

variables. **CONCLUSIONS:** Economic development is important support for health development, but economic growth will not naturally improve health especially for the government investment on health. Rational incentives for the government is essential for health development.

## PHP26

**VALIDATION OF ELECTRONIC DATABASE IN COMMUNITY HOSPITALS IN PATIENTS WITH ATRIAL FIBRILLATION**

Chotchaisuwatana S<sup>1</sup>, Jedsadayamat A<sup>2</sup>, Chaiyakunapruk N<sup>2</sup>, Jampachaisri K<sup>1</sup>

<sup>1</sup>Naresuan University, Muang, Phitsanulok, Thailand; <sup>2</sup>Naresuan University, Muang, Phitsanulok, Thailand

**OBJECTIVES:** The electronic databases (ED) has been increasing used for clinical research since it reflects a routine care with large and heterogeneous samples. However, few studies report on its validity for such purposes, especially the ED from community hospitals. This study aims to assess the validity of EDs based on data from patients with atrial fibrillation (AF) receiving care from community hospitals in Phitsanulok. **METHODS:** The validity of ED was determined using out-patient medical records (OPMRs) as a gold standard. A total of 200 AF patients were randomly sampled from a pool of patients with ICD-10 of AF (I48) from two community hospitals during August 2007–July 2008. For each patient, data of a randomly selected visit from the ED was matched to data of the same visit from OPMRs, abstracted by a standardized data collection form. The ED was cross-validated with OPMRs based on patient's comorbidities (risk factors for stroke) and bleeding events. All data were tabulated in a 2 × 2 format to calculate sensitivity, specificity and the Cohen's Kappa adjusted for chance agreement. **RESULTS:** Out of 200 AF patients, 176 were documented as having diagnosis of AF in OPMRs (88%). The ED data on risk factors of stroke showed moderate to high sensitivity (range 66.67–100%) and high specificity (range 99.36–100%). These results suggest that the risk factors of stroke were coded accurately. Based on these data, the agreement between two databases was considered good to very good (calculated kappa range 0.7940–0.9680). The specificity based on major bleeding was 100%; however, sensitivity and the Cohen's Kappa could not be determined because the major bleeding diagnosis was found neither in the EMRs nor the OPMRs. **CONCLUSIONS:** The electronic database of AF patients from community hospitals was valid and in good agreement with the OPMRs.

## PHP27

**USING COLLABORATIVE PROGRAM BETWEEN PHARMACISTS AND NURSES TO IMPROVE SPONTANEOUS ADVERSE DRUG REACTION REPORTING SYSTEM IN THAILAND**

Prakongsai N<sup>1</sup>, Pongchaidecha M<sup>2</sup>

<sup>1</sup>Prapokklao Regional Hospital, Ministry of Public Health, Chantaburi province, Thailand;

<sup>2</sup>Silpakorn University, Nakorn Pathom Province, Thailand

**OBJECTIVES:** To evaluate the collaborative program between pharmacists and nurses in improving the spontaneous reporting system (SRS) of ADR in Prapokklao hospital, and to explore the impact of the collaborative program on nurses' knowledge about ADRs, capacity in detecting and reporting ADRs, and the level of satisfaction. **METHODS:** Several methods including experimental approach which categorized nurses into experimental and control groups, then compared knowledge before and after a training program and performance in detecting and reporting ADRs between both groups. Eight out of 52 nurses in the experimental group were intensively trained with knowledge about ADRs, and how to report ADRs in hospitalized patients. The rest (44 nurses) in the experimental group obtained knowledge from researchers and the training nurses. Nurses in both experimental and control groups were assessed about knowledge before and after the start of the program, performance in monitoring and reporting ADRs compared to pharmacists, and satisfaction using a self-administered questionnaire. **RESULTS:** Eight nurses trained by the program and 44 nurses in the experimental group had a significant higher score of knowledge than before training. Differences in the pre and post-test scores between experimental and control groups were statistically significant at 0.05. Intensive ADR monitoring indicated that experimental wards had 3572 patients with 371 ADR problems, while control wards had 3467 patients with 266 problems. Nurses in the experimental groups could correctly report 174 ADR problems (46.9%), while 29 problems (10.9%) were reported by their counterparts. The difference in the capability to reporting ADR was at the significance level of 0.05. The level of probability and the difference in the proportion of ADR reported by the experimental group was fourfold to the control group. **CONCLUSIONS:** This collaborative program between pharmacists and nurses significantly improved performance and knowledge of nurse in SRS reporting system in Prapokklao hospital.

## PHP28

**IMPACT OF SAFETY ISSUES' BASED DECISIONS OF CONSULTATIVE COUNCIL ON THE POLISH NATIONAL HEALTH FUND'S BUDGET**

Farkowski MM, Baran J, Matusewicz W

Agency for Health Technology Assessment in Poland, Warsaw, Poland

**OBJECTIVES:** Nowadays growing number of new health technologies entering market together with more aggressive therapies administered by physicians lead to increase in number and cost of care of related adverse effects (AE). We were interested in the impact of costs of AE related to medicines not recommended for public funding by the Consultative Council (CC) of Polish Health Technology Assessment Agency (AHTAPol) on the ground of safety issues on the Polish National Health Fund's budget. **METHODS:** Among decisions of CC published until the end of 2009, we distinguished those where safety issues were significant arguments for decline, and

