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Survey on Patient Assistance Programs for Auto-Immune Disease Patients

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Abstract: Auto-immune diseases are one of the greatest health challenges of our time, and a leading cause of death in every corner of the world. Currently, around 40 % of all deaths occur due to auto-immune diseases in developing countries. Proper treatment is one of the major and important aspect in the medical industry. Many pharmaceutical industries have various programs in developing countries for tackling the costs of care. Treatment is only one aspect. Many patients are unable to afford the costs of the medications and hence treatment becomes difficult. There are many patient assistance programs by the pharmaceutical companies to ease the financial burden on such patients. PAPs are a diverse collection of programs that vary in how they obtain funding, what steps they take to ease the burden and how these steps are implemented. Sadly, not many patients are aware of these programs due to lack of knowledge and awareness by the pharmaceutical companies and the medical practitioners. These programs are underused, inexpensive methods to tackle the financial obstacles of treatment and care. The patients can be made aware of these programs by campaigns and awareness programs. Surveys and studies have shown that most of the patients are in need of an assistance program for their treatment. Pharmaceutical companies have specific criteria for offering their assistance programs, which include the financial status of the patient, age and the severity of the disease. The surveys were done using electronic reviews, telephonic surveys, asking patients and pharmaceutical companies with specifically designed questionnaires. Most of the companies base their eligibility of the PAP on basis of income. Many companies are not willing to disclose their income criteria. If more companies take part in the PAPs, it will be a very beneficial move towards the treatment of patients in the country.

Keywords: Auto-immune, PAP, survey, eligibility criteria

1. Introduction

1.1. What are auto-immune diseases?

Auto- immune diseases are those in which the immune system starts attacking one's own healthy cells in the body. In normal circumstances, the cells of the immune system detects foreign invaders such as bacterias, viruses and other types of micro-organisms [5]. There are various types of auto immune diseases. Some only affect a single organ in the body whereas some can spread throughout the body. Some examples of auto immune diseases are type 1 diabetes which only affects the pancreas whereas Immune thrombocytopenia purpura (ITP) affects the platelet count. There still isn't a specific explanation of the occurrence of auto-immune diseases [5]. But some diseases run in families which indicate that there may be some genetic factors associated with it. It is also seen that some diseases more prevalent in some ethnic groups and geographical locations [5]. There are more than 80 different types of auto immune diseases. Rheumatoid arthritis is one of the most commonly occurring diseases. ITP is a relatively more rare disease but it is a very fatal disease and can cause loss of life of the patient.

1.2. Immune thrombocytopenic purpura (ITP)

Immune thrombocytopenic purpura (ITP) is a disorder in which the immune system destroys platelets present in the blood which are necessary for blood clotting. Due to this, the patients have very less amount of platelets and as a result they bleed intensively [9]. ITP is a type of autoimmune disease in which the immune system produces antibodies against one's own cells. The antibodies attach to the platelets. The body destroys the platelets that carry the antibodies. In children, the disease sometimes follows

a viral infection. In adults, it is more often a long-term (chronic) disease and can occur after a viral infection, with use of certain drugs, during pregnancy, or as part of an immune disorder. Currently, around 65% of all ITP deaths occur in low- and middle-income countries and this figure is rising [9]. Although high-income countries continue to have the highest overall incidence rates, the figures are either increasing or decreasing. This is largely due to decreases in known risk factors, early detection rates and improved treatment.

People suffering from this disease often have purple bruises on the skin or in the mucous membrane of the mouth. These purple bruises are called purpura. These bruises may also appear as pinpoint-sized red or purple dots on the skin called petechiae [9]. Petechiae often look like a rash. ITP can occur in both children and in adults. It's occurrence shows a link between ages in men and women. At an early age, it is more common in women whereas in older ages, it is more common in men. Children can suffer from this disease due to occurrence of viral illness. There are two main types of ITP, acute and chronic. Acute is short term which usually lasts less than six months [9]. Chronic can last for more than six months to years. ITP is generally classified as secondary i.e. it occurs alongside a different condition.

