

Background Materials Overview

In this section are some of the articles and papers that were shared with HoW participants to help them prepare for discussions related to the quality indicators.

♥ **HEARTcare**

This one-page statement produced by the Colorado quality improvement organization reinforces the joint commitment of CMS and JCAHO in the use of ACE-I over ARB. The statement encourages dialogue with specialty societies as guidelines related to the quality measures are reviewed.

♥ **New Report Shows Heart Patients Aren't Getting Appropriate Care**

This brief article from *AHQQA Matters* reinforces the need for improvement.

♥ **The Underutilization of Cardiac Medications of Proven Benefit, 1990 to 2002**

This large study published in the *ACC Journal* discusses the need for continued physician education regarding the use of ACE-I at discharge and other medications that have been proven to lengthen lives.

♥ **Implications of Recent Clinical Trials for Heart Failure Performance Measures**

This position statement from the Heart Failure Society of America discusses two recent clinical trials: the CHARM program and the Valiant study. The guideline recommends that ACE-I be considered as first line therapy. In addition, the guideline stresses the need to consider the inclusion/exclusion of ARB for the performance measure.

Background Materials Overview



The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Centers for Medicare and Medicaid Services (CMS) understand that the use of angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) in acute myocardial infarction and heart failure is an area in which the evidence is changing rapidly resulting in some level of controversy around first-line therapy. Over the last several months, this controversy has increased with the release of two important studies known as CHARM and VALIANT.

The measurement staff at JCAHO and CMS understand the concerns and have been working together; we jointly approached the leaders of guideline development for the American College of Cardiology, American Heart Association and Heart Failure Society of America. Controversy remains around this complex issue, and there is insufficient consensus among these leaders that ACEI and ARB are equivalent at the present time. Consequently, in the face of this uncertainty, the JCAHO and CMS have decided to retain the existing ACEI for LVSD measure in both the acute myocardial infarction measure set and the heart failure measure set.

JCAHO and CMS will together continue to maintain dialogue with the appropriate cardiovascular clinical leadership and encourage them to expedite their guideline review and recommendations on this topic. We will closely monitor their response, and will react to their recommendations and reexamine our position as the specialty societies' decisions are officially made public. The measurement staff at the JCAHO and CMS believe that, in general, guidelines should drive performance measure development and evolution. We encourage practitioners with specific concerns about the guidelines to contact their cardiac specialty societies. We look forward to continuing to work on this issue with experts in cardiovascular care.

AHQA Matters

The American Health Quality Association
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New Report Shows Heart Patients Aren't Getting Appropriate Care

Despite general recognition that ACE inhibitor drugs are a necessary treatment for congestive heart failure, a new survey has revealed that nearly one-third of patients leave the hospital without receiving the drugs. In a recent study, Dr. Gregg Fonarow of the University of California, Los Angeles, looked at how often patients hospitalized with heart failure are discharged with four standard kinds of care, including ACE inhibitors at patient discharge; discharges without a complete set of instructions; smoking cessation counseling; and a measure of the left ventricle pumping power. "There are certain hospitals in the United States where 100% of the patients get this," Dr. Fonarow told the *Associated Press*. "There are others where patients had a better chance of winning the lottery than getting the indicated care."

The survey found that 31% of patients considered ideal candidates for ACE inhibitors are sent home without them. Even at elite teaching hospitals affiliated with medical schools, more than one-quarter did not receive the drugs, the survey said. The report also found that 72% of patients were discharged without receiving a complete set of recommended discharge instructions; 69% of smokers with heart failure were never told to quit; and 18% of patients did not receive a measure of their left ventricular ejection fraction, which is a standard indicator of heart failure.

The report analyzed discharge data on 54,639 heart failure patients at 260 hospitals between October 2001-January 2003. The data was presented recently at the American Heart Association's Annual Scientific Meeting in Orlando, FL. The *Associated Press* article reporting on the conference cited Dr. Kenneth LaBresh of MassPRO. Dr. LaBresh said that working with the American Heart Association and its "Get with the Guidelines" program has improved treatment of heart attacks by helping hospitals establish systems that automatically prompt doctors to provide the appropriate care. Of the first 123 hospitals to sign up for the program, Dr. LaBresh said doctors at these hospitals are more likely to give accepted treatments for heart attacks such as aspirin, beta blockers, and cholesterol drugs.

