

An Economic Model of Stroke in Atrial Fibrillation: The Cost of Suboptimal Oral Anticoagulation

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Abstract

Using a disease model, the current economic burden of stroke in the 2.3 million US patients with atrial fibrillation was estimated, and potential savings in direct costs obtainable by optimization of oral anticoagulation were projected using a disease model. Cost estimates were based on published epidemiologic data on risks in 3 main prevention scenarios (ie, none or aspirin alone, warfarin in routine care, and warfarin in anticoagulation clinic settings) and 2003 Medicare cost data. According to the model described, the approximately 1.265 million (55%) patients currently not receiving prophylaxis, suffer 58 382 strokes annually with an associated total direct cost to Medicare of \$4.8 billion. For the 1.035 million receiving warfarin, 38 468 strokes are predicted every year, costing an estimated \$3.1 billion. If 50% of those not receiving warfarin prophylaxis were optimally anticoagulated, 19 380 emboli would be prevented and \$1.1 billion would be saved. If 50% of those currently receiving warfarin in routine medical care were optimally anticoagulated, 9852 emboli would be prevented and \$1.3 billion would be saved. The risk of bleeding increases in the first of these “what if” scenarios but drops substantially in the second. These estimates do not account for the costs of optimization. Given the continued underutilization and poor anticoagulation control observed with warfarin, despite 50 years of use and widespread awareness of its effectiveness, the feasibility of achieving the projected 50% increases in optimal usage is questionable. Although efforts to optimize warfarin use must continue, the best opportunity for Medicare or managed care organizations to reduce stroke rates and costs at magnitudes approaching those analyzed in this model may come with use of newer oral anticoagulants that are easier to manage.

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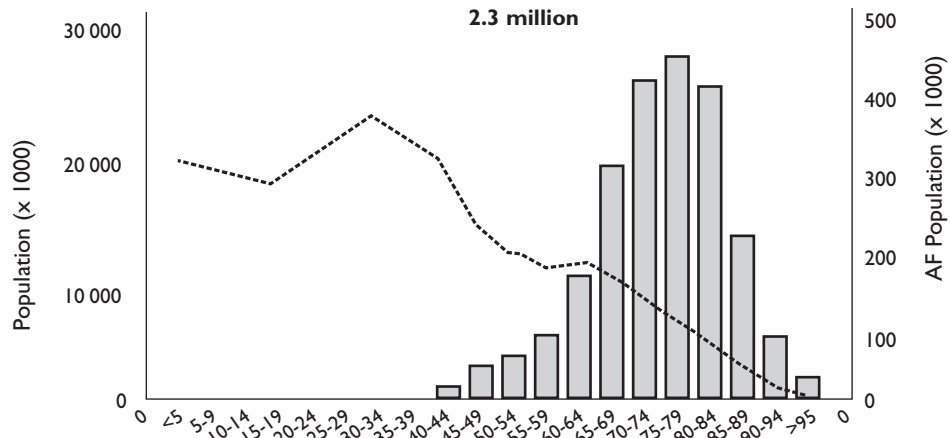
Atrial Fibrillation and Stroke: The Risks of Both Increase with Age

The prevalence of atrial fibrillation (AF) in the United States is estimated to be about 2.3 million.^{1,2} This rapid and unpredictable beating of the atria is often found in people with other heart disease, particularly ischemic or hypertensive. Accordingly, the prevalence increases dramatically with age, from about 0.1% in those younger than age 55, to 5.9% in those older than 65 years, and to 10% after age 80 years.^{2,3} Thus, most cases of AF occur in the Medicare-aged population (**Figure 1**), with a median age of 72 years, and the number of people in the age group continues to expand. The absolute number of these individuals at increased risk of stroke is expected to more than double during the next 20 years as the population ages.³

In addition to symptoms such as palpitations, fatigue, and decreased exercise tolerance, AF can also lead to more serious problems like syncope and impaired cardiac output. The most feared complication is the formation of an embolism in the atrial chamber that in most cases travels to the brain. AF is thought to cause as many as 1 of every 5 of the 700 000 strokes that occur every year in the United States¹; in those older than 80 years of age, AF is linked to as many as 1 of every 3 strokes.⁴