ITP can be diagnosed by a complete blood count test. If the platelet count is low, a bone marrow test is also advised. If the platelet count in the bone marrow is normal, it indicates that you have ITP. This is because, the platelets are destroyed in the spleen and bloodstream after they leave the bone marrow by the immune system. Acute ITP generally does not require treatment. If the bleeding is serious and the platelet count is dangerously low, doctors prescribe medications to avoid this bleeding. The medications for ITP involve, corticosteroids, intravenous

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immunoglobulin (IVIg), Rituximab, Thrombopoietin receptor agonists and general immuno-suppresants [9]. The treatments used are quite expensive and cannot be afforded by the general population at all times.

1.3. Rheumatoid arthritis

Rheumatoid arthritis is a chronic disease which causes pain and inflammation of joints. The symptoms of RA can be seen beyond painful joints. Some of the symptoms include fatigue, weight loss, fever and bumps under the skin [5]. One complex aspect of RA are the flares. Flares are severe episodes of symptoms which are quite painful. The flares may be excess of any symptom but most commonly stiffness and pain in the joints [5]. The pain and duration of the flares vary every time. Diagnosis of RA can be done by several tests. The medical practitioner looks for swelling and redness of joints, checking for tenderness and warmth of affected joints [1]. Blood tests are also conducted to check if there are any elevated levels of antibodies. Imaging tests also reveal if there is any damage occurred to joints. There are mainly three types of RA.

• Seropositive RA

If the blood test for rheumatoid factor is positive, it indicates that the patient has antibodies that cause the immune system to attack the joints.

• Seronegative RA

If the blood test is negative for rheumatoid factor and anti-CCP, but you experience the symptoms of arthritis, it indicates that the antibodies may result to start attacking the joints, resulting in seropositive RA.

• Juvenile idiopathic arthritis(JIA)

JIA is the type of arthritis which occurs in children who are of age 17 years or younger. In addition to the symptoms of RA, the patients also experience eye inflammation and problems with physical development.

Rheumatoid factor test, Antinuclear antibody test, C-reactive protein test are some of the blood tests used to diagnose rheumatoid arthritis. There is no cure for rheumatoid arthritis at present [3]. Medications can be used to ease the pain. Non-steroidal anti- inflammatory drugs, corticosteroids and acetaminophen are the types of medications used [1]. The cost of medications is quite high for the general population [3]. The expense is roughly \$ 1000 to \$3000 per month. This expense cannot be afforded by everyone and hence there is a need for PAP and awareness programs initiated by the pharmaceutical companies [3].

1.4. Role of pharmaceutical companies in PAP

In strengthening the care continuum in LMCs, pharmaceutical companies have a unique role to play: they have the ability and opportunity to improve the accessibility and affordability of the ITP treatment

products they produce in ways that meet the specific needs of people living in developing countries. In addition, such companies can provide locally tailored capacity building activities that address different stages of the care continuum, working on their own or with partner organizations. They can also support infrastructure development, or provide other forms of financial or onthe-ground support [2]. Many initiatives include projects to raise awareness and reduce the misconceptions and fear of auto immune diseases like ITP as well as RA. To ensure that the population receives best medical care, some pharmaceutical companies offer patient assistance programs to help ease the financial burden of the patients [2]. These PAP are completely voluntary and the companies have a certain eligibility criteria for recruiting patients for the program. The companies contact healthcare professionals who can then contact patients for applying for the programs. The patients can also contact the pharma companies themselves through helpline numbers and websites [3]. The patients need to fill out the form provided on the company websites or given by the companies in case of manual applications. Some companies also provide discount cards which are provided to the patients wherein they get a certain amount of discount for the medications. Some discounts are based on the income of the patient whereas others follow the income criteria set by the companies [3].

2. Literature Review

2.1 Background of Patient Assistance Programs

Patient assistance programs are offered in developed countries under the insurance policies set by the government. Majority of the PAP are for cancer patients as it is a very serious disease and the cost of cancer care is very financially burdensome. There are PAP available for other diseases too. Many types of copayment policies are also a type of PAP. The cost of ITP care is also on the higher side of the financial spectrum. Many clinical trials conducted are also a form of PAP as the medicines and care provided during the trials is all bore by the company which is conducting the trial. The patients are majorly attracted by these policies for better care. These policies have a certain criteria to enroll patients for the programs. These criteria differ from company to company [3]. The main criterias include income of the patients, diagnosis/medical criteria, insurance status, etc. The application process also differs for each company. The supply of the medicine is based on the availability and the cost of the drug. According to surveys conducted, more than 300 drugs are associated with PAP and pharma companies spend about \$4 billion each year on these programs [8]. The funding of patient assistance programs by companies is an attempt to blunt the impact of drug copayments and coinsurance.

