Research Objective: Comparative effectiveness studies that rely on health insurance claims are difficult to interpret because they lack important clinical information, and could therefore result in biased inferences. The objective of this study was to provide clinical information that would assist in interpreting the results of a comparative effectiveness study of selective serotonin reuptake inhibitors.

Study Design: Retrospective analysis of medical and pharmacy insurance claims with supplemental chart review. Abstracted data elements included the chief complaint and reason for the visit, diagnoses, current medications, signs and symptoms of depressive disorder based on DSM-IV criteria, the provider’s assessment and disposition, side-effects, and symptoms of depressive disorder based on DSM-IV criteria.

Population Studied: The claims analysis included 43,921 patients in six health plans across the US with new episodes of antidepressant treatment with escitalopram or an alternative SSRI (citalopram, fluoxetine, or paroxetine) between July 1, 2002 and July 1, 2005. From this universe of patients, we selected a subset for chart abstraction. Our final sample included 457 patients initiating treatment with escitalopram (183) or alternative SSRIs (254), including 169 patients who discontinued treatment two months after initiating treatment (escitalopram 68, other SSRIs 101) and 288 patients who continued treatment at two months (escitalopram 115, other SSRIs 153).

Principle Findings: Overall, 30.2% of the sample had four or more symptoms recorded, consistent with DSM-IV criteria for Major Depressive Disorder, while 38.2% had two or three symptoms, consistent with criteria for dysthymia or minor depression. Having more symptoms was significantly associated with continuing treatment at 2 months ($\chi^2=89.9$, df=3, p<0.0001). While few patients had complete remission, about two-thirds of patients with a recorded clinician assessment improved within three weeks of starting treatment. Improvement based on clinician assessment ($\chi^2=13.3$, df=2, p<0.001) or symptom counts as recorded at follow up ($\chi^2=117.6$, df=3, p<0.0001) was significantly associated with continuing treatment. In the claims analysis compared with patients taking other SSRIs, patients on escitalopram were more likely to continue treatment at 2 months ((OR = 1.30; 95% C.I. 1.24 – 1.35; p < 0.01). In the chart analysis escitalopram patients who continued treatment at two months were more likely to have improved based on their physician’s assessment ($\chi^2=8.1$, df=3, p=0.05) compared to patients who started on other SSRIs. Few side effects were recorded for any patients.

Conclusion: Our analysis of pharmacy claims suggests that patients initiating treatment on escitalopram were more likely to continue treatment at two months. The results of the chart analysis suggest that the claims-based study may have underestimated escitalopram’s clinical effectiveness because it failed to take into account possible differences in clinical response associated with adherence behavior.

Implications for Policy, Practice or Delivery: While limited by small sample size and missing data not recorded in the charts, our results suggest that lack of clinical information resulted in a conservative estimate of the relative effectiveness of escitalopram compared to alternative antidepressants. Such possible bias should be taken into account when interpreting the results of claims-based comparative effectiveness studies.

Funding: Forest Research Institute
HTE weak or nonexistent but authors call for differential treatment or more research); or understated (evidence for HTE strong or moderate but no call for differential treatment or more research).


**Principle Findings:** Among 87 RCTs, 53 claimed prespecified covariates examined for HTE. Only 29 studies gave specific reasons for inclusion, 17 for all covariates and 12 for some. Reasons were substantive in 22 and statistical in 7. Studies (percentages) were classified as showing strong (7), moderate (13), weak (29), or negligible (18) evidence for clinicostatistical divergence, while 33 percent could not be classified due to lack of data on stratum-specific effect sizes or statistical tests. Authors interpreted their own studies (percentages) as showing: evidence for HTE sufficient to support differential treatment (11); evidence sufficient to warrant more research but not differential treatment (36); evidence of absence of HTE (23); or no interpretation (30). HTE-related evidence was overstated in 23 and understated in 8 studies.

**Conclusion:** Our findings reveal frequent inconsistencies in the design (lacking prespecification or rationale), reporting (unreported data), and interpretation (understating or overstating) of HTE analyses in high-profile general medical journals.

