
Medicare and Atrial Fibrillation/ Consequences in Cost and Care

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Executive Summary

Atrial fibrillation (AFib) is a common and serious cardiovascular disease associated with significant morbidity and mortality. Given the incidence, prevalence, and life-threatening complications of AFib increase with age, Medicare is forced to absorb a majority of the substantial clinical and economic burden. Avalere Health prepared this issue brief on AFib to:

- + Describe the burden of AFib on the Medicare program;
- + Depict the current state of AFib Medicare quality improvement efforts; and
- + Identify potential strategies to improve the quality of care and patient outcomes for AFib patients, and reduce healthcare costs.

AFib is a highly prevalent disease and associated with significant cardiovascular morbidity and mortality

AFib is the most common arrhythmia in the United States, affecting more than 2.5 million adults, 80 percent of whom are 65 years and older.¹ In the next 40 years, the prevalence of AFib is projected to more than double to 5.6 million adults.² AFib significantly increases the risk of stroke³ and heart disease, both of which are leading causes of death in the United States.⁴ AFib is also associated with significant impairments in patient quality of life.⁵ Further, AFib patients often have several age-related cardiovascular comorbidities: valvular heart disease, heart failure (HF), coronary artery disease, and hypertension.⁶ As a result, AFib patients with heart disease have higher mortality rates compared to patients with normal heart rhythm.⁷

AFib costs Medicare more than \$15.7 billion annually due to costly complications

In a study published in 2006, researchers estimate the total direct annual medical cost for treatment of AFib patients over and under age 65 is \$6.65 billion, with hospitalizations accounting for the largest share.⁸ However, a 2008 study estimates that Medicare alone pays \$15.7 billion annually to treat newly diagnosed AFib patients.⁹ These costs are largely driven by the greater utilization of health-care services associated with AFib complications, including stroke, HF, acute myocardial infarction, and tachycardia. Importantly, these costs are considered by some to be an underestimate since they exclude deductibles, copayments, medical costs not covered by Medicare,¹⁰ and patients who have previously been diagnosed with AFib and are currently undergoing treatment. Within the first year following an AFib diagnosis, patients with AFib were more likely to have HF (36.7 percent versus 10.4 percent) and/or stroke (23.1 percent versus 13.3 percent) than those without the disease.¹¹ HF was the second most expensive complication, costing Medicare \$12,117 per patient within the first year of diagnosis.¹² One study estimates the annual cost of stroke among Medicare AFib patients is \$8 billion.¹³

Screening and diagnosis of AFib is limited in Medicare

Even though the risk factors and serious complications of AFib are well known, AFib has not received the same attention as other chronic conditions to improve diagnosis, treatment, and prevention. For example, although early diagnosis of AFib is critical to effective patient management, the initial preventive physical exam for new Medicare beneficiaries does not include screening or prevention efforts targeting AFib.¹⁴

Treating elderly AFib patients is complex

AFib is difficult and costly to manage due to variations in disease presentation. The presence of comorbid conditions in the elderly increase risks for drug interactions and other serious complications. The goal of treatment is to prevent stroke, manage heart rate and rhythm, and reduce risk factors for HF and stroke.¹⁵ Treatment options range from medication therapy to invasive and/or surgical-based procedures.¹⁶

AFib is not a focus of Medicare's current quality improvement programs

Medicare's current quality improvement initiatives use various quality metrics to assess whether clinicians are adhering to clinical practice guidelines and accepted standards of care. Compared to other chronic diseases such as hypertension, HF, or diabetes—which have dozens of quality improvement metrics—AFib only has nine quality measures focused exclusively on the prevention of stroke and Medicare only uses one of these in its current programs.¹⁷

Conclusion

A need exists for Medicare to find ways to reduce overall costs and improve the quality of care for AFib patients

Our findings suggest an urgent need for Medicare to focus on AFib in order to improve patient management and outcomes and reduce overall Medicare costs. A recent report released by the Institute of Medicine, *Initial National Priorities for Comparative Effectiveness Research*, recommends AFib among the top 25 highest priorities that would benefit from a new national investment in comparative effectiveness research.¹⁸

Federal policymakers should consider including AFib among the chronic conditions targeted for Medicare's current and proposed quality improvement programs. Reforms aimed at quality improvement, cost management, care coordination, and new research will support the advancement of AFib treatment, improve patient outcomes, and reduce Medicare costs.

Medicare should consider the following potential strategies to meet these goals:

- + Analyze Medicare claims data to further assess AFib costs and health outcomes
- + Create a national AFib patient registry to collect real-world data
- + Develop and incorporate health risk assessment tools into screening efforts to assess beneficiaries' risk of AFib
- + Develop and implement additional AFib quality measures
- + Target AFib as a condition for medication therapy management programs
- + Incorporate quality measures targeting care coordination
- + Bundle payments for AFib-related episodes of care to incentivize providers to offer better care management
- + Create a "medical home" model for AFib patients to better coordinate care

These proposed strategies are not an exhaustive list of how to improve AFib quality of care, but instead offer initial strategies that, if implemented, have the potential to significantly improve patient outcomes and reduce healthcare costs for the Medicare population.

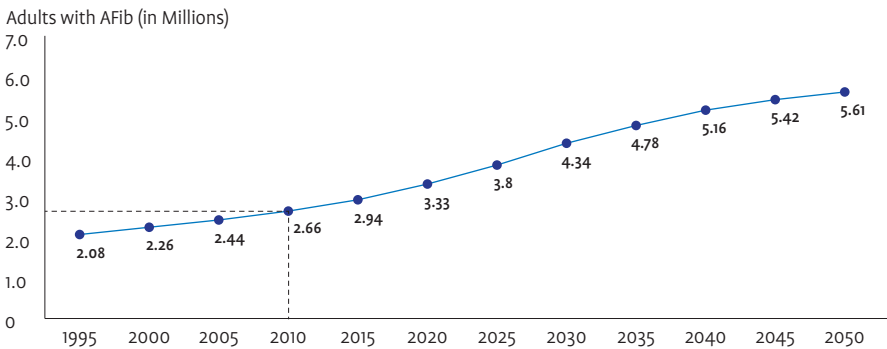
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Atrial Fibrillation Imposes Substantial Clinical and Economic Burden on Medicare

Atrial fibrillation (AFib) is the most common arrhythmia in the United States affecting more than 2.5 million adults, 80 percent of whom are 65 years and older (Figures 1 and 2).¹⁹ By 2050, the prevalence of AFib is projected to increase to 5.6 million adults, almost 90 percent of whom will be 65 years and older.²⁰ AFib is most prevalent in the elderly because the structure and function of the heart changes as the body ages, predisposing older individuals to develop AFib.²¹

