and positive predictive values (PPVs) were calculated based upon diagnostic criteria by Sampson et al. **Results:** Of the 131 potential available cases, adjudicators determined that 77 were anaphylaxis, 45 were not anaphylaxis, and 9 were determined to have inadequate information to confirm whether or not a case was anaphylaxis. Overall, the PPV was 63.1% (95% confidence interval, 53.9%-71.7%). PPVs ranged from 48.1% to 78.9% across the Data Partners. In comparing different criteria, algorithms which included codes for allergy (ICD-9-CM 995.3) or adverse effects of drug, medicinal and biological substance (ICD-9-CM 995.2, E930-E949) in combination with additional treatment or symptom codes, such as injection of epinephrine, had a lower PPV (PPV = 45.8%) than algorithms that included codes specifically indicating anaphylaxis (ICD-9-CM 995.0, 999.4), although confidence intervals were wide and overlapped. **Conclusions:** While the PPV of the developed algorithm was higher than those reported in previously published studies, the PPV of anaphylaxis remains low. Further evaluation of individual codes and combinations of codes is ongoing as part of the present study.

Keywords: Anaphylaxis; Mini-Sentinel; Adverse Drug Event

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B3-4:

Identification of Adverse Drug Events Post-Hospital Discharge in a Geriatric Population

Jennifer Donovan¹; Abir Kanaan¹; Jennifer Tjia²; Terry Field²; Shawn Gagne³; Lawrence Garber³; Sarah Cutrona²; Leslie Harrold²; Peggy Preusse³; George Reed²; Jerry Gurwitz²

¹Massachusetts College of Pharmacy and Health Sciences; ²University of Massachusetts Medical School; ³Meyers Primary Care Institute

Background/Aims: Adverse drug events (ADEs), especially those that may be preventable, are among the most serious concerns regarding medication use in older persons. The purpose of this study was to describe the incidence, severity and preventability of ADEs occurring within 45 days post-hospitalization in an ambulatory geriatric population. **Methods:** We studied 1000 consecutive discharges of patients aged 65 and older who received medical care from a large multispecialty medical group in Central Massachusetts. Discharges were excluded if the discharge diagnosis was psychiatric or if discharges were not to home. Three clinical pharmacist investigators reviewed the ambulatory records of each discharged patient to identify drug-related incidents occurring during the 45-day period post hospital discharge. Drug-related incidents were presented to a pair of physician-reviewers who independently classified incidents as to whether an adverse drug event was present, the severity of the event, and whether the event was preventable. When the physician-reviewers disagreed on the classification of an incident, they met and reached consensus; consensus was reached in all instances where there was initial disagreement. **Results:** There were 242 ADEs identified, of which 35% (n = 84) were considered preventable. Of the preventable ADEs, 63% (n = 53) were categorized as significant, 32% (n = 27) were serious, and 5% (n = 4) were life-threatening. Nearly half of all ADEs occurred within the first two weeks following discharge. **Conclusions:** Adverse drug events are common and often preventable among older persons in the ambulatory setting. The substantial portion of serious events that were considered preventable suggests opportunities for improving care during the post-hospital discharge period.

Keywords: Adverse Drug Event; Geriatrics

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PS3-6:

Blood Safety Continuous Active-Surveillance Network Feasibility Evaluation (Blood-SCAN)

Meghan Baker¹; Michael Nguyen²; Jerald Mullersman²; Jillian Lauer³; Craig Zinderman²; Karen Riedlinger⁴; Cynthia Nakasato⁵; Elizabeth Chrischilles⁶; Crystal Garcia³; Carolyn Balsbaugh³; Madhavi Vajani³

¹Harvard Medical School, Brigham and Women's Hospital; ²Food and Drug Administration; ³Harvard Medical School; ⁴Kaiser Permanente Northwest; ⁵Kaiser Permanente Hawaii; ⁶University of Iowa

Background/Aims: In 2011, the US Food and Drug Administration (FDA) created the Blood Safety Continuous Active-Surveillance Network (Blood-

SCAN), the first nationwide active surveillance system for monitoring the safety of FDA-regulated blood components and blood-derived products. Blood-SCAN employs the Mini-Sentinel Distributed Database (MSDD) which contains 126 million individuals within 17 Data Partners. Blood-SCAN is intended to augment the existing safety surveillance system and improve US biovigilance efforts. As a first step in creating Blood-SCAN, we assessed the feasibility of using the current MSDD to evaluate blood component and blood-derived product exposures and related health outcomes.

