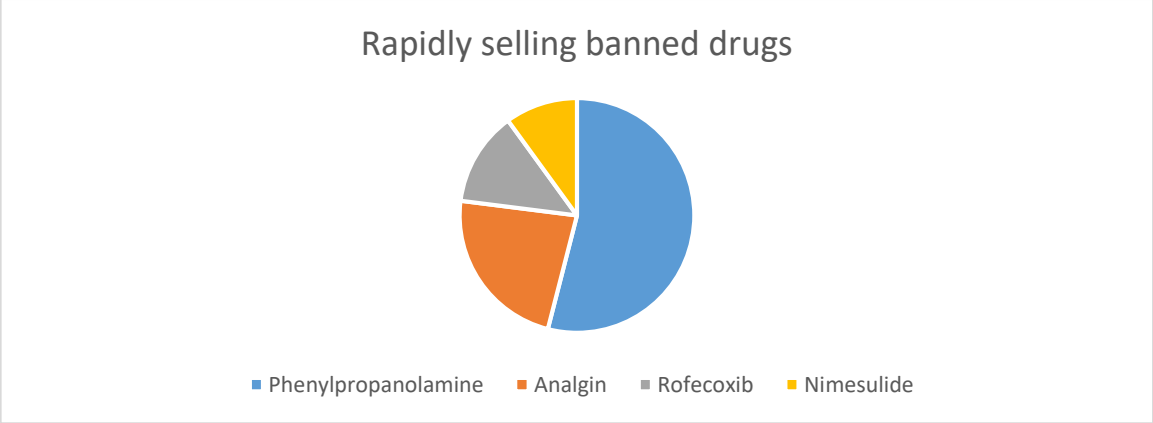


Figure 4: Rapidly selling banned drugs

3.5 Flow chart of process of banning:

The below flow chart (figure5) explains how the process is held during the banning of any drug that causes problem. [34,35]

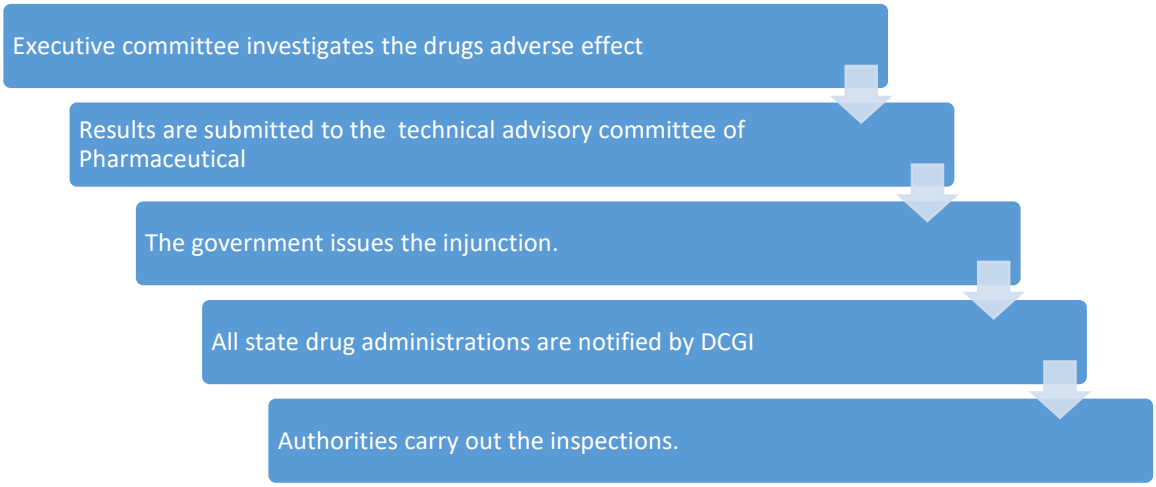


Figure 5: Process of banning the drugs

3.6 General Awareness about the banned drugs

The below pictographically represented figure 6 explains about the awareness levels among different category people working in the medicines industries and normal people living in the society. There are three kinds of people among which the comparison is done. They are layman, doctors and pharmacist and science students. [36,37]

