

“Market Investigation of Products Based on Plasma Derived Therapeutic Proteins”

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PLASMA JOURNEY

Pristine Quality
Spotless Delivery

Plasma is procured from Licensed Blood Banks after conducting series of extensive Audits.

Each bag is tested for 5 viral markers viz.

- Hepatitis B
- Hepatitis C
- H.I.V.
- Malaria
- Syphilis

By highly sensitive techniques such as NAT or ELISA.

Cold chain transport $\leq -20^{\circ}\text{C}$.

Procured plasma is stored at $\leq -20^{\circ}\text{C}$.

Maintenance of vein to bag backtracking registry at PlasmaGen BioSciences storage center.

Products tested and approved at NIB.

TESTED
APPROVED

Final product tested at the manufacturing site for 3 viral markers viz.

- Hepatitis B
- Hepatitis C
- H.I.V.

Purification Process:
Viral Inactivation
&
Viral Removal

Mini
pool
testing

Manufacturing
pool
testing

Plasma pool tested and approved at NIB.

TESTED
APPROVED





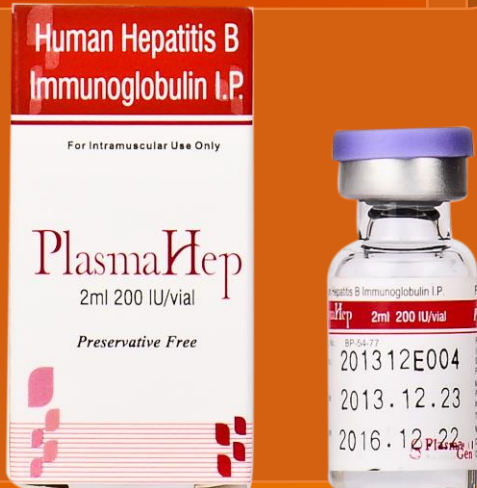
Intravenous Immunoglobulin



Human Albumin



Rho D Immunoglobulin(Intramuscular)



Hepatitis B Immunoglobulin



Rho D Immunoglobulin(Intravenous)



Human Rabies Immunoglobulin

COMPOSITION OF BLOOD



PLASMA- 55% total volume of blood

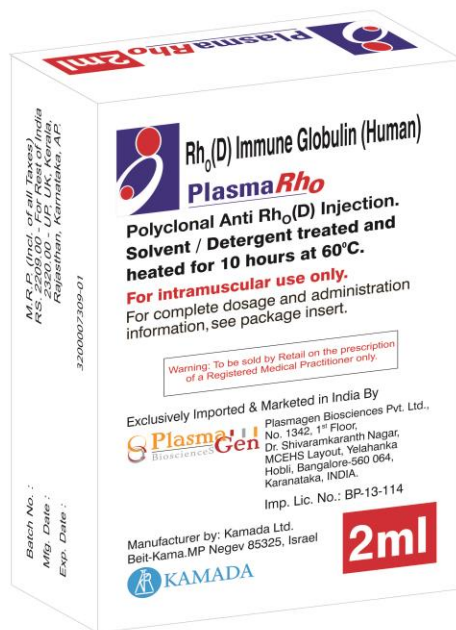
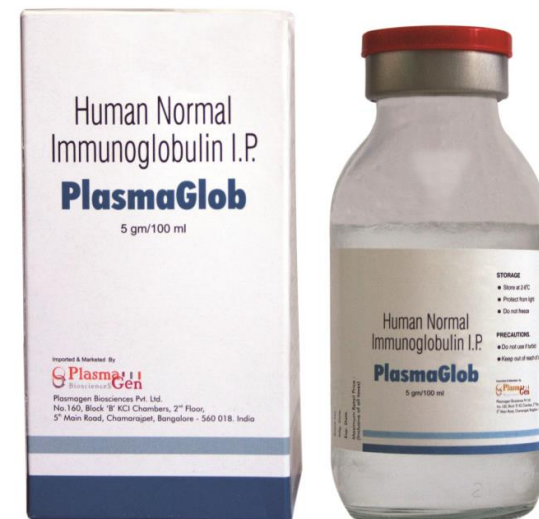
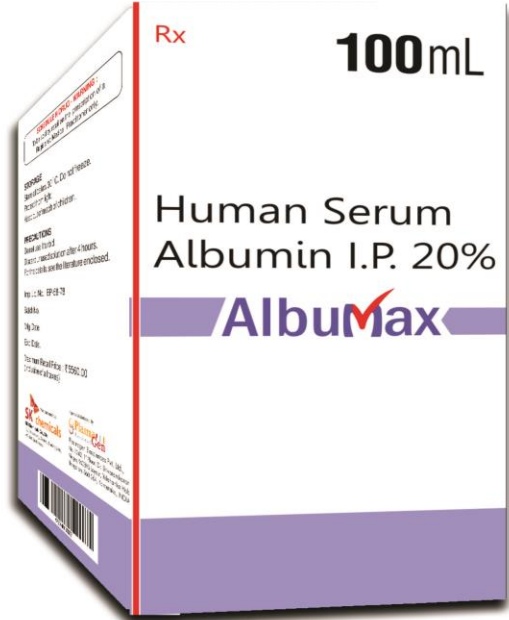
- Mostly liquid water (91%)
- Soluble blood proteins (7%)
- Hormones
- Electrolytes
- Nutrients

CELLULAR COMPONENTS- 45% total volume of blood

- **Red blood cells-** involved in carrying oxygen
- **White blood cells-** involved in the immune system
- **Platelets-** involved in blood clotting

PLASMA PRODUCTS : THERAPEUTIC VALUE

- Albumin : Shock/Trauma
- IVIG : Neurological infections
- Factor VIII : Hemophilia-A
- Factor IX : Hemophilia-B
- von Willebrand Factor : Clotting disorder
- Pro-thrombin Complex : Disseminated intravascular coagulation
- Factor VII : Clotting disorders
- Fibrinogen : Liver diseases
- Fibrin Glue Kit : Surgery



