

INTISARI

Naranjo Probability Scale (NPS) dengan limitasinya masih digunakan secara luas untuk menilai kausalitas Kejadian yang Tidak Diinginkan/Efek Samping Obat (KTD/ESO). Penelitian ini bertujuan untuk mengembangkan *Causality Assessment Tool* (CAT) berbasis aplikasi *mobile* “An-ESO” untuk menilai kausalitas KTD/ESO.

Penelitian dilakukan di Rumah Sakit Kanker Dharmais (RSKD) dengan 3 tahap. Pertama, studi *cross-sectional* dilakukan untuk mendapatkan gambaran KTD/ESO di RSKD menggunakan data retrospektif tahun 2021-2022. Studi kualitatif dilakukan untuk menganalisis hambatan tenaga profesional kesehatan dalam menilai kausalitas. Kedua, pengembangan CAT berbasis aplikasi *mobile* “An-ESO” menggunakan metode kualitatif dan kuantitatif. Ketiga, tahap evaluasi *performance* CAT berbasis aplikasi *mobile* “An-ESO” dengan desain *quasi experimental* bertujuan membandingkan hasil penilaian kausalitas KTD/ESO yang diperoleh dari NPS dan CAT berbasis aplikasi *mobile* “An-ESO” yang dikonfirmasi dengan *Physician Judgement*. Data dianalisis secara statistik untuk nilai sensitivitas, spesifisitas, *positive predictive value* (PPV) dan *negative predictive value* (NPV), waktu yang dibutuhkan, dan tingkat kesesuaian hasil penilaian. Data dianalisis secara kualitatif dan kuantitatif.

Hasil penelitian menunjukkan KTD/ESO yang banyak dilaporkan adalah mual (11,6%), dengan *suspected drug* morfin (n=48), hasil analisis kausalitas terbanyak adalah *probable* (62,4%), dan apoteker (91%) sebagai pelapor terbanyak. Hambatan tenaga profesional kesehatan diantaranya pertanyaan NPS yang ambigu hingga tingginya jawaban “tidak tahu”, kelengkapan data dan waktu untuk menilai, serta faktor pengetahuan, kompetensi dan pengalaman. CAT “An-ESO” dengan 5 butir pertanyaan dinyatakan valid dan reliabel (Cronbach alpha >0,6). Aplikasi *mobile* “An-ESO” telah dikembangkan pada platform android dan iOS dengan hasil *SUS* 85,25. CAT berbasis aplikasi *mobile* “An-ESO” lebih baik dalam hal tingkat kesepakatan terhadap *physician judgement* (0,368 vs 0,842), sensitivitas (97,4% vs 95,9%), spesifisitas (90,3% vs 35,5%), PPV (98,7% vs 91,8%), NPV (82,4% vs 53,7%), waktu yang dibutuhkan (p=0,001), serta tingkat kesesuaian hasil penilaian terhadap *physician judgement* (p=0,238 vs p=0,009) dibandingkan dengan NPS. Aplikasi “An-ESO” direkomendasikan untuk digunakan pada praktik rutin. Penelitian lebih lanjut diperlukan agar hasil dapat digeneralisasi.

Kata kunci: Kejadian yang Tak Diinginkan (KTD), Efek Samping Obat (ESO), *Causality Assessment tool* (CAT), aplikasi *mobile*, farmakovigilans

ABSTRACT

The Naranjo Probability Scale (NPS), despite its shortcomings, remains extensively utilised for evaluating the causality of Adverse Events/Adverse Drug Reactions (AEs/ADRs). This study aims to develop a mobile application-based Causality Assessment Tool (CAT) called "An-ESO".

The study was performed at Dharmais Cancer Hospital in three phases. First, a cross-sectional study was performed to acquire an overview of AE/ADR reports utilising data from 2021-2022. Qualitative studies were conducted to investigate the barriers faced by healthcare professionals (HCPs) in using NPS. Second, the mobile application-based CAT "An-ESO" development employs qualitative and quantitative methodologies. Third, the performance evaluation phase of the mobile application-based CAT "An-ESO" to compare the results between two scales confirmed by physician judgement. The data were statistically analysed for sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), time required, and level of concordance. Data were analysed qualitatively and quantitatively.

The study findings indicate that the most frequently reported ADR is nausea (11.6%), the suspected drug is morphine (n=48), the causality results are probable (62.4%), and pharmacists (91%) are the most common reporters. Obstacles faced by HCPs include ambiguous questions leading to a high number of "don't know" responses, the need for complete data and time, as well as factors of knowledge, competence, and experience. The CAT "An-ESO," comprising five items, was deemed valid and reliable (Cronbach's $\alpha > 0.6$). The "An-ESO" mobile application has been developed for Android and iOS platforms, achieving a SUS score of 85.25. It demonstrates superior performance in agreement with physician judgement (0.368 vs 0.842), sensitivity (97.4% vs 95.9%), specificity (90.3% vs 35.5%), PPV (98.7% vs 91.8%), NPV (82.4% vs 53.7%), time required ($p=0.001$), and the level of concordance ($p=0.238$ vs $p=0.009$) when compared to the NPS. The "An-ESO" application is advised for implementation in standard practice. Additional research is required to extrapolate the findings.

Keyword: Adverse Event (AE), Adverse Drug Reaction (ADR), Causality Assessment tool (CAT), mobile-based application, pharmacovigilance