obtained from 1225 patients [709 male, 516 female]. The average age of the patients was found to be 56.8±0.5 years. The average number of medications prescribed was 10.6±0.2. 585 patients were found to be aged 60 years or more and 613 patients were in the age group 18-60 years. Out of the 1225 patients, 848 did not have any medication error. An error was noted on only in 377 patient profiles. The total number of medication errors was found to be 638. Of these, 597 were errors 'with no harm' and only 41 were errors 'with harm'. Of these medication errors, drug interactions (DIs) were found to be leading the list with 50% of the medication errors. Cardiovascular agents contributed maximum to the DIs followed by anticoagulants and antimicrobial agents. Only 172 DIs had a moderate severity. DIs was followed by duplication of therapy (20%), incorrect interval (10%), monitoring error, incompleteness of prescription, omission error and overdosing, respectively. **CONCLUSIONS:** These results confirm that drug interaction continue to lead the list of medication errors in Indian tertiary health care settings. The study is ongoing to determine the interventions to reduce the errors.

PIH3

DRUGS ASSOCIATED WITH ADVERSE DRUG EVENTS IN CHILDREN: ANALYSIS OF THE UNITED STATES FDA ADVERSE EVENT REPORTING SYSTEM DATABASE

Lee WJ, Schumock GT, Lee TA
University of Illinois at Chicago, Chicago, IL, USA

OBJECTIVES: Compared to adults relatively little is known about drug safety in children. This study aims to describe the drugs and adverse events most commonly reported in the US spontaneous Adverse Event Reporting System (AERS) in children. **METHODS:** Adverse events reported to the US FDA AERS Database between 1 January 2007 and 30 June 2012 and occurring in children and adolescent (<18 years old) were examined. Demographic characteristics of the patients and reports were described by age, gender and reporter type. Additionally, the most commonly suspected drugs and the most frequently occurring adverse events in the AERS database were identified. **RESULTS:** We identified a total of 90,355 reports (average 16,428 reports/year) of primary suspect medications in children, of which 60.8% were for individuals < 12 years old and 50.6% were males. Physicians (30.5%) and consumers (27.4%) reported the majority of pediatric adverse drug events. Methylphenidate was the most frequently reported drug with 3,755 (4.2%) reports, followed by infliximab (3.0%) and isotretinoin (2.7%). Vomiting (1.3%), pyrexia (1.2%), convulsion (1.1%), drug ineffective (1.0%) and product quality issue (0.9%) were the top five reported adverse events. However, dyspnoea and pneumonia became the fourth and fifth leading adverse events respectively when restricting our analysis to only severe events (i.e., resulting in hospitalization, life-threatening events, or death). **CONCLUSIONS:** Data from post-marketing surveillance of adverse events can add to our understanding of drug safety in children. A large proportion of events reported to the FDA are not considered severe and focusing solely on severe events is likely important to identify potential high risk medications. Subsequent analyses of the most commonly reported drug causes of severe adverse events may lead to important safety questions.

PIH4

A PILOT STUDY OF PHARMACOTHERAPY (NALTREXONE) FOR HAZARDOUS DRINKING AMONG WOMEN INFECTED WITH HIV

Hu X[1], Weber K[2], Karki M[1], Cohen M[3], Young M[4], Thoma K[5], Thomas G[5], Rathore M[5], Mai D[4], Cook R[1]
[1]*University of Florida, Gainesville, FL, USA,* [2]*Stroger Hospital, Chicago, IL, USA,* [3]*Stroger Hospital and Rush University, Chicago, IL, USA,* [4]*Georgetown University Medical Center, Washington, DC, DC, USA,* [5]*University of Florida, Jacksonville, FL, USA*

