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SURVEY ON RESPIRATORY TRACT DISEASES, THEIR ADVERSE DRUG REACTIONS IN PATIENTS AND APPROACHES FOR ITS MANAGEMENT

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Abstract: It is predicted that about 95% of adverse drug reactions (ADRs) never get reported after pharmacotherapy, necessitating strategies to improve ADR reporting. The introduction of databases like VigiAccess, in which ADR data from Pharmacovigilance centers all over the world can be assessed, is a key step toward strengthening ADR reporting. This study evaluated ADR reporting patterns in VigiAccess, an open-access pharmacovigilance database, as well as the therapeutic treatment of respiratory tract infections in patients from the Delhi-NCR region. A questionnaire was used to gather information mostly on the patients with respiratory tract infections. Additionally, a comprehensive search of VigiAccess was conducted to find the categories of reported ADRs as well as the quantity and variety of ADRs reported for a few chosen medications utilized in the therapy. VigiAccess was thoroughly searched, and seven primary kinds of reported ADRs were found in the database. These included illnesses affecting the skin, subcutaneous tissues, gastrointestinal system, mental system, respiratory, thoracic, and mediastinal systems, general disorders, and problems at the administration site. To reduce morbidity and mortality caused by ADRs, diligent ADR monitoring is required, which necessitates more research on a wider population. This study showed that tracking medications that affect the respiratory system and their associated adverse drug reactions might help with quality improvement efforts and perhaps enhance patient care.

Index Terms – Pharmacovigilance, Adverse drug reaction (ADR), Adverse events (AEs), Vigiaccess, Respiratory tract

I. INTRODUCTION

Pharmacovigilance refers to the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects and other drug-related safety problems. In regard to, this broad definition, the basic goals of pharmacovigilance are to avoid harm from adverse reactions in people caused by the use of health goods within or outside the terms of marketing authorization and throughout the product's life cycle [1]. The primary purpose of pharmacovigilance is thus to promote the safe and effective use of health products, specifically by giving patients, health-care professionals, and the general public with timely information regarding the safety of health products. Pharmacovigilance is thus an activity that contributes to patient protection and public health. Many other issues are relevant to pharmacovigilance-related activities, such as medication errors, a lack of efficacy reports, off-label use, acute and chronic poisoning, drug-related mortality assessment, abuse and misuse of health products, and adverse drug interactions with chemicals and other drugs. PV is particularly concerned with adverse drug reactions (ADRs), which are unpleasant and unexpected pharmacological responses that occur at levels ordinarily employed for disease prevention, diagnosis, or therapy, or for the alteration of physiological function [2]. To maximize benefits and minimize dangers, continuous monitoring of pharmacological effects, side effects, contraindications, and overtly adverse effects that could result in a significant degree of morbidity, and in some circumstances, even mortality, is required.

Key Goals of Pharmacovigilance

(1) To promote pharmaceutical use that is safe, effective, and sensible.

(2) To raise awareness about the sensible use of medicines among patients and the general public through effective communication.

- (3) Improve patient safety and care in respect to medication use.
- (4) Recognize the hazards associated with medication use.

(5) Participate in the comparative examination of possibly useful and harmful pharmacological effects that aid in improving the nature of consumption.

(6) Recognize and report possible ADRs [3]

Significance of Pharmacovigilance: When a new drug is introduced to the market, there are still many unanswered questions about the medication's safety. Different people use these pharmaceuticals for different ailments, and they may be taking many medications and following different practices and diets, which may have an adverse effect on the medication's effect on them. A similar drug may also differ in its production process. Furthermore, adverse drug responses (ADRs) may occur when drugs are combined with conventional and natural medications, which must be monitored by pharmacovigilance. Adverse drug responses (ADRs) to specific medications may occur only in one country or region at times. To avoid all unjustifiable physical, mental, and financial suffering of patients, pharmacovigilance becomes a significant observing system (**Fig.** 1) for medication safety in a country with the assistance of specialists, drug specialists, attendants, and other health experts of the country [4].



Figure 1: Significance of Pharmacovigilance

II. ADVERSE DRUG REACTIONS - Adverse Drug Reactions (ADR) occur when prescribed medications cause harm to patients at a standard dose **[5].** A side effect is not the same as a negative pharmacological reaction. The evaluation of ADRs is a fundamental skill in the field of pharmacovigilance.

