RESULTS: Graphical diagnostics afford the analyst the ability to see subtle or dramatic departures from the model’s distributional assumptions that might not be as obvious by using an analytical model that provides a single summary statistic. CONCLUSIONS: The performance of a diagnostic procedure to assess the presence of a gamma distribution is a cost-effective and discriminate model or its ability to explain between two distributions and another is important; however, other factors must be considered before an analyst makes his or her final choice. The ease of executing the technique, its relative clarity of interpretation, and availability in a software package (without having to write extensive programming beyond what is provided by a standard statistical package) must all be considered to ensure that model adequacy testing may be performed readily so that the choice of a distribution for an expenditure model may be considered sound.

RESEARCH ON METHODS – Databases & Management Methods

PMR50 USING TEXT MINING OF ELECTRONIC MEDICAL RECORDS TO IDENTIFY KRAS TESTING STATUS IN MCRC PATIENTS
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OBJECTIVES: To develop algorithms identifying if metastatic colorectal cancer (mCRC) patients were tested for KRAS (a tumor biomarker of EGFR-inhibitor response) using text documents (e.g., physician progress notes) within electronic medical records (EMR). METHODS: The sample consisted of 1,385 mCRC patients from the ACORN Data Warehouse. 300 patients were randomly selected for chart review. The remaining 1,085 patients comprised a scoring dataset. Results: The models proved to predict KRAS testing status in the training sample. Decision tree (DT), random forest (RF), and adaptive boosting (AB) models performed best when applied to validation data not used in the earlier model development process. RF outperformed DT and AB. RF was the only model to produce a kappa > 0.80 (within rounding) for both the validation and testing datasets. It also produced the highest kappa in the testing dataset (kappa=0.7994), as well as fewer false negatives. RF was used to score the remaining 1,085 patients. All patients predicted “tested” and a random sample of patients predicted “not tested” underwent chart review. The model correctly predicted KRAS “tested” 482/500 times (PPV=96.4%) and “not tested” 196/200 times (NPV=98.0%). CONCLUSIONS: These models were able to identify KRAS testing status with high accuracy, and may be used as a tool to reduce the need for labor-intensive and costly chart reviews for clinical trial eligibility.

PMR51 THERE BUT FOR GRACE? A VALIDATED SCREENING TOOL FOR QUALITY OBSERVATIONAL STUDIES OF COMPARATIVE EFFECTIVENESS
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OBJECTIVES: To be able to identify observational studies of good enough quality to recommend support by validating a set of screening questions to qualify study samples likely to produce reasonably accurate and unbiased estimates of comparative effectiveness (CE). METHODS: An 11-item checklist was developed through literature review and consultation with experts from ISPOR, ISPE, payer groups, private sector and academia. Item content covers four quality domains: comparability of subjects, information about the exposure or intervention, outcome measurement, and statistical analysis, which are metrics similar to those used in assessing observational study quality for systematic reviews. Checklist items were tested using studies of drugs, medical devices and medical procedures. We focused on research quality, not applicability to any decision. A fundamental challenge was to find a gold standard against which to test checklist items. 113 volunteers from 5 countries each rated ≥3 articles (N=280 assessments) from three validation sets of studies that 1) had quality assessments published in systematic reviews; 2) were assessed for quality by one of the nine advisors from academic and payer groups; or 3) were assessed for quality by two of the nine advisors. RESULTS: Expert reviews uncovered an unsettling lack of agreement about what “good” looks like, especially in situations that lack context, with 52% concordance (5 experts, 23 assessants). The single best performing checklist item, data quality valid (0.80), or tested p-value > 0.67 for positive predictive value in 4 of 6 samples and > 0.67 for negative predictive values in all 6 samples. Another high scoring question, sensitivity analysis of a positive predictive value > 0.67 for all samples. CONCLUSIONS: This quantitative study shows that many content items recommended by experts do not consistently distinguish high quality observational CE studies.

PMR52 ASSOCIATION BETWEEN CARDIOVASCULAR BIOMARKERS LEVELS AND CIGARETTE SMOKING AMONG CURRENT SMOKERS, PAST SMOKERS AND NON SMOKERS USING NHANES 2007-2010
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OBJECTIVES: To examine the association between smoking status and biomarker levels in a large, nationally representative sample. METHODS: The study used the 2007-2010 NHANES survey, a nationally representative, multi-stage probability sample of the civilian non-institutionalized population. The sample was divided into Current Smokers (CS), Former Smokers (FS), and Never Smokers (NS). An analysis of covariance was conducted for the comparison of biomarker levels across smoking status groups. RESULTS: A total of 5,617 participants were included in the study. The biomarker levels were significantly higher in CS compared to FS and NS for all the biomarkers except for adiponectin. The biomarker levels were significantly lower in FS compared to CS for all the biomarkers except for ghrelin. CONCLUSIONS: This study provides evidence for the association between smoking status and biomarker levels in the general population.