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A Business Case for Early Detection of Cardiovascular Disease

The financial impact of current trends in population screening programs

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Introduction

The economic impact of cardiovascular disease in the U.S. is enormous. Considered as a whole, the annual cost of treating Americans with CVD currently exceeds $200 billion. This represents actual expenditures, and is the most spent on any single disease category. But the indirect cost of CVD is just as staggering—each year the morbidity and early mortality attributed to CVD represents a drain of over $140 billion from the U.S. economy in the form of lost productivity (see Tables 1 and 2). This is a huge burden borne by U.S. employers and reduces American competitiveness around the world.

With these amounts of resources at stake, any program to detect heart disease in its earlier (and less costly) stages stands to make an important contribution to both the health and the economy of the country. If screening programs can reduce the acute treatment costs and associated morbidity of CVD by just 10% over five years, a positive impact of over $350 billion would be realized by the overall economy. This is more money than is being considered under some of the current Medicare prescription drug benefit proposals. Fortunately, there is a growing body of medical evidence about the benefits of actively screening certain populations for CVD. We are issuing this white paper in response to the need for sound advice on the issue of how hospitals and physicians can use screening programs to improve the quality and profitability of cardio-vascular care while simultaneously controlling costs and reducing waste. Our intent is to provide cardiovascular leaders with a framework to evaluate the appropriateness of pursuing a variety of different screening strategies in their own cardiovascular programs.

> *Cardiovascular disease is a huge economic burden that reduces American competitiveness in the global economy*

Clinical Burden of Disease

This year, an estimated 1.1 million Americans will experience a new or recurrent coronary attack (defined as myocardial infarction or fatal CHD). About 650,000 of these will be first attacks and over 40 percent of the people who experience an attack in a given year will die from it. Coronary heart disease thus represents the single largest killer of American males and females, accounting for more than 20% of all deaths (1). The way in which heart disease manifests itself is also of critical importance. About 225,000 people a year die of CHD without being hospitalized. In 50 percent of men and 63 percent of women who died suddenly of CHD, there were no previous symptoms of this disease [1]. Because of the wide variety of conditions covered under the heading of CVD, for practical purposes in this paper we focus on CHD, which represents the largest subset of CVD in terms of patient volume and expense. However, CHD is also highly correlated with the existence and/or prediction of additional forms of CVD—especially peripheral vascular disease (PVD). While CHD can take a number of forms, one of the most important is atherosclerosis of the coronary arteries. Atherosclerosis is a process that leads to a group of diseases characterized by a thickening of artery walls. Atherosclerosis is also a leading cause of many deaths from heart attack [1]. When atherosclerosis develops in the vessels of the heart it is commonly referred to as coronary artery disease (CAD). CAD is a leading cause of death in the U.S. and constitutes a tremendous population burden in terms of morbidity, early mortality, and economic costs. As a progressive disease, it is generally recognized that the ability to detect and treat CAD earlier in its development is a desirable goal and could greatly reduce its health and economic costs [2-4].

If screening programs reduce the acute treatment costs and associated morbidity of CVD by just 10% over five years, a positive impact of over $350 billion would be realized by the U.S. economy.

Table 1 - U.S. Annual Indirect Costs of Cardiovascular Diseases

(All cost data in $US Billions)

Census Division	2003 Resident Population	CVD Morbidity	CVD Mortality*	Total Indirect Costs of CVD	
New England	14,242,639	$1.82	$6.19	$8.01	5.6%
Mid Atlantic	40,265,612	$5.27	$17.90	$23.17	16.3%
South Atlantic	54,460,829	$5.63	$19.14	$24.77	17.4%
East North Central	45,902,617	$4.99	$16.94	$21.93	15.4%
East South Central	17,348,761	$1.59	$5.41	$7.00	4.9%
West North Central	19,572,241	$1.91	$6.50	$8.42	5.9%
West South Central	32,920,319	$3.39	$11.53	$14.93	10.5%
Mountain	19,450,326	$1.95	$6.62	$8.57	6.0%
Pacific	47,292,817	$5.78	$19.65	$25.43	17.9%
United States	**291,456,161**	**$32.34**	**$109.88**	**$142.21**	**100%**

* Lost future earnings of persons who will die in 2003, discounted at 3%.

