# A Cross-Sectional Observational Study on Audit of Biotherapeutics Used in Pediatric Patients in a Tertiary Care Hospital

**Shritama Banerjee[1], Manab Nandy[1], Suhena Sarkar[1], Rakesh Mondal[2], Agnidipa Sanyamath[1]**

**Mitaj Halsana[1], Atanu Adak[3], Tanmoy Gangopadhyay[1*]**

*[1] Department of Pharmacology, Medical College and Hospital, Kolkata, India.*

*[2] Department of Pediatrics, Medical College and Hospital, Kolkata, India.*

*[3] Multidisciplinary Research Unit, Medical College and Hospital, Kolkata, India.*

***Received: 2024-12-26, Revised:2025-02-18, Accepted: 2025-03-15, Published:2025-03-31***

**Abstract**

***Background:*** Biotherapeutics are a class of therapeutic products derived from biological sources and used in the treatment of different diseases and disorders. Data on biotherapeutic utilization in different diseases is inadequate in the pediatric population.

***Methods:*** This observational, cross-sectional study was conducted for a year to audit the use of biotherapeutics in Pediatric patients (1-12 yrs) at a tertiary care hospital. The data on biotherapeutics was collected in Case Report Forms (CRFs) validated by peers and subject experts. The adverse reaction of biotherapeutics was recorded in the Suspected Adverse Drug Reaction Form (version 1.4). The price of biotherapeutics was calculated as the average price of a standard manufacturer available at the hospital.

***Results:*** A total of 141 patients were recruited and it was found that intravenous immunoglobulin (IVIG) (35.46%), 20% human albumin (25.53%), recombinant human growth hormone (17.02%), filgrastim (7.80%), rituximab (6.38%), Tocilizumab (1.41%), factor VIII (2.12%), diphtheria antitoxin (0.70%), erythropoietin (0.70%), infliximab (0.70%), factor VIIa (0.07%), insulin and insulin with glargine (0.07%) and streptokinase (0.07%) were used in treatment of various diseases and disorders. About one-third of patients (35%) received biotherapeutics as a 1st line of treatment, and 90% experienced no adverse effects. Regardless of biotherapeutic use, we observed headache, fever, respiratory distress, and ankle swelling as adverse effects. The annual biotherapeutics budget was INR 6,786,137, with intravenous immunoglobulin (IVIG) accounting for the main expenditures at INR 5,720,000.

***Conclusion:*** In developing countries, technological advancements and increased availability of biotherapeutics and the use of biosimilars may reduce costs in the future. This study will also help in the formulation of budgets for tertiary care hospitals.

J Pharm Care 2025; 13(1): 49-57.

**Keywords:** Biotherapeutics; Pediatric Patients; Tertiary Care Hospital; Budget

## Introduction

Biotherapeutics are known as biological medical products, or biopharmaceuticals, derived from living organisms or produced using biotechnology. Biotherapeutics are used to treat a wide range of medical conditions, including serious ones like cancer, autoimmune disorders, and infectious diseases (1, 2). Biotherapeutics, derived from living sources, are complex and variable, making them harder to produce and control the quality of than regular drugs (3). However, the effectiveness of biotherapeutics in targeting specific biological pathways and mechanisms has made them an important part of modern medicine, offering new treatment options for patients with previously untreatable

*** Corresponding Author:** Tanmoy Gangopadhyay
Address: Department of Pharmacology, Medical College, Kolkata, West Bengal, India.
Email: tanmoy_ganguly@yahoo.co.in

or poorly managed conditions. Biotherapeutics have also improved the outcomes of various diseases, including cancers, diabetes, blood disorders, infectious diseases, and autoimmune diseases (4, 5). The development and approval process for biotherapeutics is rigorous, involving extensive research, comprehensive clinical trials, and ongoing post-market surveillance to ensure their safety and efficacy. Biotherapeutics are regulated by health authorities such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to ensure they are safe and effective for their intended uses (6). In India, biotherapeutics are used for a variety of therapeutic purposes, similar to their use in other parts of the world. The Indian pharmaceutical market for biotherapeutics is experiencing rapid growth, driven by factors such as increasing public awareness, improvements in healthcare infrastructure, and the rising prevalence of chronic diseases. Significant investments in research and development are being made by both domestic and international companies to develop novel biologic therapies (7). Biosimilars, which are highly similar to original biologic medications, are gaining prominence in India. The Indian government and regulatory bodies, such as the Central Drugs Standard Control Organization (CDSCO), play a crucial role in ensuring the safety, efficacy, and quality of all biotherapeutics available in the country (8). In India, a total of 98 biosimilars, including vaccines, monoclonal antibodies, insulin, and recombinant proteins approved and are mainly used in the treatment of autoimmune diseases, oncology, and diabetes. The use of biosimilars is expanding in India; however, the cost constraints remain a significant challenge in developing countries. However, biosimilars offer a targeted approach like biotherapeutics to treat diseases by focusing on specific molecular pathways or cells. This precision allows for effective treatments with fewer side effects compared to traditional broad-acting drugs. By minimizing side effects, it reduces the need for additional medications and hospital stays, thereby lowering overall healthcare costs. Data on biotherapeutic utilization within the pediatric population is very limited. This study was designed to investigate the use of biotherapeutics in pediatric patients at a tertiary care hospital in Eastern India. Auditing biotherapeutic use in pediatric care can provide valuable data for policy and budget decisions related to childhood diseases.

