BPSZ-BLISS is naturalistic and designed to obtain outcomes data with minimum impact on BPSZ and clinical processes. METHODS: Data are entered, using an Interactive Voice Response System (IVRS), by MDs at baseline and at usual care visits up to 12 +/- 2 months; subjects report self-measured BP, persistence, compliance, and treatment satisfaction at 3, 6, and 12 months. Final cohort characteristics are reported. RESULTS: After 18 months, 10,067 eligible US subjects have been enrolled by 734 IRB approved MDs. Subjects are 48% male, mean aged 56 (SD = 13) years, and 27% newly diagnosed with hypertension. Most are Caucasian (70%), or African-American (22%); only 5% are Hispanic, or other (3%) ethnicity. Median diastolic and systolic BP qualifying subjects (without diabetes or kidney disease) for study enrollment were 98 mmHg and 134 mmHg respectively. In chronic hypertensives, most common anti-hypertension medications prior to baseline were angiotensin receptor blockers (ARB) or ARB combination (38%), calcium channel blockers (CCB) or CCB combination (32%), beta blockers (BB) or BB combination (27%), or angiotensin converting enzyme inhibitors (ACE I) or ACE I combination (24%), and diuretics (18%). Automated IVRS validations have maintained data quality (<5% error on key variables). Completion of patient follow-up is scheduled for June 2008. CONCLUSION: An innovative design and automated data management and quality control methodologies have been shown to be feasible to collect MD and patient data in a nationwide health education program. Baseline study data are available for comparison with other real-world datasets.

TRENDS IN MORTALITY, LENGTH OF STAY AND READMISSIONS AMONG PATIENTS WITH ACUTE STROKE AT THE NATIONAL HEALTHCARE GROUP, SINGAPORE, 2000–2006
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OBJECTIVE: To describe the trends of intra-hospital mortality, length of stay (LOS) and readmissions of patients with acute stroke at the National Healthcare Group (NHG), Singapore, 2000–2006. METHODS: All patients aged 21+ years discharged with a primary diagnosis of stroke (ICD9CM 430-435) from the three public hospitals in NHG from January 2000 to December 2006 were studied. Data extracted from computerized datamart included demographic characteristics; co-morbid conditions; and outcomes of interest; i.e. LOS, intra-hospital mortality, and readmissions within one, three, and six months of discharge. Patients were stratified into hemorrhagic stroke (HS), ischemic stroke (IS) and transient ischaemic attack (TIA). Data were analysed by one-way ANOVA, logistic regression and chi-square test using SPSSv15. RESULTS: During the period 2000–2006, there was a total of 22,428 deaths and discharges of patients with acute stroke. Prevalence of hypertension was highest in HS (>60%), with the rate decreasing significantly from 2000–2006 (p = 0.001). However, the prevalence of dyslipidaemia was highest among IS, with a significant increase in rate in all during the period in all types of stroke (p < 0.001). Overall, HS was associated with highest intra-hospital mortality rate (95%CI: 22.3%–24.3%) and longest average LOS (95%CI: 17.1–18.7 days). A significant increasing trend in average LOS (p < 0.001) was noted in both HS and IS. Readmissions within the 1-month, 3-month, and 6-month all decreased significantly over the period (p < 0.001). The readmission rates within 1-month for HS and IS were higher than that of TIA, while there were no difference in readmission rates within three (5%) and six (6%) months for all stroke types. CONCLUSION: More studies into the causes of increased LOS should be carried out. Targeted primary interventions are needed to address the high rates of hypertension among those with IS and the increasing trend in dyslipidaemia among all types of stroke.

