RESEARCH ON DATABASE METHODS STUDIES

DB1

CRITICAL PROBLEMS OF CODING DATA IN HEALTH CARE: OBESITY, SMOKING, AND ALCOHOL USE BY METHOD OF MEASUREMENT

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OBJECTIVES: The measurement of healthcare is increasingly based on risk-adjusted outcomes derived from coded comorbidities in large datasets. However inaccurate or haphazard assessment of risk factors for morbidity and mortality in medical record codes can have tremendous implications for quality improvement and healthcare reform. The purpose of this study is to compare the prevalence of obesity, overweight, tobacco use and alcohol abuse of a large administrative dataset with a direct data collection survey. **METHODS:** We used the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes for four leading comorbidities in the Nationwide Inpatient Sample (NIS) to compare them with a direct survey in the Behavioral Risk Factor Surveillance System (BRFSS) in 2011. The national and state estimates and the Pearson correlation coefficient for obesity, overweight, smoking and alcohol abuse between NIS and direct survey were calculated. **RESULTS:** Compared with direct participant questioning in BRFSS, NIS reported substantially lower prevalence of obesity, overweight, smoking and alcohol. The prevalence of obesity, overweight, smoking and alcohol were 27.7%, 35.8%, 20.1% and 18.3% in direct survey and 9.6%, 0.21%, 12.2% and 4.6% in NIS. The correlation between NIS and direct survey was 0.27 for obesity ($p=0.06$), 0.09 for overweight ($p=0.55$), 0.62 for smoking ($p<0.01$) and 0.40 for alcohol ($p<0.01$). **CONCLUSIONS:** The prevalence of obesity, tobacco smoking and alcohol abuse based on ICD-9-CM codes in NIS is not consistent with prevalence rates by direct questioning. Patient-level data extraction as a part of Meaningful Use standards, rather than ICD-9-CM codes, would improve the accuracy of these important contributors to patient outcomes in NIS. Ensuring accuracy of important comorbidities is critical to quality improvement efforts and healthcare reform policies that are based on measuring risk-adjusted outcomes.

DB2

A NEW METHOD FOR COUNTING HEMOPHILIA-RELATED BLEEDING EVENTS IN CLAIMS DATA

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OBJECTIVES: Hemophilia-related bleeding events are difficult to quantify. Insurance claims' data may capture the information, but there is no robust methodology to identify these events. **METHODS:** Using 2004-2012 Truven Health MarketScan commercial claims database (coverage of >30 million employees in th United States), we evaluated males under age 65 having ≥1 inpatient/≥2 outpatient claims 30-day apart for hemophilia A or B (ICD-9: 286.0, 286.1), and ≥1 pharmacy claim for clotting factors VIII or IX with ≥12 months continuous enrollment from first hemophilia treatment were selected. Bleeding events were identified using ICD-9 codes for hemarthrosis, hematoma or other acute bleeds in inpatient/outpatient claims. Hemophilia treatment guidelines recommend 1-14 day treatment depending on bleeding severity. We explored aggregating claims within varying time windows (1, 7, 10, and 14 days) to capture a single bleeding event and assessed sensitivity of the time differences using pairwise rank correlations. **RESULTS:** We identified 2,425 and 269 hemophilia A and B patients. Using a 7-day window, average annual bleeds ((total bleeds ÷ patient-months)*12) among patients with ≥ 1 bleed equaled 2.31 (range: 1-33) for hemophilia A and 1.92 (range: 1-18) for hemophilia B. Results were similar for a 10-day window (hemophilia A: 2.21 (1-31), hemophilia B: 1.81 (1–14)) and 14-day window (hemophilia A: 2.10 (1–24), hemophilia B: 1.69 (1–12))). A 1-day window produced somewhat higher numbers (hemophilia A: 2.99 (1-66), hemophilia B: 2.72 (1-45)), but pairwise rank correlation remained high across the four assumptions (coefficients ≥ 0.99, p-values <0.01 for both disease types). Frequencies are comparable to a large US-based study reporting bleeds in moderately-severe patients, albeit smaller than studies of severe patients. **CONCLUSIONS:** Claims data can be utilized to construct stable, robust indices of bleeding events in hemophilia patients, permitting reliable studies of factors influencing bleeding frequency and healthcare burden.

DB3

THE IMPLICATIONS OF USING A 30-, 60-, OR 90-DAY GAP IN TREATMENT TO SPECIFY LINES OF CARE IN GASTRIC CANCER TREATMENT

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OBJECTIVES: Compare changes in patterns of care and duration of therapy resulting from increasing the treatment gap designating a new line of therapy in metastatic (M) gastric cancer (GaCa). **METHODS:** Two large integrated claims databases (Pharmetrics, MarketScan) spanning July 2008 to September 2012 were used to identify patients ≥18 years old diagnosed and treated for GaCa. Patients were required to be continuously enrolled for ≥6 months pre- and post-diagnosis. Eligible patients were stratified into cohorts based on the presence and timing of metastasis (M) diagnosis: no metastasis (NM), ≤120 days (M1), and ≥121 days (M2). Treatment gap intervals were varied at ≥30, ≥60 and ≥90 days to indicate the start of a new line of chemotherapy. **RESULTS:** There were 6,509 (3,486 NM; 1,469 M1; 654 M2) and 3,203 (2,004 NM; 875 M1; 324 M2) patients in each of the databases meeting all inclusion criteria. Comparing the 30- and 90-day gaps, mean length of treatment (days) increased for M1 patients from 69.8-71.0 to 83.4-84.5 in first, 55.4-56.6 to 55.7-60.3 in second, and 56.5-59.7 to 60.1-64.9 in third line. Using a 30-day gap, 46.4%-54.2% of M1 and 36.1%-46.6% of M2 received second line while 25.6%-32.3% of M1 and 18.2%-25.1% of M2 received third line. Increasing the gap to 60 days decreased the total rate of second line therapy slightly for M1 patients to 43.0%-51.3% and to 33.0%-45.1% for M2. The rate of third-line therapy was similarly lower at 23.0%-30.0% for M1 patients and 17.3%-23.2% for M2. Increasing from a 60-day to 90-day gap resulted in an absolute decline in the 60-day rate of therapy of 0.8%-2.6% in second line and 0.3%-3.1% in third line across both the M1/M2 groups. **CONCLUSIONS:** The data are in agreement between the 2 databases, and analysis by varying treatment gaps did not significantly impact results.

