QUALITY OF ANTICOAGULATION CONTROL IN PATIENTS WITH ATRIAL FIBRILLATION MANAGED IN ROUTINE MEDICAL CARE IN THE UNITED STATES
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OBJECTIVE: To quantify the quality of anticoagulation control in routine medical care in the US: Long-term oral anticoagulation reduces the risk of ischemic stroke in atrial fibrillation but only if the international normalized ratio (INR) is tightly controlled between two and three. METHODS: A cohort study was carried out in practices with no staff dedicated to anticoagulation in four states. Charts of patients 18 years or older with atrial fibrillation and on an anticoagulant at least 60 consecutive days between July 1, 2001 and June 30, 2002 were reviewed by trained abstractors based on a standard form that covered monitoring tests, results and patient outcomes. Data were entered via touch-tone telephone (IVRS) and sensitivity analyses were performed. RESULTS: Charts of 686 patients from 11 practices (most internal or family medicine) and 67 practitioners were reviewed. Mean age was 75 years; 53% male; 79% received warfarin and mean interval between INR tests was 25 ± 22 days; 52% of physicians gave occasional face-to-face consultations in connection with INR tests and 78% used clinical judgment alone to adjust anticoagulant dose. A total of 53% of charts specified a target INR of 2–3; patients spent 42% of the time with INRs out of this range, most (27%) too low, yet the anticoagulant dose was adjusted only a third of the times that INRs were out of range. CONCLUSION: Concerted efforts to improve anticoagulation have been made for more than a decade. Nevertheless, despite increasing costs with frequent INR testing, there remain severe deficiencies in the routine management of anticoagulation in the US.

DATA CAPTURE VIA INTERACTIVE VOICE RESPONSE SYSTEM IN A NATIONAL STUDY OF ANTICOAGULATION MANAGEMENT
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Electronic data capture and remote study monitoring are being implemented more frequently instead of traditional paper format data collection methods for clinical trials. In outcomes research, electronic data capture is only beginning to be used; few studies report on the efficiency and feasibility of this technique. OBJECTIVE: To assess the use of a telephone-based interactive voice response data entry system (IVRS) used in a national chart review study of anticoagulation management. METHODS: Following a one day training, nurses abstracted chart data using a 68 question (mostly closed) paper questionnaire. Anonymized data were entered into the study database using a password-protected IVRS accessed using a nationwide toll-free telephone number available round the clock. RESULTS: Data entered by 10 study nurses were 100% complete for all 686 subjects enrolled at four study sites in four US States (CA, MA, IN, NC). Site initiated data corrections occur for only 5% of subjects. Time from database lock to a clean dataset was 10 working days. Mean data entry time per subject was 16 minutes (min = 1; max = 20) or 14 seconds per question. Key IVRS features designed to facilitate use (e.g., question repeat, invalid answer prompt and automatic re-entry to last question answered when entry was interrupted) all worked well. CONCLUSIONS: Data capture and remote study monitoring using IVRS is an efficient and accurate means of collecting detailed health economic data with a minimum of oversight.

