**Original Research Article**

**A Retrospective Study On Assessment Of Safety And Effectiveness Of Antibiotics Among Infectious Disease Patients In A Secondary Care Hospital**

**ABSTRACT**

**Aims:** To assess the safety and effectiveness of the antibiotics among infectious disease patients

**Study Design:** Retrospective study

**Place and Duration of Study: Palana Institute of Medical Sciences, Palakkad, between** April 2024 to September 2024

**Methodology:** A Retrospective study of 6-month duration was conducted in a secondary care hospital. The study included all the inpatients diagnosed with an infectious disease and received at least one antibiotic. The patient data collection form was designed in order to collect the patient demographic details and details of antibiotic therapy and the details of the culture sensitivity test using hospital software (HIMS). Data collection was performed and the collected data were analysed using descriptive statistics and MS Excel

**Results:** A total of 74 patients were included in this study, among which 39 were male and 35 were female.Majority of the participants were among the age group of 60-75 years (29.73%). Out of 74, 33 patients were diagnosed with respiratory tract infections. 51.43% of study population were performed their culsture sensitivity test for both blood and urine samples.Penicillins and Cephalosporins were the most commonly prescribed antibiotics and the common adverse effects with these drugs were itching, rashes and redness. 14 (37.84%) of the study population were both sensitive and resistance to at least one antibiotic, 8 (21.62%) of the study population were Sensitive to all antibiotics

**Conclusion:** Rational use of antibiotics plays an important role in controlling the unnecessary use of it and also prevents the development of antibiotic resistance and adverse drug reactions.

*Key Words: Antibiotics, Culture Sensitivity Test, Antibiotic Resistance, Safety, Efficacy, Adverse Drug Reactions*

1. **INTRODUCTION**

Usage of antibiotics among infectious patient was increasing. Most of the patients were resistant to antibiotics. This was due to the irrational use of the antibiotics. Development of ADR was also shown in patients die to the irrational usage of antibiotics The resistance of antibiotics can be prevented by early performance of antibiogram or culture sensitive test. The study aims to identify different adverse reactions related to antibiotics as well as different sensitivity patterns of organisms towards antibiotics.

Antibiotics are chemicals generated by bacteria that either eradicate or hinder the existence of various other microbes.

Antibiotics have served as highly important in diminishing hospitalizations and death rates from transmissible illnesses, despite knowing that improper consumption of such medications results in resistance to drugs by bacteria along with undesirable pharmacological consequences. Antimicrobial agents are chemical substances that either eliminate or hinder the proliferation of microorganisms. These might be synthesized chemically or by naturally occurring substances. Antimicrobial drugs, which are utilized to cure both major as well as mild illnesses, are among the more often employed drugs. Infectious conditions were of greater relevance since they are particularly prevalent within countries that are underdeveloped. Nevertheless, inaccurate and reckless administration of antibiotics has led to unsuccessful therapies, a spike in death and disability, and an appearance of microbes prone to drugs [1].

 1.1 **REQUIREMENT FOR ANTIBIOTICS**

* + Antibiotics tend to be beneficial towards curing infections caused by bacteria. Antibiotics are not able to cure infections caused by viruses, that make up almost all the ailments cured throughout clinical procedure, or prevent individuals from developing infections caused by bacteria later onward.
	+ Even though a bacteria-related etiology has been identified established, antibiotics are sometimes not necessary.
	+ If the pus gathering is surgically exhausted, antibiotics typically are never required. A lot of bacterial illnesses resolve themselves [2].

**1.2 ANTIMICROBIAL RESISTANCE**

 Antimicrobial resistance (AMR), a rapidly expanding global medical anxiety, is one of the foremost 10 public health challenges. The deaths, disabilities, and persistent ailments brought on by AMR impose an enormous economic drain on national economies. Excessive consumption and exploitation of antibiotics may increase patient’s mortality and disease levels. Antibiotic instructions are flouted by medical professionals, which leads to this sort of personality traits. It can be noted that medical professionals worldwide frequently give antibiotics in inappropriate manners. The administration of antibiotics in the treatment of paediatric diseases has recently grown ubiquitous.

