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ADR: A BIG CHALLENGE IN HEALTH CARE A PHARMACIST PERSPECTIVE

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ABSTRACT

Adverse Drug Reactions (ADRs) are a major cause of death and morbidity, posing a significant burden on society. Many studies have found that antibiotics are a major class of drugs that cause adverse drug reactions (ADRs). From November 2013 to April 2014, a retrospective, non-interventional study was conducted in the Medicine and Pediatrics unit of a tertiary care hospital in Ghaziabad to monitor the adverse drug reactions of antibiotics prescribed by physicians and pediatricians. The goal was to identify the ten most common antibiotics that caused ADRs, determine the most commonly affected organ system, and assess causality. A total of 126 adverse drug reactions (ADRs) were identified in 80 patients, with 42 (52.5%) occurring in male patients and 38 (47.5%) in female patients. The age wise distribution revealed that adult patients showed more incidence (ADR), Antibiotics, Beta of ADRs 46(57.5%), followed by children 26 (32.5%) and Geriatrics 8 (10%).

Keywords: Adverse drug reaction, adverse drug event, Paediatrics, Geriatrics.

INTRODUCTION

ADRs are defined as any response to a drug which is noxious and unintended, and occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or to relieve suffering, but drugs themselves can prove fatal and result in modification of physiologic function. ADRs are significant contributors to mortality and morbidity. Vigilant surveillance is necessary to ensure drug treatment safety, efficacy, and cost-effectiveness, especially with the constant introduction and monitoring of new drugs each year [1].

Antibiotics currently rank as the most frequently prescribed drugs in hospitals worldwide. However, excessive initiation lead to a critical limitation: increased drug resistance. combating bacterial growth. Rational antibiotic use is vital to combatting this issue. 126 ADRs analyzed during the monitoring period, employing the WHO causality assessment and addressing major health needs. Proper assessment scales aid in ADR prevention [2]. The data collected over the six-month monitoring

period reaffirmed the national directive to institutionalize ADR reporting. Adverse Drug Reaction (ADR) was expanded to include reactions caused by error, misuse, or abuse, as well as suspected reactions [3]. Adverse effects typically indicate a hazard from future administration and may require prevention, specific treatment, dosage adjustments, or withdrawal of the product expanded to include reactions that occur as a result of error, misuse, or abuse, as well as suspected reactions to medicines that are unlicensed or used off-label in addition to the authorized use of a medicinal product in normal doses [4].

While this change may affect the reporting and surveillance practices of manufacturers and pharmaceutical regulators, it should have no impact on our approach to managing ADRs in clinical practice [5]. Seminal research conducted in the late twentieth and early twenty-first centuries in the United States and the United Kingdom demonstrated that ADRs are a common occurrence in clinical practice, including as a cause of unscheduled hospital admissions, occurring during hospitalization, and manifesting after discharge [6]. The prevalence of ADRs has remained relatively stable over time, with research indicating that 5% to 10% of patients may experience an ADR at admission, during admission, or at discharge, despite various preventative measures. The frequency of events is inextricably linked to the method used to identify them, and the vast majority of ADRs do not cause serious systemic manifestations [7].

Type of ADR

Type – A (Augmented) → Dose related, predictable,

Type – B (Bizarre) → Non dose related, unpredictable,

Type – C (Continuous) → Dose related and time related

Type – D (Delayed) → Time related

Type – E (Ending of use) → Withdrawal

Type – F (Failure of efficacy) → Unexpected failure

Importance of ADR Reporting

An effective adverse reaction reporting system is critical to al l pharmacovigilance programs around the world. This will be explained below after examining published works on the subject. It is now an accepted, understood routine and an integral part of the responsibilities of healthcare worker sin many developed countries such as the United States, Europe, Canada and Japan [8]. Every ADR report

is important and can make a big difference. For example, a case report by an Australian obstetrician of thalidomide-induced phocomelia generated tremendous awareness among drug regulator sand health professionals worldwide. The worldwide withdrawal of NSAID rofecoxib in 2004 requires a redefinition of drug safety monitoring [9]. The WHO database contains about 4.6 million reports (January 2009), growing by about 250,000 reports per year. Many developing countries around the world have either very poor or non-existent ADR reporting systems. The FDA began collecting reports of adverse drug reactions and sponsoring hospital drug monitoring systems in the 1960s [10].