The degree to which stroke risk increases with AF has been estimated in several ways. Based on Framingham Heart Study data, for example, the embolic risk in a population of 75-year-olds with AF, a mean systolic blood pressure of 155 mm Hg, 41% prevalence of diabetes, and 23% with prior stroke is calculated to be about 4.1% per year.⁵ A raw data

Figure 1. Atrial Fibrillation (AF): An Age-Related Stroke Risk Factor



Source: Feinberg WM, et al. *Arch Intern Med.* 1995;155:469-473.

meta-analysis of 5 major clinical trials of warfarin in patients with AF showed that the overall stroke rate in the patients not receiving well-controlled warfarin was 4.7% per year,⁶ ranging from about 3% in the Boston Area Anticoagulation Trial in Atrial Fibrillation (BAATAF)⁷ to about 7% in the Stroke Prevention in Atrial Fibrillation (SPAF)¹ trial.⁸ More recently, the large Stroke Prevention by Oral Thrombin Inhibitor in Atrial Fibrillation (SPORTIF) III trial reported a 2% annual stroke rate in patients with AF receiving warfarin.⁹ Based on the effect of warfarin known from previous trials (69% relative risk reduction), these SPORTIF data imply that, untreated, high-risk stroke patients would have an annual stroke risk of approximately 7.5%. Thus, estimates derived from various sources indicate that at least 1 of every 20 untreated patients with AF will have a stroke each year, with an even higher risk in the older individuals with other risk factors.

The Costs of Stroke

In the United States, the overall cost of stroke has been estimated by the American Heart Association to be \$54 billion—\$21 billion for lost productivity and \$33 billion for direct medical costs.¹ The full, direct economic burden of stroke is often underappreciated by health system managers and payers, who may not be responsible for the costs of long-term rehabilitation and nursing

home care that often follow the initial hospitalization. A recent estimate based on 10 international studies found the per-patient long-term costs for stroke to be up to \$200 000.¹⁰ This same study found that severe strokes cost 11% to 71% more than minor strokes, which, although not surprising, is extremely relevant because AF-related strokes tend to be more severe.^{11,12} One recent study of more than 1000 patients with ischemic strokes found that 41% of those with AF were bedridden compared with only 24% of those without AF.¹³

Even during shorter time periods, however, the tangible costs of inpatient and short-term outpatient care associated with treating stroke patients can be staggering. In a multinational study of resource use in 1341 patients with ischemic stroke (of whom about 25% had AF), total 12-week management costs ranged from \$268 to \$110 032 with a mean cost of \$13 668.¹⁴ Initial hospitalizations, which averaged 24 days, accounted for 71% of these costs. In this and other stroke cost studies, an array of unit costs for stroke-related treatments need to be captured—ranging from the cost per day of a medical bed, to a computed tomography scan or echocardiogram, to a tablet of warfarin.¹⁵⁻¹⁷ The variations in these unit costs from health system to health system, and the extreme range of patient courses based on patient mix, complicate the estimation of “an average cost” for treating stroke. But such estimates

are necessary to assist government and managed care organization (MCO) decision makers in evaluating the costs of stroke compared with other conditions and thereby allocating resources for treatment, education, and prevention in an appropriate manner.

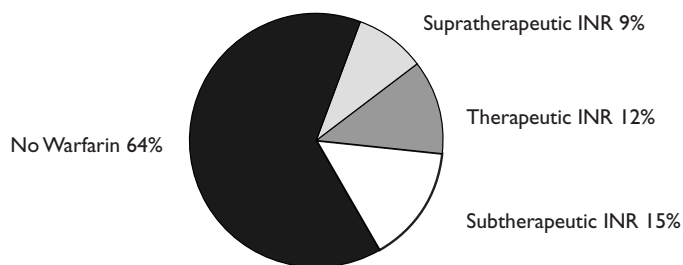
The Potential Benefit of Anticoagulation

The ability of well-managed warfarin to reduce the risk of stroke in patients with AF has been the subject of several large trials documenting a reduction in the incidence of stroke by about two thirds.^{6-8,18-21} The intensity of a stroke and mortality rate is higher if the international normalized ratio (INR) at admission is less than 2.0.²² Studies evaluating hospitalized patients with AF show that a large proportion are not receiving warfarin and only about one third of those who do receive warfarin actually have a therapeutic INR (Figure 2).²³ The high proportion of out-of-range INRs is significant because the risks of embolic events and bleeding are closely linked with the INR, with the stroke risk rising dramatically below an INR of 2.0 and the bleeding risk rising steadily after an INR of 3.0.^{24,25}