FIGURE 1: AFIB IS INCREASINGLY PREVALENT IN THE UNITED STATES

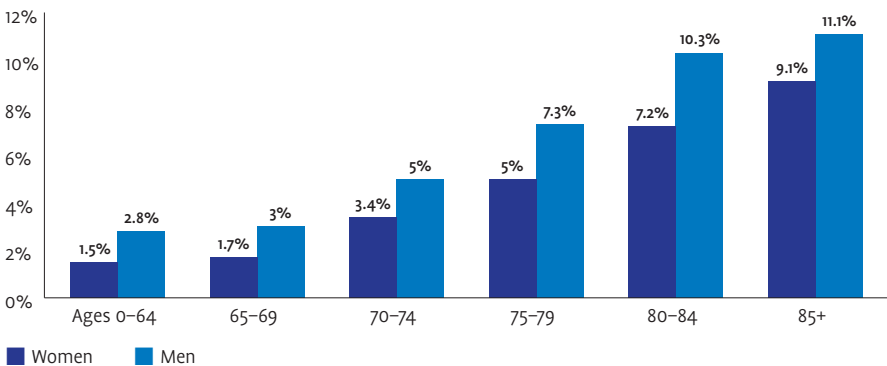
Projected Number of Adults with AFib in the United States



Alan S. Go; Elaine M. Hylek; Kathleen A. Phillips; et al. Factors In Atrial Fibrillation (AFIB) Study Stroke Prevention: The Anticoagulation and Risk National Implications for Rhythm Management and Prevalence of Diagnosed Atrial Fibrillation in Adults. *JAMA*. 2001;285(18):2370-2375.

FIGURE 2: MOST AFIB PATIENTS ARE ELIGIBLE FOR THE MEDICARE PROGRAM

Prevalence of AFib by Age and Gender

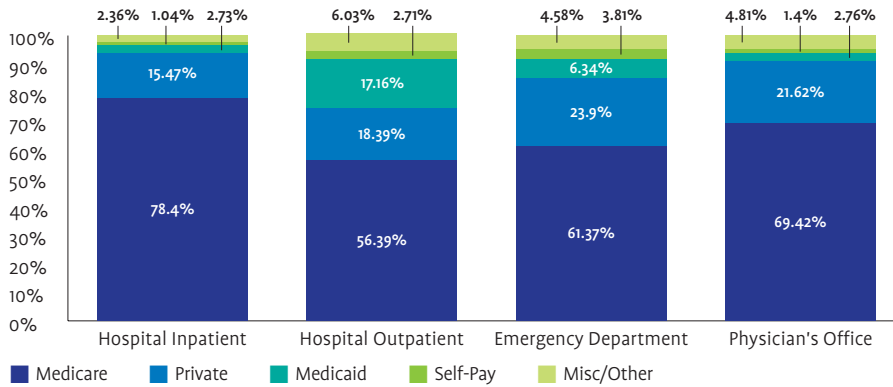


Alan S. Go; Elaine M. Hylek; Kathleen A. Phillips; et al. Factors In Atrial Fibrillation (AFIB) Study Stroke Prevention: The Anticoagulation and Risk National Implications for Rhythm Management and Prevalence of Diagnosed Atrial Fibrillation in Adults. *JAMA*. 2001;285(18):2370-2375.

AFib significantly increases the risk of stroke²² and heart disease, both of which are leading causes of death in the United States.²³ It is also often associated with several age-related cardiovascular comorbidities, such as valvular heart disease, heart failure (HF), coronary artery disease, and hypertension.²⁴ AFib patients with heart disease also have higher mortality rates compared to patients with normal heart rhythm.²⁵

Since the incidence, prevalence, and complications of AFib increase with age, the Medicare program absorbs a majority of the burden of care. An Avalere Health analysis of public and private payer survey data identifies Medicare as the primary payer of AFib across all settings of care (Figure 3).²⁶

FIGURE 3: MEDICARE IS THE PRIMARY PAYER FOR AFIB ACROSS ALL SETTINGS OF CARE



Avalere Health analysis of data from the National Hospital Discharge Survey, National Ambulatory Medical Care Survey and National Ambulatory Medical Care Survey Outpatient Department and Emergency Department for years 1997–2006 for ICD-9 diagnosis code 427.31.

DESCRIPTION OF DISEASE	
How does the heart work?	<p>To appreciate how AFib affects the heart and blood flow, it is important to have a general understanding of the circulatory system. The heart consists of four chambers, two upper chambers called atria and two lower chambers called ventricles. The heart also has valves that control the flow of blood in one direction only, which open and close based on the difference in pressure across the valves.²⁷</p> <p>The process begins at the right atrium with the heart's natural pacemaker, the sinoatrial (SA) node. The SA node initiates an electrical impulse for the heartbeat (referred to as rate), which then follows an organized electrical sequence (referred to as rhythm) to pump blood through the chambers of the heart to the lungs and to other parts of the body.²⁸</p>
What is AFib?	<p>In AFib, the rate and rhythm of the heartbeat is affected. The heart's upper chamber (atria) quivers (fibrillates) instead of contracts, causing a rapid and irregular heartbeat.²⁹</p> <p>Heart rate refers to the number of times the heart beats per minute, while heart rhythm describes the pattern of the heartbeat. In AFib, the atrial cells fire at rates of 400-600 times per minute. A resulting heart rate this fast would lead to rapid death, which is prevented by the atrioventricular (AV) node filtering the atrial impulses before they activate the ventricles. Therefore, heart rate is no longer controlled by the heart's natural pacemaker, the SA node, but instead by the interaction between the atrial rate and the AV node. This can result in an irregular heart rhythm, as well as a rapid heart rate. In AFib, a typical heart rate is in the range of 150 beats per minute, compared to a normal heart rate of 60 beats per minute at rest and 180-200 beats per minute at peak exercise.³⁰</p>
What are AFib's symptoms?	<p>May include palpitations (a sudden "fluttering" feeling in the chest), anxiety, shortness of breath, weakness and difficulty exercising, chest pain, sweating, dizziness, or fainting.³¹</p>
What are the types of AFib?	<p><i>Paroxysmal</i>—Characterized by AFib episodes that end spontaneously. Symptoms can range in severity, and the irregular heart rhythm can last from 30 seconds to hours or longer before the heart returns to a normal rhythm on its own. These episodes may occur repeatedly for years.³²</p> <p><i>Persistent</i>—Irregular heart rhythm episode extending beyond seven days. Medical treatment is necessary to restore normal sinus rhythm.³³</p> <p><i>Permanent</i>—Long-standing irregular heart rhythm, in which restoration of a normal heart rhythm has failed or been foregone.³⁴</p>

