

Summer Training at



**Plasmagen Biosciences
(March 1, 2013 to June 15, 2013)**

**GAP Analysis - Demand and Supply of Hyperimmune Proteins in the
Indian Plasma Product Industry**

**By
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**Under the guidance of
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**Post Graduate Diploma in Pharmaceutical Management
2012-2014**



**Institute of Health Management Research,
Jaipur
2013**

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CERTIFICATE

This is to certify that **Mr. Mithlesh**, student of Post Graduate Diploma in Pharmaceutical Management from Institute of Health Management Research, Jaipur has undergone summer training on the following topic at Plasmagen Biosciences, Bangalore.

GAP analysis - demand and supply of Hyperimmune proteins in the Indian plasma product industry.

The candidate has successfully carried out the study assigned to him during summer training and his approach to study has been sincere, and analytical. He has been focused and diligent in his task.

I wish him all the success for the future endeavors.



Dr. Ashok Kaushik

Dean (Academics and Students Affairs)

IIHMR, Jaipur



Dr. N.K. Gurbani

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ACKNOWLEDGEMENT

I would like to extend my sincere thanks to **Dr. Ranjeet S. Ajmani**, Chief Executive Officer, PlasmaGen BioSciences for the faith shown upon me and guidance given to me without which the assignment would not have been possible.

Without the guidance & blessings of **Dr. S.D. GUPTA**, Director, IIHMR, Jaipur and Institute of Health Management & Research, Jaipur summer internship would not have been possible for me.

I would like to thank **Dr. N.K. Gurbani**, Professor, Post Graduate Diploma in Pharmaceutical Management, for the support, facilitation & coordination which I have received from him.

Last but not the least almighty God who gave us courage & strength to perform my duties efficiently. I thank everybody again.

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Executive Summary

The Project undertaken is a market research on availability, affordability, safety, consumption pattern and market potential of plasma product. As we all know plasma products such as IVIG, Human Albumin, Anti D, Hepatitis and Tetanus Immunoglobulins are all very expensive in the market because their only source is Human Blood & blood donors charge hefty sums of any donations they make. Despite the fact that all plasma products are life saving drugs & the last line of defense for many doctors, many patients refrain from buying it as their price are well beyond the reach of many poor people which form the large proportion of our population. Also because of the fact that plasma products are new in the market, there is not much of awareness among doctors & patients regarding its uses & implementation.

India has made very impressive growth in many areas of development including medical sciences. But, timely availability of safe blood and blood products at an affordable price is still a very big challenge in India. Many patients loose battle of life because of non-availability of safe blood. In 21st century, when we are looking at “Incredible India”, we are living with very high level of vulnerability in terms of availability of safe blood/blood products which is integral part of critical healthcare system. This scene must change and we must be part of this change or facilitate this change.

The area assigned to me was Northern India consisting 7 cities, 6 of them were of UP and one was in MP. Through all the responses collected from the doctors in the 7 cities, it was evident that drug safety and quality are the two parameters on which the doctors prescribes hyper immunes.

Secondly, the higher cost of hyper immunes is the major parameter of not prescribing the hyper immunes.

Also the low patient pool forces doctors to not prescribe the hyper immunes. Especially in cities like Agra and Aligarh, patient quotient is very low, so the usage of these products is almost zero. However if cases come, they are in tertiary condition, so doctors preferably refer them to the big city hospitals.

Following few pages are the graphical representations of the responses I gather from the doctors in the territory assigned to me.

Introduction

Plasma is the fluid part of blood and makes up most of the volume. It contains substances that can be used to treat different conditions.

Blood is made up of four elements, which each perform a different function:

- **red blood cells** – these carry oxygen around the body and remove carbon dioxide
- **white blood cells** – these help the body fight infection
- **platelets** – these tiny cell fragments trigger the process that causes the blood to clot (thicken)
- **plasma** – this yellow fluid transports blood cells and platelets around the body and contains a number of substances, including proteins

What is plasma?

Plasma is the largest component of blood, making up about 55% of its overall content. It is mainly made up of water and surrounds the blood cells, carrying them around the body.

Plasma also stores body fluids, helps maintain blood pressure and regulates body temperature. It contains a complex mix of substances used by the body to perform important functions. These substances include:

- minerals
- salts
- proteins
- hormones

Three important proteins are found in plasma:

- albumin
- clotting (coagulation) factors
- immunoglobulins

Uses of plasma products

The following plasma products can be used to treat a variety of different conditions.

Albumin

Albumin cleans the blood, carries substances around the body and helps to maintain the correct amount of fluid circulating in the body.

Human albumin solution can be used as a treatment to help people with severe burns, or with liver or kidney disease.

Clotting factors

Clotting (coagulation) substances, called factors, help to control bleeding and work together with blood platelets to ensure that the blood clots effectively.

Fresh frozen plasma and clotting factors can be used to treat blood clotting disorders such as haemophilia, an inherited condition in which the lack of a specific clotting factor can cause prolonged bleeding.

Immunoglobulins

Immunoglobulins are part of the immune system (the body's natural defense against illness and infection).

Immunoglobulins are antibodies that the body produces to fight unwanted viruses and bacteria. For example, they are used to fight health conditions such as:

- tetanus – a serious but usually short-lived bacterial infection
- hepatitis – a viral infection that causes the liver to become inflamed (swollen)
- rabies – an infection of the central nervous system that is passed on to humans from infected animals

Normal human immunoglobulins can be used to support people who are having cancer treatment when their immune system is having difficulty producing antibodies.

Plasma is the source of anti-D immunoglobulin, a substance often given by injection to pregnant women with a rhesus negative blood group (RhD negative) and whose unborn baby may have a rhesus positive blood group (RhD positive).

This treatment prevents the mother becoming sensitized to the baby's blood and stops immune anti-D developing. Immune anti-D can cause rhesus disease in subsequent pregnancies, which is a potentially fatal condition.

How is plasma products used?

Plasma products can be used in a number of different ways, depending on the condition they are being used to treat.

The main uses of plasma products include:

- **fresh frozen plasma transfusion** – plasma is separated from donated blood and frozen until needed, it is then thawed under controlled conditions and transfused to the recipient
- **plasma exchange** – a special machine is used to remove plasma from the blood, the plasma is then replaced with a substitute plasma product
- **fractionation** – removed plasma is treated to separate it into different proteins, these can then be used to treat certain conditions

Risks of using plasma products

Some people can experience further problems after a plasma transfusion.

These can vary in severity from a slight temperature rise, to the development of variant Creutzfeldt-Jakob disease (vCJD) in very rare cases.

Rationale of the Project

This project would enable us to understand the public health aspect and the market dynamics of Hyperimmune proteins in India. Through this we want to determine the health perspective on the availability, affordability, safety, consumption pattern and market potential of each product.

Problem Statement

GAP analysis - demand and supply of Hyperimmune proteins in the Indian plasma product industry.

Title

“Hyper-immune Plasma Proteins in Indian Tier I and Tier II Cities- determine the public health perspective on the availability, affordability, safety, consumption pattern and market potential of each product.”

Objectives

For each category of product:

- To estimate awareness about hyper immune products
- To understand public health perspective of hyper immune products in the regions.
- To determine the number of diagnosed cases in the given region.
- To understand the disease management by doctors
- To analyze whether the existing demand for the products are fulfilled.
- Perception of doctors in these regions regarding the hyper immunes.
- Factors affecting the growth of hyper immune plasma protein market in Tier I and Tier II cities
- To determine the factors that would promote usage of these products in Tier I and Tier II cities

General Product description & Target Doctors

A group of plasma products, “Hyper immune globulins”, are used to treat patients suffering from various diseases like hepatitis B, rabies, tetanus, hemolytic disease of the new born (HDN) etc. These products have a complex manufacturing process because they are prepared from plasma collected from donors with high antibody levels against these diseases. Unfortunately, India doesn’t have a facility to collect such hyper immune plasma and hence we have to be strictly dependent upon import of these products. These products face various issues like poor clinical awareness, high prices, shortage of supply, inconsistent availability etc. To better understand the ground reality of hyper immune plasma products in India, we would like to conduct a detailed scientific/technical and marketing study titled, “Availability and Usage of Hyper immune plasma proteins in Tier I and Tier II cities in India”.

Hepatitis B immune globulin

Hepatitis B immune globulin (HBIG) is a human immune globulin that is used to prevent the development of hepatitis B. Infants and young children usually show no symptoms.

In about 7 out of 10 older children and adults, short-term hepatitis B causes the following:

- Loss of appetite (not wanting to eat)
- Fever

- Tiredness
- Pain in muscles, joints, and stomach
- Nausea, diarrhea, and vomiting
- Dark urine
- Yellow skin and eyes

Symptoms of short-term illness usually appear 3 or 4 months after infection.

Preparation

HBIG is prepared from the plasma of donors who have high antibody levels of the hepatitis B surface antigen. It is extracted from the Cohn Fraction II. During the process, viruses are deactivated, and in the final steps, solvents used in the preparation are removed. The preparation is tested for absence of HIV, HCV, herpes virus, and reovirus

Indications

HBIG is indicated as a postexposure prophylaxis for people at risk to develop hepatitis B because they have been recently exposed to body fluids of individuals who have hepatitis B. This includes babies of mothers with hepatitis B, sexual partners, healthcare workers, police and fire workers, and morticians. It provides a temporarily induced immunity by the transfer of immunoglobulins.

The medication is given as an intramuscular injection. Side effects include allergic reactions, back pain, general feeling of discomfort, headaches, muscle pain, nausea, and pain or bleeding at the injection site. Allergy to human immune globulin is a contraindication. HIV has never been transmitted by HBIG. As with all blood-derived products, the transmission of prions is possible as a residual risk.

Target Doctors-

- Pediatrics
- Gynecologists
- Intensivists
- Hepatologist
- Gastroenterologist

Rabies Human Immune Globulin

Rabies is a zoonotic disease (a disease that is transmitted from animals to humans) that is caused by a virus. It is known to be present on all continents except Antarctica and infects domestic and wild animals.

Rabies is spread to people through close contact with infected saliva via bites or scratches. The main route of rabies transmission to humans is the bite of rabid dogs. Most of the deaths occur in the absence of post-exposure prophylaxis. Rabies is nearly always fatal when left untreated.

Although it is a vaccine-preventable disease, rabies still poses a significant public health problem in many countries in Asia and Africa where 95% of human deaths occur even though safe, effective vaccines for both human and veterinary use exist.

Nearly half of those bitten by suspect rabid animals are children under 15 years of age. Although the efficacy and safety of modern cell culture vaccines have been recognized, some countries still produce and use nervous tissue vaccines, which are less effective.

- Human rabies immune globulin (HRIG) is administered only once, at the beginning of anti-rabies prophylaxis, to previously unvaccinated persons. This will provide immediate antibodies until the body can respond to the vaccine by actively producing antibodies of its own. If possible, the full dose of HRIG should be thoroughly infiltrated in the area around and into the wounds. Any remaining volume should be injected intramuscularly at a site distant from vaccine administration.
- HRIG should never be administered in the same syringe or in the same anatomical site as the first vaccine dose. However, subsequent doses of vaccine in the four-dose series can be administered in the same anatomic location where the HRIG dose was administered.
- If HRIG was not administered when vaccination was begun, it can be administered up to seven days after the administration of the first dose of vaccine. Beyond the seventh day, HRIG is not recommended since an antibody response to the vaccine is presumed to have occurred.

- Because HRIG can partially suppress active production of antibody, no more than the recommended dose should be administered. The recommended dose of HRIG is 20 IU/kg body weight. This formula is applicable to all age groups, including children.

Indications-

Rabies immunoglobulin (passive immunization) is indicated for all persons known or suspected to have been exposed to the rabies virus and is used in conjunction with the rabies vaccine (active immunization).

Rabies immunoglobulin must be given for any mucous membrane exposure to saliva i.e. licks, and all single and multiple bites or scratches inflicted by a suspected rabid animal, especially if associated with any signs of bleeding, irrespective of the interval between exposure and initiation of treatment.