## Methods

This observational, cross-sectional study was conducted at Medical College and Hospital, Kolkata, a tertiary care hospital. Ethical approval was obtained from the Institutional Ethics Committee of Medical College and Hospital, Kolkata (reference number MC/KoL/IEC/Non-Spon/1526/109/2022, dated September 9, 2022). The data collection form was formulated following the Case Report Forms (CRFs) guideline and validated by peers and subject experts to ensure that the collected data was accurate, reliable, and complete. The standard textbook of Nelson's textbook of Pediatrics (22nd edition) and The Pharmacological Basis of Therapeutics by Goodman and Gillman (14th edition) were followed as databases for checking the indications of the agents. The adverse reactions of biotherapeutics were recorded in the Suspected Adverse Drug Reaction Form (version 1.4), formulated by the Indian Pharmacopoeia Commission. Data were collected from October 2022 to September 2023. Patients aged 1-12 years were included in the study after taking proper consent from their parents admitted in the pediatric inpatient setting and pediatric intensive care unit of the hospital. Patients who did not complete the course of treatment, as well as those whose parents provided incomplete consent, were excluded from the study. Due to a lack of epidemiological data, the sample size was calculated based on previous records. The records indicated an average of three patients receiving biotherapeutics per week. Over a 12-month data collection period (52 weeks), the estimated total number of pediatric patients receiving biotherapeutics was approximately 156 patients. Data were collected prospectively that included patients' history, diagnosis, biotherapeutics use, dose, routes of administration and indications, and adverse drug reactions were recorded at the time of data collection. The price of biotherapeutics was calculated as the average price of a standard manufacturer available at the hospital. Quantitative data collected were double-entered and analyzed using GraphPad Prism version 9, whereas qualitative data were presented as frequency (percentage).

## Results

Data on biotherapeutics used for 141 patients aged 1-12 years were included in the study. During the study, 57.44% of patients receiving biotherapeutics were male, while 42.55% were female. Additionally, 15.60% of the patients were between 1 and 4 years old, 21.27% were between 5 and 8 years old, and 56.02% were between 9 and 12 years old. The most common treatment was intravenous immunoglobulin (IVIG) at 35.46%, followed by 20% human albumin at 25.53%, recombinant human growth hormone at 17.02%, filgrastim at 7.80%, rituximab at 6.38%, factor VIII at 2.12%, and tocilizumab at 1.41%. Diphtheria antitoxin, erythropoietin, and infliximab were used in 0.70% of the cases, while factor VIIa, insulin, insulin with glargine, and streptokinase were used in 0.07% of the cases (Figure 1).