**Implications for Policy, Practice or Delivery:** HTE analysis can be a powerful tool in individualizing care in diverse populations. To address inconsistencies in HTE assessment that may limit its usefulness, authors’ should prespecify covariates, use tests for heterogeneity or interaction, and clearly report subgroup analysis design, results, and interpretations.

**Funding:** Pfizer

### Comparing the Effectiveness of Carotid Stent Systems Versus Endarterectomy

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**Research Objective:** Carotid stent systems (CSS) were FDA-approved in 2004 as an alternative treatment to vascular surgery (i.e., carotid endarterectomy) for carotid arterial stenosis. Randomized clinical trials have reported conflicting results of the effectiveness of CSS versus endarterectomy, and concern persists that CSS patients have worse outcomes. Accordingly, Medicare covered this technology beginning on March 17, 2005, but only for CSS performed at hospitals that met rigorous clinical standards. Only 724 hospitals met these standards in 2005, compared to the over 2100 U.S. hospitals that provided carotid endarterectomy. Our objective was to compare short term clinical outcomes among similar Medicare beneficiaries in non-experimental clinical settings who received either CSS or endarterectomy after the March, 2005 coverage decision.

**Study Design:** We examined Medicare hospital claims (MEDPAR) from April-December, 2005 (the initial period of Medicare coverage for CSS) for all hospitalizations in which either carotid stenting or carotid endarterectomy occurred. We then fit a propensity score logistic regression model in which receipt of CSS versus endarterectomy was the dependent variable, and patient demographics, Elixhauser comorbidities, the presence of stroke or transient ischemic attack on admission, and hospital characteristics (e.g., academic, urban, admission volume) were independent variables. Based on this model's results, we then matched CSS and endarterectomy patients by propensity score. Finally, we fit a proportional hazards survival model comparing overall survival between CSS and endarterectomy patients, with survival determined based on death dates reported in the Medicare enrollment database.

**Population Studied:** Medicare beneficiaries receiving invasive carotid procedures from Apr-Dec, 2005.

**Principle Findings:** We identified 4,268 CSS recipients and an identical number of matched endarterectomy patients who had received carotid procedures between April and December, 2005. We observed no statistically significant difference in survival between CS and CE patients (mortality hazard ratio for CS = 1.12, 95% confidence interval 0.90-1.39). The finding was consistent across quintiles of propensity score. There was also no difference in survival within areas (hospital referral regions) that were heavy users of CSS, or within areas that had relatively low utilization of CSS.

**Conclusion:** In a propensity-score matched analysis of Medicare beneficiaries receiving CSS versus beneficiaries receiving endarterectomy, we observed no evidence of inferiority of CSS in comparison with carotid endarterectomy for survival after carotid revascularization.

**Implications for Policy, Practice or Delivery:** This observational study, with over 20 times the number of patients, yielded findings similar to those of the SAPPHIRE randomized controlled trial. Our study provides evidence that in the carefully selected clinical settings at which Medicare beneficiaries can receive CSS, outcomes of care are comparable to those achieved by endarterectomy.

**Funding:** Institute for Health Technology Studies

### Sixty-Four-Slice Computed Tomography of the Coronary Arteries: Cost-Effective Analysis of Patients Presenting to the Emergency Department with Low Risk Chest Pain

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**Research Objective:** To use a computer model to evaluate the cost-effectiveness of 64-slice multidetector computed tomography of the coronary arteries (MDCT) in comparison to...
current risk stratification strategies for evaluation of low risk chest pain patients in the emergency department (ED).

**Study Design:** A decision analytic model was developed to compare health outcomes and costs that result from three different risk stratification strategies for low risk chest pain patients in the ED: stress ECG testing after observation unit (OU) care, stress echocardiogram after OU care, and MDCT with no OU care.

**Population Studied:** Three low risk patient populations were modeled with the prevalence of symptomatic coronary heart disease (CAD) being: very low risk: 2%, low risk: 6% (base case), and moderate risk: 10%. Outcomes were measured as quality adjusted life years (QALYs). Incremental cost-effectiveness ratios were calculated for comparisons among each regimen. We estimated prevalence of CAD, sensitivities, specificities, morbidity, mortality, costs, and utilities based on the published literature with the exception of OU hospital costs and cost of MDCT, which came from the authors’ institution. Sensitivity analyses were conducted to test the robustness of the results to assumptions regarding the characteristics of the risk stratification strategies, costs, utility weights and likelihood of events. TreeAge Pro 2006 Suite (TreeAge Software, Inc, Williamstown, Massachusetts) was used to calculate costs and outcomes.