The gap between optimal warfarin therapy as delivered in anticoagulation clinics or clinical trials and suboptimal treatment often found in routine medical practice can be measured in both excess strokes and excess costs. The gap between warfarin outcomes obtained in clinical trials and those seen in routine medical care is widely acknowledged.^{26,27} During the past decade, the emergence of anticoagulation clinics with their structured regimens of INR testing, dose adjustment, physician consultations, and patient education has shown improved use of warfarin and better stroke prevention.²⁸ Specialized management of patients in anticoagulation clinics can help maintain patients in the narrow target INR of 2.0 to 3.0 and more closely approximate the results seen in the seminal clinical trials with this drug. In the recent SPORTIF trials, patients taking warfarin were well managed as indicated by 67% of the time being spent in the target range of 2.0 to 3.0 (using Rosendall linearity method).

The introduction of a nonwarfarin oral anticoagulant with efficacy equivalent to

Figure 2. Anticoagulation Use and Adequacy in Patients with Atrial Fibrillation



INR indicates international normalized ratio.

Source: Bungard TJ, et al. *Pharmacotherapy*. 2000;20:1060-1065.

warfarin, but with less bleeding risk and/or a reduced need for close monitoring and dose adjustment, could improve the chances of rapid, widespread anticoagulation optimization in the United States. This direct thrombin inhibitor does not require routine anticoagulation monitoring and yet appears to provide a stroke risk reduction on par with optimized warfarin,⁹ although there are concerns about liver toxicity.²⁹ Other agents, such as once-weekly subcutaneous pentasaccharides (eg, idraparinux), are also being tested against warfarin in stroke prevention.³⁰ Such agents may eventually provide better means of closing the clinical and economic gaps of suboptimal anticoagulation than any further investments in anticoagulation clinics.

Model Concept and Assumptions

The objective of this study was to develop a practical and up-to-date economic model of AF-related complications that allows examination of various economic scenarios relevant to the Centers for Medicare and Medicaid Services (CMS) in the United States and also to MCOs in the United States. The model allows estimation of the national economic and clinical burden caused by complications and treatment in elderly patients with AF. It also allows an estimate of the health benefits and economic implications of optimizing oral anticoagulation by increasing both the number of patients and the number of patients receiving well-managed anticoagulation and/or

increasing the number of treated patients who are well managed.

The economic model considers a stable population of patients with AF, such as might be found in an MCO or a state's Medicare group. The population is dynamic, meaning that it allows for movement of individuals with AF in and out of the population during the course of a year (unlike a typical cohort population that follows the same aging and steadily diminishing group of patients with no addition or subtraction of living patients). Embolic and hemorrhagic event rates are calculated for this population based on the proportions of patients in each treatment category. Scenarios are created to represent the current situation in the population of interest and compared with other potential scenarios of care.

Costs. Costs were estimated for the management of emboli (stroke, transient ischemic attack, renal, or limb), bleeds (intracranial hemorrhage, gastrointestinal, other major and limb), and monitoring visits and tests. Cost estimates were based on actual treatment and cost data rather than expert opinion as much as possible.

Inpatient Costs. Inpatient costs for acute hospital care were calculated from the discharge databases available from 7 states: Arizona, California, Florida, Massachusetts, Maryland, Washington, and Wisconsin. In addition, 5 years of patient-level data were available from Massachusetts. The other studies were discharge-level data while the Massachusetts data was patient-level. The data for elderly patients (age at least 65 years) were extracted, including information on demographics, admission sources, length of stay, disposition status, use of emergency departments, special care units (eg, stroke units), procedures, and costs.

Outpatient Costs. Outpatient costs captured in the model included those near-term costs that would typically be expensed to Medicare, including short-term nursing home, inpatient rehabilitation, physician services (2003 Medicare fee schedule), limited home services, and readmission. These outpatient data were typically available in

either the National Ambulatory Medical Care Survey or in Medicare data. In a few cases where information was missing (eg, resource use in nursing homes), the literature was tapped as a source.