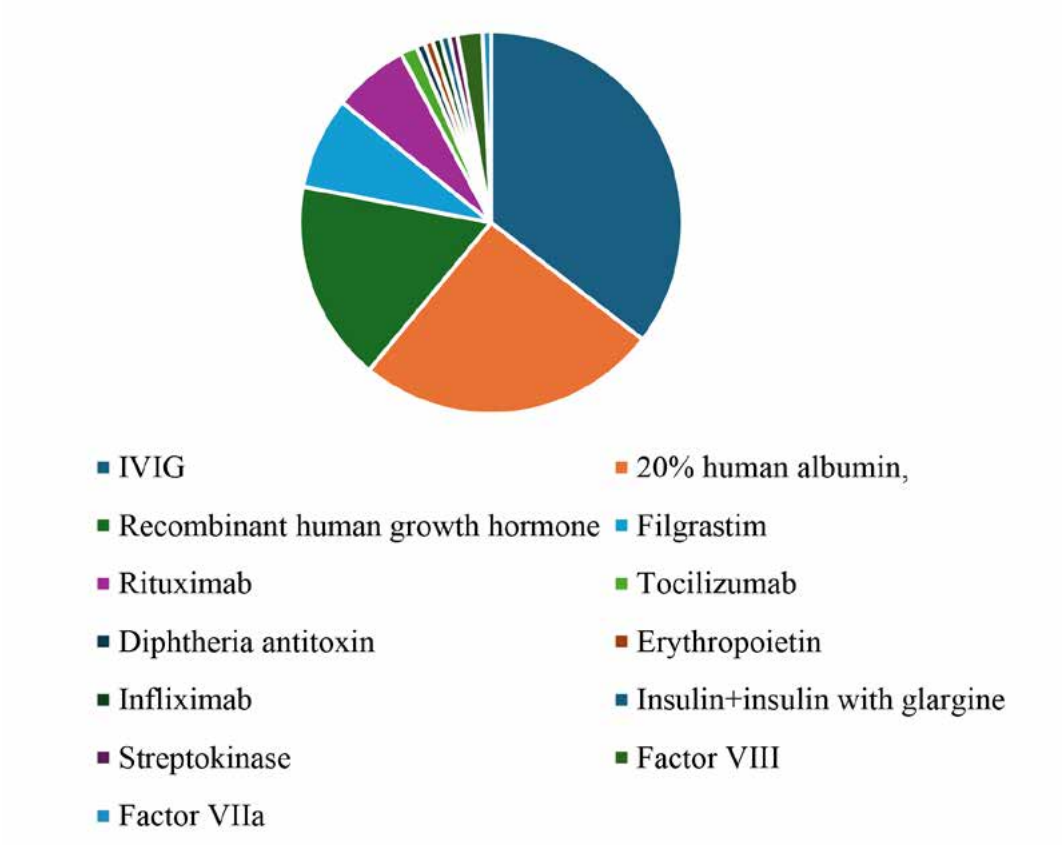


**Figure 1. Use of different biotherapeutics in Pediatric population**

IVIG was primarily used to treat Guillain-Barre syndrome (GBS) (34%), followed by idiopathic thrombocytopenic purpura (ITP) (18%) and Kawasaki disease (KD) (12%). It was also used for various other conditions, including multisystem inflammatory syndrome, sepsis, severe combined immunodeficiency (SCID), scrub typhus, myasthenia gravis (MG), acute kidney injury (AKI), acute inflammatory demyelinating polyneuropathy (AIDP), encephalitis, and upper respiratory tract infection (Figure 2).

