of 690,321 children aged 2-19 years who were enrolled in an integrated prepaid health plan between 2007/2008. Percentile of body mass index [BMI]-for-age was calculated according to the sex-specific 2000 Centers for Disease Control and Prevention growth charts to assign weight class (normal weight, overweight, moderate and extreme obesity). **Results:** GERD was diagnosed in 1.5% of boys and 1.8% of girls ($P < 0.001$). Moderate and extreme obesity were associated with 16% and 32% higher odds for GERD in children aged 6-11 years compared to normal weight, respectively (OR 1.16, 95%-CI 1.02-1.32 and 1.32, 95%-CI 1.13-1.56). In children aged 12-19 years, moderate and extreme obesity were associated with 16% and 40% higher odds for GERD compared to normal weight, respectively (OR 1.16, 95%-CI 1.07-1.25 and 1.40, 95%-CI 1.28-1.52). Obesity was not related to an increased odd for GERD in children aged 2-5 years of age. **Conclusions:** In conclusion, extreme obesity in youth may increase GERD risk by up to 40%. Increasing obesity epidemic among youth may further contribute to an increased incidence of other diseases associated with GERD such as esophagitis and esophageal adenocarcinoma. Early screening of obese youth and treatment of GERD symptoms may help to avoid persistence of GERD into adulthood.

Keywords: Gastroesophageal reflux disease, Childhood obesity, Early obesity screenings

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PS2-21:

Patient Response to a Clinical Study for Diabetes Education Interventions: Demographic Differences Between Patients Who Enrolled and Those Not Interested in Participating

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Background and Aims: The Journey for Control of Diabetes: the IDEA Study, a randomized clinical study, is evaluating the effectiveness of an interactive, group-based learning experience using Conversation Maps™. Patients with uncontrolled diabetes were sent letters describing the study and subsequently contacted to assess eligibility and interest. Recruitment, estimated to take 5 months, was extended to 11 months due to difficulties in obtaining a committed group of eligible participants. Because of these recruitment difficulties, we examined differences between the enrolled subgroup and those who indicated they were not interested in participation in an attempt to identify patient characteristics of those who enrolled. **Methods:** Of the 4197 patients sent recruitment letters, 286 enrolled, 1345 were not interested in participating, and the remaining 2567 were unable to participate for a variety of reasons. Demographic variables of interest were gender, age, ethnicity and A1C level. We used a software tool, GUESS, which utilizes surname to determine ethnicity. A logistic regression model predicting enrollment was fit to the data using a binary logit link. **Results:** The model had a strong predictive accuracy with a likelihood ratio test resulting in $p < 0.0001$. To further dissect the significance of the variables, individual maximum ratio tests were performed. Age was a very significant predictive variable ($p < 0.0001$) with older subjects less likely to enroll. Gender was not significant ($p = .14$). The subjects' A1C prior to recruitment was also significant ($p < 0.0001$) with the highest enrollment in the groups close to goal ($A1C < 7.5$) and those with very high A1C's ($A1C > 9.0$). Finally, ethnicity was significant ($p = 0.0005$) with white non-Hispanics more likely to enroll than Hispanics. **Conclusions:** Several demographic variables were used to assess their impact on a person's desire to participate in the IDEA Study. Of those who met the eligibility criteria, enrolled people were younger, fewer were Hispanic, and more had A1C's either almost at goal or extremely out of control. A better understanding of which potential participants may be more willing to enroll in a study could provide insight into more effective recruitment.

Keywords: IDEA study patient participation, Recruitment strategies, Effective recruitment

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PS2-22:

Pre-Operative Diabetes is Associated With Poor Weight Loss Outcomes Following Roux-en-Y Gastric Bypass Surgery

