

lines informing the use of UDM, there appears to be a general consensus among practitioners that utilize UDM on: which patients to monitor, how often to monitor, and which substances are most important to detect.

MEDICAL DEVICE/DIAGNOSTICS – Research on Methods

PMD55

PREDICTIVE ACCURACY OF METHODS FOR IDENTIFYING PATIENTS RECEIVING PERITONEAL DIALYSIS AND HEMODIALYSIS USING HEALTH CARE ADMINISTRATIVE DATA

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OBJECTIVES: To estimate the predictive accuracy of methods used to identify patients receiving peritoneal dialysis (PD) and hemodialysis (HD) in healthcare administrative data. **METHODS:** The study population consisted of all persons aged 18-63 years with evidence of end-stage renal disease (ESRD) who were members of a large US urban health maintenance organization between January 1, 2005 and December 31, 2008 ("study period"). Using healthcare administrative data, we identified all those with any dialysis-related procedure or diagnosis codes; the date of each patient's first such encounter was then designated as the "anchor date". Using only codes in healthcare administrative data within 30 days of anchor date, we then designated each patient as either PD or HD. Medical records were then reviewed by trained abstractors using a 180-day window around each patient's anchor date to ascertain positive predictive value (PPV) of procedure and diagnosis codes in administrative data for receipt of PD and HD. **RESULTS:** We identified a total of 233 patients with ESRD and one or more healthcare encounters with dialysis-related procedure and diagnosis codes. Of these, 43 had codes suggesting receipt of PD, and 173 had codes suggesting receipt of HD; dialysis modality could not be determined for the remaining 17 patients. PPV of PD-related codes for identifying patients receiving PD within 30 days of anchor date was 34.9%; it was 67.4% within both 90 days and 180 days of anchor date. PPV of HD-related codes for identifying patients receiving HD within 30 days of anchor date was 86.7%; it was 90.8% within 90 days of anchor date, and 93.1% within 180 days of this date. **CONCLUSIONS:** While HD-related procedure and diagnosis codes appear to have relatively high predictive accuracy for identifying patients receiving HD, predictive accuracy of the codes used to identify patients receiving PD is much lower.

PMD56

USING ADVANCED HEALTH CARE DATA ANALYTICS TO IDENTIFY AND CHARACTERIZE CENTRAL VENOUS CATHETERIZATION EPISODES VIA ELECTRONIC HEALTH RECORDS IN THE VETERANS AFFAIRS

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OBJECTIVES: Observational health care data are often used to study patient populations and outcomes of interest. Electronic Health Record (EHR) data provide a granular and longitudinal look at patient care; however, much information is buried within the narrative text of clinical notes and is not typically available for research. Diagnosis and procedure codes pose two difficulties when identifying central venous catheter (CVC) episodes: 1) they are underused and 2) they are associated with the encounter and not the actual CVC event. **METHODS:** We applied advanced healthcare data analytics with natural language processing (NLP) to extract meaningful information about patient care from text clinical information in the Veteran Affairs nationwide EHR database. The NLP was designed to help identify and characterize CVC episodes for patients with an inpatient encounter. Patients were characterized as having (a) a billing code for catheter insertion and (b) having had a chest x-ray during an inpatient encounter where the presence of a CVC was identified by NLP. **RESULTS:** 1.2M patients with an inpatient encounter were found in the VA between January 1, 2006-December 31, 2010. Of them, 54,676 patients were identified as having at least one inpatient CVC episode using billing codes. 119,768 additional patients were preliminarily identified via NLP, resulting in a total of 174,444 CVC patients. **CONCLUSIONS:** Fifteen percent of inpatients had a CVC placed and 69% of CVC patients were only identified via NLP. These rates are consistent with previously published literature. This work shows that NLP provides an effective way to leverage rich observational data. We will use this to study health outcomes in relation to the catheter placement and related interventions.

