Thesis Title Factors Affecting Spontaneous Reporting System of Adverse Drug Reaction

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ABSTRACT

Spontaneous reporting of adverse drug reaction (ADR), occurred in patients remains the single most important source of information on serious and rare ADR. Nevertheless, substantial underreporting exists and the factors affecting are unclear. Therefore, this study was performed to clarify these factors. The questionnaire was designed and sent to the health professionals including physicians, pharmacists and nurses in the hospitals which are under the Ministry of Public Health in the North-Eastern region of Thailand. The main data collection were general information of respondents, reporting knowledge and perception, attitudes and reporting behavior. Of 965 questionnaires, there are 664 respondents. Response rate was 69 percent. Only 56 percent of respondents were aware of the National Adverse Drug Reaction Monitoring Center(NADRMC)'s reporting system. While 65 percent of respondents had detected ADR in their practice during the previous year, only 14 percent of them reported these events directly to the NADRMC. The health professionals give their opinion that the financial support would improve reporting system and pharmacists are the important personnels to support of the achievement of the SRS. The main reasons for underreporting were diffidence, unavailable forms, unclear objectives of the spontaneous reporting system (SRS) of NADRMC, mild or expected reaction. Thus the NADRMC should publicize the SRS information to all health professionals more effectively. All health

professionals should be born in mild about the important of the SRS which is the early warning signs for drug safety and efficacy for patients. This should be done as earlier as in the curriculum of all medical school. In addition,extention of the establishment of ADR monitoring center in each hospitals would augment the reporting rate to the NADRMC.