Severe Consequence of ADR [11].

Unexpected adverse drug reaction - An unfavourable reaction whose type or intensity deviates from the drug's expected properties or from domestic labelling or market authorization

Serious adverse effect- Any untoward medical event that, at any dosage, results in death, necessitates hospital admission, extends a previous hospital stay, causes persistent or severe disability, incapacitates a person, or shortens their life expectancy.

Signal - information that has been reported about a potential link between a medication side effect and an unidentified adverse occurrence; incomplete records.

Medication error -Any avoidable incident that could result in improper drug use, patient injury, or both while the medication is under the patient or consumer's control.

Probiotics have undergone evaluation in over 30 randomized controlled trials (RCTs Antibiotic-Associated Diarrhea (AAD) in children. A study involving 650 children publishedin2003 reported an AAD frequency of11%among outpatients. However, the AAD2% to 80%, as indicated by a 2019 Cochrane review [12]. Heterogeneity in reported incidence may stem from small, underpowered studies and variations in AAD diagnostic criteria, including stool frequency, duration of antibiotic therapy, and microbiological techniques used to exclude other causes of diarrhea. Early-life modification sin microbiota composition may lead to obesity, allergies, auto immune diseases, and neuro developmental abnormalities. the long-term health effects of probiotics and antibiotics administered during infancy, this outcome is not typically standard trial design [13].

Common acute ambulatory pediatric conditions and antibiotic use

The updated guidelines from now include timing and selection of antibiotics. However, prescribing practices differ among physicians and regions. with AOM necessitates antibiotic therapy. According to a analysis, approximately showed improvement in less than 24 hours, regardless of whether they

received antibiotics. Nevertheless, a higher percentage of children experience acute otitis media, as indicated by the review [14].

Clinically significance of ADRs

Antibiotic-associated two groups: clinically significant and non-clinically significant. category was assigned, with the more severe category chosen if multiple criteria were met. Out of the 324 antibiotic-associated adverse drug events (ADEs) identified, 314 (97%) were classified as clinically significant [15]. This classification was based on various factors, including new hospitalizations (n = 10 [3%]), extended hospital stays (n = 77 [24%]), additional visits to clinics or emergency departments (n = 29 [9%]), and the need for extra laboratory tests, electrocardiograms, or imaging (n = 198 [61%]). No deaths were attributed to antibiotic- associated adverse events [16].

Treatment of Patients with Penicillin Allergy

Small percentage of people are thought to have angioedema, or anaphylaxis; five to ten percent known to be allergic to penicillin distinguish between a one that is reported because those who claim to have one who do not [17].

Adverse Effects of Antibiotic Use

Drugs can have a variety of negative impacts, including the potential for chronic sickness, the spread of multidrug-resistant bacteria worldwide, and repercussions person using the medication to treat an infection [18].

DISCUSSION

Suspected aa-ADRs were common upon admission and during the hospital stay. The incidence of aa-ADRs in our study was threefold higher than in a French cohort of 3963 hospitalized patients which could be attributed, in part, to our inpatients' increased use of antibiotics for HIV-associated comorbidities [19]. Antibiotics were administered to the majority of our inpatients, with HIV-infected patients receiving significantly more The medical wards had a higher HIV seroprevalence (38%) than gynecology, where HIV- seroprevalence (9%) was comparable to the national estimate (7.3%) (Uganda AIDS Our study is epidemiologically efficient because the majority of patients received antibiotics [20].

CONCLUSION

Most trials do not assess real-life outcomes like patient and parent-reported quality of life. This review highlights the need for a new core outcome set that includes important domains and outcomes for patients, families, and clinicians to make informed decisions. Antibiotic use in children has doubled over the last few decades, and roughly one-quarter of these antibiotics are unnecessary. Antibiotic use has unintended consequences, including short and long-term effects on individual patients, as well as negative societal effects caused by the selection of antibiotic-resistant bacterial strains. Antimicrobial resistance is increasing, threatening the effectiveness of available antibiotics. The projected global impact on morbidity, mortality the male-to female ratio for ADR occurrence was 0.55. This trend was seen in both ADR-related the discovery of antibiotics was medical advances for children's health, dramatically reducing morbidity and mortality from infectious

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