Sources: U.S. Census Bureau population data; National Heart, Lung & Blood Institute cost models; CACI regional healthcare cost indices; U.S. Bureau of Labor Statistics. Note: totals reflect rounding.

Figure 1 – Per Capita Average CVD Spending by Census Region (Age 45+)

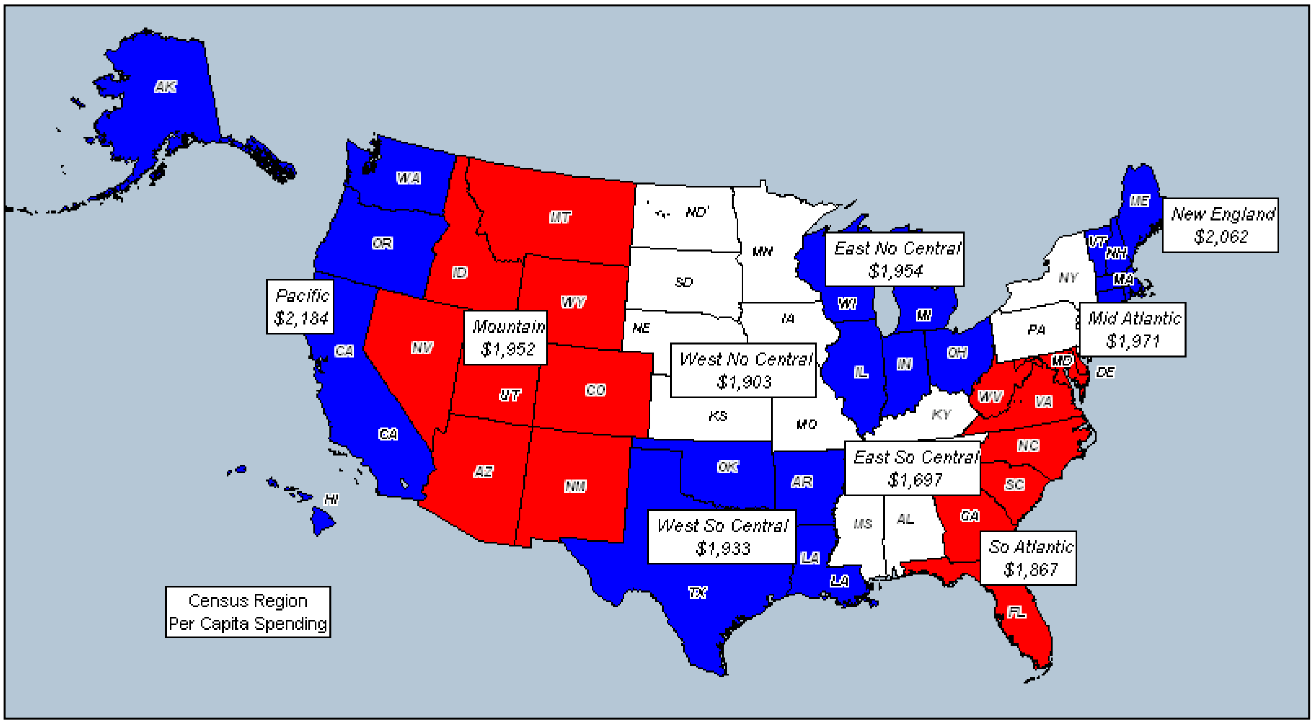

Table 2 - Annual U.S. Spending on Cardiovascular Disease

(Spending data in $US Billions, except per capita amounts)