Quality
Safety
Purity

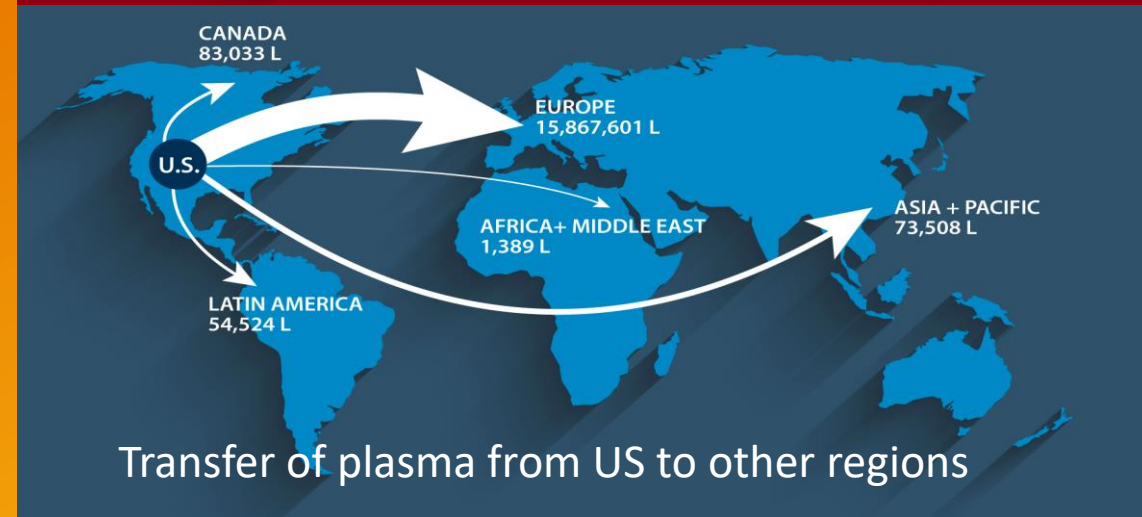
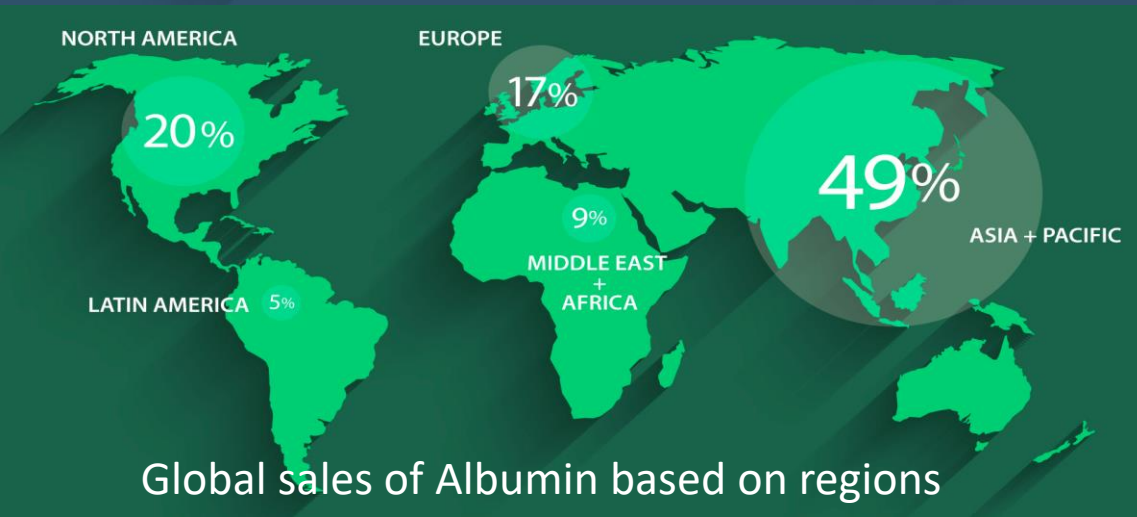
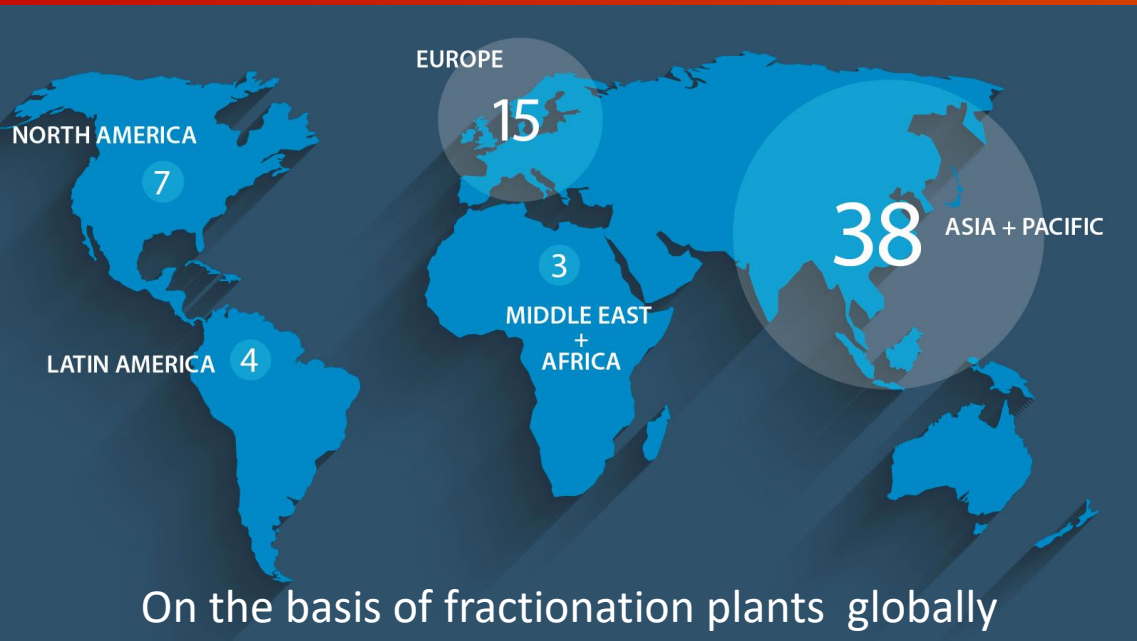


IVIIG Indications

- 1.Primary Immunodeficiency Diseases (PID)
- 2.Idiopathic Thrombocytopenic Purpura (ITP)
- 3.Chronic Lymphocytic Leukemia (CLL)
- 4.Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- 5.Kawasaki Disease (KD)
- 6.Guillian-Barren Syndrome (GBS)