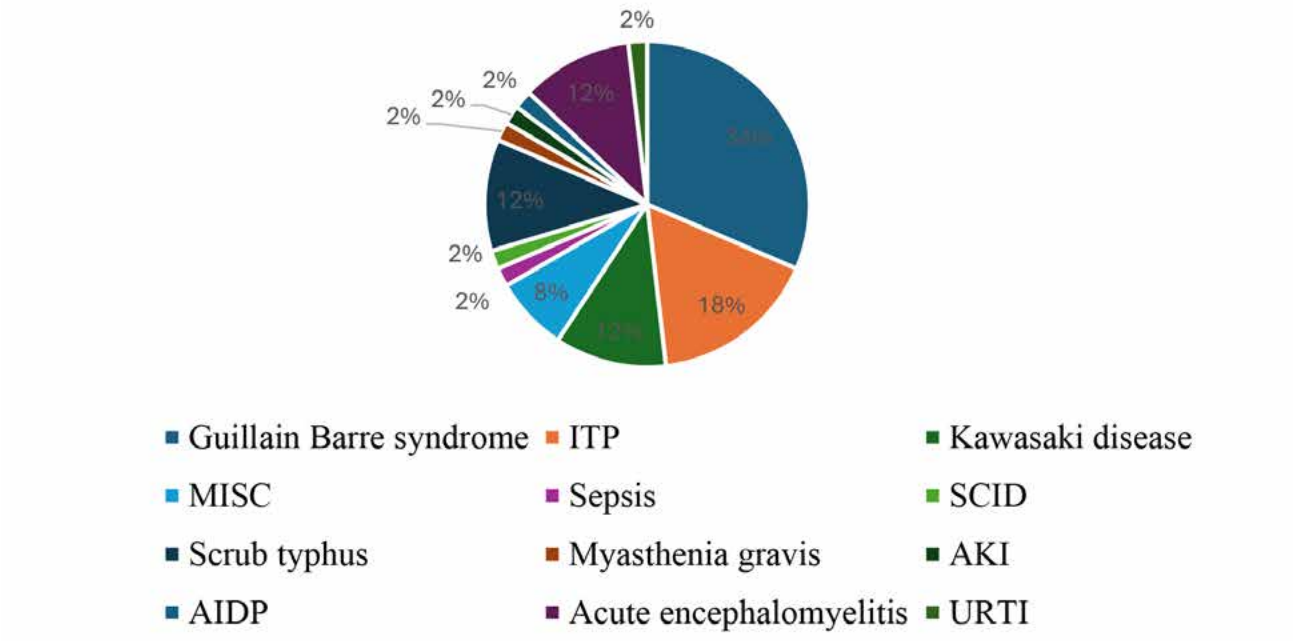


**Figure 2. Use of Intravenous immunoglobulin (IVIG) in different diseases and disorders of the pediatric population**

It was observed that 35% of the patients received biotherapeutics as the first line and others as a second line of treatment. In the first line of treatment, major cases were from endocrine disorders, and a few cases from hematological diseases like hemophilia A, anemia secondary to chronic kidney disease, factor VIII deficiency, and a neurological complication due to acute disseminated encephalomyelitis. IVIG was used as the first line of treatment in GBS (34%) and other diseases, it was used as the second line of treatment. Considering the various systems, it was found that biotherapeutics use was highest in nephrology (43.71%), followed by neurology and endocrinology, each at 35.25%. Other areas where biotherapeutics were used, in descending order, include hematology (23.97%), hemato-oncology (21.15%), immunology (14.1%), infectious diseases (11.28%), cardiology (8.46%), and respirology (5.64%) (Figure 3).