DB4

DEVELOPMENT AND VALIDATION OF ALGORITHMS TO IDENTIFY STATIN INTOLERANCE IN A US ADMINISTRATIVE DATABASE

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OBJECTIVES: Develop and validate an algorithm to define statin intolerance (SI) in an administrative database (AD). **METHODS:** Adults with ≥1 qualifying change in statin therapy and ≥1 prior diagnosis of hyperlipidemia, hypercholesterolemia, or mixed dyslipidemia were identified from the AD of the Health Alliance Plan at Henry Ford Health System (HFHS). A sample of 1000 patients was drawn from the pool of eligible adults using an 80/20 ratio of patients taking a moderate- to low-intensity statin or a high-intensity statin at the time of qualifying change in therapy. Statin utilization and adverse events data were abstracted from the AD and the HFHS electronic medical record (EMR). Patients were stratified by high or low cardiovascular risk based on comorbidities, and any SI was categorized as absolute (AI) or titration (TI). In both the AD and the EMR, identification of SI was based on statin treatment patterns and potential statin-related adverse events. With EMR as the reference, measures of concordance (Cohen's kappa [κ]) and accuracy (sensitivity, specificity, positive predictive value [PPV]) were reported for AD algorithms. **RESULTS:** In the sample population (n=990), any SI was identified in 11.5% and 14.0%, AI in 2.2% and 3.1%, and TI in 9.7% and 11.8% of patients in the EMR and the AD, respectively. The algorithm identifying any SI had substantial concordance (κ=0.66) and good sensitivity (78.1%), but modest PPV (64.0%). The TI algorithm performed better (κ=0.74, sensitivity=85.4%, PPV=70.1%) than the AI algorithm (κ=0.40, sensitivity=50.0%, PPV=35.5%). Specificity was high (>94%) across all 3 algorithms. In the high cardiovascular risk cohort (n=353), the any SI algorithm demonstrated robust concordance (κ=0.73) and good sensitivity (80.9%) and PPV (75.3%), all of which were even higher for TI. **CONCLUSIONS:** A conservative but comprehensive, easily implementable, and valid SI algorithm from an AD is available for real-world research.

HEALTH CARE MANAGEMENT STUDIES

HM1

UTILIZATION OF ANTIDIABETICS AFTER FDA SAFETY ANNOUNCEMENTS

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OBJECTIVES: FDA-issued safety alerts and warnings play a vital role in post-market drug surveillance. We examine the effects of the FDA safety announcements for rosiglitazone and pioglitazone on the utilization of these drugs and other oral antidiabetics. **METHODS:** We link safety announcements from the FDA MedWatch database to Medicare drug claims (Parts D & B) from 2006 to 2010. We examine the timing, direction and level of demand responses to safety announcements, and how they differ by patients' race/ethnicity, socioeconomic status and plan type (PDP vs MA-PD). We then estimate the fraction of patients that continue using an "alerted" medication, switch to another oral antidiabetic, or stop use altogether (without adding another oral medication), and how these responses differ by patient group and plan type. **RESULTS:** The demand for rosiglitazone plummeted after the second safety alert (in May 2007), and decreased further after a (black box) warning was issued (in August). After the alert, 27% to 28% of rosiglitazone users switched to another oral antidiabetic (predominantly pioglitazone) within 6 months of the alert depending on patient groups and plan type; 28% to 33% discontinued use of rosiglitazone, but did not add another oral antidiabetic; 38% to 44% continued using rosiglitazone. After the warning, the numbers were 17% to 19%, 30% to 32% and 49% to 52% respectively. Discontinuation rates were slightly higher among Hispanics (32%) and those in MA-PD plans (32%). In contrast, the demand response for pioglitazone was more muted, while it increased slightly after the warning (in August). **CONCLUSIONS:** The demand response to safety warnings for rosiglitazone was large and abrupt, and a substantial fraction of those who stopped did not replace it with another oral antidiabetic. The demand response was fairly constant across race/ethnicity, socioeconomic status, and plan type, although large responses raise concern about adverse health consequences.

HM2

DIFFERENCES IN MASTECTOMY RATES BASED ON HORMONE RECEPTOR STATUS IN EARLY STAGE TUMORS: A SEER DATABASE ANALYSIS

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OBJECTIVES: Breast cancer molecular subtypes provide important prognostic information that is useful for determining adjuvant treatment strategies; however, there is no evidence to indicate molecular subtypes should influence choice of surgical treatment. The purpose of this study is to investigate the rates of mastectomy (TM) versus lumpectomy (BCT) for each T-stage subgroup based on hormone receptor status. **METHODS:** The SEER registry was queried for all females ages 15 – 85 diagnosed with stage T1 or T2 invasive breast cancer from 2010-2011. Patients were stratified by T-stage and race. Logistic regression was used within each stratum to compare