For more info, www.bestofsessions.org.

The Underutilization of Cardiac Medications of Proven Benefit, 1990 to 2002

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OBJECTIVES	To evaluate recent trends, we examined longitudinal national data on the outpatient use of warfarin in atrial fibrillation (AF), beta-blockers and aspirin in coronary artery disease (CAD), and angiotensin-converting enzyme inhibitors (ACEIs) in congestive heart failure (CHF).
BACKGROUND	Previous studies indicate that specific cardiac medications are underutilized.
METHODS	We used the National Disease and Therapeutic Index (NDTI) (produced by IMS HEALTH, Plymouth Meeting, Pennsylvania) for 1990 to 2002, and the National Ambulatory Medical Care Surveys (NAMCS) for 1990 to 2000 to follow nationally representative samples of outpatient visits. For visits by patients with AF (total n = 14,634 visits), CAD (n = 35,295), and CHF (n = 33,008), we examined trends in the proportion of visits with the selected medications reported.
RESULTS	Warfarin use in AF increased from 12% in 1990, to 41% in 1995, to 58% in 2001 in NDTI; a similar moderation of recent increase was seen in NAMCS. For CAD in NDTI, beta-blocker use increased slowly from 19% in 1990, to 20% in 1995, then to 40% in 2001; NAMCS showed this same pattern. Aspirin use in CAD in NDTI increased from 18% in 1990, to 19% in 1995, to 38% in 2001; NAMCS, however, showed lower use rates. For NDTI, ACEI use in CHF increased from 24% in 1990 to 36% in 1996, but increased to only 39% by 2001, a general pattern also seen in NAMCS.
CONCLUSIONS	Both national datasets demonstrate continuing underutilization of these cardiac medications of proven benefit. Although use is increasing, it remains lower than expected, and some increases noted in earlier years have slowed. Substantial public health benefits would result from further adoption of these effective therapies. (J Am Coll Cardiol 2003;41:56–61) © 2003 by the American College of Cardiology Foundation

Despite the considerable investment in developing evidence-based clinical treatment guidelines for cardiac disease, recommended cardiac medications may not always be used when appropriate (1–5). Substantial consensus has been developed through randomized clinical trials and population studies about the use of warfarin in the management of atrial fibrillation (AF), angiotensin-converting enzyme inhibitors (ACEIs) (including angiotensin receptor

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blockers) in congestive heart failure (CHF), and beta-blockers and aspirin in coronary artery disease (CAD). Underutilization of these medications unnecessarily increases the risk of adverse outcomes for patients with these prevalent conditions.

Atrial fibrillation is a leading cause of stroke and the most prevalent chronic cardiac rhythm disorder, affecting 4% of the population older than 60 years (6). Six randomized

controlled trials conducted between 1989 and 1994 demonstrated that long-term anticoagulation with warfarin can safely reduce the risk of stroke attributable to AF (7,8). Despite evidence of benefit and several resulting expert recommendations, the diffusion of warfarin use into practice has been slow and incomplete. As of the mid-1990s, warfarin use was reported in <40% of patients with AF for whom it appeared to be an appropriate therapy (1,9).

Congestive heart failure is a common clinical end stage for several cardiovascular diseases including CAD, hypertension, cardiomyopathy, and valvular disease. Recommended management of CHF has changed dramatically over the past decade. Evidence of reduced mortality from randomized clinical trials and the development of subsequent professional evidence-based guidelines have established ACEIs as the first-line medication therapy in the treatment of CHF (10,11). While past studies show a gradual increase in the use of ACEIs through the 1990s, these increases have been limited, and less than half of eligible patients are taking ACEIs (5,12). Utilization of this class of medications remains low (5,10,12–14), particularly among family physicians (15).