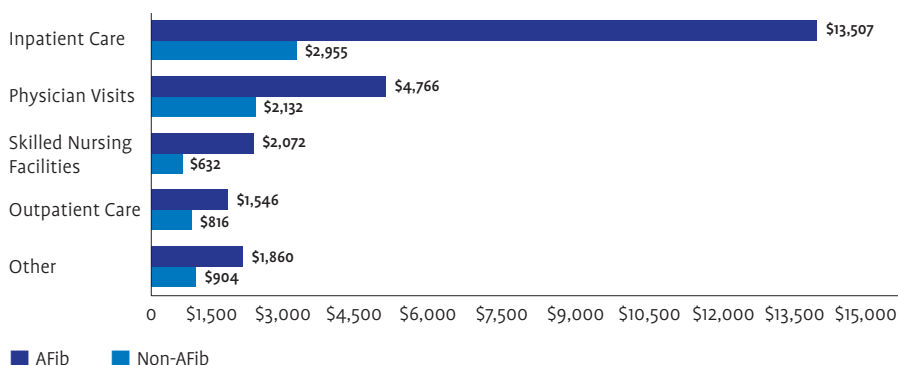
Annual treatment costs for Medicare AFib patients estimated at more than \$15.7 billion

According to a study published in 2006, researchers estimate the total medical cost for treatment of AFib is \$6.65 billion in patients over and under age 65, with hospitalizations accounting for the largest share of that number.³⁵ The total cost of treating a privately insured population is an estimated \$12,350 per patient, which is approximately five times greater than treating patients without AFib.³⁶

However, a study published in 2008 estimates Medicare alone pays \$15.7 billion annually to treat patients newly diagnosed with AFib.³⁷ This is predominately due to utilization of healthcare services associated with AFib's serious complications. AFib patients incur an additional average \$14,199 per person in direct medical costs compared to non-AFib patients during the first year following diagnosis. Hospitalizations account for the largest proportion of these costs (Figure 4).³⁸ Although the financial impact identified in this new study is higher than previously reported estimates, the latest report only included Medicare patients while earlier studies included AFib patients of all ages³⁹ or younger, typically healthier patients.⁴⁰ Additionally, these earlier studies had data limitations, which may have resulted in an underestimate of the total costs.⁴¹

FIGURE 4: MEDICARE AFIB PATIENT'S HEALTHCARE UTILIZATION AND COSTS HIGHER THAN PATIENTS WITHOUT THE DISEASE

One Year Cost Components for AFib and Non-AFib Medicare Patients



Other category includes: home health care, durable medical equipment and hospice.
 Lee W. Lamas G. Balu S., et al. "Direct treatment cost of atrial fibrillation in the elderly American population: a Medicare perspective." *Journal of Medical Economics* 11 (2008): 281-298.

Importantly, \$15.7 billion annual treatment cost is considered by some to be an underestimate of the actual financial burden of AFib for multiple reasons. This figure excludes deductibles, copayments, and medical costs not covered by Medicare. The study was also conducted prior to implementation of the Medicare prescription drug benefit, so oral medications, which are the first line of therapy for AFib patients, are not reflected in this analysis.⁴² Additionally, this research only reflects newly diagnosed AFib patients and does not include the costs of treating Medicare patients previously diagnosed who are currently undergoing treatment.

AFib patients at risk for costly complications

Prior to diagnosis, Medicare AFib patients have a higher prevalence of common chronic health conditions, such as diabetes, hypertension, and chronic obstructive pulmonary disease (COPD), which have all been identified as risk factors for AFib.⁴³ In addition, after being diagnosed with AFib, patients are at increased risk of cardiovascular morbidity and mortality, due primarily to stroke, HF, and other complications such as acute myocardial infarction, tachycardia, drug toxicity, and chest pain (Figure 5).

FIGURE 5: AFIB HAS SEVERAL RISK FACTORS AND RESULTS IN SERIOUS COMPLICATIONS

ATRIAL FIBRILLATION	
Risk Factors	Complications
Hypertension	Thromboembolism
Congestive Heart Failure	Ischemic Stroke
Previous Myocardial Infarction	Heart Failure
Diabetes	Acute Myocardial Infarction
Pericarditis	Chest Pain
Mitral Valve Disease	Tachycardia
Chronic Obstructive Pulmonary Disease	Drug Toxicity
Obesity	
Sleep Apnea	

Nattel S. New ideas about atrial fibrillation 50 years on. *Nature*.415:6868; 219-226. January 10, 2002. Go AS, Hylek EM, Phillips KA; et al. Factors In Atrial Fibrillation (ATRIA) Study Stroke Prevention: the Anticoagulation and Risk National Implications for Rhythm Management and Prevalence of Diagnosed Atrial Fibrillation in Adults. *JAMA*. 2001;285(18):2370-2375. CDC. Atrial Fibrillation Fact Sheet. http://www.cdc.gov/DHDSPLibrary/pdfs/fs_atrial_fibrillation.pdf [August 26,2008] Lee W, Lamas G, Balu S., et al. "Direct treatment cost of atrial fibrillation in the elderly American population: a Medicare perspective." *Journal of Medical Economics* 11 (2008): 281-298.

Within the first year following an AFib diagnosis, patients with AFib were more likely to have HF (36.7 percent versus 10.4 percent) and/or stroke (23.1 percent versus 13.3 percent) than those without the disease.⁴⁴ The risk of stroke is intensified by other comorbid conditions that are commonly seen with AFib patients, including diabetes, hypertension, and prior stroke.⁴⁵ AFib patients are also more susceptible to acute myocardial infarction, palpitations, tachycardia, and chest pain compared to patients without AFib (Figure 6).⁴⁶

FIGURE 6: COMPLICATIONS IN AFIB PATIENTS ARE MORE COMMON AND COSTLY

COMPLICATION	PREVALENCE*	INCREMENTAL MEDICARE COSTS** (PER YEAR/PER PATIENT)
Heart Failure	36.7% vs. 10.4%	\$12,117
Stroke	23.1% vs. 13.3%	\$7,907
Chest Pain	22.8% vs. 12.5%	\$5,776
Tachycardia	11.4% vs. 2.5%	\$10,143
Palpitations	7.0% vs. 2.6%	\$1,993
Acute Myocardial Infarction	5.0% vs. 2.0%	\$12,162

*Prevalence of complications post-AFib diagnosis compared to non-AFib patients.

**Incremental costs during first year following AFib diagnosis compared to non-AFib patients and adjusted for differences in baseline demographic variables, clinical comorbidities, total baseline costs, and complications in the post-index period. Lee W, Lamas G, Balu S., et al. "Direct treatment cost of atrial fibrillation in the elderly American population: a Medicare perspective." *Journal of Medical Economics* 11 (2008): 281-298.

