

INTISARI

Penggunaan Obat *off-label* tidak berarti ilegal, dikontraindikasikan, tidak patut, atau bersifat investigasi tetapi penggunaan tetapi hanya bertentangan dengan label yang disetujui. Penelitian ini dilakukan untuk mengetahui gambaran profil penggunaan obat *off-label* pada pasien pediatri yang menjalani rawat inap di Rumah Sakit Akademik UGM periode Januari-Desember 2023.

Penelitian dilakukan dengan metode observasional menggunakan rancangan penelitian yang bersifat deskriptif kuantitatif. Data diambil secara retrospektif melalui rekam medis pasien pediatri usia 0-11 tahun yang menjalani rawat inap periode Januari – Desember 2023. Penelitian ini mengacu pada sumber Informatorium Obat Nasional Indonesia (IONI) cetakan Tahun 2017 dan brosur obat, serta BNF for Children 2019 jika diperlukan. Obat yang diperoleh digolongkan dengan sistem ATC (*Anatomical Therapeutic Chemical*). Analisis dilakukan secara deskriptif untuk mengetahui gambaran karakteristik pasien (usia dan jenis kelamin pasien), diagnosis, serta kategori penggunaan obat *off-label* (usia, dosis, indikasi, rute pemberian, dan kontraindikasi).

Hasil penelitian ini diperoleh persentase pasien pediatri paling banyak adalah pasien laki-laki 50,5% (49 pasien) dan usia dominan adalah anak-anak 6-11 tahun yaitu sebanyak 50,5% (49 pasien). Diagnosis yang paling banyak ditemukan adalah pneumonia sebanyak 8,4% (32 kasus). Berdasarkan 97 rekam medis pasien diperoleh total 434 terapi obat, yang mana untuk satu terapi obat dapat dikategorikan lebih dari satu kategori *off-label*. Dalam penelitian ditemukan total terapi obat *off-label* adalah sebanyak 311 terapi obat (63,2%) sedangkan obat *on-label* sebanyak 181 terapi obat (36,8%). Dari 311 terapi obat *off-label*, kategori terbanyak adalah *off-label* dosis sebanyak 243 terapi obat (78,1%) yang mana jenis obat terbanyak adalah pada paracetamol. Selain itu, ada *off-label* indikasi sebanyak 50 terapi obat (16,1%) dengan jenis obat terbanyak yaitu ondansetron, *off-label* usia sebanyak 17 terapi obat dengan jenis obat terbanyak yaitu sucralfate, *off-label* kontraindikasi sebanyak 1 terapi obat (0,3%) yaitu ketorolac, dan tidak ditemukan *off-label* rute pemberian.

Kata Kunci: *off-label*, pediatri, rekam medis

ABSTRACT

Off-label drug use does not mean illegal, contraindicated, inappropriate, or investigational. It is only contrary to the approved label. This study was conducted to determine the profile of off-label drug use in pediatric patients who were hospitalized at the UGM Academic Hospital from January to December 2023.

The study was conducted using an observational method using a quantitative descriptive research design. Data were taken retrospectively through medical records of pediatric patients aged 0-11 years who were hospitalized in the period January-December 2023. This study refers to the Indonesian National Drug Informatorium source printed in 2017 and drug brochures, and BNF for Children 2019 if necessary. The drugs obtained were classified using the ATC (Anatomical Therapeutic Chemical) system. The analysis was carried out descriptively to determine the description of patient characteristics (patient age and gender), diagnosis, and categories of off-label drug use (age, dose, indications, route of administration, and contraindications).

The results of this study showed that the highest percentage of pediatric patients were male patients 50.5% (49 patients) and the dominant age group was children 6-11 years, namely 50.5% (49 patients). The most common diagnosis found was pneumonia, with a presentation of 8.4% (32 cases). Based on 97 patient medical records, a total of 434 drug therapies were obtained, where one drug therapy could be categorized as more than one off-label category. In the study found that the total number of off-label drug therapies was 311 drug therapies (63.2%) while on-label drug therapies were 181 drug therapies (36.8%). Of the 311 off-label drug therapies, the largest category was off-label dosage with 243 drug therapies (78.1%) of which the largest type of drug was paracetamol. In addition, there were off-label indications of 50 drug therapies (16.1%) with the largest type of drug being ondansetron, off-label age of 17 drug therapies with the largest type of drug being sucralfate, off-label contraindications of 1 drug therapy (0.3%) was ketorolac, and no off-label route of administration was found.

Keywords: *off-label, pediatrics, medical records*