The condition that develops whenever a microbe shows resistance when exposed to a variety of antibiotics is known as antimicrobial resistance. Changes within the microorganism's genetic information, mutations in the genome, the insertion of another gene, as well as "infestation" of the bacterium using plasmids, transposable parts, inegronia, and numerous other phases can all cause this situation [3]. Whenever microbes develop defences towards medications that are anticipated to eradicate them, antibiotic resistance results. Therapy requires the intake of a number of medications, which could be unsuccessful or suffer from additional adverse reactions if susceptibility to a particular antibiotic has emerged. Sometimes bacteria enhance resistance to every antibiotic on the market, leaving people suffering from bacterial illnesses without any further alternatives for therapy. Additionally, resistant bacteria might infect others within the residence or in a healthcare centre [4].

* 1. **TWO CATEGORIES OF ANTIMICROBIAL RESISTANCE EXIST**

**1.3.1. Natural resistance:**

A number of microbes consistently exhibit resistance to certain AMAs. It lacks the metabolic route and targeted area that the particular drug influences. Typically, this is a characteristic of a species or genus. For instance, metronidazole typically has no effect on organisms that breathe, penicillin G has no effect on gram-negative bacilli, aminoglycoside antibiotics do not hinder anaerobic bacteria, and M. tuberculosis isn't susceptible to tetracyclines. There won't be any severe clinical difficulties with this form of resistance.

* + 1. **Acquired resistance:**

A prolonged use of AMA can cause a microbe that was formerly susceptible to become resistant. Any microbe has the potential to cause this significant clinical problem. But the microorganism and the medication may both lead to the development of resistance.

Certain bacteria, including staphylococci, coliforms, and tubercle bacilli, are notorious for rapidly becoming resistant. Despite being widely used for almost 50 years, certain organisms, remain without prominent resistance to penicillin. Unlike the poor-quality and retarded resistance to penicillin, gonococci exhibited resistance to sulfonamides rather quickly. However, within the past 40 years, gonococci that are highly resistant to penicillin and manufacture penicillinase have surfaced. Resistance might occur as an outcome of evolutionary changes or gene transfer [5, 6].

**1.4. Factors Affecting Antibiotic Resistance:**

Numerous factors contribute to the complexity of the antibiotic resistance issue. Here are a few of the primary reasons why antibiotic resistance develops as well as how it distributes.

**1.4.1**. **Exploitation and mistreatment**: The primary factor driving antibiotic resistance is the excessive and improper use of antibiotics. Antibiotic prescriptions, their usage for viral illnesses (such as the flu or a normal cold), violation with a recommended therapy plan, and self-administration despite proper medical guidance are all covered by this.

**1.4.2**. **Antibiotic use in agriculture**: Antibiotics are widely used in agriculture as well as livestock to promote development in animals and prevent disease. Individuals may eventually acquire antibiotic-resistant bacteria via food consumption or contact with the environment as a consequence of this utilization of antibiotics.

**1.4.3**. **Inadequate infection prevention procedures**: When sufficient sanitation and prevention measures aren't afterwards, antibiotic-resistant microbes can proliferate effortlessly. This may occur in medical settings such as hospitals, where there is a greater chance of interaction between patients, medical staff, and surfaces.

**1.4.4. Absence of new antibiotics:** the manufacturing and identification of fresh antibiotics has slowed significantly in the last century. This suggests that there are less choices for managing illnesses caused by antibiotic-resistant bacteria.

**1.4.5. Modernization and overseas journey:** Whenever individuals visit other countries, antibiotic-resistant bacteria can span continents and borders. Resistance could evolve globally as a result of migrants bringing resistant bacteria back to their home nations.

**1.4.6. Noncompliance with medical care**: One of the factors that can contribute to the emergence of antibiotic resistance is noncompliance with recommended antibiotic schedules, which includes not taking medications as directed or quitting medication at the wrong time. When antibiotics aren't utilized as instructed, the microbes might not have been entirely wiped out; this might result in other bacteria getting resistant. 7. Environmental factors: One method that antibiotic-resistant bacteria and residual medication may enter into the atmosphere is through inadequate pharmaceutical management [7, 8, 9].

**1.2. ANTIBIOTIC SENSITIVITY TESTS**

A screening for sensitivity to antibiotics could aid in determining which antibiotic is appropriate for your medical condition.
On top of that, the screening might help find a remedy for antibiotic-resistant illnesses. The occurrence of antibacterial resistance occurs when standard drugs become ineffective or cease to operate towards particular bacteria. Antibiotic resistance may transform once-treatable illnesses into ones that are severe and sometimes deadly. Antimicrobial tolerance evaluation, sensitivity evaluation, and testing for susceptibility to antibiotics are alternative titles for such assays [10].