PMD57

NEW APPROACHES FOR GRAPHING PROBABILISTIC PATIENT-RELEVANT HEALTH OUTCOMES: THE CASE OF RENAL DENERVATION FOR RESISTANT HYPERTENSION

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OBJECTIVES: Probabilistic sensitivity analysis (PSA) repeatedly runs a simulation model with randomly selected inputs to characterize the plausible distributions of projected outcomes. In cost-effectiveness analysis, PSA results are conventionally displayed as incremental cost-effectiveness scatter plots or cost-effectiveness acceptability curves. We explored patient-relevant health outcomes other than QALYs and investigated approaches for displaying probabilistically generated values, using the case of catheter-based renal denervation (RDN) for resistant hypertension. **METHODS:** A Markov model with 54 input distributions simulated the impact of RDN on stroke, myocardial infarction (MI), coronary heart disease (CHD), heart failure (HF), end-stage renal disease (ESRD), cardiovascular (CV) and all-cause death based on the Symplicity HTN-2 RCT and the literature. We report

medians and 95% credible intervals (95% CI), defined as containing 95% of all simulation results, of 10-year relative risk reductions. One-sample t-tests and ANOVA were used to compare posterior distributions. Additional analyses evaluated alternative time horizons, with values ranging from one year to lifetime. **RESULTS:** Relative risk reductions over ten years (95% CI) were: stroke 31.4% (23.1; 36.0%), MI 30.0% (8.9; 38.1%), CHD 22.2% (9.0; 29.4%), HF 13.9% (11.0; 21.7%), ESRD 30.7% (28.8; 34.5%), CV death 30.3% (12.6; 35.7%), and all-cause death 14.4% (4.1; 20.1%). All clinical outcomes were significantly different from 0% and between each other ($p < 0.0001$). Distribution dotplots, cumulative hazard curves, and survival curves with 95% credibility intervals were developed as graphic representations of probabilistic results. **CONCLUSIONS:** While model-based projections suggest that catheter-based renal denervation leads to clinically and statistically significant event reductions across clinical outcomes, considerable differences exist between the distributions of individual reductions. Graphic, probabilistic representation of patient-relevant endpoints may facilitate a deeper understanding of uncertainty associated with the long-term clinical effectiveness of new therapies. In addition to informing clinicians and payers, the proposed conceptual approach could also contribute to patient education and shared decision making.

PMD58

COST-EFFECTIVENESS OF APPLYING PROLONGED MECHANICAL VENTILATION IN TAIWAN

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OBJECTIVES: The conventional incremental cost-effectiveness ratio (ICER) and cost-per-expected life in patients undergoing prolonged mechanical ventilation (PMV), stratified by different underlying diseases, were determined. **METHODS:** A nationwide sample of 50,481 patients who had received continual mechanical ventilation for more than 21 days was collected during 1997-2007. After stratifying the patients according to specific diagnoses, a latent class analysis (LCA) was performed to categorize PMV patients with multiple co-morbidities into several homogeneous groups. The survival functions were estimated for individual groups using the Kaplan-Meier method and extrapolated to 300 months through a semi-parametric method. The survival functions were adjusted with a utility value measured by EQ-5D from a convenient sample of 142 PMV patients to estimate the quality-adjusted life expectancies (QALE). The lifetime expenditures paid by National Health Insurance (NHI) were estimated by multiplying the average spending with the survival probability for different duration-to-dates and summed up for different groups. **RESULTS:** The results showed that PMV therapy costs over 58,000 USD (U.S.dollars) per QALY for almost all patients with poor cognition. For patients with partial cognition, PMV therapy costs less than 33,000 USD per QALY for those with cancer, liver cirrhosis, intracranial or spinal cord injuries, or multiple co-morbidities who are less than 65 years of age; it costs about 52,000-63,400 USD per QALY for those with end stage renal disease, degenerative neurological diseases, or multiple co-morbidities over age 85. All costs-per-expected life were below 38,000 USD except for those with a longer life expectancy or QALE. **CONCLUSIONS:** The conventional ICER for PMV varies greatly depending on the different underlying causes and co-morbidities. The maintenance treatment for PMV patients with poor cognition is the least cost-effective. The indicator of cost-per-expected life could be considered to improve fairness in resource allocation.