In terms of advertised remedies, an acceptable definition of an adverse drug reaction is as follows:

1) *Unanticipated/Unlisted Adverse Drug Reactions (ADRs):* An adverse drug reaction (A.D.R.) is the nature or severity of medication that isn't consistent with the relevant drug information available at the time of clinical studies [5]. The organization requested assistance during the distribution of agents' booklets for an unapproved medicine. A summary of the medication information sheet for an authority item.

2) *Expected/Recorded Adverse Drug Reactions (ADRs):* Data on adverse drug reactions (A.D.R.s) such as the nature, seriousness, and specificity of the medicine are now recorded [6].

CLASSIFICATION OF ADVERSE DRUG REACTIONS:

a) Type A - Expanded (augmented) pharmacological effect: These are predicted effects that are dosedependent; these effects are the result of overstated pharmacological consequences. These side effects (type A) are widespread and dose-dependent, and they can frequently be avoided by using dosages that are appropriate for the individual patient.

b) Type B - Unusual effects (idiosyncratic or bizarre): These are unanticipated effects that are dosage unrelated (Patient reactions) and often occur in a small number of patients with few or dose-independent linkages. These consequences (category B) are rare and unpredictable.

c) Type C - These side effects are long-term and refer to pharmaceutical use for unknown reasons, which increases the recurrence of a "spontaneous" sickness. These consequences (Type C) are both prevalent and serious (much like cancer) and can have a negative impact on overall health. These effects are unintended and generally related to the effects of extending the haul.

d) Type D - These effects include delayed onset (dose unrelated) carcinogenic effects (for example, immunosuppressant) and teratogenic effects (for example, fetal hydantoin syndrome).

e) Type E - The treatment's impact has ended.

f) Type F - Therapy failure.

REPORTING OF ADVERSE DRUG REACTIONS - When an unpleasant reaction to a medicine is possibly genuine or clinically significant, all medical care workers, including experts, chemists, attendants, and other health care providers, are mentioned to demonstrate it. It is critical to report adverse drug reactions to pharmacovigilance.

- a) Regionalization of the Spontaneous Reporting System.
- b) Recovery of extra information.
- c) Access to extremely valuable pre- and post-marketing data.
- d) Exact medicine usage details.
- e) A standardized assessment of causation and significance.
- f) Persuasion/Encouragement [7]

III. DEFINITIONS:

- Absolute Risk: The probability of an event affecting members of a specific population (e.g. 1 in 1,000) in a population of exposed people. Absolute risk can be calculated over time (incidence) or at a specific point in time (prevalence).
- *Adverse Event* (*AE*): Any unfavorable medical occurrence that may occur during treatment with a pharmaceutical product but is not necessarily related to the treatment.
- Adverse Drug Reaction (ADR): A noxious and unintended response to a medical product that occurs for doses normally used in humans for disease prevention, diagnosis, or therapy, or for the modification of a physiological function.
- Attributable Risk: This is the difference between the risk in an exposed population (absolute risk) and the risk in an unexposed population (reference risk). An absolute comparison of outcome frequency measurements, such as incidence, yields attributable risk.
- *Effectiveness vs. Risk:* A quantitative assessment of the merit of a medicine used in routine clinical practice is the balance of a medicine's rates of effectiveness versus the risk of harm. The most useful information is comparative information between therapies. This is more useful than pre-marketing efficacy and hazard predictions, which are limited and based on selected subjects.
- *Pharmacovigilance:* The science and activities concerned with the detection, assessment, comprehension, and prevention of adverse effects or other drug-related problems.
- **Relative Risk:** Relative risk is defined as the 'ratio of the risk in an exposed population (absolute risk) and the risk in an unexposed population (reference risk)'. Relative risk is the result of a comparison of outcome frequency measurements, such as incidences.
- **Risk:** The likelihood of harm being caused; the likelihood (chance, odds) of an occurrence [8].