U.S. Census Division	Hospital Services	Physician Services	Other CVD Spending*	Total U.S. Spending on CVD	Avg. Per Capita Spending**
New England	$5.51	$1.73	$4.11	$11.35	$2,062
Mid Atlantic	$15.94	$4.58	$9.92	$30.43	$1,971
South Atlantic	$16.44	$5.83	$16.17	$38.44	$1,867
East North Central	$15.93	$4.99	$12.05	$32.97	$1,954
East South Central	$5.62	$1.65	$3.66	$10.92	$1,697
West North Central	$6.95	$2.09	$4.79	$13.83	$1,903
West South Central	$9.66	$3.29	$8.50	$21.45	$1,933
Mountain	$4.80	$2.03	$6.31	$13.13	$1,952
Pacific	$13.10	$5.40	$16.76	$35.27	$2,184
United States	**$93.94**	**$31.57**	**$82.28**	**$207.80**	**$1,959**

* Includes spending on drugs, devices, medical durables, home health, nursing home, and other misc. services for cardiovascular patients.

**Average per capita spending is based on population aged 45 years and older.

Sources: U.S. Census Bureau population data; National Heart, Lung & Blood Institute cost models; CACI regional healthcare cost indices; U.S. Bureau of Labor Statistics. Note: totals reflect rounding.

Traditional CHD screening tools

There are four traditional methods of screening for coronary heart disease: 1) Risk factor analysis (RFA); 2) Exercise (treadmill) stress testing (ETT); and, 3) Myocardial perfusion imaging through single photon emission computed tomography (SPECT, also known as nuclear imaging). In some circumstances, 4) stress echocardiography, is also used. While each of these methods has been shown to be of limited value in the screening of asymptomatic individuals, they are widely used for this purpose[3,4]. There is widespread variation in the application of traditional approaches to CHD screening around the country and among different practitioners. Often an easier, inexpensive test will be followed by a series of more costly and invasive tests if positive results are first achieved. Table 3 depicts a traditional screening/testing pathway commonly used for the identification and triage of individuals with suspected heart disease. In theory, the primary benefits of screening for heart disease would be the ability to identify individuals at the greatest risk for acute coronary events. It would facilitate the detection of disease in its preclinical stages in order to prevent its progression and/or more aggressively manage its natural course, thus reducing the morbidity and early mortality that would otherwise occur. Ideally, an effective screening tool for heart disease would distinguish between those individuals that are at risk for a coronary event and those that are not. Table 4 outlines a set of guidelines that has been suggested for deciding whether a given screening tool or population-screening program is appropriate in a community setting [2].

Table 3. A Traditional CHD Screening Pathway

Level	Clinical Tests	Provider	Typical Cost	If positive triage to:
1	**INITIAL TESTS** Weight, Vital Signs, Pulse Blood Pressure Cardiac Risk Factor Assessment Body Fat Analysis Total Cholesterol	LPN or RN	Free or minimal charge	Level 2
2	**LEVEL 1 PLUS:** Resting and/or Exercise EKG HDL/LDL/Triglycerides Nurse/PA Brief Exam Blood Sugar/Urinalysis	LPN or RN	<$50	Level 3
3	**LEVEL 2 PLUS:** Comprehensive PCP Exam Maximal Stress Treadmill Full Blood Panel	LPN, RN, PA, MD	>$200	Further tests or treatment (per physician)
4	**LEVEL 3 PLUS:** Exam by Cardiologist Stress Thallium or Stress Echo Full Blood Panel	Cardiologist	>$500	Further tests or treatment (per cardiologist)

Table 4. Guidelines for Evaluating a Heart Disease Screening Program

1. Has the program's effectiveness been demonstrated in a randomized trial, and if so,
2. Are efficacious treatments available?
3. Does the current burden of suffering warrant screening?
4. Is there a good screening test?
5. Does the program reach those who could benefit from it?
6. Can the healthcare system cope with the screening program?
7. Will those who had a positive screening comply with subsequent advice and interventions?

