GUIDANT

May 7, 2004

Re: Docket 2004S-0170 Medicare Prescription Drug, Improvement and Modernization Act-Section 1013: Suggest Priority Topics for Research

Dear Sirs:

Guidant Corporation welcomes the opportunity to recommend priority topics for research under Section 1013 of the Medicare Modernization Act. We request that our recommendations be considered for the initial priority list. In line with the intent of Section 1013, our recommended topics focus on areas where there is a potential to significantly improve prevention and treatment of disease and on conditions that impose high direct and indirect costs on patients and society.

Headquartered in Indianapolis, Indiana, with manufacturing and/or research and development facilities in the states of Minnesota, California and Washington, as well as in Puerto Rico and Ireland, Guidant Corporation is a leading designer and manufacturer of medical technologies used primarily to treat cardiac and vascular illnesses. Guidant's products save and enhance lives.

Recommended Research Topics

1) Access to Cardiovascular Care for Women in the Medicare Program

Issue

Cardiovascular disease (CVD) is the number one cause of death among women, killing roughly 500,000 women each year.[1] Furthermore, since 1984, more women die each year of cardiovascular disease than do men.[2] Heart disease represents a particularly serious health risk for older women. According to the National Heart, Lung, Blood, Institute (NHLBI), one in four women over the age of 65 has heart disease. Research by WomenHeart: the National Coalition for Women with Heart Disease indicates that of the 435,000 American women that have heart attacks each year, 80% are over the age 65. As the population continues to age, the number of elderly women with heart disease will increase, compounding the seriousness of this healthcare problem.

With the availability and adoption of advanced medical technologies and therapies in the last few decades such as pharmacological therapy, angioplasties, stents, pacemakers, and implantable cardiac defibrillators (ICDs), mortality in men from CVD has been declining, yet women have not experienced similar benefits as demonstrated by the following:

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- 38% of women yet only 25% of men will die within one year of a first recognized heart attack. [3]
- 35% of women yet only 18% of men heart attack survivors will have another heart attack within six years. [4]
- 46% of women yet only 22% of men heart attack survivors will be disabled with heart failure within six years. [5]
- Women are almost twice as likely as men to die after bypass surgery. [6]

Women with coronary artery disease are more likely than men to receive suboptimal and less aggressive care. For example, women are less likely to be scheduled for stress testing or referred for coronary angiography after initial exercise treadmill testing.[7] A recent evaluation of the Heart and Estrogen/progestin Replacement Study (HERS) found that in women with known coronary artery disease, there was an under use of preventative pharmacological treatments that have been established as beneficial, notably aspirin, ß-blockers and statins.[8] Women receive only 33% of angioplasties, stents and bypass surgery; 28% of implantable defibrillators, and 36% of open heart surgeries. Furthermore, women comprise only 25% of participants in all heart related research studies. [9]

Research conducted by the Agency for Healthcare Research and Quality acknowledges that the reasons for the disparity in treatment and outcomes are not well understood.[10] Research to date indicates that reasons for the continued high mortality and morbidity rates for women include lack of awareness by both female patients and their doctors, the difficulty of diagnosing warning symptoms, under referral for diagnostic testing and specialists including cardiologists, possible gender differences in the disease and efficacy of therapies and the presence of coexisting and chronic conditions. All of these factors lead to under treatment and poor outcomes for women.

While programs such as the NHBLI's "Heart Truth Campaign" and its "Red Dress Project" as well as the American Heart Association's "Go Red for Women" Campaign have begun to increase awareness regarding risk factors and prevalence, more work is needed to understand this discrepancy in access to and outcomes of cardiovascular care.