IV. RESPIRATORY TRACT DISEASES

Respiratory tract diseases are disorders that affect the respiratory system's components, such as the nasal passages, bronchi, and lungs. They include everything from acute infections like pneumonia and bronchitis to chronic illnesses like asthma and chronic obstructive lung disease. Any disease or dysfunction of the airways and lungs that affects human respiration is referred to as a respiratory ailment. Respiratory system diseases can affect any of the structures and organs involved in breathing, including the nasal cavities, pharynx (or throat), larynx, trachea (or windpipe), bronchi and bronchioles, lung tissues, and respiratory muscles of the chest cage.



Figure 2: Pneumonia and Lungs (source- https://www.mayoclinic.org/diseases-conditions/pneumonia/ symptoms-causes/syc-20354204)

1. Pneumonia - Pneumonia is an illness that causes the air sacs in one or both lungs to become inflamed. The air sacs may become clogged with fluid or pus (purulent material), resulting in phlegm or pus cough, fever, chills, and trouble breathing. Pneumonia can be caused by a variety of species, including bacteria, viruses, and fungus. The severity of pneumonia can range from minor to life-threatening. It is especially dangerous for newborns and young children, persons over the age of 65, and those who have health problems or compromised immune systems [9]. *Streptococcal pneumonia* (also known as pneumococcal pneumonia) is the most prevalent form of the disease (**Fig. 2**). This type of pneumonia starts quickly with a high fever and severe malaise, then resolves naturally in survivors over several days or more. Pneumonia caused by *Klebsiella pneumoniae* infection can be difficult to treat and typically manifests as a series of bouts of pneumonia, each lasting a long time and resolving slowly.

2. Tuberculosis - *Mycobacterium tuberculosis* is the bacteria that causes tuberculosis (TB). TB germs often attack the lungs, but they can attack any region of the body, including the kidney, spine, and brain (**Fig. 3**). Not everyone infected with tuberculosis becomes ill. As a result, there are two TB-related conditions: latent tuberculosis infection (LTBI) and TB illness. TB disease can be lethal if not treated appropriately.





(Source-https://my.clevelandclinic.org/health/diseases/11301-tuberculosis)

Tuberculosis treatment is determined by whether an individual has tuberculosis infection or tuberculosis illness. Streptomycin was the first anti-tuberculous medicine to be clinically successful; nevertheless, it is now only used on occasion. Isoniazid (iso-nicotinic hydrazide) is used to treat the majority of tuberculosis infections. Typically, treatment lasts six to nine months. In the treatment of active tuberculosis, the combination of isoniazid, rifampin, pyrazinamide, and ethambutol is frequently used for six months to a year.

3. Asthma - Asthma is distinguished by spasmodic contraction of the smooth muscle of the airways, increased production of an excessively viscous mucus by bronchial mucous glands, and, in severe cases, airway obstruction due to mucus accumulation in the bronchial tree. As a result, breathing may become more or less difficult. When you breathe regularly, the muscles around your airways relax, allowing air to flow freely and softly (**Fig. 4**). Three things can happen during an asthma attack:

- **Bronchospasm:** occurs when the muscles surrounding the airways constrict (tighten). When they contract, your airways narrow. Through restricted airways, air cannot move freely.
- **Inflammation**: The lining of your airways swells. Swollen airways restrict the amount of air that enters and exits your lungs.
- **Mucus production**: Your body produces more mucus during an attack. This thick mucus obstructs the airways.



Figure 4: diagram shows that left part of lung is normal and right part is affected with asthma

(source-https://www.shalby.org/knowledge-resource/asthma-triggers-and-precautions/) A severe acute asthmatic attack is distinguished by acute difficulties breathing in which mucus plugs the air passageways, allowing air to be inspired but not expelled. Despite serious respiratory difficulties, the patient is fully aware. *Status asthmaticus* is the most-deadly type of the illness. The bronchial spasm intensifies over several hours or over the course of a day, causing the bronchi to get clogged with thick mucus and airflow to become increasingly restricted.

4. Chronic obstructive pulmonary disease (COPD) - COPD is a general term for a set of disorders that induce irreversible respiratory damage by growing airflow obstruction across the bronchi of the lungs. This illness affects around 210 million people globally and is more common in current or previous regular cigarette smokers (**Fig. 5**). The World Health Organization estimates that COPD accounts for 5% of all deaths worldwide. COPD is often comprised of two components, both of which may be present to variable degrees: chronic obstructive bronchitis and pulmonary emphysema. Individuals with emphysema suffer symptoms that differ from those with chronic bronchitis in detail; yet, both conditions contribute to shortness of breath during exertion and general impairment.