PMD59

ASSESSMENT OF ADMINISTRATIVE DATA FOR EVALUATING THE SHIFTING ACQUISITION OF CLOSTRIDIUM DIFFICILE INFECTION IN ENGLAND

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OBJECTIVES: Little is known about the acquisition of Clostridium difficile infection (CDI) and whether it represents hospital- or community-acquired infection. The objective of this study is to test the feasibility and value of using national hospital admissions data from Hospital Episode Statistics to examine trends in CDI in England. **METHODS:** Hospital Episode Statistics from the period 1997/98 to 2009/10 were used. Time trends were analysed using two different denominators of hospital activity: total admissions and total bed-days. We explored the impact of sociodemographic factors, comorbidity and healthcare pathways on the risk of CDI. **RESULTS:** CDI rates per admission and per bed-days increased from 1997/98 to 2006/07, then decreased significantly by >50% from 2008/9 and 2009/10. This pattern was similar for patients regardless of probable source of infection but the proportion of probable community-acquired CDI cases rose steadily from 7% in 1997/98 to 13% in 2009/10. CDI rates were higher among older patients (odds ratio: >65 years, 10.9), those with more comorbid conditions (odds ratio for Charlson index: >5, 5.6), and among patients admitted as an emergency compared with elective admissions, but no relationship was found with deprivation score. **CONCLUSIONS:** Our findings support not only the falling trend in CDI found in the national mandatory surveillance scheme from the Health Protection Agency, but a growing proportion of CDI presenting on admission with no evidence of prior hospital exposure in the previous 90 days. We suggest that these may be community-acquired CDI cases.

PMD60

DESIGN OF A BAYESIAN NETWORK AS A DECISION MODEL FOR THE DIAGNOSIS OF APPENDICITIS

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OBJECTIVES: Diagnosing Appendicitis is a difficult challenge for emergency departments. Appendicitis has been the subject of numerous investigations, but a diagnostic tool of quality and applicability in the clinical routine has not yet been identified. We constructed a clinical predictive model for Appendicitis using a Bayesian network, using a decision analysis approach. **METHODS:** We designed a methodology for the construction of decision models to support the process of clinical diagnosis, which was applied specifically to the diagnosis of Appendicitis. The methodology starts with a multiple correspondence analysis (MCA) for the selected variables with the highest power of discrimination, based on which an initial Bayesian network is proposed. This network was refined with the support of a group of medical experts in the diagnosis, to define the final structure of the Bayesian network. Finally, the model is validated through cross-validation method. For validation we used Sanabria, Bermudez, Dominguez and Serna's (2007) database, which consists of 349 patients with suspected Appendicitis. **RESULTS:** The implementation of the methodology produced results in a Bayesian network that included eleven variables associated to signs, symptoms and laboratory results. The results of the proposed model, with respect to medical assessment without specialized tools for diagnosis, showed significant improvements in accuracy, from 81% to 94%; in sensitivity, from 85% to 98%; and in specificity, from 76% to 90%. **CONCLUSIONS:** The Bayesian network constructed based on the MCA improved the accuracy of Appendicitis diagnosis in comparison to other models available in the literature, among which are the Alvarado score and the Fenyo score. Additionally, the constructed Bayesian network has characteristics that facilitate its applicability in the clinical routine.