Emerging Trends in Screening—Calcium Scoring with EBT

Recently electron beam computed tomography (EBT) has been suggested as an imaging modality with the ability to accurately detect coronary artery calcification (CAC), an acknowledged marker for atherosclerosis, and predict future cardiac events due to CAD. Though EBT has been available for almost 10 years, its deployment has been limited due to differing opinions surrounding its validity and its potential impact on the health care system. Proponents claim that EBT represents a significant technological advancement that can non-invasively identify the presence of CAD, and that the cost is reasonable in light of its effectiveness in identifying heart disease in otherwise asymptomatic individuals. Critics counter that the technology lacks good positive predictive value for hard events associated with CAD, that existing alternatives are less costly and equally effective, and that it is difficult to identify the niche where EBT can fit into a screening program for asymptomatic individuals.

To promote a better understanding of these issues we conducted an analysis of the available evidence of the usefulness of EBT as a screening tool in diagnosing early stage CAD and predicting future coronary events. We were particularly interested in answering the following questions:

- How well does EBT currently work?
- How does calcium scoring by EBT compare with existing screening tools?
- What are the diagnostic limitations of the test?
- What would constitute an appropriate target population?
- What are the potential benefits and harms of the test?

Nature of EBT Scanning

Scanning of the coronary arteries with EBT is conducted using an electron gun and a stationary tungsten "target" rather than a standard x-ray tube to generate x-rays [(2)]. This constitutes a distinct technological difference from other advanced CT scanners, and the technology in this form originated as a proprietary asset of San Francisco-based Imatron, Inc. The scanners themselves typically cost in excess of $1 million, and in the marketplace individual scans are usually priced between $300 and $500, and are not yet widely covered by insurance. An EBT scan is completely noninvasive, requires only a few seconds of scanning time, and is typically completed within 10 to 15 minutes. During an EBT scan 30 to 40 serial transaxial images are obtained in 100 ms with a scan slice thickness of 3 to 6 mm for the purpose of detecting coronary calcium. The scans usually are obtained during 1 or 2 breath-holding sequences using ECG triggering near end diastole before atrial contraction, thus minimizing the effect of cardiac motion(2). Calcium in the arterial walls is identified because of its high CT density relative to soft tissue and blood(5). Rather than relying on visual interpretation, sophisticated algorithms have been developed to compute the total extent and density of calcification of the coronary arteries as detected by EBT. The most commonly used scoring system is known as the Agatston method. As confirmed by coronary angiography, it has been reported that a score of 0 - 10 indicates an extremely low likelihood of any obstructive CAD. A score between 10 and 400 is associated with a significant risk of future cardiac events, especially when scores are >100. A calcium score >400 implies the presence of extensive CAD. The clinical significance of a particular score is influenced by age and gender. A score of 150 may be average for a 70-year-old man, but would be considered abnormal for a 40-year-old woman (6).

Literature Review

We initially reviewed approximately 40 articles identified via a Medline search on terms related to 'electron beam computed tomography' and a hand search of more recent, as yet unindexed publications. After the initial review we narrowed our sources to seven studies that met the criteria outlined in Table 5. We rejected from our analysis studies that were retrospective in nature, those that dealt primarily with symptomatic patients (or those with confirmed CAD), and those that did not assess the future course of disease in terms of the endpoints listed in Table 5. Our primary aim was to learn what is known and what remains uncertain about the use of EBT as a screening tool for CAD.

Table 5. Criteria for Inclusion in Analysis

Study Design

Prospective cohort studies (results of any randomized trials have not been published)
Use of EBT in comparison/conjunction with existing screening tools (ETT, SPECT, RFA)

Target Population

Study population essentially asymptomatic
Subjects followed for at least 1.5 years post test

Outcomes of Interest

Study endpoints including at least one of the following:

1) Diagnosis of obstructive CAD or silent myocardial ischemia
2) Myocardial infarction
3) Death
4) Coronary revascularization

Effectiveness of EBT—Analysis of the Evidence

In analyzing the results presented in our core group of studies we were particularly interested in data dealing with the prediction of hard endpoints in previously asymptomatic individuals. We considered hard endpoints to include the occurrence of MI or death due to CHD as a primary cause. We judged soft endpoints to include diagnosis of CAD or myocardial ischemia, and subsequent revascularization (coronary angioplasty or coronary artery bypass graft surgery). We gave lesser weight to the mere diagnosis of CAD on the grounds that there is imperfect knowledge regarding the natural course of CAD in terms of which types of plaque are most important in predicting future acute coronary events[7]. Likewise, we attributed little significance to the ability of EBT to predict future revascularization because positive tests can introduce a bias towards further testing and intervention, though there is no published evidence that additional testing necessarily results from the use of EBT [2,8].

