procedure once data entry is complete. 3b. A master stored procedure can call individual procedures in order (e.g., importing a positive lab result may trigger randomization). **Results:** The ETL process described above has proven itself to be robust and adaptable in a variety of study contexts. **Conclusions:** An automated system for adding clinical data to a patient registry or tracking database can save staff time, allow access to near real-time data, and facilitate integration of data from different sources.

Keywords: Patient Registry; Electronic Medical Record; Tracking Database
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PS2-42:

Assessment of Drug Induced Liver Injury Using an Automated Causality Assessment Tool

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Background/Aims: Drugs are a common cause of acute liver failure. However, confirming the diagnosis of drug-induced liver injury (DILI) is challenging due to its low incidence, lack of diagnostic markers and idiosyncratic nature. Our aim was to develop an automated scoring algorithm to identify potential DILI cases based on the Roussel Uclaf Causality Assessment Method (RUCAM) and test it in healthcare data. **Methods:** RUCAM includes seven criteria of causality assessment. Operational scoring definitions were developed for each of the criteria in collaboration with DILI experts and programmed into an automated algorithm. The automated algorithm was then tested on a retrospective cohort of patients at Kaiser Permanente Southern California. Study participants were ≥ 18 years old with twelve months of continuous membership plus drug benefit prior to exposure to one of 14 drugs commonly associated with DILI. Eligible patients filled at least one of the study drugs between January 1, 2003 and August 31, 2011. Patients were scored and cases were categorized into one of five categories ranging from 'Highly Probable' to 'Excluded'. Rates of DILI events per 10,000 exposures were calculated and frequency counts of possible scores for each of the seven criteria were analyzed. **Results:** We identified 14,925 potential DILI events following 3,321,835 study drug exposures. Four antibiotics accounted for 89.4% of events. The average (SD) patient age was 60 (16) years and 54.5% of potential DILI events occurred in females. Cholestatic injury (65.0%) was the most common type followed by hepatocellular 29.4%, and mixed 5.6%. DILI events were categorized as probable or highly probable in 15.5% of cases, 59.6% were identified as possible, and 24.9% were unlikely or excluded. The overall rate of probable or highly probable DILI events was 6.9 per 10,000 exposures. The scores for most criteria spanned the entire range of possible scores and there were no obvious floor or ceiling effects. However, Criteria 5 (other non-drug causes of liver injury) showed poor discrimination of possible scores. **Conclusions:** An electronic causality assessment algorithm was developed and successfully tested on healthcare data. Further validation is needed comparing these results with the 'gold standard' medical record review by DILI experts.

Keywords: Drug Induced Liver Injury; Causality Assessment
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PS2-43:

Sensible Use of ICD-9 Diagnosis of Observational Data in Breast and Endometrial Cancer Research

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Background/Aims: Utilization of administrative data (such as EHR data) in population-based research is resource advantageous, despite its potential limitations. Few studies have fully assessed the validity and efficiency of EHR-retrieved data. We developed ICD-9 based algorithms and operational processes to evaluate applicability of EHR-derived cancer data. **Methods:** We retrieved data between 01/01/2002-12/30/2011 from 4 different EHR sources and developed 3 ICD9-based diagnostic algorithms (1+, 2+ and 5+). Women were classified into breast or endometrial cancers or benign breast

conditions (BBC). One trained abstractor manually reviewed medical records and recorded data into a structured database. Every 10 observations were selected and reviewed. Basic descriptive statistical analyses were conducted; observations with questionable values were flagged for re-evaluation. The final dataset was considered the "gold standard" and used to validate the algorithms and to assess the duration between the diagnostic and administrative dates. **Results:** A total of 1,056 women contributed to this study. Of these, 189 were diagnosed with breast and 40 with endometrial cancers. An additional 268 women had BBC. For breast cancer, using the first algorithm we calculated a sensitivity of 95.2% and specificity of 96.4%. Application of the second algorithm yielded a sensitivity of 94.2% and specificity of 97.6%. For the third one, our calculations indicated 89.0% sensitivity and 97.9% specificity. Our analyses based on the same algorithms yielded similar sensitivity and specificity for endometrial cancer. For BBC, we calculated a sensitivity of 82.5% and specificity of 56.7% based on the first, 73.1% sensitivity and specificity of 71.9% for the second, and 38.8% sensitivity and specificity of 90.5% for the third algorithm. The average duration between diagnostic and administrative dates for incident breast, endometrial cancers and BBC was 0.65, 0.01, and 0.31 years, respectively. **Conclusions:** Our initial findings confirm the validity and potential utility of EHR for population-based cancer research. The algorithm of "2+ ICD-9 Coding System" yielded the most efficient process. The observed lower sensitivity and specificity for BBC potentially can be attributed to the wider pathologic spectrum of BBC. The relatively short duration between the EHR and diagnostic dates suggests unbiased interchangeability of dates.

Keywords: Observational Data (EHR); Validation of ICD-9 Diagnostic Code; Breast and Endometrial Cancer

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PS2-51:

Comparison of Two Different Methods of Classifying Periodontal Disease Severity

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Background/Aims: Accurately determining the severity of periodontal disease has historically been a challenge in the dental practice. The object of this pilot effort was to compare two different methods of classifying periodontal disease severity based on provider-documented data among a random sample of dental patients at Marshfield Clinic. The Marshfield Clinic's electronic dental record provides an opportunity to collect specific data points for each tooth and its different surfaces as part of the periodontal charting conducted by the dental hygienist. The dental hygienists also classify the overall periodontal condition based on the American Dental Association (ADA) classification of gum diseases. **Methods:** A random sample of 50 dental patients with at least one comprehensive periodontal screening was used to conduct this retrospective study. Using the Marshfield Clinic's electronic dental record, the study compared how the dental hygienist coded the periodontal condition based on ADA classification with that of a computer-based algorithm that was developed to classify periodontal condition based on criteria as described by the American Academy of Periodontology (AAP) and the Centers for Disease Control and Prevention (CDC). We then mapped the periodontal disease severity classifications from both methods to investigate how many of the sample of 50 patients were similar. **Results:** Out of the 99,255 dental patients in our data warehouse, 67,487 (68%) have had a visit in our medical system at least once in the last 3 years. Periodontal measures have been done on 44% (29,573/67,487) of these patients that have medical and dental data available. When comparing the hygienists' classification of periodontal disease severity (using ADA guidelines) to an electronic algorithm using clinical attachment and probing depth to classify periodontal disease, there was a 72% (36/50) agreement. **Conclusions:** Although one limitation of this pilot study is that the purpose of ADA classification of periodontal condition (meant for clinical classification) differs from that of the joint CDC/AAP classification (meant for population-based surveillance), the results encourage utilizing measurable data points from the periodontal chart to help providers make accurate diagnosis of the periodontal condition.

Keywords: Dental; Periodontal Disease

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