ORIGINAL PAPER

### Further Opportunities for Cost Reduction of Medical Care

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**Abstract** The already high and still rising cost of health care has become a matter of serious concern and a subject of political dispute. The problem has no magic cures but, as is shown here, there are a number of promising modifications in current practice that promise to reduce the required outlays without impairing appropriate health care. Continual reports of new medicines, new tests, and new procedures have created an urgent need for careful comparison and evaluation of the advantages and beneficial results that these innovations offer. The same is true for the growing knowledge of genetic variations, which affects the course of therapy for some patients. Costs also can be saved, in some instances, by utilization of medical therapy, rather than interventional procedures. Preventive medicine provides still more opportunities for cost savings. This paper provides an overview of promising potential approaches to reduce the cost of health care.

**Keywords** Cost reduction · Medical care · Recommendations

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#### Introduction

As we all know, the cost of health care in the United States is rising at a disturbingly rapid rate. What is not widely recognized, however, is that this is true throughout the world, in all developed nations [1]. This paper, which expands on our prior publication<sup>1</sup> on the subject [2], identifies a variety of ways in which these costs can be reduced without worsening health problems—even if the growth of health care costs does not slow.

#### Cost Savings via Accurate Evaluation of Medical Treatments: Reduction of Sampling Errors and Faulty Testing and Analyses

The explosion of medical technology has expanded the diagnostic and therapeutic modes of medical care. The many options in diagnostics and therapy have multiplied their applications but also have added to the cost of medical care. Given this, gaps in our knowledge and short-comings in our analyses of the safety and effectiveness of these medical technologies can lead to unnecessary expenditures and pose new dangers to patients.

Throughout medical history, conventional wisdom has been, at times, the only available treatment option. All too often, however, such approaches subsequently may be proven to be wrong or inadequate. As such, their use increased medical care costs but offered few, if any, offsetting benefits. However, many writings on statistical analysis, as applied to other disciplines, have taught us that

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<sup>&</sup>lt;sup>1</sup> In the interest of thoroughness, some of the examples cited in our previous paper [2] are repeated here.

careful measurement and analysis subsequently may reveal the incorrectness of conventional wisdom.

For instance, until the mid-1950s, conventional wisdom dictated complete bed rest for several months for heart attack patients. This was accompanied by a high mortality rate, due to inactivity, from deep vein thrombosis and pulmonary embolism. By the 1960s, however, hospitals had begun to encourage first-day ambulation and subsequent hospital discharge within one to three days, following a heart attack—a remarkable medical and economic accomplishment. During that time period, hospital mortality for acute myocardial infarction patients dropped from 47% in 1954, in a city hospital before the introduction of coronary care units (CCUs), [3] to 22% in 1967 (with CCUs) [4], to 10% in 2002, and currently is in the less than 5–10% range [5–7].

Research that evaluates the effectiveness of medical treatments may help us avoid ineffective and even harmful treatments. But research and statistical analysis have their own pitfalls<sup>2</sup>—the misinterpretation of mere correlation as evidence of causation, for instance, can be a source of serious error.

Another key shortcoming is exemplified by standard methods of testing a new medicine by comparing its effectiveness with that of a placebo, rather than a substitute medication in earlier or current use. The placebo comparison reveals any special threats posed by the new medication and whether or not it is more effective than the absence of treatment. However, it prevents researchers from determining whether or not some older substitute is just as good as, or even better than, the novel product. This is particularly important if the new treatment is more costly than the earlier approach. Moreover, this issue is confounded by the "placebo-effect phenomenon"-the curious fact that a number of patients appear to derive benefits from placebos. (Of course, it must be noted that not all studies of new medication entail comparison with placebos; some are tested against standard medications.)

Sampling procedures also have their dangers. A report in the *Annals of Surgical Oncology* of nine trials [8] in 13,991 surgical procedures for cancers of the prostate, colon, lung, and breast was rendered questionable by problems in the selection of cases, in terms of age and sex. For instance, although 62% of these cancers occur in people over age 65, only 27% of the study's sample was in that age group. In addition, very few female participants were included in the colon and lung cancer groups, thus raising additional questions about those findings. The old axiom that each individual patient is different needs reiteration and understanding.<sup>3</sup>

#### Cost Savings via Avoidance of Procedures and Treatments Shown To Be Unnecessary or Harmful

One of the most promising opportunities for cost reduction occurs when an expensive procedure or medication is proven to be unnecessary or even dangerous. Here, as in other situations that will be described in this section, it is essential to recognize that even the most careful studies may be flawed.