Target doctors-

- General and community physicians
- Pediatrics
- Emergency ward doctors
- BAMS/ BHMS

Tetanus Immunoglobulin

Tetanus is a serious disease caused by a toxin (poison) made by bacteria. It causes painful muscle stiffness and can be deadly.

Tetanus in children starts with headache, jaw cramping, and muscle spasms (sudden, involuntary muscle tightening).

It also causes the following:

- Painful muscle stiffness all over the body
- Trouble swallowing
- Seizures (jerking or staring)
- Fever and sweating
- High blood pressure and fast heart rate

Tetanus is often called “lockjaw” because the jaw muscles tighten, and the person cannot open his mouth.

Tetanus immune globulin provides immediate, short-term protection against the bacteria that can cause tetanus ('lockjaw'). It can prevent the illness or make the illness less severe.

Tetanus immune globulin has large amounts of tetanus antibodies taken from donated human blood. Antibodies are proteins that a person's immune system makes to fight pathogens like bacteria and viruses.

Indications-

Passive, transient protection against tetanus in any person that may be contaminated with tetanus spores when:

- (1) patient's personal history of immunization with tetanus toxoid is unknown or uncertain,
- (2) Person received less than 2 prior doses of tetanus toxoid, or
- (3) Person received 2 prior doses of tetanus toxoid, but delay of more than 24 h occurred between time of injury and initiation of tetanus prophylaxis.

Target Doctors-

- General and community physicians
- Pediatrics
- Emergency ward doctors
- BAMS/ BHMS

Anti D Immunoglobulin

Rhesus antigen is a chemical that is found on the surface of red blood cells in some people. Some people have rhesus antigen on their blood cells and others do not. People that have rhesus antigen on their blood cells are called rhesus positive and people that do not are called rhesus negative.

It is possible for a foetus to be rhesus positive even when the mother is rhesus negative. If any of the blood from a rhesus positive foetus somehow gets into the mother's bloodstream and she is rhesus negative then the mother's immune system will start to attack the foetus's red blood cells. This is because the mother's immune system sees these red blood cells as foreign. This can lead

to complications that may affect the baby after birth, or complications with a different pregnancy at a later stage should the mother become pregnant again. Anti-D Immunoglobulin is given to the mother to reduce the chances of these antibodies being formed and any subsequent complications.

- Anti-D (RHO) Immunoglobulin is a medicine which is used in preventing antibody formation in rhesus negative women who have a rhesus positive baby and treating rhesus negative people who have been given a blood transfusion of rhesus positive blood.

Indications

- Rh-ve women pregnant with Rh +ve baby
- Rh -ve people who have been transfused Rh +ve blood to stop them from developing antibodies to the blood transfusion
- Idiopathic Thrombocytopenic Purpura (ITP)

Target doctors-

- Gynecologists
- Neonatologists
- Pediatrics
- Medical oncologists
- Hematologists

Area

Territory Assigned	State
Noida	Uttar Pradesh
Ghaziabad	Uttar Pradesh
Agra	Uttar Pradesh
Aligarh	Uttar Pradesh
Gwalior	Madhya Pradesh
Meerut	Uttar Pradesh
Muzaffarnagar	Uttar Pradesh

Research Methodology

Study Design: A descriptive Study was done to find out the demand and supply of hyper immune products

Sampling: A purposive sampling technique was used to carry out the survey as doctors were approached randomly (when they were available)

Target Population:

1. For Hepatitis b

- Pediatrics
- Gynecologists
- Intensivists
- Hepatologist
- Gastroenterologist

2. For Tetanus

- General and community physicians
- Pediatrics
- Emergency ward doctors
- BAMS/ BHMS

3. For Rabies

- General and community physicians
- Pediatrics
- Emergency ward doctors
- BAMS/ BHMS

4. For Anti – D

- Gynecologists
- Neonatologists

- Pediatrics
- Medical oncologists
- Hematologists

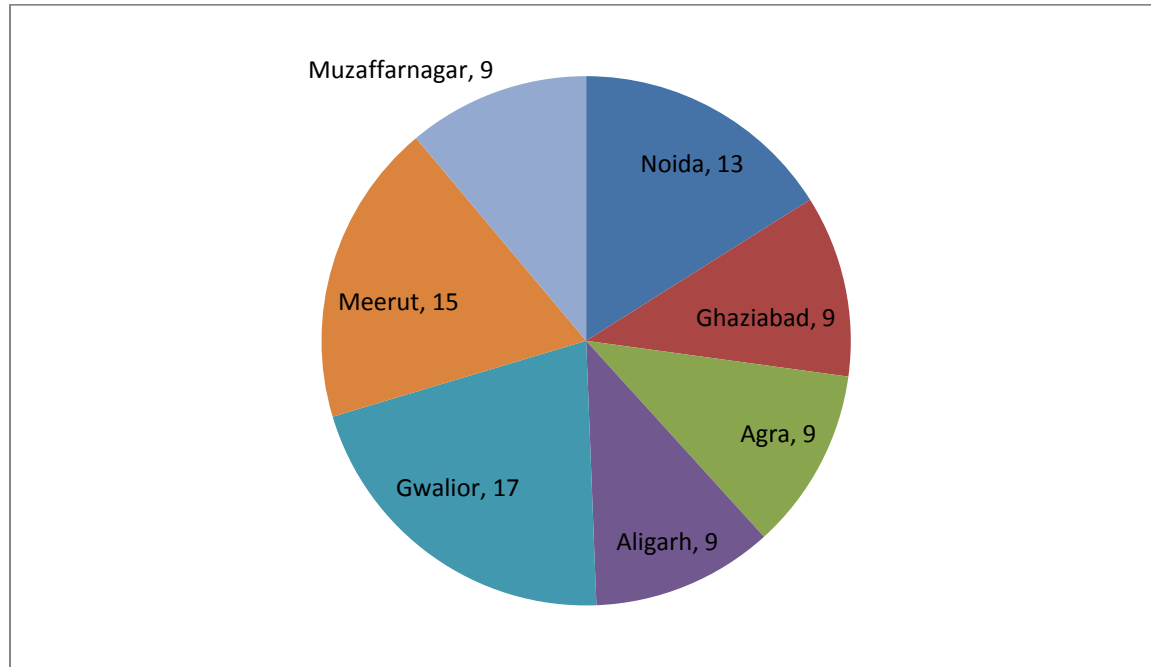
Data Collection:

Tool: A semi structured questionnaire prepared by Plasmagen Biosciences was the tool for the study which contained both open ended and closed ended questions.

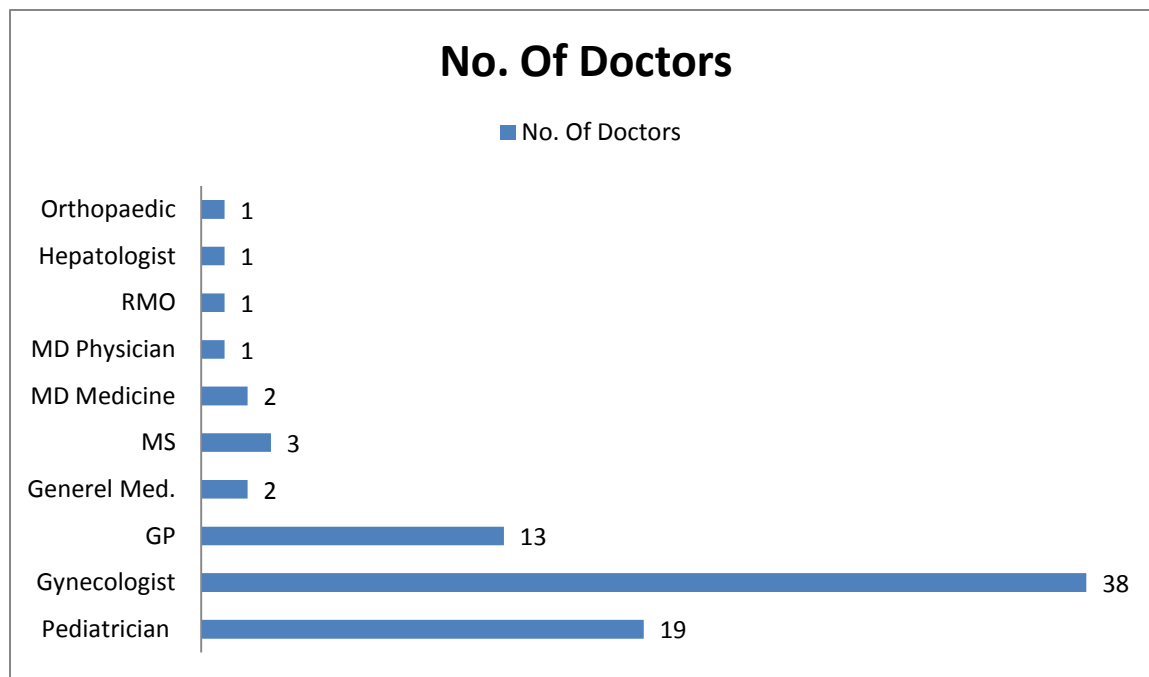
Technique: A Face to face interview was the technique adopted for the survey.

Data Analysis

Territory wise classification of doctors who took part in the study

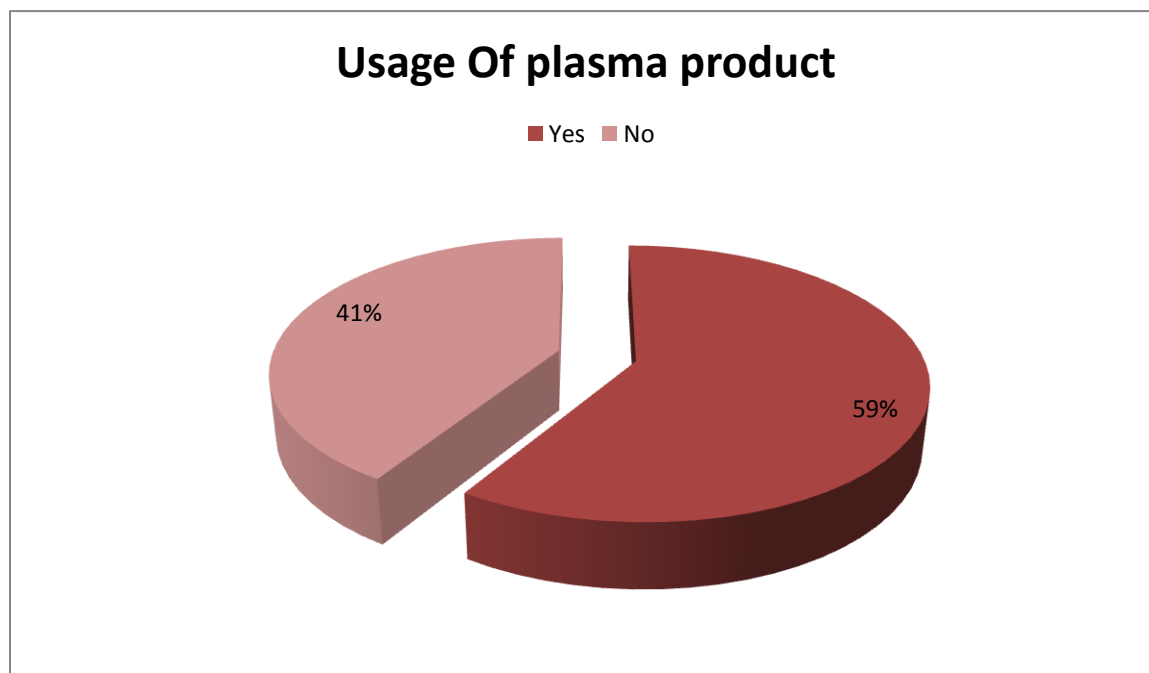


General Classification of the Specialty of Doctors who were the part of this study