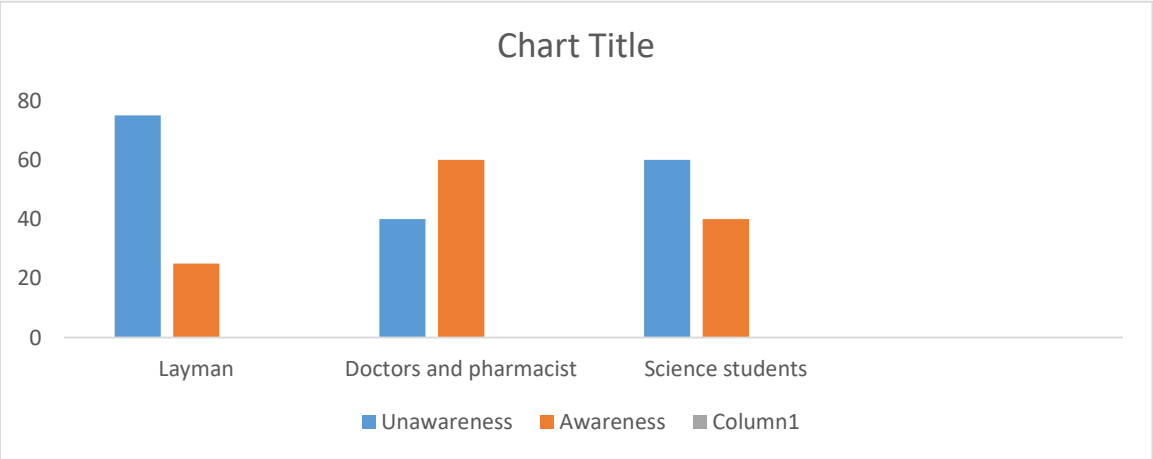


Figure 6: General Awareness about the banned drugs in different sectors

3.7 Some steps towards improvement:

- **PCV in Public Health Programs**

  When studying the way public health systems are organized, these countries may have public health plans for diseases and operate separately from the main public health systems. The main goals of PCV in the public health plan are the same as those of the national PCV system. The structure and organization of the existing national system will help determine how to design and integrate the PCV of public health programs. In some cases, the country may not have a national PCV system. In this case, the system of public health planning will be more important and may provide a model for the final establishment of the national system. [44,45,46]

- **Developing Staff Capacity**

It’s important to note that drug safety is a concept that everyone should understand and should make sure that all the medical staff people including the people from different background of the medical should be made sure that all people working in the medical care knows about the medicines that are used and if someone comes with some symptom that can be easily identified and medicated to make medicines safer and also people.

- **Measure performance**

The performance of PCV system should be continuously measured or controlled by government agencies and policy makers in developing countries, and always maintain clear and transparent benchmarks and targets. Measures taken by government agencies should be realistic, including not only the number of ADR’s but also the repeated investigation and review of the level of PCV awareness among health professionals, patients and other major actors. In addition, national and international NGOs can provide support based on the political will of the countries concerned.

- **Raise awareness**

In most countries, research shows that for various reasons, the public and even health professionals have limited knowledge of PCV system. Many countries are trying to increase the awareness about the system by adapting many different type of approaches such as use of social media is the new platform where the system is enhancing to its core. In addition to social media, many countries also raise awareness through other factors, such as sports, seminars and workshop activities. In some cases, an online reporting mechanism needs to be establishes. This work needs to be strengthened. The awareness of the public and professionals about the necessity and importance of PCV, and making the report as simple and clear as possible and practical, should be at the forefront of any drug regulatory agency.

- **Professional training**

In view of the relatively low level of awareness of health professionals in all developing countries, it is worth exploring the idea of introducing PCV in medical training and professional qualification certification courses for health professionals. In most developing countries, the biopharmaceutical industry is mainly composed of local generic drug

manufactures, who have made slow progress in implementing PCV standards and activities. In addition, healthcare professionals have relatively limited awareness of PCV activities This is due to the lack of resources (funds and time) required for proper training, and the lack of experts for such training. It is important to regularly issue PCV announcements and disseminate safety issues and warnings through seminars and symposia, focusing on PCV training and disseminating PCV knowledge within medical institutes. International non-governmental organization can provide support.

- **Patient awareness of PCV**

Spreading the awareness not only to the health professionals but also to the patients is a very essential parameter that needs to be taken into consideration as spreading awareness to the patients can also contribute in reducing the adverse drug effect of the medication. Patients in the current stage do not have that much awareness as comparatively they need to have and thus all the countries around the world should make sure to spread the awareness.

- **Unqualified and counterfeit drugs**

The impact of unqualified and substandard drugsis a very crucial problem in most of the countries and particularly in developing countries where there is no proper awareness. Control on substandard and counterfeit medicines should be a foremost priority for the Regulatory bodies in the developing countries to reduce huge impact on public health.

