**PM13**


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**OBJECTIVES:** We aimed to validate the telephone administration of the Revised Pre-screening Denver Questionnaire (R-PDQ) and the Ages and Stages Questionnaire (ASQ), 2 tools used to pre-screen and screen children development, respectively.

**METHODS:** Pregnant women were recruited through nine North American Teratogen Information Networks. Women were administered MMAS-4 in 2011 or MMAS-8 in 2012. The two adherence scales were administered through telephone when pre-screening infant development. Only the R-PDQ gross and fine motor and language scales should be administered, whereas for the ASQ, both scales (ICC = 0.76; 95% CI (0.63;0.84)), racial and age group comparisons were made. Overall, 61 and 56 women filled the ASQ and R-PDQ, respectively. Concordance between the self and telephone-administered ASQ was substantial for the communication scale (ICC = 0.76; 95% CI [0.63;0.84]), almost perfect for the gross motor scale (ICC = 0.83; 95% CI [0.77;0.89]), and moderate for the fine motor, problem-solving and personal-social scales (ICC = 0.44; 95% CI [0.21;0.62]; ICC = 0.43; 95% CI [0.19; 0.61]; ICC = 0.52; 95% CI [0.31; 0.68], respectively). Regarding the R-PDQ, the following concordance estimates were found: gross motor scale (ICC = 0.90; 95% CI [0.83; 0.94]), language (ICC = 0.58; 95% CI [0.38; 0.72]), personal-social scales (ICC = 0.27; 95% CI [0.07; 0.49]). The agreement was perfect for the fine motor scale.

**CONCLUSIONS:** The telephone administration of the ASQ is a valid method of child development screening. However, only the R-PDQ gross and fine motor and language scales should be administered through telephone when pre-screening infant development.

**PM14**

**DEVELOPING A COHORT OF LINKED MOTHER-BABY PAIRS TO STUDY PRETERM LABOR: HARMONIZING REAL-WORLD DATA FROM FOUR LARGE UNITED STATES INTEGRATED DELIVERY NETWORKS**

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**OBJECTIVES:** Integrated delivery networks (IDNs) capture patient data across the continuum of care and are valuable tools for real-world research, with potential to study large, diverse cohorts with rich information on patient characteristics, treatments, physician decisions and outcomes. However, using multiple IDNs requires coordination of dissimilar data to create a uniform post hoc analysis database. We used this approach to create a novel cohort to examine maternal and neonatal characteristics with the goal of better understanding preterm labor, a critical step in developing effective tocolytic treatments.

**METHODS:** Retrospective data on births occurring from 2001-2012 were collected from 4 large United States, New Mexico and central states [Missouri/Arkansas/Kansas/Oklahoma] participating in Quinlivan’s COMPArative effectiveness Patient Safety and Surveillance (COMPASS) Research Network. The IDNs were combined to create a resource with wide types of electronic medical records, catchment areas and institution types. Detailed data specifications were defined, mothers and babies were linked using medical record numbers and mothers were populated with secondary sources. A total of 109,583 mother-baby pairs among women with uncomplicated, singleton pregnancies was built each associated with their clinical records. Data were collected on maternal medication use and specific pregnancy complications (e.g., eclampsia/HELLP, placental conditions and infections) and neonatal characteristics including demographics, weekly gestational age, procedures, treatments and hospital-based clinical outcomes. CONCLUSIONS: IDNs offer an in-depth source of real-world data to evaluate clinical characteristics of otherwise difficult-to-study populations. However, employing routine care information from diverse settings for research presents challenges and varying definitions, coding processes and facility characteristics should be considered before analyses. Processes must be developed to translate clinical research results to standardized analytical research datasets. Development of detailed specification and harmonization processes allowed creation of a cohesive and unique mother-baby linked data resource that could be extended to a broad range of perinatal epidemiology and health outcomes research questions.

**PM15**

**SOME STATISTICAL CONSIDERATIONS IN ESTIMATING A DISEASE PROGRESSION MODEL FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)**

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**OBJECTIVES:** To estimate associations between attributes of COPD and to develop a statistical model that predicts economic outcomes associated with disease progression. **METHODS:** We used data from ECLIPSE (clinicaltrials.gov identifier: NCT00292552), a three year cohort study of COPD patients to estimate the associations between COPD attributes (exacerbations, lung function, exercise capacity, and symptoms) while adjusting for co-morbidities, body composition (BMI), biomarkers, smoking history, age, and gender. As disease progression endpoints we used the total score of the St. George’s Respiratory Questionnaire (SGRQ) and mortality. We applied random coefficient models to assess the relationships. However, severe exacerbations in the preceding 12-months were associated with an average decline in lung function (FEV1) of up to 10 ml (P<0.05) and with a reduced exercise capacity (6 minute walk test) of 13 meters (P<0.0001). A 1% increase in FEV1, % predicted was also associated with a 5% reduction in the probability of experiencing dyspnea on most days/week (P<0.0001). All central attributes were found to significantly impact disease progression, measured by the SGRQ, with the largest estimated effect for dyspnea on most days/week (18 point increase in the SGRQ score; P<0.0001). Lung function and exercise capacity, however, were the only central attributes that were significant predictors of mortality (P<0.05). **CONCLUSIONS:** The use of appropriate analytical techniques to account for the longitudinal nature and endogeneity of COPD attributes enables the estimation of their impact on important health outcomes. Our results confirm the expected associations between the central attributes of COPD and their effect on patient health status (SGRQ) and mortality.
PrM17
METHODS FOR EVALUATING THE EFFECT MODIFICATION IN THE OBSERVATIONAL STUDIES: A RETROSPECTIVE ANALYSIS ON THE IMPACT OF SIMVASTATINA AND EZETIMIB AND STATINS ON ACUTE MYOCARDIAL INFARCTION

