

Kajian penggunaan obat off-label pada pasien pediatrik di Bangsal Anak Rumah Sakit Umum Pusat Nasional Dr. Cipto Mangunkusumo pada periode Januari-Desember 2018 = Evaluation of off-label drug use on patients in pediatric ward Dr. Cipto Mangunkusumo National Central General Hospital.

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Abstrak

Pendahuluan: Penelitian di beberapa negara menunjukkan tingkat penggunaan obat off-label yang tinggi pada pasien pediatrik. Penggunaan obat off-label sendiri berpotensi meningkatkan kejadian efek samping obat. Penelitian ini bertujuan untuk mengevaluasi penggunaan obat off-label kategori usia pada pasien bangsal anak RSUPN Dr. Cipto Mangunkusumo (RSCM) yang belum pernah diteliti sebelumnya. Metode: Desain penelitian adalah observasional analitik cross sectional. Sampel merupakan data sekunder dari rekam medis pasien pediatrik yang dirawat di Bangsal Anak RSCM yang dipilih secara consecutive sampling. Kriteria inklusi adalah rekam medik pasien anak 0-18 tahun yang dirawat di Bangsal Anak RSCM periode Januari – Desember 2018, dan kriteria eksklusi berupa data pengobatan yang sulit dibaca, tidak lengkap, serta persepsan elektrolit, suplemen, dan obat luar. Obat yang diberikan dicatat dan ditabulasi. Status persepsan off-label ditentukan berdasarkan usia ketika obat diresepkan dan dicocokkan dengan ketentuan yang tertera pada label atau referensi yang relevan. Beda proporsi penggunaan obat off-label antar kelompok dianalisis menggunakan uji Chi-Square. Hasil: Dari 456 sampel persepsan, 12,5% (CI95 = [9,46%; 15,54%]) di antaranya diberikan secara off-label kategori usia. Berdasarkan klasifikasi ATC, golongan obat terbanyak yang diberikan secara off-label adalah agen antineoplastik dan imunomodulasi (61,2%) dan sistem muskuloskeletal (20,0%). Tidak didapatkan hubungan bermakna antara jenis kelamin dengan penggunaan obat off-label ($p = 0,571$; PR = 1,19; CI95 = [0,732; 1,942]) serta antara kategori usia bayi, anak, dan remaja dengan penggunaan off-label ($p = 0,392$). Kesimpulan: Tingkat penggunaan obat off-label kategori usia di bangsal anak 12,5%. Dalam penelitian ini, jenis kelamin dan kelompok usia tidak berpengaruh terhadap prevalensi penggunaan obat off-label.

.....Introduction: Various studies conducted in many countries showed high level of off-label drug use in pediatric patients. Off-label drug use may increase the occurrence of adverse drug reactions. This study aims to evaluate off-label drug use in Dr. Cipto Mangunkusumo National Central General Hospital (RSCM) which has never been conducted. Methods: Samples were secondary data from medical records of pediatric patients admitted to RSCM Pediatric Ward and collected using consecutive sampling method. Inclusion criteria were medical records of patient of 0-18 years old admitted in the period of January-December 2018, and exclusion criteria were unreadable or incomplete medication record, and electrolyte, supplement, or external medicine. Collected data were recorded and tabulated. Off-label status was determined based on patients' age when the drug was prescribed and then was matched with the information on the label of the drug or relevant references. Results: Of 456 evaluated prescriptions, 12,5% (CI95 = [9,46%; 15,54%]) were administered off-label according to age category. Based on Anatomical Therapeutic Chemical (ATC) classification, the most frequent drugs prescribed off-label were anti-neoplastic and immunomodulating (61,2%) and musculoskeletal system drugs (20,0%). There was no association between gender and off-label

drug use ($p = 0,571$; $PR = 1,19$; $CI95 = [0.732; 1.942]$), and also between infant, children, and adolescent age categories and off-label drug use ($p = 0,392$). Conclusion: The prevalence of off-label drug use according to age category in the pediatric ward was 12.5%. In this study, gender and also infant, children, and adolescent age categories had no effect on the prevalence of off-label drug use.