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ABSTRACTS

ISPOR 16th ANNUAL INTERNATIONAL MEETING RESEARCH ABSTRACTS

PODIUM SESSION I: CANCER OUTCOMES RESEARCH

CN1

MONOTHERAPY OF ANDROGEN DEPRIVATION THERAPY VERSUS RADICAL PROSTATECTOMY AMONG VETERANS WITH LOCALIZED PROSTATE CANCER: A COMPARATIVE EFFECTIVENESS ANALYSIS OF RETROSPECTIVE COHORTS

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OBJECTIVES: There is no consensus regarding the optimal treatment for localized prostate cancer. This study aimed to examine the comparative effectiveness of monotherapy of either primary androgen deprivation therapy (PADT) or radical prostatectomy (RP) in terms of overall survival rate. **METHODS:** Male patients with localized prostate cancer were identified in the Veterans Affairs Veterans Integrated Service Network 16 data warehouse (January, 2003-June, 2006), with one year baseline and at least 3-year follow-up (till 06/2009). Eligible patients (18-75 years old) had no other cancer history and used PADT or monotherapy of RP within 6 months after the first diagnosis of prostate cancer. The overall survival from initiation of index treatment was analyzed using Kaplan-Meier method and Cox proportional hazard regression, adjusted for age, race, marital status, insurance type, cancer stage, Charlson comorbidity index, alcohol and tobacco use. **RESULTS:** The age was 66.2(6.07) [Mean(SD)] years in 211 PADT patients, 59.9(6.15) in 215 RP patients. During the follow-up of 4.2(0.95) years, the cumulative incidence of death was 29 (13.74%) among PADT patients and 6 (2.79%) among RP patients ($p<0.001$). The overall 3-year survival rate was 89.57% in PADT and 98.60% in RP ($p<0.001$). Patients who received PADT had almost 4 times as high mortality risk as those using RP (HR =3.820, 95% CI=1.483 to 9.845, $p=0.006$). **CONCLUSIONS:** Overall survival rate following RP among localized prostate cancer patients was significantly higher than that after PADT, controlling for other covariates. More research among a larger population with longer follow-up are warranted to confirm this finding.

CN2

ESTIMATED EFFECTS OF THE NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM ON CERVICAL CANCER MORTALITY

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OBJECTIVES: The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is the largest organized cancer screening program for low-income, un-insured and under-insured women in the United States. The program's effectiveness in increasing the life expectancy of participating women has never been measured. We estimated the benefits of NBCCEDP-funded cervical cancer screening (Program) in terms of life-years (LYs) saved compared to No Program and No Screening scenarios. **METHODS:** Based on an existing model developed by Myers et al., we constructed a cervical cancer simulation model by modifying the age and screening schedule of the cohort to reflect screening frequency for NBCCEDP participants from 1991-2007. We estimated screening habits in the absence of the program based on data from the 1990-2005 National Health Interview Survey. We performed Markov cohort analysis for each age in the 18-64 range and calculated an overall weighted average using the age distribution at first NBCCEDP Pap test for screening. Weighted averages were produced for three scenarios – women receiving testing from the NBCCEDP (the Program), women receiving testing from alternative sources in the absence of the program (No Program), and women receiving no testing at all (No Screening). We compared LY estimates for 69,100 women detected with human papillomavirus infection, low-and-high-grade squamous intraepithelial lesions or cervical cancer under the program to the counterfactual of having their disease undetected under No Program and No Screening scenarios. **RESULTS:** From 1991-2007, we estimate that the Program added 10,369 LYs to the total lifespan of tested women when compared to No Program, and 101,509 LYs when compared to No Screening. Furthermore, the Program prevented an estimated 325 cervical cancer deaths relative to No Program, and 3,825 relative to No Screening. **CONCLUSIONS:** These estimates suggest that NBCCEDP cervical cancer screening may have reduced mortality among medically underserved women in the United States.