Stroke is considered the most severe and debilitating complication of AFib.⁴⁷ AFib directly causes an estimated one-fourth of all strokes in the elderly.⁴⁸ The incremental treatment costs associated with stroke during the first year following AFib diagnosis are estimated at \$7,907 per Medicare patient (Figure 6). A separate study examining the economic impact of stroke for AFib patients shows the annual cost of stroke to Medicare is approximately \$8 billion. This study reports that more than 1.2 million, or 55 percent, of Medicare AFib patients who should receive stroke prevention therapy do not. This lack of compliance contributes to more than 58,000 strokes annually, with an associated direct cost to Medicare of \$4.8 billion.⁴⁹ Of patients who do receive the recommended therapy, many are not adequately monitored, resulting in more than 38,000 strokes and costing Medicare \$3.1 billion.⁵⁰

Since AFib and HF are strongly linked, due to the predisposition of one to the other, it is difficult to estimate the actual percentage of HF cases directly caused by AFib.⁵¹ However, HF is one of the most costly diseases to treat, with an estimated \$30 billion spent in the United States in 2007.⁵² HF is the most common reason for hospitalization among Medicare patients.⁵³ A total of 80 percent of hospitalizations and 90 percent of HF-related deaths occur among those 65 or older.⁵⁴ Hospitalizations for HF among the elderly cost approximately \$13.4 to \$15.1 billion annually, representing approximately 75 to 85 percent of total HF hospital costs.⁵⁵ Annual incremental costs associated with HF are \$12,117 per Medicare patient among AFib patients, according to estimates (Figure 6).

The incremental costs of AFib's other serious complications also add to the disease's economic impact on the Medicare program. Although only 5 percent of patients experience acute myocardial infarction within the first year following AFib diagnosis, the incremental treatment costs have been estimated at \$12,162 per patient. Similarly, 11 percent of patients experience tachycardia, costing Medicare an incremental \$10,143 per patient in the first year (Figure 6).⁵⁶

Greater use of healthcare services among AFib patients

Medicare AFib patients utilize a significantly greater number of healthcare services compared to beneficiaries without AFib. During the first year following AFib diagnosis:⁵⁷

- + 28 percent of AFib patients versus 7 percent of non-AFib patients have ≥ 3 hospital admissions;
- + 14 percent of AFib patients versus 3 percent of non-AFib patients have ≥ 3 emergency room visits; and,
- + 72 percent of AFib patients versus 61 percent of non-AFib patients have ≥ 3 outpatient visits.

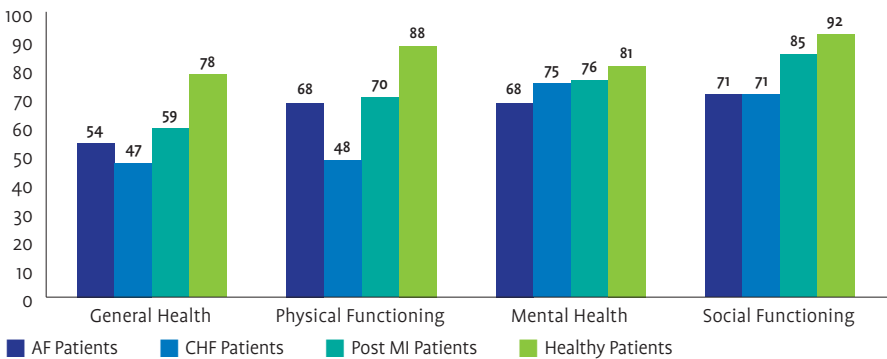
In a separate study, 10 percent of AFib patients under the age of 65 were readmitted to the hospital within one year. One-fifth of these readmissions occurred within the first month. Researchers suggest that an even greater rate of readmissions would occur in the Medicare population.⁵⁸

AFib reduces patients' quality of life

Studies have found that patients with AFib have significantly poorer quality of life (QOL) compared to the general population and other patients with coronary heart disease.⁵⁹ When measured against HF, post-myocardial infarction, and healthy patients, AFib patients often fare poorly, particularly in the mental health and social functioning components of QOL (Figure 7).⁶⁰ Contributing to their decline in QOL, in the 12 months preceding this assessment, approximately 90 percent of AFib patients reported symptoms of palpitations, fatigue, or shortness of breath. Additionally, many patients had AFib episodes (60 percent) more than once a week, had visited the emergency room (45 percent), and were hospitalized at least once (51 percent) during a one-year period.⁶¹

FIGURE 7: AFIB REDUCES PATIENTS' QUALITY OF LIFE

Quality of Life Scores for AFib Patients Compared to Patients with Other Cardiovascular Conditions and Control Group



Dorian P, Werner J, Newman D, et al. "The impairment of health-related quality of life patients with intermittent atrial fibrillation: implications for the assessment of investigational therapy." *Journal of the American College of Cardiology*. 36 (2000) No. 4. AFib = atrial fibrillation; CHF = congestive heart failure; Post MI = post myocardial infarction

Timely diagnosis of AFib may be inadequate in Medicare

AFib has not received the same attention as other chronic conditions regarding diagnosis, treatment, and prevention, even though early diagnosis of AFib is critical to effective patient management and cost avoidance.

New beneficiaries entering the Medicare program are entitled to an initial preventive physical exam, commonly referred to as the "Welcome to Medicare Visit." Among the several screening and prevention services, such as for mood disorders and certain cancers, the exam screens new beneficiaries for diabetes and cardiovascular conditions. However, effective for 2009, the electrocardiogram (ECG or EKG) is no longer included in Medicare's routine screening and prevention initiatives.⁶² An EKG identifies heart rhythm irregularities and may identify patients at risk for developing AFib, whether the patient is symptomatic or asymptomatic.

Since the EKG is no longer included in the “Welcome to Medicare Visit,” AFib may go undetected in many Medicare patients who have AFib but are asymptomatic. Without a timely diagnosis, appropriate treatment is likely to be delayed, putting AFib patients at risk for serious complications, such as stroke and HF.

AFib treatment for Medicare patients is complex

AFib is difficult and costly to manage due to variations in disease presentation and the presence of comorbid conditions in the elderly, which increase risks for drug interactions and other serious complications. Identifying the most appropriate treatment for patients is critical for effective management of AFib. Treatment strategies are designed to:⁶³

- + Prevent blood clots to reduce the chance of stroke;
- + Control heart rate and/or restore rhythm;
- + Treat heart conditions and other medical conditions that may be causing or contributing to the arrhythmia; and
- + Reduce the risk factors for heart disease and stroke.

AFib treatment options range from medication therapy to invasive and/or surgical-based procedures (Figure 8).

FIGURE 8: AFIB TREATMENT RANGES THE SPECTRUM OF CARE

ANTICOAGULANTS	Used to prevent clotting of static blood in atria
ANTIARRHYTHMICS	Used to maintain sinus rhythm
RATE CONTROL	Used to slow down rapid heart rate associated with AFib
CARDIOVERSION	Used to restore normal heart rhythm pharmacologically or with an electric shock
ABLATION	Bursts of radiofrequency energy are delivered to destroy tissue that triggers abnormal electrical signals or to block abnormal electrical pathways
SURGERY	Used to disrupt electrical pathways that generate AFib
PACEMAKER IMPLANTATION	Can be implanted under the skin to regulate the heart rhythm

*Prevalence of complications post-AFib diagnosis compared to non-AFib patients.