Using a sensitivity evaluation for antibiotics is perhaps the most effective method of managing a bacterial disease. This may be utilized as well for choosing particularly successful treatments against specific antifungal ailments.
You may require this if the illness is being found to have become resistance to antibiotics and is especially tough to cure. If your bacterial or fungal sickness is not getting better with traditional treatments, you might also need this examination. These consist of Clostridium difficile, MRSA, and TB [11].

**1.3. RATIONAL USE OF DRUGS**

The increasing frequency of infectious illnesses in developing countries contributes to an overall spike in consumption of drugs due to noncompliance and budgetary limitations that promote the growth of medication resistance. Despite the introduction of updated antimicrobials, the industry's poor pace for novel antimicrobial compound’s introduction is unable to meet demand that is increasing. Organizations around the world are taking steps to tackle this problem by encouraging ethical consumption of antibiotics. An antibiotic therapy is considered acceptable whenever its consumption, dose, the rate, and length are appropriate for the illness being treated. Responsible usage of antibacterial medications is increasingly recognized as a critical component in reducing adverse reactions, reducing therapy expenses, and stopping the worldwide propagation of antibiotic resistance [6, 13].

**1.4. ADVERSE DRUG REACTION:**

The broadly accepted definition of an adverse drug reaction (ADR) is "noxious, unintended, and occurs at doses normally used in man"[14].

**1.4.1 ANTIBIOTICS RELATED ADR [15, 16]**

Table No:1 Antibiotic related ADR

|  |  |
| --- | --- |
| **ANTIBIOTICS** | **ADR** |
| Inj. Ceftriaxone  |  Rash, Diarrhoea, Gastritis, Epigastric pain, Hypotension/ Anaphylaxis, Nausea and vomiting, Thrombophlebitis at the injection site, Tachycardia, Epigastric discomfort, Restlessness, Vomiting, Itching/Pruritis , Nephrotoxicity, Stomach cramp, Oral candidiasis, Anxiety, Shivering/Chills, Breathlessness, Deranged RFT, Dizziness, Anaemia, Tachyarrhythmia , Oral thrush, Palpitation, Abnormal movement of the limb, Hypoglycaemia, Drowsiness, Jaundice, Giddiness, Glossitis, Toothache. |
| Inj. Ciprofloxacin  | Diarrhoea, Allergic reactions, Drowsiness, Abdominal pain, Abdominal discomfort, Urticaria |
| Inj. Amikacin | Mild rash, Pain Abdomen, Nephrotoxicity, Hypotension/Anaphylaxis, Itching/Pruritis, Dizziness, Increased frequency of micturition |
| Inj. Ampicillin  | Rash, Gastritis |
| Inj. Tazobactam  | Allergic reactions, Severe gastritis, Oral candidiasis, Vomiting |
| Inj. Ceftriaxone + Sulbactam  | Rash, Diarrhoea  |
| Inj. Ampicillin + Cloxacillin  | Severe allergic reactions |
| Tab. Azithromycin  | Diarrhoea, Gastritis, Epigastric pain, Rash, Urticaria, Toxic epidermal necrolysis, Oral thrush, Headache |
| Tab. Trimethoprim sulfamethoxazole  | Rash, Bullous pemphigoid, Vasculitis |
| Tab. Cefoperazone + sulbactam  | Urticaria  |

1. **METHODOLOGY**
	1. **Study Type:** Retrospective study

 **2.2. Study Duration:** 6 months

 **2.3. Study Population**: Infectious disease patients who were admitted from April 2024- September 2024 at Paalana Institute of Medical Science, Palakkad

 **2.4. Study Materials:** Data collection form

 **2.5. Study Criteria:**

**2.5.1. Inclusion criteria:**

Inpatient from April 2024 to September 2024 who were diagnosed with an infectious disease and prescribed with at least one antibiotic.

**2.5.2. Exclusion criteria:**

* Patients with incomplete data
* Patients with incomplete administration of antibiotics or Discharge against medical advice.