2.2 Challenges in PAP

Many a times, patients are unaware of the programs due to lack of knowledge and availability of the means of information. Due to this, the patients avoid the use of expensive medicines and hence medical care gets affected

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in the country. This is a major loss for the patients and healthcare professionals. Also, the companies take advantage of these programs and increase the prices of the drugs. They take advantage of the insurance policies. In many countries, majority of the general population is underinsured and cannot avail higher quality of medicare.

Promoting the programs to penetrate in the general population can be challenging for both physicians and patients. Also, it is a bit difficult to identify the disease and search for the patient assistance program available for it. Many people, though financially stable, take advantage of these programs. Due to this, the person who is actually needy is left out from the program. Many healthcare professionals also feel that copay assistance and PAP are a band-aid solution to the problems faced by the patients. This ignorance and inadequacy of knowledge hampers medical care. The other main problem is obtaining the consent of the patients [10]. These programs cannot be forced on individuals by anyone. There should be complete disclosure of the motives, processes and information about the companies so that the patient understands that his/her care will be in good hands of the physician specialties. Many a times, patients though financially stable, opt for PAP programs and this results in the patients really in need of the program to be left out. This decreases overall use of the available medications for patients due to high costs.

2.3 Purpose of PAP

The main purpose of PAP is to improve the survival chances and quality of life after the disease is diagnosed for the patient as well as his/her loved ones. The understanding that copay, palliative and assistance programs are most effective when used at the early stages of the treatment of disease can lead to a better development of healthcare model for the country. Assistance programs are a boon for manufacturers [8]. They result in the increase of demand, give permissions to companies to charge higher prices and provide publicrelations benefits. Some companies have one or more access initiatives addressing pricing [12]. Many of these are organized in patient access or support programmes (PAPs and PSPs), which generally provide some form of discount or donation directly to patients enrolled in the programme [8]. It was seen that India has the most number of initiatives launched by companies. This helps to vastly improve treatment and healthcare.

3. Aims and Objectives

3.1 Aim

To find out about the patient assistance programs offered by the pharmaceutical companies for Immune Thrombocytopenia purpura and Rheumatoid arthritis patients in India.

3.2 Objectives

- To conduct online surveys and questionnaire with companies through helpline numbers and patients respectively to obtain the required data.
- To spread awareness about the existence of patient assistance programs among the general population to help improve the quality of treatment and care.
- Conduct general survey to know the level of awareness in the society.

4. Materials and methods

For this research study, surveys were conducted with pharma companies to collect data and establish a database. Questionnaires were also prepared and data from patients was obtained electronically [8]. The questionnaires used specifically contained the name of the disease, the drug provided and the criterias for the enrollment in the program.

4.1 Survey methodology

In the surveys conducted, telephonic methods and electronic mediums such as sending official emails was carried out. The toll free numbers of the PAP helpline was obtained through online means. The companies responses were recorded and noted in the personal diaries for future use. The questions asked to the companies were strictly official and a dedicated questionnaire was prepared for this purpose [8]. The questionnaire included the following questions:

- What is the means by which patients can contact the pharma companies?
- What is the criteria set by the companies by which patient enrollment is carried out?
- Are there any geographical barriers set by the manufacturers and companies for the patients?
- Is there any specific cap of subsidized amount set for the drugs?
- On what basis is the amount set for the drug provided?
- Can the company exclude the patient from the program if it sees any violations of the use?
- Is it necessary for the patients to have medical insurance?
- Can healthcare professionals contact the companies on behalf of the patients?
- Is it necessary for the patient to physically come and collect the drug?
- Is a healthcare professional's permission necessary to avail the schemes and benefits of the program?

The survey conducted with patients also had a questionnaire to ease the data collection process.

The patient's identity and confidentiality was maintained throughout the research study.

The questionnaire included the following:

- Name of the disease
- Company offering the PAP
- Eligibility requirement for the enrollment in the program

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- Duration for which the PAP is provided (if any)
- Application process to enroll
- Subsidized amount
- Contact no. of the company

The patient database was obtained through healthcare professionals and hospitals which treat ITP. The patients were contacted by telephonic methods and electronic medium. Some patients were given the questionnaire through messaging applications such as whatsapp. Patient convenience was taken care of during the whole conduct of the study and confidentiality was maintained.