The risks of stroke, other emboli, and bleeds were incorporated based on published rates of warfarin utilization and on the efficacy observed in the recent SPORTIF III and V trials. Importantly, these rates were adjusted to reflect actual clinical practice patterns with these treatments. The patients were divided into 3 groups: (1) those currently not receiving any anticoagulation (including those taking aspirin alone), (2) those receiving warfarin in routine medical care, and (3) those receiving warfarin in the setting of an anticoagulation clinic. The stroke rate in patients managed in an anticoagulation clinic was estimated to be 1.8% versus 4.5% for those managed in routine practice. These percentages were calculated by multiplying 0.015 (pooled SPORTIF III and V embolic rate in warfarin) by 1.2 (estimated deterioration between a randomized control trial and actual patients, based on expert opinion (Chiquette E, et al). The difference between 1.2% and 2.3% in the SPORTIF trials was calculated by multiplying 0.015 by 3.0 (estimated deterioration between a randomized control trial and routine care based on expert opinion (Chiquette E, et al). Survival after stroke was based on published data and adjusted for age, gender, and other characteristics.

Results

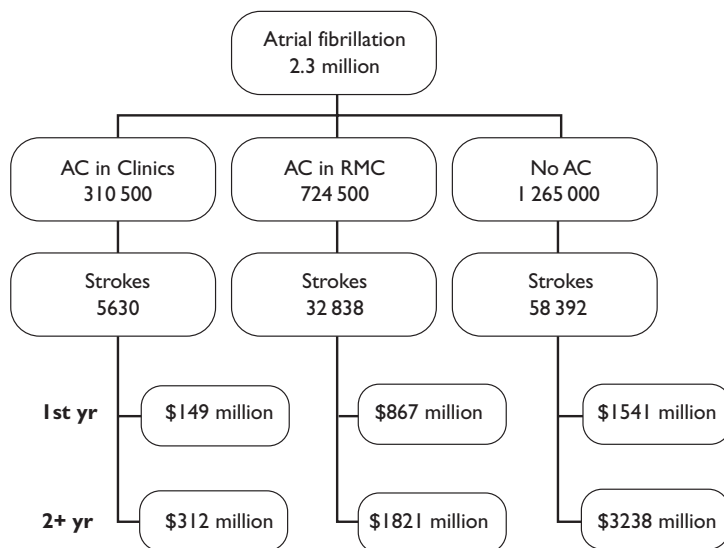
Of the estimated 2.3 million patients with AF in the United States, slightly more than half (1.3 million) are not receiving oral anticoagulants, whereas the remaining million receive warfarin—about 70% of them in the setting of routine medical care without special support and only 30% in an anticoagulation clinic. Of the patients not receiving any warfarin, about half were assumed to be receiving aspirin alone. Over the course of 1 year, 58 392 strokes are estimated to occur in the 1.265 million patients not taking anticoagulants and 38 468 in the 1.035 million who do take them.

Almost 50% of stroke survivors will go home after discharge, 25% will require special skilled nursing care, 20% will go to rehabilitation centers, and the remaining patients will need intermediate levels of care, such as that provided by a skilled nursing facility. Even in those who go home, however, only about 50% get by with no need for care other than follow-up physician visits; approximately 25% of these individuals require home health care, about 15% participate in rehabilitation, and another 10% go to day-care facilities.

The total direct costs of these 96 860 AF-related strokes were estimated to be almost \$8 billion, including \$2.6 billion in the year of the event itself and another \$5.4 billion in Medicare-covered costs anticipated in subsequent years. This total cost works out to about \$3435 per AF patient, or \$286 per patient per month. Projected costs for patients in the 3 main treatment groups (Figure 3) reflect the varying stroke rates in those groups. The per-patient stroke costs for individuals in the well-controlled setting of the anticoagulation clinic were \$1485 versus \$3710 for those receiving warfarin in routine medical care and \$3778 for those not getting any oral anticoagulant. Note that costs in the routine medical care group were almost as high as those in the untreated group mainly because they also included the costs necessary to treat complications of anticoagulation therapy (such as gastrointestinal bleeding).

