Limitations of these studies include failure to control for important confounders, small sample size and short study period, which may have impact on the risk of cancer. **CONCLUSIONS:** Given the fact that cancers are rare and often take a long time to develop, further studies require very large population with long follow up time to have sufficient power to detect a possible effect. This, combined with small proportion of insulin users who were exposed to glargine, may be a reason to studies that found no association, which leaves a question of a class effect. Future studies to explore the effect of all other insulins and the possible mechanism may help to untangle this question.

PCN5

ASSESSMENT OF NEUROPATHY IN CLAIMS DATA AND THE ASSOCIATION WITH DOCETAXEL (DC) AND PACLITAXEL (PC) IN ADJUVANT BREAST CANCER (BC)

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OBJECTIVES: Neuropathy, a common side effect of taxanes, is often dose-limiting and may result in changes in treatment. This study examined the occurrence of neuropathy in claims data from commercially insured US patients with BC treated with adjuvant DC or PC. **METHODS:** This retrospective database analysis used eligibility, medical and pharmacy claims data from a large US health care organization, including subjects with a claim for BC and a claim for DC or PC-containing chemotherapy from 1/1/98–12/31/05. Subjects were stratified by dosing interval (weekly (qw) or Q 21 days (q3w)). Neuropathy was defined using ICD-9-CM codes 356.4, 356.8, 356.9, 357.2, 357.4, 357.5, 357.6, 357.7, 357.8x, 357.9, 377.34, 354.4, 354.5, 354.8, 354.9, 355.7x, 355.8 and 355.9. Neuropathy grade could not be assessed by claims data. Subjects were followed until the earliest of date of death or last enrollment or 12/31/06. Chi-square was used to compare descriptive variables. Logistic regression (LR) was used to examine the independent association of index medication and neuropathy. Covariates included age, geographic region, baseline co-morbidity score and use of medications for neuropathy. **RESULTS:** A total of 3619 subjects were identified for PC (n = 329, qw; 1685, q3w) or DC (n = 204, qw; 1045, q3w). A significantly lower frequency of neuropathy was seen in the follow-up period for DC-based treatments compared to PC (7.0% vs 10.6%, p < 0.001). Differences were also noted when stratifying by dosing interval (6.7% vs 10.0%; p = 0.003 in q3w, 9.3% vs 13.7%; p = 0.061 in qw). After adjusting for covariates, the odds of neuropathy remained significantly lower with DC-based treatment (OR = 0.70, CI = 0.559, 0.920; p = 0.010). **CONCLUSIONS:** Less neuropathy was noted with DC-based treatment compared to PC. This difference persisted with stratification by dosing interval. The lower occurrence of neuropathy with DC may favor maintenance of dose intensity.

PCN6

EVALUATION OF THE RELIABILITY OF ELECTRONIC MEDICAL RECORD DATA IN IDENTIFYING COMORBID CONDITIONS AMONG PATIENTS WITH ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC)

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OBJECTIVES: Traditional methods for identifying comorbidities in retrospective observational research have relied primarily on claims data. The purpose of this study was to validate a 2-phased strategy to search EMR data to identify comorbidities among cancer patients. **METHODS:** Advanced stage NSCLC patients (N = 2513) who received chemotherapy from July 1, 2006–June 30, 2008 were identified using iKnowMed, US Oncology's proprietary oncology-specific EMR system. EMR data were searched for documentation of the following comorbidities: moderate/severe renal disease, congestive heart failure (CHF), dementia, chronic obstructive pulmonary disease (COPD), cerebrovascular disease, paralysis, diabetes, peripheral vascular disease (PVD), myocardial infarction (MI), liver disease, and AIDS. The search was conducted in 2 phases. Initially, a series of programmatic queries were conducted to search standardized information on concomitant illnesses, patient history, review of systems, and diagnoses other than cancer. In a second phase, keyword searches of text-based fields (i.e., physician dictation notes, problem lists, etc.) were conducted. To evaluate the validity of the comorbidity information derived from the EMR, we randomly sampled 450 patients for whom we found no documentation of comorbidities using our 2-phased approach. We then exhaustively scanned available claims data and conducted comprehensive chart reviews to confirm that these patients did not have any of the comorbidities of interest. Negative predictive values (true negatives / (true negatives + false negatives) were calculated. **RESULTS:** Using our 2-phased search of the EMR, we found an overall prevalence of comorbidities of 22%. The most commonly identified conditions were COPD, diabetes, PVD, and CHF. Among the random sample of 450 patients for whom no comorbidities were identified, we identified 36 who had evidence of comorbidities after scanning claims data and conducting chart reviews (negative predictive value = 0.92). **CONCLUSIONS:** Results of this study suggest that efficient queries of EMR data may provide reliable data on comorbid conditions among cancer patients.