 **2.6. Study Procedure:**

A Retrospective study of 6-month duration was conducted in a secondary care hospital. The study included all the inpatients diagnosed with an infectious disease and received at least one antibiotic. The patient data collection form was designed in order to collect the patient demographic details and details of antibiotic therapy and the details of the culture sensitivity test using hospital software (HIMS). Data collection was performed and the collected data were analysed using descriptive statistics and MS Excel.

1. **RESULTS AND DISCUSSIONS**

Table No.2 shows that Among 74 individuals analysed 39(52.71%) subjects of study population were male and the remaining 35(47.29%) were female.

**Table No. 2: Categorisation of study population based on gender(N=74)**

|  |  |  |
| --- | --- | --- |
| **Gender** | **Frequency** | **Percentage (%)** |
| Male | 39 | 52.71 |
| Female | 35 | 47.29 |
| **Total** | 74 | 100 |

Table No.3 shows that Out of 74, 22(29.73%) patients among the study population were belonging to the age group of 60-75, and lowest study population was 7(9.46%) were belonging to the age group of 0-15.

**Table No. 3: Categorisation of Study Population Based on Age (N=74)**

|  |  |  |
| --- | --- | --- |
| **Age Group (Years)** | **Frequency** | **Percentage (%)** |
| 0-15 | 7 | 9.46 |
| 15-30 | 11 | 14.87 |
| 30-45 | 10 | 13.51 |
| 45-60 | 14 | 18.92 |
| 60-75 | 22 | 29.73 |
| 75-90 | 10 | 13.51 |
| **Total** | 74 | 100 |

Table No.4 shows that the majority of 38(51.35%) patients were from General Medicine, 17(22.97%) were from Pulmonology. The least number of patients were 1(1.35%) belongs to Hepatology Department.

 **Table No. 4: Department Wise Distribution of Study Population (N=74)**

|  |  |  |
| --- | --- | --- |
| **Department** | **Frequency** | **Percentage (%)** |
| General Medicine | 38 | 51.35 |
| Gynaecology | 5 | 6.76 |
| Pulmonology | 17 | 22.97 |
| Paediatrics | 5 | 6.76 |
| Urology | 3 | 4.05 |
| Gastroenterology | 5 | 6.76 |
| Hepatology | 1 | 1.35 |
| **Total** | 74 | 100 |

Table No.5 shows that 33 subjects of the study population were diagnosed with Respiratory Tract Infections and 39 were diagnosed with other diseases.

**Table No. 5: Categorisation of Study Population Based on Their Diagnosis (n=117)**

|  |  |
| --- | --- |
| **Diagnosis** | **Frequency** |
| Respiratory tract infection (RTI) | 33 |
| Urinary tract infection (UTI) | 20 |
| Gastritis | 11 |
| Hepatitis | 1 |
|  Undiagnosed Fever | 13 |
| Others | 39 |

.

**Others include**

Fever, Acute transverse myelitis, Vomiting, Umbilical granuloma, Cystitis, T2DM, Hypertension, Sepsis, Follicular Tonsilitis, Cancer, Cholangitis, Post measles

Table No.6 shows that 32(96.9%) were having Lower Respiratory Tract Infection (LRTI) and 1(3.03%) were having Upper Respiratory Tract Infection (URTI).

**Table No. 6: Distribution of RTI among study population (n=33)**

|  |  |  |
| --- | --- | --- |
| RTI | **Frequency** | **Percentage (%)** |
| LRTI | 32 | 96.97 |
| URTI | 1 | 3.03 |
| Total | 33 | 100 |

Table No.7 shows that Within 74 individuals, 71(95.94%) were having no relevant social habits, 2(2.71%) patients among the study population were smokers and 1(1.35%) was alcoholic.

**Table No. 7: Categorisation of study population based on social habits** **(N=74)**

|  |  |  |
| --- | --- | --- |
| **Social habits** | **Frequency** | **Percentage (%)** |
| Smoking | 2 | 2.71 |
| Alcoholism | 1 | 1.35 |
| Nil | 71 | 95.94 |
| Total | 74 | 100 |

Table No.8 shows that Out of 74 study population 70(94.60%) were performed Antibiogram. Remaining 4(5.40%) doesn’t performed Antibiogram.

