

PS2-09:

Combining Clinical Databases With the EHR to Identify a Study Population: An Example Using Acute Myocardial Infarction

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Background/Aims: Study populations are commonly identified using a single data source. However, the inclusion criteria may result in an unacceptable level of false positives/negatives. The utilization of multiple sources may allow for more complex inclusion criteria, therefore improving the accuracy of identification of cases and controls for use in research. For this study, Geisinger's electronic health record (EHR) was combined with clinical databases to identify a population of patients with suspected Acute Myocardial Infarction (AMI). **Methods:** The Geisinger Acute Myocardial Infarction Cohort (GAMIC) database was created to conduct research on AMI. Geisinger databases were queried to identify all patients who had elevated cardiac enzymes during an inpatient hospital admission at Geisinger Medical Center from Jan. 1, 2001 to Dec. 31, 2006. Data from the resulting patients were gathered and extensively reviewed for validity and coherence. When possible, overlapping data were collected from different sources to check for internal consistency. Discrepancies between sources were reviewed and resolved. The medical charts of patients who did not go to catheterization were manually reviewed to determine the reason for not going. Similarly, charts of patients with elevated cardiac enzymes who also had invasive surgery on the same visit were reviewed to determine the timing of the enzyme elevation. After applying all criteria, a cohort of AMI cases was derived and retained in the final GAMIC database. **Results:** There were 3,625 patients who had elevated cardiac enzymes during an inpatient encounter; 58% went for catheterization. Of the 3,625 suspected AMI cases, the most common reasons for exclusion were elevated enzymes occurring post open-heart surgery (n=275) and admissions with elevated enzymes but with a recent catheterization (n=61). Only 3,265 (90%) fulfilled all criteria applied from the diverse set of data sources. Interestingly, of the 360 that were excluded and the 3,265 AMI cases, 40% and 90% had an AMI discharge diagnosis for the inpatient admission, respectively. **Conclusions:** A more careful approach to identifying a study population and validating the data for internal consistency results in greater accuracy. In addition, more resources utilized in the beginning of the study to better capture the population of interest can lead to a reduction in resources needed later in the study if issues or questions arise from a poorly identified cohort.

PS2-16:

Excessive Gestational Weight Gain is Predictive of Postpartum Weight Retention Among Obese Women

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Background: The prevalence of obesity among reproductive age women has increased significantly. The goal of this analysis was to determine whether gestational weight gain above the Institute of Medicine recommendation for obese women (at least 15 pounds [lbs] for term pregnancy) is predictive of postpartum weight retention at one-year. **Methods:** We conducted a retrospective cohort study of 25,789 pregnancies beginning and ending between January 2000 and December 2005 in a large health maintenance organization (Kaiser Permanente, Northwest) and resulting in live birth. Obesity was defined as BMI >30 kg/m². Total gestational weight gain (last available pre-delivery weight at pregnancy onset [-180 to +90 days]) was categorized as <0, 0–15, and >15 lbs. Postpartum weight retention (postpartum weight at one year [lowest weight measured within 243–547 days post delivery] weight at pregnancy onset) was defined as <0, 0–10, and >10 lbs, and by mean change. Descriptive, linear regression and multivariate logistic regression analyses were performed. **Results:** There were 1,656 obese women who met eligibility criteria and had weights available at each key time

point. Compared to women who lost weight or who gained 0–15 lbs during pregnancy, women who gained >15 lbs were younger, had lower first trimester weights and BMI, had fewer live births, and were less likely to have diabetes or depression. Mean change in weight at one-year postpartum was higher for women who gained >15 lbs during pregnancy, resulting in a net gain (7.2 lbs ± 18.6), compared to a net loss among women who either gained 0–15 lbs or who lost weight during pregnancy (net loss -1.7 lbs ± 6.2 and -2.3 lbs ± 16.3, respectively) (*P*<0.001). Total gestational weight gain was a significant predictor of weight gain at one-year postpartum (beta = 0.39, R² = 0.11, *P*<0.001). Women who gained >15 lbs during pregnancy were more likely to retain >10 lbs (39.7%) at one year postpartum than women who gained 0–15 lbs (15.6%) and who lost weight (24.1%, *P*<0.001). There was a 3.6 fold increased odds (Odds Ratio 3.65, 95% CI 2.69–4.95) of weighing over 10 lbs more at one-year postpartum than at pregnancy onset if pregnancy weight gain was >15 lbs compared to 0–15 lbs. **Conclusion:** Weight gain above 15 lbs during pregnancy is associated with significant risk of postpartum weight retention at one year among obese women. Nutritional counseling should be provided to help prevent excessive weight gain.

