

domized clinical trials (RCTs), with follow-up times from 1 to 36 months. Efficacy at three months of follow-up (estimated as the posterior median) ranged from 87.5% for the levonorgestrel-releasing intrauterine system (LNG-IUS) to 14.2% for progestogens administered for less than two weeks out of four in the menstrual cycle. The 95% credible intervals for most estimates were quite wide, mainly because of the limited evidence for many combinations of treatment class and follow-up time and the uncertainty from estimating %MBL < 80mL from other outcome data. **CONCLUSIONS:** LNG-IUS and endometrial ablation have high efficacy for HMB. The study yielded useful insights on MTC in sparse evidence networks. Diversity of outcome measures and follow-up times in the HMB literature presented considerable challenges. The Bayesian credible intervals reflected the various sources of uncertainty.

#### PIH4

##### IS SILDENAFIL – APOMORPHINE SUBLINGUAL COMBINATION SIGNIFICANTLY MORE EFFECTIVE THAN SUBLINGUAL SILDENAFIL IN TREATING ERECTILE DYSFUNCTION?

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**OBJECTIVES:** To test the efficacy of a sildenafil (50 mg) and apomorphine (3 mg) sublingual combination in treating male Erectile Dysfunction (ED) in comparison to sublingual sildenafil (50 mg) that shows an increasing number of non-responders. **METHODS:** In all, 50 eligible ED patients were enrolled into a prospective single-blinded crossover study with two treatment periods, each of 4 weeks, separated by a 2-week washout period. A randomization list in blocks in closed packets was used to randomize the patients to receive sildenafil then the combination or the combination then sildenafil. The primary efficacy endpoint was the percent of attempts resulting in erection firm enough for intercourse. Other efficacy endpoints included the percent of attempts resulting in successful intercourse, change in the score of the 5-item version of the International Index of Erectile Function (IIEF-5) from baseline, response to Sexual Encounter Profile (SEP) diary questions 2 and 3, and patient's preference (Of the two study interventions, which one did you prefer?). **RESULTS:** Only 43 patients completed the whole schedule and had results evaluable for efficacy. Sildenafil - apomorphine combination had a significantly higher estimate than sildenafil in regard to the mean percent of attempts resulting in erection firm enough for intercourse (77.6% vs. 63.1%,  $p < 0.001$ ) and resulting in successful intercourse (51.1% vs. 34%,  $p < 0.001$ ), as well as erectile function as evaluated by the change in the median IIEF-5 score from baseline (18 vs. 15 with baseline of 7,  $P < 0.001$ ). Also, the proportion of affirmative answers regarding the SEP diary was significantly higher after the combination (question 2: 79.1% vs. 55.8%  $P < 0.01$  and question 3: 65.1% vs. 44.2%,  $P < 0.05$ ). At the end of the study, patient preference was 88.4% for the combination and 4.6% for sildenafil. **CONCLUSIONS:** Sildenafil - apomorphine sublingual combination was significantly more effective than sublingual sildenafil in treating ED.

#### PIH5

##### SYSTEMATIC REVIEW COMPARING THE EFFICACY OF THE 5-ALPHA REDUCTASE INHIBITORS (5-ARIS) DUTASTERIDE AND FINASTERIDE IN THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA (BPH)

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**OBJECTIVES:** Benign prostatic hyperplasia (BPH) is a chronic, progressive disease with important healthcare and economic implications. 5-alpha reductase inhibitors (5-ARIs), dutasteride and finasteride are effective treatments. If untreated, BPH may lead to complications such as acute urinary retention (AUR) and the need for surgery (NfS). The aim of this review is to compare the efficacy of dutasteride and finasteride in reducing episodes of AUR and the NfS related to BPH. **METHODS:** MEDLINE, Lilacs and the Cochrane Central Register of Controlled Trials were searched (from inception to September 2011) to retrieve randomized clinical trials (RCTs) and observational studies evaluating these drugs. The search included articles published in English, Portuguese, and Spanish. Patients with confirmed diagnosis of BPH were included. We analyzed data from studies that reported the number of AUR or NfS following treatment with dutasteride or finasteride. **RESULTS:** The literature search identified 24 potential full-text publications; 9 RCTs (where 9 were duplicates) and 6 observational/retrospective studies. No RCT head-to-head comparison was found. Indirect efficacy comparison between the two 5-ARIs, based on RCTs, was deemed inappropriate due to the heterogeneity of the patients included in the trials, differences in outcome measurements, study design and combination therapies (i.e., alpha blockers) used in the studies. Direct comparison of dutasteride and finasteride was available from 3 retrospective cohort studies, indicating that dutasteride may be more effective in reducing the episodes of AUR (Odds ratio = 0.79; 95%CI = 0.68-0.93;  $p = 0.0042$ ) and the NfS (Odds ratio = 0.77; 95%CI = 0.61-0.98;  $p = 0.03$ ) relative to finasteride. **CONCLUSIONS:** The current evidence on the efficacy of dutasteride and finasteride makes an indirect comparison between the two 5-ARIs difficult; however, data retrieved from observational studies indicate improved clinical performance of dutasteride compared to finasteride.

