D plans in California were included if they had diabetes; signed up for Part D between November 15, 2005 and March 1, 2006; and had a drug coverage gap starting at $2,250. Entry and exit into the gap was determined using pharmacy databases. Beneficiaries hit the gap after incurring $2,250 in total drug costs; beneficiaries exited the gap after incurring $3,600 in out-of-pocket costs. **Results:** In 2006, 25% of the 45,732 beneficiaries reached the coverage gap and then paid the full price of their drugs. Only 1% of beneficiaries exited the gap and qualified for 'catastrophic' drug cost assistance. On average, diabetes beneficiaries incurred $1,942 in total drug costs during 2006. For beneficiaries who did not enter the coverage gap, total drug expenditures and out-of-pocket drug expenditures remained stable over the year. For the beneficiaries who fell into the drug coverage gap in 2006, total drug costs were much higher overall and decreased over the year as out-of-pocket expenses increased. **Conclusions:** This is the first examination of diabetic Medicare beneficiaries under the Part D program. Fewer entered the coverage gap than had been previously estimated. Those entering the gap, however, had lower subsequent monthly drug expenditures. Potential reasons for both include lower than expected drug prices or drug adherence and higher than expected use of less expensive drugs, such as generics. Future work will examine these alternative explanations and explore risk factors for entering the Part D coverage gap.

Cardiovascular Disease

Abstract C-D1-02

Disparities in Patients' Ability to Participate in a Web-Based Intervention to Improve Blood Pressure Control

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Background: Electronic medical records and Web communications bring new opportunities to provide healthcare. Still unknown is whether this type of care will improve health outcomes and its affect on utilization and costs. Care in this environment may also be limited by the 'digital divide' between users and nonusers of Web communications. 'Electronic Communications and Home Blood Pressure Monitoring (e-BP)' is a randomized controlled trial designed to test the effectiveness of home BP monitoring, Web communications (secure patient e-mail that interfaces with an electronic medical record shared between patients and providers), and pharmaceutical care to improve hypertension control. We describe the proportions and characteristics of hypertensive patients willing and able to participate in an electronic healthcare intervention. **Methods:** Patients with uncomplicated hypertension received mailed invitations, a telephone survey, and in-person visits to determine their eligibility and willingness to participate. Eligibility requirements included access to a computer, the Internet, and an e-mail address. We performed a cross-sectional study on the subset willing to answer the telephone survey (n=7286), evaluating demographic differences between three populations: (1) those ineligible due to at least one computer access reason; (2) those eligible based on computer access, but not enrolled in the study for other reasons; and (3) those eligible and enrolled. We ran Pearson's chi-square test to evaluate bivariate associations. All *P*-values were two-sided. **Results:** Of those answering the telephone survey, 78% had computer, Internet, and e-mail access. These patients were significantly more likely to be male ($P<0.001$), younger ($P<0.001$), Caucasian ($P=0.01$), more educated ($P<0.001$), employed ($P<0.001$), and with a commercial healthcare plan ($P<0.001$), but no more likely to have a home BP machine. Enrolled patients with computer access and uncontrolled hypertension were not more likely to be male, but otherwise they were similar to those with computer access but not enrolled for other reasons. **Conclusions:** Most patients we contacted with hypertension had computer, Internet, and e-mail access, but a 'digital divide' persists. Chronic disease disproportionately affects older people, racial minorities, and those with less education. If electronic healthcare is to be effective in improving chronic disease health outcomes, additional efforts will be required to include these patients.

Abstract C-D1-03

Atrial Flutter is an Independent Predictor of Increased Mortality During Long Term Follow-Up

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Background: Atrial flutter (Afltr) and atrial fibrillation (Afib) are the two cardiac arrhythmias most frequently encountered in medical practice. Unlike Afib for which epidemiologic data paved the way for clinical trials that subsequently revolutionized its treatment, little is known about the course of the estimated 200,000 new cases diagnosed with Afltr in the U.S. every year. The purpose of this investigation was to determine whether Afltr is an independent predictor of death. **Methods:** Using the Marshfield Epidemiologic Study Area, a database that captures nearly all medical care and deaths among its 58,820 residents, we identified all patients newly diagnosed with Afltr in the region from July 1, 1991, through June 30, 1995. Incident cases were age and gender matched with controls and all were followed prospectively. To minimize the potential contribution of associated comorbidities, the analysis was limited to incident Afltr cases without Afib and adjusted for 11 pre-existing risk factors selected *a priori*; age, gender, stroke, myocardial infarction, heart failure, hypertension, rheumatic heart disease, hyperlipidemia, chronic pulmonary disease, diabetes mellitus and thyroid abnormality. Multivariate Cox models were fitted to obtain hazard ratios and 95% confidence intervals. **Results:** A total of 1356 person-years of follow-up were completed in 76 patients and 76 controls. There were 54 deaths (71%) among Afltr group and 37 deaths (49%) among controls ($P=0.0079$). After adjustment, the risk of death among incident cases with Afltr was 1.5 times that of controls (Hazard Ratio=1.56; 95% Confidence Interval: 1.01-2.41, $P=0.04$). **Conclusions:** (1) Our data suggest that Afltr is an independent predictor of death. (2) Since Afltr can now be easily and safely cured in the outpatient setting in virtually all patients, if our findings can be reproduced in other populations, consideration should be given to conducting prospective randomized trials to determine whether eliminating Afltr can improve survival in these individuals.

IRB

Abstract C-D4-01

IRB Review of Multi-Institutional Research

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Statement of the Problem: Because IRB review of multi-institutional research can involve as many IRBs as there are institutions participating in the research, the process can be frustrating, time-consuming, and unnecessarily iterative for both IRBs and researchers, and can also possibly cause researchers to miss funding opportunities. **Definition of the Intended Outcome:** Among a network of 16 affiliated large organizations engaged in significant epidemiologic research, each with its own IRB, arrive at a method to improve the IRB review process of multi-institutional research, while at the same time, assuring that regulatory and policy requirements are met. **Description of Program:** Determine which group of low-risk data-only studies will be used to beta test the new approaches to IRB review of inter-institutional research. Communicate with involved researchers, IRB Chairs, and IRB Administrators to discuss the review process options to determine the approaches to be tested. Evaluate the processes used for the review of each study and modify process as appropriate for the next study. Inform Chairs and Administrators of the results of each test. Recommend an approach for adoption by all members of the network. **Evaluation Method:** Testing of procedures currently underway. **Suggestions:** When completed, this process may prove adaptable to others engaged in multi-institutional research review.