INTISARI

Adverse Drug Reaction/ADR) didefinisikan sebagai respons berbahaya dan tidak diinginkan terhadap suatu obat. Metode penilaian ADR sistem WHO-UMC dan algoritma Naranjo merupakan metode yang paling banyak digunakan dalam penilaian kausalitas. Badan Pengawas Obat dan Makanan (BPOM) sebagai pusat MESO Nasional menyediakan fasilitas pelaporan ADR bagi tenaga kesehatan melalui website www.e-meso.pom.go.id. Tujuan dari penelitian ini untuk mengetahui karakteristik pelaporan MESO dan mengetahui kesepakatan/*agreement* penilaian kausalitas antara sistem WHO-UMC dan algoritma Naranjo dan menganalisis korelasi hubungan kedua metode.

Metode penelitian ini adalah *cohort retrospektif study* dengan data pelaporan ADR yang diperoleh dari website MESO Badan POM pada wilayah Daerah Istimewa Yogyakarta (DIY). Data yang dikumpulkan dievaluasi oleh 2 kelompok penilai secara independent kemudian dianalisis kesepakatan/*agreement* untuk kedua metode dengan uji statistic SPSS koefisien Kappa Cohen. Sejumlah 169 laporan dianalisis, mencakup 255 *suspected drug* dan 255 kejadian ADR.

Penelitian ini mengidentifikasi Apoteker sebagai pelapor terbanyak dalam pelaporan MESO, pasien terbanyak berjenis kelamin wanita dengan kelompok usia terbanyak kelompok usia dewasa (18-65 tahun). Terdapat tiga kelompok utama karakteristik penyakit pasien, yaitu : *Diseases of the circulatory sistem* (15,38%), *Certain infectious and parasitic diseases* (11,24%), dan *Diseases of the respiratory sistem* (9,47%). Terkait jenis ADR berdasarkan *Sub Organ Class* (SOC), *Skin and subcutaneous tissue disorders* (21,57%) merupakan sistem organ yang paling banyak terdampak. Kelompok antibiotik adalah *suspected drug* terbanyak (34,90%), dengan Levofloxacin dan Ceftriaxone menjadi penyebab utama ADR (11,24%). Hasil Analisa SPSS nilai kesepakatan koefisien Kappa cohen antara kriteria WHO-UMC dan Algoritma Naranjo pada seluruh kejadian ADR 0,384 termasuk kategori *minimal agreement*. Kategori ini mengindikasikasikan terdapat *inadequate agreement* pada kedua metode tersebut. Hasil Analisa korelasi menggunakan *Spearman's coefficient correlation* 0,501 dengan nilai signifikansi 0,00 termasuk *moderate correlation*. Hal ini menunjukkan kedua metode valid dalam penilaian kausalitas namun kedua metode memiliki perbedaan inheren yang dapat menyebabkan variabilitas dalam penilaian kausalitas ADR.

Kata Kunci : Pelaporan ADR, e-MESO (e-Monitoring Efek Samping Obat), Badan POM, sistem WHO-UMC, Algoritma Naranjo

ABSTRACT

Adverse Drug Reaction (ADR) is defined as a harmful and unintended response to a drug. The WHO-UMC causality assessment system and the Naranjo algorithm are the most commonly used methods for causality assessment. As the National MESO Center, the Indonesian Food and Drug Authority (BPOM) provides ADR reporting facilities for healthcare professionals through the website http://www.e-meso.pom.go.id. This study aims to understand the characteristics of the MESO report, compare the agreement assessment between the WHO-UMC system and the Naranjo algorithm, and investigate the correlation between the two methods.

The research employs a retrospective cohort study design, utilizing ADR reporting data sourced from the MESO website of BPOM in the Special Region of Yogyakarta (DIY). The collected data were analyzed by two assessors who tested for agreement between the two methods using the SPSS statistical test with Cohen's Kappa coefficient. A total of 169 reports were analyzed, covering 255 suspected drugs and 255 ADR events.

This study identifies pharmacists as the most frequent reporters in MESO reporting. The majority of patients are female, with the largest age group being adults (18–65 years old). The three primary categories of patient disease characteristics are diseases of the circulatory system (15,38%), certain infectious and parasitic diseases (11,24%), and diseases of the respiratory system (9.47%). Regarding the type of ADR based on the Sub Organ Class (SOC), Skin and subcutaneous tissue disorders (21,57%) are the most affected organ systems. The antibiotic group is the most frequently suspected drug type (34,90%), with Levofloxacin and Ceftriaxone being the main causes of ADR (11,24%). The Cohen's Kappa coefficient agreement between the WHO-UMC criteria and the Naranjo Algorithm for all ADR events is 0,384, indicating minimal agreement. It can be simplified as follows, the value of kappa indicates inadequate agreement among the raters. The result of the correlation analysis, using Spearman's correlation coefficient of 0.501 with a significance value of 0.00, indicates a moderate correlation. This indicates that both methods are valid in causal assessment; however, they have inherent differences that may lead to variability in ADR causality assessment.

Keywords: Adverse Drug Reaction Reporting, e-Adverse Drug Reaction Monitoring (e-MESO), BPOM, system WHO-UMC, Naranjo algorithm