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DARANEE CHIEWCHANTANAKIT: STUDY OF ADVERSE DRUG REACTIONS AT QUEEN SIRIKIT NATIONAL INSTITUTE OF CHILD HEALTH. THESIS ADVISORS: CHALERMSRI PUMMANGURA, M.S. (CLINICAL PHARMACY), SRISUPALUK SINGALAVANIJA, M.D., Diploma of Thai Board of Pediatric., Diploma of Thai Board of Dermatology. 167 P. ISBN 974-663-437-2

The objectives of the study of adverse drug reactions at Queen Sirikit National Institute of Child Health were (1) to find the percentage of ADRs of hospitalized pediatrics patients, (2) to find predisposing factors or risk factors of ADRs in Thai pediatric patients and (3) to compare the causality assessment method between Naranjo's Algorithm and RUCAM algorithm (only 29 cases of skin reaction).

The study was designed as prospective intensive monitoring at 5 wards during October 1998 to May 1999. The particular wards were special ward (cardiovascular, hematological, neurological and genito-urinary), gastro-intestinal and nutrition ward and three wards of general diseases. All information was collected from patient charts. The missing data or detailed information would be obtained from physicians, nurses, guardians or patients themselves. There were 2,023 patients (1,180 male and 843 female) whose mean age was 2.206 years. Most patients were less than 1.01 years old. The majority cause of admission was infectious disease (927 cases, 45.82%). Four hundred and fifty seven patients (22.59%; 278 male and 179 female) had experienced 695 counts of ADRs. Mean age of ADR patient was 2.93, but most patients were over 6 years of age. From 695 ADRs, there were 187 serious ADRs from 131 patients. CNS drug group caused the most ADRs (343 cases, 49.35%). The common drugs causing ADRs were diazepam and phenobarbital sodium. Antihistamine and antimicrobial were 125 cases and 81 cases, respectively. System involvement were mainly CNS (455; 65.46%), GI (84; 12.08%) and dermatology (59, 8.49%). Drowsiness, nausea/vomiting and skin rash were the top three ADRs. Regarding severity, 499 ADRs (71.80%) were mild, only 3 ADRs were severe. The majority of ADRs were due to known pharmacological action of drugs (619 ADRs, 89.06%) and 475 events (68.35% from total ADRs) were preventable. Four hundred and eighty seven ADRs were completely recovered without intervention. Causality assessment ADR by Naranjo's Algorithm were "probable" (96.98%), only 1% was "definite". Only ADRs involving dermatological system were re-assessed by using RUCAM algorithm. The results from using RUCAM algorithm were almost identical to that identified by physician more than the result from using Naranjo's Algorithm. There were many factors associated significantly with ADRs (1) age (P value = 0.01), (2) length of stay (P value = 0.01), (3) number of prescribed medications (P value = 0.01). Sex was not related to ADRs.

It was concluded that ADRs is an important problem in hospitalized patients which require special attention. ADRs could be detected by intensive monitoring. Most ADRs were predictable by pharmacological action of drugs, however, the problem of ADRs could be prevented by healthcare professionals, especially clinical pharmacist themselves.