Methods: The assessment consisted of 4 activities: (1) an expert working group identified 20 blood components and blood-derived products and 10 health outcomes of interest (HOIs) to evaluate the data available in the MSDD, (2) a literature scan was conducted to identify electronic algorithms to capture these product exposures and HOIs, (3) HOI and exposure frequencies were tabulated using established Mini-Sentinel programs, and (4) structured discussions were conducted with all Mini-Sentinel Data Partners to assess the availability, content, and quality of data within their databases. **Results:** Claims codes were available for all of the blood components and blood-derived products, and many of the claims codes for blood-derived products were sufficiently specific to allow analyses by product manufacturer, fulfilling an important regulatory need. Adequate counts of exposures to immunoglobulin products indicate the potential for future surveillance studies on these products. MSDD analyses suggest that blood-derived products are captured effectively in outpatient settings but not in inpatient settings, limiting the scope of therapeutic indications that can be assessed. Blood component exposures are also captured in outpatient settings within the MSDD; however, because most transfusions occur in inpatient settings, these data may not be completely representative of the patient population, reason for transfusion, and dose. Most Data Partners reported no current ability to access inpatient blood component exposures through existing claims data streams. **Conclusions:** The current MSDD supports safety surveillance for a variety of blood components and blood-derived products in the outpatient setting. Expanding the MSDD to include inpatient data streams will ensure that Blood-SCAN achieves its full potential.

Keywords: Blood; Active-Surveillance; Mini-Sentinel

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PS3-7:

Improving the Detection of Drug-Induced Liver Injury with an Electronic Causality Assessment Tool

Janet Shin¹; Christine Hunt²; Fang Niu¹; Julie Papay²; Rich Murray³; Gregory Powell²; Steph Reisinger³; T. Craig Cheatham¹

¹Kaiser Permanente Southern California; ²GlaxoSmithKline; ³United BioSource Corporation

Background/Aims: The Roussel Uclaf Causality Assessment Method (RUCAM) is the most commonly used algorithm to evaluate drug-induced liver injury (DILI). It uses 7 criteria to assess causality and provides a total score ranging from -9 to 15, which is stratified into 5 categories describing the likelihood of DILI ranging from 'Highly Probable' to 'Excluded'. An electronic RUCAM (eRUCAM) was previously developed at Kaiser Permanente Southern California (KPSC) with the Observational Medical Outcomes Partnership and GlaxoSmithKline to detect DILI in an electronic medical record. The study aim was to identify areas of improvement for future iterations of the eRUCAM based on results from chart review. **Methods:** The eRUCAM was used to score potential cases of DILI identified in patients taking at least one of 14 drugs commonly associated with DILI. Patients were required to be at least 18 years of age and have 12 months of continuous membership plus drug benefit prior to drug initiation. A random sample of 20 patients without pre-existing liver disease was selected for chart review to perform quality assurance on the programming specifications and identify areas for improvement in the algorithm. A hepatologist manually scored each patient using the paper-based RUCAM. Scores from the hepatologist were compared to those from the eRUCAM using the Wilcoxon signed rank test. Qualitative findings from chart review regarding future improvements to the algorithm were summarized. **Results:** The total score from eRUCAM was identical to those of the hepatologist for 6 cases (30%). The absolute difference between the hepatologist and eRUCAM scores was greatest for Criteria 5, which assesses non-drug causes of liver injury (P = 0.001). Differences in scores were not statistically significant for other remaining criteria. Issues that were identified with Criteria 5 included:

inadequate time windows for identifying non-drug causes, failure to consider laboratory results (e.g., hepatitis serology), incomplete lists of ICD-9 codes for non-drug causes, and inability to extract information from physician progress notes. **Conclusions:** Future work related to the development of an electronic causality assessment tool based on the RUCAM should focus on improving Criteria 5 by using wider time windows to identify non-drug cases, laboratory results, and natural language processing.