PS2-18:

The Maccabi Healthcare Services Cardiovascular Information System: Integration of Patient Care Data, Registries, and Gui

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Abstract Background: The present study describes a registry of cardiovascular disease (CVD) patients in a large health maintenance organization in Israel aimed to be used by health professionals to identify CVD patients and follow the courses of their illnesses and risk factors. **Methods:** In 1998, the registry was initiated using advanced information technology that integrated personal computerized community and hospital records, data from laboratory tests, dispensed medications, physiological signals, radiological images, and reports from investigations and procedures. **Results:** Between 1998 and 2007, the number of patients included in the registry has increased from 34,144 to 80,339. During this period, the age-adjusted prevalence rates of known disease have risen from 3.7% to 5.1% and from 1.9% to 2.6%, among men and women, respectively. The percentage of ischemic heart disease patients who reached target LDL was doubled, from 21% in 2000 to 50% in 2006. During the study period, the average stay in hospital declined from 11.7 days to 8.6 days. Primary myocardial infarction rates declined 33% and 54% in men aged 54–65 and women aged 65–74 years, respectively. **Discussion:** The present study provides, for the first time in Israel, data on selected quality of care and clinical outcomes using a large, population-based registry of cardiovascular disease patients. It demonstrates a significant improvement in the adherence with LDL tests and achieving target LDL levels and a subsequent decline in incidence of myocardial infarction within ten years since its establishment. The methods described can be used in establishing similar registries in similar organizations.

PS2-23:

Cardiovascular Disease Surveillance to Optimize Care: Pros and Cons of a Managed Care Research Network System

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Background: With the goal of identifying where care process improvement could mitigate the impact of heart disease, we have developed a heart disease analysis model, The Perfect Care Model. Accounting for all individuals, all deaths, and all cardiac events in a population, this model estimates the number of deaths that might be prevented or postponed (DPP) with improved care. With data that are usually available in the electronic medical record or health assessment of a managed care organization (MCO), the model can calculate the potential impact of changing any risk factor level, risk factor intervention, or any evidence-based therapy. **Methods:** To assess the feasibility and benefits of basing a CVD surveillance system like the one advocated by the National Forum for Heart Disease & Stroke Prevention in

an MCO research network (MCORN) or state health department (SHD), we compared the data available to an MCORN to the data available to an SHD. **Results:** Data available to the SHD included hospital discharges, case fatality rates by diagnosis for hospitalized patients, counts of surgical procedures, and death certificate data. The disadvantage of organizing a surveillance system through an SHD is that hospitalizations are not linked to services provided during the hospitalization or survival after discharge. Likewise, behavioral risk factor data, medication data and data on ventricular function of patients with heart disease are not available. While MCOs have these data and data linkages, the disadvantage of organizing a surveillance system through an MCORN is that, although covering a significant segment of the US population, the surveillance system would not be strictly population-based. **Conclusions:** The data required to identify clinical opportunities to prevent and postpone deaths are available to a greater extent through MCOs than an SHD. The large populations covered by MCORNs, their geographic range, the relatively stable populations, and the implementation of electronic medical records all make large MCORNs attractive alternatives to SHD surveillance systems.

PS2-33:

Understanding Racial Disparities in Physician Advice and Patient Actions to Control Blood Pressure in an MCO

