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AN APPROACH TO GENERALIZE CLINICAL TRIAL RESULTS TO NON-STUDY POPULATIONS FOR COST-EFFECTIVENESS EVALUATIONS—THE CASE OF THE COLLABORATIVE ATORVASTATIN DIABETES STUDY (CARDS)

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OBJECTIVES: In The Collaborative Atorvastatin Diabetes Study (CARDS), atorvastatin 10 mg reduced CHD (36%) and stroke (48%) in primary CVD prevention patients in the UK with type 2 diabetes compared to placebo. However the transferability of the clinical and economic benefits for treatment algorithms and populations beyond the UK are not known. Despite the fact that relative risk reductions are similar between different populations, baseline risk varies according to population. This study outlines an approach to estimate baseline risk in a non-study diabetes population and calculate cost-effectiveness therein using the trial treatment effect. **METHODS:** A Markov model was developed using the UKPDS risk function to model the incidence of CHD and stroke assuming "no treatment". The model allows re-calibration of risk for non-study diabetes populations by substituting the UKPDS population, individual, and mean risk factors with those of the population of interest. The treatment effect is determined by multiplying estimated incidence rates by the hazard ratio observed for CHD and stroke in CARDS. Competing hazards are used to estimate non-CV mortality. Model endpoints include event rates, estimated costs, survival and QALYs gained associated with atorvastatin 10 mg treatment. **RESULTS:** Validity was tested by substituting the CARDS trial population individual and mean risk factors with those from the UKPDS risk function. The re-calibrated UKPDS risk function resulted in four-year "no treatment" CHD predicted risk of 6.70% vs. actual risk of 6.52% (97.4% of predicted value). The corresponding stroke incidences were 2.37% and 2.48% (104.8% of predicted value). **CONCLUSION:** This approach improves the external validity by using the annual adjustment of baseline risk and maintains the internal validity by using observed clinical trial treatment effects. The re-calibrated model accurately predicted the incidence rates observed in the CARDS trial and enhances generalizability of clinical results to a non-study, non-UK population of diabetes patients.

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CARDIOVASCULAR DISEASE—Patient Reported Outcomes

PCV49

PATIENT ADHERENCE TO AHA GUIDELINES PRE- AND POST AMI

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OBJECTIVE: For patients that suffered from an acute myocardial infarct (AMI), the 2001 guidelines of the American Heart Association (AHA) recommend indefinite treatment with 1) statins; 2) beta-blockers; 3) ace inhibitors or, if not tolerated, angiotensin-receptor blockers; and 4) aspirin. This study investigates how the recommendations are followed by patients and physicians as observed in pharmacy claims. **METHODS:** Retrospective, claims database study performed using data from a large health insurer in the Mid-Atlantic region. Patients were selected if they had an initial AMI episode (ICD-9 Code: 410. × 1) between January 1, 2002 and August 31, 2004. These patients were then matched to their pharmacy claims between January 1, 2001 and December 31, 2004. For each patient, adherence is defined as the proportion of days covered. **RESULTS:** A total of 1958 patients were identified. The mean age was 60 years and 58% were male. Overall post-AMI adherence rates with recommended therapy were as follows: 1) statins: 43%; 2) beta-blockers: 45%; 3) ace-inhibitors or ARB's: 36%. Requiring at least 6 months (1 year, 2 years) of follow-up data post discharge, adherence rates drop to 1) statins: 42% (40%, 35%); and 2) beta-blockers: 43% (41%, 35%), ace-inhibitors or ARB's: 35% (33%, 29%). A total of 13% of patients can be defined as adherent to the AHA recommendations, filling more than 80% of all recommended prescriptions, whereas 19% of patients have filled zero of the recommended prescriptions. Notably, 12%-15% of patients were receiving at least one of the drugs even before their first AMI. In this subgroup adherence rates decrease after the AMI by 1) statins: 20%; and 2) beta-blockers: 22%, ace-inhibitors or ARB's: 30%. **CONCLUSION:** The AHA post-AMI treatment recommendations are followed only by a minority of patients. In addition, mean adherence rates drop after the AMI if the patient was receiving prophylactic therapy.

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STATIN THERAPY PERSISTENCE IN A MANAGED CARE POPULATION

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OBJECTIVE: To describe persistence patterns in the use of statin therapy in a U.S. managed care population. **METHODS:** Three years of pharmacy and eligibility claims data from a managed care health plan with over two million members were utilized. Patients with at least one paid statin prescription claim in 2002 were identified. Those with continuous eligibility for six-month pre- and two-year post-index statin prescription and no statin claims in a six-month washout period were included. Patients with statin prescriptions filled at mail order pharmacies were excluded. Individuals were followed for 2 years and proportion of days covered (PDC) was calculated at 6, 12, 18, and 24 months to assess medication persistence. Days supplied for overlapping refills and last censored fill were adjusted to account for changes in statin therapy, early refill, and days supplied beyond the study period. **RESULTS:** A total of 14,047 patients met the study criteria. Twenty percent were greater than 65 years of age, 56% were male, 20.5% had at least one diabetes-related prescription, 63.5% had atorvastatin as index drug, and median age was 55. Mean PDC at 6, 12, 18, and 24 months were 0.63, 0.54, 0.49, and 0.47 respectively. At 6 months, only 42.1% of the study population remained adherent with their statin therapy, with PDC of at least 80%. By 24-months, only 26% were adherent. Patients taking diabetes related medications had higher prevalence of adherence than their non-diabetic counterparts after 6 months and this trend continued for all subsequent time intervals over two years ($p < 0.002$). **CONCLUSIONS:** Adherence rate of statin therapy remains suboptimal in this managed care population. Programs to maintain patients on statin therapy are essential to improve health outcomes and reduce drug wastage costs due to therapy non-compliance.