**Incremental costs during first year following AFib diagnosis compared to non-AFib patients and adjusted for differences in baseline demographic variables, clinical comorbidities, total baseline costs, and complications in the post-index period.

Lee W. Lamas G. Balu S., et al. “Direct treatment cost of atrial fibrillation in the elderly American population: a Medicare perspective.” *Journal of Medical Economics* 11 (2008): 281-298.

Pharmacological Agents: Clinical guidelines recommend anticoagulants as first-line therapy to prevent stroke, rate control agents to slow conduction through the AV node (e.g., beta blockers, certain calcium channel blockers, and digoxin), and antiarrhythmics to restore and/or help maintain normal heart rhythm.⁶⁴

- + *Anticoagulants:* The physician's choice to use an anticoagulant, such as warfarin, is difficult to make because of the potential side effects. Older patients have both the highest risk for stroke without warfarin but also the highest risk for hemorrhaging on warfarin.⁶⁵ An Avalere analysis of Medicare claims data supports this finding, as the most common procedure observed with AFib (either when AFib is a primary or secondary diagnosis) is the monitoring needed for long-term use of anticoagulants.⁶⁶

Although the anticoagulant warfarin significantly reduces the incidence of stroke in AFib patients,⁶⁷ one study reports that 64 percent of AFib patients are not on warfarin therapy and only 12 percent of patients are being optimally managed on warfarin.⁶⁸

Other risks that factor into a physician's decision whether to use anticoagulants in the elderly are the greater susceptibility to falls, dementia, and noncompliance with prescribed medications.⁶⁹ In addition, warfarin interacts with other medications and certain foods, which can compromise its effectiveness.

For patients at low risk of developing clots or for whom warfarin is not advised, guidelines recommend the use of aspirin.⁷⁰

- + *Rate Control Therapy and Antiarrhythmic Drugs:* Physicians can opt to control the rate of heart-beat through a rate control strategy and/or a rhythm control strategy. If physicians choose a rhythm control strategy, they can choose to maintain and/or restore heart rhythm. The course of care initially selected may prove unsuccessful and the physician may need to pursue an alternate strategy.⁷¹

Pharmacological agents used to control rate or rhythm also pose risks, and patient safety and comorbid conditions must be considered when selecting a treatment. For example, some rate or rhythm drugs interact strongly with warfarin and some increase mortality in patients with heart disease. Other medications should be avoided in patients with renal impairment, and some must be accompanied by monitoring due to the possibility of proarrhythmic effects and risk of extracardiac toxicities.⁷² In the Medicare population, these risks increase and the need for monitoring patients intensifies.

Other Procedures: If medications are ineffective, patients will likely receive more invasive therapies, such as ablation, cardioversion, or implantation of a pacemaker.

While invasive therapies are more expensive compared to prescription drugs, the cost-effectiveness of these alternate treatments for AFib remains unclear. A study evaluating the cost-effectiveness of left atrial catheter ablation compared to two standard approaches (rhythm control with amiodarone and medical rate control therapy) found that ablation may be cost-effective for some AFib patients but not for all.⁷³ The Centers for Medicare & Medicaid Services (CMS) included ablation on its list of potential national coverage determination topics.⁷⁴

AFib Quality Improvement Efforts in Medicare

Despite the increasing prevalence, related complications, and substantial cost burden of AFib, there has been limited focus on quality improvement activities in Medicare for this chronic disease, as only one Medicare program includes a quality measure for AFib. The goal of quality improvement activities is to enhance patient outcomes, promote efficiency in patient care, and reduce program costs. The challenges of treating AFib and its comorbidities, coupled with the variation in treatment provided to AFib patients, may make it difficult to implement Medicare quality improvement efforts. However, given the substantial clinical and economic burden, AFib is an ideal target for quality improvement efforts.

AFib guidelines inform physicians about recommended care

The quality improvement process includes three components: generation of evidence, development of clinical guidelines (Table 1), and creation of performance metrics. Research collected through clinical trials, patient registries, and quality programs are reviewed regularly and then incorporated into clinical guidelines, which reflect the best level of care. Physicians use guidelines to inform their decision-making. Clinicians must use clinical judgment to apply the guidelines to individual patients⁷⁵ and determine how best to adapt the standard of care for their patients. This approach to care is particularly important for a disease like AFib since many patients have multiple comorbidities and are at risk for serious complications.

Generally, guidelines are reviewed annually and are considered current unless they are updated, revised, or subject to sunset provisions and withdrawn.

TABLE 1: OVERVIEW OF AFIB CLINICAL GUIDELINES

ATRIAL FIBRILLATION GUIDELINES	
Guideline Developers	<ul style="list-style-type: none"> + American College of Cardiology (ACC) + American Heart Association (AHA) + Institute for Clinical Systems Improvement + Heart Rhythm Society (HRS) + National Institute for Health and Clinical Excellence + Agency for Healthcare Research and Quality + American College of Physicians/American Academy of Family Physicians + European Society of Cardiology (ESC) + European Heart Rhythm Association
ACC/AHA Partnership	<ul style="list-style-type: none"> + Partnership is the main producer of guidelines for cardiovascular disease + Produce AFib guidelines by collaborating with multiple entities
ACC/AHA/ESC 2006 Guidelines*	<p>Guidelines focus on:</p> <ul style="list-style-type: none"> + Pharmacological rate control + Preventing thromboembolism + Cardioversion + Maintenance of a normal regular heart rhythm (sinus rhythm) <p>Additional considerations include:</p> <ul style="list-style-type: none"> + Postoperative AFib + Heart attack + AFib during pregnancy + Other more specific areas of care
ACC/AHA/HRS 2008 Guidelines**	<ul style="list-style-type: none"> + Addresses the use of pacemakers
<p>*ACC/AHA/ESC 2006 Guidelines for Management of Patients with Atrial Fibrillation **ACC/AHA/HRS 2008 Guidelines for Device Based Therapy of Cardiac Rhythm Abnormalities</p>	
<p>Source: Fuster, V., et al., ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation-executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients with Atrial Fibrillation). Eur Heart J, 2006. 27(16): p. 1979-2030.</p> <p>Epstein, A., et al., ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices) Developed in Collaboration With the American Association for Thoracic Surgery and Society of Thoracic Surgeons. Journal of the American College of Cardiology, 2008. 51: p. 1-62.</p>	

In addition to informing clinical decisions about diagnosis, treatment, and prevention of AFib, clinical guidelines serve as the basis for the development of quality measures that assess whether clinicians are performing recommended practices. The design of measures aligns incentives and influences provider behavior to improve the quality of patient care, improve patient outcomes, and reduce healthcare costs.