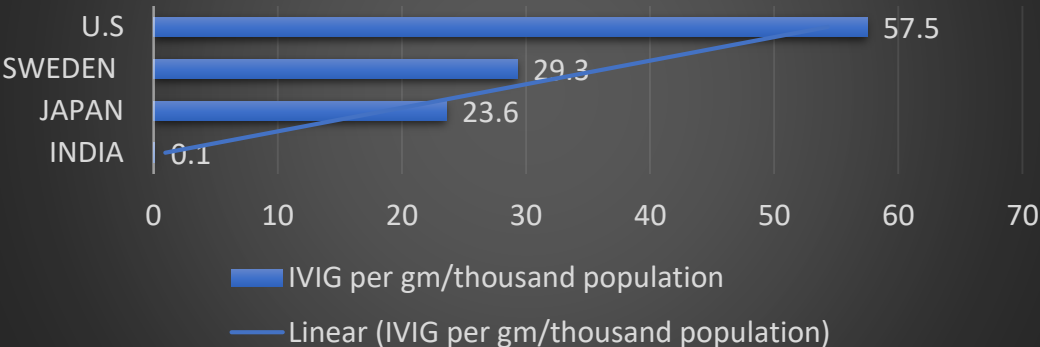


GLOBAL PLASMA MARKET

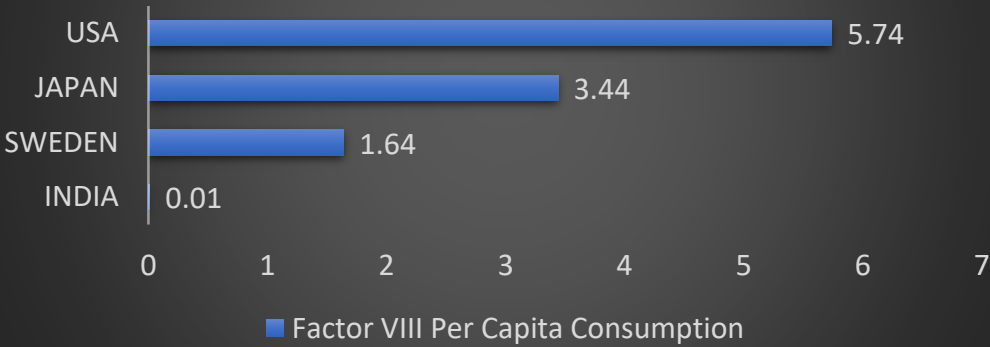


COMPARISON WITH INDIAN PLASMA MARKET

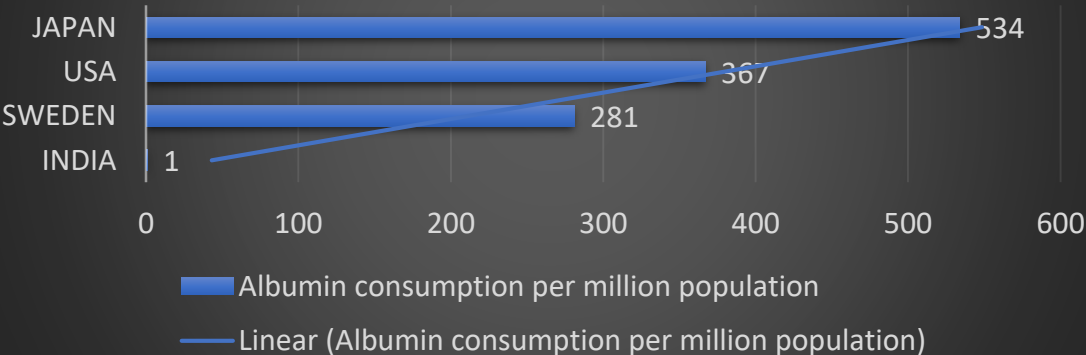
IVIG per gm/thousand population



Factor VIII Per Capita Consumption



Albumin consumption per million population



RESEARCH METHODOLOGY



- **Research Instrument:** A structured questionnaire
- **Data Collection Technique:** Primary data collected from doctor with the help of questionnaire
- **Sampling Technique:** Non probability, Convenience sampling
- **Sample size:**
 - Number of doctors: 120
- **Target Population:** Gynecologist, Hematologist, Intensivists, Neuro-physicians, Pediatricians
- **Area Surveyed:** Bangalore (Karnataka)
- **Pilot Study:** pilot study was carried out at Bangalore and the feed backs were taken and minor changes in the questionnaire were done.



OBJECTIVES

1. To study the Global growth pattern of the products based on plasma derived therapeutic proteins.

- **Scope of study:**

- To understand growth of the product based on plasma derived therapeutic proteins & its indications.
- To study the current scenario of product based on plasma derived therapeutic proteins & its future markets.

OBJECTIVES

2. To study the usage pattern of products based on plasma protein therapies by the Medical Fraternity in Bangalore (Karnataka).

- **Scope of study:**
- Doctor's awareness about the currently used plasma products.
- Effect of the attributes such as availability, free from risk of infection, cost, quality etc. on the prescription pattern.
- To examine the level of satisfaction among doctors for currently available plasma products.