Figure 5: Diagram shows two diseases under COPD; chronic bronchitis and emphysema (Source- https://www.halodx.com/lung/copd/)

5. Chronic bronchitis - Chronic bronchitis' chronic cough and sputum production were once dismissed as "smoker's cough," with no major consequences. Breathing filthy air (especially in areas with unregulated coal burning) may promote the growth of mucous cells and the development of chronic bronchitis. The alterations are not limited to the major airways, despite the fact that they produce the primary symptom of chronic sputum production. Smaller bronchioles undergo obliteration and inflammation as a result of changes. All of these alterations, if severe enough, can cause disruptions in the distribution of ventilation and perfusion in the lung, resulting in a decrease in arterial oxygen tension and an increase in carbon dioxide tension.

6. Pulmonary emphysema - This incurable illness causes alveolar wall disintegration. It is classified into two types: centrilobular emphysema, in which the destruction begins in the lobule's centre, and pan-lobular (or pan-acinar) emphysema, in which alveolar damage occurs in all alveoli within the lobule at the same time. Centrilobular emphysema is the most prevalent type of emphysema seen in cigarette smokers, and some experts feel it is exclusive to smokers. Pan-acinar emphysema can occur in smokers as well; however, it is the sort of emphysema that is typically observed in patients' lower lobes. Pulmonary emphysema is a long-term lung disease. It is a kind of COPD, which is a group of lung illnesses that produce airflow obstruction and breathing difficulties. It evolves slowly over time. It is most commonly caused by smoking. It causes shortness of breath, which often worsens with exertion, as well as a variety of other symptoms such as wheezing, coughing, anxiety, and heart difficulties. The injured lung tissue cannot be repaired or regrown. The goal of treatment for persons with pulmonary emphysema is to make them more comfortable, regulate their symptoms, and keep the condition from worsening.

SIDE EFFECTS OF RESPIRATORY DISEASES TREATMENT

- Sore mouth or throat
- Reflex cough or tracheal (windpipe) spasms
- Reduced bone density in adults
- Impaired growth in children
- Increased nervousness
- Insomnia in children
- o Nausea
- o Fever
- o Bronchospasm
- Vomiting
- Headache
- o Pain
- Dizziness

- o Cough
- Allergic reaction
- o Sweating/Chills
- o Dyspepsia
- o Unexplained loss of appetite
- Persistent tingling, numbress, or burning of hands or feet
- Persistent weakness
- Fatigue
- Blurred vision or changed vision
- Oral infections
- o Hoarseness
- o Excess phlegm or sputum

EPIDEMIOLOGY

India is a vast country with a hugely diversified population. India has 18% of the world's population and is seeing an increase in the prevalence of chronic respiratory diseases. There are considerable geographical, environmental, ethnic, religious, cultural, and social differences in India that affect human health and sickness occurrence. Respiratory infections are the third largest cause of death in both developed and developing countries. Acute respiratory infections (ARI), particularly lower respiratory tract infections (LRTI), are the leading cause of morbidity in children under the age of five, killing an estimated two million children worldwide **[10].** Respiratory diseases account for one-fifth of all under-five mortality in developing countries, equating to around 12 million deaths per year. Bangladesh, India, Indonesia, and Nepal are expected to account for 40% of global respiratory illness mortality. ARI is responsible for around 30-50% of health-care visits and 20-40% of hospital admissions.