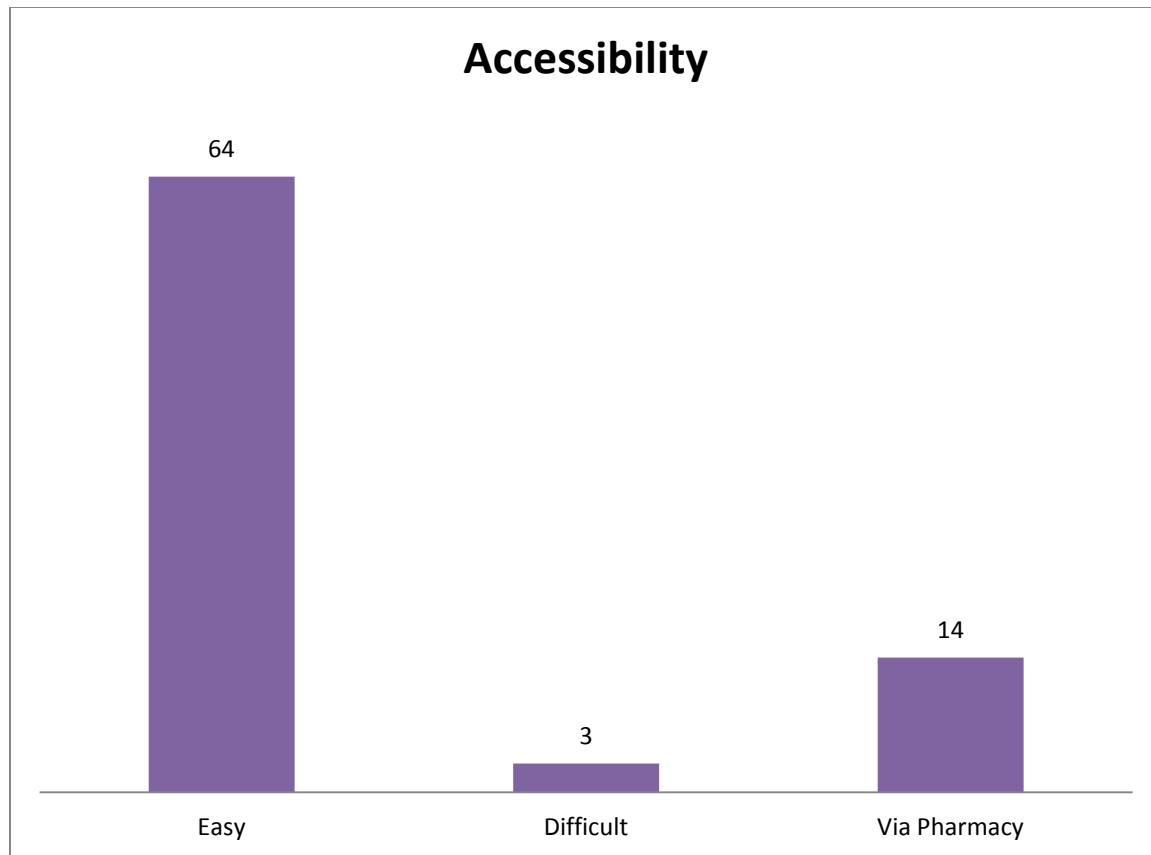
Q) 1. Usage of Plasma product

General Analysis



59% of doctors prescribe for the immunoglobulins, rest does not.

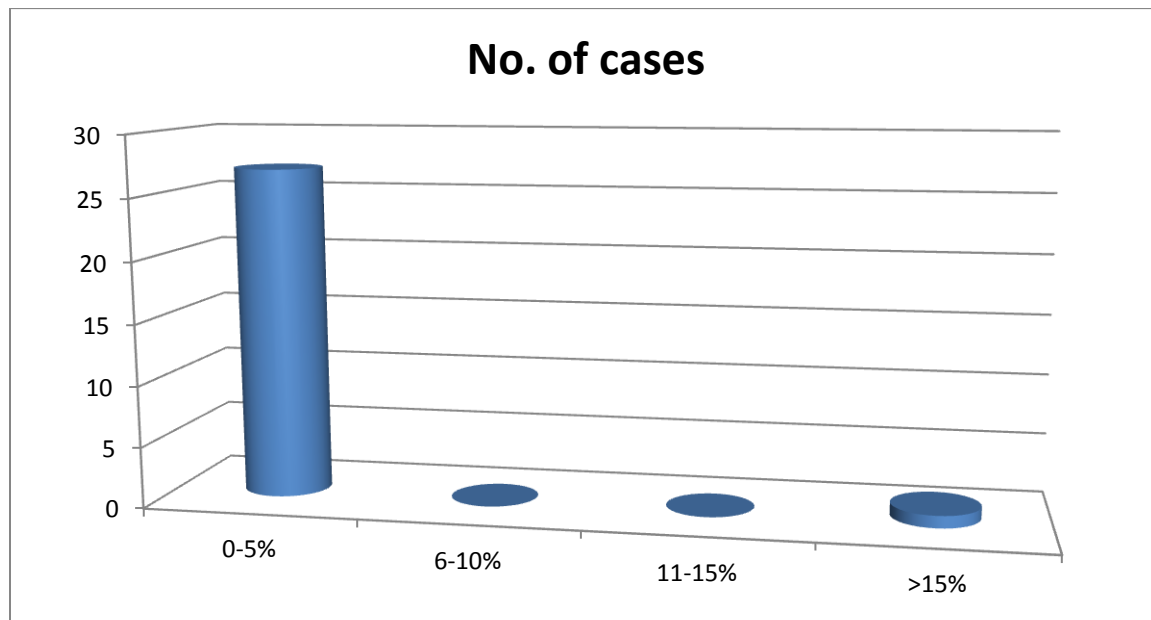
Q) 2. Accessibility of plasma product



Out of 81 doctors in 7 cities, 64 said the products are easily accessible, only 3 said it was difficult, also there were some doctors who said it is not our headache; the chemists inside the hospital arrange it for them.

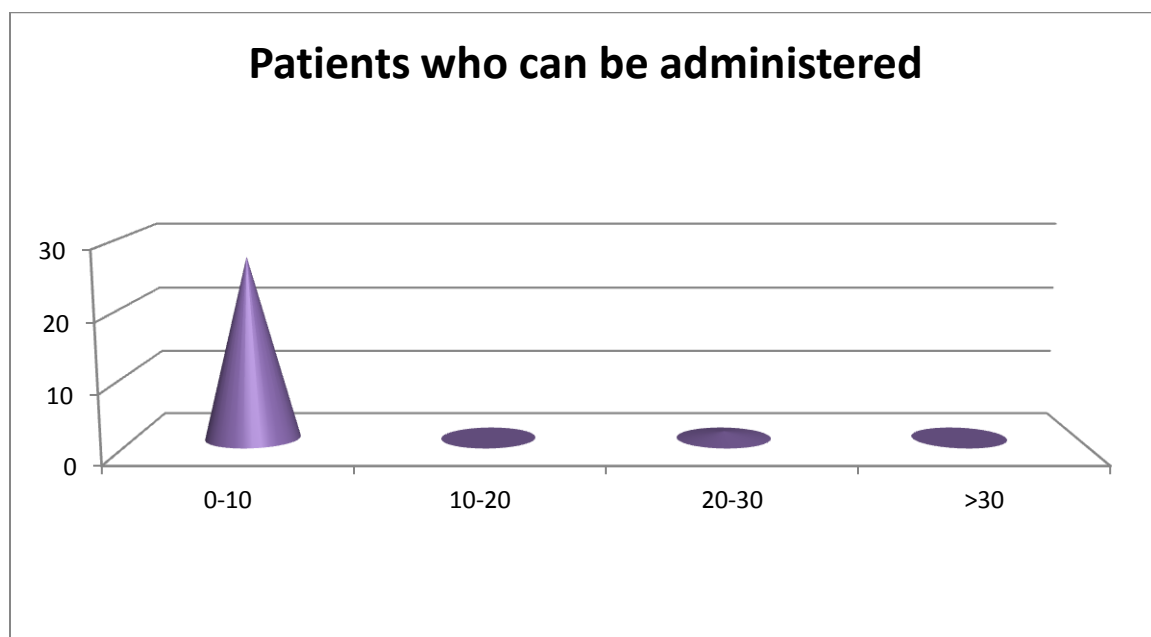
Data Analysis for Hepatitis-B immunoglobulins

Q) 3. No. of cases of Hepatitis-B



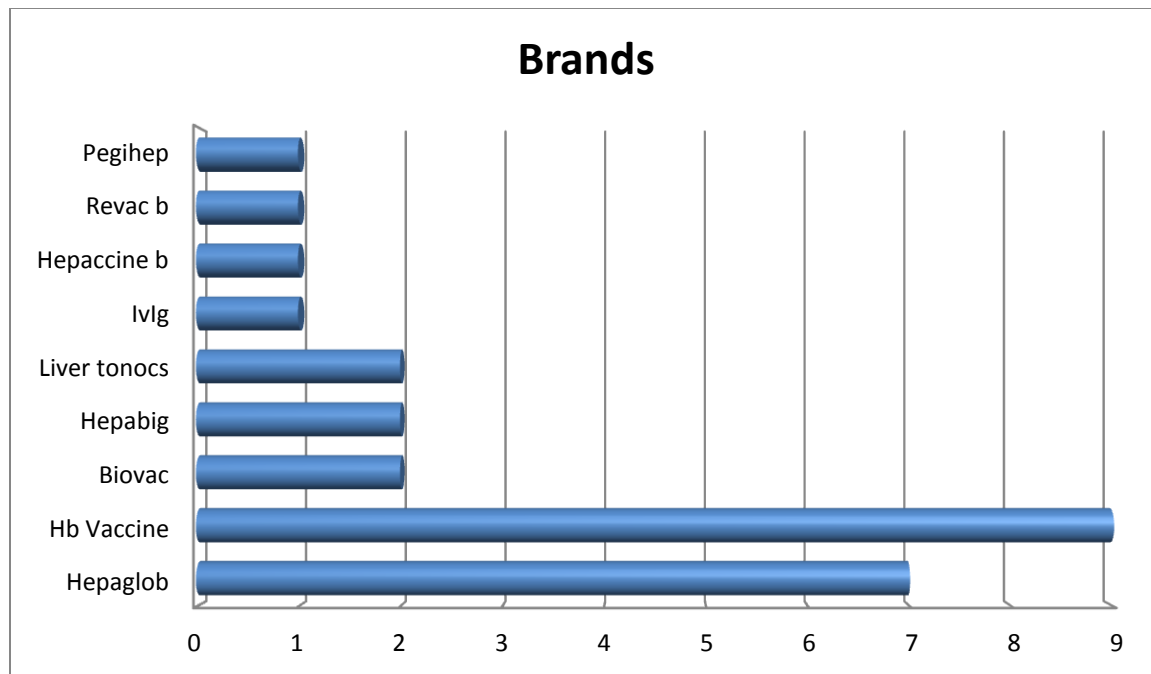
Out of 28 positive responses, 27 doctors said cases generally vary within the 0-5 range.