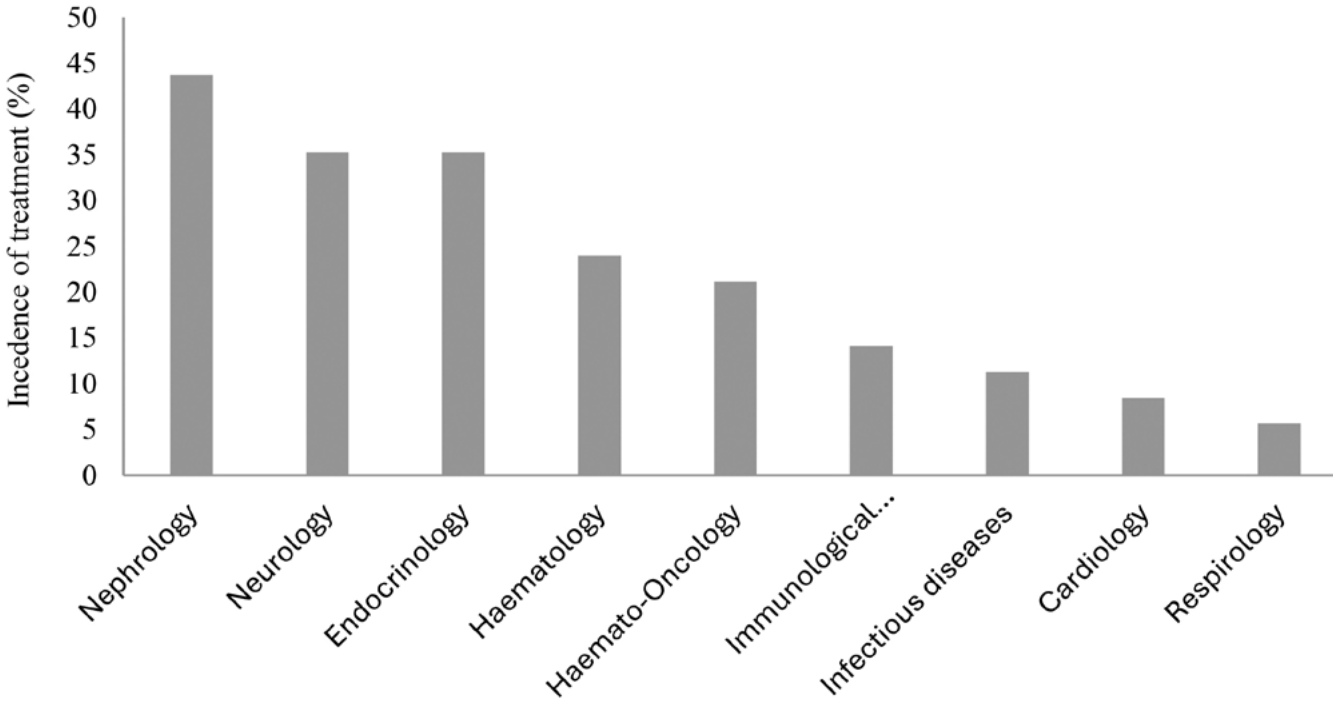


**Figure 3. Use of biotherapeutics in different diseases in various systems involved in the diseases**

Biotherapeutics used in different diseases and disorders for the complications of the different systems were represented in Table 1. For nephrological conditions, IVIG and 20% human albumin were used to treat acute kidney injury, nephrotic syndrome, and steroid-dependent nephrotic syndrome. Neurological applications of IVIG and filgrastim included treatment for acute disseminated encephalomyelitis, autoimmune encephalitis, epilepsy, GBS, sarcoma, AIDP, and acute meningoencephalitis. Endocrinological treatments with insulin glargine and growth hormones addressed diabetic ketoacidosis, Turner syndrome, growth hormone deficiency, and Noonan syndrome. Hematological conditions treated with tocilizumab, IVIG, recombinant factor VIII, erythropoietin, and rituximab included multicentric Castleman disease, ITP, hemophilia A, anemia secondary to CKD, factor VII deficiency, pemphigus vulgaris, and autoimmune hemolytic anemia. In hemato-oncology, filgrastim and rituximab were used for T-ALL, sarcoma, acute leukemia, and ITP. Also, IVIG and Rituximab were used for the treatment of immunological disorders such as SCID (T and NK cell deficiency) and MG.

**Table 1. Biotherapeutics used in different systemic complications**

| Name of the system | Disease diagnosis | Biotherapeutics used |
|---|---|---|
| Nephrology | Acute Kidney Injury | IVIG |
| | Nephrotic syndrome | Albumin |
| | Steroid-dependent nephrotic syndrome | |
| Neurology | Acute disseminated encephalomyelitis | IVIG |
| | Autoimmune encephalitis | Filgrastim |
| | Epilepsy under evaluation | |
| | Guillain Barre syndrome | |
| | Sarcoma | |
| | AIDP | |
| | Acute meningoencephalitis | |
| Endocrinology | Diabetic ketoacidosis | Insulin Glargine |
| | Turner | Growth hormones |
| | GHD | |
| | Noonan | |
| Haematology | Multicentric Castleman disease | Tocilizumab |
| | Idiopathic thrombocytopenic purpura | IVIG |
| | Haemophilia A | Recombinant Factor VIII |
| | Anemia secondary to CKD | Erythropoietin |
| | Factor VII deficiency | Rituximab |
| | Pemphigus vulgaris | |
| | AIHA | |
| | ITP | |
| Haemato-Oncology | T- Acute lymphocytic leukemia (T-ALL) | Filgrastim |
| | Sarcoma | Rituximab |
| | Acute leukemia | |
| | ITP | |
| | Sarcoma | |
| Immunological disorder | Severe immunocombined disorder (T and NK cell deficiency) | IVIG |
| | Myasthenia gravis | Rituximab |
| Infectious diseases | MISC | IVIG |
| | Sepsis and coagulation disorder | |
| | Severe septic shock with thrombocytopenia and multi-organ failure | |
| | ITP | |
| | Scrub typhus with COVID IgG positive | |
| Cardiology | Kawasaki disease | IVIG |
| Respirology | Recurrent pneumonia | Tocilizumab |
| | Right-sided empyema with URTI | IVIG |
| | cough, cold, respiratory distress | Injectable Streptokinase |
| | Diptheria | Diptheria antitoxin |

IVIG: Intravenous Immunoglobulin, AIDP: Acute Inflammatory Demyelinating Polyneuropathy, GHD: Growth Hormone Deficiency, CKD: Chronic Kidney Disease, AIHA: Autoimmune Hemolytic Anemia, ITP: Immune Thrombocytopenic Purpura, COVID: Coronavirus Disease, URTI: Upper Respiratory Tract Infection.