EFFECTS OF INTENSIFYING LIPID-ALTERING THERAPY ON CHD EVENTS IN A SECONDARY PREVENTION POPULATION WITH HIGH NON-HDLcholesterol
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OBJECTIVE: Many patients with dyslipidemia fail to reach treatment goals on the lowest dose of a single drug. We assessed the effects of intensified lipid-modifying therapies on the expected rates of coronary events among a cohort of 10,000 people aged 50+ years with established CHD and high non-HDL-cholesterol levels. METHODS: This model-based analysis used data from the recent SEACOAST clinical trial and a published equation for secondary prevention of CHD from the Framingham Heart Study (FHS), based on the total-cholesterol/HDL-C ratio, to calculate the expected number of CHD events over five years. Finding from the SEACOAST trial showed that patients treated with a fixed-dose extended release niacin/simvastatin (ERN/S) combination had significant improvements in non-HDL-C, HDL-C, and triglyceride levels when compared to patients treated with simvastatin therapy alone. Age, sex, and coronary risk-factor data for patients with CHD and non-HDL-C cholesterol >130 mg/dl were obtained from 1999–2002 NHANES. The drugs of interest included simvastatin alone and ERN/S. The scenarios of interest reflected increasing the dose of simvastatin or adding ERN to simvastatin. RESULTS: We estimated that 1741 CHD events would occur over five years among 10,000 patients treated with 20 mg of simvastatin. The number of CHD events would decrease by 8.9% with 1000/20 mg of ERN/S. Relative to a maximum dose of 80 mg of simvastatin, intermediate (1000/40 mg) and maximum doses (2000/40 mg) of ERN/S would reduce CHD events by 4.9 and 11.1 percentage points, respectively. CONCLUSION: Based on this FHS risk model for a secondary prevention population with elevated non-HDL cholesterol, intensifying lipid-modifying therapy with selected fixed-dose ERN/S combinations may reduce the number of CHD events relative to the use of simvastatin monotherapy. Confirmation of the predicted clinical events of the fixed-dose combination in a secondary prevention patient population would be useful.

ASSESSMENT AND QUANTIFICATION OF THE BENEFIT RISK RATIO OF ROSUVASTATIN AND ATORVASTATIN FROM A META-ANALYSIS OF HEAD TO HEAD RANDOMISED CONTROLLED TRIALS
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OBJECTIVE: Statin therapy is fundamental in cardiovascular disease prevention. Benefit of statin therapy is proportional to low-density lipoprotein cholesterol reduction and no threshold has been identified as a limitation below which benefit is reduced. Serious side-effects are infrequent, but the adverse experience with the agent Cerivastatin justifies scrutiny of the relationship between therapeutic effect and the risk of side-
effects. Meta-analysis of head-to-head comparisons represents a robust method for anticipating the benefit and risk of an emergent statin, such as rosuvastatin, in comparison to an extensively studied agent such as atorvastatin. METHODS: A systematic literature search to identify head to head clinical studies of R and A was conducted. Data were available for 30 comparisons of 1:1 dose ratios (R10mg vs. A10mg etc), 24 comparisons of 1:2 dose ratios (R5mg vs. A10mg etc) and six comparisons of 1:4 dose ratios (R5mg vs. A20mg etc). Treatment difference in benefit (% Low Density Lipoprotein-cholesterol [LDL-c] reduction) and risk (odds ratios for myalgia, serious adverse events and withdrawals due to adverse events, elevated Alaninaminotransferase [ALT] [3xULN], and Creatine Kinase [CK] (>10xULN), were estimated by meta-analysis (random effects) and presented in benefit risk planes. RESULTS: Analysis of 25 studies (~24,000 pts) demonstrated rosuvastatin to be significantly more efficacious than atorvastatin, for LDL-c reduction, at 1:1 and 1:2 dosage ratios. There were no significant differences between rosuvastatin and atorvastatin, at any dose ratio, for i) withdrawals due to adverse events, ii) myalgia, iii) serious adverse events, iv) death, v) ALT >3x upper limit of normal (ULN), and vi) creatine kinase (CK) >10xULN. CONCLUSION: Alt 1:1 and 1:2 dose ratios, significant additional reductions in LDL-c are obtained by rosuvastatin at a comparable risk of the adverse events presented.