Current AFib quality measures are lacking

Compared to other chronic diseases, such as hypertension, HF, or diabetes, where dozens of quality improvement metrics exist, there are only nine AFib quality measures (Figure 9).⁶

FIGURE 9: FEW AFIB MEASURES EXIST RELATIVE TO OTHER SERIOUS HEALTH CONDITIONS

CONDITION	NUMBER OF MEASURES*
Cardiovascular Disease	130
Heart Failure	69
Hypertension	23
Stroke	10
Atrial Fibrillation	9
Other	19
Diabetes	95

*General estimate of current measures. Search conducted through AHRQ's National Quality Measures Clearinghouse. Measures developed internationally and those U.S. measures not directly relevant to the condition are not included. AHRQ's National Quality Measures Clearinghouse. Accessed June 25, 2009. <http://www.qualitymeasures.ahrq.gov/>

Current AFib quality measures broadly assess provider adherence to three primary recommendations focused exclusively on the prevention of stroke:¹

- + Use of pharmacologic therapy. For example, assessing whether AFib patients at risk for thromboembolism or blood clots receive an anticoagulant.
- + Assessment of risk factors for thromboembolism and disease progression. For example, whether practitioners have documented risk factors of thromboembolism for AFib patients.
- + International Normalized Ratio (INR) monitoring. For example, whether clinicians have assessed the INR of patients within one week after the first dose of anticoagulants.

The nine quality measures fit within these three recommendations, but the measures only address the prevention of stroke (Figure 10). While effective anticoagulation is important, the full management of AFib is not reflected in these measures. For example, there are no measures to assess the use of rate and rhythm pharmacological therapies and the more invasive treatments, such as ablation.

1. Avalere Health analyzed AFib measures developed by the following organizations: American College of Cardiology/ American Heart Association, American Medical Association Physician Consortium for Performance Improvement, American Academy of Neurology, American College of Radiology, Institute for Clinical Systems Improvement, National Committee for Quality Assurance, and Resolution Health, Inc.

FIGURE 10: MEDICARE USES ONLY ONE AFIB QUALITY MEASURE

ATRIAL FIBRILLATION MEASURE	DEVELOPERS	NQF ENDORSEMENT (YES/NO)	CURRENT USE
Percentage of patients (without contraindications to anticoagulation) with paroxysmal, persistent, or permanent AFib/atrial flutter with risk factors for thromboembolism who are on warfarin	ICSI	No	Private Payers
Percentage of patients 18 and older with the diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal AFib who were prescribed an anticoagulant at discharge	AAN, ACR, NCQA, PCPI	Yes	Medicare's PQRI
Patients with AFib receiving anticoagulation therapy at discharge	Joint Commission	Yes	Hospitals
Percentage of patients with HF who also have paroxysmal or chronic AFib who were prescribed warfarin therapy	ACC/AHA, PCPI	Yes	N/A*
Percentage of patients with AFib diagnosed during the measurement year newly started on warfarin with an INR test within one week after the first dose	RHI	No	Private Payers
Prescription of warfarin for all patients with nonvalvular AFib or atrial flutter at high risk for thromboembolism ¹	ACC/AHA/PCPI	No	N/A
Patients with nonvalvular AFib or atrial flutter in whom assessment of thromboembolic risk factors has been documented ¹	ACC/AHA/PCPI	No	N/A
Assessment of INR at least once monthly for patients with nonvalvular AFib or atrial flutter receiving anticoagulation therapy with warfarin ¹	ACC/AHA/PCPI	No	Private Payers
Number of patients with nonvalvular AF/flutter with risk factors for thromboembolism having a CHADS ₂ score of 2 or greater (without contradictions to anticoagulation therapy) who are receiving warfarin	ICSI	No	Private Payers

Note: General estimate of current measures

*CMS proposes in the Medicare Physician Fee Schedule and Other Revisions to Part B for CY 2010 to include this measure in the 2010 PQRI program

ICSI: Institute for Clinical Systems Improvement ; AAN: American Academy of Neurology ; PQRI: Physician Quality Reporting Initiative; ACR: American College of Radiology; INR: International Normalized Ratio; RHI: Resolution Health, Inc. Estes, N.A., 3rd, et al., ACC/AHA/Physician Consortium 2008 Clinical Performance Measures for Adults with Nonvalvular Atrial Fibrillation or Atrial Flutter: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and the Physician Consortium for Performance Improvement (Writing Committee to Develop Clinical Performance Measures for Atrial Fibrillation) Developed in Collaboration with the Heart Rhythm Society. J Am Coll Cardiol, 2008. 51(8).

Various public and private payer quality improvement programs rely on quality measures to gauge, encourage, and reward provision of recommended care. Often these measures are linked to financial or non-financial incentives for providers. With such few AFib measures, providers and payers cannot assess if clinical guidelines improve care and reduce healthcare costs.

AFib is not targeted in Medicare’s quality improvement programs

CMS operates multiple quality improvement programs. Measures used by CMS must be endorsed by the National Quality Forum (NQF). (Figure 10)

CMS’ use of AFib quality measures is not widespread. In two previous demonstration programs—Doctor’s Office Quality-Information Technology⁷⁷ and Medicare Care Management Performance Demonstration⁷⁸—CMS only used one AFib measure. Moreover, AFib is not a strong focus of Medicare’s current, most influential initiatives operating in the hospital, outpatient, and physician office settings (Table 2).

TABLE 2: CURRENT MEDICARE QUALITY IMPROVEMENT PROGRAMS

QUALITY IMPROVEMENT PROGRAM	DESCRIPTION
Reporting Hospital Quality Data for Annual Payment Update	Pay-for-reporting program requiring hospitals to submit data for specific inpatient quality measures for common health conditions typically resulting in hospitalization for Medicare beneficiaries. If hospitals do not report on the measures, they receive a 2 percent reduction in their Medicare Annual Payment Update. However, payment is not based on actual performance. The quality of care delivered by hospitals is publically available to consumers. Of the 30 measures required for reporting, AFib measures are not included. ⁷⁹
Hospital Outpatient Quality Data Reporting Program	Pay-for-reporting program in which hospitals that do not submit data for specific outpatient quality measures receive a 2 percent reduction in their Medicare Annual Payment Update. Payment is not based on actual performance. Of the 11 measures required for reporting, AFib measures are not included. ⁸⁰
Physician Quality Reporting Initiative (PQRI)	Voluntary pay-for-reporting program offering doctors a bonus payment when they satisfactorily report on a range of quality measures for covered services furnished to Medicare beneficiaries. ⁸¹ PQRI’s 2009 program currently uses 153 measures, 28 of which are related to cardiovascular disease. Only one AFib measure (anticoagulant therapy prescribed at the time of hospital discharge) is currently in use in the PQRI program. Since this is a voluntary program there is limited representation by participating Medicare physicians.

The use of only one measure in just one of CMS’ main programs makes it difficult for the Medicare program to assess the quality of care offered to beneficiaries. More comprehensive AFib measures addressing the full spectrum of care have the potential to encourage and improve the treatment of AFib patients and reduce program costs.