CN3

THE VALUE OF RESEARCH FOR ERCC1 TESTING IN STAGE I NON-SMALL CELL LUNG CANCER

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OBJECTIVES: To assess the value of additional research for ERCC1 expression testing to guide adjuvant chemotherapy decisions in fully resected Stage I non-small cell lung cancer (NSCLC). **METHODS:** We refined a previously-developed decision-analytic model to estimate the expected value of perfect information (EVPI) and expected value of sample information (EVSI) for two treatment strategies: 1) ERCC1 testing to inform adjuvant chemotherapy decisions, with ERCC1+ patients receiving no chemotherapy and ERCC1- patients receiving chemotherapy; 2) standard care, with all patients receiving no chemotherapy. Model parameters and uncertainty ranges were derived from a retrospective analysis of the International Adjuvant Lung Cancer Trial, published literature, and government sources. The affected population was derived from SEER incidence estimates, and examined over a discounted 10-year time horizon. **RESULTS:** At a willingness-to-pay of $150,000 per quality-adjusted life year, ERCC1 and standard care strategies resulted in average net-benefits of $630,500 and $625,200, respectively. The ERCC1 and standard care strategies produced greater net-benefit in 64% and 36% of 10,000 simulations, respectively. The average net-benefit difference was $14,000 in simulations where the standard care strategy was optimal. With an affected population of 233,825; EVPI was $1.2 billion. Preliminary estimates suggest an EVSI of approximately $20 million at plausible sample sizes. **CONCLUSIONS:** Considerable value could be realized through additional research to reduce uncertainty about the comparative health outcomes of ERCC1 and standard care strategies. The EVPI of $1.2 billion was driven by the large 10-year affected population, probability that ERCC1 testing is not the optimal strategy, and consequences of selecting the non-optimal strategy. Forthcoming results will enable estimation of the expected net-benefit of sampling, which compares the EVSI of various study designs and sample sizes to the cost of conducting such studies. These findings can assist stakeholders in prioritizing funding for ERCC1 research relative to alternative research investments.

CN4

PALONOSETRON VERSUS OTHER 5-HYDROXYTRYPTAMINE$_3$ RECEPTOR ANTAGONISTS FOR PREVENTION OF CHEMOTHERAPY INDUCED NAUSEA AND VOMITING AMONG MEDICARE PATIENTS WITH CANCER

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OBJECTIVES: To assess the rate of uncontrolled chemotherapy induced nausea and vomiting (CINV) associated with palonosetron initiation versus other 5-hydroxy tryptamine$_3$-receptor antagonists (5-HT$_3$-RAs) among Medicare patients with cancer on chemotherapy (CT) treatment in a hospital outpatient setting. **METHODS:** Medicare patients with a cancer diagnosis initiating CT and anti-emetic prophylaxis with palonosetron (Group 1) and other 5-HT$_3$-RAs (Group 2) for the first time (index date) between April 1, 2007 – March 31, 2009 were identified from the Premier Perspective database. Inclusion criteria were no evidence of nausea and vomiting, CT, and anti-emetic medication in the 6-month pre-index date period and 36-consecutive months of data submission. A negative binomial distribution generalized linear multivariate regression model estimating the rate of CINV events on CT emetogenicity and cycle matched groups in the follow-up period (first of eight CT cycles or six months post-index date) was developed after adjusting for several demographic and clinical variables. **RESULTS:** Of 4799 identified patients, 962 initiated palonosetron (Group 1; 20.1%). Group 1 patients were significantly younger [70.4 (SD: 9.3) versus 71.6 (9.0) years; $p<0.0001$], comprised more females [52.9% versus 48.6%; $p<0.0001$], less African Americans [8.7% vs. 11.3%] and more Hispanic patients [6.3% versus 2.5%]; all $p<0.0001$, more highly and moderately emetogenic CT [33.6% versus 20.7% and; 47.3% versus 40.3%, respectively; $p<0.0001$], and more lung and breast [30.9% vs. 24.9% and 12.3% vs. 9.6%, respectively; $p<0.0001$]. In the follow-up period, the regression model predicted a 11.8% decrease in the CINV events per CT cycle for Group 1 patients versus Group 2 patients; $p<0.05$. **CONCLUSIONS:** In this retrospective hospital outpatient study, after matching for CT emetogenicity and cycle and adjusting for other potential confounders, Medicare patients with cancer initiated on palonosetron were more likely to experience a significantly lower rate of CINV events per CT cycle versus those initiating other 5-HT3-RAs.