In addition, IVIG was used to treat several infectious diseases, including Multisystem Inflammatory Syndrome in Children (MIS-C), sepsis with coagulation disorders, severe septic shock, ITP, and scrub typhus with COVID IgG positivity. For KD, a cardiac condition, IVIG was also used. In the realm of respiratory illnesses, diphtheria antitoxin, tocilizumab, IVIG, and streptokinase were employed for recurrent pneumonia, right-sided empyema with upper respiratory tract infection (URTI), and general cough, cold, and respiratory distress. The World Health Organization (WHO) defines Adverse Drug Reaction (ADR) as "A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or the modification of physiological function". Of 141 patients, 127 patients (90%) showed no adverse drug reactions during treatment with biotherapeutics. The most common adverse effects were headache, fever, respiratory distress, and swelling of the ankles, irrespective of biotherapeutics use. However, some patients experienced minor side effects such as nausea, rashes, and diarrhea during biotherapeutic treatment; none of these reactions were severe enough to necessitate discontinuation of therapy. Generally, biotherapeutics are used for the treatment of particular diseases according to the body weight, which may vary from patient to patient. In the present study, the use of biotherapeutics was recorded during treatment, and the price was calculated accordingly following the average price of a standard manufacturer. The highest expenditure for a biotherapeutic was for IVIG, costing 5,720,000 Indian Rupees (INR), which was substantially more expensive than all other biotherapeutics (1 INR ≈ 0.0120 USD). The second highest cost was for Albumin at INR 558,000. Other biotherapeutic costs included Rituximab at INR 146,662.5, Infliximab at INR 72,000, growth hormone at INR 117,225, and Tocilizumab at INR 47,250. The expenses for different biotherapeutics are shown in Figure 4. The total annual expenditure for biotherapeutics was approximately INR 6786137 for pediatric patients in a tertiary care hospital.

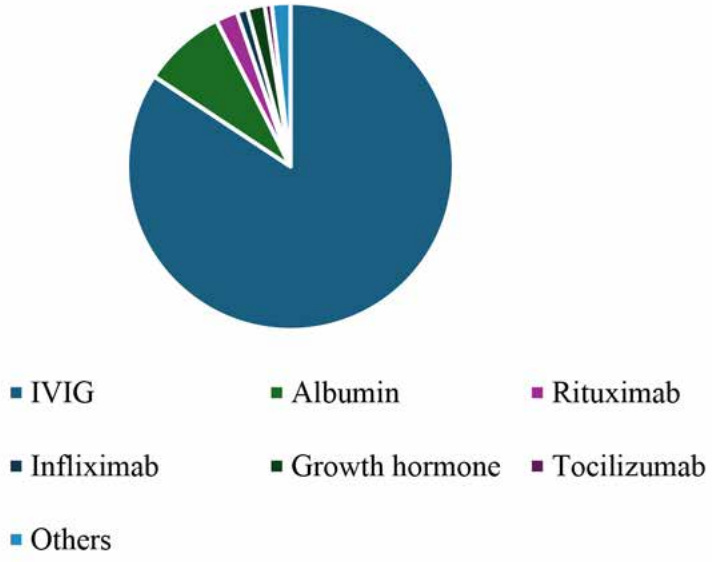


**Figure 4. Annual expenditure for different biotherapeutics for the treatment of different diseases in the Pediatric population**

## Discussion

India is home to nearly 19% of the world's children, with over one-third of the country's population, approximately 480 million people, being under the age of 18. Children, in general, are healthier than their adult counterparts, particularly as adults reach the fifth decade of life and beyond (9). However, children do have multiple acute illnesses each year, and a substantial number of children, often estimated to be 20% or more, are burdened with chronic health disorders, some of them disabling or life-threatening. Medical attention, including evidence-based prescription of drugs or biotherapeutics, is vital for their well-being. Biologicals are a diverse group of medicines that includes vaccines, growth factors, gene therapy, recombinant proteins, immune modulators, monoclonal antibodies, as well as products derived from human blood and plasma (10). Since the early 1980s, a total of 239 therapeutics have been approved for clinical use by the US-FDA (11). Also, vaccines are biotherapeutics used for preventing infectious diseases and protecting public