METHODS FOR INDIVIDUALIZING THE BENEFIT AND HARM OF WARFARIN
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OBJECTIVE: To extend beyond the current approach of predicting warfarin benefit and harm independently in new atrial fibrillation (AF) patients by refining methods to identify predictors of the four combined benefit/harm outcome groups—i) no stroke/no bleed; ii) no stroke/bleed; iii) stroke/bleed; iv) no stroke/no bleed. METHODS: We analyzed patient-level data from the Atrial Fibrillation Investigators RCT database (n = 9155) and an observational database of AF patients managed by Kaiser Permanente Colorado (n = 5475). We classified patients based on the four benefit/harm outcome groups and applied decision tree modeling (CART) and polytomous logistic regression (PLR) to identify patient factors predicting each outcome group. Statistical significance was set at alpha = 0.05. RESULTS: CART and PLR consistently identified age and warfarin use as predictors for all outcome groups. Both techniques identified predictors of stroke/no bleed and no stroke/bleed not previously included in AF stroke and bleed risk-assessment tools that predict these outcomes independently (e.g., CHADS2 and HEMORR3HAGES). Methodology strengths and limitations were evident. CART provides a visual algorithm approach to risk. However, there is a lack of quantitative measurement (e.g., odds ratios [OR], confidence intervals) for predictors. While PLR results were thorough and predictor parameter estimates could be converted to ORs to indicate strength of association, the result of PLR is number-intensive. To calculate a patient’s probability for each of the four outcome groups, the patient’s data must be inputted into three separate equations. While both techniques can be used to calculate an individual patient’s probability for each outcome group, PLR likely has more scope for application in a clinical setting. Once refined, a clinical prediction rule could be created based on identified predictors and their ORs. CONCLUSION: While methods under study need further refinement, these individual patient data analyses provide a useful step forward in the movement towards evidence-based individualization of drug therapy.

ANGINA FOLLOWING REVASCULARIZATION—FREQUENCY, PATIENT CHARACTERISTICS AND TIMING
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OBJECTIVE: Angina is relieved by CABG, PCI and stenting procedures but reoccurs over time in a percentage of patients. Little is known about the frequency of recurrent angina following percutaneous and surgical procedures, the characteristics which put a patient at risk for recurrent angina and the timing of angina recurrence. METHODS: Patients enrolled in a large national managed care plan with a claim for a CABG, PCI or stent from January 1, 2003 to December 31, 2004 were selected if they were 35 or older, and enrolled one year prior and one year following their procedure. Patients were followed for one year after their index procedure for medication use, angina diagnosis by ICD-9 code and additional revascularization procedures. RESULTS: Following selection criteria 18,240 patients were eligible for analysis. The average age was 59 years, with 25% age 65 years and older. Most patients were male (78%). Of the 18,240 patients, 46% (8420) experienced angina (identified by angina diagnosis and/or two or more nitrate prescriptions) within a year following their index procedure. Of those patients experiencing angina, approximately a third (30%/2904) had another revascularization procedure following the angina diagnosis. The average time from initial procedure to second procedure, after angina diagnosis, was 73 days, although there is a wide range among patients (SD = 103 days). Risk factors for having angina following a revascularization procedure were younger age, female gender and having a PCI without a stent. CONCLUSION: Angina reoccurs in a considerable percentage of patients in the year following a percutaneous or surgical coronary procedure. A third of patients experiencing angina have a second procedure after experiencing recurrent angina.

EVALUATION OF RESISTANT HYPERTENSION IN A USUAL-CARE SETTING
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OBJECTIVE: Resistant hypertension is defined as the failure to reach blood pressure (BP) goals while treated at adequate doses with three or more antihypertensive agents (AHYs) where one is a diuretic. Clinical trials have found that 2–15% of treated patients have resistant hypertension. The exact prevalence of resistant hypertension in clinical practice is unknown. This analysis evaluates the prevalence of resistant hypertension in a real-world setting. METHODS: Hypertensive patients aged 18 and older were identified from the General Electric Electronic Medical Records (EMR) database during the period of November 1, 2002 to November 30, 2005. Resistant hypertension was defined as a blood pressure reading over 140/90 mmHg (130/80 mmHg for patients with diabetes or kidney disease) within one year after the last AHY agent was prescribed during a treatment observation window of November 1, 2003 to November 30, 2004. RESULTS: A total of 29,474 hypertensive patients were identified with an average age of 63.3 years (SD ± 13.3).