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.

CARDIOVASCULAR DISEASE—Congestive Heart Failure/Heart Failure

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€ 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-