

**OBJECTIVES:** The current study looks to explore young children from high-risk families in the Taipei City setting. High-risk social welfare intervention was investigated. First, differences between enrollees and non-enrollees for medical subsidy program among high-risk family whose cases were started in 2009 or 2010 will be looked at. Second, the study will try to determine the social welfare intervention's effectiveness in increasing application for medical subsidy program and finding any predictors which may have helped or harmed application for enrollment. **METHODS:** The study sample included under 6 year old children high-risk families (n=199). High-risk family database and medical subsidy database were linked. Differences between high-risk subsidy enrollees (n=87) and non-enrollees (n=112) and effectiveness of a social welfare intervention in increasing subsidy application were investigated in a pre-post analysis of high-risk social welfare intervention. Individual level as well as relative residential level characteristics were explored. **RESULTS:** Medical subsidy enrollment was correlated with younger age at time of a high-risk intervention and relative district level variables. Pre-post comparison suggests high-risk interventions significantly increased subsidy application by 7.4%. Logistic regression indicates older age at time of intervention was associated with 40% less chance of application. **CONCLUSIONS:** The study provides empirical evidence for potential effects of a high risk social welfare intervention on the accessibility to health care. Findings also show where policy makers can improve intervention in order to address the needs children at-risk, especially for different age groups.

#### PIH96

##### WHAT FACTORS ARE ASSOCIATED WITH VACCINATION PROGRAMME SUCCESS? van Oorschot DAM

Radboud University, Nijmegen, The Netherlands

**OBJECTIVES:** When the WHO launched the Expanded Programme on Immunisation (EPI) in 1974, <5% of the world's children were vaccinated against polio, measles, diphtheria, tetanus, pertussis and tuberculosis. Nowadays coverage rates are increasing and more vaccines have been added to the programme. This project aims to identify factors associated with successful programmes based on EPI coverage. **METHODS:** The relationship between multiple socio-demographic and economic factors and EPI coverage (primarily obtained from the WHO and World Bank) was investigated using simple linear regression, Principal Component Analysis (PCA) to identify explanatory variables, and finally multiple linear regression analysis. 132 countries with data on self-funded health care programmes were included in the analysis. These were ranked according to Gross National Income (GNI) per capita and lower (L), lower-middle (LM), upper-middle (UM) and upper (U) quartiles were identified. **RESULTS:** Income (GNI/capita) was not significantly associated with achieving high EPI coverage rates. Within the income groups the factors trending with improved EPI coverage included: 5-yr mortality and corruption index in L, sanitary facilities in LM, 5-yr mortality, sanitary facilities, birth-rate and life-expectancy in UM. In U all countries achieved >90% coverage. **CONCLUSIONS:** Identifying simple predictive variables of successful vaccination programmes is complex because of multicollinearity. However, by exploring within homogeneous income groups, it was possible to identify underlying factors related to vaccination programme success. As the core EPI vaccines were introduced 40yrs ago one would expect introduction to have been fully implemented thus reducing the likelihood of a relationship between country income and coverage today, however it could have been expected some time ago. To further explore the relationship between country income and vaccination programme success, one could expand the analysis to include the newer vaccines as soon as coverage information is available for a majority of the countries.

#### PIH97

##### PATIENT-REPORTED OUTCOMES (PRO) IN GO/NO-GO DECISION MAKING IN DRUG DEVELOPMENT

Ingelgard AP<sup>1</sup>, Nokela M<sup>2</sup>, Cole JC<sup>3</sup>, Berger AK<sup>3</sup>

<sup>1</sup>Covance Market Access, Solna, Sweden, <sup>2</sup>Covance Market Access Services, Solna, Sweden,