Key Considerations to Improve the Quality of Care for AFib Patients and Reduce Medicare Costs

AFib's high and increasing prevalence, serious comorbidities, related complications, and substantial economic burden warrant further prioritization and focus by CMS. As the Medicare population continues to grow and the prevalence of AFib increases, successful management of AFib will be imperative for decreasing cardiovascular morbidity and mortality, improving patient QOL, and reducing costs.

In light of current health reform discussions, focusing on expanding coverage, reducing costs, and improving care quality, federal policymakers have the opportunity to include AFib among the chronic conditions targeted for Medicare's current and proposed programs. Reforms aimed at additional research, quality improvement, and cost management will support the advancement of AFib treatment, improve patient outcomes, and reduce costs for the Medicare program.

Table 3 serves as a starting point for developing a long-term strategy to meet the clinical and financial challenges associated with early diagnosis and high-quality management of AFib patients. Avalere rates each of these considerations based on its potential to improve morbidity among AFib patients and reduce healthcare costs, as well as how feasible the recommendation would be to implement.

TABLE 3: KEY CONSIDERATIONS

POTENTIAL FEASIBILITY			
Least/Minimal		Greatest/Most	
OBJECTIVE	DESCRIPTION	STRATEGY	IMPLEMENTATION
Increase Research and Data Collection	More research and better data collection is needed to fill evidence gaps regarding optimal treatment	<i>Analyze Medicare claims data</i>	Moderate Potential/ Most Feasible
		<i>Create a patient registry</i>	Moderate Potential/Feasible
Improve Quality	Greater need to identify patients at risk, enhance patient outcomes and promote efficient care	<i>Develop and implement health risk assessments</i>	Greatest Potential/ Most Feasible
		<i>Develop and implement quality measures</i>	Greatest Potential/ Most Feasible
		<i>Expand medication therapy management programs</i>	Greatest Potential/ Most Feasible
Control Costs and Coordinate Care	Incentivize providers to coordinate care making treatment more efficient and less costly	<i>Incorporate care coordination quality measures</i>	Greatest Potential/ Most Feasible
		<i>Create a "medical home"</i>	Moderate Potential/Feasible
		<i>Bundle payments</i>	Moderate Potential/Feasible

Increased Research and Data Collection

Evidence gaps exist for many questions surrounding AFib, such as optimal treatment, targeting which patients are at risk for AFib, treatment outcomes, and what factors predict successful outcomes. Providers, policymakers, and other stakeholders should consider promoting the need for additional Medicare research to address these wide knowledge gaps. A first step in this assessment is the Institute of Medicine's recent announcement that the full range of AFib therapies is a priority area for comparative effectiveness research (CER).⁸² Although CER is important, additional research is necessary. Potential approaches to gathering new data about AFib include building on existing data collection efforts used to evaluate current treatments and identify areas to improve patient care management and establishing new registries. Listed below are two areas to consider.

→ Analyze Medicare claims data to further assess AFib costs and health outcomes

There are many existing data sources available to help answer important questions about AFib costs and outcomes. For example, CMS could undertake research and/or MedPAC could be asked to commission a research study using CMS data from Medicare Parts A, B, and D to investigate a broad array of AFib patient care issues. Sample research topics include understanding how AFib treatments, such as oral medications for anticoagulation or rate/rhythm control (Part D) or procedures in the inpatient setting (Parts A or B), affect the incidence of AFib episodes or complications such as stroke. Such information will augment efforts to identify the best way to treat patients with AFib and help explain how Medicare can improve the delivery of care.

Implementation: Moderate Potential/Most Feasible

CMS has a plethora of detailed data regarding healthcare services utilization (Parts A, B, and D) of its own beneficiaries. However, due to patient privacy concerns, outside researchers do not have complete access to this data, particularly for the Part D drug utilization. CMS only allows non-government researchers with a limited amount of data to answer their specific research questions. Therefore, Medicare has the ability to analyze its own data and assess how care is being provided to AFib patients. Similar to the registry option, the results could be used to identify gaps in care and areas for quality improvement.

→ Create a national AFib patient registry

Patient registries collect information on the natural history of a disease, assess “real-world” effectiveness and quality of care, and identify safety issues.⁸³ An AFib registry could yield valuable data to inform future choices about optimal patient management.

Currently, there are no patient registries focused specifically on AFib. The American College of Cardiology (ACC), the likely organization to organize an AFib registry, sponsors the National Cardiovascular Data Registry and partners with multiple stakeholder organizations to administer six registries—five hospital and one physician office-based.⁸⁴ Since these registries do not focus on AFib—either they focus on specific technologies (e.g., implantable cardioverter defibrillators) or on related cardiovascular conditions—they capture only limited information about AFib patients.

An AFib-specific registry would enable clinicians to assess the effectiveness of various treatments, identify safety issues, determine if treatments prevent the onset of complications, and/or reduce the utilization of healthcare services. If the data are compelling, clinical guidelines could be updated to reflect the most effective treatment.

Implementation: Moderate Potential/Feasible

Data collected through registries have the potential to provide clinicians and Medicare with valuable information on what is happening in the practice of medicine for AFib patients. One option is to expand current registries to include AFib and its associated treatments. This data would function to inform quality improvement efforts and address important gaps in clinical evidence. However, there are limitations to registries. Data collected through a registry will not be as “clean” compared to data collected in randomized controlled clinical trials and therefore, may pose unique analytical challenges. Additionally, implementing a registry requires multiple resources, including time, funding, and coordination of various stakeholders.

Quality Improvement Initiatives for AFib Patients

The goal of quality improvement is to enhance patient outcomes and promote efficiency in care. This can be achieved through efforts that focus on assuring Medicare providers deliver up-to-date, effective care, patients comply with their providers' recommendations, and CMS reduces barriers that limit patients' compliance and adherence to treatment protocols. Listed below are potential avenues to explore that could enhance current quality improvement efforts.

→ **Develop health risk assessment tools to assess AFib risk**

Recently, the National Heart, Lung, and Blood Institute (NHLBI) raised awareness of the need to develop prevention strategies for AFib.⁸⁵ Evidence suggests aging, diabetes, hypertension, obesity, and cardiovascular disease are all risk factors.⁸⁶ Developing health risk assessment (HRA) tools that include questions related to AFib risk factors could identify patients more susceptible to AFib. This assessment could be added to the Welcome to Medicare Visit. Screening patients early would ensure that patients receive needed treatments before the disease advances and becomes more costly and complicated to manage.

Implementation: Greatest Potential/Most Feasible

In light of the annual \$15.7 billion costs⁸⁷ to treat newly diagnosed Medicare AFib beneficiaries, detecting AFib early is essential to minimizing AFib complications such as stroke and HF and managing comorbidities commonly associated with AFib. Developing HRAs to aid in screening Medicare patients for AFib is a relatively inexpensive task. Funding could be appropriated to the NHLBI to develop risk assessment tools. If patients were assessed, diagnosed, and treated at the earliest opportunity, Medicare would likely see a reduction in healthcare utilization and costs, and AFib Medicare patients would likely experience an improvement in their quality of life.