Q) 3. Percentage of patients who can be administered by HbIG



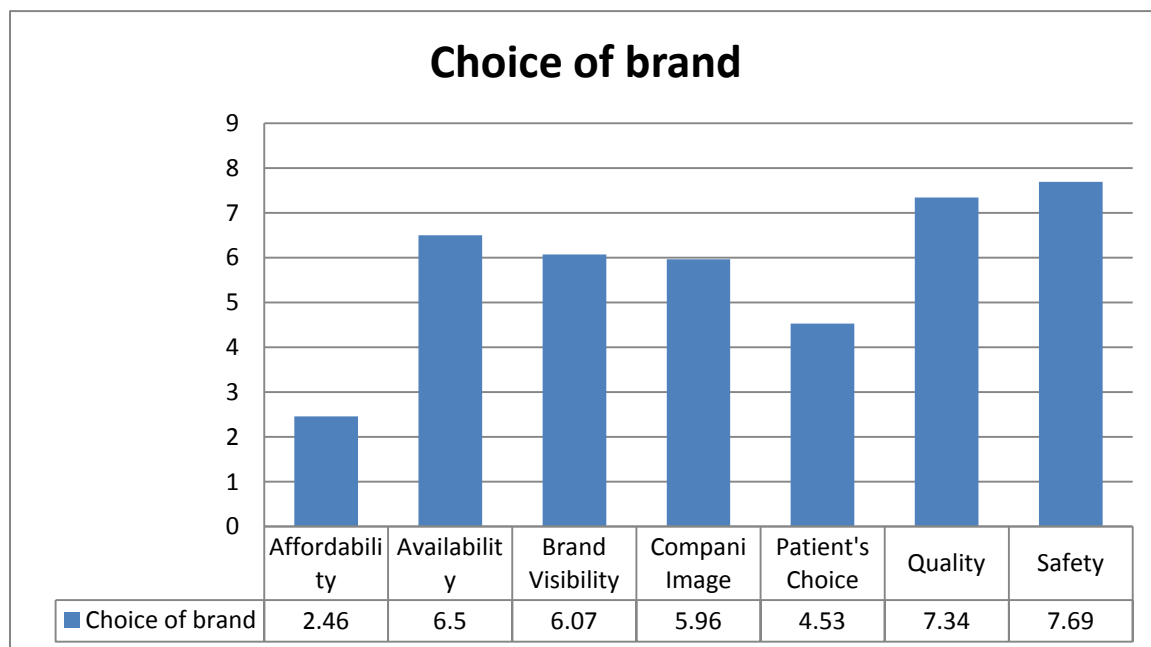
All the Doctors said that the % of patients falls within 0-10 Range

Q) 4. Brands in Hepatitis –B



Q) 5. Choice of Brand

Hepatitis b Immunoglobulins



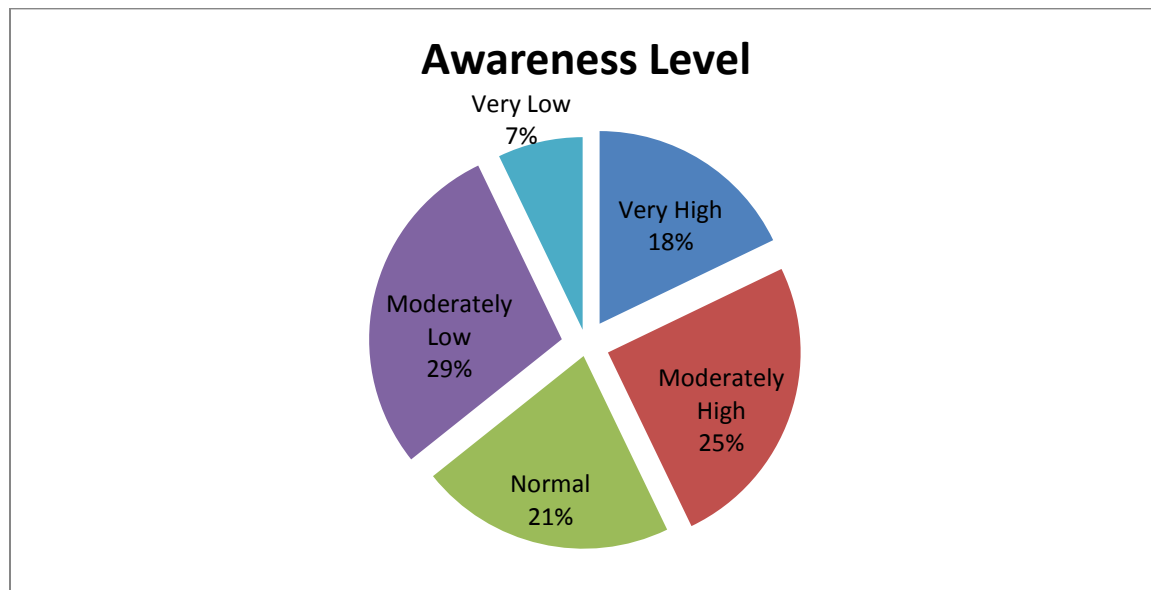
Q) 6. All over the territories, not a single doctor wrote that they use immunoglobulins in any other indication.

Q) 7. Satisfaction Level in case of Hepatitis b

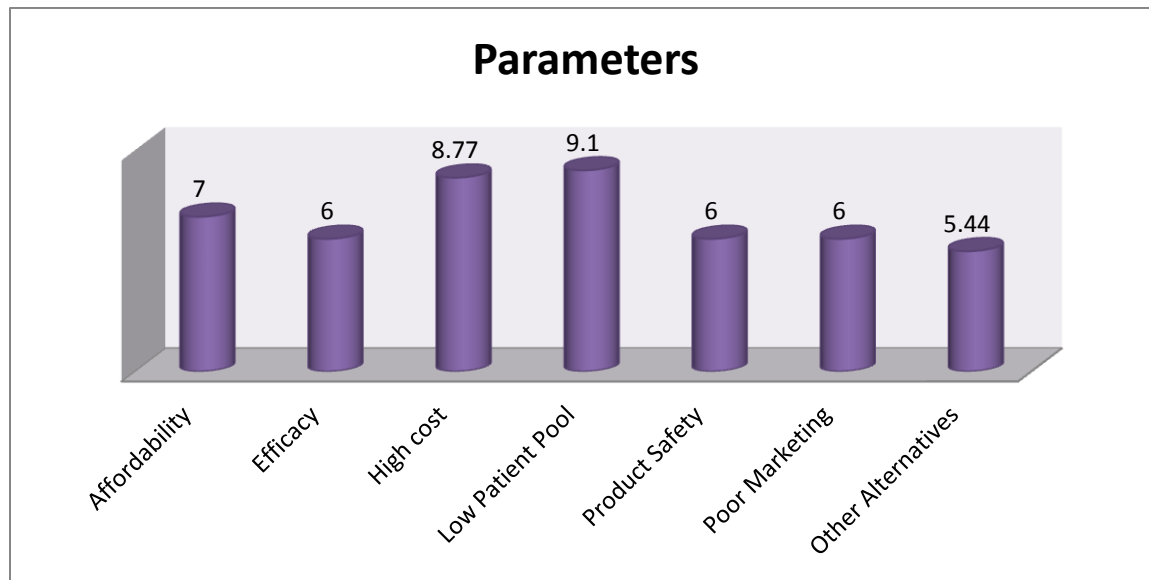


Satisfied-14 Normal-11 Dissatisfied-3

Q) 8. Awareness level in case of HBIG

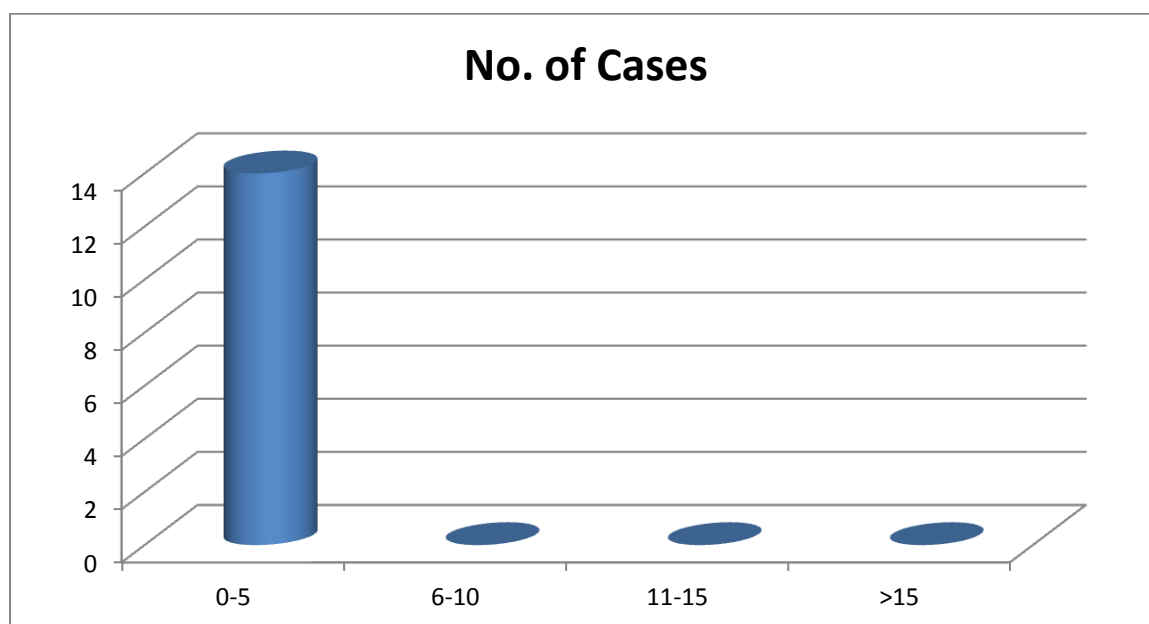


Q) 9. Why Ig is not a part of your study

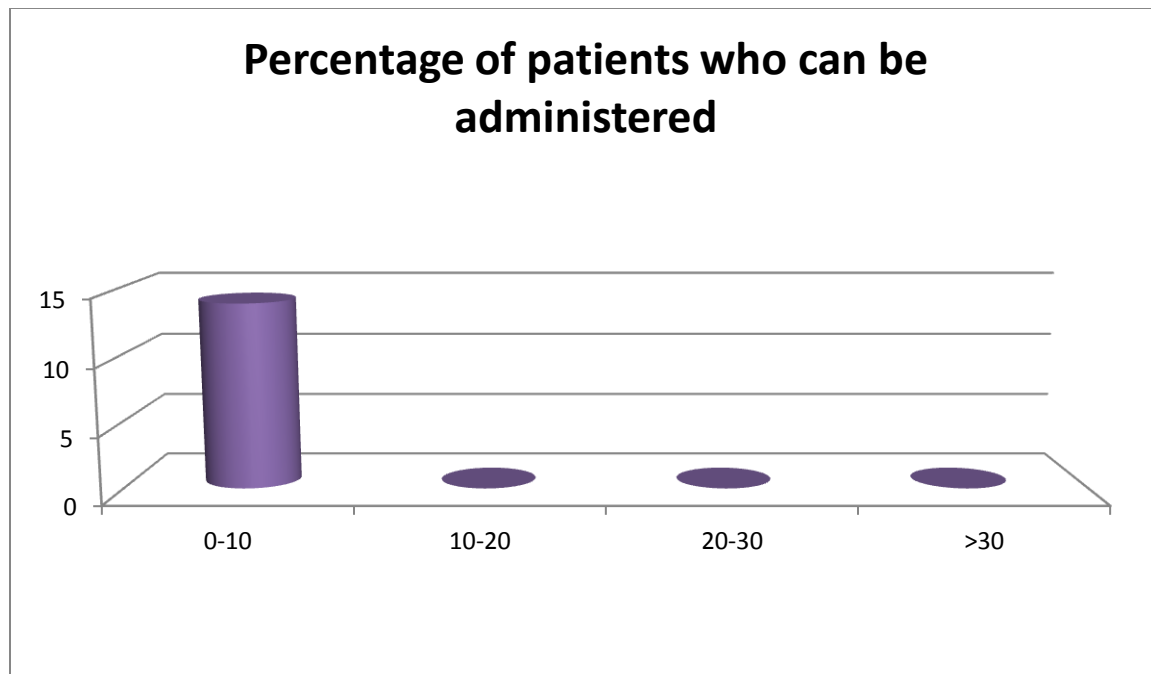


Low patient pool and the high cost of hyper immunoglobulins are the two major criteria's which affect the prescription of these products.