OBJECTIVES: Pharmacological treatment is effective in reducing hazardous drinking in persons with alcohol dependence, while little is known whether it is effective in HIV patients. The purpose of this study was to examine feasibility and effectiveness of using pharmacotherapy (naltrexone) on women infected with HIV. **METHODS:** The NIAAA-sponsored pilot study was a double-blind, randomized controlled trial. Women with HIV who met criteria for NIAAA-defined past-year hazardous drinking were recruited from HIV clinical settings in Jacksonville (FL) and the Women's Interagency HIV Study (WIHS) in Chicago (IL) and Washington DC. Participants were randomized 2:1 to oral naltrexone (50mg) or placebo for 4 months; outcomes were assessed 2, 4 and 7 months after enrollment. **RESULTS:** From December, 2010 to February, 2012, 19 women were enrolled (mean age 48.8 years, 95% African American). Approximately 70% of eligible women were successfully enrolled at two WIHS sites, compared with 12% at the clinical site in Jacksonville (FL). Almost all women reported prior use of other drugs (heroin, 3; methadone, 3; cocaine, 13; marijuana, 14; tobacco, 16). Among 14 (74%) women who completed the study, average daily alcohol consumption dropped significantly from 7.13 standard drinking units (SDUs) at baseline to 0.46 SDUs at month 7. **CONCLUSIONS:** Although the sample is small, this pilot study demonstrates the feasibility of conducting a larger study to determine the impact of naltrexone on alcohol consumption and health outcomes in women with HIV. Although enrollment of HIV-infected women into alcohol treatment trials can be challenging, we demonstrated that these challenges can be minimized by recruiting from previously established long term cohorts that directly address alcohol consumption. Health outcome, especially alcohol consumption reduction, reported in this study will provide valuable input for future decision analytical models to evaluate the cost-effectiveness of using pharmacotherapy treating hazardous drinking among HIV patients.

PIH5

EFFECT OF ASCORBIC ACID ON BLOOD LEAD LEVELS AMONG SCHOOL GOING ADOLESCENTS IN KARACHI: A CLUSTER RANDOMIZED TRIAL

Gilani AH[1], Ilyas M[2], Nuruddin R[2], Islam M[3]
[1]*Department of Biological and Biomedical Sciences, The Aga Khan University, Karachi, Pakistan,* [2]*The Aga Khan University, Karachi Pakistan, Karachi, Pakistan,* [3]*The Aga Khan University, Karachi Pakistan, Karachi, PR*

OBJECTIVES: There is no safe range for Blood Lead Levels (BLL) in humans. Lead is associated with many adverse health outcomes in children because of more susceptibility to environmental lead. We aimed to explore a convenient and cost-effective strategy for decreasing BLL among adolescent with the objective to assess the effect of Ascorbic-acid on BLL among school going adolescent of Karachi. **METHODS:** A cluster randomized trial was conducted in schools, randomized to 250mg or 500mg of Ascorbic-acid (four clusters each). BLL was measured at baseline and after four weeks of intervention. Lead exposure was assessed through a questionnaire at baseline and dietary Vitamin-C through Food Frequency Questionnaire (FFQ) at follow-up. The cluster adjusted difference between the groups calculated through independent t-test and within group difference through paired t-test. A multiple-linear-regression model was built for adjusting residual confounders. **RESULTS:** A total 144 individuals were recruited. The overall mean BLL at baseline was 12.9mg/dl (95%CI; 12.2-13.8). For Ascorbic-acid 250mg and 500mg it was 13.4mg/dl (95%CI; 12.1-14.7) and 12.5mg/dl (95%CI; 11.7-13.4) respectively. The mean decline in BLL was 2.7mg/dl (p=0.002) and 3.29mg/dl (p<0.001) in 250mg and 500mg respectively. The mean difference in BLL decline between two group was 0.6mg/dl (p=0.824). On an average, for one mg/dl increase in baseline BLL, the decreased was 0.8mg/dl after adjusting for chipping-off of school paint and intervention group (p<0.001). **CONCLUSIONS:** The overall mean baseline BLL of our sampled population was above the acceptable level recommended by CDC (10mg/dl). Oral supplementation of Ascorbic-acid in both 250mg & 500mg significantly decreased BLL. However, the dose dependent decline was statistically insignificant. In adolescent who had initially elevated BLL showed greater decline at follow-up. Thus, using Ascorbic-acid 250mg or 500mg daily could be a cheap, safe and easily available strategy to lower BLL among adolescent particularly those living in highly exposed areas.