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OBJECTIVES: Fundamental potential weaknesses of observational studies are bias and effect modification. In this situation, computing an overall estimate of association is questionable. The approach was to reshape a traditional multivariable-adjusted model with a propensity score (PS) model and a cluster analysis (CA) model, in estimating the association between type of lipid modifying agent and hospitalization for Acute Myocardial Infarction (AMI). Methods: Thirty-five hospitals in Emilia- Romagna (Italy; more than 10 Million records; 4.4 Million Inhabitants) was used to select between January 1st, 2006 and December 31st, 2011. Statins and Simvastatin and Ezetimibe (SE) naïve users. A PS was constructed, predicting treatment assignment from age, gender, use of diabetic agents, different pharmacologic agents, comorbidity level and utilization of outpatient services. For analysis’ purpose, the effect of the treatment on the risk of IMA was measured by estimates of hazard ratios (HR), and in PS using: multivariate Cox regression model adjusted for PS, CR model within each cluster identified by a K-means method. Results: Over 2.6 Million inhabitants (>40 years) 57,902 (92.2%) patients were naïve users of Statins, 4,804 (7.8%) were SE users. Compared with Statins, the risk of IMA for SE resulted similar in the adjusted CRM and in the propensity CRM (HR =1.47 and HR=1.49 respectively). While the CRMs performed within each cluster yielded different treatment effect estimates (HR = 0.39 for Cluster 1, HR=1.36 for Cluster 2, 1.37 for Cluster 3). Conclusions: The CA performed well, with a clear identification of specific subgroups of patients, with homogeneous risk features. The CRM within each cluster yielded different treatment effect estimates that might suggest the presence of unmeasured confounders. In that case, traditional regression model and PS developed using administrative data do not necessarily balance patient characteristics contained in clinical data. Choice among different approaches for investigating effect modification should be sensitive to the circumstances of the data analysis in applying observational studies.

PrM18
MULTI-CRITERIA DECISION ANALYSIS IN ONCOLOGY: AN OVERVIEW

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OBJECTIVES: Diagnosis, treatment, and management decisions in oncology can be problematic due to a combination of diagnostic and therapeutic uncertainties, patients’ preferences and values, as well as costs. These decisions involve trade-offs between possible benefits and harms. There is growing interest in the development and application of alternative decision-making frameworks within oncology, including multi-criteria decision analysis (MCDA). Even though the literature includes several reviews on MCDA methods, applications of MCDA in oncology are lacking. This study sought to discuss the rationale for using MCDA in oncology. In this context, the following research question emerged: How can MCDA be used to develop a clinical decision support tool in oncology? METHODS: This study surveyed several applications of MCDA in the field of oncology. In particular, the study reviewed key contributions addressing screening and treatment decision-making in this area. It proposed research opportunities in this context of oncology, and presented a hypothetical scenario to show how MCDA could be applied in oncology. RESULTS: The literature review identified eight studies. Five studies examined decision making for cancer screening. Four studies demonstrated applicability and acceptability of the Analytic Hierarchy Process (AHP) as a means to involve patients in oncology decisions and translate evidence into clinical practice. The study showed that a wider range of MCDA methods exist; each has its strengths and weaknesses. Choosing the appropriate method may depend on the source and nature of information used to inform decision-making. CONCLUSIONS: Given recent advances and movement toward evidence-based, multidisciplinary teams, and shared decision-making, the field of oncology will certainly seek ways to make comprehensive and transparent decisions. MCDA appears to be a promising tool to support clinical decision-making and help assess trade-offs regarding preferences. Nonetheless, field-testing is desirable before MCDA becomes an established decision-making tool in oncology.