4.0 REMEDIES

4.1 Social networking sites and their relevance to PCV

The applications allow people and consumers to talk, communicate, exchange information, network which makes the awareness about the PCV stronger and social media helps the people to communicate their problems which can be helped by the health care staff and if the information provided is worse the government bodies can also take action. The below pictographically representation explains how the media listens and detects the drug adverness that causes people suffer to its core. The information is obtained by the users by different social networking sites such as LinkedIn, Facebook, twitter, YouTube. The Sponsors within the industry are utilizing social media for different purposes and the most utilized thing by the

social media is that the distribution of information about diseases and their treatment, medicines and company announcements are done via social media which spreads the news in a wider manner to the people and country. Commercial arms of pharmaceutical companies are also utilizing social media platform to know what are the conversations done between the patients and healthcare professionals. A few companies also use social media for patient participation or for recruitment and retention in clinical trials. [11,45,46]

The information is obtained in the form of URL (uniform resource locator) of ADR (adverse drug reaction) reporters. All the adverse drug reaction information from different blogs are obtained and are clubbed together in order to find which drug is causing the adverse reaction to the patients and what are to be stopped in order to make sure the reaction of the drug doesn't cause much problem to the patients, people using it and animals as well. After the drugs with an adverse reaction are obtained and send to world health organisation to make a final decision to continue or not in the market. In such a way the people in social media posting the information helps the organisation to know which drug is causing problem for the people out there and can fastly work on the treatment or can stop it in the market to be sold. [48,49,50]

The following figure7 talks about the cycle how the information is collected from different networking sites and how the crises are managed in order to avoid the seriousness that can happen by consuming the drug by the people.

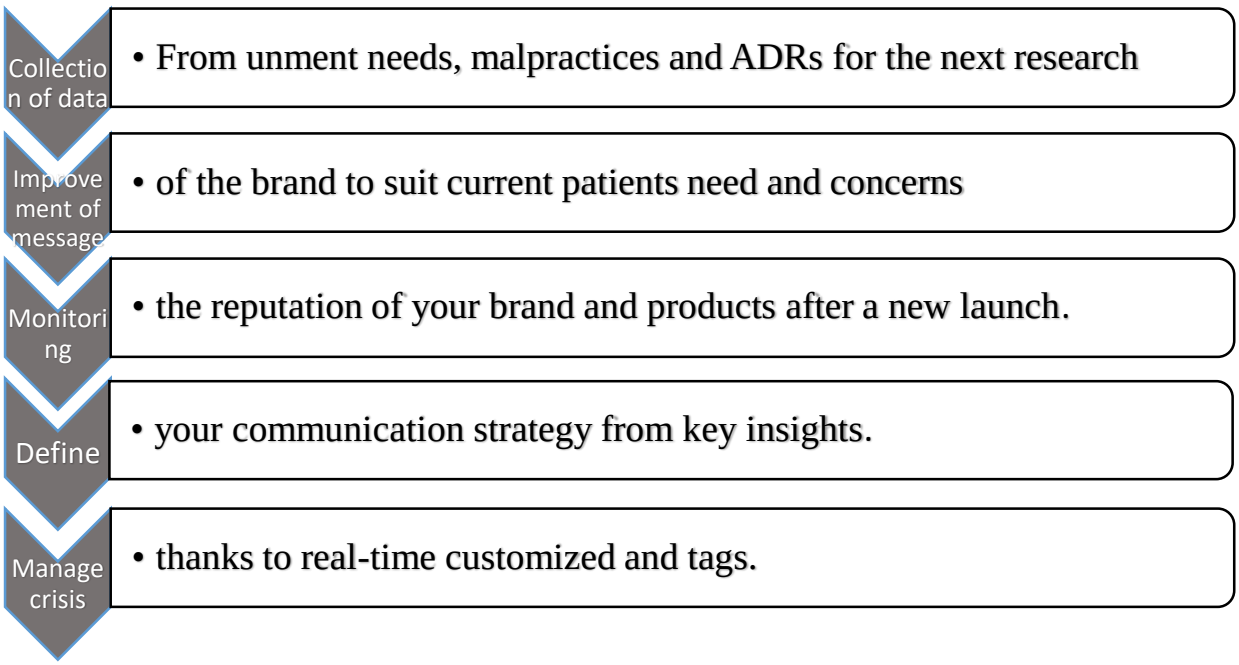


Figure 7: Drug cycle showing the information been collected from different networking sites and the crisis been handled

4.2 The potential of digital media in PCV

There is constant promotion and use of social media and online health network platforms as a way of addressing patients and health-related topics. Many of these patients use these sites regularly to share their concerns and potential medication related adverse events. This provides an incentive for such data to be used in ADR signal identification and monitoring of public safety. The use of social media has been thoroughly proven in public safety surveillance. Previous research has shown how to use social media data during natural disasters to identify the most affected area. During infection outbreaks, screening of social media data has also shown patterns in news. Research on the use of social media in PCV to data has centred on the data mining techniques essential for large-scale screening of safety information at these locations. The results of these studies combine the potential of filtering adverse event-related information from social networking sites, as a means of ADR signal detection.