**Table No. 8: Categorisation of study population based on Antibiogram performed (N=74)**

|  |  |  |
| --- | --- | --- |
| **Antibiogram performed** | **Frequency** | **Percentage (%)** |
| Yes | 70 | 94.60 |
| No | 4 | 5.40 |
| Total | 74 | 100 |

Table No.9 shows that the 36 (51.43%) of patients among the study population were performed both urine and blood, 20 (28.57%) of patients among the study population were performed blood only, 7 (10%) of patients among the study population were performed both blood and sputum, 3 (4.29%) of patients among the study population were performed urine and sputum and 1 (1.42%) of patients among the study population were performed both urine and sputum.

**Table No. 9: Categorisation of study population based on Culture sample (n=70)**

|  |  |  |
| --- | --- | --- |
| **Culture sample** | **Frequency** | **Percentage (%)** |
| Urine | 3 | 4.29 |
| Blood | 20 | 28.57 |
| Sputum | 3 | 4.29 |
| Urine+ Blood | 36 | 51.43 |
| Urine +Sputum | 1 | 1.42 |
| Blood+ Sputum | 7 | 10 |
| Total | 70 | 100 |

**Figure No.1: Distribution of study population based on culture growth status (n=70)**

Table No. 10 shows that the 29 (72.5%) of patients among the study population doesn’t found any organisms in urine culture and 11 (27.5%) of patients among the study population were found organisms in urine culture.

**Table No. 10:** **Analysis of study population based on urine culture outcomes (n=40)**

|  |  |  |
| --- | --- | --- |
| **Organism Found In Urine** | **Frequency** | **Percentage (%)** |
| Yes | 11 | 27.5 |
| No | 29 | 72.5 |
| **Total** | 40 | 100 |

Table No.11 shows that 52 (82.54%) of patients among the study population doesn’t found any organisms in blood culture and 11 (17.46%) of patients among the study population were found organisms in blood culture.

**Table No. 11: Analysis of study population based on blood culture outcomes(n=63)**

|  |  |  |
| --- | --- | --- |
| **Organism Found In Blood** | **Frequency** | **Percentage (%)** |
| Yes | 11 | 17.46 |
| No | 52 | 82.54 |
| **Total** | 63 | 100 |

Table No.12 shows that 6 (54.55%) of patients among the study population were found organisms in sputum culture and 5 (45.45%) of patients among the study population doesn’t found any organisms in sputum culture.

**Table no. 12: Analysis of study population based on sputum culture outcomes(n=11)**

|  |  |  |
| --- | --- | --- |
| **Organism found in sputum** | **Frequency** | **Percentage (%)** |
| Yes | 6 | 54.55 |
| No | 5 | 45.45 |
| **Total** | 11 | 100 |

**Figure No. 2- Categorisation of study population based on Sensitivity and resistance pattern.**

Table No.13 shows that 6 individuals within the study population shows adverse drug reaction. The most common ADR shown in the patients were itching and redness.

**Table. No. 13: Categorisation Of Adverse Drug Reactions And Its Suspected Drug**

|  |  |
| --- | --- |
| SUSPECTED DRUGS | ADR |
| Inj Xonocef, Inj Ampilox, T Septran | Redness and vomiting |
| Inj Cefomed | Itching and redness |
| Inj Ceftriaxone | Chills and shivering |
| Inj Taxomac | Rash and redness |
| Inj Zonomax E S | Itching and redness |
| Inj Akazo P | Burning sensation, Itching |

**Figure No. 3- Grouping participants by progress in patient health (N=74)**

74 individuals were participated in this retrospective study which evaluated the safety and efficacy of antibiotics in infectious disease patients in secondary care hospital. Our findings highlight key aspects of antibiotic use, patient outcomes, and adverse events, crucial for antimicrobial stewardship.

Among 74 individuals analysed 39(52.71%) subjects of study population were male and the remaining 35(47.29%) were female. The observations are consistent with the study conducted by **Wiebke Schroder, Harriet Sommer et al.**,(July 2016) the study entitled “Gender differences in antibiotic prescribing in community: A systematic review and meta-analysis” in the Journal of Antimicrobial Chemotherapy [17].

Out of 74, 22(29.73%) patients among the study population were belonging to the age group of 60-75, and lowest study population was 7(9.46%) were belonging to the age group of 0-15. The same age group were predominant in the study conducted by **Valentina Orlando, Beronica Russo et al.,** (Jan 2020) entitled “Drug Utilization Pattern of Antibiotics: The Role of Age, Sex and Municipalities in Determining Variations” in Risk Management and Health care Policy [18].