Keywords: Drug-Induced Liver Injury; Roussel Uclaf Causality Assessment Method; Electronic Medical Records

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PS3-8:

Identification of Severe Cutaneous Reactions and Genomic Risk Factors in Users of Antiepileptic Drugs

Mia Gallagher¹; Maryam Asgari²; Joseph Boscarino³; James Burmester⁴; Lee Cromwell¹; Melody Eide⁵; Heather Feigelson⁶; Jennifer Kuntz⁷; Lois La Grenade⁸; Eric Macy⁹; David Margolis¹⁰

¹Kaiser Permanente Southeast; ²Kaiser Permanente Northern California; ³Geisinger Health System; ⁴Marshfield Clinic / Security Health Plan of Wisconsin; ⁵Henry Ford Health System / Health Alliance Plan; ⁶Kaiser Permanente Colorado; ⁷Kaiser Permanente Northwest; ⁸Food and Drug Administration; ⁹Kaiser Permanente Southern California; ¹⁰University of Pennsylvania

Background/Aims: Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are rare, life-threatening cutaneous reactions that may occur following exposure to certain medications, including antiepileptic drugs (AEDs). No reliable incidence estimates of SJS/TEN for US populations have been calculated since the introduction of ICD-9 codes specific for SJS/TEN in October 2008. This study seeks to: 1) investigate the incidence of SJS/TEN using retrospective case identification, 2) test the positive predictive values of ICD-9 codes prior/post-October 2008, and 3) pilot the feasibility of conducting a population-based pharmacogenomic study. **Methods:** With input from dermatologists, pharmacoepidemiologists, and pharmacogeneticists at FDA, HealthCore, and 11 HMORN sites, we validated ICD-9 codes associated with SJS/TEN in 3 cohorts: 1) patients with an inpatient code of 695.1x between 01/01/01–12/31/08; 2) codes 695.12–695.15 from 08/01/08–08/31/12; and 3) codes 279.5, 279.51, 279.53, 695.8, 695.81, 693.0x, 694.8x, 694.4x or diagnosis codes 692.9, E85x.x-E858.9, 693.8, 692.89, 695.89, 695.1x, 692.3x, 695.0 in an inpatient setting plus specific drug exposure between 01/01/01–08/31/12. We extracted a standardized clinical and laboratory dataset. A sample of 265 potential SJS/TEN cases at 5 sites was selected for adjudication by medical chart review. Statistical models will be created to estimate the total number of SJS/TEN cases at all sites based on the positive predictive value of the case identification algorithm. To pilot the feasibility of a pharmacogenomic study, we estimated the number of living cases available, contacted potential cases, and tested 100 random DNA samples from the Marshfield Clinic Personalized Medicine Research Project for HLA-A*3101/HLA-B*1502 alleles to establish a control source. **Results:** A total of 54,049 patients was identified from electronic records: 3,058 in cohort 1; 1,733 in cohort 2; and 49,258 in cohort 3. Potential cases (n = 9) were identified and will be invited to participate in a genetic study. Among the 100 samples genotyped, 5 were positive for HLA-A*3101 and none were positive for HLA-B*1502, consistent with known frequencies. **Conclusions:** We identified a large number of potential SJS/TEN cases using code-based algorithms that will be used to determine the incidence of these events and to plan a larger follow-up study of specific AEDs and genomic factors.