PCN7

A COMPARISON OF INTRAVENOUS AND ORAL FORMULATIONS OF FLUDARABINE IN THE TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA

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OBJECTIVES: Fludarabine (F) has been proven to be highly effective in the treatment of chronic lymphocytic leukemia (CLL). Both oral and IV F are used internationally. Recently, the oral formulation of fludarabine was approved in the US for treating CLL, which may offer advantages for providers, payers and patients. This study is a systematic review of clinical trial and retrospective data for oral and IV fludarabine, focusing on differences in efficacy, complications, resource utilization, cost and patient preference. **METHODS:** PubMed and manual bibliographic searches were conducted to identify relevant publications for oral and IV F. Studies were included if they were: 1) published after January 1, 2000, 2) derived from human subjects, 3) written or translated in English 4) focused on CLL, and 5) evaluated efficacy, resource utilization, complications, costs or patient preference. **RESULTS:** There were 17 articles that met inclusion criteria. Results indicated that the pharmacokinetic profile of oral and IV F were similar, with 25 mg/m² of IV being equivalent to 40 mg/m² of oral. Oral F has similar efficacy and safety to IV F, and eliminates infusion related adverse events and administration costs. Studies indicated that providing oral F was more convenient for patients and nurses due to the absence of IV administration. No cost or pharmacoeconomic data were found. **CONCLUSIONS:** Oral and IV F were found to have similar clinical efficacy and safety. The oral formulation may potentially lead to substantial economic benefits when factoring in possible reductions in infusion related administration and adverse events. Future studies need to compare real-world clinical outcomes and economic impact of oral vs. IV F, taking into account decision-making in clinical practice of both health care providers and patients.

PCN8

IMPACT OF 5-HT3-RECEPTOR ANTAGONIST STEP THERAPY ON CHEMOTHERAPY INDUCED NAUSEA AND VOMITING ASSOCIATED HOSPITAL AND EMERGENCY ROOM EVENTS

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OBJECTIVES: To explore the impact of step therapy policies requiring the use of a 1st-generation 5-hydroxytryptamine- receptor antagonist ($5\text{-HT}_3\text{-RA}$) treatment before palonosetron (a 2nd generation $5\text{-HT}_3\text{-RA}$) on the incremental risk of chemotherapy induced nausea and vomiting (CINV) associated with a hospital or emergency room (ER) event. **METHODS:** Claims data (PharMetrics) were used to identify continuously enrolled adult patients diagnosed with breast cancer (BC) and initiated on cyclophosphamide-based chemotherapy (CT) within 4 months post-diagnosis or with lung cancer (LC) and initiated on carboplatin-based CT. Patients were stratified into those initiated and maintained on palonosetron throughout CT (Group 1) versus those treated on day 1/cycle 1 with any other $5\text{-HT}_3\text{-RA}$ regimen (Group 2). Risks and frequency for CINV-associated hospital or ER events identified through ICD-9-CM codes for nausea, vomiting, and/or dehydration during a 6-month follow-up period were estimated using logistic and Poisson regression models, controlling for age, gender (LC only), comorbidity, and CT days. **RESULTS:** Of 3606 BC and 4497 LC identified patients, 1864 BC (52%) and 1806 LC (40%) initiated palonosetron. Groups 1 and 2 had comparable comorbidity and CT treatment days. Compared to group 2 patients, group 1 patients had a significantly lower probability of CINV-associated hospital or ER events (3.5% vs. 5.5% in BC and 9.5% vs. 12.8% in LC), had 47.4% (BC) and 29.1% (LC) fewer hospital or ER days with CINV, and fewer $5\text{-HT}_3\text{-RA}$ claims (mean ± SD 6.2 ± 3.3 vs. 7.9 ± 4.1 in BC and 7.7 ± 4.9 vs. 10.3 ± 6.4 in LC), all at p < 0.05. Risk for CINV was 38% (BC) and 29% (LC) lower for group 1 patients (Odds Ratio = 0.62 in BC and 0.71 in LC, p < 0.05). **CONCLUSIONS:** LC or BC patients initiated and maintained on palonosetron throughout CT were at significantly lower risk for costly CINV versus those on any other $5\text{-HT}_3\text{-RA}$ on day 1/cycle 1 of CT treatment.