 A majority of 38(51.35%) patients were from General Medicine, 17(22.97%) were from Pulmonology. The least number of patients were 1(1.35%) belongs to Hepatology Department. The observations are similar to those concluded by **Md Mahbubur Rashid, Shahana Parveen et al.,** (June 2022) in their study entitled by “Pattern of Antibiotic Use among Hospitalized Patients according to WHO Access, Watch, Reserve (AWaRe) Classification: Findings from a Point Prevalence Survey in Bangladesh” in the Journal of Antibiotic (Basel) [19].

33 subjects of the study population were diagnosed with Respiratory Tract Infections and 39 were diagnosed with other diseases including Fever, Acute transverse myelitis, Vomiting, Umbilical granuloma, Cystitis, T2DM, Hypertension, Sepsis, Follicular Tonsilitis, Cancer, Cholangitis, Post measles. Only 1 patient was diagnosed with Hepatitis.

32(96.9%) were having Lower Respiratory Tract Infection (LRTI) and 1(3.03%) were having Upper Respiratory Tract Infection (URTI).

Within 74 individuals, 71(95.94%) were having no relevant social habits, 2(2.71%) patients among the study population were smokers and 1(1.35%) was alcoholic.

Out of 74 study population 70(94.60%) were performed Antibiogram. Remaining 4(5.40%) doesn’t performed Antibiogram.

36 (51.43%) of patients among the study population were performed both urine and blood, 20 (28.57%) of patients among the study population were performed blood only, 7 (10%) of patients among the study population were performed both blood and sputum, 3 (4.29%) of patients among the study population were performed urine and sputum and 1 (1.42%) of patients among the study population were performed both urine and sputum.

45 (64.28%) of patients among the study population doesn’t shows any culture growth and 25 (35.72%) of patients among the study population shows the culture growth.

29 (72.5%) of patients among the study population doesn’t found any organisms in urine culture and 11 (27.5%) of patients among the study population were found organisms in urine culture.52 (82.54%) of patients among the study population doesn’t found any organisms in blood culture and 11 (17.46%) of patients among the study population were found organisms in blood culture. 6 (54.55%) of patients among the study population were found organisms in sputum culture and 5 (45.45%) of patients among the study population doesn’t found any organisms in sputum culture.

14 (37.84%) of the study population were both sensitive and resistance to at least one antibiotic, 8 (21.62%) of the study population were Sensitive to all antibiotics. Among 74 study population, the positive fact is that only 1 (2.70%) of the study population were Resistance to all antibiotics.

The negative fact is that 6 individuals within the study population shows adverse drug reaction. The most common ADR shown in the patients was itching and redness.

Out of the study population, 65 patients (87.84%) noticed an improvement in their symptoms, 5 people (67.75%) died from infectious diseases, and 4 patients (5.40%) experienced a worsening of their health.

1. **CONCLUSION**

Antibiotic use was more common among males, with the highest consumption observed in individuals aged 60-75 years. Most prescriptions were issued by the General Medicine Department, primarily for treating Lower Respiratory Tract Infections (LRTI). A large number of patients underwent antibiogram and culture sensitivity tests, revealing bacterial growth in both urine and blood samples. While the majority of patients were responsive to at least one antibiotic, only a few exhibited resistance to all. The most frequently reported adverse drug reactions (ADR) were itching and redness, commonly linked to Ceftriaxone + Sulbactam, Cefoperazone Sulbactam, and Piperacillin Tazobactam.

**Ethical Approval:**

As per international standards or university standards written ethical approval has been collected and preserved by the author(s).

**Interest Conflicts**

The authors have declared no conflicts of interest. All of the co-authors have evaluated the article, agree with its contents, and have no financial conflicts to declare. The submission is our original work, and we certify that no other magazine is considering it for publication.

Disclaimer (Artificial intelligence)

Author(s) hereby declare that generative AI technologies such as Large Language Models, etc. have been used during the writing or editing of manuscripts. This explanation will include the name, version, model, and source of the generative AI technology and as well as all input prompts provided to the generative AI technology

Details of the AI usage are given below:

1. QuillBot

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