Data Analysis of Rabies Immunoglobulin

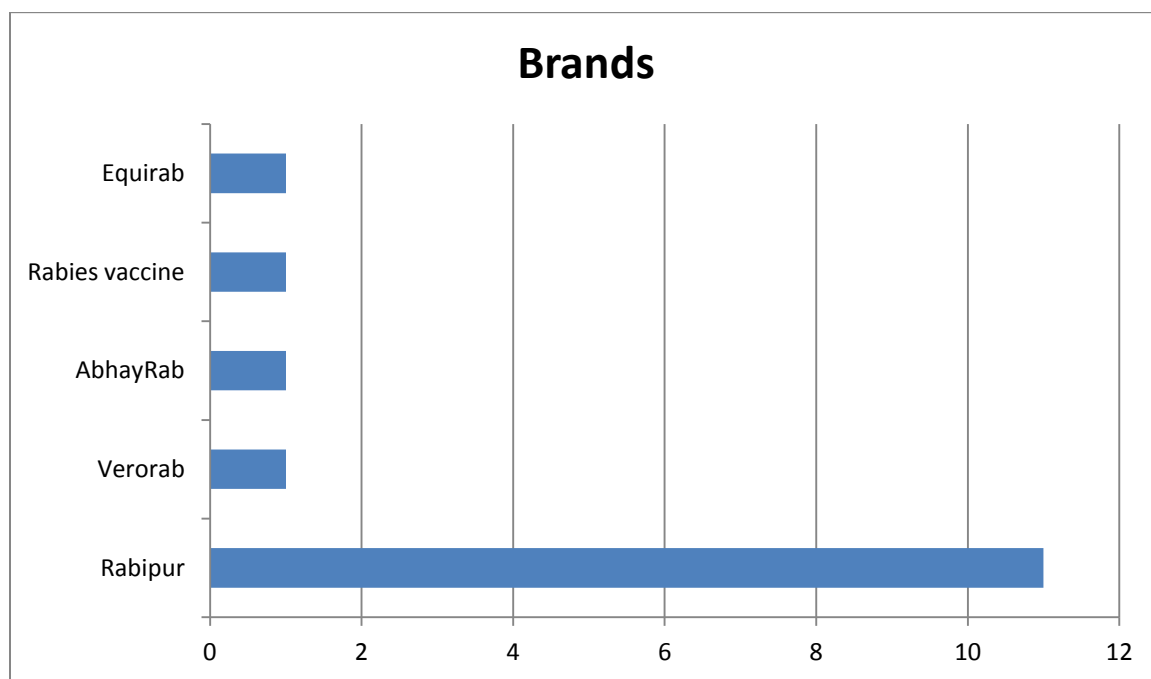


Percentage of patients who can be administered by hyper immunes



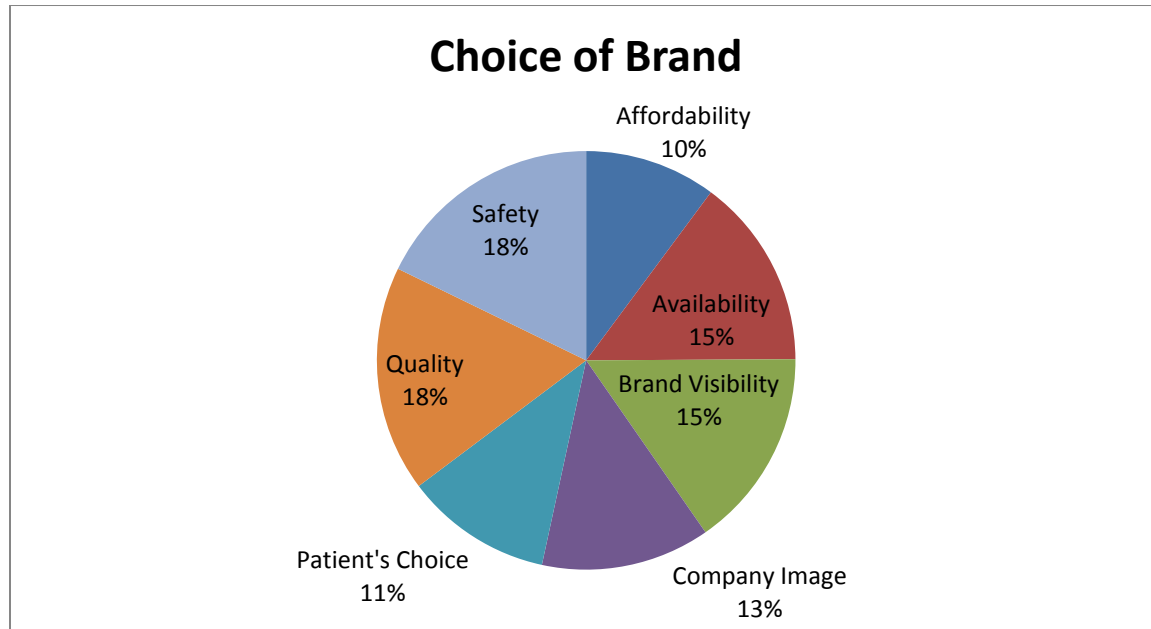
All the 14 responses fall in 0-10 category.

Brands Prescribed



Rabipur is used extensively in treatment of rabies.

Choice of Brand for anti rabies hyper immunes

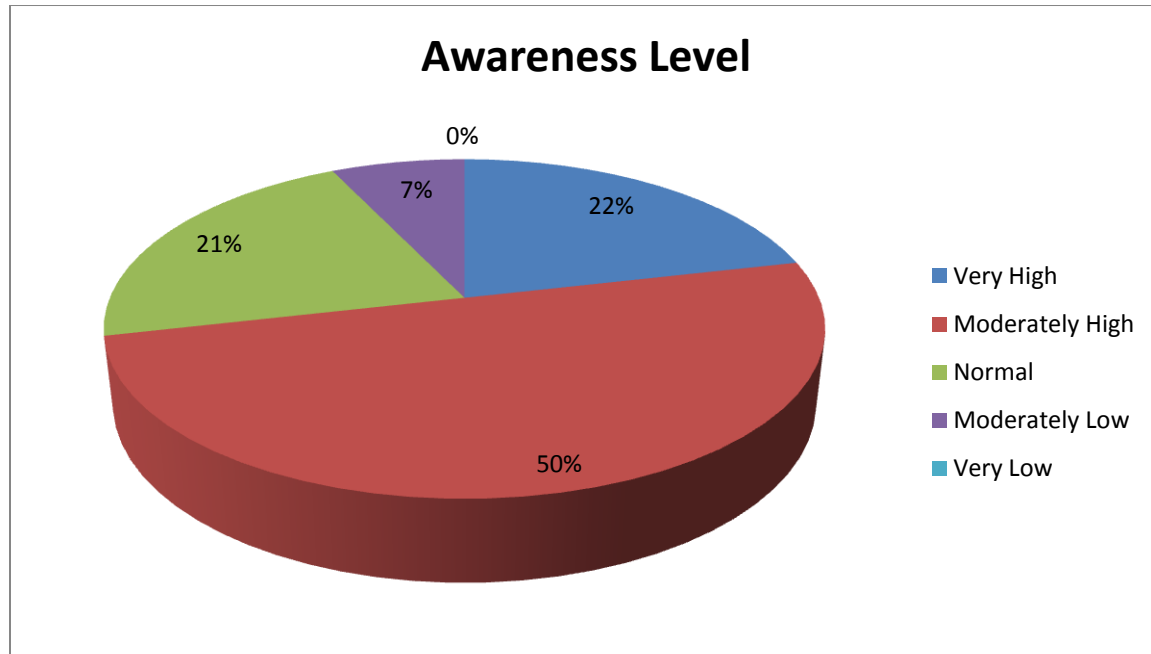


Safety and quality are two major parameters which affects the choice of brands among doctors.

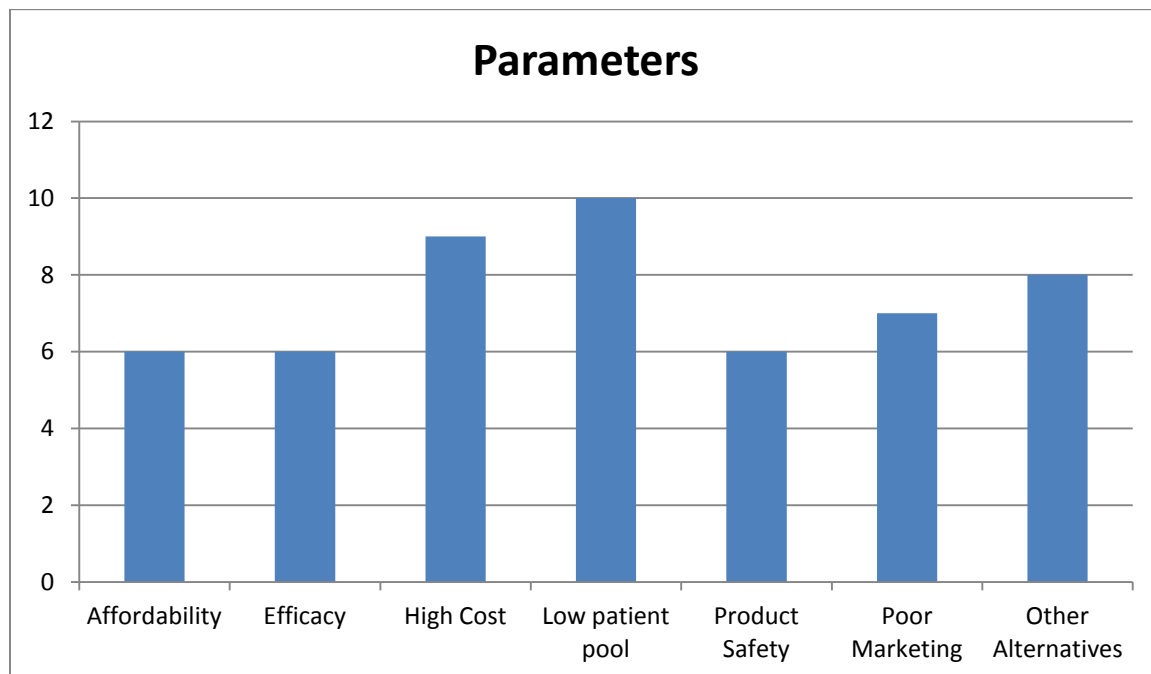
Satisfaction level



Awareness

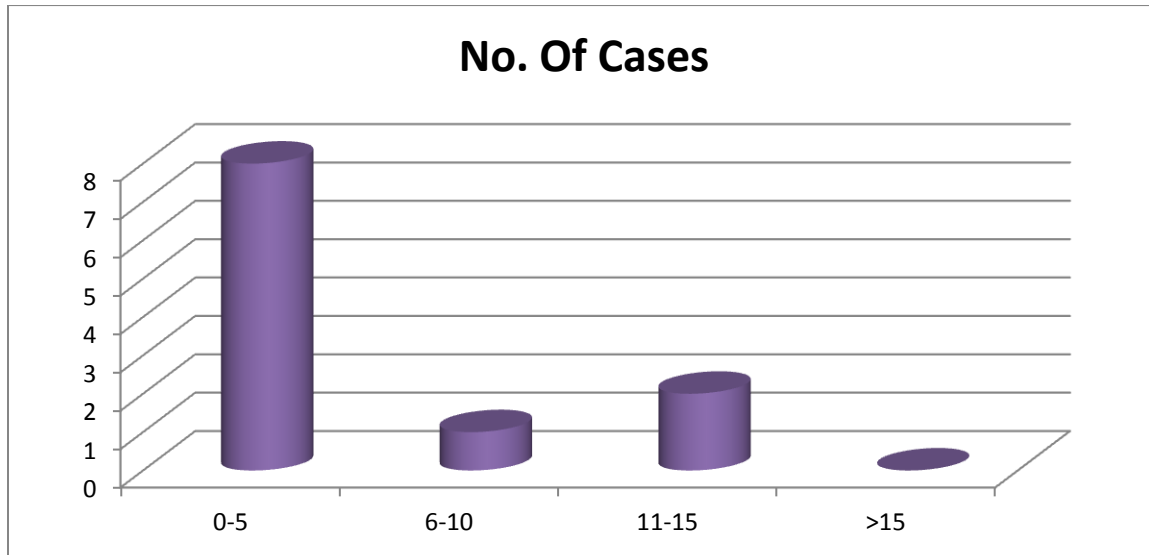


Q) 9. Why hyper immunes are not a part of your study?