PODIUM SESSION I: COMPARATIVE EFFECTIVENESS RESEARCH

CO1

COMPARATIVE EFFECTIVENESS ANALYSIS OF TNF BLOCKERS IN RHEUMATOID ARTHRITIS (RA) PATIENTS IN A REAL-WORLD SETTING

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OBJECTIVES: To evaluate effects of dose escalation on clinical outcomes of RA patients initiating TNF-blocker treatments in community practice. **METHODS:** TNF-blocker-naïve adult RA patients initiating etanercept, adalimumab, or infliximab (index) between July 1, 2005 and May 31, 2008 with ≥12 months' enrollment post-index were identified from the Ingenix database. Patients receiving <9 months TNF-blocker treatment or diagnosed with psoriasis, psoriatic arthritis, ankylosing spondylitis, or Crohn's disease were excluded. Rates of dose escalation using 3 different methods were calculated using claims data. Participating physicians provided de-identified charts. Each chart was reviewed by 4–6 clinical rheumatologists to evaluate and agree on overall clinical change from baseline to the visit closest to 1 year post-index (12±3 months). Multivariate models compared change in clinical outcomes and dose escalation rates, controlling for differences among etanercept, adalimumab, and infliximab patients at index. **RESULTS:** Overall, 715 etanercept, 501 adalimumab, and 393 infliximab patients were identified from claims; 141 etanercept, 115 adalimumab, and 104 infliximab patients had evaluable charts. Patient characteristics were similar among the claims and charts. Regardless of dose escalation method used, significantly fewer etanercept-treated patients had dose escalations (1.8%, 5.2%, 6.7%) than patients treated with adalimumab (9.8%, 8.6%, 10.4% respectively) or infliximab (50%, 31%, 34% respectively) ($p<0.05$ for all comparisons). After treatment initiation, 86% of etanercept-treated patients had "much better" or "better" clinical outcomes at 12±3 months, versus 82% of adalimumab patients and 78% of infliximab patients. Multivariate analyses showed significantly fewer dose escalations in etanercept patients ($p<0.05$), with no significant difference in clinical change score between etanercept patients and adalimumab ($p=0.22$) or infliximab ($p=0.07$) patients. **CONCLUSIONS:** This study showed dose escalation in fewer etanercept than adalimumab or infliximab patients, but similar improvements in clinical outcomes for all 3 treatments, indicating that higher dose escalation rates may not be associated with better clinical outcomes.

CO2

REAL-WORLD COST-EFFECTIVENESS ANALYSIS OF CANCER DRUGS: COMPARATIVE EFFECTIVENESS RESEARCH USING RETROSPECTIVE CANADIAN REGISTRY DATA BEFORE AND AFTER DRUG APPROVAL

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OBJECTIVES: Using linked administrative databases from Ontario, our study examined the "real world" cost, effectiveness and cost-effectiveness of Rituximab in diffuse-large-B-cell lymphoma. **METHODS:** Patients were defined as those who had a diagnosis of diffuse-large-B-cell lymphoma according to ICD-O histology classification between January 1997 and December 2007 and received either CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or R-CHOP (CHOP plus Rituximab) as first line treatment. We used a historical cohort design to compare the overall survival, toxicity profiles, direct costs, and cost-effectiveness of CHOP before Rituximab was approved (pre-era CHOP) with R-CHOP after Rituximab approval (post-era RCHOP). R-CHOP and CHOP patients were hard-matched on age, and then subsequently matched on propensity scores by use of a 1:1 matching algorithm. Propensity scores were calculated from demographic and clinical history information. We estimated resource use and direct medical costs using the linked administrative data. To analyze censored cost data, we employed and compared different methods, including the simple non-adjusted average, the Kaplan-Meier sample average estimator, inverse probability weighting estimator, Pfeifer and Bang's estimator (2005) and Basu's two-part estimator (2010). **RESULTS:** A total of 1131 matched pairs of patients were evaluated. 3-year overall survival was significantly improved in the post-era RCHOP group compared to pre-era CHOP (69% [95%CI 66-71] vs 59% [95%CI 56-62]; Klein test $p<0.001$). Groups did not differ in the frequency of adverse events, but 3-year direct cost was significantly higher in the post-era RCHOP group. The incremental cost-effectiveness ratio varied depending on the method employed. **CONCLUSIONS:** This study illustrated how different methods can be applied to observational data to estimate costs and cost-effectiveness. The results from this study can be compared to those from clinical trials and economic models. This will help drug decision-makers calibrate healthcare policies while helping researchers evaluate assumptions made and methods used in economic models.

CO3

PROJECT LIBRA: A NEW ANALYTIC TOOL FOR COMPARATIVE EFFECTIVENESS ANALYSES OF MULTIPAYER CLAIMS DATABASES

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OBJECTIVES: The project aimed to develop a secure, interactive tool to enable researchers to perform comparative effectiveness studies and other types of research on a multipayer claims database with reduced need for complicated programming. **METHODS:** A common data model, through which multiple data sources are standardized and linked via common data structures and vocabularies, was established. It was used to format five administrative databases: the Medicare Chronic Condition Warehouse, the Thomson Reuters MarketScan® Medicaid Multistate, Medicare Supplemental, and Commercial databases, and the Healthcare Cost and Utilization Project National Inpatient Sample database. A web-based User-Interface was developed that captures the logic typically required by CER methods and capitalizes on the longitudinality of administrative data. Tools were developed to allow users to search taxonomies to select particular drugs, diagnoses, or procedures by typing in substrings of the numeric codes or textual descriptions. The tool allows researchers to apply enrollment and demographic constraints and create variables. CER studies were conducted including a comparison of atrial fibrillation treatment with rate or rhythm control medications. **RESULTS:** The tool allowed users to quickly define a study sample. Flow diagrams graphically illustrated the attrition of the sample size and visualization of treatment and outcomes. Embedded SAS procedures enabled reporting and analysis of comparison populations. The analyses revealed a higher rate of coronary artery disease and heart failure prior to drug initiation among the amiodorone versus the calcium channel blocker population and a higher rate of post-drug initiation acquired hypothyroidism, and pulmonary disease among the amiodorone versus the calcium channel blocker population. **CONCLUSIONS:** New data designs and software analytic tools may allow claims databases to be more efficiently leveraged. The tool developed for this project has the following advantages: 1) allows for a substantial portion of the research exploration, hypothesis generation; and statistical analysis to be performed in real-time using a web-based interface; 2) improves the speed of research; and 3) allows access to a multipayer database.