Various “what if” analyses of other scenarios of care illustrate the range of savings possible with more widespread or more fully optimized anticoagulation. If, for example, half of all those who currently do not receive anticoagulation were to receive well-controlled warfarin, approximately 19 000 strokes would be prevented each year and payers would save more than \$1.1 billion in direct costs (Table 1). The emboli-related treatment costs are actually reduced by about \$1.3 billion (from \$4 billion to less than \$2.7 billion) in this scenario, but an additional \$21.4 million is required to treat the 916 additional bleeds that are expected to occur because of the increased use of prophylactic warfarin. This estimate of savings does not include the extra costs of warfarin

Figure 3. Stroke in Patients with Atrial Fibrillation: Prevalence and Cost Depend on Anticoagulation Use



AC indicates anticoagulation; RMC, routine medical care.

that would be required for these newly treated patients. Given the Medicare perspective of this model, this makes sense, but other payers or MCOs could easily adjust this scenario for their perspective by factoring in the additional drug expense. The estimated savings also do not consider the costs (eg, capital costs for additional clinics and operating costs for personnel) needed to deliver such powerful levels of stroke reduction.

In a second “what if” analysis (Table 2), the potential savings related to improving anticoagulation in routine medical care were estimated. If half of the patients currently receiving warfarin in routine care were to have their anticoagulation optimized, approximately 9000 additional strokes would be prevented, more than 29 000 bleeds would be averted, and a savings of more than \$1.3 billion would accrue. Again, this scenario does not include the extra costs that would be required for optimization because Medicare would not cover them. The savings in this scenario result not only from a reduction in emboli-related costs but also from a sizable reduction in costs as a result of treatment-

Table 1. What If More Patients with Atrial Fibrillation Received Warfarin?

	Strokes	Costs (\$)
Current scenario		
1.265 million untreated AF patients	58 392/year	4.586 billion (emboli: 3.975 million)
If 632 500 (50%) of these patients received warfarin	39 012/year	3.446 billion* (emboli: 2.856 million)
Summary result of modeling	19 380 strokes prevented, but 916 more bleeds	1.140 billion* saved

*Not including extra drug or monitoring costs.

Table 2. What If More Patients Taking Warfarin Had Optimized Anticoagulation Care?

	Strokes	Costs (\$)
Current scenario		
724 500 AF patients now receiving anticoagulation in routine medical care	38 468/year	4.923 billion (emboli: 2.305 million)
What if		
If 362 250 (50%) of these patients received care in anticoagulation clinic settings	28 616/year	3.578 billion* (emboli: 1.630 million)
Summary result of modeling	9852 strokes prevented, plus 29 423 bleeds prevented	1.345 billion* saved

*Not including extra capital and operating costs related to optimization.

related bleeding. The expenses of treating a warfarin-related gastrointestinal bleed—which might require surgery, intensive care unit stays, and blood transfusions—can be considerable.

Unlike previous studies in this area, this analysis was from the economic perspective of CMS rather than from a societal or other

perspective. Although this Medicare-based view of costs is, by definition, narrower than the broader societal view, it is more practical and also more applicable to other insurers, such as MCOs and large health plans. The occurrence of complications in the population is considered during a period of 1 year, with the population assumed to be stable. The downstream (beyond 1 year) costs of events that occur during the year are brought to net present value at a discount rate of 3%. The model's population was assumed to have baseline characteristics like those seen in Medicare-aged patients in SPORTIF (ie, 1 or more risk factors for stroke in addition to AF).⁹

Conclusion

Stroke in patients with AF is a significant economic burden, costing Medicare more than \$8 billion annually. This burden will only grow as the population ages. Despite more than 2 decades of concerted efforts to prevent stroke in patients with AF, only a fraction of the potential benefit of oral anticoagulation with warfarin has been captured. In fact, if none of the current estimated population of 2.3 million patients with AF were treated with prophylactic anticoagulants, there would be approximately 105 000 AF-related strokes every year. Currently, there are almost 97 000 such strokes each year. Thus, only about 10% of the potential benefit of warfarin is currently being realized. Even accounting for the fact that many AF patients are not eligible for warfarin therapy, this points to a huge margin for improvement in current US stroke prevention efforts.

