

surement with more than one endpoint is the generation of a cardinal index/score. Without the prioritization and weighting of multiple endpoints a deduction of recommendations might be questionable. **METHODS:** A pilot study was conducted to elicit patients' preferences about antiviral therapy of chronic hepatitis C. For the Discrete-Choice-Experiment (DCE), 7 attributes were selected with 3 Levels each. Therefore an orthogonal, balanced and efficient design was used and results were analysed with random effects logit models. **RESULTS:** Patients and experts prioritized the respective endpoints in almost the same order, but weighted them differently. Sustained-Virological-Response received the highest weight followed by frequency of application (patients) or duration of therapy (experts). **CONCLUSIONS:** Aim was to demonstrate how DCEs can be used to empirically determine which PREs should be included in the efficiency frontier analysis. Further it is demonstrated how such methods can be used to prioritize across such multiple efficiency frontiers. The survey demonstrated how DCEs could be used to empirically determine which PREs are important in antiviral treatment of chronic hepatitis C. The results could be used for the development of innovative therapeutic schemes and new drugs which could meet patients' needs. For IQWiG purposes the weights of PREs are included in the health economic evaluation.

PSY81

PERCEPTIONS ABOUT 'RAPID' WARFARIN REVERSAL WITH FRESH FROZEN PLASMA TO REDUCE THE INR: A NOVEL SURVEY METHODOLOGY

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OBJECTIVES: To determine health care provider perceptions about timing of 'rapid' warfarin reversal-related patient care events using novel survey methodology. **METHODS:** Forty-eight adult and pediatric trauma centers were contacted to participate in a direct-to-provider (DTP) survey. Participants were asked to provide aggregate information about patients receiving fresh-frozen plasma (FFP) for acute warfarin reversal. **RESULTS:** Nineteen to 25 health care professionals from 18 centers provided information by survey. Average perceptions of time needed to infuse FFP under this setting (mean 4.6 hrs from time of triage; 95% CI 1.0 – 8.2 hrs) are consistent with actual, published values. In contrast, average perceptions of time needed for initial International Normalized Ratio (INR) normalization using FFP (mean 5.8 hrs; 95% CI 2.8 – 8.8 hrs) underestimate actual, published values by 6 – 26 hrs. Health care providers perceived that relatively little cumulative time lapses (1.6 hrs, on the average) for completing the first FFP infusion. There is little perceived time lag between ordering and beginning the first FFP infusion (0.3 hrs, on the average), consistent with actual, published values. There is substantial reported time (an additional 3.0 hrs, on the average) needed to complete subsequent FFP infusions, amounting to 52% of all perceived time lapsing for initial INR normalization in this setting. **CONCLUSIONS:** DTP survey methodology appears to be an efficient method for gathering clinical information for research purposes. Healthcare providers may have perceptions that are different from published studies, including inaccurate perceptions of the delay between the time FFP infusions are completed and time of initial INR normalization. To our knowledge, this is the first study to show that subsequent-to-first FFP dose infusion times account for the majority of perceived INR normalization time. Delays to treatment completion may present serious downstream consequences. Such perceptions may influence clinical decision making, and warrant further analysis and investigation.

Urinary/Kidney Disorders – Clinical Outcomes Studies

PUK1

INCIDENCE AND 30-DAY MORTALITY OF COMMUNITY ACQUIRED PNEUMONIA (CAP) IN THE MEDICARE FEE-FOR-SERVICE (FFS) POPULATION

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OBJECTIVES: To estimate CAP episode incidence and 30-day mortality rates in the Medicare FFS population ≥ 65 years of age. **METHODS:** Claims data from the Medicare 5% sample were used to identify pneumonia diagnoses between July 1, 2007 to June 30, 2008. We defined pneumonia hospitalizations as either Part A (PA) primary discharge diagnosis (pdd) of pneumonia, or sepsis or respiratory failure as pdd plus pneumonia as secondary diagnosis. Outpatient pneumonia was defined as a pneumonia diagnosis from PA outpatient or non-hospital sourced Part B, with claim for chest x-ray within 14 days of pneumonia diagnosis. CAP episodes were defined as being indexed on the first pneumonia claim date followed through the last pneumonia claim date preceded and followed by a 90 day clean period, respectively. Episodes were defined as outpatient, unless beginning with or containing a CAP hospitalization, in which case they were considered inpatient CAP episodes. We further excluded evidence of hospitalization, long-term care and mechanical ventilator use from claims within 14 days of the CAP index date. Incidence and mortality were stratified by inpatient status and age. **RESULTS:** A total of 56,262 CAP episodes were identified; 38.4% were inpatient. The average inpatient and outpatient episode length was 32.7 days (SD 46.3) and 12.8 days (SD 27.6), respectively. Corresponding incidence rates were 1,767/100,000 person-years for inpatient and 2,837/100,000 for outpatient CAP. Overall incidence rises with increasing age, ranging from 2,786/100,000 person-years for those 65-69 to 8,449/100,000 for those 85+. Overall 30-day case-fatality was 5.6%; 8.5% for inpatient and 3.8% for outpatient CAP. Case-fatality rates also increase with increasing age. **CONCLUSIONS:** The overall incidence of CAP in the Medicare FFS population of 4,604/100,000 person-years is substantial. These results suggest an estimated 1.13 million cases of CAP and 63,000 CAP-related deaths annually among this population. CAP remains an important public health burden in the United States.