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Background and Aims: Identification of preoperative predictors of weight loss after Roux-en-Y gastric bypass surgery may lead to better clinical management. The purpose of this study was to identify whether any clinical variables were different in patients with the best versus worst weight loss outcomes at 24 months following RYGB. **Methods:** Patients who were recruited were enrolled in the Bariatric Surgery Program of the Geisinger Clinic Center for Nutrition and Weight Management. Only Caucasian patients with a BMI greater than 35 kg/m² who underwent primary Roux-en-Y gastric bypass were included in the analysis. An analysis of available data on more than 200 clinical variables related to medication use, co-morbidities, and baseline laboratory and survey data was performed to determine whether any differences present between the 150 patients who lost the most weight and the 150 patients who lost the least. Chi-square tests and Wilcoxon Rank sum tests were used after a Bonferroni correction. **Results:** A total of 1001 patients (80% female) with a mean age of 46.5 years and a mean initial BMI of 50.2 mg/kg were studied. The diagnosis of diabetes was almost twice as frequent in patients who lost the least weight ($p < 0.0001$). Initial weight, BMI, excess body weight, and waist circumference were also statistically higher in patients who lost the least weight ($p < 0.0001$), although the differences were likely not clinically significant in patients of this BMI range. Post-operatively, the percentage of patients with pre-operative diabetes that had a hemoglobin A1c over 6.5% was approximately 2-fold higher in the group who lost the least weight. **Conclusions:** A pre-operative diagnosis of diabetes and post-operative elevation of hemoglobin A1C levels were more prevalent in those patients with the poorest weight loss outcomes following Roux-en-Y gastric bypass surgery.

Keywords: Roux-en-Y gastric bypass surgery, Pre-operative diabetes, Poor weight loss outcomes

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PS2-23:

Prevalence of Extreme Obesity in Southern California

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Background and Aims: Specific weight goals and treatment options for extremely obese children and adolescents have been suggested. The objective of this study is to provide current estimates of the prevalence of extreme obesity in a large multiethnic youth cohort. **Methods:** In a cross-sectional study, measured weight and height were extracted from electronic medical records of 710,949 patients aged 2-19 years (87.8 % of eligible patients) who were enrolled in an integrated prepaid health plan between January 1, 2007 and December 31, 2008. Prevalence of extreme obesity was defined as body mass index [BMI]-for-age = 1.2×95 th percentile according to the sex-specific 2000 Centers for Disease Control and Prevention growth charts or BMI = 35 kg/m². **Results:** Extreme obesity was observed in 7.3% of boys and 5.5% of girls. The prevalence first peaked at about 10 years of age with a bimodal distribution in girls (second peak at 18 years, P for sex $\times$ age interaction = 0.036). The prevalence of extreme obesity varied among ethnic/racial and age groups with highest prevalence in Hispanic boys (up to 11.2%) and Blacks girls (up to 11.9%). In 12-19 year olds, the prevalence of obesity class 3 (BMI 40-49.9 kg/m²) and class 4 (BMI = 50 kg/m²) was 1.8% and 0.2%, respectively, with the highest prevalence in Blacks (3.5%) compared to Whites independent of sex ($P = 0.001$). **Conclusion:** Extreme obesity in

Southern California youth is a serious issue and frequently observed at relatively young age. The shift towards extreme body weights is likely to cause an enormous burden of adverse health outcomes once these youth grow older.

Keywords: Extreme Obesity in Southern California youth, Obesity treatment, Adolescent health outcomes

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HMORN Infrastructure

PS1-27:

Use of Tumor Registry to Obtain Family History Information

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Background: The Human Genome project has revolutionized the field of medicine to move toward personalized medicine. The family history is a screening tool to identify families at risk for common conditions allowing for personalized care. For breast cancer syndromes, genetic testing, counseling and prophylactic treatment are available. While there are data about the efficacy and clinical utility of the family history, there are areas that still need investigation. Does obtaining the family history lead to patient recommendations? Do patients FDA's Mini-Sentinel Initiative: The HMORN's Role.