The simple economic model presented here provides an up-to-date estimate of the potential clinical and economic gains associated with improvements in warfarin utilization. Are the “what if” projections of 50% optimization too optimistic? Can such improvements in uptake or optimization realistically be expected to occur with currently available anticoagulants in today's reimbursement and cost environment? The answer to this question is uncertain and depends in part on the willingness of health systems to increase investments in anticoagulation clinics. The answer also depends on each MCO's own cost structure, patient pop-

ulation, geographic location, and current starting level of stroke prophylaxis. Obviously, health systems starting from the lowest levels of warfarin usage or optimization have the most room for large early gains in clinical and economic outcomes. On the other hand, the likelihood of increased numbers of anticoagulation clinics being created in rural settings and smaller communities seems especially doubtful.

This economic model has some limitations. The assumptions used to determine the relative proportions of warfarin-treated patients in routine management versus anticoagulation clinic care were based on limited data (1 study). Similarly, the treatment effectiveness of warfarin in routine medical care is uncertain since it is inherently difficult to study such treatment prospectively without altering clinician or patient behavior. Finally, it bears repeating that this model, because of its Medicare perspective, does not account for medication costs, long-term nursing home costs, expenses borne by patients or their families, or for any indirect costs, such as those incurred from the loss of employment or diminished work productivity. Although widely acknowledged as constituting a significant proportion of the overall economic burden of stroke,¹ the indirect and long-term costs are often more difficult for a healthcare system or MCO to address, and therefore this model was designed with a narrow but highly relevant perspective that considered only the most measurable and apparent direct costs associated with AF-related stroke.

Overall, our economic model suggests that if half of all current patients with AF receiving suboptimal or no anticoagulation could be optimized at effectiveness levels reported in trials, then 28 000 strokes could be prevented every year and the United States could save approximately \$2.5 billion in total direct costs. The extent to which the longstanding difficulties in using warfarin can be overcome in actual practice to achieve these benefits remains a major concern. However, the projected reduction in total direct costs from about \$9.5 billion to about \$5.5 billion provides MCOs with a practical sense for the relative magnitude of the potential savings achievable (ie, -31%)

with more fully optimized anticoagulation therapy—whether that optimization comes via renewed efforts at aggressive clinic-guided warfarin prophylaxis or, eventually, via selection of a nonwarfarin alternative, such as an oral direct thrombin inhibitor.

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Q&A WITH DR CARO

Kenneth Schaecher, MD, Medical Director of Utilization Management at Intermountain Healthcare in West Valley City, Utah, interviewed Dr Caro about his economic model. Below are the highlights of their conversation.

The Economic Model

Dr Schaecher: Dr Caro, can you briefly describe the main components of stroke costs in your model?

Dr Caro: The model looks at the burden to Medicare of atrial fibrillation [AF], its treatment, and its complications. It divides the current US population of patients with AF into 2 groups: those currently treated with anticoagulants and those treated with aspirin or no anticoagulant.

Dr Schaecher: So it's 2 populations, in 2 parts, anticoagulated and not anticoagulated.

Dr Caro: Yes. And for each of them, the model considers the number of strokes and other embolic events, the number of major

bleeds, and treatment costs, if any. For Medicare, obviously, treatment costs are just monitoring visits and tests, because the drugs themselves are not paid for. For events, the strokes and bleeds, the model considers Medicare-paid acute management and post-acute management, meaning rehabilitation or things like that. And then in years beyond the first year of analysis, the model captures the net present value of any costs accrued, for example, through readmissions in the future. Deaths are also considered as they happen. Only costs relevant to Medicare are included.

Dr Schaecher: So, getting right to the bottom line, what is the annual economic burden to Medicare of stroke in AF patients?

Dr Caro: It's estimated to be \$9.5 billion per year.

Dr Schaecher: What were your main sources for the cost estimates?

Dr Caro: Unit cost estimates are based on extensive Medicare admissions data from 6 states. The hospitalizations, rehab, and so on, are all Medicare-specific data.

Dr Schaecher: Using real data from real patients, at rates really paid by Medicare, makes the model relevant. But what stroke-related costs might be missed in this type of model?

Dr Caro: Anything that Medicare does not pay for. So, warfarin is not included. And long-term nursing care is only included for the proportion of patients who end up on Medicaid.

Dr Schaecher: What other stroke drugs would not be covered?

