

ABSTRACT

THE ANALYSIS OFF-LABEL DRUG USE ON ADVERSE DRUG REACTION INCIDENTS IN PEDIATRIC INPATIENT AT THERSD DR A. DADI TJOKRODIPO

By

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Background: Off-label medication occurs when a drug is administered not according to the labelling or permission approved by the BPOM or FDA. The use of off-label drugs triggers adverse drug reactions or unwanted drug reactions. These reactions occur as the body's response to drugs used in the patient's usual dose.

Methods: The study was conducted analytical observational with a study sample of 89 paediatric patients aged 0-18 years. The data collection technique used purposive sampling method. Identification of off-label drugs with the British National Formulary 2020-2021 and the Indonesian National Drug Informatory 2017. And causality assessment related to adverse drug reactions using the WHO-UMC system.

Results: The results of bivariate statistical analysis showed that H_0 was accepted, namely that there was no relationship between the use of off-label drugs and the incidence of adverse drug reactions in paediatric patients in the inpatient installation of RSD DR A. Dadi Tjokrodipo for the period January - June 2023 with a p-value of 1,000.

Conclusion: There is no relationship between the use of off-label drugs and the incidence of adverse drug reactions in paediatric patients at the inpatient installation of RSD DR A. Dadi Tjokrodipo for the period January - June 2023.

Keyword: Adverse drug reaction, Off-label, Paediatric

ABSTRAK

ANALISIS PENGGUNAAN OBAT *OFF-LABEL* TERHADAP KEJADIAN *ADVERSE DRUG REACTION* PADA PASIEN PEDIATRI DI INSTALASI RAWAT INAP RSD DR. A. DADI TJOKRODIPO

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Latar Belakang: Obat *off-label* yaitu terjadi ketika obat diberikan tidak sesuai pelabelan atau izin yang disetujui oleh BPOM atau FDA. Penggunaan obat *off-label* memicu terjadi *adverse drug reaction* atau reaksi obat yang tidak dikehendaki. Reaksi ini terjadi sebagai respon tubuh terhadap obat yang digunakan dalam dosis lazim pasien.

Metode: Penelitian yang dilakukan observasional analitik dengan sampel penelitian berjumlah 89 pasien pediatri usia 0-18 tahun. Teknik pengambilan data menggunakan metode *purposive sampling*. Identifikasi obat *off-label* dengan *British National Formulary* 2020-2021 dan Informatorium Obat Nasional Indonesia 2017. Serta penilaian kausalitas terkait *adverse drug reaction* menggunakan WHO-UMC *system*.

Hasil: Hasil analisis statistik bivariat menunjukkan H0 diterima yaitu tidak terdapat hubungan antara penggunaan obat *off-label* dengan kejadian *adverse drug reaction* pada pasien pediatri di instalasi rawat inap RSD DR A. Dadi Tjokrodipo periode Januari – Juni 2023 dengan nilai *p-value* 1,000.

Kesimpulan: Tidak terdapat hubungan antara penggunaan obat *off-label* terhadap kejadian *adverse drug reaction* pada pasien pediatri di instalasi rawat inap RSD DR A. Dadi Tjokrodipo periode Januari – Juni 2023.

Kata Kunci: *Adverse drug reaction*, *Off-label*, Pediatri