Coronary artery disease is the most prevalent cardiac disorder, affecting over 12 million in the U.S. It is estimated that each year over one million individuals in the U.S. suffer a coronary event (either myocardial infarction or sudden

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Abbreviations and Acronyms

ACEI	= angiotensin-converting enzyme inhibitor
AF	= atrial fibrillation
CAD	= coronary artery disease
CHF	= congestive heart failure
ICD-9-CM	= International Classification of Disease Codes, 9th revision, Clinical Modification
NAMCS	= National Ambulatory Medical Care Survey
NDTI	= National Disease and Therapeutic Index

cardiac death) (16). Randomized clinical trials have shown that beta-blockers reduce the risk of mortality after myocardial infarction, reduce ischemic events in patients with mildly symptomatic disease, and improve survival when compared with diuretics (17). Population studies, augmented by clinical trials results, have demonstrated the benefits of aspirin therapy, particular after acute coronary syndromes (17,18). Both beta-blockers and aspirin appear to have tremendous long-term benefits in secondary prevention (19,20). Past assessments have shown that aspirin and beta-blockers are underused in CAD, despite their clinically proven benefits and cost-effectiveness (3,4,18,19,21-28). When used to treat myocardial infarction, beta-blocker usage increased steadily until 1994, when it reached steady state usage near 60% (21). Similarly, aspirin use has increased over time although utilization remains low, perhaps as low as a quarter of outpatients with CAD in 1996 (23).

We analyzed two ongoing national surveys of office-based physicians' prescribing patterns to track recent longitudinal patterns in the use of cardiac medication therapies of proven benefit. Using information available from the federal National Ambulatory Medical Care Surveys (NAMCS) and the National Disease and Therapeutic Index (NDTI) produced by IMS HEALTH (Plymouth Meeting, Pennsylvania), we provide a national update of recommended cardiac medication use in an outpatient setting.

METHODS

Data sources. Data for this study were obtained from two sources of longitudinal national data on physician prescribing practices: NAMCS for 1990 through 2000 (29) and NDTI for 1990 through the first quarter of 2002 (30).

The NAMCS is a continuing survey conducted annually by the National Center for Health Statistics that provides ongoing nationally representative diagnostic and prescribing information on U.S. office-based physicians and their patients. Physicians from the master lists of the American Medical Association and the American Osteopathic Association (both in Chicago, Illinois) are selected by random stratified sampling by specialty and geographic region. Nonpatient care specialties, most notably anesthesiology, pathology, and radiology, are excluded. For each participating physician in each year, one week is randomly selected

and visits during this week systematically sampled. Non-office contacts, such as phone or institutional encounters, are excluded.

Physicians completed encounter forms detailing clinical interactions, up to six continuing and newly ordered medication therapies (including over-the-counter and self-medication), patient demographic information, and diagnosis information coded into International Classification of Disease Codes, 9th revision, Clinical Modification (ICD-9-CM) (31) and NAMCS-specific reason-for-visit codes. For each visit record, the National Center for Health Statistics calculates a visit weight using physician and visit sampling rates adjusted for nonresponse. Visit weights can be used to extrapolate to national practice patterns for office-based physicians.

The NDTI is an ongoing survey of U.S. office-based physicians conducted by IMS HEALTH providing nationally representative diagnostic and treatment data (32). Like NAMCS, physicians from the American Medical Association and the American Osteopathic Association master lists are randomly sampled by region and specialty. Once an adequate sampling panel has been established, at least 3,500 participating physicians are sampled quarterly by region and specialty. Physicians are permitted to remain in the sample as long as they wish, with replacements selected for attrition.

Each quarter, physicians participating in NDTI report on each patient encounter during a randomly selected, consecutive, two-workday sampling period. They record information detailing patient diagnosis, prescribed and known over-the-counter medication therapies, and demographic information. Patient contacts are largely comprised of office visits (85% in 2000), but also include hospital (10%) and nursing home (1%) visits, as well as telephone contacts (3%). Each encounter can generate multiple, separate data records for each physician-reported diagnosis. Because we have used summary tabular data available from NDTI, we were not able to account for medication contraindications.

For both data sources, ICD-9-CM codes were used to classify patients with AF, CHF, and CAD (31). Atrial fibrillation was identified by ICD-9-CM diagnostic code 427.3 (excluding 427.32 for NAMCS). Congestive heart failure was identified by ICD-9-CM codes 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, and 428. Coronary artery disease was identified using ICD-9-CM codes 413.0, 413.9, 414.0, 414.2, 414.5, 414.8, and 414.9. Some NAMCS visits were excluded because of the presence of additional diagnoses that represent relatively strong contraindications for the medications under consideration. For warfarin use, we excluded AF patients with peptic ulcer disease, gastritis, duodenitis, alcoholism, gait abnormality, ataxia, Alzheimer's or other dementia, cerebral hemorrhage, seizure disorder, benign or malignant central nervous system tumors, and renal insufficiency. In assessing ACEI use in CHF, we excluded hyperkalemia. Two separate samples were formed among

CAD patients: for aspirin, we excluded peptic ulcer disease, gastritis, duodenitis, and cerebral hemorrhage, while for beta-blockers we excluded bronchospasm, chronic obstructive pulmonary disease, asthma, cardiac conduction blocks, and peripheral vascular disease.