Chronic respiratory disorders (CRDs) impair the lungs' airways and other structures. Chronic obstructive pulmonary disease (COPD), asthma, occupational lung disorders, and pulmonary hypertension are among the most frequent. Other risk factors, in addition to tobacco smoke, include air pollution, occupational toxins and dusts, and repeated lower respiratory illnesses throughout childhood. Although CRDs are not curable, several forms of treatment that help open the airways and relieve shortness of breath can help control symptoms and enhance everyday life for persons living with these disorders. The objective of the WHO Global Alliance against CRDs (GARD) is "a world in which all people can breath freely." GARD is concerned with the needs of persons living with CRDs in low- and middle-income countries **[12].**

In 2017, over 808 000 children under the age of five died from pneumonia, accounting for 15% of all pediatric mortality. Adults over the age of 65, as well as those with pre-existing medical issues, are at risk of pneumonia. Acute respiratory infections in children under the age of five are the largest cause of lung disease death worldwide, accounting for about 4 million deaths each year. Tuberculosis is the leading single pathogen-related cause of death in people aged 15 to 49 years (causing 2 million to 3 million deaths each year). Respiratory infections are the most prevalent consequences of immune weakness [13].

V. METHODOLOGY OF SURVEY

Aim: Survey on Adverse effects of therapies and medications given to respiratory tract diseases patients in Delhi NCR Region and approaches for management of these adverse drug reaction in patients.

Objective:

- Prepare of Questionnaire
- Direct interaction with patients suffering with respiratory diseases
- Usage of "Vigiaccess.org" software for Adverse Drug Reactions worldwide data

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We have successfully completed our survey on 50 Patients in the hospitals of Delhi-NCR Region, India during February 2023 to April 2023. The project was carried out at various hospitals viz. Ram Gopal Healthcare clinic, Muradnagar, Surya hospital, Muradnagar, Tuberculosis District Hospital, Ghaziabad, District Hospital, Ghaziabad. A questionnaire was prepared via thorough literature search and approved by the institutional committee. The purpose of survey questionnaire was explained in detail to the participants. Further interaction with patients was carried out physically and telephonically along with the follow up process. The participants filled the questionnaire with or without the help of authors. Patients demographic details like patient initial, age, sex, medication history, Adverse Drug Reactions, etc. was recorded and analyzed.

SURVEY QUESTIONNAIRE OF PATIENTS SUFFERING FROM REPIRATORY TRACT DISEASES AND THEIR PRESCRIPTIONS

I. KNOWLEDGE 1. Awareness/ Knowledge about their disease. No Yes 2. Knowledge about the mode of treatments. Yes No **II. ATTITUDE** 3. What type of respiratory condition is being treated? b. ASTHAMA c. T.B. a. COPD d. OTHERS 4. Length of time using current medication for respiratory tract disorder a. Less than 3 months b. 3-6 months c. 6-12 months d. More than 12 months 5. Prescription of medication effectiveness in managing respiratory condition a. Satisfied b. Very much satisfied c. Not-satisfied 6. Use of alternative treatments for respiratory conditions b. Homeopathy c. Yoga a. Ayurveda d. Exercise **III. PRACTICES** 7. Have you ever experienced any adverse effects from your medication? No Yes 8. Frequency of forgetting to take medication a. Never b. Rare c. sometimes d. Often 9. History of hospitalization for respiratory tract problems a. Once b. Twice c. Others 10. Use of emergency inhaler for sudden breathing problems No Yes **11. Smoking frequency and status** a. Regular Smoker b. Occasional d. Never e. Former Smoker c. Rarely 12. Presence of other medical conditions or medications that may interact with respiratory medication No Yes 13. Presence of other health problems Hypertension Cardiovascular Disease Pregnancy Glaucoma Others 14. History of changing or stopping medication without consulting the healthcare provider No Yes **IV. DEMOGRAPHICS AND MEDICAL HISTORY** 15. Family history or environmental factors contributing to the respiratory condition Family History Environmental conditions 16. Preferred dosage form (tablets/capsules, injections, inhalers) 17. Types of diagnostic tests undergone a. X-RAYS b. Blood Tests c. Sputum test d. CT Scan e. MRI f. Others 18. Use of other drugs beyond prescribed medications

Yes No

Specify/Adverse effects

VI. ANALYSIS OF SURVEY QUESTIONNAIRE

We had a total of 50 subjects in our study with a male: female ratio of 28:22. As **Fig. 6** shows, out of the 50 patients we accessed, there were **28 males** representing 56% of the total participants and **22 females** contributing **44%** of the total subjects.