An important case in point is the hormone replacement therapy (HRT) study [10] in 1990, sponsored by the American Heart Association, the American College of Obstetrics and Gynecology, and the American College of Physicians, which established that hormone replacement was a preventive measure for heart disease and osteoporosis in menopausal women. By 2001, 15 million women had filled prescriptions for HRT. However, by the summer of 2002, as noted in the New York Times [11] and elsewhere, the supplemental estrogens had been shown to be a cardiac health hazard for patients who were menopausal. The Women's Health Initiative in 2002 [12] showed increments in heart disease, stroke, blood clots, and breast cancer if estrogens were taken after menopause. Thus, the universal prescription of a preventive medicine turned out to be an ill-fated and unjustified therapy for those women with menopausal symptoms.

Similarly, in a study of 367 hysterectomies, 70 procedures were found to be unnecessary [13]. The failure to evaluate properly the cause of a uterine malady may result in unnecessary hysterectomy, rather than appropriate and less costly medical treatment.

Another example is a recent federal study of more than 10,000 middle-aged and older Type 2 diabetes patients [14], which found that those with lower blood sugars had increased deaths from coronary disease. There were substantially more deaths in the group because of more rigid blood sugar control, probably secondary to severe hypoglycemia. However, this observation needs to be balanced against the knowledge that lower blood sugars in diabetics are protective against kidney disease, blindness, and amputations. Medical experts, for whom conventional wisdom dictated the importance of keeping blood sugar low, were stunned by this result. The consequences of

<sup>&</sup>lt;sup>2</sup> For instance, in testing new cardiovascular devices, the United States Food and Drug Administration premarket approval process has been found to be lacking in strength and also subject to possible bias, as noted in a report published in the *Journal of the American Medical Association* by Dhrunetal et al. (December 23/30, 2009, Vol. 302, pp. 2679–2685).

<sup>3</sup> There is a large literature on statistical and econometric methods in which the pitfalls of the use of careless statistical evidence are spelled out. For an illuminating and amusing compendium of widespread economic misunderstandings resulting from careless statistical reasoning, see *Freakonomics* [9].

hypoglycemia from overaggressive drug use are always a concern, most particularly for the heart and the brain.

Similarly, excessive treatment of hypertension can cause a serious drop in blood pressure and diminished blood flow to the heart and brain, resulting in heart attack or stroke [15]. In addition, there are multiple side effects associated with the most frequently used antihypertensive medications, diuretics (these side effects include electrolyte imbalance and dehydration). However, a predisposing factor for acute coronary events among the participants in the study may have been severe emotional stress because of the high frequency of tests, medications, and close personal observation.

Moreover, the rush to diagnostic cardiology by noninvasive CT angiography recently has been tempered by concerns about radiation exposure from medical imaging procedures.<sup>4</sup> Newer techniques have been able to reduce the amount of necessary radiation exposure, but not the cost. "CT angiograms utilize a one million dollar machine to study the heart and coronary arteries [16]. This is billed at \$1000 to \$3000 per test. There is no evidence that this information is any better than the standard coronary arteriogram whose typical cost is less than \$1000, and with much less radiation exposure" [17]. Furthermore, a standard coronary arteriogram is necessary if an intervention is required and provides more usable information.

As another illustration, aprotinin was used for 14 years as an additional hemostatic agent to reduce blood loss by stopping or preventing bleeding during coronary artery bypass grafting (CABG) and given to about 200,000 patients worldwide, as dictated by conventional wisdom. However, two subsequent studies by Schneeweiss et al. [18] at Harvard and by Shaw et al. [19] at Duke found that there was a higher mortality rate and more kidney dysfunction among patients receiving aprotinin than in those patients who only received aminocaproic acid as a hemostatic agent. This exemplifies the potential limitations in comparative efficiency and safety of new medications when compared to conventional therapy.

Similarly, cardiac pacemaker implantation in only the right ventricle for bradyarrhythmias or heart block also was a standard therapy until it was observed that this could cause left ventricular dysfunction, as well as nonsynchronous contraction of the ventricles [20]. Biventricular coordinated pacing of the ventricles is now standard and effective.

Finally, in cases of inadequate lipid lowering with a statin alone, conventional wisdom has suggested that the addition of another lipid-lowering drug, ezetimibe (Zetia<sup>®</sup>),

an intestinal exchange resin that decreases intestinal absorption of lipids, would enhance lipid lowering. The combination, however, has not been shown to achieve better results than a full dose of a statin alone [21]. In contrast, an old-time vasodilator drug, niacin, in an extended release form—plus lovastatin (Advicor<sup>®</sup>)—has more tangible vasodilating and lipid-lowering effects, which are additive to statins, and is much less costly.<sup>5</sup> Niacin also raises high-density lipoproteins (HDL) and reduces low-density lipoproteins (LDL) [22].