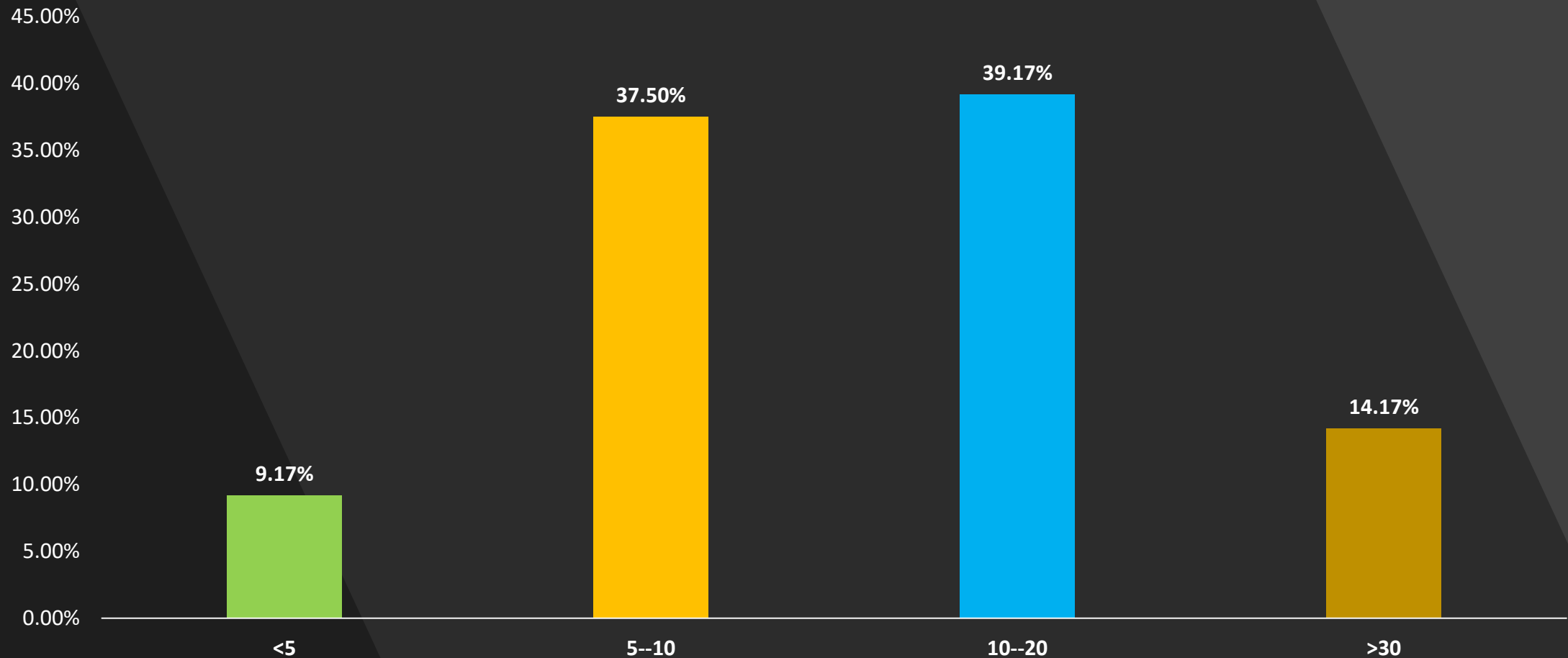
FINDINGS

&

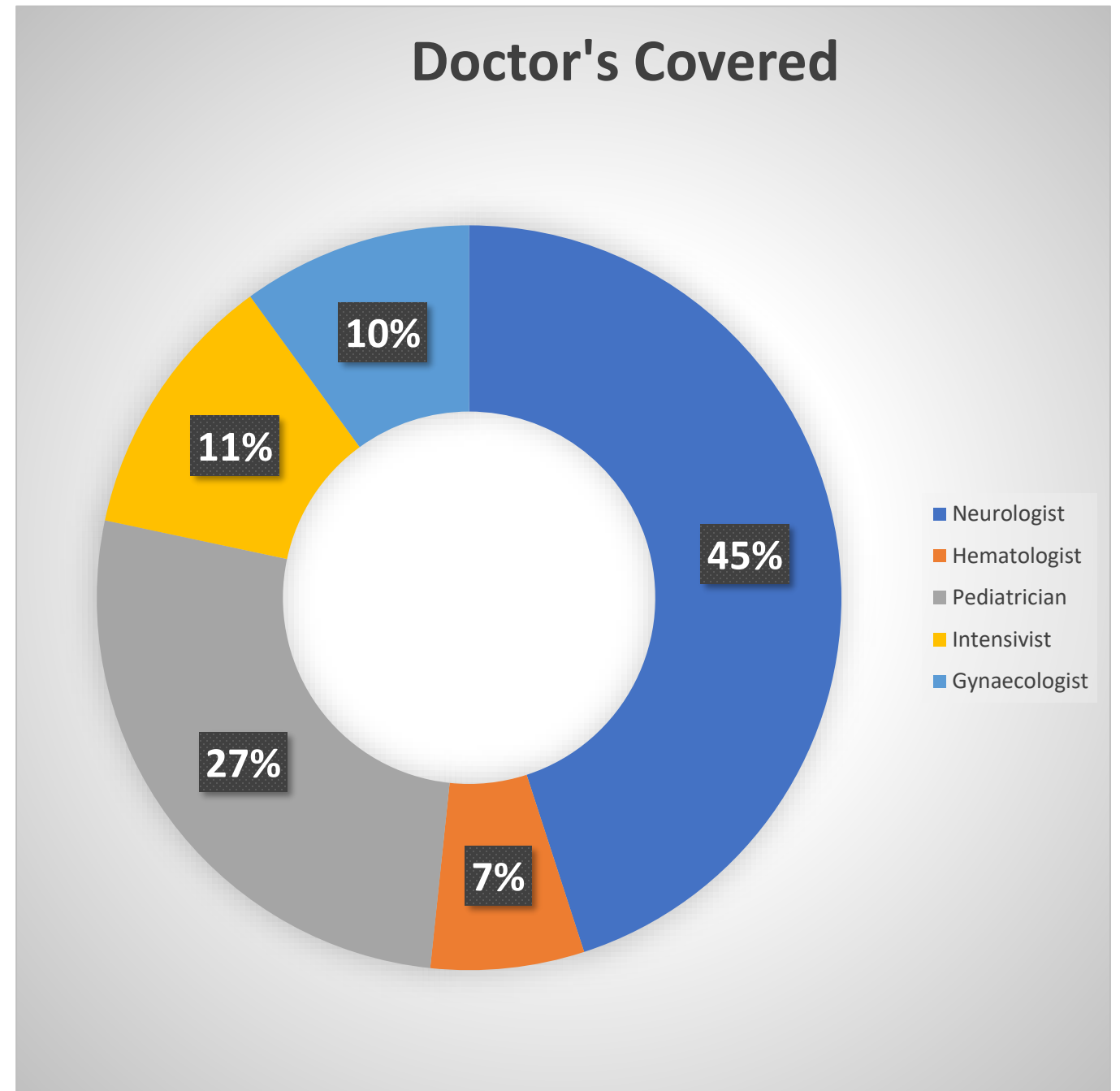
INTERPRETATIONS

1. Average number of patients examined by you in your daily practice:

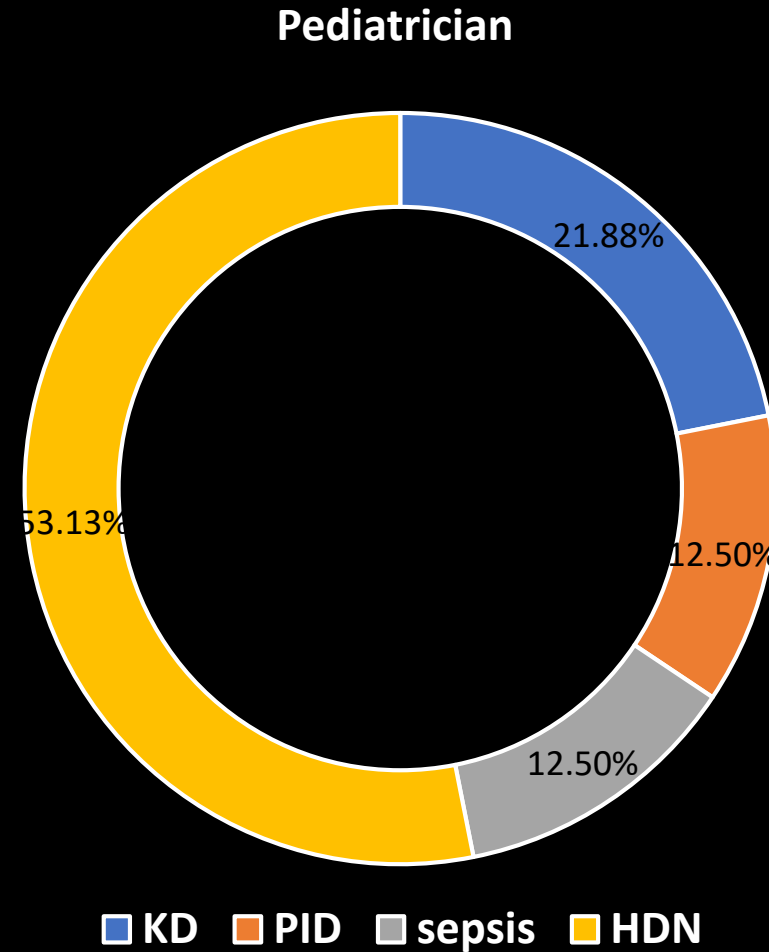
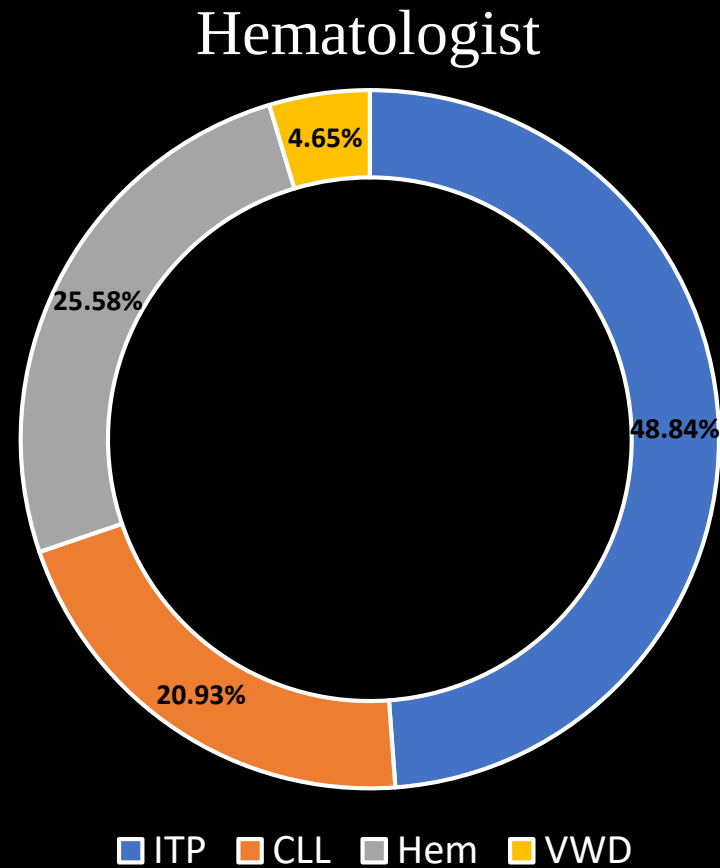
Patients Examined By Doctors



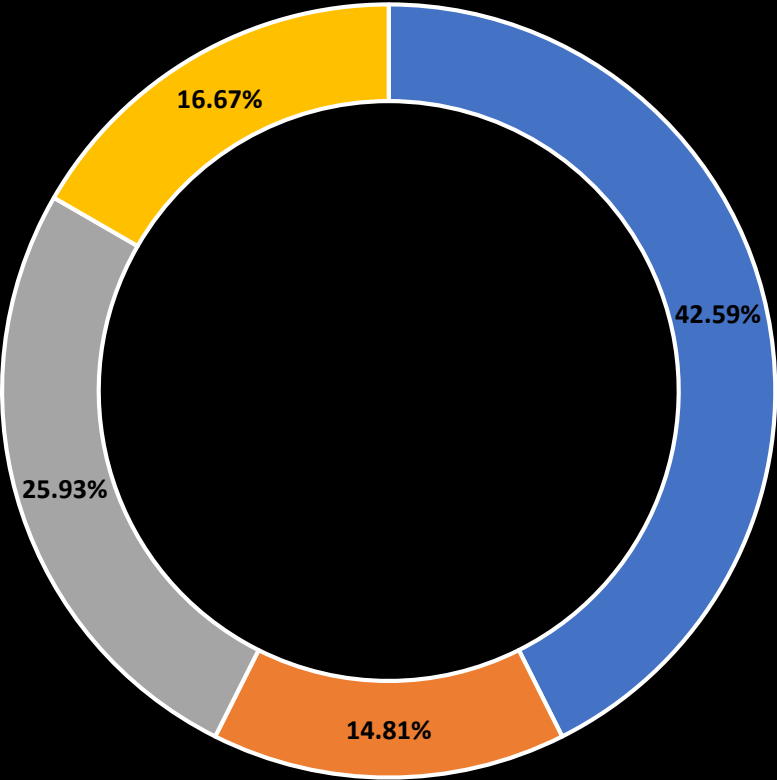
Doctor's covered with different specialty:



Percentage of patients treated for the following disease by specialty with plasma products:

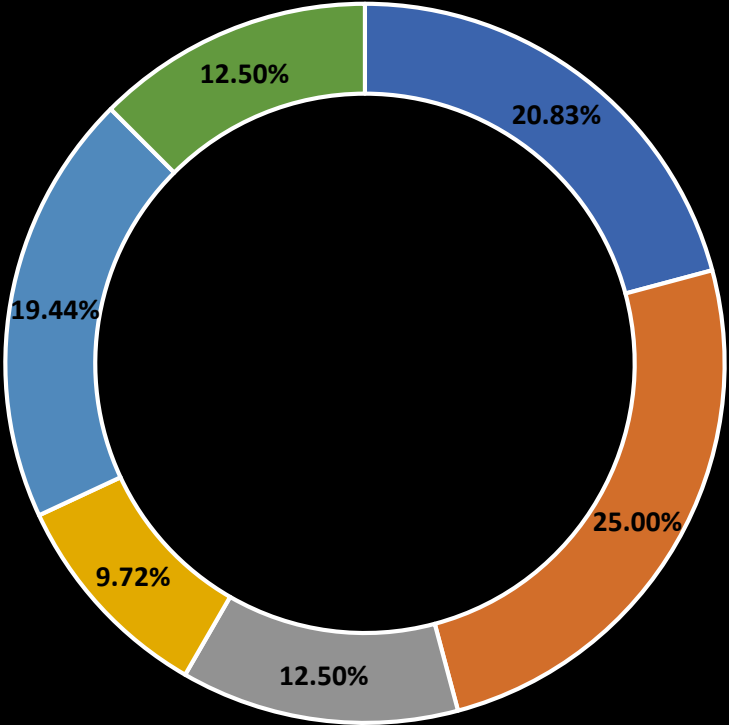


Neurologist



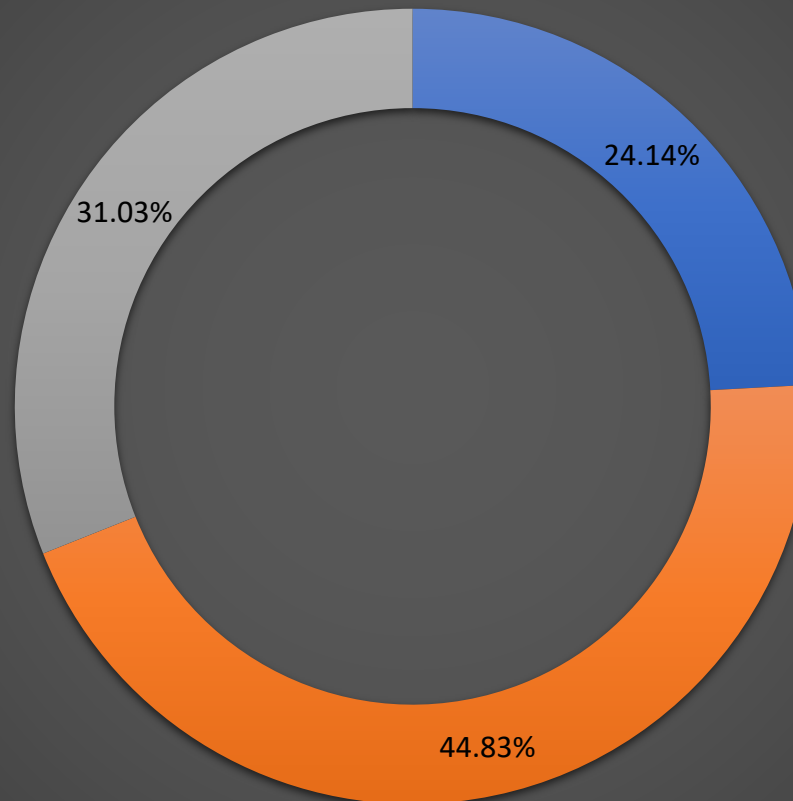
■ GBS ■ MS ■ CIDP ■ MG

Intensivist



■ Burn ■ shock ■ organ Transplantation
■ Severe infections ■ Cardiac surgery ■ Liver disease

