Clinical and Informatics Research on Large Clinical Databases

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Research Abstract

Clinical Projects A. Association between use of Androgen Deprivation Therapy (ADT) and

incidence of Alzheimers disease among patients diagnosed with prostate cancer This project is to explore how likely patient receiving androgen deprivation therapy, which is the first line treatment for metastatic prostate cancer and the main treatment for advanced prostate cancer, would develop Alzheimers disease in the future. Using 2000 – 2014 100% Medicare Master Beneficiary Summary, Physician, Inpatient and Skilled Nursing Facility files, we identified 1,388,645 male Medicare old age and survivors insurance (OASI) beneficiaries who were 67 or more and diagnosed with prostate cancer between 2000 and 2014. Using a set of HCPCS codes, we defined treatments that patients received for their prostate cancer; androgen deprivation therapy, chemotherapy, radiation therapy, prostatectomy and watchful waiting. To explore whether risk of Alzheimers disease is associated with a type of treatments patients received, we implemented a competing risk regression model using age as the time scale (left truncation of entry). As opposed to the previous report (hazard ratio of 1.88), we found that the use of androgen deprivation therapy is not associated with the risk of Alzheimer's disease, with hazard ration of 1.004. B. Association between use of Cardiovascular Medications (Statins , hypertensive drugs) and incidence of Alzheimers disease or related dementia This study is to investigate whether or not some medications such as lipid-lowering medications and anti-hypertensive medication have secondary benefits of delaying or preventing Alzheimers disease or related dementia in addition to the benefit they are approved for. Using 2007 – 2014 Medicare Master Beneficiary Summary and Prescription Drug Event files for 10% Medicare Part D enrollees, we identified 737,524 eligible study subjects and their prescription drug use. Medications of interest include lipid-lowering drugs (Statins), hypertension drugs (beta blocking agents, ace Inhibitors, calcium-channel blocking agents, diuretics, angiotensin II receptor blockers) and proton pump inhibitors. In order to determine whether or not use of medications of interest delays incidence of Alzheimers disease or related dementia, we adopted four approaches Cox regression and competing risk regression using not only time-on-study but also age as the time scale. We found that some drugs exhibit greater benefit than other drugs in preventing Alzheimer's disease or related dementia. Centrally acting medications were more effective than non-centrally acting medications, except for calcium channel blockers. Overall, the size beneficial effect was, however, not as large as previously reported. C. Diabetes, Hypertension, Depression In 2014, multiple organizations formed a research consortium called Observational Health Data Sciences and Informatics (OHDSI). This consortium maintains a Common Data Model (CDM) for representing clinical and administrative data in a relational database and an associated clinical terminology framework that relies on standard terminologies such as SNOMED CT, RxNorm or LOINC (Logical Observation Identifiers Names and Codes). We participated in extending the CDM and contributing to the development and testing of software tools that allow data characterization, cohort definition or statistical analysis 1-3. We used 5 large databases made available to researches within the Innovation in Medical Evidence Development and Surveillance (IMEDS) project of the Reagan-Udall Foundation (RUF) for the Food and Drug Administration. Within the OHDSI consortium, we participated on a collaborative study that looked at treatment pathways (specifically, sequence of drug treatments) in three common condition (diabetes, hypertension and depression) 4. This study is a pioneering example of a single analytical algorithm (that represents a clinical question) that can be executed across multiple datasets which all follow the common data model and common set of target terminologies for semantic data integration (in this study, RxNorm and SNOMED CT). D. Sepsis and Disseminated Intravascular Coagulation Easy availability of clinical databases to researchers is an ongoing challenge. MIMIC2 database (that originated at MIT), allows access to de-identified data on intensive care unit patients. The MIMIC database is

unique in pioneering relatively streamlined access to clinical data to researchers. We have used this database to study Disseminated Intravascular Coagulation (DIC) condition in 2,257 patients with sepsis using the MIMIC2 database 5. E. Comparing the performance of commercial drug knowledge bases in detecting drug-drug interactions Drug-drug interactions are a significant cause of adverse drug events and hospital admissions. Physicians rely on clinical decision support systems to alert them of potential interactions. These systems are often based on a drug interaction knowledge base (KB) from a single vendor. Previous studies have shown significant variation between knowledge sources. To compare the performance of different commercial KBs in a simulated clinical context, we applied 3 commercial KBs to a large data set of patient prescription data (acquired from Symphony Health) to evaluate the overall alert level and coverage of a list of clinically significant drug interactions. Informatics infrastructure for large clinical databases F. Data quality We conducted two studies that examine the quality of the data present in large clinical databases. In the first study, we adapted an earlier framework for comparing the size and comprehensiveness of a database to utilize the OHDSI common data model. In an evaluation, we executed the resulting tool (called IRIS) on 17 large databases 6. In the second data quality study, we have extended the OHDSI data characterization tools (called Achilles) and OHDSI data quality assessment (DQA) tool (called Achilles Heel) with new data quality rules. We conducted an evaluation study of this tool and a qualitative survey about DQA at 7 sites. publication accepted but not yet in pubmed, eGEMs Multi-site Evaluation of a Data Quality Tool for Patient-Level Clinical Datasets tentative citation: 7 Optionaly, reference to a related AMIA podium abstract can be included:8 G. Clinical Data Representation Ability to easily execute an analysis across multiple datasets is a well-recognized informatics goal. In order to allow execution of OHDSI research projects on the MIMIC database, wWe worked on conversion of this database into the OHDSI common data model 9. The converted MIMIC allows the use of OHDSI data characterization and data quality tool and execution of any consortium-initiated analyses on the converted MIMIC data. In a second related project, we used the RxNorm terminology to infer drug route from pharmacy dispensing data within large medical claims databases using NLMs RxNorm drug terminology 10. Claims data lack drug route information and we created an informatics method that provides and inferred drug route using the knowledge embedded in the RxNorm drug terminology. This inferred field, for example, allows exclusion of drug that are not administered systemically. H. Research Data representation Another category of large databases represent repositories of patient level data from clinical trials. Our research focused on informatics standards capable of representing trial metadata and trial protocol within such databases. One such standard is the Operational Data Model (ODM) standard created by the Clinical Data Interchange Standards Consortium (CDISC). We conducted a suitability assessment of the ODM standard 11, literature review of the use of the ODM standard 12 and analysis of research protocols 13.

Further information available at:

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