The Drug Effectiveness and Review Project [23] compares the safety and effectiveness of new drugs with older medications. Newer is not necessarily always better, though it is often more expensive.

#### **Cost Savings via Use of Patients' Genetic Information to Guide Medication and Treatment**

Costs also may be reduced by more careful attention to genetic differences among patients. The heterogeneity of patients implies that expensive treatments, which may be effective for patients with a particular set of attributes, may be ineffective for others with different characteristics. There has been progress in recognition of such distinctions and in modification of treatments in accord with this information, which may result in cost savings.

In addition, genetic information can be used to provide earlier diagnosis and, therefore, more cost effective therapy. For instance, it is now commonly recognized that cancer of the breast and ovary may result from a single gene mutation (BRCA1 or BRCA2) [24]. A single genetic variance has also been linked with hereditary non-polyposis colon cancer [25].

The newly expanding use of genetic testing in coronary disease provides another significant example. Indeed, such testing now encompasses diagnostic testing, susceptibility testing, and drug testing, which may be able to identify genes that affect the metabolism of drugs and the individual response of a given patient [26]. One example of the promise of research in this arena is the ability to establish an individual risk profile. This information may quantify a patient's risk of coronary disease and identify specific and appropriate therapy more cost effectively.

For instance, myopathy from statins has been linked to a gene variant, SLCO1B1\*5 [27]. For these patients, there will be additional costs associated with pain relief, treatment of myopathy, and alternate lipid-lowering therapy.

Genetic foot-printing by DNA analysis of molecular markers [28] also may identify the cause of increased

<sup>&</sup>lt;sup>4</sup> CT angiography carries with it a risk of cancer because of radiation exposure. There has been some diminution of radiation dosage in the process, but there is wide variability among institutions in this change. The number of all CT scans performed annually in the United States is estimated to be 75 million, as reported by Wachser in *Newsmax* (December 24, 2009).

<sup>&</sup>lt;sup>5</sup> The vasodilating flushing effect of niacin is largely minimized by the addition of aspirin, or by slow uptitration of niacin.

susceptibility to fatal cardiac arrhythmias. The long QT syndrome, by EKG, for instance, has three major types of genetic DNA and is a harbinger of sudden cardiac death. Type I is treatable with beta blockers, which slow the heart, but Types II and III may require an implantable cardioverter defibrillator to prevent sudden death. In addition, much investigation is underway to identify genetic markers for atrial fibrillation and cardiomyopathy, which also can relate to sudden cardiac death, as well as pulmonary embolism. In genetic analysis, certain malignant *DNA variations* have been found to be either preventive or provocative of fatal cardiac arrhythmias. This may explain why all patients with a potentially malignant DNA do not die from fatal cardiac arrhythmias [29].

Finally, three genetic variants have been found to be linked to the occurrence of Alzheimer's disease. These genetic codes potentially could allow for early diagnosis and possible genetic intervention, thereby providing tremendous cost savings via early treatment of a chronic disease that is increasingly common and costly [30].

# Cost Savings via Identification of Less Expensive Interventions—Both New and Old

Some novel procedures or medications clearly do decrease the expense entailed in treating a patient. Sometimes, however, these new treatment options increase the cost of treatment without offering any significant offsetting benefits.

The decrease in deaths from coronary heart disease in the United States from 1980 to 2000 has been clearly linked both to a decrease in the major risk factors and to the use of evidence-based optimal medical therapies (OMT). OMT includes aspirin, beta blockers, angiotensin converting enzyme inhibitor/angiotensin receptor blockers (ACEI/ ARB), and statins. Clearly, these options are also much less expensive than interventional treatment. In men with coronary heart disease, the death rate dropped from 524.9 to 266 per 100,000 people between 1980 and 2000; in women, it fell from 263.3 to 134.4 deaths per 100,000 people-a total of 341,745 fewer deaths from coronary disease in 2000 versus 1980. Furthermore, the study revealed that in 44,372 patients in the United States, Canada, Europe, and South America the death rate attributable to heart attack, heart failure, and shock after a heart attack decreased by 18% during that time period [31].

There is evidence that in many cases the cardiac patient who is asymptomatic may be better off without interventional treatment after an episode. Interventional therapy for patients with heart attacks who, after 48–72 h, are without shock, arrhythmia, heart failure, or recurrent pain, has been explicitly questioned in the OAT Study [32] and the COURAGE Study [33] with a six-year follow up. This is predicated on the fact that the development of collateral circulation has proven to be a natural and beneficial consequence of a heart attack. In an effort to relieve a specific coronary artery obstruction, the complications of angioplasty and stenting may be either early or late and may include restenosis, bleeding, or a repeat heart attack. The presence of diffuse obstructive coronary disease in an asymptomatic patient may not require a procedural intervention, with its risks and consequences, as this only addresses one local obstruction. OMT is a better alternative and is effective in treating diffuse coronary artery disease.