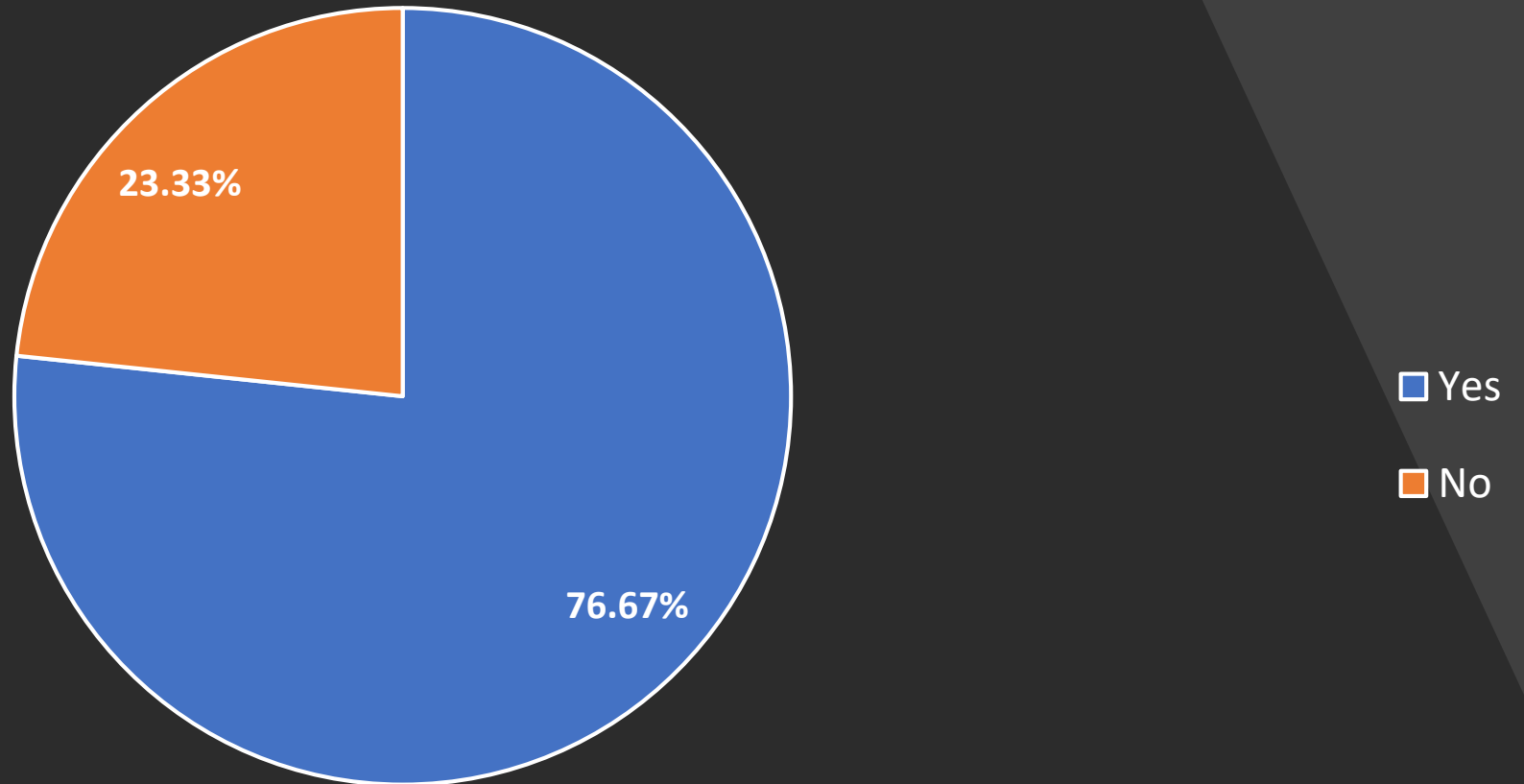
Gynaecologist



■ Rh-Incompatibility ■ APS ■ RPL

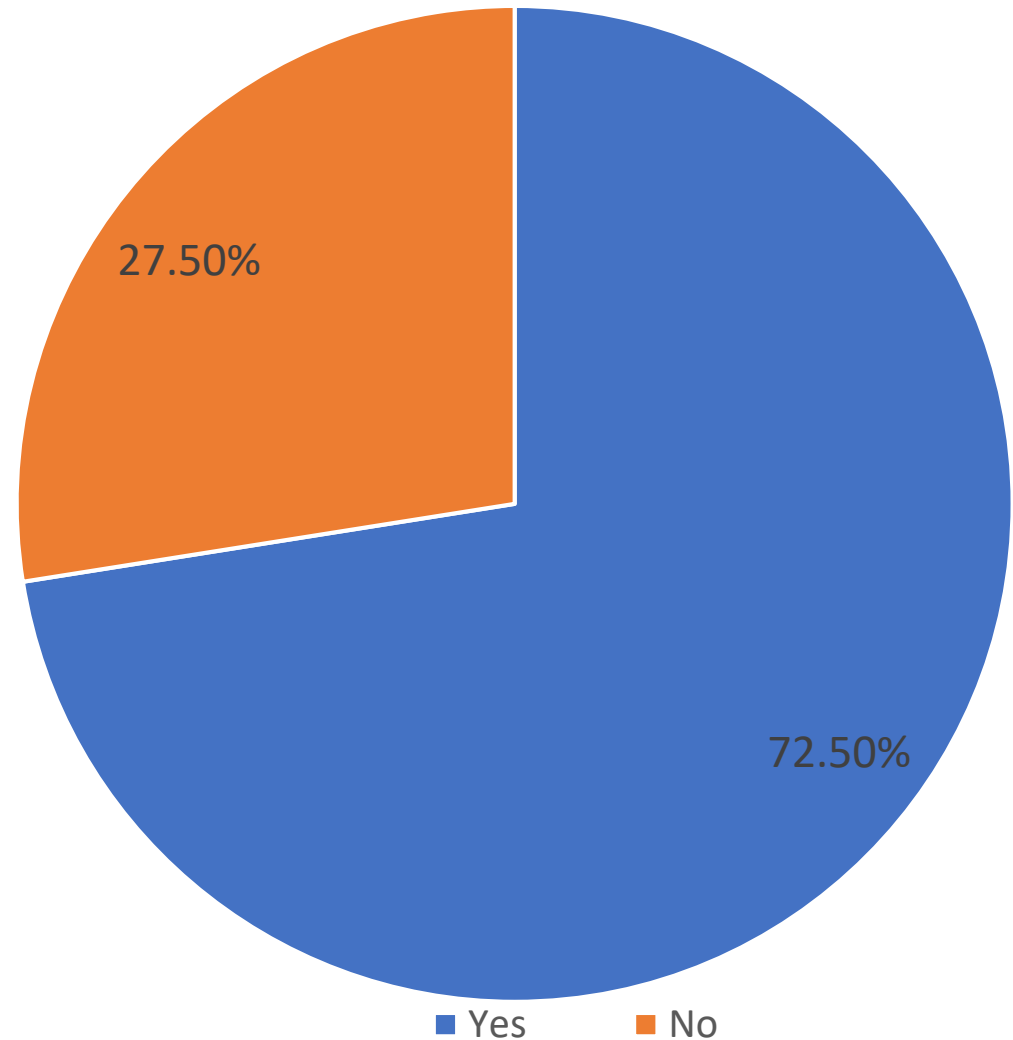
Percentage of Doctors aware about the existing brand of plasma product in the market:

Awareness about existing Plasma Products



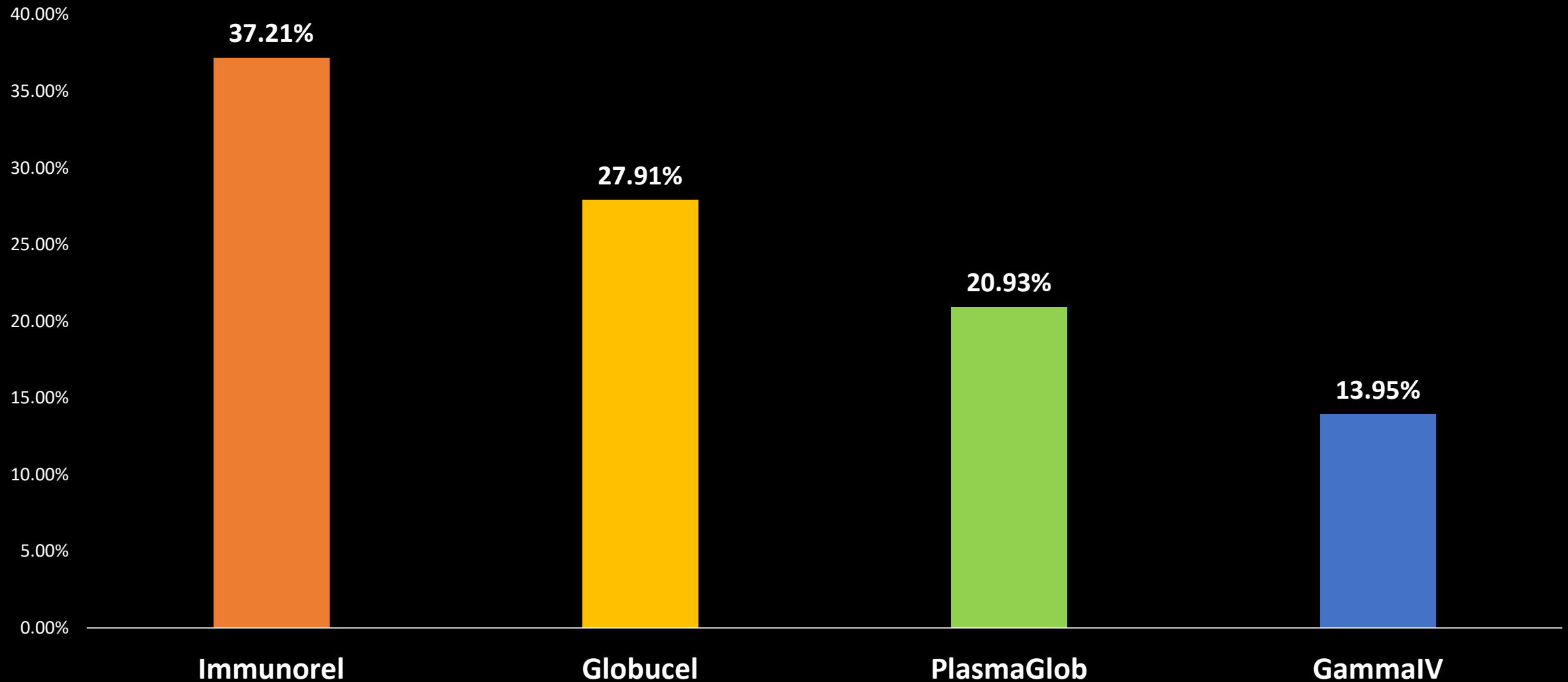
Percentage of
Doctors having
specific
preference for a
well-established
brand in plasma
product
category:

Brand preference by respondents

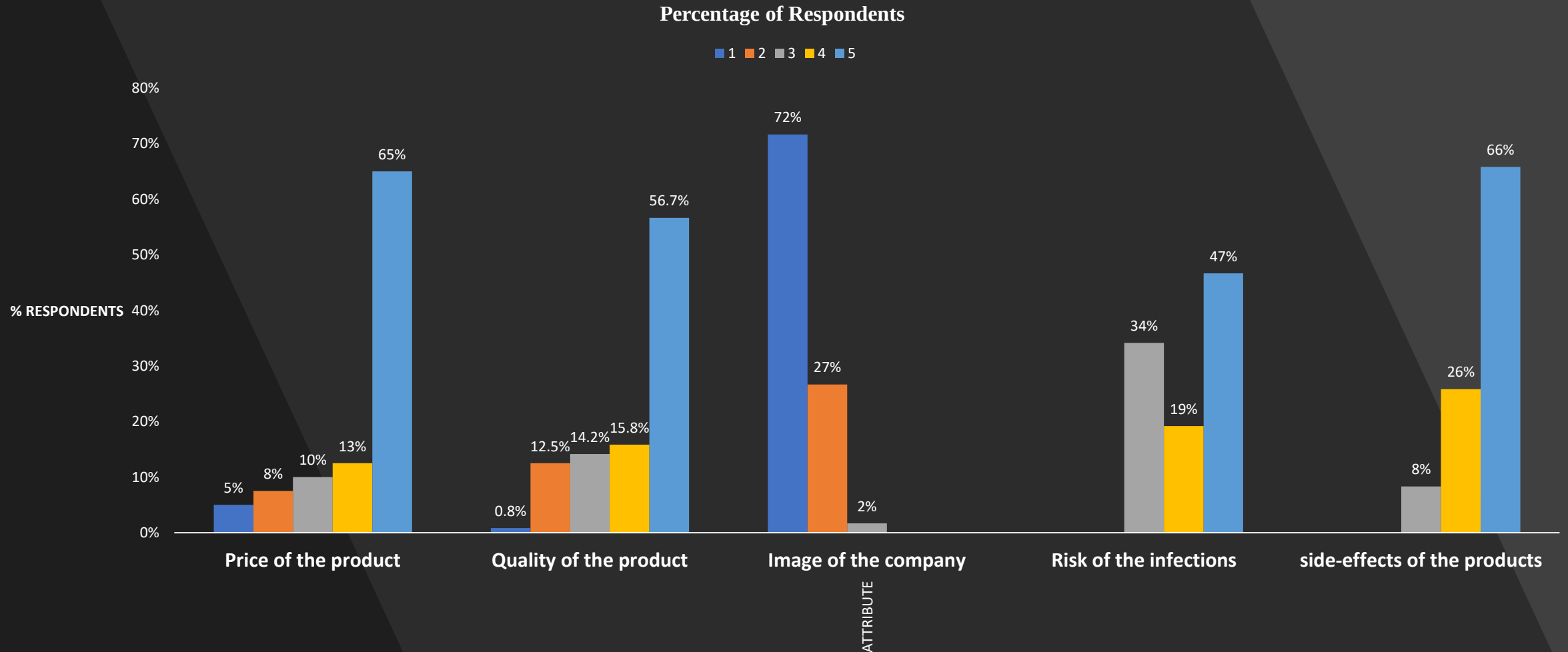


Most popular brand used by Fraternity:

Brand preferred by Respondents%



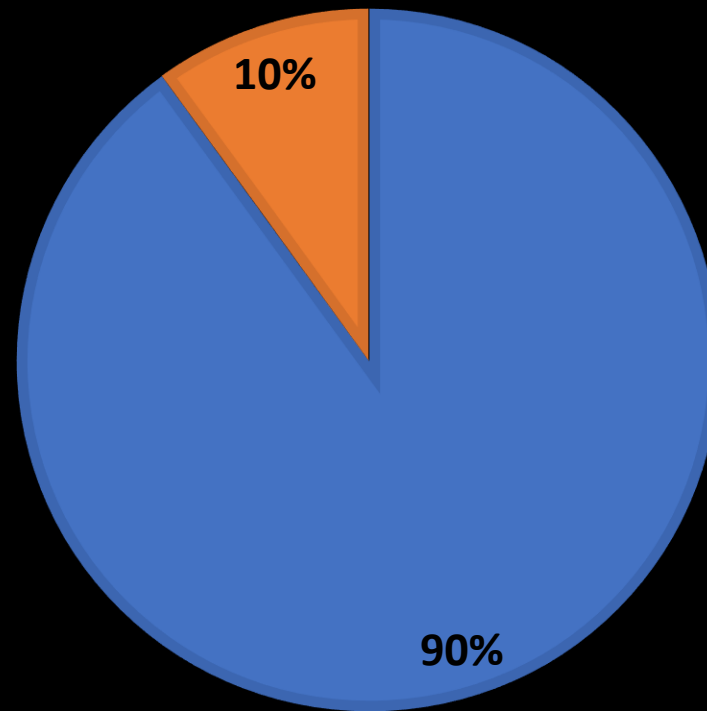
Attributes considered while prescribing the plasma products:



Percentage of doctors satisfied with the performance of available plasma products in the market.