PrM19
A COMPARISON OF PROPENSITY SCAres FOR ASSESSING PATIENT REPORTED OUTCOMES: A MONTE CARLO STUDY

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OBJECTIVES: Many medical and epidemiological research studies are based on observational data. In this study, we compare three different propensity scores: unadjusted propensity score (UPS), propensity propensity score (IPW), and prognostic propensity score (2PS2) using the inverse probability weighted (IPW) estimator for assessing patient reported outcomes (PROs) in terms of average treatment effect (ATE) and average treatment effect on the treated (ATT). METHODS: We conducted a Monte Carlo simulation study to evaluate these three propensity scores for estimating ATE and ATT in terms of bias, mean squared error (MSE), and average treatment effect on the treated. RESULTS: The simulation results show that PS1 has the poorest performance compared to UPS and PS2 in terms of bias, MSE and CP. CONCLUSIONS: Based on these simulation results, we recommend using UPS and PS2 for estimating ATE and ATT for patient reported outcomes in practice.

Re: PrM18
The Aga Khan University Hospital, Karachi, Pakistan

OBJECTIVES: In oncology, MCDA is an area of concern for health care providers and policy makers. The large number of preventable errors, risk of litigation, patients’ insecurity and lack of confidence in health care provision is a concern globally in an underdeveloped country like Pakistan. Patient safety is an integral part of the health care system for patient safety is need of the hour. Both management and health care systems and policy makers. The large number of preventable errors, risk of litigation, patients’ insecurity and lack of confidence in health care provision is a concern globally. In an underdeveloped country like Pakistan, patient safety is an integral part of the health care system. Objectives of this cross-sectional analytical study are, to estimate the rate of medical errors and to assess the factors that influence medical error reporting. The cross-sectional analytical study was conducted during International Conference organized by Radiological Society of Pakistan in November 2009 at Sheraton Hotel, Karachi. Data were collected using a structured, self-administered questionnaire from participants willing to participate in research registered for Annual Radiology Residents’ Conference, via online radiology residents’ conference technique. Data were analyzed using SPSS versions 19.0.Means±SD were computed for quantitative and proportions calculated for qualitative variables. Chi square and ANOVA were used for comparison of categorical variables. A p-value of <0.01 was considered significant. RESULTS: Response rate was 76% (n=7/103), 65.4% agreed that conducting research in the field of radiology is difficult. Most of the participants (62.3%) were willing to participate in research activities. A PS was not published, by health care providers and factors that influence error-reporting, were considered significant. 385 participants, including doctors, nurses and paramedics from different private and government hospitals of Karachi were selected by non-probability convenience sampling technique. 385 participants, including doctors, nurses and paramedics from different private and government hospitals of Karachi were selected by non-probability convenience sampling technique. Questionnaire elicited information about number of errors witnessed and to ascertain barriers in conducting research, more residents than consultants believed that lack of time to conduct research, diminished income in research activities were identified as most important barriers in conducting research. Similar responses were observed among residents and consultants regarding barriers in conducting research, more residents than consultants believed that lack of time to conduct research, diminished income in research activities were identified as most important barriers in conducting research. Similar responses were observed among residents and consultants regarding barriers in conducting research.

PrM21
VIEWS OF HEALTH CARE PROVIDERS ON MEDICAL ERRORS IN KARACHI, PAKISTAN

Re: PrM18
The Aga Khan University Hospital, Karachi, Pakistan

OBJECTIVES: Incidence of medical errors is an area of concern for health care providers and policy makers. The large number of preventable errors, risk of litigation, patients’ insecurity and lack of confidence in health care provision is a concern globally in an underdeveloped country like Pakistan, patient safety is an integral part of the health care system. Objectives of this cross-sectional analytical study are, to estimate the rate of medical errors and to assess the factors that influence medical error reporting. The cross-sectional analytical study was conducted during International Conference organized by Radiological Society of Pakistan in November 2009 at Sheraton Hotel, Karachi. Data were collected using a structured, self-administered questionnaire from participants willing to participate in research registered for Annual Radiology Residents’ Conference, via online radiology residents’ conference technique. Data were analyzed using SPSS versions 19.0.Means±SD were computed for quantitative and proportions calculated for qualitative variables. Chi square and ANOVA were used for comparison of categorical variables. A p-value of <0.01 was considered significant. RESULTS: Response rate was 76% (n=7/103), 65.4% agreed that conducting research in the field of radiology is difficult. Most of the participants (62.3%) were willing to participate in research activities. A PS was not published, by health care providers and factors that influence error-reporting, were considered significant. 385 participants, including doctors, nurses and paramedics from different private and government hospitals of Karachi were selected by non-probability convenience sampling technique. Questionnaire elicited information about number of errors witnessed and to ascertain barriers in conducting research, more residents than consultants believed that lack of time to conduct research, diminished income in research activities were identified as most important barriers in conducting research. Similar responses were observed among residents and consultants regarding barriers in conducting research.

PMR22
EVALUATING THE RELATIONSHIP BETWEEN BODY MASS INDEX (BMI) OF DIABETIC PATIENTS AND HEALTH CARE COSTS

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OBJECTIVES: Although a number of studies have been conducted to estimate the economic implications of comorbid obesity in diabetic patients, mixed conclu-