COST-EFFECTIVENESS EVALUATION OF EPLERENONE IN PATIENTS WITH HEART FAILURE FOLLOWING AMI IN GERMANY
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OBJECTIVE: The EPHESUS study demonstrated that aldosterone blockade with eplerenone decreased mortality in patients with left ventricular systolic dysfunction (LVSD) and heart failure after acute myocardial infarction (AMI). The EPHESUS pharmacoeconomic analysis presented below was performed to evaluate the cost-effectiveness of eplerenone in the German setting. METHODS: A total of 6632 patients with LVSD and heart failure after AMI were randomized to eplerenone or placebo and followed for a mean of 16-months. The co-primary endpoints were all-cause death and the composite of cardiovascular death/cardiovascular hospitalization. The evaluation of resource use included hospitalizations, outpatient services, and medications. Survival beyond the trial period was estimated using data from the Framingham Heart Study, the Saskatchewan Health database, and the Worcester Heart Attack Registry. The incremental cost-effectiveness of eplerenone in cost per life-year and quality-adjusted life-year gained was estimated. RESULTS: The number of life-years gained with eplerenone was 0.1014 based on Framingham (95% CI: 0.0306–0.1740), 0.0636 with Saskatchewan (95% CI: 0.0229–0.1038) and 0.1337 (95% CI: 0.0438–0.2252) with Worcester survival estimates. Total costs were 961.2 € higher over the trial period in the eplerenone arm, due to drug cost. The incremental cost-effectiveness ratio was 9,173 € per life-year gained with Framingham (98.8% under 50,000 € per-life year gained), 14,627.8 € with Saskatchewan, and 6,955.6 € with Worcester survival estimates. CONCLUSION: Eplerenone is effective in reducing mortality and, in Germany, is also cost-effective in increasing years of life for patients with heart failure after AMI.

MODELING THE ECONOMIC CONSEQUENCES OF CARDIAC RESYNCHRONIZATION THERAPY IN THE UK
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OBJECTIVE: To assess the economic implications of implantation with a cardiac resynchronization device (CRT) versus optimum pharmacologic treatment (OPT) for NYHA class III or IV heart failure. METHODS: A discrete event simulation of the course of heart failure was used to compare 1000 pairs of identical patients—one receiving CRT, the other OPT—for two years, in terms of hospitalizations for heart failure, device-related complications, NYHA class, and QOL (mortality assumed equal). All input rates were derived by specific analyses of the data obtained in the Multicenter InSync Randomized Clinical Evaluation (MIRACLE). Changes in NYHA class were translated to QOL via the corresponding distributions of Minnesota Living with Heart Failure scores and the related utilities. Direct medical costs to the NHS, reported in 2002 British Pounds Sterling (£), dis-
counted at 6%/yrs, were obtained from HRG codes E18–19. Benefits were discounted at 1.5%. Extensive multivariate sensitivity analyses were done. RESULTS: In these patients with mean age of 64 yrs, 91% in class III, 23% dead at two yrs, CRT reduced hospitalization for heart failure by 42%, leading to total costs of £3,500 per patient vs. £3,000 with OPT. Based on 100 replications, mean improvement of 0.16 QALY (SD 0.009) is achieved with CRT at mean net cost of £526 (SD £167) per patient, a mean cost-effectiveness ratio of £3,379/QALY. Extensive sensitivity analyses revealed the greatest cost/QALY variability when the length of stay for heart failure was varied ± 25% (£562–£6,354). CONCLUSION: Despite the cost of implantation, cardiac resynchronization therapy decreases hospitalization and increases QOL sufficiently to be cost-effective in treating advanced heart failure.

PCV15

POTENTIAL MEDICAL COST OFFSETS OF TREATMENT WITH ISOISORBIDE DINITRATE PLUS HYDRALAZINE IN AFRICAN AMERICANS WITH HEART FAILURE

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OBJECTIVE: Combination therapy with isosorbide dinitrate and hydralazine was recently shown to significantly improve clinical and survival outcomes in African Americans with congestive heart failure (CHF). The objective of this analysis was to measure the potential economic impact of this combination in the US African American population with CHF. METHODS: The population of African Americans with heart failure was estimated from US Census Bureau and US NCHS 2002 NHANES data. We then aggregated and compared drug and hospital costs over a 10-month period (the duration of the trial) under a combination therapy scenario vs. a usual-care scenario. Costs were calculated in 2004 USD from the payer perspective. Cost of the generic combination drug regimen (40 mg isosorbide dinitrate and 75 mg hydralazine, three times daily) was calculated using the AWP. The rates of first hospitalizations for treated and untreated patients were drawn from the trial (24.4% of patients without drug combination and 16.4% with drug combination). Hospital costs were estimated based on Medicare reimbursement rates for DRG 127. RESULTS: The use of the drug combination resulted in a cost savings of over £270 million dollars for the entire population (n = 800,097), or $338 per person receiving the drug combination. Cost savings with the drug combination were realized over a wide range of clinical and cost parameters and assumptions. CONCLUSION: Usage of the isosorbide dinitrate and hydralazine combination in African Americans with heart failure can be expected to generate cost savings in addition to the significant clinical benefits of the drug combination. Further studies of the drug combination over longer time horizons, brand pricing (including pricing for a yet-to-be-approved combination pill), and consideration of other costs such as treatment of adverse events and physician fees will give a more complete picture of the benefits of the drug combination in this population.