How well does EBT technology work?

An assessment of EBT technology should include not only the detection of CAC, but also the clinical and prognostic significance of these results. It is well documented that EBT is extraordinarily sensitive in detecting CAC[9]. More important is an understanding of the degree to which CAC correlates with future coronary events. Table 6 includes data extracted from the studies in our analysis that specifically studied hard outcomes in the study population. It is readily apparent that different studies have produced conflicting results, with relative risk for MI or death due to CHD ranging from a low of 2.4 (for those with CACS greater than the group median) to a high of 22.1 (for those with CACS

Table 6. Synthesis of EBT Studies Analyzing Post-Test Hard Coronary Events in Asymptomatic Subjects

Study	N=	Event Definition	Mean Follow-Up, yrs.	RR of MI or death	CACS RR Threshold Criteria	Overall Accuracy*	Main Conclusion
Arad et al, 1996	1173	Cardiac death, MI, stroke, revasc.	1.6	22.1	>160	91%	"EBT-based screening…data support the routine use of…EBT to screen for occult CAD in asymptomatic middle-aged men and women."
Arad et al, 2000	1172	Cardiac death, MI, stroke, revasc.	3.6	15.8 MI, 22.2 death	>160	84%	"In asymptomatic adults, EBT…predicts coronary death and nonfatal MI and the need for revascularization…"
Detrano et al, 1999	1196	Death, MI	3.5	2.4	>group median	64%	"Neither risk-factor assessment nor EBT calcium is an accurate event predictor in high-risk asymptomatic adults…Its use in clinical screening is not justified at this time."
Raggi et al, 2000	632	Death, MI	2.7	7.2	>median for age sex groups	N/A	"Coronary calcium is present in most patient who suffer acute coronary events."
Secci et al, 1997	326	Death, MI	2.7	3	>median in group	62%	"Coronary calcium appears to be a weak predictor of coronary death and infarction."

Note: follow-up in all studies > 99%. * Area under curve on ROC graphs.

scores of >160.) The studies in Table 6 represent the work of 3 teams: Arad et al.[3,8], the EBT research foundation [13], and the South Bay Heart Watch group [7,12]. The methods used for recruitment of subjects varied considerably, as did the risk-factor profiles and pre-test profiling of subjects. Arad's group included self-referred as well as doctor recommended asymptomatic patients on Long Island whereas the South Bay Heart Watch group consisted mostly of individuals with two or more cardiac disease risk factors in a large prospective study in Southern California. It does appear that criticisms of the studies producing negative conclusions on the predictive ability of EBT on the grounds that the study population was highly skewed toward high-risk individuals are justifiable. However, the lack of consistency across studies still serves as a powerful indicator that a randomized trial of a broad cross-section of the target population with long-term analysis of the occurrence of hard endpoints will be necessary before significant doubts about the usefulness of the CACS can be resolved. In the mean time, scientists and industry supporters continue to improve the technology and refine the scoring algorithms, suggesting that the validity and usefulness of EBT scanning is likely to improve over time.