Medications were defined using NAMCS-specific drug codes and by generic and proprietary names in NDTI. Warfarin use was defined to include other anticoagulants, including heparin. Aspirin use was identified in patients prescribed single-ingredient aspirin formulations, combination drugs containing aspirin (excluding those medications indicated for acute analgesia), various antiplatelet aspirin alternatives such as ticlopidine and clopidogrel, and anticoagulants. Beta-blockers were defined as all beta-blockers available as single or combination products and included alpha-beta-blockers. Angiotensin-converting enzyme inhibitor use included all ACEIs, as well as angiotensin II receptor blockers.

For the 11 years of study under NAMCS, 1,532 patient visits were recorded for AF, 3,113 for CHF, 7,977 for CAD with beta-blockers, and 7,700 for CAD with aspirin. The NDTI provided much larger sample sizes. For the 13 years of study, NDTI provided data on 16,138 patient visits for AF, 29,727 for CHF, and 65,194 for CAD.

Statistical analysis. Our analysis focused on estimating the rate of warfarin used for AF, ACEIs used for CHF, and beta-blockers and aspirin used for CAD by U.S. office-based physicians. Patients receiving one or more of the selected medications were identified on the basis of the coding of the generic or proprietary names of each medication in each drug class among as many as six possible medication codes for NAMCS and an unlimited number for NDTI for each visit. For both NAMCS and NDTI, our outcome measure was the proportion of visits where the use of the selected medications was reported.

For both NAMCS and NDTI, the figures we report are weighted to reflect national patterns of practice. In each survey, weights are associated with each visit-level record that allows extrapolation to national estimates. These weights account for the probability of sampling based on the physician's specialty and geographic area, adjusted for non-response. Our estimates of national practice contain uncertainty due to the sampling process used in each survey. In more recent years, our annual estimates for warfarin use in AF have 95% confidence limits of $\pm 10\%$ for the NAMCS estimates and $\pm 2\%$ for the NDTI estimates. For ACEI use in CHF, the 95% confidence limits are $\pm 8\%$ for NAMCS and $\pm 1.5\%$ for NDTI. For beta-blocker and aspirin use in CAD, the 95% confidence limits are $\pm 5\%$ for NAMCS and $\pm 1\%$ for NDTI.

These two surveys of office-based physicians' practices provide similar, but distinct, sources of information on whether physicians prescribe cardiac medications of proven benefit. Each data source has particular strengths and weaknesses. The short lag time in the availability of NDTI and its larger sample size must be balanced against its

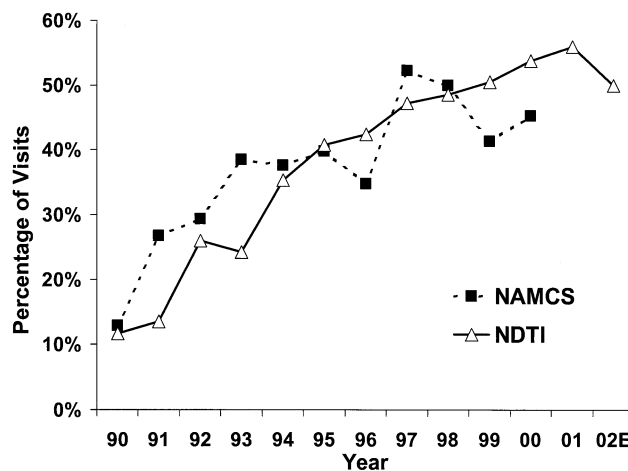


Figure 1. Reported warfarin use in patients with atrial fibrillation, 1990 to 2002, National Ambulatory Medical Care Survey (NAMCS) and IMS HEALTH, National Disease and Therapeutic Index (NDTI). Data for 2002 are estimated (E) from data for January 2002 through March 2002.

nonrandom selection of physicians and the inability to exclude patients with contraindications to specific medications. Although NAMCS' ability to control for contraindications is an advantage, specific medications may go unreported as physicians are permitted to report only six medications per visit record. The sample sizes associated with NDTI allow the derivation of more statistically reliable estimates through this data source. While neither data source reports on adherence or unreported medication use, these two data sources complement each other and offer the potential for comparison of their results.