health. Gene therapy is also a therapy that involves altering a person's genes to treat or prevent diseases. While it holds great potential, it also raises several ethical concerns. For this reason, vaccines and gene therapy were excluded from the present study. In the present study, the most common biotherapeutics used in pediatrics were IVIG, human albumin, recombinant human growth hormone, filgrastim, rituximab, factor VIII, tocilizumab, diphtheria antitoxin, erythropoietin, and infliximab. Each biotherapeutic has a specific mode of action that mainly targets specific molecules of a pathway of a disease. These biotherapeutics can be used as the first or second line of therapy. Typically, patients initially receive conventional synthetic drugs as a first-line therapy. If these prove ineffective, biotherapeutics are used to treat the specific condition and achieve a more effective outcome. The present study showed that mostly biotherapeutics are used in the pediatric population as the second line of therapy. Sometimes, the first line varies depending on the specific condition being treated in the patients. IVIG was found to be used mostly frequently biotherapeutic. It is mainly used in the treatment of (a) immunodeficiencies, (b) autoimmune diseases, and (c) acute infections. In the present study, IVIG was used in GBS and KD as the first line of therapy whereas in other diseases, it was used as a second line of treatment ITP, sepsis, SCID, Scrub typhus with hemophagocytic lymphohistiocytosis (HLH), myasthenia gravis, AIDP and autoimmune encephalitis. Worldwide, it was also observed that IVIG had a major impact on the treatment of neurological disorders, including dermatomyositis, GBS, chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy, myasthenia gravis and stiff person syndrome (12, 13, 20). In the present study, 20% albumin was used to replace the protein lost in nephrotic syndrome. Generally, 20% human albumin is also used in the treatment of liver failure, haemolytic disease of the fetus and newborn, and post-operative liver transplant management (14, 15). Among the top three utilized biotherapeutics, recombinant human growth hormone is used as the first line therapy in growth deficiency. The treatment is received more by females than by males. Apart from IVIG, 20% albumin, and growth hormone treatment, filgrastim was used in T acute lymphocytic leukemia (T-ALL) and sarcoma for management of neutropenia. Recombinant factor VIII was used in hemophilia A, and factor VII deficiency as the first line of treatment. Infliximab targeted the binding and neutralizing TNF-α which was used in cyclosporine resistant psoriasis (16). Rituximab is a chimeric monoclonal antibody targeted against CD20, a surface antigen presents on B cells that was used in acute leukemia. Interleukin-6 (IL-6) is a cytokine that plays an important role in immune response and is implicated in the pathogenesis of many diseases (17). Tocilizumab is a humanized monoclonal antibody against the interleukin-6 receptor (IL-6R) used in Multicentric Castleman disease and recurrent pneumonia. Erythropoietin is a glycoprotein that stimulates red blood cell production (erythropoiesis) in the bone marrow. In the present study, erythropoietin was used in anemia secondary to CKD (18). Apart from these biotherapeutics, diphtheria antitoxin was used in diphtheria, streptokinase was used in cough, cold, respiratory distress, insulin with glargine was used in diabetic ketoacidosis insulin with glargine. Mostly, biotherapeutics were used in nephrology followed by neurology, endocrinology, hematology, hemato-oncology, immunological disorders, infectious diseases, cardiology, and respirology. Previously, it was reported that a total of 89 drug variants treated in metabolic disorders, followed by immunological, and hematological diseases, cancer therapy, hormonal disorders, genetic disorders, infectious diseases, cardiovascular disorders, bone disorders, neurological disorders, and respiratory disorders, given as adjunct, eye disorders, and used in malabsorption disorders (19). The high cost of IVIG, the primary component of a tertiary care hospital's approximately INR 6,786,137 annual biotherapeutics budget, poses a significant challenge to healthcare budgets. While other biotherapeutics like Rituximab, growth hormone, Infliximab, and Tocilizumab also contribute to expenses, IVIG's dominance necessitates careful consideration of resource allocation and policy decisions (20). Furthermore, the high cost of IVIG may limit patient access, highlighting the ethical and social imperative to improve affordability and equity. Currently, budgetary constraints in India often dictate the use of drugs and conventional medications as the first-line therapy. However, the demonstrated efficacy and improved outcomes of biotherapeutics in pediatric patients are attracting increasing attention from clinicians. The generalizability of the study was limited due to its focus on a specific population and healthcare setting. Additionally, the findings of the study may be affected by biases introduced through hospital-specific data collection practices and a limited sample size. Future research may address the efficacy and cost-effectiveness of biotherapeutics in pediatric care.

## Conclusion

The continuous evolution of this field has resulted in a wider range of biotherapeutics with diverse applications.

This includes not only treatments for diseases like cancer and autoimmune disorders but also the diagnosis of diseases. The increasing availability and affordability of biotherapeutics, along with the use of biosimilars, could have a significant positive impact on developing countries.

## Conflicts of Interest

The authors have nothing to declare.

## Acknowledgement

The authors acknowledged the support of the Multi-disciplinary Research Unit, Medical College and Hospital, Kolkata, a scheme of the Department of Health Research, Government of India, for this research in data analysis and manuscript writing.