PUK2

DUTASTERIDE FOR BENIGN PROSTATIC HYPERPLASIA: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: This study systematically reviews existing evidence to determine the efficacy and adverse events of dutasteride, alone or in combination, versus a placebo or control, used for the treatment of benign prostatic hyperplasia (BPH). **METHODS:** Medline and the Cochrane Library were searched for randomized controlled trials that were longer than six months in duration. The study population was men, aged 50 or older, with moderate and severe symptoms of BPH as determined by the International Prostate Symptom Score (IPSS) and clinical parameters including maximum urinary flow rate (Q_{max}) and prostate volume. A meta-analysis with a random effects model was conducted to synthesize the findings of multiple studies. Heterogeneity among the studies was assessed both graphically with forest plots and statistically with I^2 statistics. **RESULTS:** Dutasteride was superior to the placebo in reducing urinary symptoms measured by IPSS [weighted mean difference (WMD) = -2.50, 95% confidence intervals (CIs) = -2.91 to -2.09], prostate volume (WMD = -12.90, 95% CIs = -14.27 to -11.53) and in increasing Q_{max} (WMD = 1.30, 95% CIs = 0.99 to 1.61). However, risk ratios for any adverse events (1.27, 95% CIs = 0.99 to 1.62) and for drug-related adverse events (1.47, 95% CIs = 0.77 to 2.79) were not significantly different between those treated with dutasteride and those in the control group. When dutasteride was administered with tamsulosin, the reduction in IPSS scores and the increase in Q_{max} were greater than if the medications were administered alone, although prostate volume changed little. For both BPH-related acute urinary retention (AUR) and BPH-related surgery, no significant difference in risk ratio was observed between the combination group and the dutasteride group. **CONCLUSIONS:** Dutasteride can be used for those with moderate to severe BPH symptoms when benefits from efficacy are considered to be greater than the loss from adverse events.

PUK3

DRUG-INDUCED ACUTE RENAL FAILURE USING THE FDA ADVERSE EVENT REPORTING SYSTEM DATABASE

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OBJECTIVES: The incidence of acute renal failure (ARF) is increasing. A substantial proportion of these cases are due to drug-induced nephrotoxicity. Data from post-marketing surveillance programs, like the FDA Adverse Event Reporting System (AERS), can be useful in assessing the risk of adverse drug events. Our objective is to describe reports with ARF (cases) and reports without ARF (non-cases) and outcomes resulting from ARF using the AERS database. **METHODS:** Data were extracted from the AERS database from 2004-2009. All reports of cases and non-cases were described and analyzed in term of suspected drugs, health outcomes, and other characteristics. Descriptive statistics (frequencies and proportions) and Chi-square tests were used. **RESULTS:** The AERS data used in this study represents 2,231,689 reports from 184 countries with 27,190 involving reports of ARF (cases). There was approximately a two-fold increase in the percentage of reports of ARF from 2004 to 2009 (n = 3,594; 13% to n = 6,104; 22%, respectively). Most reports were submitted by manufacturers (cases = 89%, non-cases = 93%). The majority of reports were for infants (cases = 75%, non-cases = 57%). In cases, drugs were the primary suspect, the secondary suspect and concomitant in 18%, 14% and 66% of reports, respectively. The five drugs with the highest reported frequencies of ARF were rofecoxib, valacyclovir, metformin, simvastatin, and digoxin. Unfavorable outcomes were more likely to occur in cases than non-cases (death 24% vs. 12%, life threatening condition 21% vs. 5%, initial/prolonged hospitalization 76% vs. 33%, disability 6% vs. 4% and required intervention 4% vs. 2%; p-value < 0.001, for all comparisons). **CONCLUSIONS:** These preliminary findings present an overall picture of reports with ARF. These findings can be informative for regulatory authorities and healthcare professionals. Additional analyses with reporting odd ratios (ROR) are needed to support these initial findings.

PUK4

CUMULATIVE EXPOSURE TO NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS) AND THE PROGRESSION OF CHRONIC KIDNEY DISEASE (CKD)

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OBJECTIVES: To examine the relationship between NSAID use and the progression of CKD for a cohort of elderly patients within the military health system. **METHODS:** All patients with at least one serum creatinine measurement in each of the time periods July 1-December 31, 2006 and July 1-December 31, 2008 with a baseline estimated glomerular filtration rate (eGFR) representing CKD stage 2 or 3, who were ≥ 67 years of age, continuously eligible for TRICARE, and received care at a military treatment facility were included in a retrospective database analysis. Logistic regression analyses were used to explore associations between NSAID use and rapid progression of CKD defined as a decrease in eGFR of ≥ 15 mL/min/1.73m². Covariates included age, gender, diabetes, hyperlipidemia, hypertension, and NSAID exposure level. **RESULTS:** A total of 34,295 patients (median age 73.5, 50.2% male) met the inclusion/exclusion criteria. A total of 14,576 patients had some NSAID use, while 19,719 had no NSAID use. Rapid CKD progression occurred for 10.5% of no use NSAID patients (2,063 of 19,720), 11.2% of low to medium NSAID use patients (1,465 of 13,125), and 13.4% of high NSAID use patients (195 of 1,450). Logistic regression results showed that stage 2-3 CKD patients with low to medium