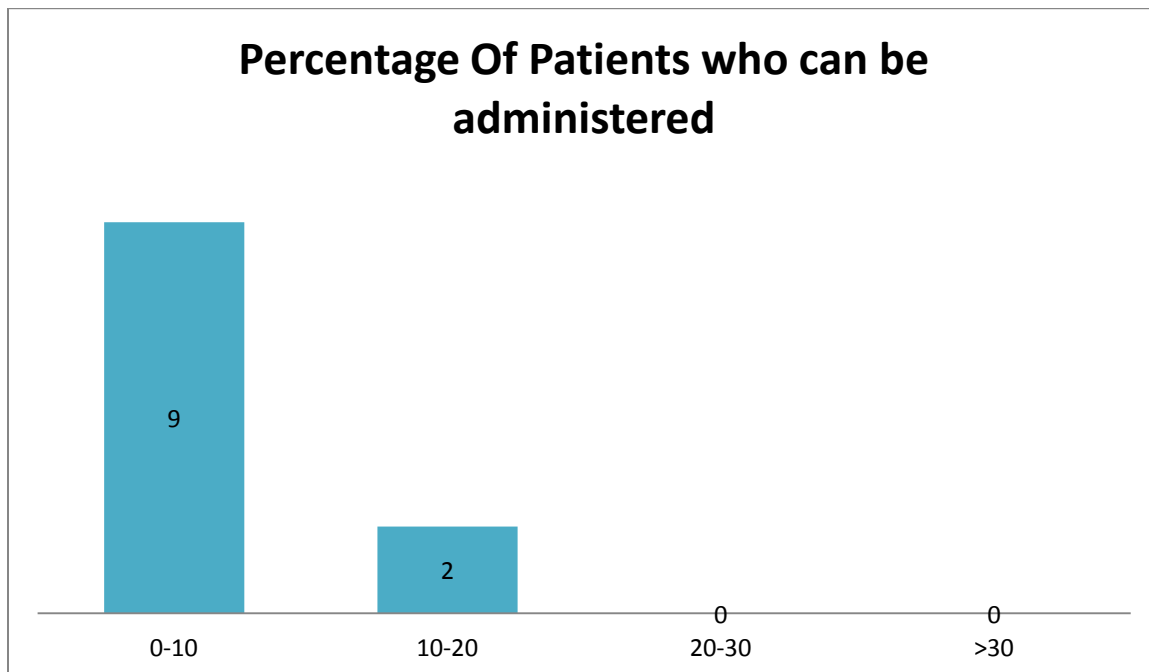
As shown in above graphical representation, low patient pool and high cost of hyper immunes are two major criteria's of not prescribing these products.

Data analysis of Tetanus Immunoglobulins

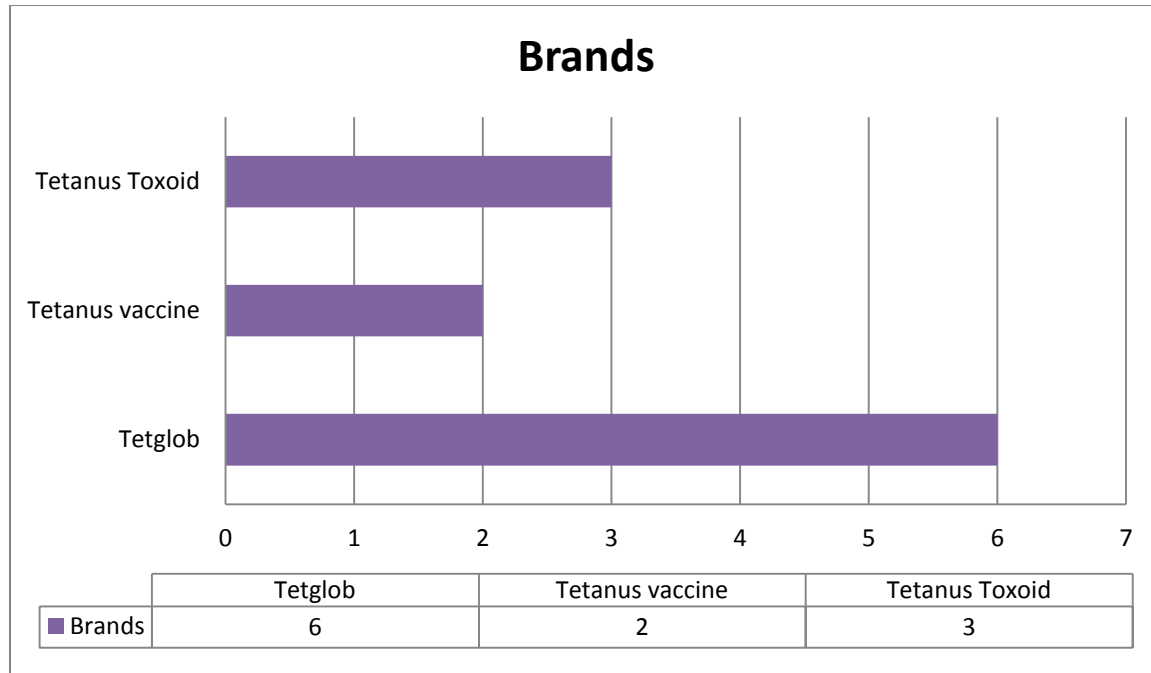


No. of cases fall within range 0-5 = 8, 6-10 = 1, 11-15 = 2

Percentage of Patients who can be administered

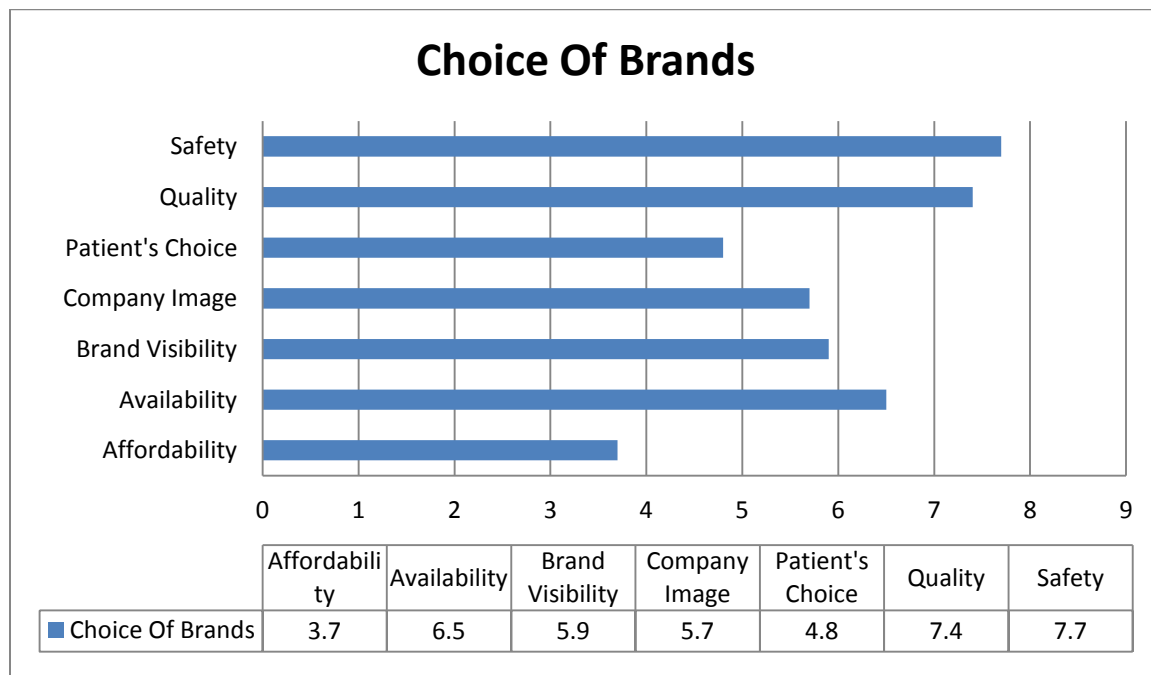


Brands



Tetglobe is the major brand which is preferred by most of the doctors.