CO4

POTENTIAL COST SAVINGS FROM COMPARATIVE EFFECTIVENESS RESEARCH: LESSONS FROM COURAGE STUDY

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OBJECTIVES: During the debate over health reform, comparative effectiveness research was touted as a relatively painless approach to reducing costs. A comparative effectiveness study of two treatments will find either that the costlier treatment is more effective or is not more effective than a less expensive alternative. Studies that report negative results have the potential to reduce costs, but only if findings affect clinical practice. One concern is that the same factors that promote rapid adoption of new therapies in the U.S. may retard the abandonment of existing technologies found to be ineffective. **METHODS:** The COURAGE trial found that optimal medical therapy is as effective as percutaneous coronary intervention (PCI) for patients with stable angina. PCI refers to stenting and angioplasty. The trial was published and widely publicized in early 2007. We evaluate trends in PCI volume pre- and post-COURAGE by indication using 1) 100% samples of outpatient and inpatient discharge data for California, Florida, New Jersey, and Maryland, 2) a 100% sample of discharge data for Veteran's Administration hospitals and 3) data from a proprietary cardiac catheterization laboratory registry at 15 hospitals. **RESULTS:** Between the fourth quarter of 2006 and the fourth quarter of 2007, PCI volume in California, Florida, New Jersey, and Maryland among patients without serious coronary disease declined from approximately 17,000 to 13,000 procedures (an 18% decline). There was only a 5% decline among patients with unstable angina, who were not included in COURAGE. We found similar patterns in the other datasets. **CONCLUSIONS:** Publication of the COURAGE trial had an impact on PCI volume. Many patients with stable angina continue to receive PCI. The results are consistent with the view that as long as the health system is configured around procedural-based medicine, the impact of trials which find that medical therapy is as effective as invasive procedures will be modest.

PODIUM SESSION I: EFFECTS OF DRUG MANAGEMENT PROGRAMS ON PATIENTS

DM1

IMPACT OF A PHARMACY REFILL MANAGEMENT SYSTEM ON OUTCOMES IN END STAGE RENAL DISEASE (ESRD) PATIENTS

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OBJECTIVES: In dialysis patients, bone and mineral (phosphorous, calcium) and regulatory hormones (parathyroid hormone (PTH)) become dysregulated, increasing risk of fractures, cardiac events and death. First line treatment is a low phosphorus diet and prescription phosphate binders. We examined the impact of a refill management system (RMS) - which helps patients proactively manage their refills using predictive algorithms and refill reminders for prescriptions - on serum phosphorus, calcium and PTH in patients prescribed phosphate binder monotherapy. **METHODS:** Data from a large dialysis organization were used to identify dialysis patients prescribed monotherapy phosphate binder between 1/1/2008-9/30/2010 with at least 6 months of follow-up. Patients enrolled in the RMS were 1:1 propensity score matched to patients not enrolled utilizing age, race, gender, dialysis vintage, body mass index, baseline laboratory values (albumin, calcium, Kt/V, phosphorus, PTH, normalized protein catabolic rate), Charlson comorbidity score, and other comorbid conditions commonly associated with ESRD. The matched cohorts were compared on the percent meeting guideline ranges for phosphorus (3.5-5.5 mg/dL), corrected calcium (8.4-9.5 mg/dL) and PTH (150-600 pg/mL). Values were assessed over the 6-months following the first phosphate binder prescription. Differences between groups were tested using chi-square for proportions. **RESULTS:** 3,247 RMS patients met the inclusion criteria and were matched 1:1 to a cohort of non-RMS patients. There were no significant differences between the groups on any baseline variables. Patients enrolled in the RMS were more likely to be in target range over the 6 month period on all 3 measures: phosphorus (58.0% vs 55.1%); corrected calcium (74.3% vs. 69.1%) and PTH (80.5% vs. 77.2%), compared to propensity matched controls. All differences were significant at the $p<0.05$ level. **CONCLUSIONS:** Results indicate that participation in a pharmacy RMS is associated better laboratory outcomes for dialysis patients.