PCN9

USING PROPENSITY SCORES TO REDUCE SELECTION BIAS IN AN OBSERVATIONAL STUDY COMPARING RASBURICASE TO ALLOPURINOL IN THE US

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BACKGROUND Randomized clinical trials remain the gold standard in evaluating different drug therapies on outcomes but are resource intensive. Retrospective studies using observational data are inexpensive but prone to selection bias due to non-random differences between the intervention and comparator groups. The Propensity Score (PS) method is a novel, multivariate adjustment procedure that reduces confounding and selection bias. **METHODS:** This case-control study used the *Health Facts®* database (Cerner Corporation, Kansas City, MO), which integrates patient information from hospitals throughout the United States. Cancer patients receiving rasburicase or allopurinol were eligible for study inclusion. Both drugs reduce uric acid (UA) elevation otherwise resulting from tumor lysis syndrome. The PS is the

probability of receiving rasburicase and is calculated from a non-parse logistic regression model that is adjusted for age, demographics, lab tests, ICU admission, Charlson Comorbidity Index, hospital characteristics, and other factors. Each rasburicase patient's PS is matched via a 5:1 digit Greedy algorithm to that of an allopurinol patient to reduce confounding. Alternatively, the PS is added as another predictor in a non-parse Generalized Linear Model when estimating the effect of rasburicase on outcomes. **RESULTS:** Of 8,257 patients, 71 rasburicase patients met our inclusion criteria and were matched to 71 allopurinol patients. Before matching, the median [25th, 75th percentile] total costs of rasburicase patients vs. allopurinol patients were $30,681 [$17,259, $58,241] vs. $18,106 [$8,937, $39,084]. After initial matching, median costs were lower with rasburicase: only $30,681, vs. $58,438 ($P = 0.007$), while pre-Rx minus post-Rx mean UA differences were significantly greater with rasburicase vs allopurinol (9.3 vs. 0.9 mg/dL, $P < 0.001$). **CONCLUSIONS:** Multivariate PS adjustment reduces selection bias and confounding when quantifying treatment effects of drug therapies. A preliminary PS analysis demonstrated that rasburicase was associated with greater UA reduction than allopurinol, as well as lower medical care costs.

PCN10

ESTIMATION OF G-CSF EFFECTIVENESS IN REDUCING NEUTROPENIA HOSPITALIZATION AMONG NON-HODGKIN'S LYMPHOMA (NHL) PATIENTS TREATED WITH ANTHRACYCLINE-BASED CHEMOTHERAPY
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OBJECTIVES: Examine the effectiveness of using prophylactic G-CSF among NHL patients treated with anthracycline-based chemotherapy in practice. **METHODS:** Using the national Surveillance, Epidemiology and End Results (SEER)-Medicare linked database, we studied patients 66 years or older diagnosed as NHL and on anthracycline in one of the 13 SEER registry areas from 1994–2002. Prophylactic G-CSF use was designated if a patient had a G-CSF claim within the first 5 days of the first chemotherapy cycle. Neutropenia hospitalization (NH) was identified within 6 months of diagnosis. Multiple regression estimates were used to examine whether treated patients actually benefited. Instrumental variable estimates using local area prophylactic G-CSF treatment rates as instruments were used to estimate whether increases in the G-CSF utilization rate could lead to further reductions in the rate of neutropenic hospitalization. **RESULTS:** Only 9.83% of study patients had early G-CSF. After adjustment for patient demographic and clinical risk factors, multiple regressions indicated prophylactic G-CSF significantly reduced NH events for the patients who received G-CSF (OR = 0.54, 95% CI = 0.34–0.87). Chow F-statistics showed our instrumental variable described a statistically significant portion in the variation in G-CSF use (F = 14.65, P = 0.0001). Our instrumental variable estimates were not statistically significant from zero. **CONCLUSIONS:** Among elderly NHL patients on anthracycline-based chemotherapy, our multiple regression estimates suggest that prophylactic G-CSF treated patients reduced their neutropenia risk. However, our instrumental variable results suggest that expanding prophylactic G-CSF use rates will not significantly reduce NH rates. These results suggest that providers optimally sorted the use of G-CSF patients to those patients that are most apt to gain.

PCN11

ASSESSING THE TREATMENT EFFECT OF RASBURICASE ALONE VERSUS RASBURICASE AND ALLOPURINOL COMBINATION THERAPY USING PROPENSITY SCORES
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BACKGROUND: Retrospective observational studies are often the only practical way to assess drug effects on uncommon diagnoses. However, because treatment assignment is not randomized, selection bias and confounding can distort the effect estimates. A new multivariate statistical method based on the Propensity Score (PS) of receiving treatment minimizes this bias. **METHODS:** This case-control study used the *Health Facts®* database (Cerner Corporation; Kansas City, MO), which integrates patient information from hospitals throughout the United States. Cancer patients receiving rasburicase or a combination of rasburicase and allopurinol were eligible for study inclusion. Both therapies reduce uric acid (UA) elevation otherwise resulting from tumor lysis syndrome. The PS is the probability of receiving rasburicase and is calculated from a non-parse logistic regression model that adjusts for age, demographics, lab tests, ICU admission, Charlson Comorbidity Index, hospital characteristics, and other factors. Each rasburicase patient's PS was matched via a 5:1 digit Greedy algorithm to that of a Combination patient. Alternatively, the PS was added as another predictor in a non-parse Generalized Linear Model when estimating the effect of rasburicase on outcomes. **RESULTS:** Of 71 rasburicase and 123 combination patients, 47 matched pairs were created. Differences in confounders by group were non-significant after matching. Before matching, the median [25th, 75th percentile] total costs of rasburicase patients vs. combination patients were $30,681 [$17,259, $58,241] vs. $54,862 [$25,907, $108,454]. After initial matching, rasburicase patients had lower median costs ($32,831 vs. $73,226; $P = 0.02$) and greater pre-Rx (baseline) minus post-Rx mean differences in UA levels (9.0 vs. 2.5 mg/dL; $P = 0.004$). **CONCLUSIONS:** Multivariate PS adjustment reduces confounding when quantifying treatment effects of drug therapies. A preliminary PS analysis demonstrated that rasburicase