→ Prioritize AFib as a key disease area for quality improvement

CMS has identified priority areas for quality measure development. These priority areas are conditions that have the greatest mortality and morbidity for the Medicare population. They are also high-volume, high-cost conditions for the Medicare program, and conditions for which there are wide variations in cost and treatment, even in the presence of clinical guidelines.⁸⁸

Implementation: Greatest Potential/Most Feasible

Current health reform proposals include funding for quality measure development. Given the substantial clinical and economic impact of AFib on Medicare, CMS should establish this disease as a priority area for measure development and implementation. Increasing the number and use of AFib measures may help to improve the quality of care provided to Medicare AFib patients and would provide useful information on the effectiveness of AFib treatment management. Measures targeting AFib should reflect the most up-to-date clinical evidence. As such, emerging clinical evidence on AFib should be routinely reviewed and incorporated into guidelines, and measures should be updated as appropriate.

→ Target AFib as a condition for MTM programs

Medication therapy management (MTM) is a component of the Medicare drug benefit (Part D).⁸⁹ MTM programs target beneficiaries who have multiple chronic conditions, take multiple Part D drugs, and/or incur a predetermined annual cost threshold for their drug expenditures.⁹⁰ MTM focuses on enhanced communication between the pharmacist and beneficiary to reduce risk of adverse events, including adverse drug interactions, and to optimize therapeutic outcomes and reduce healthcare costs.

In most cases, AFib patients would likely meet the MTM eligibility requirements since they typically have comorbidities, such as HF, diabetes, or hypertension (three conditions that MTM programs must target),⁹¹ and take multiple drugs to manage their AFib, prevent stroke, and treat their comorbidities. However, AFib is not included on the Medicare program's list of chronic conditions that MTM programs must target.

Implementation: Greatest Potential/Most Feasible

Studies have shown the value of MTM's return on investment, including improved health outcomes, reduced costs, and patient adherence to recommended care.⁹² Part D MTM programs could easily incorporate AFib as a target condition through the sub-regulatory process and it could be adopted as early as the 2011 plan year. AFib patients would be more closely monitored by their health plan and or pharmacist. Given the current treatment regimen, complexities of anticoagulation, and issues related to drug-to-drug interactions, AFib patients would likely benefit from the targeted services of MTM programs. In return, Medicare may experience a reduction in program costs as beneficiaries' AFib would be better managed using fewer healthcare resources.

Coordination of Care for AFib Patients

Many stakeholders believe that the current healthcare delivery system lacks incentives for providers to coordinate care. MedPAC has pointed to the Medicare fee-for-service (FFS) payment system as a cause of the misaligned provider incentives that support volume, rather than value of care.⁹³ Proposals focusing on increasing dialogue and accountability among providers, decreasing duplicative services, and centering care on the patient would benefit AFib patients. In developing these new models, policymakers should consider key issues for AFib patients, including options for screening, disease management, care for comorbidities, such as stroke and HF, the complexity of anticoagulation, and hospitalizations.

→ Incorporate quality measures targeting care coordination into Medicare

In addition to disease-focused quality measures, metrics can also be used to foster improvements in structure and processes of patient care. For example, measures can focus on tracking patients across various providers and settings of care, communication between provider(s) and patient, and the use of information systems to facilitate coordination. To ensure care is not wasteful, medications are not overused, underused, or misused, and care by various providers is not conflicting, care should be well coordinated across all settings.⁹⁴ Coordination measures maximize the value of services delivered over time by facilitating beneficial, efficient, safe, and high-quality patient experiences and improved outcomes.⁹⁵

Implementation: Greatest Potential/Most Feasible

Given the complications, comorbidities, and care transitions from multiple settings for treatment of AFib, the development and use of care coordination measures will help to: 1) assess how well providers are coordinating care, 2) identify areas for improvement, and 3) drive improvement in coordination of care for patients. Currently under review by the National Quality Forum is a care coordination measure for AFib cardiology consultation.⁹⁶ This measure along with other more general care coordination metrics—such as those focusing on transitions of care, reconciled medication list at hospital discharge and others—could be used to enhance AFib patient care management.

→ Create a “medical home” model for AFib patients

A patient-centered “medical home” is a physician-patient relationship, where the healthcare provider—either primary care physician, nurse practitioner, or other related clinician—serves as a locus of the patient’s medical information and coordinates the patient’s ongoing care with other physicians, including specialists. Medical homes receive additional per patient payments to support practice infrastructure development and services that assist in managing and coordinating patient care.

Implementation: Moderate Potential/Feasible

Similar to proposals aimed at bundling payments, the medical home model would likely benefit AFib patients while at the same time controlling Medicare costs. Given the complications of managing patients with AFib and the need to customize patient treatment plans based on AFib severity, symptoms, and treatment response, the medical home model may be a promising approach for facilitating optimal patient management.

→ Bundle payments for AFib-related episodes of care

Under bundled payments, physicians receive reimbursement for a linked set of services delivered by one or a few providers. Bundled payments can span across settings and frequently receive consideration in the context of hospitalization, readmissions, and post-acute care. At a June 2009 Avalere Health conference Jack Lewin, CEO of the American College of Cardiology, stated bundling Medicare payments could involve one or more hospitals, a number of aligned primary care physicians, and specialists accountable for total Medicare spending and quality of care. Incentives would tie to overall Medicare spending and quality measures.⁹⁷ With a shared incentive, the intention is for bundled payments to create incentives for providers to collaborate on patient care while reducing costs.

Implementation: Moderate Potential/Feasible

Bundled Medicare payments for the treatment of AFib may incentivize healthcare providers to more efficiently manage AFib patients. Since physicians will be paid by the episode of care (to be defined) rather than by the amount of healthcare services a beneficiary seeks, physicians will be encouraged to better manage patients at the time of initial diagnosis. Moreover, this suggested new payment model may also help in reducing hospital readmissions for AFib patients and decrease the incidence of stroke and HF, key drivers of medical costs. Bundling payments in tandem with other policy considerations such as HRAs and developing and implementing quality measures, will make it possible for physicians to identify patients with AFib, initiate appropriate treatment, and avert costly and debilitating complications.

Conclusion

Successful management of AFib for Medicare patients requires a focus on early screening, treatment, care coordination, cost management, performance improvement, and data collection and research. As the Medicare population continues to expand and the prevalence of AFib increases, focusing on this serious cardiovascular disease will only grow in importance. Given current health reform discussions, a window of opportunity is available to change the course of care for Medicare patients with AFib. The policy considerations discussed above are not an exhaustive list of how to improve AFib quality of care. Instead, the brief offers an initial direction that, if acted on, has the potential to significantly improve care and patient outcomes, and control costs for the Medicare population.

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