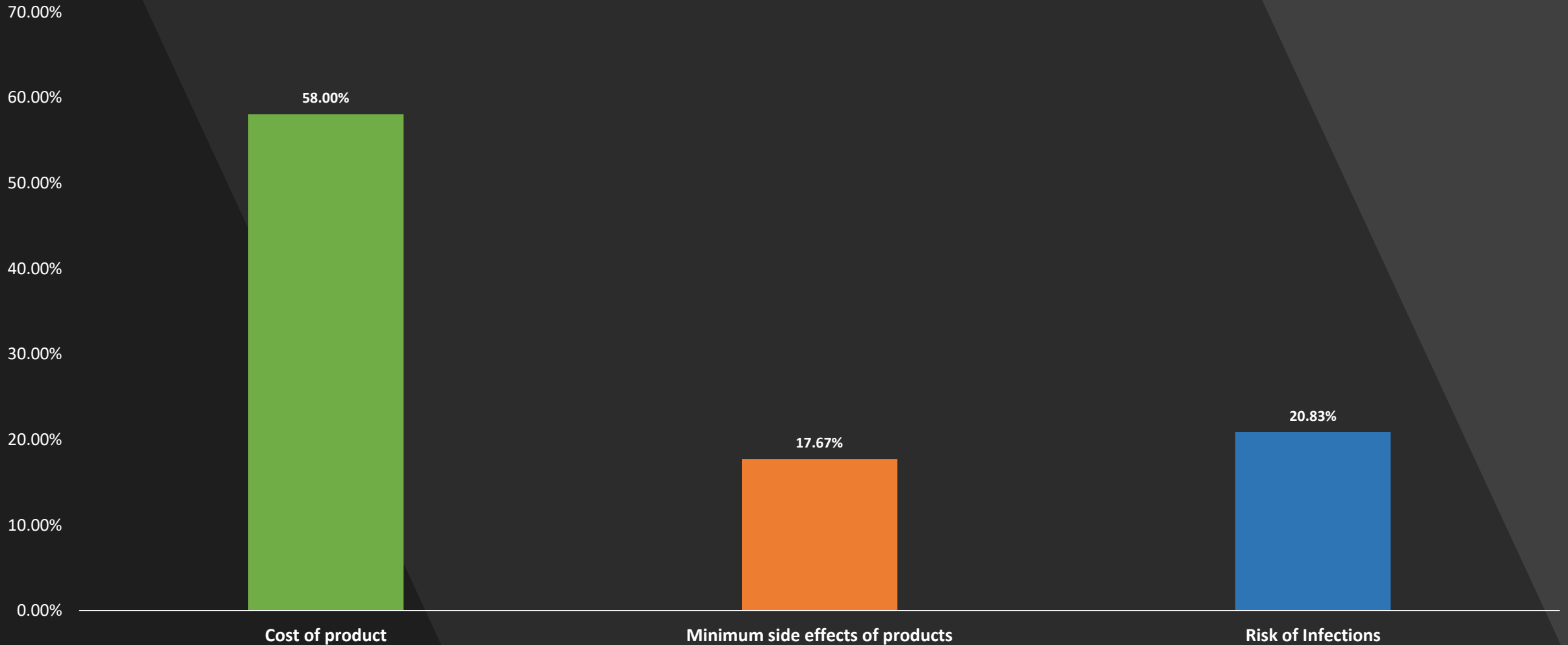
PRODUCT SATISFACTION WITH PLASMA PRODUCTS

■ Yes ■ No



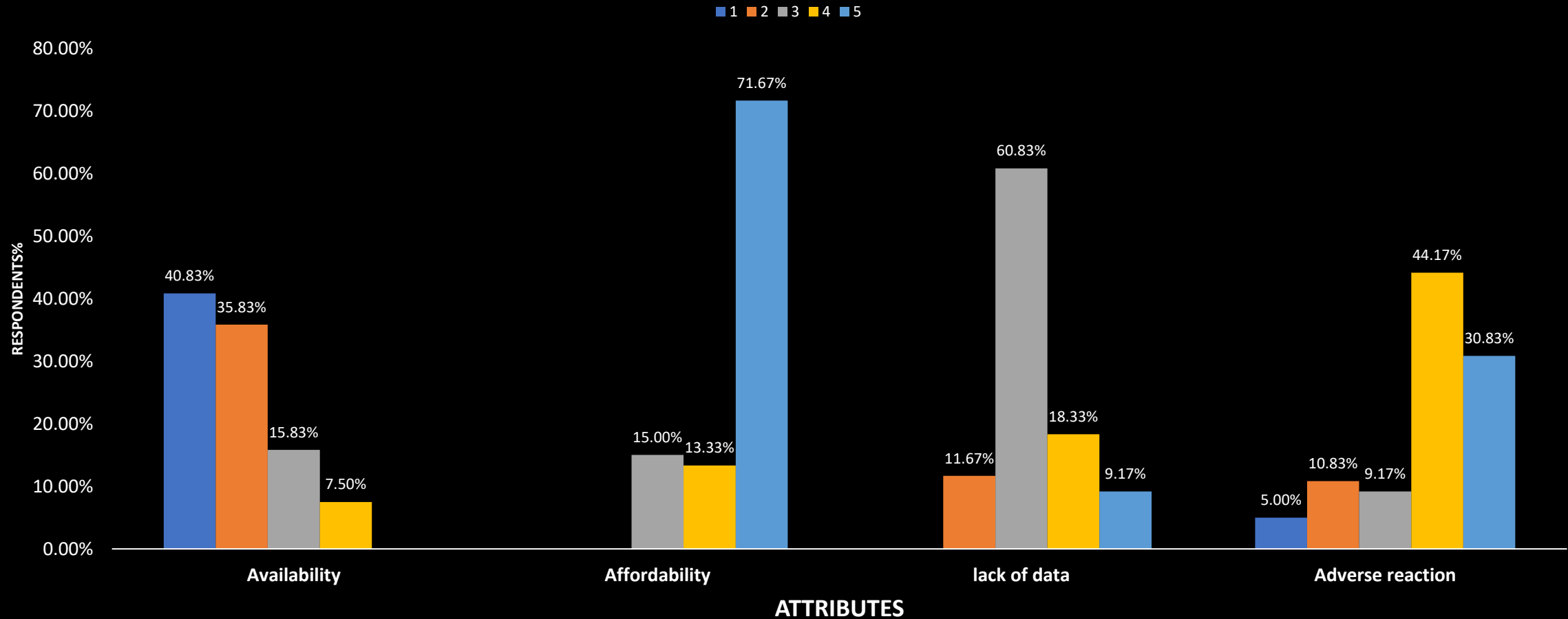
Benefits that unsatisfied respondents are looking for

Benefits seek by unsatisfied respondents



Problems considered while prescribing plasma product

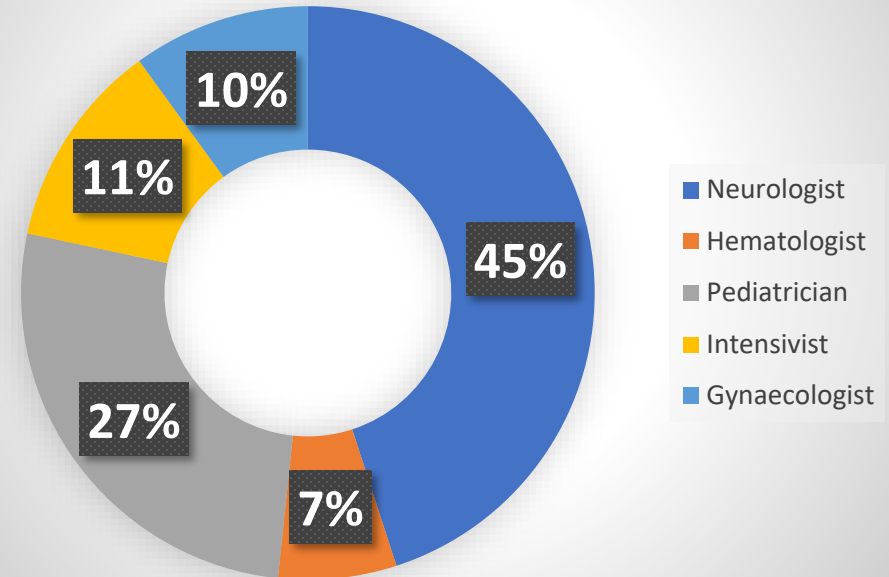
Percentage of Respondents



RESULTS

- “100% of the respondent interviewed prescribe the plasma products to their patients. These 100% of the respondents comprises of the doctors who were prescribing all the plasma products like human albumin, IVIG and clotting factors to their patients”.
- “The 45% of the prescribers who prescribes the plasma products to 10-25% of their Patients comprises of the physicians, Haemato-oncologists and Intensivists”.
- “It was observed that the respondents were prescribing the albumin to the patients. This group comprises of physicians, pediatricians, intensivists and surgeons. Its use in current clinical replaced by the dextran and other polymer type of the volume expanders because they are easily available and less prone to the viral and other type of blood borne infections”.

Doctor's Covered



CONT.....

- The gynecologists are also using the albumin in preterm baby and to maintain the volume loss in the post-operative patients after in obstetric surgery.
- The albumin is also used by the general surgeons in post-operative patients.
- There is the more demand for the low salt albumen in the market as this is frequently prescribed.
- About 45% of the respondents were prescribing the intravenous immunoglobulin to their patients, this percent mainly consists of general physicians, hemato-oncologists, neuro physicians.
- “The Hemato oncologists mainly prescribe IVIg for ITP, all immune thrombocytopenia and AIDS related thrombocytopenia. Neuro-physicians were using IVIg in GBS, Evans Syndrome, myasthenia, stiff person syndrome and in some newer indications like dermatomyositis and demyelination”.

CONT.....

- About 71% of respondents were not prescribing clotting factors to their patients. This percentage of not using the clotting factors is since doctors were using whole human blood, whole human plasma cryoprecipitate instead of specific clotting factors”.
- The clotting factors are most commonly used in Hemophilia, Von Willebrand disease, Liver disease and DIC (Disseminated Intravascular Coagulation).
- The pediatrician prescribes the clotting factors in neonatal liver disease and septicemia.
- After interacting with some respondents, it was found that individuals with <1% of the normal level of clotting factors have severe hemophilia and have a higher need for substitution therapy.



CONT....

- 77% of the respondents were aware of the existing brands of plasma products. Most able to recall the brand names of the plasma products.
- 72% of the respondents said that there is a well-established brand in the plasma product category.
- “39% of the respondents said that (Reliance Lifesciences) is the most popular brand of the plasma product category where as 29% of the respondents said that (Intas) is the most popular brand and 13% of the respondents said that (PlasmaGen Biosciences) is the popular brand in recent market”.
- 23% of respondents are not satisfied with available plasma products in the market and they were looking for the benefits like and risk of infection followed by the cost of the products.
- Problem of cost of the product (65%), Lack of data in special indications (71%), adverse reactions (44%), were the major problems while prescribing the plasma products.



CONCLUSION

Price of the product

Lack of data availability

Lack of diseases
diagnosis

