

Identification of Off-label Drug Prescription for Inpatient Pediatric Patients at Ciamis Regional Hospital

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ABSTRACT

Rational and appropriately indicated drug administration to each patient is an effort to provide quality health services in hospitals and provide optimal therapy for patients. In reality, in some places there are drugs that are prescribed but do not comply with official drug information and do not comply with what is stated in the distribution permit, which are called off-label drugs. Drugs are categorized as off-label indications if the drugs used are outside the indications stated in the leaflet. The purpose of this study was to determine the description of off-label drug prescriptions for pediatric patients at General Hospitals in the Ciamis Region.

Data collection on off-label drug prescriptions was carried out retrospectively, by taking inclusion and exclusion data, which were in accordance with the criteria for rational drug use.

The sampling technique used was total sampling, namely taking data from medical records of inpatient pediatric patients from November to April. Data processing was carried out using descriptive analysis. The samples used were all prescriptions received that met the inclusion and exclusion criteria for pediatric patients. Of the 1,461 drug prescription samples obtained, no prescription of off-label indication drugs was found in pediatric patients. In other words, 100% of the samples were included in the list of drugs in the on-label indication category. From this study, it can be concluded that no prescription of off-label indication drugs was found in pediatric inpatients at Ciamis Regional Hospital.

Keywords : Identification, drug, off-label, hospital.

INTRODUCTION

Off-label drugs are drugs that are prescribed but do not comply with official drug information such as drug indications that do not comply with those stated in the distribution permit and dosage, patient age and route of administration that are not appropriate (Anny, 2017). Based on the 2014 IAI Decree in pharmaceutical care practice, it is stated that pharmacists are required to provide counseling to patients so that patients understand the benefits and risks associated with the use of off-label drugs, so pharmacists also need to recognize and understand the use of off-label drugs (IAI, 2017). In clinical practice, and under certain conditions, off-label drugs are a therapeutic option that is widely used by medical personnel (Cahyaningsih 2017). Based on research conducted by Khodijah (2014), the number of drug prescriptions obtained was 1,306, there were 4 drugs (0.22%) included in the category of off-label drugs with indications. The list of off-label drugs prescribed during the period January to December 2014 was Misoprostol, Ondansetron, and Domperidone. The results of this study were conducted at the PKU Muhammadiyah Hospital in Yogyakarta.

The phenomenon of off-label drug administration is very common in several cases. It is agreed by the majority of health workers that prescribed off-label drugs must disclose clear information and be documented for reporting, but this is still very low at 4.8%-32.4%. In practice, off-label administration in elderly patients is more often used for off-label indications. One of them is the prescription of off-label psychotropic drugs carried out by more than 50% of psychiatrists in the treatment of schizophrenia. This is because psychiatrists are not aware that they are giving off-label prescriptions. (Pratiwi, 2013).

One study was conducted to see the familiarity of community pharmacists with off-label drugs. The study reported that 73% of community pharmacists admitted to being familiar with the concept of off-label administration (Rizki, 2017). Familiarity with off-label administration was reported based on the experience of administration. This is mostly done unconsciously. Recent research shows that community pharmacists are more familiar with the term unlicensed drugs as much as 93%.

Based on the information presented above, the researcher wants to conduct research on "Identification of off-label drug prescriptions for indications in pediatric inpatients at hospitals in the Ciamis area".

TOOLS AND MATERIALS

The tools and materials used in this study were checklist sheets and medical records of inpatient pediatric patients at the regional hospital in Ciamis. DIH (Drug Information Handbook) and related journals were used as references and standards.

METHODS

The collection of off-label drug prescription data was carried out retrospectively, by taking inclusion and exclusion data, which were in accordance with the criteria for rational drug use. The sampling technique used was total sampling, namely taking data from medical records. The samples used were all incoming prescriptions that met the inclusion and exclusion criteria in pediatric patients.