<sup>3</sup>Covance Market Access Services, Inc., San Diego, CA, USA

**OBJECTIVES:** Despite existing examples of the great impact successful integration of PRO science and know-how may have on improving market access, PROs are typically not part of drug development decision making such as go/no-go decisions. The objective of this study is to identify decision making instances in drug development when important go/no-go decision making also could have included PROs but typically weren't. Additionally, search for any strategies and activities that might better enhance the likelihood for senior decision makers also to integrate PRO science and knowhow in drug development decision making. **METHODS:** A literature search was carried out including terms such as PRO, strategy, decision-making, go/no-go decisions, drug development and phases I to IV. **RESULTS:** Typical go/no-go decisions mentioned in the literature include decisions to move a drug candidate from one development phase to the next stage, i. e. from target-to hit to launch decisions. There were very few references found where go/no-go decision-making in drug development also included PROs. Many references also states the necessity to include the patient (e. g. listen to the patient) early on in drug development. However, no concrete suggestions on how to carry out these ambitions in practice were found. **CONCLUSIONS:** There is little research to be found in the literature on go/no-go decision making in drug development where PRO science and knowhow are taken into account. The lack of clear practical guidance and examples on when and how to start inclusion of PROs science and knowhow in go/no-go decision making may be one impediment to their successful inclusion. Perhaps, a best practice rule could be as simple as including a PRO opportunity assessment in phase I-II go/no-go decisions where the feasibility, pros and cons for potentially including PRO in the clinical development program are summarized. At least, a first overview of PROs potential is done.

#### PIH98

##### ESTIMATION OF SERUM CALCIUM LEVEL IN PERI AND POSTMENOPAUSAL WOMEN: A COMPARATIVE STUDY

Paras P<sup>1</sup>, Shobha Rani R<sup>1</sup>, Shobha G<sup>2</sup>

<sup>1</sup>Al-Ameen College of Pharmacy, Bangalore, India, <sup>2</sup>St. Philomena's Hospital, Bangalore, India

**OBJECTIVES:** To estimate the calcium levels in peri menopausal and postmenopausal women and to evaluate the need for calcium supplementation among them. **METHODS:** A prospective study was conducted at gynecology department of a tertiary care hospital for the period of six months to estimate the serum calcium levels among them. Study populations were divided into to perimenopausal and post menopausal group. All the eligible patients were enrolled after obtaining informed consent. Study subjects from both the group were estimated for serum calcium levels to identify if they need calcium supplements. Unpaired T test was performed to find out any significant difference between both groups and Pearson's correlation coefficient (r) was applied to assess the relation between age and calcium levels. **RESULTS:** During the study period, 53 of 100 patients enrolled were postmenopausal with the mean age of 60.8±10.47 years and 47 of 100 patients enrolled were perimenopausal with mean age of 44.6±3.54 years. The mean calcium level of 47 perimenopausal women was found to be 9.32±0.55 (reference level: 8.0-11.0 mg/dl) and 8.56±0.54 for 53 postmenopausal women. In post menopausal women there was highly significant drop observed in serum calcium levels with increasing age, compared to peri menopausal women. (CI: 95%, p<0.0001, r: -0.81). **CONCLUSIONS:** The serum concentrations of calcium in majority of our study population were within the normal range. There was a good source of dietary intake of calcium in most of the patients. The levels of calcium were lower in postmenopausal women compared to perimenopausal women. Since there is an negative effect of calcium on the bone mineral density in postmenopausal women, it can be recommended that calcium supplementation can be given as prophylaxis to prevent the long term bone loss and to decrease the risk of fracture and osteoporosis.

#### PIH99

##### PATIENT CHARACTERISTICS AND MEDICATION TREATMENT PATTERNS AMONG MEN WITH ERECTILE DYSFUNCTION (ED), LOWER URINARY TRACT SYMPTOMS SECONDARY TO BENIGN PROSTATIC HYPERPLASIA (BPH-LUTS), OR CO-OCCURRING ED AND BPH-LUTS IN THE UK PRIMARY CARE SETTING

Illo D<sup>1</sup>, Raluy-Callado M<sup>2</sup>, Graham-Clarke P<sup>3</sup>, Donaldson R<sup>2</sup>, Birt J<sup>4</sup>, Sadasivan R<sup>2</sup>, Zhu Y<sup>4</sup>, Neasham D<sup>2</sup>

<sup>1</sup>Lilly UK, Hampshire, UK, <sup>2</sup>Evidera, London, UK, <sup>3</sup>Eli Lilly Australia Pty Ltd., NSW, Australia, <sup>4</sup>Eli Lilly and Company, Inc., Indianapolis, IN, USA