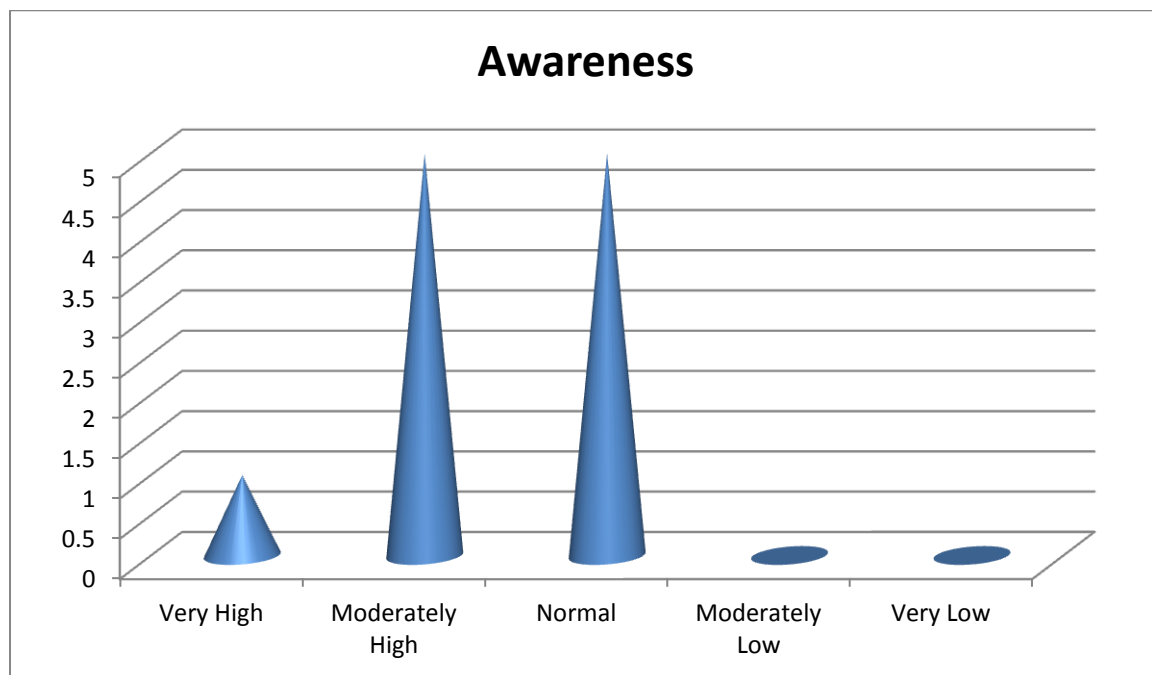
Choice of Brand



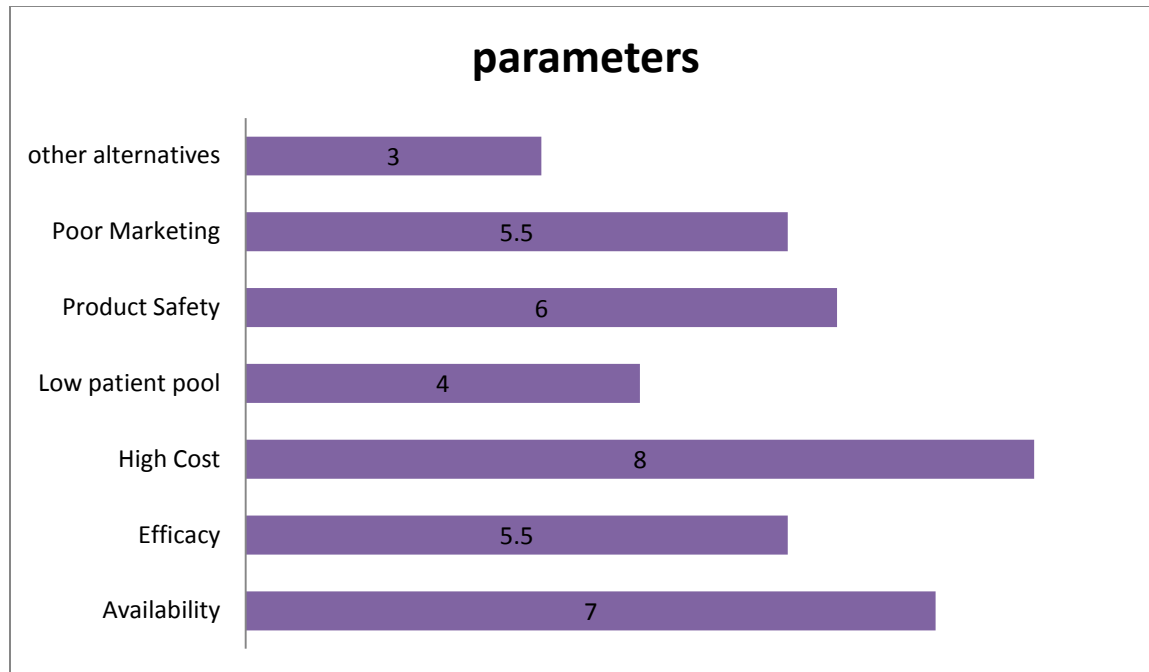
Satisfaction Level



Awareness Level



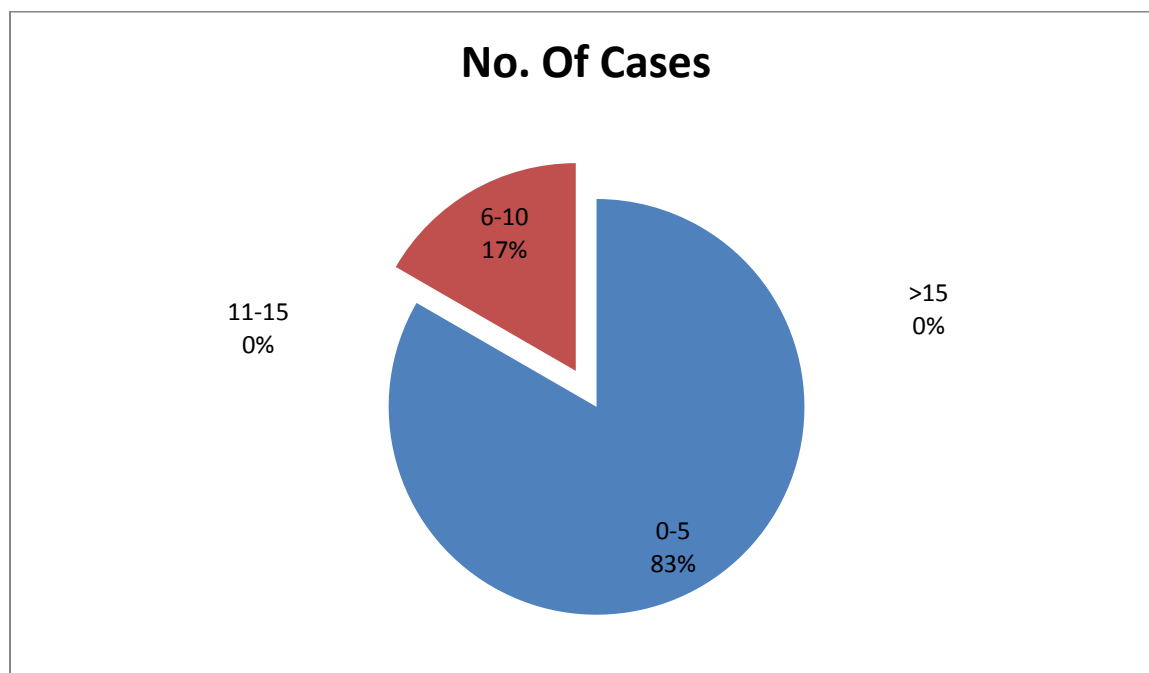
Q) 9. Why Hyper immunes are not a part of your therapy



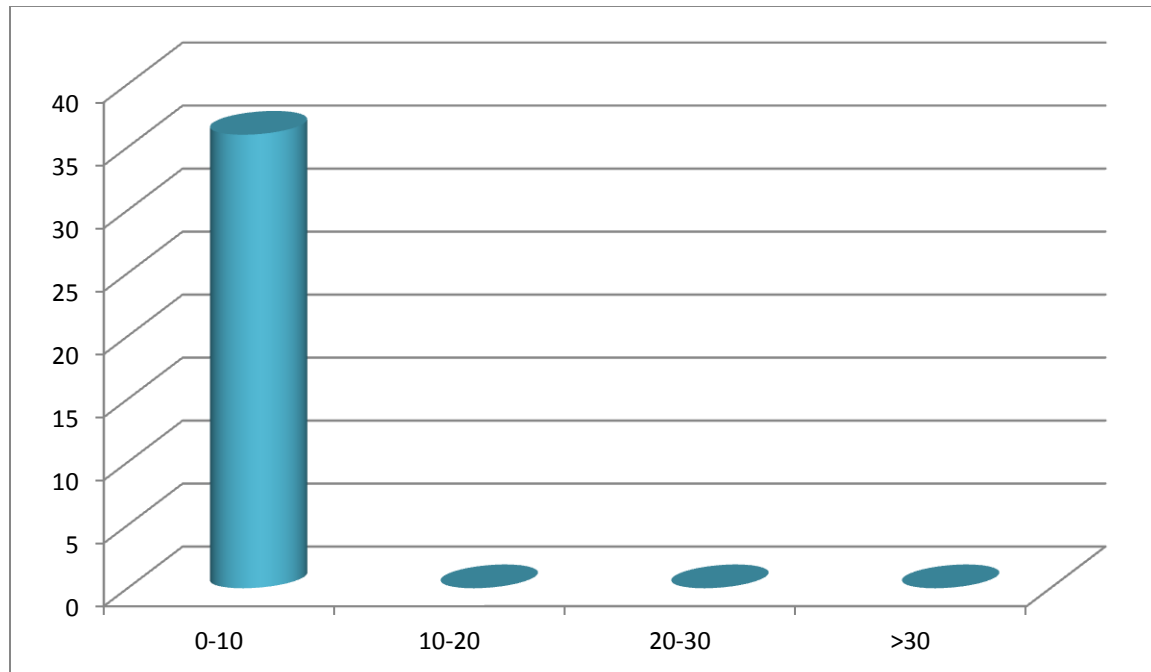
In case of tetanus immunoglobulins, high cost and availability are a major criterion which affects the doctor's prescription.