Comparison of EBT to Traditional Screening Tools

Table 7 provides a summary of meta-analysis derived assessments of sensitivity, specificity and predictive accuracy of the various approaches to CHD screening, as published elsewhere[2]. Based on these data, EBT is shown to have the highest aggregate sensitivity of any of the tests (91%), but the lowest specificity (49%), with a total predictive accuracy of 70%, which falls in the middle of the range of values calculated for other approaches. In order to maximize the usefulness of EBT, it would thus be advisable to stratify subjects in such a way as to improve the sensitivity. One of the studies we evaluated[10] sought to address this issue by creating a probabilistic model for optimizing the use of calcium scoring in coronary-event prediction. Because the sensitivity and specificity scores are established by comparison to results confirmed through coronary angiography, there is a significant 'workup' or 'verification' bias inherent in the results[2]. In adjusting for this bias, Bielak et al. were able to improve the specificity from 38.6% to 72.4%, with little change in the sensitivity scores (97% vs. 99.1%)[10].

Scientists and industry supporters continue to improve EBT technology, suggesting that the validity and usefulness of EBT scanning is likely to improve over time.

In the studies we evaluated, there was no clear consensus on the appropriate order or sequence of tests. Some investigators studied EBT in isolation. Others directly compared EBT to ETT and/or SPECT. In some cases the results of EBT in combination with other tests were evaluated. In general, the studies seemed to favor using EBT as an adjunctive test providing additional

Table 7. Comparison of Various CHD Screening Modalities (from O'Rourke et. al. [2])

Grouping	No. of Studies	Total No.of Patients	Sensitivity, %	Specificity, %	Predictive Accuracy, %
Meta-analysis of standard exercise ECG	147	24,047	68	77	73
Excluding MI patients	41	11,691	67	74	69
Limiting workup bias	2	2,350	50	90	69
Meta-analysis of exercise test scores	24	11,788			80
Perfusion scintigraphy	2	28,751	89	80	89
Exercise echocardiography	58	5,000	85	79	83
Nonexercise stress tests					
Pharmacological stress scintigraphy	11	<1,000	85	91	87
Dobutamine echocardiography	5	<1,000	88	84	86
EBT	16	3,683	91	49	70

information, rather than as a substitute for more traditional screening tests. Such an approach might limit the potential cost-effectiveness of EBT as a screening modality. However, one study of EBT found that it was superior to RFA and ETT as a predictor of a positive SPECT, implying that EBT might serve a useful function in narrowing the indications for SPECT, thus saving money and preventing certain harms that might result from the cascade of testing potentially triggered by nuclear imaging[10].

What are the diagnostic limitations of the test?

While we were concerned primarily with the usefulness of coronary calcium scores generated through EBT screening, this is not the only application of the technology. In addition to its use as a screening tool, EBT imaging is being studied for uses in a number of additional heart disease and general imaging applications. However, compared to other imaging modalities, EBT is not as helpful in defining location of coronary stenoses or in defining prognosis. The most powerful cardiology tool for defining clinical prognosis is nuclear stress testing. Patients with significant coronary calcium deposition are typically further considered for nuclear stress testing. In general, echocardiography is superior for evaluating valvular structures and valvular function of the heart[2,11]. Nor is EBT a replacement for coronary angiography (cardiac catheterization). At the present coronary angiography remains the 'gold standard' for accurately assessing luminal narrowing within the coronary circulation [2]. It appears unlikely that EBT coronary scanning would evolve as a substitute for these diagnostic modalities in the future.

What should the target population be?

