OBJECTIVES: To compare the post-cessation weight gain following the use of different FDA-approved smoking cessation medication strategies among obese smokers. **METHODS:** A retrospective cohort study was conducted using the General Electric (GE) electronic medical record database (2006 – 2011). The cohort consisted of obese adult smokers newly initiating use of an FDA-approved smoking cessation medication. The outcome variable was weight change at 3, 6, or 12 months following the first prescription. Descriptive analyses and t-tests were conducted to assess the frequency distribution of sample characteristics and their association with the post-cessation weight change. Multivariate linear regression models were carried out to identify predictors of weight change at 3, 6, and 12 months after assessing the model assumptions, with the use of multiple imputation to account for missing data for covariates. **RESULTS:** The mean weight change was 1.14 (±17.26), 2.06 (±18.46), and 3.06 pounds (±20.78) at 3-, 6-, and 12-month, respectively. Obese smokers who were prescribed varenicline had a mean weight gain of 1.18 (±16.75), 2.14 (±18.14), and 3.12 pounds (±20.89) for each follow up, while those who were prescribed bupropion had a mean weight gain of 0.23 (±25.90), 0.22 (±25.32), and 1.47 pounds (±17.50), respectively. Descriptive analysis showed that obese smokers taking bupropion had less weight gain than those taking varenicline at each follow up; however, this association was not statistically significant after accounting for all covariates (β = -1.16 [-3.84 – -1.53] month 3; β = -3.16 [-6.54 – -0.21] month 6; β = -0.18 [-3.92 – 3.55] month 12). Significant predictors of weight change included: being diagnosed with diabetes, hyperlipidemia, taking weight-influencing medications, and smoked >= one cigarette/day. **CONCLUSIONS:** While patients using bupropion gained slightly less weight compared to those using varenicline, type of smoking cessation medication was not a significant predictor of weight change in the multivariate linear regression model.

CE2

DETERMINING COMPARATIVE EFFECTIVENESS BENCHMARKS FOR EMERGING TREATMENTS FOR HEPATITIS C VIRUS (HCV) INFECTION IN THE SINGLE ARM STUDY DESIGN SETTING

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OBJECTIVES: Several single arm phase III trials have recently completed or are currently ongoing in various HCV patient populations. The goal of this study is to use meta-analysis to determine the rates of sustained virologic response 24 weeks after treatment (SVR24) required for a new HCV treatment to declare superiority over standard of care (SOC) in the setting of a single arm trial where there is no network of treatment arms that can bridge between the new treatment and SOC. **METHODS:** We conducted a literature search for studies of standard dose peginterferon-alfa plus ribavirin (IFNα+R) as well as telaprevir (TPV) or boceprevir plus IFNα+R among HCV-infected adults and synthesized the results by performing a meta-analysis based on a Bayesian hierarchical model. We then introduce hypothetical single arm trials into the meta-analysis and determine the efficacy relative to SOC. Benchmarks are the SVR24 rates required to have at least a 95% probability of superiority to SOC. **RESULTS:** Benchmarks for a new treatment studied in a single arm trial of 400 patients relative to TPV+IFNα+R are 84%, 72%, and 54% in genotype 1a or 88%, 78%, and 62% in genotype 1b across treatment naïve, previous partial responders, and previous null responders respectively. Benchmarks for a new treatment studied in a single arm trial of 200 treatment naive patients relative to IFNα+R are 91%, 88%, and 69% in genotypes 2, 3, and 4 respectively. Benchmarks were insensitive to the sample size of the single arm trial. **CONCLUSIONS:** Our meta-analysis method extends indirect treatment comparison methodology to make comparative effectiveness inference for treatments studied in single arm phase III trials. Our broad based meta-analysis platform is flexible enough to make inference across patient populations.

CE3

COMPARATIVE EFFECTIVENESS OF SURGERY AND DRUG THERAPY IN NEWLY DIAGNOSED PATIENTS WITH CAROTID ARTERY STENOSIS

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BACKGROUND: Randomized clinical trials comparing surgery to drug therapy in newly diagnosed carotid stenosis patients, are less relevant today with advancement in drug therapy and increased utilization. Effectiveness of surgery versus current drug therapy in carotid artery stenosis patients hasn`t been studied in real world practice. **OBJECTIVES:** Compare time to death and other cerebrovascular events in newly diagnosed patients treated with carotid endarterectomy (CEA), carotid stenting (CAS) or drug therapy **METHODS:** Patients were identified using the Humana dataset for the years 2007 – 2012. The date of first diagnosis of carotid stenosis is set as the patient's index date if followed by a confirmatory carotid duplex ultrasound. An episode of treatment consisted of the 6 months prior to and 12 months post index date. Propensity score matching was employed to match patients using drug therapy to surgery patients. Surgery patients using CAS or CEA were matched separately. Cox proportional hazards models and logistic regression were used to estimate the impact of surgery versus medications, and surgery type using only surgery patients. Outcomes were defined as time to death and time to stroke or other cerebrovascular event. **RESULTS:** 103,703 newly diagnosed patients were identified over age 50. A total of 4921 patients received surgery of which 476 died (9.7%). Of the 98,782 patients who received only drug therapy, 7395 died (7.4%). Initial Cox and logistic models of death using the propensity score matched samples found no statistically significant risk associated with surgery versus medical management. Similarly, we found no statistically significant effects of CAS vs CEA in patients treated with a surgical intervention. **CONCLUSIONS:** Current clinical studies suggest stand-alone drug therapy as treatment of choice. Initial analysis of this study suggests no real world difference in effectiveness of drug therapy and surgery or between surgery types for carotid stenosis patients.