This study was carried out under Human Subjects approval by the Stanford University Institutional Review Board.

RESULTS

Using two independent national surveys of outpatient physicians in the U.S., we noted sizable increases in the use of cardiac medications of proven benefit. For each of the four medications, however, the most recent data indicate that rates of medication use remain lower than expected.

AF. From 1990 to 2000, NAMCS estimates an annual average of 3.1 million visits for AF by patients not contraindicated for warfarin therapy. Warfarin anticoagulation among these AF patients increased rapidly from 13% in 1990 to 39% in 1993. Inconsistent increases have continued to be as high as 52% in 1997, although in 2000 the rate was only 45%.

The NDTI estimates an annual average of 4.6 million patient visits for AF. Similar to NAMCS, NDTI also showed a rapid increase in warfarin use in the early 1990s, with an increase from 12% in 1990 to 41% in 1995. Subsequent increases have been less rapid, but consistent, with warfarin use continuing to increase to 51% in 2002 (Fig. 1).

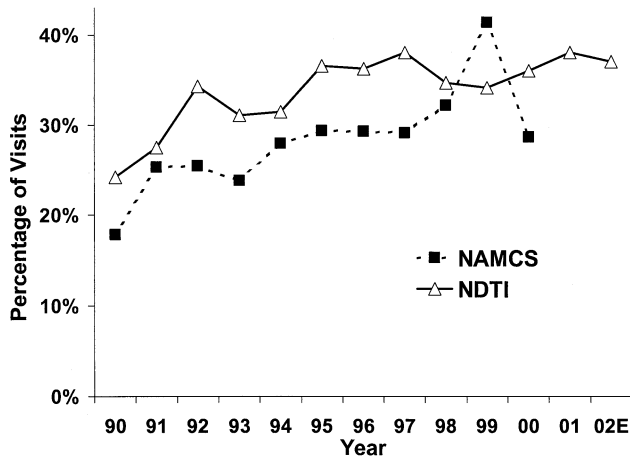


Figure 2. Reported angiotensin-converting enzyme inhibitor and angiotensin receptor blocker use in patients with congestive heart failure, 1990 to 2002, National Ambulatory Medical Care Survey (NAMCS) and IMS HEALTH, National Disease and Therapeutic Index (NDTI). Data for 2002 are estimated (E) from data for January 2002 through March 2002.

CHF. Estimates from NAMCS suggest an annual average of 7.5 million patient visits for CHF. Among these visits, ACEI utilization increased from 18% in 1990, to 28% in 1994, to 41% in 1999, but with a plateau effect between 1994 and 1997. We observed a sudden drop in ACEI use to 28% in 2000. The NDTI provides data on an extrapolated estimate of 8.4 million annual encounters for all patients with CHF. For these CHF patients, NDTI data suggests an initial increase in ACEI use from 24% in 1992 to 34% in 1992, followed by a fluctuating plateau with gradual increase to 38% in 2002 (Fig. 2).

CAD. The NAMCS estimates 15.8 million annual visits by patients with CAD, without contraindications to beta-blockers. The NAMCS indicates a fluctuating trend towards increasing beta-blocker use from 14% in 1990, to 23% in 1992, to 32% in 2000. The NDTI provides data on an extrapolated estimate of 18.4 million annual encounters for all patients with CAD. The NDTI shows a pattern of steadily increasing beta-blocker use from 19% in 1991, to 26% in 1996, to 45% by 2001 (Fig. 3).

With an annual average of 15.3 million visits by CAD patients without contraindications to aspirin, NAMCS showed increasing aspirin use from 20% in 1990 to 32% in 1995, but then unchanged or even declining use in subsequent years, with 26% in 1999. In NDTI, aspirin use increased more consistently from 14% in 1990, to 30% in 1996, to 44% in 2002 (Fig. 4).