Figure 6: Pie Chart showing the proportion of males and females of the survey

We have been come through in this survey that there was a large difference in maximum and minimum age. The mean age of the subjects was **47 years**, ranging between 0 to >75 years. As **Fig. 7** shows, of 50 Patients majority of the subjects (**44%**) suffering from major respiratory diseases comes under the range of **41-60** years.



Figure 7: Graph showing the age group of patients

1. Do patients have knowledge about their disease and mode of treatment?

As in question no. 1 of our questionnaire, we come to know that 36 patients have knowledge about their disease and mode of treatment.



Figure 8: Chart represents knowledge about disease and treatment

2. What type of respiratory condition is being treated?

Here we consider mainly 3 diseases. These are Asthma, COPD, T.B, and the remaining diseases were considered as others. Through this we came to know that there are 8 patients suffering from COPD, 12 with asthma, 10 with T.B., and remaining in others like pneumonia, bronchitis, emphysema etc. covers about 20 patients.



Figure 9: Chart represents respiratory diseases considered in survey

3. Length of time using current medication for respiratory tract disorder?

In this question we consider the time period of treatment i.e. since when the patient is undergoing treatment and we observed that some patients are taking treatment for less than 3 months, 3-6 months and some of them are taking treatment for more than 12 months.

4. Prescription of medication effectiveness in managing respiratory condition?

In response to this question, we divided a few classes of effective treatment i.e. the patient is satisfied, very much satisfied or not satisfied with the treatment. We observed that most of the patients were satisfied with their treatment.

5. Use of alternative treatments for respiratory conditions?

In this question we take alternative treatments like Ayurveda, homeopathy, yoga, exercise and not taking any treatment. Under this we came to know that most of the patients were not taking any other alternative treatment while few of them taking Ayurveda treatment (8%), homeopathy (12%), exercise (2%).



Figure 10: Alternative treatment methods

6. Have you ever experienced any adverse effects from your medication?

In this question we discussed with the patients that how their health is, after taking medication. Most of the patients are not aware about the adverse effects, they consider adverse effects as their part of disease. We found that about 39% were not suffering from any adverse effects, few patients told about effects which were not very dangerous.

7. Frequency of forgetting to take medication?

In this question, we created the levels for measuring the frequency of forgetting medications, these are never, rare, sometimes, often and we found that most of the patients were take their medicines on time but a few patients forgot to take medications or we can say that rarely forget.

8. History of hospitalization for respiratory tract problems?

Here, we discussed the hospitalization of the patients in terms of number of times they were admitted to the hospital, the answers were noted once, twice or more than twice. As a result, we found that most of the patients were admitted to the hospital one or more times.

9. Use of emergency inhaler for sudden breathing problems?

In response to this question, we come to know that inhalers are used in emergency by patients who have severe breathing problems. Here we found that 8% of the patients used emergency inhalers and 42% patients did not use inhalers.

10. How often patient is smoking?

Here, we discussed about the frequency of smoking, that is how often patients are smoking. It can be measured as 5 points i.e. regular smoker, sometimes, occasionally, never, Ex-smoker and we found that 10 patients rarely smoke, 32 never smoke and 8 patients were former smokers.



Figure 11: Frequency of smoking

11. Presence of other health problems/other conditions?

In response to this question we interacted with the patients and discussed whether they have any other health problems apart from respiratory diseases, as a result we found that 7% of patients are suffering from hypertension, 6% are suffering from heart disease, 4% are suffering from diabetes and another 5% women were pregnant.



Figure 12: Graph represents alternative diseases or health problems

12. History of changing or stopping medication without consulting the healthcare provider?

We found that approximately 45 patients did not change or discontinued medication without consulting a healthcare provider, while rest 5 changed medication without consulting a doctor or healthcare provider, which is not good for patient's health.

13. Family history or environmental factors contributing to the respiratory condition?

We discussed with patients about their family or environmental history of respiratory illness from which they are suffering. As a result, we come to know that majority of patients do not have any family history i.e about 35 patients have environmental history and remaining 15 have family history.

14. Preferred dosage form?

After interaction with patients we got the result that around 30 patients were taking combination of tablet and capsule, other taking combination of tablets, capsule, injection i.e. 42% and remaining 8% using inhalers.