In May 2008, the FDA Commissioner announced FDA's intention to create the Sentinel Initiative. The Sentinel Initiative is an effort by the FDA to create a coordinated national electronic medical product safety surveillance system. The Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated FDA develop methods to obtain access to disparate data sources and to establish an active post-market risk identification and analysis system linking and analyzing data from multiple sources. The law sets a goal of 25 million patients under surveillance by July 1, 2010, and 100 million patients by July 1, 2012. With the funding and support provided by FDAAA, the FDA laid out the vision for Sentinel Initiative. In September 2009, the FDA awarded a single contract to a consortium of 28 institutions led by the Harvard Medical School Department of Population Medicine at the Harvard Pilgrim Health Care Institute, including 13 HMORN members (all Kaiser Permanente plans, Group Health Cooperative, Lovelace Clinic Foundation, Myers Primary Care Institute, Marshfield Clinic Research Foundation, HealthPartners Research Foundation and Henry Ford Health Services), CIGNA, Humana, WellPoint [HealthCore] and Tennessee's Medicaid system, comprising ~60 million covered lives. Additional data resources include the HMORN's ambulatory electronic medical records linked to enrollment and claims data for ~10 million patients; inpatient electronic medical records (EMRs), including blood product use from 88 adult and pediatric hospitals (approximately half are Kaiser plans); plus device and disease registries. Mini-Sentinel will create a 'laboratory' for developing and evaluating safety surveillance scientific methodologies and offers FDA the opportunity to evaluate safety issues in existing automated healthcare data system(s) while learning about the barriers and challenges inherent in these activities. The collaboration provides FDA with a public-private solution that leverages the strengths of the private sector and academia. Over the next five years, this collaboration will work with FDA to create the foundation for the Sentinel Initiative's long-term goal of setting up a coordinated national post-market safety surveillance system.

Keywords: Tumor registry, Family history screening, Sentinel Initiative

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PS1-28:

Kaiser Permanente Center for Effectiveness and Safety Research

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Background: Kaiser Permanente has inaugurated an interregional research initiative focusing on comparative effectiveness and safety (CESR). All eight regions will partner to take advantage of their large and diverse populations, exceptional scientists, and extensive data resources. **Aim:** To provide HMORN collaborators: (1) an understanding of where CESR is and where it will be going; (2) a description of CESR governance rules; and, (3) a guide to pathways for partnerships with collaborators.

Keywords: Inter-regional research, Comparative effectiveness and safety

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PS1-29:

Resources to Facilitate Multi-site Collaboration: the PRIMER Research Toolkit

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Background and Aims: The national research enterprise has typically functioned in a decentralized fashion, resulting in duplicative or undocumented processes, impeding not only the pace of research, but diffusion of established best practices. To remedy this, many long-standing networks have begun capturing and documenting proven strategies to streamline and standardize various aspects of the research process. The project, "Partnership-driven Resources to Improve and Enhance Research" (PRIMER), was funded through the Clinical and Translational Science Awards (CTSA) initiative to leverage the collective expertise from two networks: the HMO Research Network and Practice Based Research Networks (PBRNs). Each network has a shared goal of propagating research resources and best practices. **Methods:** We created and distributed an online survey to 92 CTSA and PBRN representatives in March, 2009 to define critical needs and existing resources that could inform a resource repository. The survey identified barriers and benefits to forming research partnerships, and assessed the perceived utility of various tools that could accelerate the research process. The study team identified, reviewed and organized tools based on the typical research trajectory from design to dissemination. **Results:** Fifty-five of 92 invitees (59%) completed the survey. Respondents rated the ability to conduct community-relevant research through true academic-community partnerships as the top-rated benefit of multi-site research, followed by the opportunity to accelerate translation of research into practice. The top two perceived barriers to multi-site research were 'funding opportunities are not adequate (e.g., too few, not enough to support true collaborations), and 'lack of research infrastructure to support [all] partners (e.g., no IT support, IRB, dedicated research staff). Respondents' ratings of the utility of various tools and templates was used to guide development of an online repository: www.ResearchToolkit.org, which is comprised of over 120 distinct resources. **Conclusions:** We are disseminating the ResearchToolkit website via academic and media channels, and identifying options for making it a sustainable resource. Given the dynamic nature of the research enterprise, maintenance and accuracy of a web-based resource is challenging. Still, the positive response to the toolkit suggests that there is high interest in sustaining it. We will demonstrate the Toolkit as part of this conference.

Keywords: Partnership-driven Resources to Improve and Enhance Research, Research processes, Forming research partnerships

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