Dr Caro: Well, inside the hospital, things like tissue plasminogen activator (tPA) would be covered, but ongoing aspirin outside the hospital would not, nor would seizure medications. In addition, the model did not account for costs that the patient bears directly for transportation, loss of work, caregiver time, or home nursing. Those costs would only be captured in a societal perspective model.

Cost: A Matter of Perspective

Dr Schaecher: So, the \$9.5 billion is really a significant underestimate of the real cost of this disease.

Dr Caro: The \$9.5 billion is the real cost to Medicare. Costs are always subject to your point of view, and so I wouldn't say that it's an underestimate of a real cost even if it leaves out components that might be important to other people.

Dr Schaecher: But, given the fact that AF is a problem predominantly of an elderly Medicare population, why should a commercial managed care plan care about the Medicare cost for stroke?

Dr Caro: That's a tough question because the relevance varies with the type of managed care plan, what kinds of people they treat, and how they deal with Medicare patients. The Medicare analysis is useful because it shows the relative impact of various treatments and approaches, not just the absolute cost impact. So, even if that \$9.5 billion is per se not meaningful to an organization, the fact that costs will drop by a given percentage when you treat more patients, and treat them optimally, then the model becomes meaningful.

Dr Schaecher: Is it fair to say that most commercial managed care plans would end

up having to pay more per patient with a stroke than a Medicare plan would because they typically cover the drugs plus inpatient and outpatient costs?

Dr Caro: It depends on the stroke patient's age and the plan's provisions for coverage. For example, if the patient has a stroke at age 64, the fact that we include the net present value of future costs might not be appropriate for that person in a given Medicare or managed care plan. It's not generalizable.

Dr Schaecher: How does your \$9.5 billion compare with Medicare costs for other major diseases?

Dr Caro: That's hard to say because most cost-of-illness studies are not Medicare-specific. They include productivity losses and drugs and so on.

Dr Schaecher: Can we make a subjective comparison about the magnitude of the stroke cost?

Dr Caro: Yes. We presented these data to individuals at the Centers for Medicare and Medicaid, and they said it was very large even compared with costs for other major conditions, such as breast cancer, lung cancer, colon cancer, and heart disease. They looked at our data and ranked stroke costs in the same position as some of their other high-cost conditions.

Questioning Assumptions

Dr Schaecher: Your model assumes that 45% of AF patients receive anticoagulation, 55% do not. How did you pick those percentages?

Dr Caro: That's the average across a number of studies in the literature that have looked at the percentage of patients who receive anticoagulation. Treatment estimates vary from about 30% to 60% by region and by type of healthcare organization.

Dr Schaecher: How did you generate the stroke rates for these 2 groups of patients?

Dr Caro: We assumed that the stroke rates for patients who were anticoagulated in a specialized clinic were the same as for patients in the clinical trials. But if they received anticoagulation in a nonspecialized setting, in routine medical care, then we deteriorated that benefit. We assumed their stroke rate was higher by a proportion—a ratio of 3.0 was

derived from published studies comparing the experience in clinics with the experience in routine care. For patients not anticoagulated, the assumed stroke rate depended on whether they received aspirin or not. The aspirin rates came from a meta-analysis of the aspirin arms of trials, and the untreated rates came from the placebo arms of the trials.

Dr Schaecher: What were the costs in those anticoagulated versus those not?

Dr Caro: The total costs are roughly similar at about \$4.5 billion in each group. It's similar because the stroke costs, which are much higher in the nonanticoagulated group, tend to get offset by the higher bleeding costs in the anticoagulated group, particularly in routine medical care subgroups where the INRs [international normalized ratios] run higher. Plus this anticoagulated group has extra costs for monitoring visits and lab tests which are still paid for by Medicare. There are also more patients in the untreated groups.

Dr Schaecher: Did you assume patients in the treatment group would live longer than those in the untreated group?

Dr Caro: We used age- and gender-appropriate mortality rates from epidemiologic studies combined with event-specific rates. For example, ischemic embolic stroke has a 7% acute mortality. Based on these actual underlying rates, yes, the overall death rates in the 2 groups turn out to be different.

Savings with Optimized Anticoagulation

Dr Schaecher: Your model also calculated how much these total management costs of stroke could be reduced by getting 50% more AF patients to initiate anticoagulation, or by getting 50% more AF patients currently receiving anticoagulation to optimize their therapy. What did you find?