analyzed submission budget impact analyses (BIA) of those medicines in order to find the incremental costs of AE related to the treatment. Then, we compared those costs to the total incremental costs of public funding reported by manufacturers. **RESULTS:** Among 148 CC's decisions analyzed, 70 were negative and in 22 safety issues were significant arguments against the positive recommendation (31% of all negative decisions). Out of 22 analyzed BIA's only in two cases (10%) incremental costs of AE were explicitly stated, both medicines being used in oncology. In one case (4.5%), a reason for absence of those costs was stated. Stated incremental cost of AE of those two medicines was about 0.25 to 0.35 million USD in years 1 to 3 of public funding, which corresponds to about 2.5% of total incremental cost of those medicines and only 0.2% of total incremental costs of all 22 submissions (about 110 to 135 million USD). **CONCLUSIONS:** In submissions rejected by CC where one of the main concerns were safety issues, manufacturers failed to explicitly show the impact of costs of adverse effects of their drugs on Polish National Health Fund's budget.

## PHP29

**ASSESSMENT OF THE ORPHAN DRUG PRICING AND REIMBURSEMENT LANDSCAPE IN THE ASIA PACIFIC REGION**

Mukku SR<sup>1</sup>, Pang F<sup>2</sup>

<sup>1</sup>Double Helix Consulting, London, UK; <sup>2</sup>Shire Human Genetic Therapies, Basingstoke, UK

**OBJECTIVES:** In recent years, there has been a steady increase in products for chronic rare diseases. The aim of this research is to assess the current pricing and reimbursement framework for orphan and ultra-orphan drugs - identifying emerging trends, defining the key components of health technology assessments, observing government and payer policies, and reviewing previous access decisions in relation to the Asia-Pacific region. **METHODS:** Interviews were conducted with a variety of stakeholders (payers, academics, KOLs) to identify the key determinants influencing the pricing and reimbursement and access strategies of orphan drugs in AP countries including Australia, China, Japan, India, Singapore, South Korea. These were supported by in-depth secondary analyses from government websites, the WHO, reports and OECD statistics. **RESULTS:** Decisions reviewed for a selection of drugs (e.g., Naglazyme, Glivec, Tracleer) across a number of therapeutic areas in the context of indicators including population size, price level, %GDP on health care (Singapore 3.4%, India 4.9%, China 4.5%, Australia 9.1%), number of specialists etc, inferred that there is significant variability in uptake. Orphan definitions vary by country from 4/10,000 in Japan to 1.2/10,000 in Australia. Pricing, payment and regulation mechanisms also differ across countries including financial incentives, protocol assistance, fast-track procedures and market exclusivity (Years: US = 7, EU = 10, Japan = 10, Australia = none). Nearly 100 orphan drugs have been approved over the past 12 years in Japan. In predominantly self-pay markets such as China and India, many orphan diseases remain untreated. Policy determinants include economic troubles impacting health-care budgets, stakeholder attempts to rationalize investment, population demographic shifts, affordability, desire for consistency across and within markets and the requirement to contain rising health-care costs while respecting the philosophy of the health-care system (egalitarian vs. utilitarian). **CONCLUSIONS:** Health system and payer attitudes toward health provision are evolving over time, impacting the type of approach taken to address orphan and ultra-orphan product access in the Asia-Pacific region.

## PHP30

**MARKET ACCESS, AFFORDABILITY AND PRICE COMPONENTS OF MEDICINES IN THE UNITED ARAB EMIRATES (UAE)**

Ansary A<sup>1</sup>, Abuelkhair M<sup>2</sup>, Mukku S<sup>3</sup>

<sup>1</sup>University of Cambridge, Cambridge, UK; <sup>2</sup>Health Authority-Abu Dhabi, Abu Dhabi, United Arab Emirates; <sup>3</sup>Double Helix Consulting, London, UK

**OBJECTIVES:** The research was aimed at understanding the complexities of pricing and reimbursement practices in UAE with analysis focussing on price mark-ups, affordability, stakeholder analysis and strategic recommendations for pharmaceutical companies to launch products in this market. **METHODS:** Interviews were conducted with Payers and KOLs to understand patient flow, health-care issues and drug pricing in UAE. In addition in-depth secondary analysis was conducted. **RESULTS:** UAE with a population of 4.2 million has seen more than 700% growth from 1975–2006, contributed mostly by expatriate work force. This has significantly impacted on the management of health care in recent years. Medicines priced in the UAE are generally high because of the lack of pharmaceuticals manufacturing base and subsequent reliance on imports. While individuals spend \$52 in the gulf countries and \$20 in other Arab countries on medicines, an individual in the UAE spends about \$80 a year. There is a markup of up to 20% and 24% by the wholesalers and retail pharmacies, respectively; which is relatively high in comparison to many other countries resulting in expensive drugs that become unaffordable. A lack of competition legislation and anti-competitive practices means that pharmacies in the UAE are required to buy medicines solely through few agents who hold exclusive rights to importing and distributing products. Also there are differences among the UAE regions; e.g., HAAD is introducing additional controls through a differential co-payments and reference pricing when insufficient competition is observed. As part of market access policy development, the UAE MoH has started applying basic pharmaco-economic methodologies that considers the active ingredient's strength, dosage, and therapeutic effect. **CONCLUSIONS:** The pricing and reimbursement policy in its current form is not-sustainable. New pricing models need to be considered in order to ensure a healthy population with good access to affordable medicines and health care in the UAE.