PCV51

OUTPATIENT DISCONTINUATION AND RESTARTING OF POST-MYOCARDIAL INFARCTION BETA-BLOCKER THERAPY

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OBJECTIVE: To estimate the one-year cumulative incidence of discontinuation of post-MI beta-blocker therapy after hospital discharge and the one-year cumulative incidence of restarting therapy following discontinuation. **METHODS:** We conducted a retrospective, population-based, inception cohort study among all enrollees (n = 1334) of Group Health Cooperative (GHC, a health maintenance organization) aged 30–79 years who survived a first hospitalized MI during 1986–1996 (mean follow up 1.4 years) and were discharged from the hospital on beta-blocker therapy. Using the GHC computerized pharmacy database, we calculated the duration of therapy by assuming subjects were on average 80% compliant with each beta-blocker prescription fill. We considered subjects to have discontinued therapy on the 60th consecutive day they were without medication and to have restarted therapy on the first day they obtained a prescription fill following discontinuation. In sensitivity analyses, we varied when we considered subjects to have discontinued therapy (i.e., on the 30th and the 90th consecutive day without medication). We estimated the cumulative incidence using failure time analyses. **RESULTS:** By one year post-discharge, 511 subjects discontinued therapy; the cumulative incidence of discontinuation was 39.0% (95% CI: 36.3, 41.6). The cumulative incidence increased to 50.7% (95% CI: 47.9, 53.3) and decreased to 33.4% (95% CI: 30.9, 36.0) when our discontinuation definition required 30 and 90 days without medication, respectively. By one year post-discontinuation, the cumulative incidence of restarting was 42.7% (95% CI: 39.1, 46.2). The cumulative incidence of restarting increased to 52.9% (95% CI: 49.6, 56.1) and decreased to 32.0% (95% CI: 28.4, 35.6) when our discontinuation definition required 30 and 90 days without medication, respectively. **CONCLUSIONS:** Our results indicate that patients are likely to restart post-MI beta-blocker therapy after having discontinued it. Studies considering only time to first discontinuation may be oversimplifying the long-term utilization patterns of therapy by misclassifying patients who subsequently restart.

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MEDICATION ADHERENCE: PREDICTORS AND IMPACT ON HOSPITALIZATION RISK

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OBJECTIVES: The objectives of this study were to investigate factors associated with adherence to medications for diabetes and hyperlipidemia, and to assess the impact of adherence on hospitalization risk. **METHODS:** Administrative claims and cash prescriptions data from Wolters Kluwer Health's IHR database were utilized. This extensive database provides longitudinal prescription history on about 157 million patients, prescription and physician services' history on about 35 million, and prescription, physician services' and hospitalization history on about 6 million patients. Adult patients initiating therapy for either condition between July 2003 and June 2004 and having claims activity in the 12 months period prior to and following the index prescription were identified. A Medication Possession Ratio °Ý 80% was considered to be indicative of adherence. Hospitalization risk was defined as the probability of being admitted to a hospital in post-index period. Logistic regression was employed to identify predictors of adherence including: age, gender, payer type, charlson index, chronic disease score, presence of disease conditions and pill burden. Relationship between hospitalization risk and adherence was also modeled using logistic regression after adjusting for the same covariates described previously. **RESULTS:** About 48.4% of the 116,607 diabetes patients and 38.5% of the 285,853 hyperlipidemia patients were adherent. Predictors of improved adherence in both disease groups were male gender, being a Medicaid beneficiary, a higher chronic disease score and lower pill burden. Comorbid diseases including AMI, CAD, CHF, stroke and hyperlipidemia were associated with higher adherence in the diabetes group. For both disease conditions, hospitalization risk was significantly higher in non-adherent patients [Diabetes OR: 1.47 ($p < 0.0001$), Hyperlipidemia OR: 1.24 ($p < 0.0001$)]. **CONCLUSIONS:** Adherence to therapy is suboptimal for diabetes and hyperlipidemia, two chronic diseases that are major drivers of health care spending. Furthermore, non-adherent patients faced a significantly higher risk of hospitalization compared to adherent patients.

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STATIN NONCOMPLIANCE AFTER CHD HOSPITALIZATION AND SUBSEQUENT HOSPITALIZATION AMONG NEW STATIN USERS

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OBJECTIVES: Examine the relationship of statin noncompliance to subsequent hospitalization among new statin users after coronary heart disease (CHD) hospitalization. **METHODS:** Medstat Marketscan 1999–2002 databases including inpatient, outpatient and pharmacy claims were utilized for this study. The first statin prescription fill date within six months of CHD hospitalization was identified as the index date. The sample consisted of adults who had no statin use during the year prior to the CHD hospitalization and had at least 2-years continuous