monotherapy was associated with greater UA reduction than rasburicase-allopurinol combination, when either is administered in the context of TLS management in a "real-world" clinical setting.

PCN12

HORIZON SCANNING TO SUPPORT PRIORITY-SETTING FOR PROSPECTIVE COMPARATIVE EFFECTIVENESS RESEARCH (CER) IN CANCER GENOMICS
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OBJECTIVES: The Center for Comparative Effectiveness Research in Cancer Genomics (CANCERGEN) is a multi-disciplinary, national consortium established with the aim of generating high-quality evidence on the clinical utility and economic value of Genomics and Personalized Medicine (GPM) applications. This type of effort requires horizon scaning to identify promising candidates for evaluation in a randomized controlled trial (RCT). **METHODS:** A search of the peer-reviewed literature was performed using MEDLINE. Keywords included terms likely to be included in studies reporting the results of genomic-based prognostication and prediction for cancer. References were restricted to the last five years to identify technologies sufficiently developed to be appropriate for study in a RCT. The search was restricted to the five cancers with the highest prevalence and to key clinical journals (Abridged Index Medicus), as the unrestricted literature would identify targets too early in the development cycle for a RCT. The peer-reviewed literature was supplemented by searching the "grey" literature including major conferences in cancer for the last two years, allowing for inclusion of technologies which have not entered the peer-reviewed literature. The results were further analyzed for relevance using criteria such as: the title/abstract containing reference to a new/existing genetic test, biomarkers or gene targets relevant to cancer prognostication and/or effectiveness of existing/potential adjuvant therapy. **RESULTS:** In the peer-reviewed literature, our search strategy indicated 199 references matching our keyword search and restrictions. After application of criteria above, the list was reduced to 71 candidates. As an example of the "grey" literature search, 42 additional results were obtained from a search of the San Antonio Breast Cancer Conference (2008). **CONCLUSIONS:** A horizon scanning study is needed to identify genetic-based technologies for cancer, for which CER can be performed in a RCT. The results from this horizon-scan will drive development of new GPM trial designs incorporating CER.

PCN13

TAXANE USE AND NEUROPATHY IN EARLY STAGE BREAST CANCER PATIENTS – RESULTS FROM A US COMMUNITY ONCOLOGY CENTER
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OBJECTIVES: A randomized trial comparing doxetaxel (D) and paclitaxel (P) treated patients has shown greater neurologic toxicity with P given weekly. This study aimed to compare neuropathy (NP) and NP-related outcomes between D and P in a community practice. **METHODS:** The analysis was conducted using the Georgia Cancer Specialist Database (2003–2008) supplemented by chart abstraction. Patients with stage I-III breast cancer (BC) and treated with adjuvant D or P-containing chemotherapy (CT) were followed from initial treatment to the earliest of death, loss to follow-up, or switch to other regimens. NP and NP-related outcomes were measured as (1) 6-month rate of severe NP (CTC grade 3/4), (2) 6-month rate of receiving NP-related medications (NPMs), (3) proportion of patients whose CT was affected due to NP (CT being held, discontinued, or dose reduction). Univariate and multivariate analyses with adjustment of clinical and demographic characteristics were performed to compare the outcomes between D and P groups. **RESULTS:** A total of 591 (63.6%) and 338 patients treated with D and P were included. The univariate analyses showed that P had higher rates of severe NP (4.9% vs. 1.0%) and NPMs use (28.1% vs. 7.6%) within 6 months, and their CT was more likely to be affected (7.1% vs. 1.5%), compared with D group (all p < 0.001). Similarly, the adjusted results (all p < 0.001) showed that P was at higher risks for severe NP (HR = 3.50), NPMs use (HR = 6.40), and CT interruption (OR = 5.40). **CONCLUSIONS:** This study found that P was associated with higher risks for severe NP and CT interruption, compared to D. The findings are consistent with published trials and call for close observation of NP when using P. The results should also be viewed in the context that NP poses higher economic burden over non-NP patients. The findings need to be confirmed by addition studies from community settings.