Recommendation for Research

Guidant recommends that AHRQ include on its priority list for research the topic of access to and outcomes of cardiovascular care for female Medicare beneficiaries with heart disease. The study should address the following issues:

- The extent to which there is a disparity in the level and quality of cardiovascular care and in outcomes for women vs. men

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- Clinical and economic impact of inadequate access to cardiovascular care for women
- The barriers to adequate cardiovascular care for women including lack of beneficiary awareness with regard to heart disease, physician education and practice and referral patterns, limited participation in clinical trials and economic and social factors
- Examination of how the various barriers impact women's access to cardiovascular care
- Possible solutions to remove/address barriers to adequate cardiovascular care for women and improve outcomes

2) Screening for Carotid Artery Stenosis (CAS) for Prevention of Stroke

Issue

Stroke related to cerebrovascular disease is the third leading killer in the United States today with projected annual costs of $51 billion in 2003, including $12 billion in nursing home costs alone.[11] 87% of deaths and 74% of hospitalizations occur in seniors, 65 years and older [12] but the burden of the debilitating consequences of stroke affects both seniors and their family members, often resulting in deteriorated quality of life and requiring skilled care in an institutional setting. Payment for post-acute care is one of the fastest growing categories in Medicare spending, and stroke has been identified as one of the diagnostic-related groups with the highest number of beneficiaries using post-acute care. [13] Socioeconomic costs for patients who experience debilitating stroke are on the rise, especially as the aging population strains the long-term care infrastructure.

Screening tests could be used to identify individuals with hemodynamically significant (>60%) CAS who may be at enhanced risk of stroke. The benefit of such early detection is that early clinical intervention could reduce the morbidity resulting from cerebrovascular disease. Options for treating asymptomatic CAS include (1) medical therapy, (2) surgical plaque removal (carotid endartarectomy), or (3) carotid stenting (CMS is currently in the process of considering coverage for carotid stenting procedures for high-risk patients). Improvements in drug technology, surgical techniques and device technology continue improving outcomes in all three categories. Additionally, individuals with CAS less than 60% would also benefit from screening, as the diagnosis might motivate them to alter some risk factors (smoking, hypertension, physical inactivity etc.) thereby reducing the probability of experiencing a stroke later in life. Another benefit of a screening program is that it would increase awareness about stroke amongst Medicare beneficiaries, which could lead to early detection of stroke and lower costs.

Recommendation for Research

Guidant recommends that AHRQ include on its priority list for research a study of the clinical benefits and economic viability of early screening for carotid artery disease in Medicare beneficiaries. The project would involve identifying the appropriate subset of Medicare beneficiaries to screen, examining screening options and determining a suitable screening protocol.

The hypothesis behind this proposal is that a carotid screening program would provide socioeconomic benefit by reducing incidence of stroke in the long-term. Individuals diagnosed with CAS would seek appropriate treatment early and thus decrease the probability of experiencing a debilitating stroke in the long-term.

We believe that additional research to examine the reasons for suboptimal cardiovascular care and outcomes for female Medicare beneficiaries and to study the potential to decrease the incidence of stroke through early screening, as described above, would benefit Medicare beneficiaries and the Medicare program.

Sincerely,

Barbara J. Calvert
Director, Reimbursement Strategies

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Notes

1) Vital Statistics Report, Vol. 50, No. 15, September 16, 2002.

2) 2003 Heart and Stroke Statistical Update; 2002:4.

3) Adapted from WomenHeart website: www.womenheart.org "Women and Heart Disease Fact Sheet"

4) Adapted from WomenHeart website: www.womenheart.org "Women and Heart Disease Fact Sheet"

5) Adapted from WomenHeart website: www.womenheart.org "Women and Heart Disease Fact Sheet"

6) Adapted from WomenHeart website: www.womenheart.org "Women and Heart Disease Fact Sheet"

7) Cleveland Clinic Journal of Med. 2001; 441-448

8) Ann Intern Med 2003; 138:81-89

9) Adapted from WomenHeart website: www.womenheart.org "Women and Heart Disease Fact Sheet"

10) Adapted from Agency for Healthcare Research and Quality website: www.ahrq.gov/research/womenheart.htm

11) American Heart Association. Heart disease and stroke statistics---2003 update. Dallas, Texas: American Heart Association, 2002

12) CDC. State-specific mortality from stroke and distribution of place of death---United States, 1999. MMWR 2002;51:429--33.

13) Kane RL, Lin W, Blewett LA. Geographic variation in the use of post-acute care. Health Serv Res 2002;37:667--82.

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