#### PIH6

##### ANTIPSYCHOTIC USE AND RISK OF NURSING HOME ADMISSION AMONG COMMUNITY-DWELLING DUAL ELIGIBLE BENEFICIARIES

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**OBJECTIVES:** Antipsychotic agents are often used for behavioral symptoms of dementia and psychoses. This study evaluated the risk of nursing home admission associated with use of antipsychotics among community-dwelling (Medicare and

Medicaid) dual eligible beneficiaries in the United States. **METHODS:** The study involved a retrospective cohort design matched on propensity score using Medicare and Medicaid Analytical eXtract (MAX) data from four US states. The study population included all elderly dual eligible community dwelling beneficiaries (aged > 65 years) who initiated antipsychotics anytime during July 1, 2001 and December 31, 2003. Antipsychotic users were followed till the occurrence of nursing home admission or, end of the study period, whichever occurred earlier. The risk of nursing home admission was modeled using Cox proportional model and extended Cox hazard model stratified on matched pairs based on propensity score, using typical agents as the reference category. **RESULTS:** Analysis of Medicaid-Medicare community dwelling dual eligible data revealed that there were 88,989 antipsychotic users (47,090 atypical and 41, 919 typical users) in the unmatched cohort and 60,840 users in the matched cohort (30,420 atypical and 30, 420 typical users). The unadjusted rate of nursing home admission was 20.58% (6, 260) in the atypical cohort and 16.15% (4, 914) in the typical cohort. The results of Cox regression [average HR, 1.29; 95% CI, 1.23 -1.34] as well as extended regression [ $< 40$ days: HR, 1.15; 1.08-1.23 and  $> 40$  days: HR, 1.42; 1.33-1.51] suggest that, the risk of nursing home admission was higher among atypical users compared to typical users. **CONCLUSIONS:** The higher risk of nursing home admission among atypical users compared to typical users may be attributable to indication bias. Since atypical antipsychotics are often used to control behavioral symptoms of dementia, it is possible that patients with behavioral symptoms treated with atypical agents were subsequently admitted to nursing homes.

#### PIH7

##### RISK OF ALL-CAUSE HOSPITALIZATION IN DUAL ELIGIBLE BENEFICIARIES USING ANTIPSYCHOTIC AGENTS

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**OBJECTIVES:** Previous studies have reported differential safety and efficacy profiles of typical and atypical antipsychotics in the elderly. The study compared the risk of all-cause hospitalization among elderly dual eligible beneficiaries (Medicare and Medicaid) using typical and atypical antipsychotic agents. **METHODS:** A retrospective cohort study design matched on propensity score was used to examine the risk of all-cause hospitalization among dual eligible beneficiaries 65 years or older using antipsychotic agents. The study involved use of Medicare and Medicaid Analytical eXtract (MAX) data from four US states. New antipsychotic users were followed for up to six months without any censoring. The risk of hospitalization was modeled using Cox proportional model and extended Cox hazard model stratified on matched pairs based on propensity score. **RESULTS:** Analysis of Medicaid-Medicare dual eligible data revealed that, there were 1, 43, 617 new antipsychotic (91, 665 atypical and 51, 952 typical) users in the unmatched cohort and 84, 162 (42,081 atypical and 42,081 typical) users in the matched cohort. The unadjusted rates of hospitalization were 27.17% and 27.96% among atypical and typical users respectively. Cox hazards regression found that, users of typical antipsychotics were marginally at a higher average risk of hospitalization compared to atypical users [Hazard Ratio, (HR), 1.07; 95% Confidence Interval, (CI), 1.04-1.10]. Results of extended Cox regression suggest that, typical users had a higher risk of hospitalization than atypical users within the initial 40 days of therapy [HR, 1.26; 95% CI, 1.21-1.31]. However, the risk of hospitalization decreased with prolonged typical use [HR, 0.90; 95% CI, 0.86-0.94]. **CONCLUSIONS:** Overall, typical antipsychotic users were more likely to experience all-cause hospitalization than atypical users possibly due to differential safety profiles of antipsychotics. More research is needed to evaluate specific reasons for the health care impact of antipsychotic use in the elderly population.

#### PIH8

##### MEDICATION USE AND HOSPITAL ADMISSION RATES AMONG PRETERM BORN INFANTS COMPARED TO FULL TERM BORN INFANTS

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**OBJECTIVES:** About 5-12% of all pregnancies in western countries result in preterm birth. Preterm born infants may be at increased risk of adverse outcomes. This study compared hospitalization and medication use in the first year of life between preterm and full term born infants. **METHODS:** Data for this study were obtained from linking the PHARMO database network (including detailed information on drug dispensing and hospitalization histories) with The Netherlands Perinatal Registry (including perinatal medical case records). From this linked cohort, all preterm born infants (gestational age < 37 weeks) between 2004-2007 were randomly matched to 4 full term born infants on gender, month and year of birth. All infants were followed from birth until end of data collection in PHARMO or their first birthday, whichever occurred first. During follow-up, hospitalization and medication use was assessed. Cox proportional hazard regression models were used to estimate the relative risk of hospitalization/medication use among preterms compared to full terms. Population attributable risk percentages (PAR%) were calculated to estimate the proportion of hospitalization/medication use attributable to prematurity. **RESULTS:** Among the 71,607 singletons born between 2004-2007, 4,277 (6%) were born preterm of which 90% were hospitalized at birth, compared to 55% of the full terms. Premature infants were twice more likely to be re-hospitalized (RR 2.0; 95%CI 1.9-2.2), specifically for respiratory related diseases. Prematurity accounted for 6% of respiratory re-admissions. Between the age of 6-12 months, the most frequently used outpatient drugs were antibacterials and drugs for obstructive airway diseases. Premature infants were 50% more likely to receive respiratory