**Principle Findings:** In the base case, the average costs and QALYs for each risk stratification strategy were: MDCT arm $2,779 and 22.17 QALYs, stress echo arm $3,154 and 22.09 QALYs, and stress ECG arm $3209 and 22.07 QALYs. The MDCT risk stratification arm dominated (less costly and more effective) both stress echo and stress ECG arms in each of the risk strata evaluated. The thresholds where the MDCT arm remained a cost-saving strategy compared to the other risk stratification strategies were: cost of MDCT < $1875; cost OU care > $1336; prevalence of CAD < 60%; and MDCT specificity > 65%.

**Conclusion:** In this computer-based model analysis, the MDCT risk stratification strategy is less costly and more effective than both OU based stress echo and stress ECG risk stratification strategies in chest pain patients presenting to the ED with low to moderate prevalence of CAD.

**Implications for Policy, Practice or Delivery:** This computer-based model convincingly shows the MDCT as less costly and more effective through a wide range of input parameters, however further randomized multicenter studies must be done to evaluate true cost-effectiveness. This preliminary computer-based model analysis can be used as a framework for a future prospective study.

**Funding:** AHRQ

**Is Acute Rehabilitation more Cost-Effective than Sub-Acute Rehabilitation?**

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**Research Objective:** To compare the costs and discharge functional status for VA stroke patients who receive rehabilitation in acute versus subacute rehabilitation units.

**Study Design:** Prospective observational cohort study using chart-abstracted clinical data merged with VA Decision Support System (DSS) cost data. We fitted reduced-form OLS and generalized linear models with log links and gamma distributions to explain VA cost differences between acute and subacute rehabilitation units over the index rehabilitation stay, short-term (index discharge to three months), and long-term (three months to two years). We also examined outcomes models using total and motor Functional Independence Measure (FIM) scores at discharge. Our cost and outcome models controlled for exogenous influences on costs and function, including functional status at admission to rehabilitation (as measured by the total and motor FIM scores), sociodemographics (age, race, and marital status), previous stroke, type of rehabilitation unit (acute vs. subacute), and VA medical center.

**Population Studied:** Our sample consisted of 481 confirmed VA stroke patients who received rehabilitation services on acute or subacute rehabilitation units at 23 VA Medical Centers nationwide during FY 02-03.

**Principle Findings:** Rehabilitation on an acute rehabilitation unit was associated with statistically significant lower costs of the index rehabilitation stay compared to rehabilitation on a subacute rehabilitation unit. These reduced costs are substantial, averaging almost $6,000 per discharge. In addition, rehabilitation on an acute rehabilitation unit produced higher total and motor discharge FIM scores by +8.8 and +7.3 FIM points, respectively, indicating substantially higher functional status at discharge, all other factors constant. However, we were unable to detect statistically significant differences in short-term, long-term, and total costs between acute and subacute rehabilitation units.

**Conclusion:** We find that the costs of the index rehabilitation stay are lower for VA stroke patients seen on acute rehabilitation units compared to subacute rehabilitation units. In addition, we find that patients treated on acute rehabilitation units have higher total and motor discharge functional status, all other factors constant. While prior research has suggested better compliance with stroke rehabilitation guidelines in acute units compared to subacute units, the present results suggest that acute rehabilitation units yield higher functional status at discharge and are less costly, at least initially.

**Implications for Policy, Practice or Delivery:** These results have critical implications for the VA given the trend toward replacing acute rehabilitation units with subacute units. Over the past decade, the VA has closed 34 acute rehabilitation units and has opened 18 subacute rehabilitation units. The VA may want to undertake a careful review of the clinical and economic implications of its recent restructuring of inpatient rehabilitation. For stroke patients, such restructuring may not be advisable on either clinical or economic grounds.

**Funding:** VA