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Background/Objective: The Chronic Care Model (CCM) links proactive practice teams and activated patients with better chronic care outcomes. We studied the associations of blood pressure (BP) control with 1) physician advice and patient actions on lifestyle behaviors (exercise, diet, salt and alcohol intake) to control BP and 2) medication adherence in a cohort of adults with hypertension (HTN) in a managed care organization (MCO). Our primary analysis focused on the apparent paradox that, in this MCO, African Americans were more likely to report receipt of advice and be taking actions to control BP yet had worse BP control. **Methods:** Adults 18–74 years of age with HTN were identified from computerized data. Two independent samples of 3,000 adults each (750 per JNC-VII level) were randomly selected for telephone survey in October 2007 and March 2008. The survey included BRFSS items on advice and actions to control BP and self-reported race and education. Medication adherence was measured as proportion of days covered (PDC) with any HTN-related medication in the 12-month period preceding the survey. Mean SBP and DBP were measured from computerized data in the same period. Associations among receipt of advice, taking actions, PDC, and BP control were estimated using multivariate path analysis (controlling for age, gender, and education) for the 1,330 respondents who were African American (751) or white (579). **Results:** Compared to whites, African Americans had significantly ($p < 0.05$) higher SBP (standardized beta of 0.137). Better medication adherence was associated with lower SBP (0.229); however, African Americans had lower medication adherence (0.074). Patients taking action to control BP were more likely to have received physician advice to take action (0.232); and, African Americans were more likely to receive advice (0.187) and to take action (0.056). Poor SBP was associated with greater likelihood of taking action (0.075). A similar pattern of associations was observed for DBP. **Conclusions:** Compared to Whites, African Americans in this MCO were less adherent with antihypertensive medications; and, this contributed to worse BP control. Worse BP control, however, increased the likelihood that physicians advised African Americans to take actions to control BP. Consistent with the CCM, physicians appear to be directing their advice on lifestyle actions to the subset of patients most likely to benefit with improved BP control.

Clinical Effectiveness

C-C3-01:

A Conditional Sequential Sampling Procedure for Drug Safety Surveillance

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Background: Health plans' administrative claims data are known to be very useful in post-marketing drug or vaccine safety surveillance to detect certain adverse events that are difficult to capture during the preapproval clinical trials. To detect the existence of excess risk for an adverse drug event, hypothesis testing should be conducted whenever data is updated and thus appropriate group sequential or sequential analysis methods should be implemented to adjust for multiple testing and preserve the overall type I error rate. **Methods:** We propose a practical group sequential method, a conditional sequential sampling procedure, to derive valid inference on the parameter of interest, the relative risk for an adverse drug event between the drug of interest and the comparison drug. The method allows the information for both drug groups to be accumulated prospectively and thus, unlike the newly developed maximized sequential probability ratio test (MaxSPRT), doesn't require the availability of a lot of historical data for the comparison drug. Moreover, the method automatically adjusts for population heterogeneity and temporal trend and requires no a priori assumptions on how the baseline incidence rates change across strata and over time. In addition, the method remains valid (i.e., preserves the nominal Type I error rate) even when the number of interim tests is large and/or there are a lot of strata defined based on several potential confounders. We will explain why the standard general group sequential theory method might not be appropriate in such settings. **Results:** We have conducted an extensive simulation study to evaluate the performance of the new method and compare that to the performance of the general group sequential theory method in a subset of scenarios when applicable. The power performance for both methods in the considered scenarios is very similar and our new method applies to much more general settings. **Conclusions:** We will also implement this method to the data collected in the HMO Research Network CERT II study. This method can be particularly useful in prospective drug surveillance studies in which both drugs are relative new and not enough historical data is available.

C-C3-02:

Increasingly Restrictive Definitions of Hyperkalemia Outcomes in a Database Study: Effect on Incidence Estimates

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Background/Aims: Determination of hyperkalemia associated adverse outcomes incidence and risk assessment is complicated by lack of consistent hyperkalemia definitions across studies. Further, information about hyperkalemia from clinical trials, while reflecting the potential of renin-angiotensin-aldosterone system (RAAS) inhibitor treatment to increase serum potassium (K) concentration above a defined level, may not reflect risk or severity of outcomes. We sought to examine to what extent increasing levels of restriction influenced incidence estimates of hyperkalemia outcomes. **Methods:** The study cohort was drawn from a population of adult patients with diabetes at 3 HMORN sites. We identified all new users of a RAAS inhibitor between 01/01/2001 and 12/31/2006 and assessed hyperkalemia-associated outcomes within the first year of therapy. The initial definition of a hyperkalemia outcome to which other definitions were compared included any ambulatory (AV), emergency department (ED) or inpatient (IP) visit with a K level > 5.5 mmol/l or a coded hyperkalemia diagnosis within 7 days of the visit. The following restrictions were then applied: a) increasing minimum K concentration to > 6.0 mmol/l; b) reducing timeframe to 24 hours; and c) removing AV. Crude incidence rates of hyperkalemia-associated adverse outcomes were calculated using person years (p-y) determined as time from drug initiation to first outcome or other censoring event (e.g., drug discontinuation, end of study). **Results:**