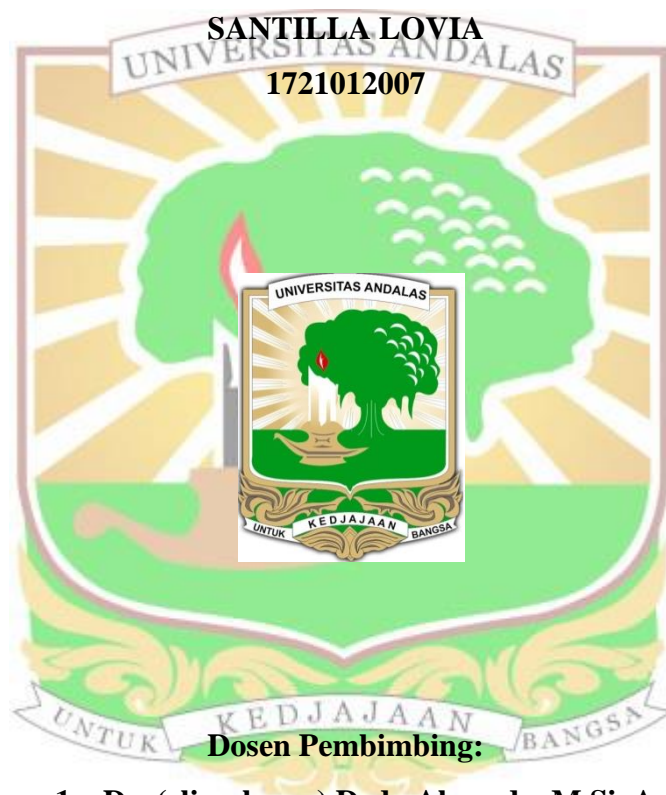


**KAJIAN KUALITATIF DAN KUANTITATIF TENTANG KEJADIAN
DAN SISTEM PELAPORAN *ADVERSE DRUG REACTION* (ADR)
DALAM RANGKA PENYUSUNAN INSTRUMEN KEWASPADAAN ADR
PADA PASIEN RAWAT INAP ANAK**

Tesis



- 1. Dr. (clin pharm) Dedy Almasdy, M.Si, Apt**
- 2. Dr. Yelly Oktavia Sari, M. Pharm, Apt**

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Santilla Lovia, Dedy Almasdy, Yelly Oktavia Sari

ABSTRAK

Penelitian ini dilakukan untuk mengkaji kejadian dan sistem pelaporan *Adverse Drug Reaction* (ADR) di bangsal inap anak RSUP DR. M.Djamil Padang serta menyusun rancangan instrumen untuk mewaspadaai terjadinya ADR pada pasien rawat inap anak. Penelitian ini merupakan *mix method research* tipe *exploratory triangulasi*. Pengumpulan data kualitatif dilakukan dengan cara wawancara semi terstruktur terhadap 30 orang responden yang terdiri dari dokter, perawat, apoteker dan pihak manajemen rumah sakit yang memenuhi kriteria inklusi dan dipilih secara *purposive sampling*. Data kuantitatif penelitian diperoleh secara retrospektif dari 100 buah rekam medis yang telah dipilih secara acak dan prospektif pada 61 orang pasien rawat inap anak periode April 2019. Data kualitatif menunjukkan 26 dari 30 orang responden pernah menemui kasus ADR dengan total 70 kasus. Secara kuantitatif sebesar 32,26% (retrospektif) dan 71,4% (prospektif) pasien rawat inap anak mengalami ADR selama dirawat. Antibiotik, analgesik, obat kemoterapi dan obat antikonvulsi adalah obat yang berkontribusi besar dalam ADR, dengan reaksi kulit (60%) sebagai manifestasi ADR terbesar, diikuti dengan gangguan saluran cerna (22,9%). Polifarmasi 86,7% (retrospektif), 65% (prospektif) dan gangguan auto imun 73,3% (retrospektif), 72,5% (prospektif) tercatat sebagai faktor resiko dominan penyebab ADR. RSUP DR.M.Djamil Padang telah memiliki sistem pelaporan ADR, namun demikian pengetahuan tenaga kesehatan tentang ADR dan kepedulian mereka terhadap pelaporan ADR sangat kurang.

Kata kunci: *Adverse Drug Reaction, Farmakovigilans, ROTD, Pediatrik*

**QUALITATIVE AND QUANTITATIVE STUDIES OF EVENTS AND
REPORTING SYSTEMS OF ADVERSE DRUG REACTION (ADR)
IN ORDER TO PREPARE ADR ALERTNESS INSTRUMENT
IN PEDIATRIC INPATIENTS**

Santilla Lovia, Dedy Almasdy, Yelly Oktavia Sari

ABSTRACT

This research was conducted to explore the incidence and reporting system of Adverse Drug Reaction (ADR) in the children's ward of RSUP DR. M.Djamil Padang and drafting instruments to be aware of the occurrence of ADR in hospitalized patients. This research is a mixed method research with exploratory triangulation type. Qualitative data collection was carried out by means of semi-structured interviews with 30 respondents consisting of doctors, nurses, pharmacists and hospital management who met the inclusion criteria and were selected by purposive sampling. Quantitative data from the study were obtained retrospectively from 100 medical records that were randomly and prospectively selected for 61 child inpatients for the April 2019 period. Qualitative data showed that 26 out of 30 respondents had encountered ADR cases with a total of 70 cases. Quantitatively, 32.26% (retrospective) and 71.4% (prospective) inpatient children experience ADR during treatment. Antibiotics, analgesics, chemotherapy drugs and anticonvulsant drugs are drugs that contribute greatly to ADR, with skin reactions (60%) as the largest ADR manifestations, followed by gastrointestinal disorders (22.9%). Polypharmacy 86.7% (retrospective), 65% (prospective) and autoimmune disorders 73.3% (retrospective), 72.5% (prospective) were recorded as the dominant risk factors for ADR. RSUP DR.M.Djamil Padang has an ADR reporting system, however, the knowledge of healthcare professionals about ADR and their concern for reporting is very lacking.

Keywords: *Adverse Drug Reaction, Pharmacovigilance, ROTD, Pediatric*