COMMENT

Using two independent representative samples of visits to office-based physicians in the U.S., we have found that physicians utilize cardiac medication of proven benefit less often than expected. Despite strong clinical evidence demonstrating the benefit of warfarin in AF, ACEIs in CHF, and aspirin and beta-blockers in CAD, use of these medications remains relatively low. While time trends indicate

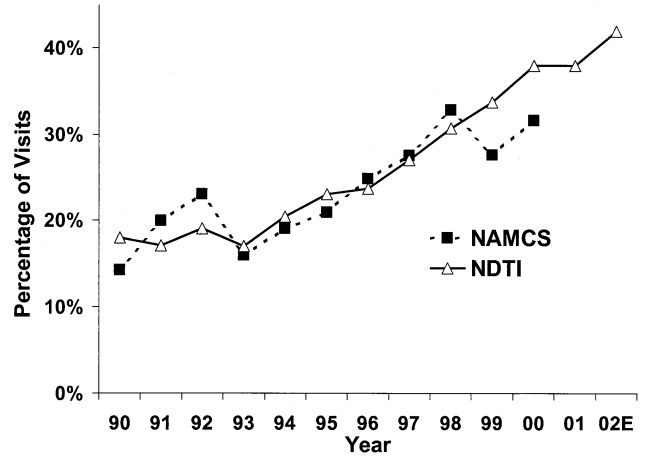


Figure 3. Reported beta-blocker use in patients with coronary artery disease, 1990 to 2002, National Ambulatory Medical Care Survey (NAMCS) and IMS HEALTH, National Disease and Therapeutic Index (NDTI). Data for 2002 are estimated (E) from data for January 2002 through March 2002.

increasing use of these medications, the rate of increase noted has been slow. Given that more than a decade has passed since conclusive evidence has been available demonstrating the benefit of these medications, more rapid adoption might have been expected. This pattern contrasts with several examples of the rapid adoption of other new medication practices, for example the diffusion of selective serotonin reuptake inhibitors for depression treatment in the late 1980s (33), the rapid increase in antiobesity medication use in the mid-1990s (34), and the sharp rise of calcium channel antagonists and ACEIs for hypertension through the 1980s (35).

Warfarin use in AF has increased from 13% in 1990 to 45% in 2002. While this dramatic change indicates that physicians have modified their practices in response to evidence of warfarin's benefits, it is concerning that warfarin

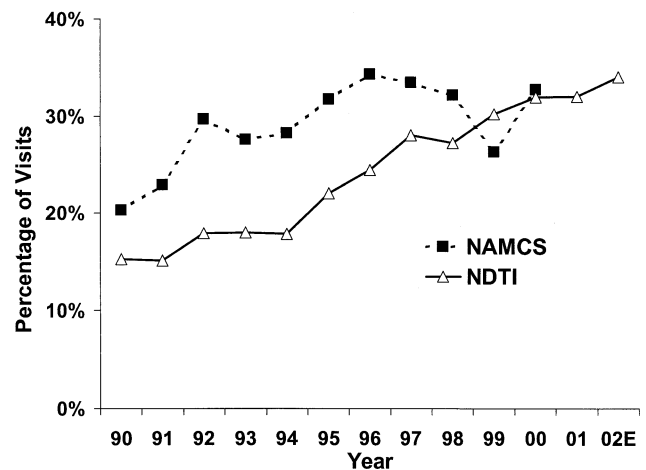


Figure 4. Reported aspirin use in patients with coronary artery disease, 1990 to 2002, National Ambulatory Medical Care Survey (NAMCS) and IMS HEALTH, National Disease and Therapeutic Index (NDTI). Data for 2002 are estimated (E) from data for January 2002 through March 2002.

use has increased only slowly over time and that current levels of use remain below desired levels. This is similar to trends reported in prior studies (1,9).

Similarly, ACEI use followed previously reported trends in the treatment of CHF (5,12,36), being used in <40% of the cases where it appeared to be an appropriate therapy. While increases in ACEI use continue, the rate of increase over the past decade has averaged only 2% per year in absolute terms.

We observed the use of aspirin and beta-blockers in CAD to be substantially lower than reported in most other studies (3,21,37–39). One explanation may be that we focused on all outpatients with CAD, whereas other studies have more narrowly focused on CAD patients after acute coronary events and/or hospitalizations. For both aspirin and beta-blockers in CAD, there have been substantial increases in use. Given that evidence of benefit has been available for longer than for warfarin in AF and ACEIs in CHF, it is notable that increasing use has been slow to occur and that the current levels of use remain below desirable levels.