PIH6

DRUG USE EVALUATION AT AN INDIAN PUBLIC TEACHING HOSPITAL

Tiwari P[1], Kumar A[2], Sachdev A[3], D'cruz S[3]
[1]*National Institute of Pharmaceutical Education and Research (NIPER), S.A.S. NAGAR, India,* [2]*NIPER, SAS NAGAR, India,* [3]*Govt Med Coll Hosp, Chandigarh, India*

OBJECTIVES: To evaluate prescribing pattern in an inpatient setting of a public teaching hospital in India. **METHODS:** Patient records were collected from general medicine wards of a public teaching hospital over a period of 7 months. The data were analyzed using WHO recommended prescribing indicators: The National List of Essential Medicines-2003 of India (NLEM-2003) was used to analyze prescribing from essential drug list. The results were presented as average±SEM, median (inter quartile range) and percentages, as applicable. **RESULTS:** A total of 710 inpatients' records were analyzed. Over two thirds of patients (67.6%) had only one diagnosis and the average number of diagnosis was 1.4±0.02. The average number of medicines prescribed was found to be 7.3. The percentage of medications prescribed from NLEM was 65%. Approximately 14.6% medications were prescribed by generic names. The percentage of prescriptions with an injection(s) and antibiotic(s) were 85.9% and 68.6%, respectively. **CONCLUSIONS:** This study has provided real-time evidence that the prescribers in public teaching hospital were aware of the NLEM-2003. There are areas, in addition to this, which require consolidation to promote rational drug therapy.

PIH7

THE PREVALENCE, INCIDENCE, AND TREATMENT RATES OF HYPOGONADISM IN MEN ACROSS GEOGRAPHIES: A SYSTEMATIC LITERATURE REVIEW

Huang MY[1], Parker G[2], Zarotsky V[2], Carman W[3], Morgentaler A[4], Jones H[5], Singhal P[6]
[1]*Temple University, West Point, PA, USA,* [2]*Optum, Eden Prairie, MN, USA,* [3]*Optum, Ann Arbor, MI, USA,* [4]*Men's Health Boston, Boston, MA, USA,* [5]*Robert Hague Centre for Diabetes and Endocrinology, Barnsley Hospital NHS Foundation Trust, Barnsley, UK,* [6]*Merck & Co., Inc, West Point, PA, USA*

OBJECTIVES: To conduct a systematic literature review to assess the prevalence, incidence, and treatment rates of hypogonadism in men across geographies. **METHODS:** The literature search was undertaken within the PubMed/MEDLINE, Embase, and Cochrane databases for articles published between 1992 and 2012. Articles were excluded from this review if the sample size was less than 30. **RESULTS:** We reviewed 175 citations/abstracts and identified 109 relevant articles. Numerous cut-off points for testosterone level were used to define hypogonadism; however, the most widely used definitions were total testosterone <300 ng/dL (10.41nmol/L) and free testosterone <5ng/dL (<0.174nmol/L). Few studies used the combination of symptoms and testosterone level cut-off points to define hypogonadism. The prevalence, incidence, and treatment rates of hypogonadism across studies varied widely depending upon the population studied and how hypogonadism was defined. The overall prevalence rates for hypogonadism based on population-based studies were: US, 3.8% - 20.4%; Chile, 28.1%; Germany, 3.4% - 5%; Finland, 19.8%; Malaysia, 6.0% - 16.1%; Taiwan, 12.0% and Hong Kong, 9.5%. Prevalence also increased with age and in the presence of co-morbid conditions. The incidence per 1000 person-years was 12.3 in the US and 11.7 in Germany. Treatment rates varied dramatically in different studies and populations and were generally very low (9.6% - 11.3% of men with hypogonadism). **CONCLUSIONS:** The literature review suggested that there is potentially a significant burden of hypogonadism in the general population. Burden seems to increase with age and in the presence of certain disease conditions. Inconsistent disease definitions and diagnostic