Overall, social media activities can be boiled down to three key points:

1. **Broadcasting** *(risk communication*): Ensure that patients and health care providers are well informed. Manage and anticipate possible crises and have a procedure in place to deal with them.
2. **Listening** *(safety data reporting)*: Tune in to hear the brand and patient sentiment and have a process in place to identify potential adverse effects. This can include sifting through mentions, evaluating consumer sentiment, and creating customizable dashboards to fit your needs.
3. **Engaging** *(follow up on adverse drug reactions and adverse effects:* Reach out to those impacted via Chabot's or other traditional methods and ensure the proper measures are taken. These include moderation processes, timely responses by a trained specialist, and social media best practices.

The aim of using social media for PCV should be to enhance patient safety by analyzing information in an accurate, concise, and timely manner and by ensuring the efficiency and accountability of PCV activities. A framework for ADR detection and extraction from social media data is shown through figure8. [41,42,51]

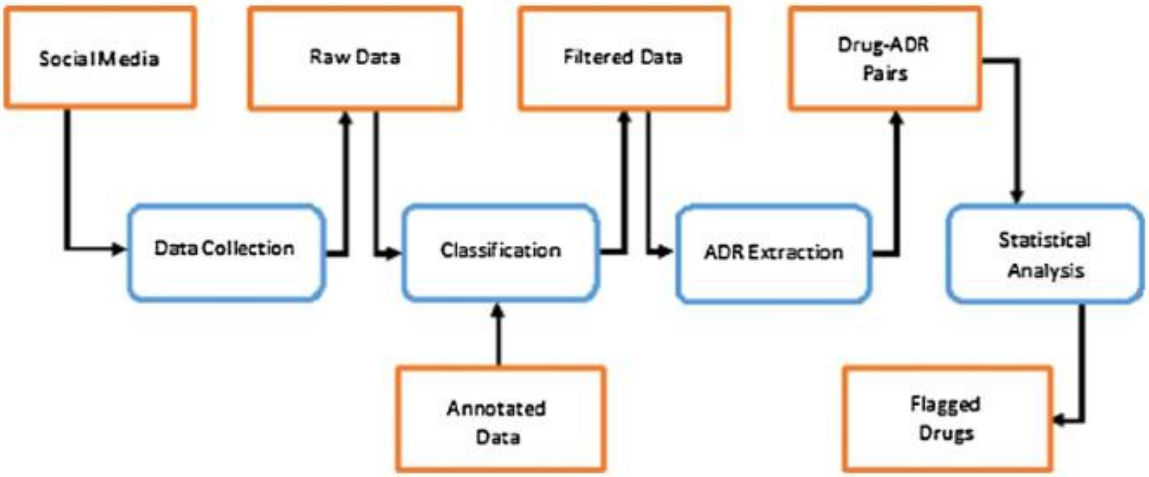


Figure8: Flow diagram for ADR detection.

CONCLUSION

PCV has provided invaluable underpinning and it has the potential to continue doing so for dedicated national programme which are working towards the control and treatment of tuberculosis, malaria, HIV AIDS and contraception medications. Health ministries, professionals and also the public can all be reassured by knowing that there is a functional and competent system in place that focuses on the safety of medicines which are used for the prevention and treatment of the medicines. No doubt PCV has helped in the betterment of the pharmaceutical industry but when it comes to the disposal of the medicine that has been cancelled after getting released in the market, no attention has been given for its proper disposal. The general practices are to incinerate these drugs that have been banned but there is no data available if these practices are implemented. As far as the present scenario of the disposal of drugs no proper measures are implement by either public or the pharmacies. If these drugs are not disposed in a proper manner then the hazardous crises come into existence such as leaching of the ground, also, aquatic life are highly affected by pharmaceutical compounds. Thus, environment and health are directly or indirectly affected by unmonitored disposal of such waste. Health safety Environment is looked into any part of activity but seen as an annexure in most of the sectors. It is necessary that HSE must be part of each activity and it is mandatory that health safety and environment must be given high priority and the same must be enforced in all the sectors so that the PCV will be effective.

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