A number of factors may contribute to poor utilization patterns noted for these medication therapies. Not all physicians may be aware of the evidence supporting the use of these medications. In some cases, physicians may over-emphasize relative contraindications, particularly for beta-blockers (40). In addition, the nature of outpatient practice may interfere with guideline adherence, as patients and physicians may stress acute care concerns while neglecting preventive issues (41).

The results noted from the federally conducted NAMCS and those noted from the privately surveyed NDTI are remarkably similar. The cross-validation noted between these two data sources allows an increased degree of confidence in the reliability of our findings. National extrapolation of patient encounters for each disease is greater for NDTI than for NAMCS. This may result because NDTI includes specific types of encounters (e.g., hospital visits) and practice settings (hospital outpatient departments) that are not included in NAMCS, as well as the exclusion of NAMCS patient visits with medication contraindications. As expected, there are greater fluctuations in the medication use rates reported from NAMCS, reflecting the smaller sample sizes available through NAMCS compared with NDTI.

Study limitations. Several limitations of our analysis suggest that care should be taken in interpreting some of our results. Physicians participating in the NAMCS and NDTI surveys may differ from nonparticipants in ways that are difficult to assess. For example, NAMCS excludes physicians practicing in publicly funded clinics. Patterns of medication use in patients seen by office-based physicians may not represent the general population of cardiac patients, as patients seeing physicians more frequently are likely to be overrepresented in both data sources.

Physicians and patients may underreport medications, particularly aspirin because of its over-the-counter availabil-

ity. Therefore, our estimates of aspirin use may well represent underestimates. On the other hand, the failure of physicians and patients to report such a critical medication in CAD management would, nonetheless, suggest that aspirin use is not being sufficiently emphasized by physicians and patients.

In NAMCS, physicians are constrained to reporting a limited number of medications: five in 1990 to 1995 and six in 1996 to 2000. When patients are taking more than these numbers, some medications will not be reported. This may be a particular issue for patients with CHF, where the number of medications used may easily exceed these limits. This could contribute to the somewhat lower rates of medication use noted for NAMCS compared with NDTI.

In NAMCS, contraindications to medication therapy may not be fully reported. This suggests that we have included some patients who were not eligible for the medications being examined. With the NDTI data, it is not possible to evaluate potential contraindications. As a result, this data source may underestimate rates of medication use in truly eligible patients. In neither NAMCS nor NDTI have we been able to identify patients who are not taking recommended medications because of past allergic or other adverse reactions.

While we recognize that the use of these medications may be influenced by a number of independent predictors such as geographic location, gender, and race (9,12,22,23), such predictor data were not included in this report.

Implications. Universal use of medications of proven benefit in the management of AF, CHF, and CAD may be neither attainable nor desirable. The use rates we note for warfarin, ACEIs, beta-blockers, and aspirin are low enough, however, to suggest that a significant burden of adverse events in these cardiac conditions may result from underutilization of these medications. A substantial burden of health care costs, morbidity, and mortality may be preventable through the more thorough application of recommendations concerning these medications.

The slow diffusion of these recommended practices calls into question current mechanisms by which new medical practices diffuse into community use. Other mechanisms that promote more rapid adoption of recommended therapies may be required. There may be a need for more complete dissemination of clinical recommendations via approaches other than clinical guidelines. In addition, health care systems might be able to improve medication use by providing feedback to physicians regarding their patterns of medication use. Other possible solutions could include mechanisms that supplant and augment the current system of clinical care. These approaches might include nurse case-management of longitudinal treatment, increased patient participation in prevention issues, and electronic medical record systems that allow for both tracking of prevention goals and real-time advice on patient management. The potential public health benefits of increasing use of these

medications may warrant substantial efforts in ensuring that their use is optimized.

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HFSA Position Statement

Implications of Recent Clinical Trials for Heart Failure Performance Measures

EXECUTIVE COUNCIL OF THE HEART FAILURE SOCIETY OF AMERICA¹

Background

Over the past five years the Centers for Medicare & Medicaid Services (CMS) and the Joint Commission for the Accreditation of Health Care Organizations (JCAHO) have striven to improve the quality of health care by promulgating indicators of quality care. These indicators, also known as performance measures, assess processes of care for several key conditions including heart failure (HF). Several criteria are applied during the definition of performance measures, but the first and perhaps most important criterion is that the measure reflects care for which there is consensus that a given procedure or treatment is useful and effective. Consensus, in turn, has been determined from guidelines published by recognized professional organizations. These indicators are growing in consequence as organizations are increasingly reporting them publicly, and some arrangements with purchasers are creating linkages between the quality indicators and bonus payments for services.