Keywords: Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis; Antiepileptic Drugs

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Prevention and Wellness / Obesity / Behavior Change

A3-4:

Recreational Physical Activity and Gestational Weight Gain in Women with Gestational Diabetes

Samantha Ehrlich¹; Barbara Sternfeld¹; Kirsten Unger Hu¹; Monique Hedderson¹; Ashley Mevi¹; Susan Brown¹; Ai Kubo¹; Assiamira Ferrara¹

¹Kaiser Permanente Northern California

Background/Aims: Excess gestational weight gain (GWG) is associated with several adverse perinatal outcomes, including increased infant size at birth and postpartum weight retention. These outcomes are particularly problematic for women with gestational diabetes (GDM), who are already at risk for delivering a large infant and developing type 2 diabetes later in life. Participation in recreational physical activity during pregnancy may mitigate excess GWG, but the association has not been previously examined in a large cohort of women with GDM. **Methods:** This study utilized baseline data from a clustered randomized intervention trial (Gestational Diabetes Effects on Moms – the GEM study) conducted at Kaiser Permanente Northern California (KPNC) to estimate the association between participation in recreational physical activity and GWG among women with GDM. Women with multiple fetuses and those on bed rest were excluded, leaving a final analytic cohort of 790 women. Recreational physical activity (walking quickly for fun or exercise, jogging, exercise classes, swimming, dancing, yoga, pilates, weight lifting/resistance exercises and team sports) in the past 3 months was assessed using the Pregnancy Physical Activity Questionnaire (PPAQ). Data on gestational weight gain per week (kg) up until the time of the oral glucose tolerance test (OGTT) was abstracted from the electronic medical record. **Results:** Compared to those who reported not participating in any recreational physical activity, women who reported participating in some recreational physical activity had a significantly reduced risk of GWG in the upper quartile [GWG >0.39 kg (0.85 lb.) per week]; this association was independent of age, prepregnancy body mass index (BMI), race-ethnicity, and parity [OR = 0.63 (95% CI 0.41-0.97)]. In sensitivity analyses limited to women who completed the PPAQ within 6 weeks (n = 448) and 4 weeks (n = 234) of the OGTT, the associations were more pronounced [OR = 0.42 (95% CI 0.24-0.72) and OR = 0.28 (95% CI 0.12-0.63), respectively]. No dose-response relationship was observed between high (>1.07 MET hours per day) and low (≤1.07 MET hours per day) recreational physical activity. **Conclusions:** Participation in recreational physical activity during pregnancy may mitigate high GWG in women with GDM.

Keywords: Physical Activity; Gestational Weight Gain; Gestational Diabetes
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C4-4:

Prevalence of Hazardous and Harmful Drinking Patterns Among Older US Adults: Data from the 2005-2008 NHANES

Sarah Knowles¹; Sandra Wilson¹; Qiwen Huang¹; Arlene Fink²

¹Palo Alto Medical Foundation for Healthcare, Research and Education; ²University of California, Los Angeles

Background/Aims: While heavy drinking and alcohol abuse pose clear health risks, even moderate alcohol consumption may be risky or frankly harmful in older adults with certain co-morbidities, medication use, symptoms, and functional limitations. However, national estimates of the prevalence of risky alcohol use by older adults are presently unavailable. **Methods:** In 2005-2008 National Health and Nutrition Examination Survey respondents 65 years and older, reported alcohol consumption was considered alone and in the context of the individual's co-morbidities, medication use, and physical and psychological functional status to classify their consumption as Harmful (already experiencing alcohol-related health problems), Hazardous (at risk of alcohol-related health problems), or Healthwise, using the classification algorithm of the Alcohol-Related Problems Survey (ARPS), a screening tool for older adults. Weighted national prevalence estimates and adjusted prevalence odds ratios in subgroups defined by sex, age, and race/ethnicity were calculated using survey statistical procedures. **Results:** Among older adult drinkers, 85.5% (14,341,531 of 16,771,716; 95% Confidence Interval [CI]: 83.2%, 87.9%) consumed alcohol within