**OBJECTIVES:** Describe patient characteristics and medication treatment patterns among newly diagnosed cases of BPH-LUTS, ED, and co-occurring ED and BPH-LUTS. **METHODS:** Retrospective cohort study using UK CPRD data on incident BPH-LUTS and incident ED patients indexed between June 2010 and May 2011. Patient records were analysed from 12 months pre-index and up to 24 months post-index. **RESULTS:** The cohort included 8912 men with BPH-LUTS-only, 2589 with an ED diagnosis followed by BPH-LUTS, 8093 with ED-only and 1641 with a BPH-LUTS diagnosis followed by ED, all aged ≥40 years. The majority of BPH-LUTS patients (~90%) were diagnosed and managed within GP practices. Men were diagnosed with BPH-LUTS alone at an older average age (68±11.9 years, IQR=59–77) compared to men in the ED/BPH-LUTS group (67±9.5 years, IQR=61–74, p=0.002). Men were diagnosed with ED at an older average age (65±9.2 years, IQR=59–72) in the BPH-LUTS/ED group compared with ED-only patients (57±9.1 years, IQR=50–64, p<0.001). Time between diagnoses was longer for ED/BPH-LUTS patients (6.8±4.76 years) versus BPH-LUTS/ED patients (5.8±5.10 years). BPH-LUTS and ED treatment patterns were similar for patients with and without co-occurring conditions. Most patients were initially prescribed alpha-blockers (62.9% BPH-only, 65.5% ED/BPH-LUTS) or anticholinergics (14.9% BPH-only, 14.0% ED/BPH-LUTS). For ED, most patients were initially prescribed sildenafil (51.6% ED-only, 49.6% BPH-LUTS/ED) or tadalafil (24.3% ED-only, 26.0% BPH-LUTS/ED). At six months post-diagnosis, ~47% incident BPH-LUTS patients and ~78% ED patients were not on any BPH-LUTS or ED treatment, respectively. **CONCLUSIONS:** Study data suggests >80% of patients are managed as either BPH-LUTS- or ED-only. Average age of BPH-LUTS/ED patients at ED diagnosis suggests patients may suffer from ED years before seeking medical attention (p=0.002). Presence of the co-occurring condition does not appear to impact treatment choice, however, a lower proportion of ED patients initiate treatment after diagnosis, compared with BPH-LUTS patients.

#### SYSTEMIC DISORDERS/CONDITIONS – Clinical Outcomes Studies

#### PSY1

##### PAIN INCIDENCE AND ANALGESIC CONSUMPTION DURING HAEMODIALYSIS SESSIONS: IMPACT ON HEALTH-RELATED QUALITY OF LIFE

Rehollo P<sup>1</sup>, Arenas MD<sup>2</sup>, Castejón N<sup>1</sup>, Reichert Garcia J<sup>2</sup>, Delgado Conde P<sup>2</sup>, Gutierrez Rivas P<sup>2</sup>, Gil González MT<sup>2</sup>

<sup>1</sup>LASER ANALYTICA, Oviedo, Spain, <sup>2</sup>Hospital Vithas Perpetuo Socorro, Alicante, Spain

**OBJECTIVES:** To analyse the incidence of pain and the need of analgesics during haemodialysis sessions, and its impact on Health-Related Quality of Life (HRQoL). **METHODS:** Data about the number of sessions in which 172 patients showed pain and needed analgesics were collected in 2 haemodialysis units in Spain during 3 months. Age, sex, comorbidities, (diabetes and cancer history), time on haemodialysis, pain complaints during haemodialysis sessions, intake of analgesics, opioids and antidepressant drugs, were collected. Generic HRQoL was assessed by means of the computer adaptive test CAT-Health, previously validated, through an iPad. A negative score means that the HRQoL is worse than that of general population and a positive score, indicates that it is better. **RESULTS:** Mean age (S. D) was 66.87 (13.32), being 44 patients (25.6%) aged over 75 years. 55.8% were male, 34.3% diabetic and 11.6% had cancer history. The median time undergoing haemodialysis was 51.50 months (27.75-84.50). 81 patients (47.4%) had pain during some session. The mean number of haemodialysis sessions with pain was 4.78 (range between 1 and 21 sessions), which represents 12.7% of the total number of sessions. 67 patients (39%) were usually taking analgesics, 37 (21.5%) opioids and 29 (16.9%) antidepressant drugs. Patients taking analgesics showed worse HRQoL: mean (S.