Anti-D Immunoglobulins

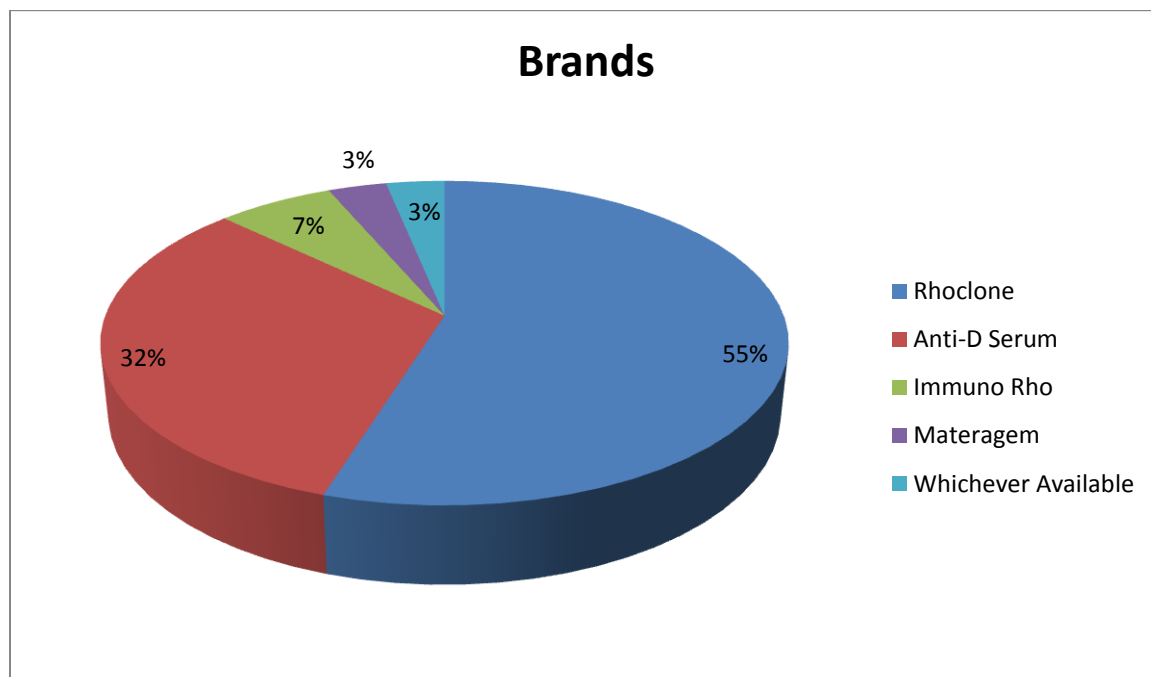
No. Of Cases



Percentage of Patients who can be administered

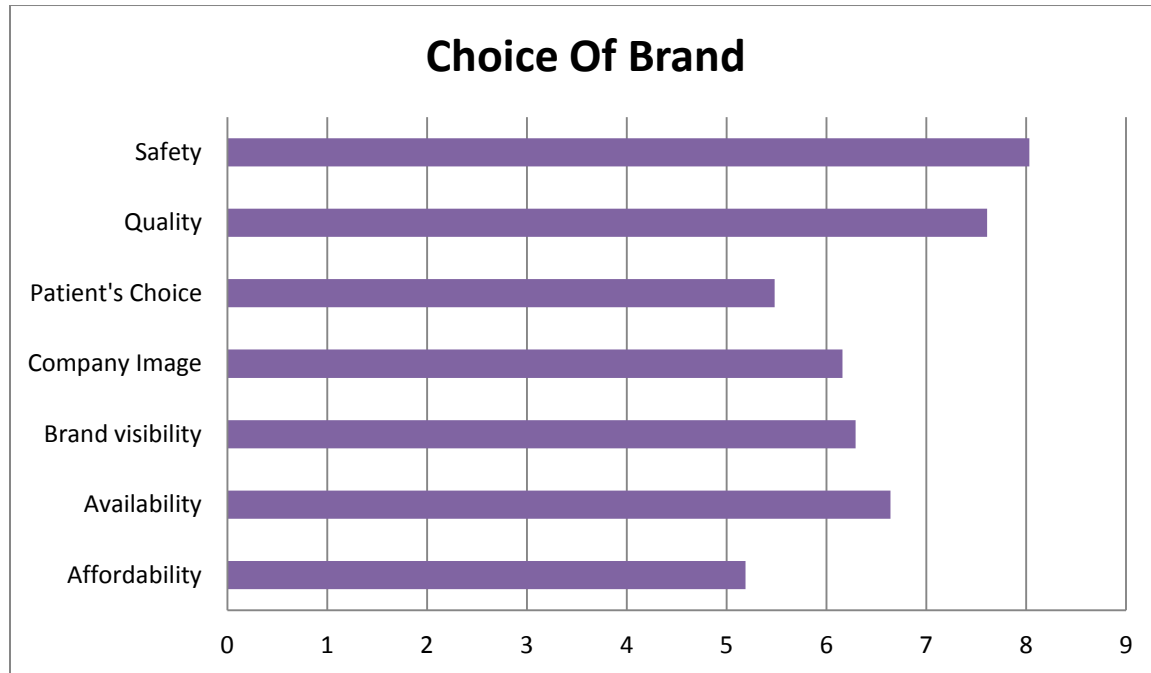


Brands

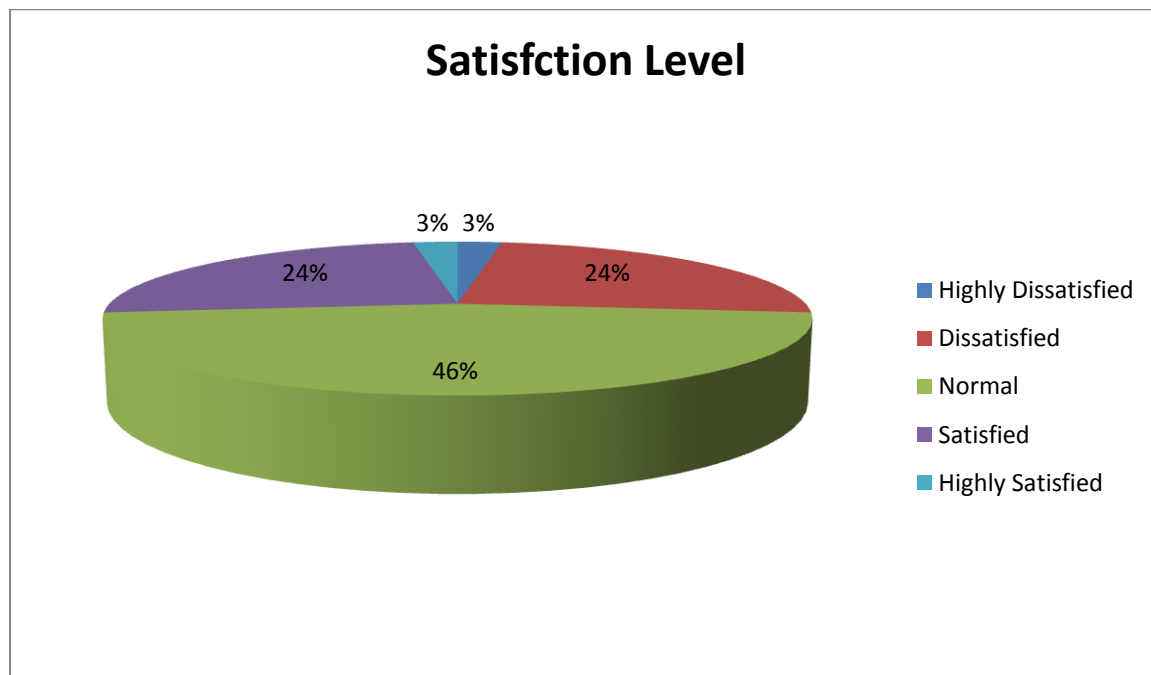


55% of the positive responses use rhoclone, and 32% of anti d serum portion

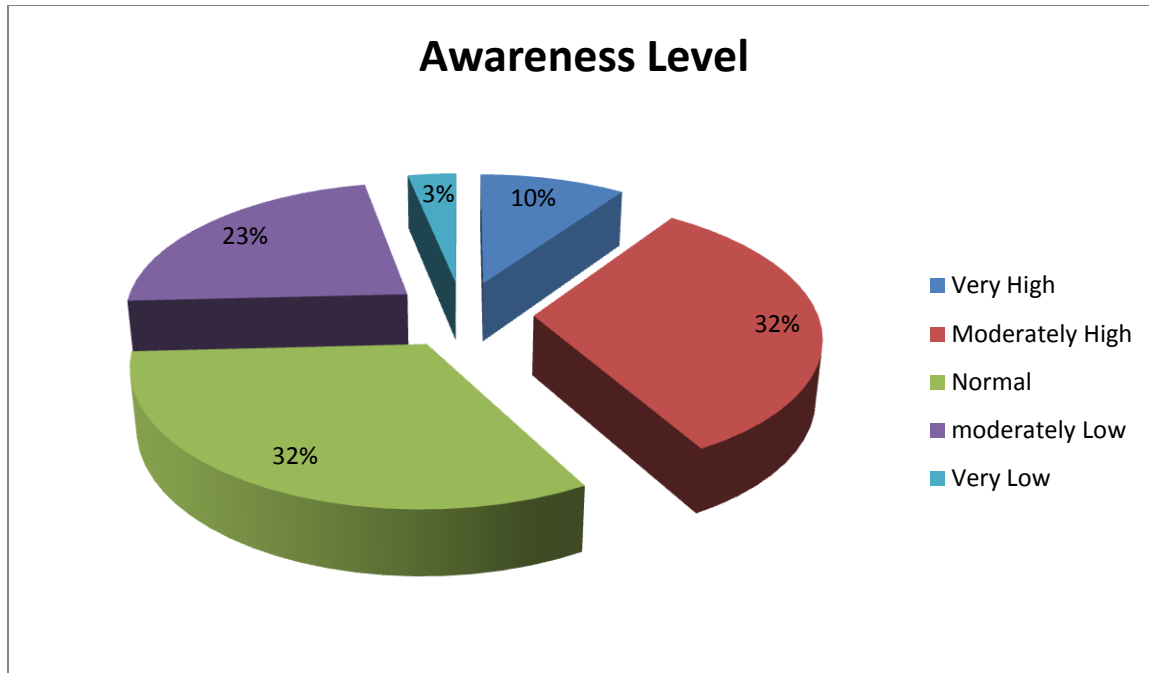
Choice of Brand



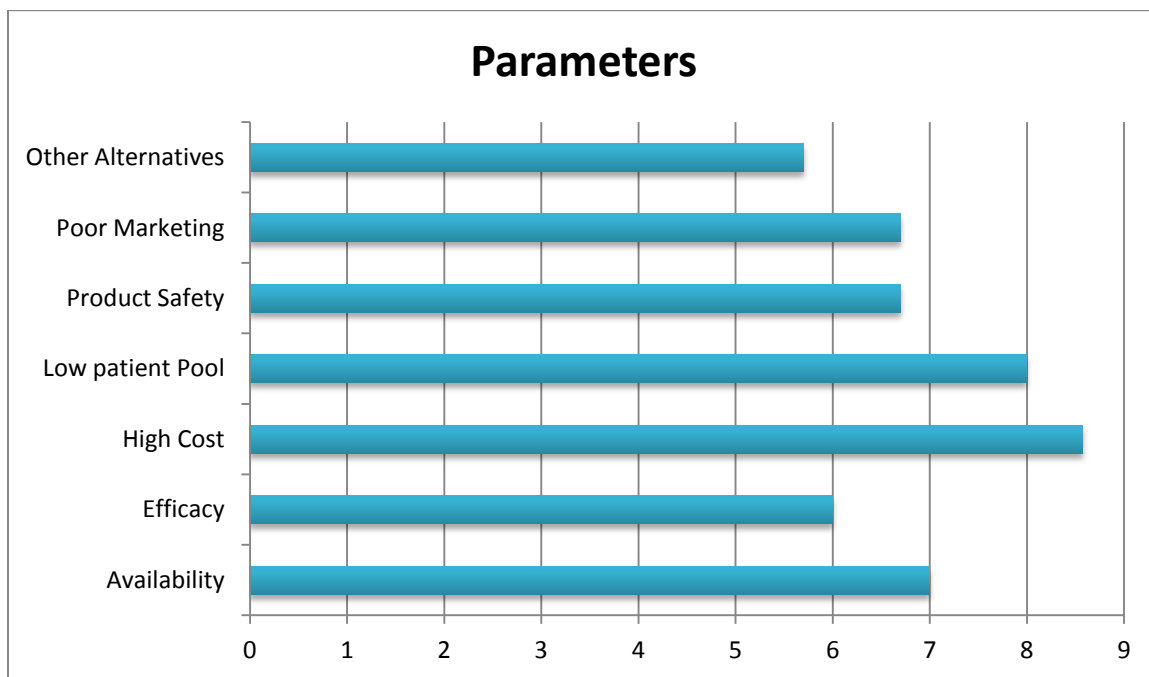
Satisfaction Level



Awareness Level



Q) 9. Why hyper immunes are not a part of your therapy?



High cost and low patient pool are two major parameters which highly affects the doctor's therapy regimen.

Observation

- 59% of the overall doctors use hyper immunes; rest 41% does not use any Ig product.
- According to the survey results, most of the doctors said that the accessibility of the products they are using is easy. A few also said that we do not take any headache for the drugs, the storekeeper keeps it updated regularly.
- The no. of cases in each category was mostly within 0-5 range. Also the percentages of patients who can be administered by hyper immunes were within 0-10 range with 1 or to variants.
- Quality, safety, availability were the three major parameters on behalf of which the doctors were choosing their brand.
- The reason for not using any plasma product in these seven cities, which I felt personally too, was the low patient pool and the higher cost of the plasma products.
- Hepaglob, Rabipur, Tetglob and Rhoclone were the brands which were extensively used by the doctors in the whole territory.
- Awareness level in case of the HBIG was average among the doctors, out of 28 positive responses, 18 were in normal to very high range.
- In case of anti rabies, the situation was far better, out of 14, 13 were in normal to very high awareness level range.
- Aligarh was the city where anti rabies hyper immunes and anti-D were not used, doctors preferably refer the patients to big hospitals.
- In Muzaffarnagar, there was no use of tetanus immunoglobulins.
- Awareness level of Anti-D hyper immunes was high, out of 31 positive responses, 74% of doctors were within normal to very high range.
- In case of tetanus immunoglobulins, all were in normal to very high awareness range. So awareness level was quite good.

Recommendation and findings

- From all the data analysis, we can easily come to know that the opportunity of plasma products in these cities is quite good. It needs proper marketing of these products.
- In case of tetanus and rabies, some of the doctors said that there are rare cases of these diseases, so usage of plasma products is quite low; they just give vaccines to the patients. Availability of these products is also a matter of concern in cities like Aligarh, Agra, Muzaffarnagar and Gwalior. Rest Noida, Ghaziabad and Meerut are quite good in availability of these products. But it needs to be improved.
- In Aligarh, there was not a single doctor prescribing Anti-D immunoglobulin. It was because of the less development of the area, I personally think.
- Opportunity are there in these cities, Aligarh, Agra, Muzaffarnagar, Gwalior are not so developed cities, so there is a huge opportunity of these products. I would also like to mention that the people out there are not so educated as compared to the metro cities; same is the case with doctors.
- They prescribe vaccines for the rabies, tetanus. When I asked the questions like which products are you using? Some of them said, hmmmmmm!!!!!! You tell the name of products, and when I took a name, they said... “yeah.. This one”. But from the body language of some doctors, it did not seem like they were actually using the hyper immunes.
- Also I would like to mention about the awareness among the doctors. They were moderately high (awareness level) aware about the plasma products on an average. But few were not aware about these, which I personally felt during these 18 days of my project. When I started talking about the awareness program, their reaction was not so good. It looked like, it was hurting their ego. But there should be awareness programs in cities like Agra, Aligarh. Muzaffarnagar, Gwalior so that they can know what actually immunoglobulin's are all about.
- As already mentioned above, the factors which affect the growth of this sector are the availability, high cost, quality and safety of the plasma products.
- Now coming over the demand and supply pattern, the demand of Anti-D is quite high in market, and also the supply to the chemists is good, but opportunity is there with the price discrimination policy. As we know that prices of Anti-D are very high, so I would like to recommend that one should come in the market with the competitive price if they want to lead this market. Because price is the major factor which affect the anti-d usage. Same is applicable in case of HBIG also. But in tetanus and anti rabies immunoglobulins, as prices are affordable and cases are very few. There is not so much of opportunity in these two categories.

Conclusion

At the end of the summer training project, I like to conclude my learning's as:

- How to conduct a survey
- How to deal with the doctors
- How to get information from the doctors

On the contrary I gathered some knowledge about hyper immune market in western UP and Gwalior. I would like to share which I personally felt.

During the 18 days of my project, I analyzed that there is a huge opportunity in hyper immunes sector. As the plasma is still imported from other countries, the manufacturing of the products are on a higher side. If we start making it in our country, then prices may fall down. So blood banks should be enabled so that they fulfill the requirements.

There is a huge scope in HBIG in cities like Agra, Aligarh. These are not so developed, so they also need some awareness programs like camps and all (but no one was ready to take this step). There are rare cases of tetanus and rabies, which can be fulfilled by their vaccines. But Anti-D is a sector which can be attacked by the new manufacturer. There is no doubt that Rhoclone is extensively used as Anti-D, but price of a single vial is around Rs 2500. So for a common man it becomes bit difficult to afford it. If some Anti-D product with lower price is launched in the market in future, then it would have some good amount of market share. But in case of Tetanus and Anti- Rabies hyper immunes, there are very few cases in cities like Aligarh, Agra and all, so there is not so much of opportunity to launch these products. Although HBIG has brighter future in this territory.