PCV16

INCREMENTAL EFFECTS OF CONCURRENT PHARMACOTHERAPEUTIC REGIMENS FOR HEART FAILURE ON HOSPITALIZATIONS AND COSTS

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OBJECTIVE: To evaluate the incremental differences of concurrent and persistent use of angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, loop diuretics, and digoxin on the risk of hospitalization and total costs with heart failure patients enrolled in a managed care organization. METHODS: Retrospective database analysis of outpatients diagnosed with heart failure within a managed care organization covering 350,000 lives from January 1, 1997 to December 31, 1999. Linear and logistic regression models were used to examine the association between treatment regimens and all-cause hospitalizations or total direct medical costs after controlling for patient demographics, comorbidities, and other risk factors. RESULTS: Of the 1903 patients meeting inclusion and exclusion criteria, 33.2% (n = 615) were observed not to have received any ACE inhibitor, beta-blocker, loop diuretic, digoxin, or angiotensin-receptor blockers (ARB). Subsequent multivariate analyses indicated that the associated risk of one year, all-cause hospitalization was 2.5 times higher (p < 0.01) for patients taking none of these medications relative to the overall sample, followed by a 43.6% higher total health care costs (p < 0.01). Patients receiving three or more of the specific medications analyzed were associated with significant decreases in risk of one year all-cause hospitalization of approximately 80% (p < 0.01) and decreases in total costs of approximately 70% (p < 0.01) relative to those utilizing no therapy. CONCLUSION: This analysis appears to indicate that a substantial portion of heart failure patients may be receiving suboptimal pharmacotherapeutic care, resulting in a higher associated risk of hospitalization and increase in total health care costs. Conversely, patients that were adherent with concurrent medication therapies were associated with decreases in both hospitalizations and total costs. The implications of this research suggest that quality improvement initiatives seek to identify and manage those not being treated or adherent to established evidence-based care.

PCV17

CAREMARK CAREPATTERNS®HEART FAILURE HOME MONITORING PROGRAM IMPROVES PARTICIPANTS’ HOME MONITORING COMPLIANCE

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Caremark has developed an in-home program that monitors weight and symptoms using a telemonitoring device. The device includes a special scale and telephone. A registered nurse monitors for any changes in the participant and further assesses their condition. The goal of this program is to encourage participants to weigh daily to recognize early symptoms and to follow their physician. OBJECTIVE: To evaluate the effectiveness of the CarePatterns heart failure home monitoring program. METHODS: Participants were selected based on severity, not on dialysis, not in any other monitoring program, not going out of town, and fewer than 320 pounds. The objectives were to get participants to meet selected benchmarks after 60 days. These included daily weight taking, action plan, and when to call their physician, no changes in weight or symptoms in prior 28 days, and fewer than three Non-Compliance alerts in 28 days. RESULTS: In total, 100 participants enrolled, 51% male 49% female, mean age of 73. Seventy-seven individuals started daily weight taking. A total of 54, or 71%, of these participants met the graduation requirement. The retention rate for the CarePatterns Heart Failure program was 98% for the enrolled group and 80% for the non-enrolled group p < 0.05. 45 participants had an alert, resulting in 16 doctor visits, two emergency room visits and two hospitalizations, 32 participants did not have an alert.