As a practical matter, it is easier to determine those who would not benefit from EBT scanning than those who would. There is general consensus that EBT screening is of little relevance to anyone with symptomatic or previously diagnosed CAD. Additionally, the investigators of the South Bay Heart Watch, a government-funded study of asymptomatic subjects in southern California, concluded that in high-risk individuals "neither risk-factor assessment nor EBT calcium is an accurate event predictor…" [12]. Because the subjects of this study were all at or above the 75th percentile for coronary risk by the Framingham criteria, the lesser prognostic accuracy of the CACS in this study has been attributed to the narrow range of observation[3]. In light of this, it appears that EBT scanning should not be extended to those individuals in the highest quartile or quintile of risk based on RFA, as in this population it does not add significant information to the presence of risk factors[12]. Raggi et al. concluded that using CACS percentiles rather than absolute CACS constitute a more effective method to stratify individuals at risk[13]. In terms of gender, it is well documented that the onset of CAD is typically delayed in women due to the cardioprotective effects of estrogen. This might seem to indicate that EBT scanning could be safely postponed in women to a later age as compared to men. However, the results of Bielak et al. indicate that the quantity of CAC that was optimal for detecting CAD differed primarily by age, but not by sex within each age group [10]. In terms of age, it appears difficult to determine cutoff points on both the low end for who would benefit from the test. This is a particularly important issue because, while individuals with high CACS at great risk for coronary events exist in age categories <50, they occur much less frequently than in the >50 age category. This might be called the 'needle in the haystack' problem, and presents difficult issues in terms of cost and the advisability of extending coverage for this test to populations where it is unlikely that a large number of people would benefit. For those >50 years old, it was reported that a CACS of 0 (absence of detected CAC) provided strong evidence of a lack of obstructive CAD and a low risk of any events, implying that there is a certain 'rule out' value that might accrue to even very old segments of the population [10].However, there is ample evidence that a large proportion of very old individuals accumulate calcium in their coronary arteries. Thus, beyond the age of 65 or 70, EBT will increasingly lose its ability to predict hard cardiac events.

The societal burden of heart disease justifies the initial cost of screening programs, provided that they are carefully targeted to those individuals that are most likely to benefit.

What are the potential benefits and harms?

In weighing the potential benefits and harms of EBT screening it is necessary to answer a number of questions. In terms of potential harm, the lack of a large, long-term randomized trial is probably the single most important element preventing more generalizable conclusions regarding the usefulness of EBT. This raises the possibility that patients might incur financial and even health costs for treating phantom conditions diagnosed through imperfect technology. Yet in the interest of all, we believe that the current societal burden of suffering due to CHD justifies the initial cost of screening programs, provided that they are carefully targeted to those individuals that are most likely to benefit. Indeed, if this is not true for heart, then it is unlikely that any other disease or condition could warrant population screening. Our assessment is that EBT has the potential to be a screening tool superior to the best available alternatives. It may even prevent the use of some tests currently used but of lesser predictive value. These benefits are based on the fact that effective therapies exist that can address the health impact of CHD.

Unintended Benefits

There may also be other benefits associated with behavior modification as a result of EBT screening. Wong et al. found that potentially beneficial behavioral changes occurred as a result of a positive EBT test, such as new aspirin usage (RR=1.86, p=<0.01), new cholesterol medication (RR=3.54, p=0.01), decreasing dietary fat (RR=1.58, p=0.12), and weight loss. On the negative side, Wong also found a slight increase in hospitalization as a result of a positive EBT scan (RR=1.18, p=0.05) and evidence of increased 'worry' on the part of those testing positive (RR=2.73, p=0.01) [14]. Finally, while the thesis of primary prevention of CHD through early detection holds great intuitive appeal, other factors (e.g., changes in diet, exercise, etc.) can also contribute to the reduction of CHD morbidity and mortality and that proving direct causality associated with any single approach will likely remain elusive.

The Cost of Screening

In considering the benefits and harms of a screening program it is also advisable to include a consideration of costs and cost-effectiveness. Establishing a comprehensive understanding of the financial impact of EBT screening would not be easy. O'Rourke et al have commented that conducting randomized trials of EBT would be difficult and expensive, and might provide little information regarding long-term benefit [2]. While currently decision-analytic models of the long-term cost-effectiveness of EBT screening and its downstream consequences are being developed, even these models might offer limited applicability to real-world practice [2]. Currently EBT is not covered by most insurance plans but has been marketed for self-referral in a number of markets. Typically, the advertised price is in the $300 to $500 range, and initial capital costs often exceed $1 million. Since there is a lack of empirical data that can be used to evaluate actual costs and benefits, Rumberger et al[15] developed a simulation model to assess the cost-effectiveness of EBT relative to a testing path way that included four separate screening tests: 1) treadmill with ECG monitoring, 2) exercise testing with echocardiography, 3) exercise testing with SPECT imaging, and 4) EBT. If any of the four tests yielded a positive test result, then angiography was performed. Analyses that computed expected costs and positive and negative predictive values were performed at five different prevalence values for obstructive heart disease. The authors conclude that the model "... provides data that support the application of EBT and quantification of coronary artery calcification as a minimum cost and maximum effectiveness approach to the diagnosis of obstructive coronary disease in specific subsets of the general population." If these results are replicated in future studies, it may become possible to develop a sound population-based policy recommendation on EBT screening.