Dr Caro: When we assumed that INRs could be brought more in line with what is observed in trials in 50% of patients already being treated in routine medical care—that is, nonoptimally—we estimated that Medicare costs would drop by around \$1.5 billion. And then in the untreated population, when we assumed half of them could be brought into treatment by some new treatment, we estimated savings of about \$1.2 billion. We did not get specific as to what this new treat-

ment would be, but rather just looked at the possibility that half of them would be brought into treatment.

Dr Schaecher: Did those savings take into account the potential cost of the new treatment?

Dr Caro: No, because we don't know what those costs might be. One possibility is that Medicare would fund the creation of specialized clinics that would be available to many more patients. Another possibility is that Medicare would initiate some sort of management optimization training program. The costs of these new programs would reduce some of the projected savings.

Dr Schaecher: What about the potential impact of a new agent, such as ximelagatran, on stroke care and costs?

Dr Caro: Yes. We did do a separate analysis looking at a new drug. When we assumed an estimated price of \$4 per day, purely for a "what if" analysis, we found that the new drug reduced the total savings in the treated group from \$1.5 billion to \$0.5 billion.

Dr Schaecher: What if that new drug was the agent used to shift 50% of the patients from untreated to treated?

Dr Caro: In that scenario, the new drug reduces the savings in the untreated population to \$0.3 billion.

Dr Schaecher: These are still significant savings.

Dr Caro: Yes. We're at about \$0.8 billion in total savings with the 2 populations, with fewer strokes.

Dr Schaecher: How do the relative costs for emboli, bleed treatment, and management/prevention/drug therapy compare in the coagulated and anticoagulated groups?

Dr Caro: In the anticoagulated group, the strokes that occur cost about \$2.6 billion, whereas the bleeds are about \$2 billion, and the remaining costs are for monitoring visits and lab tests. In the untreated group, almost all of the costs, about \$4 billion, are for stroke. There are some visits to the doctor for AF and for the background rate of bleeding, but that's minor.

Dr Schaecher: How much more effective does your model assume treatment in an anticoagulation clinic to be versus usual care anticoagulation?

Dr Caro: Three times more effective.

Dr Schaecher: How did you make that assumption?

Dr Caro: Via published literature comparing the 2 settings of care.

Dr Schaecher: Why doesn't your model include the cost of optimizing warfarin treatment?

Dr Caro: Because we don't know at this point what that cost would be.

Dr Schaecher: Do you think the extra cost of setting up anticoagulation clinics will eliminate the projected cost savings that you project?

Dr Caro: If Medicare had to bear that entire cost, then it would probably eat all of their savings away. Obviously, if Medicare shifted these clinic costs onto providers then perhaps they would retain some savings, but that would be tricky to do.

Dr Schaecher: Yes. Not many providers are willing to take on that burden for the public good.

Translating Medicare Estimates to Managed Care

Dr Schaecher: For typical health systems trying to get a handle on AF-related stroke and anticoagulation policies, would it be valid to make a quick ballpark estimate of local stroke incidence and costs by simply dropping the last 3 zeros from all of your calculations? So, for example, let's assume we have a managed care group with a total AF

population of 2300, not 2.3 million, of whom about 1000, not 1 million, are treated, and among whom there are 38 strokes per year at a cost of \$4.9 million. In this quick estimate, then, optimizing anticoagulation in the treatment population would reduce this to 29 strokes and \$3.6 million. Is that a reasonable way to downsize your model?

Dr Caro: Your quick estimate is partially valid. In terms of stroke incidence, your managed care estimate would also depend on the mix of the population. Remember, our model is all Medicare so we're modeling a population that is older than some managed care plans might see. In a population with a younger mix, you'll have more lone AF and lower rates of strokes and complications. But if your group's population was Medicare age, then your quick stroke estimate is pretty secure.

Dr Schaecher: Could we just say that our ballpark estimate for managed care, based on your Medicare numbers, was worst case?

Dr Caro: That would be fair to say as a broad estimate of strokes, but the cost side is a little questionable. As we discussed, the components of costs are very Medicare oriented, and the balances would change, for example, with having to take into account the cost of the drugs, and what is paid for after a stroke, and so on. So, as a quick ballpark it's fine, but it would be better if it was actually calculated properly for managed care.