The use of ACE inhibitors in patients with HF and reduced left ventricular ejection fraction (LVEF) is a key performance measure. The support for this measure, however, has evolved significantly over the past several months in response to the publication of two clinical trials of angiotensin receptor blocker (ARB) use. This position statement will address the impact of these trial results on the formulation of performance measures for HF care.

Recent Clinical Trials

The following two trials published in the last several months are particularly germane to this issue.

I. CHARM Program: A total of 7601 patients were enrolled in three separate randomized trials to either 32 mg candesartan or placebo in three distinct HF populations, and results were reported for each trial individually as well as for the total population. In patients with an LVEF $\leq 40\%$ who were intolerant of ACE inhibitors, candesartan reduced the primary end point of cardiovascular mortality plus HF hospitalization by 23% ($p = 0.0004$), a reduction driven principally by decreased hospitalizations. In HF patients with an LVEF $\leq 40\%$ who were already taking an ACE inhibitor and, many of them, also a beta blocker, CV mortality and HF hospitalizations were reduced by 15% ($p = 0.011$) compared with the use of an ACE inhibitor alone, though all-cause mortality was not reduced significantly. The third trial involved HF patients with LVEF $> 40\%$ and demonstrated no significant benefit, though the secondary endpoint of total HF hospitalizations was reduced significantly. For the primary endpoint of the overall analysis of all three trials, the effect of candesartan on all-cause mortality did not achieve statistical significance ($p = 0.055$).

II. VALIANT: This study compared the ARB valsartan with the ACE inhibitor captopril or a combination of the two in 14,808 patients who had reduced LVEF ($\leq 35\%$ by echocardiography or contrast ventriculography or $\leq 40\%$ by radionuclide ventriculography) or clinical or radiographic signs of HF within 10 days after an MI. There was no statistically significant difference in all cause mortality among the three treatments. The 95% confidence intervals around the mortality estimates were sufficiently small for it to be said that the ARB was not inferior to the ACE inhibitor.

Discussion

Guideline recommendations for HF will be driven by the following points: 1) the benefit of ACE inhibitors is firmly established; 2) the benefit of ARBs within HF is established among patients who are ACE inhibitor intolerant; 3) ARBs

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¹This statement was reviewed and approved by the HFSA Executive Council (Appendix 1). A single reprint is available by contacting the HFSA at 651-642-1633 or writing the HFSA, Court International Suite 240 South, 2550 University Avenue West, St. Paul, MN 55114.

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appear “non-inferior” to ACE inhibitors post-MI. These points will result in a distinction between recommendations for ACE inhibitors and ARBs, with the guidelines favoring the former as first line therapy.

Guidelines, however, are not performance measures and the distinction is important. Performance measures currently do not give partial credit for a particular clinical strategy. Thus, currently if patients are not treated with an ACE inhibitor and do not have documentation of a contraindication to an ACE inhibitor then they are given no credit by the quality indicator, whether or not they are taking an ARB. Although the Guidelines endorse ACE inhibitors more enthusiastically than ARBs, the evidence regarding the non-inferiority of ARBs to ACE inhibitors suggests that the indicator be made more permissive and count ARBs as an acceptable alternative to ACE inhibitors for patients with heart failure and reduced LVEF. The benefit of ARBs is now sufficiently established, and the differential value between the 2 classes of agents is small, at most. The counting of patients receiving ARBs as satisfying a performance measure for medical therapy in HF is a reasonable approach. Given that there remain many patients with HF and reduced LVEF who are not on either an ACE inhibitor or an ARB, it is important to send a clear message of the necessity for treatment with either of these medications. The Guideline recommendations that ACE inhibitors should be considered the first line therapy remains the policy of this organization,

but this statement recommends that physicians receive credit for using one of these agents in the appropriate setting. Moreover, for patients who are ACE inhibitor intolerant, due to cough or related symptoms, ARBs should definitely be used.

Recommendation

Performance measures should assess the proportion of patients with HF and reduced LVEF who are treated with either ACE inhibitors or ARBs. For patients intolerant to ACE inhibitor due to cough or related symptoms, ARBs should definitely be offered to the patient as an alternative therapy.

Appendix 1

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