Conclusions

Heart disease is the leading cause of death in the U.S. and constitutes a tremendous population burden in terms of morbidity, early mortality, and economic costs. As a progressive disease, it has long been recognized that the ability to detect and treat heart disease earlier in its development could greatly reduce its health and economic impact on society. Recently electron beam computed tomography has been suggested as a screening modality with the ability to accurately detect coronary artery calcification, an acknowledged marker for atherosclerosis, and predict future cardiac events due to CAD. As a result of our analysis we conclude that

1) The best designed studies of EBT scanning of the coronary arteries provide promising evidence that EBT, alone or as an adjunct to other screening tools, is better at predicting future coronary events than traditional screening through RFA, ETT and/or SPECT imaging.
2) Despite this, each of the studies we reviewed contains potentially significant threats to validity and limits on the generalizability of conclusions.
3) Insufficient information is available regarding the immediate and downstream economic costs of broad-based EBT screening programs to make a reasonable judgment of cost effectiveness. And,
4) There remains a need for a large, long-term randomized clinical trial before a definitive answer on the advisability of mass population screening is possible.

Promisingly, there appears to be a general consensus in the literature that EBT is very precise in detecting coronary calcium, which in turn is highly correlated with CAD. Sensitivity & specificity scores are good and EBT scanning produces very high negative predictive values. There are moderate marginal costs (average $400 per test), and those costs will likely drop with volume increases as economies of scale develop. Based on available evidence, it seems that EBT scanning might help prevent a significant number of unheralded deaths due to acute coronary syndromes in asymptomatic individuals through promoting the earlier onset of medical management in patients testing positive. Nevertheless, the use of EBT as a screening tool is of limited value in symptomatic individuals and/or those whose risk factor analysis concludes ‘very high risk.’ While there is minimal immediate harm (the test is non-invasive, quick and easy), downstream harms of testing from a ‘cascade of tests,’ and an additional ‘worry’ factor would probably be incurred at some level.

It is also clear that there remains a need for more study, especially a large, prospective randomized clinical trial with long-term follow-up before a definitive answer on the advisability of mass screening is possible. Fortunately, there are several additional studies being planned and conducted, including the NIH/NHLBI sponsored MESA study (multi-ethnic study of atherosclerosis), a study commissioned by the U.S. army on asymptomatic servicemen, and others. So there exist reasons to be hopeful that before too long the decision about usefulness of EBT as a screening tool for CHD can be based on reliable, consistent evidence.

Acronyms Used

CAC	Coronary artery calcium
CACS	Coronary artery calcium score
CAD	Coronary artery disease
CHD	Coronary heart disease
EBT	Electron beam computed tomography
ETT	Exercise treadmill test
MI	Myocardial infarction
PVD	Peripheral Vascular Disease
RFA	Risk-factor assessment
RR	Relative risk
SPECT	Single photon emission computed tomography

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About HealthGroup West

HealthGroup West is expert in the planning and development of cardiac and vascular healthcare services. It is one of the most knowledgeable groups of experts in the country on the development of cardiovascular markets and all types of specialized cardiovascular services and facilities. Collectively, the full-time staff and special advisors of HealthGroup West, LLC represent many years of hands-on experience in the analysis and development of cardiovascular and other specialty medical services. They hold advanced degrees in the fields of Business Administration, Health Policy, Information Science, Medicine, Law, Clinical Sciences, and others. We welcome your feedback and comments on this report.

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