All the companies have their individual forms to be filled by the patients to enroll in the patient assistance programs. The form contains various questions in the form of checklist which is essential for the companies [6]. These checklists make sure that the patient fits in the criterion which ensures that the patient is eligible.

The forms contain some necessary fields to be filled by the patient such as their name, date of birth, whether they have any medical insurance, name of the doctor prescribing the medication, their annual income, address and the signature of both the patient and the consulting doctor [7]. Some companies also ask for the name of a representative for the patient in case of any emergencies [7].

4.2 Sample size of the companies contacted

13 companies which offered Patient Assistance Programs based on the list of medications for Immune thrombocytopenia purpura and Rheumatoid arthritis were contacted in total by telephonic and electronic media. The questionnaire was given to them orally on phone or was sent through email. All the companies responded to the calls and emails. Data was successfully gathered and sufficient result was obtained by compiling it. Many drugs were obtained for ITP and rheumatoid arthritis patients and these companies provided the maximum benefits for patients. The eligibility criteria for these companies are also listed down. The eligibility criteria included the following:

- Whether financial income is disclosed or not
- Insurance status of the patient required or not
- Citizenship of the country necessary or not

Based on this, data was compiled. The drugs used in ITP and rheumatoid arthritis were listed down and based on this, PAP under various companies were found out. This list contained both generic and brand name medications used in the medical field and pharmaceutical market.

5. Results

After conducting the survey it was found that many companies offer Patient Assistance Programs for ITP and RA patients in the country [4]. These programs help the patient on a financial scale tremendously. But it was seen that the companies do not disclose these programs on a large scale. The main reason for this is that many patients

take advantage of these schemes even if they are able to afford the medications. The companies take only a limited number of applications at a specific period of time [7]. Due to this, the people who are really in need of the medicines get left out of these schemes. As a result, the patients do not obtain proper care and treatment and the medical status of the country takes a toll. To combat this, the PAP have eligibility criterias set by the companies to screen the patients in need. Some companies have multiple PAP for the diseases. These companies have more or less the same criterias except for the conditions of diagnosis which are prescribed by the physician.

Table 1: List of the ITP medications referred

Sr. no.	Name of the drug
1	Cellcept
2	Rituxan
3	Promacta
4	Nplate
5	Imuran
6	Solu-medrol
7	Winrho-injection
8	Cyclosporine
9	A-hydrocort
10	Neural
11	Millipred
12	Dexamethasone
13	Solu-cortef

Table 2: The medications referred for RA

Sr. no.	Name of the drug
1	Actemra
2	Arava
3	Celebrex
4	Cuprimine
5	Daypro
6	Duexis
7	Enbrel
8	Humira
9	Indocin
10	Kenalog- 40
11	Remicade
12	vimovo
13	Zodex

The following graphs show the companies which provide the max no. of PAP for various drugs which are used in the treatment of ITP and RA:

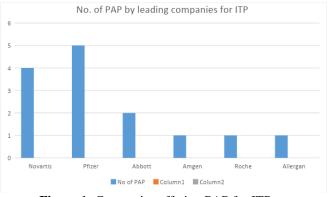


Figure 1: Companies offering PAP for ITP

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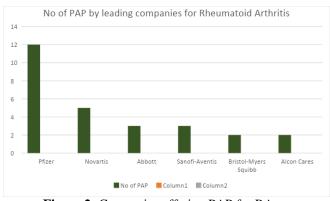


Figure 2: Companies offering PAP for RA

Of all the companies which were contacted, it was observed that many of them did not disclose their income criteria. Majority of the companies required the patient to have insurance as a compulsory eligibility, and many of the companies required the patients to have a citizenship of the country [11].