15. Types of diagnostic tests undergone?

The tests we include in our questionnaire are X-rays, blood tests, sputum tests, CT scan, MRI and other tests. As a result, we found that 12% of the patients have done X-rays, 15% for blood tests, 11% for sputum tests and another 12%.



Figure 13: Graph represents diagnostics tests performed on patients

17. Use of other drugs beyond prescribed medications?

Here, we discuss with the patients about whether they are taking any other medications apart from the medications prescribed by doctor. We found that some of the patients were taking medications before the treatment started.

VII. RESULT AND DISCUSSION

Out of 50 patients we found that most of the patients are taking some similar medicines for the treatment of their particular diseases which is Asthma, COPD, TB, Bronchitis, Emphysema, Pneumonia and others. We listed the drugs that are most often prescribed to patients with respiratory diseases, *viz.* Salbutamol (12) followed by Azithromycin (10), Theophylline (7), Isoniazid (8), Budesonide (4), Tiotropium (9) as shown in Figure 10. These six drugs comprise more than 50 % out of other respiratory drugs prescribed by doctors.



Figure 14: Graph represents most prescribed drugs in respiratory diseases

With the reference of "*Vigiaccess.org*" which is maintained by the Uppsala Monitoring Centre (**Programme of WHO**), we studied the number of ADRs recorded globally of above mentioned six common respiratory drugs of our study. As shown in **Fig. 15**, the total number of records obtained globally for Salbutamol is highest i.e., 90916 in number followed by Azithromycin (4955), Theophylline (13413), Isoniazid (57180), Budesonide (28561), Tiotropium (74887).





By taking the reference of *Vigiaccess.org*, we listed out the six types of ADRs that are reported most of the times for the most prescribed drug in our study i.e., Salbutamol which shows, Cardiac disorders : (9661), Gastrointestinal disorders: (6603), Skin and subcutaneous tissue disorders: (5822), Nervous system disorders: (13530), Eye disorders: (1614), Psychiatric disorders: (5056) & Respiratory, thoracic and mediastinal disorders: (22426), as shown in **Figure 16**.



Figure 16: Different types of ADRs of Salbutamol recorded globally

Similarly, we listed out the recorded numbers of the same ADRs of our remaining five major drugs i.e., Azithromycin, Theophylline, Isoniazid, Budesonide, Tiotropium The number of the same ADRs as of salbutamol recorded for other drugs are shown in **Figures 17, 18, 19, 20 and 21** separately.







Figure 18. Different types of ADRs of Theophylline recorded globally



Figure 19. Different types of ADRs of Isoniazid recorded globally







Figure 21: Different types of ADRs of Tiotropium recorded globally

Comparative Study Results: We compared the Respiratory drugs that we listed out against the Adverse Drug Reactions that are common in all of them as shown in **above figures** and some of the interpreted results are, Cardiac disorders; Psychiatric disorders; Nervous system disorders; Respiratory, thoracic and mediastinal disorders are more in number for Salbutamol, Skin and subcutaneous tissue disorders; Gastrointestinal disorders are more in number for Azithromycin &Eyes disorders are more in number for Tiotropium. Theophylline and isoniazid have the lowest number of ADRs in each category which is probably due to being less prescribed in comparison to other drugs.



Figure 22: Comparative study among six most commonly prescribed respiratory drugs and their ADRs

VIII. CONCLUSION

For improved therapy, the majority of respiratory tract medicines were administered in combination. Salbutamol was the most commonly recommended respiratory tract medicine we saw in our survey. Respiratory, thoracic, and mediastinal diseases were the most often encountered ADRs. The most prevalent side effects were shakiness, headache, vomiting, and restlessness (appetite loss). Because these are preventable, there is a need to enhance the management of these adverse effects, as the rates of prevention were low. The existence of co-administered medicines and the causation of side effects was low in the current investigation. Vigilant ADR monitoring is required to reduce morbidity and death owing to ADRs, which necessitates larger-scale research. To improve our understanding for the nature and impact of ADRs, measures to improve detection and reporting should be implemented. Pharmacists can increase medication safety and help health care workers provide better patient care by utilizing the ADR monitoring and reporting system. The ADR monitoring approach aids in the development of better prescribing habits for the safe and effective use of respiratory tract medicines. This may improve patients' quality of life.

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