CE4

ASSESSMENT OF COMPARATIVE EFFECTIVENESS RESEARCH METHODS GUIDANCE DOCUMENTS

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OBJECTIVES: Comparative effectiveness research (CER) methods guides have recently been released by two main CER funding agencies, the Agency for Healthcare Research and Quality (AHRQ) and the Patient-Centered Outcomes Research Institute (PCORI). We evaluated and compared these methods guides to identify consensus in recommended CER methodologies. **METHODS:** CER methods recommendations from each document were assessed and areas of overlap were identified. **RESULTS:** The PCORI Methodology Report (November 2013) made 40 CER methods recommendations. The AHRQ User Guide (January 2013) made 57 CER methods recommendations. These methods recommendations related to the following 10 methods topics: study protocol and design, patient-centeredness, heterogeneity of treatment effect (HTE), causal inference, diagnostic tests, systematic reviews, comparator selection, study variables, data concerns, and statistical analysis. Of the 57 specific recommendations made in the AHRQ guide, 24 (42%) were also made in the PCORI guide. For example, both documents support identifying gaps in evidence, explaining specific impacts of the research, developing a formal study protocol, and assessing the adequacy of data sources. Furthermore, these documents both support rigorous measurement and analysis of confounders, precisely defining exposures and outcomes, and pre-specification of data analysis plans. Both documents also supported the selection of appropriate comparators and identifying and assessing participant subgroups. Non-overlapping recommendations mostly addressed more specific methodology topics and issues including missing data, data registries, data networks, and patient-centeredness. These unique recommendations highlight areas for further debate and discussion regarding best practices in CER methods. **CONCLUSIONS:** Based upon our synthesis of CER methods recommendations, agreement was high between the AHRQ and PCORI guides. We identified a list of core CER recommendations based on the overlap of these two methods guides which may aid researchers in the conduct of CER.

MEDICAL DEVICE & DIAGNOSTIC RESEARCH STUDIES

MD1

THE IMPACT OF MEDICAL DEVICE USE ON HOSPITAL COSTS

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OBJECTIVES: Medical device utilization and price are often cited as major cost drivers of hospital care. Few sources quantify the specific % medical device spend (utilization x price) of hospital care. The purpose of this study was to assess the contribution of medical device spending in the hospital setting, as well as the impact of hospital facility type on medical device spending. **METHODS:** A third party vendor, MOSS Adams (Seattle, WA) compiled data from the 2009 U.S. Healthcare Cost Report Information system (HCRIS). HCRIS data is reported by providers through Medicare Administrative Contractors. The cost report contains information such as facility characteristics, utilization data, cost and charges by cost center (all payers). 5,452 hospitals reported medical device spending costs with total expenditures of approximately $681 billion dollars. Costs were divided into implant costs, billable supply costs, labor, capital, and all other costs including infrastructure. Total medical device costs were estimated from implant and billable supply costs. Stratification included teaching/non-teaching, sole-community/ non-sole, and urban/rural hospitals. **RESULTS:** Labor and other costs represented the largest expenditure, whereas total medical device costs represented 3.6% (median) of costs. Urban hospitals spent more than rural hospitals on medical devices (5.5% vs. 2.3%, $p<0.0001$). Teaching hospitals also spent more than non-teaching hospitals on medical devices (6.2% vs. 3.1%, $p<0.0001$). There were no differences in medical device spend for sole community/non-sole community hospitals (3.6% each). When reviewing a subset of hospitals (n=644) reporting on implantable medical device use, median total medical device spend was 7.1% including 3.5% on medical device implants. **CONCLUSIONS:** These data suggest that total spending on medical devices, including implantables in the hospital setting represents a small spend of overall hospital expenditures. Future studies should examine the role of medical device utilization in overall hospital expenditures.

MD2

COST-UTILITY OF TRANSCATHETER AORTIC VALVE IMPLANTATION COMPARED WITH SURGICAL AORTIC VALVE REPLACEMENT IN HIGH-RISK PATIENTS WITH SEVERE AORTIC STENOSIS: A PROSPECTIVE OBSERVATIONAL STUDY

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OBJECTIVES: Transcatheter aortic valve implantation (TAVI) is a treatment option for patients with severe symptomatic aortic stenosis ineligible for surgical treatment (AVR). However, the role of TAVI in patients who are potential surgical candidates remains controversial and its cost-effectiveness has only been assessed using data from one single randomized trial. We sought to estimate the cost-utility of the two existing transfemoral TAVI modalities (Edwards SAPIEN (ES) and