PMD61

EVALUATING THE USABILITY OF AN EPRO DIARY FOR MEASURING COPD SYMPTOMS AT NIGHT AND EARLY MORNING

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OBJECTIVES: To evaluate the usability of an electronic patient-reported outcome (ePRO) diary in accordance with recommendations for usability testing in the ISPOR ePRO Task Force Report. **METHODS:** The Nighttime Symptoms of COPD Instrument (NiSCI) and Early Morning Symptoms of COPD Instrument (EMSCI) were programmed into a handheld device (HTC HD2®). The device and instructions [Quick Reference Guide (QRG)] were evaluated in two rounds of testing. Each round consisted of user acceptance testing (UAT) by researchers, followed by usability assessment by COPD patients. Patients were trained to use the device and completed the diary five to seven days at home, followed by a qualitative interview in the clinic about the device's usability. Time and duration of diary completion were recorded on the device each day. At the interview, participants also completed a Device Usability Questionnaire and answered questions regarding their background and technology proficiency. **RESULTS:** Mean age of the sample (N=15) was 60 years, (range 40–87); 60% were male. All participants were diagnosed with COPD and experienced symptoms at night or early morning, per inclusion criteria. Nine (60%) reported being "moderately technically proficient". Feedback from the first round (n=5) informed the refinement of screen layout, skip patterns, and QRG, before a second round of interviews. Results from the second round (n=10) confirmed 'pop-up' message wording, readability, screen clarity, and comprehension. Of 15 participants, 66.7% found the device "very easy" to learn and 73.3% rated overall use "very easy." Participants averaged 3.5 minutes for diary completion; completion time decreased over time. **CONCLUSIONS:** This usability study confirmed that COPD patients found the electronic, HTC HD2®-based NiSCI and EMSCI patient-friendly, easy to use, and suitable for daily assessment of COPD symptoms.

PMD62

A SIMULATED CONTROL GROUP COMPARATIVE APPROACH TO USING PHASE I TRIAL DATA TO ASSESS THE OUTCOMES OF A NOVEL TREATMENT FOR ACUTE KIDNEY FAILURE

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OBJECTIVES: To develop a simulated "control" group to compare Phase 1 trial data from acute kidney failure (AKF) patients receiving novel renal-replacement therapy (RRT) with a Selective Cytopheretic Device (SCD), and to compare clinical outcomes and economic impact of SCD treatment to hemodialysis. **METHODS:** Clinicians collected data on the first 35 patients treated with the SCD. To add a second interventional trial arm, the developer needed a simulated control group (control) for comparative purposes. Data from the literature and 2009 MEDPAR files were utilized to develop a control with clinical characteristics matching those of the trial population but undergoing hemodialysis. Critically, cohorts were matched on diagnosis, SOFA score, mechanical ventilation, sepsis, and RRT treatment. Secondary sources contained mortality data, survivor RRT dependency, and resource consumption units for the control - variables captured for trial patients. Unit resource costs for trial patients were based on MedPAR data and the literature. SCD costs were manufacturer-supplied. We computed relative resource cost impact for both cohorts from imputed units and unit costs. **RESULTS:** Our methods yielded sufficient information to compare clinical outcomes and budget impact of SCD treatment relative to hemodialysis. SCD-treated patients showed 60-day mortality rates of 31% versus control rates >50%. Savings from reduced ALOS in trial patients exceeded incremental costs of SCD treatment. We estimated future payer budget impact using USRDS (2010) treatment costs for survivors in both groups with continuing RRT needs progressing to ESRD care. Results showed cost avoidance of

~\$2.0M for 100 AKF patients. Confidence in the model was supported by sensitivities to ICU ALOS and survival rates, non-estimated variables for both cohorts. The model withstood key variable manipulation of 20%+ before conclusions changed directionally. **CONCLUSIONS:** A simulated control approach is a cost-effective means for small manufacturers to conduct early hypothesis testing and build a foundation for later-stage development.