Eligibility criteria for ITP

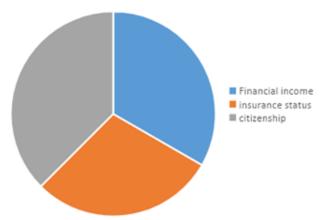


Figure 3: Eligibility criteria of different companies for

Eligibility criteria for RA

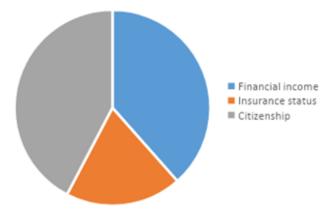


Figure 4: Eligibility criteria of companies for rheumatoid arthritis

During the survey, it was found that many of the patients were unaware of assistance programs. It was seen that when patients were unaware of PAP offered by the companies and when they were informed about it, they

seemed interested in the program after hearing about the details. Many patients were willing to enroll and fill out the forms upon consideration. Some patients were a bit skeptical and said they needed time to reconsider. As you can see, 13 companies for ITP and RA were found to be offering patient assistance programs in India. This shows that there is still a need for awareness and initiative to be taken by companies as well as health care professionals. Out of all the companies contacted, Pfizer and Novartis were the only one which offered the most no. of Patient Assistance Programs for ITP & Pfizer, Novartis and Abbott for RA.

The enrollment process of the companies was found to be quite easy and patient friendly. The language used in the forms provided by the companies was simple and easy to understand besides being straight to the point. This is very important as some patients are not well educated and find it difficult to read. It was also found that these companies have a tie up with some organizations that contact patients who are in need of such programs [7]. The organizations list down the companies according to the disease for which they provide the patient assistance program for. The patients are then redirected to the company's website where they can get all the necessary information and check whether they are eligible to apply for the program.

The leading companies which were included in the survey had a specific set of eligibility criteria which are listed below:

1. Pfizer

The eligibility criteria which were included in the PAP for Pfizer are:

- The patient should have an income less than 200% of the guidelines set by the government for entire household.
- The patient should not be covered by any insurance.
- The patient must have a citizenship of the country.

2. Novartis

The eligibility criteria which were included in the PAP for Novartis are:

- The patient must have a certain undisclosed income to enroll in the program
- The patient must have an insurance
- The patient must have a citizenship of the country

3. Abbott

The eligibility criteria which were included in the PAP for Abbott are:

- The patient must have a certain undisclosed income to enroll in the program
- The patient must be covered by an insurance
- The patient must have a citizenship of the country

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4. Allergan

The eligibility criteria which were included in the PAP for Allergan are:

- The patient should have an income less than 200% of the guidelines set by the government for entire household.
- The patient must be covered by insurance.
- The patient must have a citizenship of the country.

5. Bristol-Myers Squibb

The eligibility criteria which were included in the PAP for Bristol-Myers Squibb are:

- The patient must have a certain undisclosed income to enroll in the program
- The patient must not be covered by an insurance
- The patient must have a citizenship of the country

6. PAN Foundation

The eligibility criteria which were included in PAP for PAN Foundation are:

- The patient should have an income less than 200% of the guidelines set by the government for entire household.
- The patient must be covered by insurance.
- The patient must have a citizenship of the country.

7. Amgen

The eligibility criteria which were included in PAP for Amgen are:

- The patient must have a certain undisclosed income to enroll in the program
- The patient must be covered by an insurance
- The patient must have a citizenship of the country

8. Roche

The eligibility criteria which were included in PAP for Roche are:

- The patient should have an income less than 300% of the guidelines set by the government for entire household.
- The patient must be covered by insurance.
- The patient must have a citizenship of the country.

9. Alcon cares

The eligibility criteria which were included in PAP for Alcon cares are:

- The patient should have an income less than 200% of the guidelines set by the government for entire household.
- The patient must not be covered by insurance.

10. Salix pharmaceuticals

The eligibility criteria which were included in PAP for Salix pharmaceuticals are:

- The patient should have an income less than 200% of the guidelines set by the government for entire household.
- The patient must be covered by insurance.

11. Merck

The eligibility criteria which were included in PAP for Merck are:

- The patient should have an income less than 400% of the guidelines set by the government for entire household.
- The patient must not be covered by insurance.
- The patient must have a citizenship of the country.

12. Sanofi-Aventis

The eligibility criteria which were included in PAP for Sanofi- Aventis are:

- The patient should have an income less than 250% of the guidelines set by the government for entire household
- The patient must not be covered by insurance.
- The patient must have a citizenship of the country.

