

## **ABSTRACT**

### **ANALYSIS OF THE ASSOCIATION BETWEEN OFF-LABEL DRUG USE AND THE INCIDENCE OF SIDE EFFECTS IN GERIATRIC PATIENTS AT DR. A. DADI TJOKRODIPO GENERAL HOSPITAL**

**By**

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**Background:** *Off-label use carries a risk of increasing side effect due to limited evidence regarding safety and effectiveness, as well as pharmacokinetic and pharmacodynamic changes in geriatric patients. Nevertheless, its use continues based on clinical considerations and limited therapeutic alternatives. This study aimed to determine the prevalence of off-label drug use and the incidence of side effect in geriatric patients, as well as to examine the association between off-label drug use and the resulting side effect.*

**Methods:** *This study was employed an analytic observational design with a retrospective cross-sectional approach using secondary data from patients' medical records. Data were collected through purposive sampling, and the sample size was calculated using a proportion estimation formula, resulting in 79 medical records of hospitalized geriatric patients at RSUD dr. A. Dadi Tjokrodipo from January to June 2025. The samples were analyzed based on the IONI 2017 guidelines to identify off-label prescribing and assessed using the WHO-UMC instrument to evaluate the causality of side effect.*

**Results:** *This study was showed that based on the number of prescriptions, the prevalence of off-label drug prescriptions was 13%, while the incidence of adverse drug reactions was 2% of the total 591 prescriptions. Based on the number of patients, 57% of patients out of a total of 79 received off-label drugs, while 9% of patients reported adverse drug reactions. Bivariate analysis examining the association between off-label drug use and side effects there was no significant association ( $p=0.692$ ).*

**Conclusion:** *There was no significant association between off-label drug use and the occurrence of side effect among hospitalized geriatric patients at RSUD dr. A. Dadi Tjokrodipo.*

**Keywords:** *geriatric, off-label, side effect.*

## ABSTRAK

### ANALISIS HUBUNGAN PENGGUNAAN OBAT *OFF-LABEL* DENGAN KEJADIAN EFEK SAMPING PADA PASIEN GERIATRI RAWAT INAP DI RSUD DR. A. DADI TJOKRODIPO

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**Latar Belakang:** Penggunaan *off-label* berisiko meningkatkan efek samping karena keterbatasan bukti keamanan dan efektivitas, serta perubahan farmakokinetik dan farmakodinamik pada pasien geriatri. Namun, penggunaannya tetap dilakukan berdasarkan pertimbangan klinis dan keterbatasan pilihan terapi. Penelitian ini bertujuan untuk mengukur prevalensi penggunaan obat *off-label* dan kejadian efek samping obat pada pasien geriatri serta mencari hubungan antara penggunaan obat *off-label* dengan kejadian efek samping yang terjadi.

**Metode:** Penelitian ini merupakan studi observatif analitik dengan desain retrospektif *cross-sectional* yang memanfaatkan data sekunder berupa rekam medis pasien. Pengambilan data menggunakan teknik *purposive sampling* dan jumlah sampel dihitung menggunakan rumus estimasi proporsi sehingga didapatkan 79 rekam medis pasien geriatri rawat inap di RSUD dr. A. Dadi Tjokrodipo periode Januari–Juni 2025. Sampel penelitian dianalisis berdasarkan pedoman IONI 2017 untuk mengidentifikasi peresepan *off-label*, serta menggunakan instrumen WHO-UMC untuk menilai hubungan kausalitas kejadian efek samping obat.

**Hasil:** Hasil penelitian ini disajikan berdasarkan jumlah peresepan, prevalensi peresepan obat *off-label* sebesar 13%, sementara itu kejadian efek samping obat sebesar 2% kejadian dari total 591 peresepan. Berdasarkan jumlah pasien, sebanyak 57% pasien dari total 79 pasien menerima obat *off-label*, sementara itu sebanyak 9% pasien melaporkan kejadian efek samping. Hasil analisis bivariat hubungan penggunaan obat *off-label* dengan kejadian efek samping menunjukkan tidak ada hubungan yang signifikan ( $p=0.692$ ).

**Simpulan:** Tidak terdapat hubungan antara penggunaan obat *off-label* dengan kejadian efek samping pada pasien geriatri yang menjalani rawat inap di RSUD dr. A. Dadi Tjokrodipo.

**Kata kunci:** efek samping, geriatri, *off-label*.