SURGERY – Clinical Outcomes Studies

PSU1

ADVERSE EVENTS COMMONLY ASSOCIATED WITH OPIOID USE: IMPACT UPON LENGTH OF STAY FOLLOWING SURGICAL PROCEDURE

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OBJECTIVES: The objective of this study was to determine the impact of adverse events common to opiate use upon post-operative length of stay. **METHODS:** The study was based in Cardiff and the Vale of Glamorgan in 2004. All admissions involving a surgical procedure, other than those specifically relating to the gastrointestinal system, were extracted and those for patients with a secondary diagnosis of either constipation (ICD-10 K59), nausea and vomiting (R11), pruritus (L29), headache (R51), dizziness (R42) or fever of unknown origin (R50) were flagged. These cases were matched by age (5 year age banded) and sex to controls admitted with the same procedure (defined by three character OPCS-4 code). Length of stay for cases versus controls was compared using the Wilcoxon rank signed test. **RESULTS:** Of 116,309 hospital episodes, 58,025 included a surgical procedure. Of these 285 included one of the diagnoses listed above of which 234 (82.1%) could be matched with an age and sex control. Mean age of subjects was 53.7 (sd 23.5) and 96 (41%) were male. Overall length of stay was greater for cases (median = 11.0 days [IQR 6.0-20.25] versus controls (5.0 days [1.0-14.0] p<0.001. This was true for most subgroups: constipation 14.5 days [7-23.25] versus 6 days [2-19] p = 0.001; nausea and vomiting 14 days [6-22.25] versus 7 days [1-19.25] p<0.001; pruritus 5 days [3-12] versus 1 days [1-3] p=0.027; headache 13 days [6-39.5] versus 1.5 days [0-6.25] p=0.011 and fever 8 days [4.5-12.5] versus 1 days [0-8] p=0.011. There was no significant difference for dizziness 8 days [1.75-13.5] versus 2 days [0-10.5] p=0.229. **CONCLUSIONS:** This study demonstrates that adverse events commonly associated with opioid use have a significant impact on post-operative length of stay. Reducing these events could have benefits both in terms of the well-being of the individual patient and overall healthcare costs.

PSU2

RELATIONSHIP BETWEEN MEDICAL CO-MORBIDITIES AND HOSPITALIZATION FOLLOWING ELECTIVE TOTAL KNEE ARTHROPLASTY (TKA)

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OBJECTIVES: Demand for a primary TKA is increasing and projected to grow exponentially by 2030. Comorbidities have been identified as a contributor to increased postoperative length of the stay (LOS) of the patient in the hospital, a major contributor to the cost of TKA. The purpose of the study is to assess the effect of comorbidities (diabetes, hypertension, obesity [bmi >30 kg/m²], chronic back pain(CBP), insomnia, cancer, osteoporosis), on patient LOS after elective TKA. **METHODS:** Patients ≥40 years old with a primary unilateral TKA, excluding those with a 2nd TKA surgery within the year, were retrospectively extracted from a clinical orthopedic database between September 1, 2008 to November 30, 2010. LOS and comorbidities were obtained by chart abstraction from the electronic medical record. Unadjusted and adjusted odds ratios (OR) of having a LOS >3 days were calculated for each comorbidity. Using logistic regression analysis, ORs were adjusted for age, gender, pre-operative physical/mental health and preoperative level of physical activity. **RESULTS:** A total of 174 patients with an average age of 63.8 (SD 10.2, 41-85) years were included in the study; 63% (110) were female and 56% (98) were obese. 75% of the patient population was discharged in ≤ 3 days. Unadjusted analysis identified those with diabetes, hypertension, obesity, CBP, cancer and osteoporosis as being more likely to have a LOS >3 than those without these comorbidities. In adjusted ORs, the likelihood of having a LOS >3 days were 7.88 times (95% confidence interval[CI]=2.28-27.21) among patients with osteoporosis and 1.87 times (95% CI =1.20-9.96) among patients with a history of cancer versus those without these comorbidities. **CONCLUSIONS:** Few studies have focused on specific comorbidities that influence LOS. We found that preoperative diagnosis of osteoporosis or cancer increased the LOS following elective TKA. Previous determinants, age, gender, pre-operative level of physical activity, preoperative and physical health were not influential.

PSU3

ANALYSIS OF BARIATRIC OUTCOMES LONGITUDINAL DATABASE (BOLD) TO PREDICT PERCENT BMI LOSS AFTER BARIATRIC SURGERY

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OBJECTIVES: The objective of this study was to utilize the BOLD database to analyze percent BMI loss after bariatric surgery. Of particular interest was the determination of predictors to help explain the large variation in bariatric surgery success. **METHODS:** The dataset extracted for analysis consisted of patients age 21 or older having their first bariatric surgery (laparoscopic adjustable gastric band (LAGB), Roux-en-y gastric bypass (RYGB), or vertical sleeve gastrectomy (VSG)) between January 1, 2007 and February 26, 2010, with pre-surgery BMI of at least 30, a baseline visit and at least one postoperative visit. Subpopulations with postopera-