The following are the stages of the procedure carried out in this study: 1. Making a permit letter and submitting a research proposal for the data collection process. 2. Collecting data in the medical record according to the predetermined inclusion criteria. The data taken includes: patient name, medical record number, patient admission date, disease diagnosis, and records of drugs given. 3. Conducting data analysis using the DIH (Drug Information Handbook) book and related journals. Data from data collection (medical record review) were searched for EBM (Evidence Based Medicine) through electronic searches of PubMed, other related journals and other supporting references such as the Drug Information Handbook or Handbook of Pharmacotherapy. 4. Processing data results using a computer with the Microsoft Excel program and making a discussion. 5. Make conclusions from the data obtained.

RESULTS

The research result data is in the form of the number of off-label drug prescriptions for pediatric patients. The summarized data was then analyzed by calculating the percentage as follows:

$$\text{Percentage of drug use} = \frac{\text{amount of drug use}}{\text{total amount of drugs}} \times 100\%$$

Table 1. list of medications used by pediatric patients

No	Drug	Amount	Percentage
1	Analgesics Antipyretics (NSAIDs)	300	20,5%
2	Digestive System	250	17,1%
3	Antibiotics Antivirals and Antifungals	190	13,0%
4	Respiratory System	211	14,4%
5	Cardiovascular	150	11,0%
6	Vitamins	160	11,0%
7	Antihistamines	200	13,7%

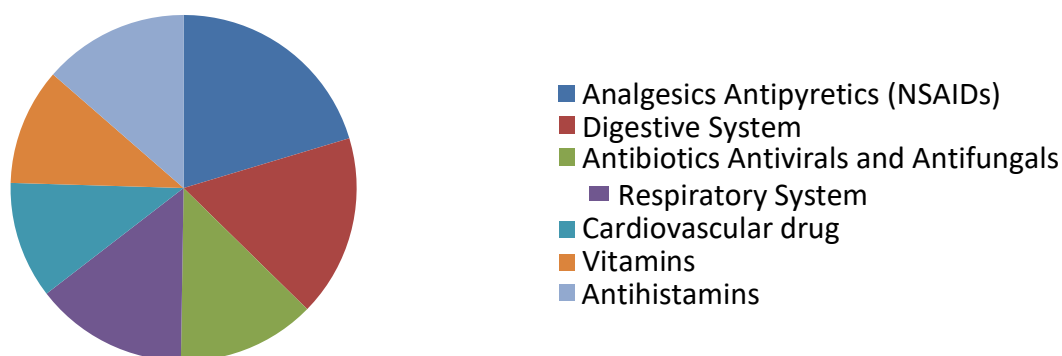


Figure 1. Patterns of medication use in pediatric patients

DISCUSSION

The most commonly prescribed drug classification percentage is the antipyretic analgesic and NSAIDs group, which is (27.4%) as seen in the image above. The most frequently used drug is paracetamol. Paracetamol is an antipyretic analgesic drug that is approved for use in children. Paracetamol can be given orally or rectally, but oral administration is better because its absorption is more constant and it is more possible to provide doses according to body weight than rectally. Paracetamol toxicity can occur after giving a single high dose or excessive multiple doses, long-term use can cause liver damage (Akbar, 2017).

Of the 767 drug prescriptions obtained, there were no prescriptions for off-label drugs for indications in pediatric inpatients at the Ciamis Regional Hospital and as many as

1,461 drug items (100%) were included in the list of drugs in the on-label indication category. At Ciamis Hospital, doctors prescribe drugs referring to experience and SOP references for the use of off-label drugs. In the inpatient pharmacy, the guidelines for determining off-label drugs are based on doctor's prescriptions, referring to literature such as the National Formulary, Regional Formulary, Hospital Formulary, Medscape and DIH (Drug Information Handbook)..

CONCLUSION

From the research results, it was concluded that there was no prescription of off-label drugs for pediatric inpatients at hospitals in the Ciamis area.

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