## References

1. Kinch MS. An Overview of FDA-approved Biologics Medicines. Drug Discov Today. 2015; 20(4):393-98.
2. Steinberg FM, Raso J. Biotech Pharmaceuticals and Biotherapy: An Overview. J Pharm Pharm Sci. 1998; 1(2):48-59.
3. Shi S. Biologics: An Update and Challenge of Their Pharmacokinetics. Curr Drug Metab. 2014;15(3):271-290.
4. Lau SJ, Huang Y, Hsieh J, Wang S, Liu Q, Slattum PW, et al. Participation of Older Adults in Clinical Trials for New Drug Applications and Biologics License Applications from 2010 Through 2019. JAMA Netw Open. 2022;5(10):e2236149.
5. Muralidhara BK, Wong M. Critical Considerations in the Formulation Development of Parenteral Biologic Drugs. Drug Discov Today. 2020; 25(3):574-581.
6. Batta A, Kalra BS, Khirasaria R. Trends in FDA Drug Approvals Over the Last 2 Decades: An Observational Study. J Family Med Prim Care. 2020;9(1):105-114.
7. Kute N, Mankar S, Bhawar S. Biosimilar and its Current Perspective–A Review. Res J Pharmacol Pharmacodyn. 2022;14(2):84-88.
8. Pawar KN, Gore RT, Palekar SR. A Review on Approval Process and Regulation of Medical Devices as per US FDA and CDSCO. Int J Drug Regul Aff. 2023;11(1):61-70.
9. Clark H, Coll-Seck AM, Banerjee A, Peterson S, Dalglish SL, Ameratunga S, et al. A Future for the World's Children? A WHO–UNICEF–Lancet Commission. Lancet. 2020; 395(10224):605-658.
10. Chhabra M. Biological Therapeutic Modalities. In: Hasija Y, editor. Translational biotechnology: Academic Press; 2021. p. 137-164.
11. Newman DJ, Cragg GM. Natural Products as Sources of new Drugs Over the Nearly four Decades from 01/1981 to 09/2019. J Nat Prod. 2020; 83(3):770-803.
12. Hartung HP, Mouthon L, Ahmed R, Jordan S, Laupland K, Jolles S. Clinical Applications of Intravenous Immunoglobulins (IVIg)–beyond Immunodeficiencies and Neurology. Clin Exp Immunol. 2009; 158:23-33.
13. Stangel M, Pul R. Basic Principles of Intravenous Immunoglobulin (IVIg) Treatment. J Neurol. 2006; 253:v18-v24.
14. Zhang J, Zhang R, Wang Y, Li H, Han Q, Wu Y, et al. The Level of Serum Albumin is Associated with Renal Prognosis in Patients with Diabetic Nephropathy. J. Diabetes Res. 2019; 2019(1):7825804.
15. Mendez CM, McClain CJ, Marsano LS. Albumin Therapy in Clinical Practice. Nutr Clin Pract. 2005; 20(3):314-320.
16. Gisondi P, Gubinelli E, Cocuroccia B, Girolomoni G. Targeting Tumor Necrosis Factor-α in the Therapy of Psoriasis. Curr Drug Targets Inflamm Allergy. 2004; 3(2):175-183.
17. Boye J, Elter T, Engert A. An Overview of the Current Clinical Use of the Anti-CD20 Monoclonal Antibody Rituximab. Ann Oncol. 2003; 14(4):520-535.
18. Ifeanyi OE. A Review on Erythropoietin. Int J Adv Res Biol Sci. 2015; 2(4):35-47.
19. Sun HY, Phan K, Paller AS, Sebaratnam DF. Biologics for Pediatric Psoriasis: A Systematic Review and Meta-analysis. Pediatr Dermatol. 2022; 39(1):42-48.
20. Roth K, Darwish C, Keller MD, Hammer B,

Ahmed-Winston S, Escalante E, Madrigal V, Patrick D, Diab Y, Grant C, Hanisch B. Implementation of a Tier System for IVIG Indications to Address IVIG Shortage at a Tertiary Care Pediatric Medical Center. Pediatr Blood & Cancer. 2024; 71(4):e30871.

**PLEASE CITE THIS PAPER AS:**

Banerjee Sh, Nandy M, Sarkar S, Mondal R, Sanyamath A, Halsana M, et al. A Cross-Sectional Observational Study on Audit of Biotherapeutics Used in Pediatric Patients in a Tertiary Care Hospital. J Pharm Care. 2025;13(1):49-57. DOI: 10.18502/jpc.v13i1.18404