13. Triax pharmaceuticals

The eligibility criteria which were included in PAP for Triax pharmaceuticals are:

- The patient must have a certain undisclosed income to enroll in the program
- The patient must not be covered by an insurance
- The patient must have a citizenship of the country

6. Discussion and conclusion

The requirement of more number of PAPs in India is the need of the hour. India has a vast population compared to many countries in the world. The amount of PAP currently present in India are unable to reach sufficient amount of population in the country. Many people live in the rural areas and there isn't enough awareness regarding life threatening diseases and their treatment. Since ITP is a genetic disease, it can occur to anyone. The lack of proper resources and treatment leads to death of the individuals. Rheumatoid arthritis is also a very critical disease which causes intense pain. Many individuals do not even know what they are suffering from. This may lead to serious health problems especially in the rural areas where there is a major lack of education. Patient Assistance Programs offered by the companies not only offer medicines and treatment at subsidized cost but also conduct awareness programs to spread the importance of timely treatment and cost of the medications for the respective diseases.

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In today's world, technology plays a major role in our lives. Mobile phones have become an important aspect of our life. Majority of the population has a mobile phone. Connectivity has increased a lot in the past 20 years. The companies and other organizations offering assistance can take advantage of this. Online exposure can result in maximum enrollment by patients and will ultimately benefit the country. The programs offered by the pharmaceutical companies are voluntary and the pharmaceutical companies can decide to withdraw the programs whenever they feel necessary. The government should take steps to initiate such programs by the guidance of the health ministry to improve the quality of life and in turn drive the health of the nation towards a better future.

In the survey conducted, the following results were obtained

1. Majority of people i.e. 70.8 % of the total participants who took part in the survey are unaware about patient assistance programs.

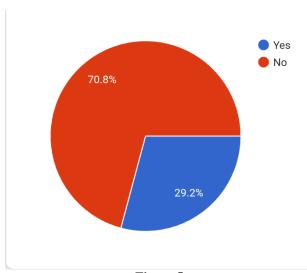


Figure 5

This indicates that there is still a need for PAP awareness in the society. The more awareness there is for PAP in the country, better will be the treatment and care provided to the patients. These programs should be provided by the government especially in India as it is a developing country and the need for such programs is most needed in such countries.

- 2. The people who were aware of the programs, got the information about them majorly through websites. Some of them came to know about the programs through healthcare professionals whereas others got to know from relatives or friends. A small portion of participants got the information from news.
- 3. It was seen from the survey that the participants claimed, they would refer about patient assistance programs to others when asked about the same. Majority of them replied yes whereas a small portion refused.

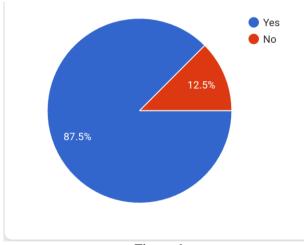


Figure 6

4. When asked if they would be willing to join these programs, 56.9 % were in two minds whether they should join or not. 33.3 % agreed and 9.7 % refused.

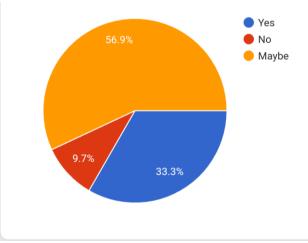


Figure 7

- 5. About 75 % of the participants had health insurance
- 6. When the participants were informed that most companies do not enroll patients with health insurance and were asked whether they would still be willing to join them, 47.2 % responded that they would think over it and could not decide right away. 27.8 % responded that they would not join and 25 % replied with a yes.

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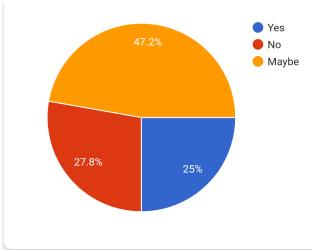


Figure 8

7. Some companies and websites provide discount cards to patients for certain medications. The participants were asked whether they would like to use such schemes. 62.5 % were willing to use them whereas 13.9 % denied. 23.6 % replied that they may consider using them in future.

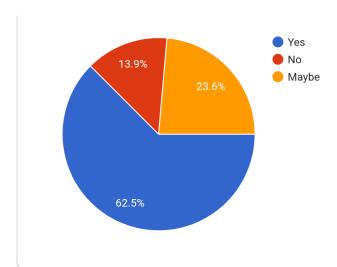


Figure 9

7. Conclusion

As seen from the survey, it is evident that majority of the participants were unaware of PAP. Majority of them had health insurance as the survey was conducted in urban areas where a major part of population is well educated and has medical and health insurance. There are some misconceptions regarding PAPs which need to be cleared by pharmaceutical companies by awareness programs and seminars. If the government takes initiatives it will surely boost the use of PAPs.

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