In addition, according to a recent study involving 315,241 patients at 1,108 hospitals, an alarmingly high rate of Medicare patients—one in seven—were readmitted within 30 days of a percutaneous coronary intervention (PCI), resulting in increased mortality and higher costs [34]. The premature discharge of Medicare patients, who may have more than one medical problem requiring treatment, is very costly and is not always the best therapeutic option.<sup>6</sup>

Javaid, Steinberg et al. [35] compared the treatment of two or three coronary-vessel disease with PCI using drug eluting stents versus CABG, in diabetic patients. It is common knowledge that PCI is less expensive and less invasive. However, in this study both short- and long-term adverse cardiovascular and cerebrovascular potential complications were less frequent in diabetic CABG patients with two vessel disease (just 9.7% of diabetic CABG patients developed complications vs. 21.2% of diabetic PCI patients) and three vessel disease (10.8% of diabetic CABG patients had complications vs. 28.4% of diabetic PCI patients). Similar data are provided for non-diabetics in a study involving 1,680 patients. This may be because the major graft artery used in CABG, the left internal mammary artery (LIMA), seldom occludes, whereas the saphenous vein grafts (SVG)-which are removed from the leg-used in PCI have a significant rate of vessel occlusion. Here it is important to note that the method of coronary revascularization (PCI vs. CABG) requires specificity and should not be determined solely by the procedures most commonly performed in a given hospital.<sup>7</sup>

<sup>&</sup>lt;sup>6</sup> For example, Medicare allocates a hospital stay of four days or less for a diagnosis of uncomplicated heart attack. This policy grants no leeway for the care of unrelated, but associated medical conditions, like gout, peptic ulcers, urinary tract infections, or other non-coronary vascular occlusions.

<sup>&</sup>lt;sup>7</sup> It is noteworthy that as many as 40% of patients with heart attacks may not have an early elevation of cardiac enzymes in the presence of an acute coronary syndrome (ACS). Although they may have low risk factors for coronary disease, inflammation or infection may provoke an acute coronary vessel occlusion by rupture and embolism of an unstable, previously non-occluding atherosclerotic placque or coronary artery spasm [36]. This, then, later may be identified as a heart attack. An autopsy study revealed that placque ruptures and placque erosion are the source of emboli causing sudden death and heart attack before microscopic anatomic cellular damages became visible [37].

For people with ongoing anginal chest pain, a new medication may negate the need for an expensive interventional procedure. Ranolazine (Ranexa<sup>®</sup>) [38] is a novel antianginal agent that functions differently than other drugs to arrest angina and myocardial ischemia, which causes angina. Ranolazine improves blood flow by endothelial dependent vasodilatation, which increases blood flow and decreases blood vessel thrombosis. It also is an inhibitor of rising cellular sodium, which is believed to cause ischemia and lack of blood supply to heart muscle cells and angina. Ranolazine may be used as an add-on medicine in patients who fail to respond to standard antianginal agents or interventional cardiology procedures. This can eliminate the cost of recurrent interventional procedures for the relief of angina.

In general, the significant cost differential between generic and brand name drugs offers cost savings of millions of dollars [39].<sup>8</sup> However, patients and doctors must be vigilant about the possible ineffectiveness and side effects that accompany some generic drugs. This is of particular concern for anticoagulation in the case of a life-threatening pulmonary embolism.

Red wine also can be considered to be a therapeutic treatment. Resveratrol [40], found in red wines, has been noted to activate sirtuins, which have been postulated to strengthen the body's resistance to diseases of aging and have been shown to reduce inflammation and antioxidants. In addition, researchers have found that sirtuins reduce lung and colon cancer, Type 2 diabetes, and cardiovascular and Alzheimer's disease in *mice*.<sup>9</sup> Other proteins that may influence longevity include insulin receptors and the antibiotic rapamycin.

Finally, an interesting new idea has been suggested by a recent study from the Massachusetts Institute of Technology and Harvard Business School [41]. The study proposes that forecasts of the expectable success of a new drug be determined early in the research and development process. Such a forecast could diminish the enormous cost of new drug development and marketing where it transpires that a new drug is not promising. However, effectiveness of such forecasts is likely to require much cooperation among rival drug corporations, as well as the compromise of both corporate and individual profit incentives.

# Cost Savings via Preventive Medicine: Avoidance of Disease and Reduction of Costs

It has become ever more apparent that the most promising approach to cost containment is the *prevention* of disease [31]. While many, if not most, preventative steps entail medical intervention in the form of prescriptions by physicians' orders, we also discuss steps that individuals can employ by themselves.

Statins alone have reduced the occurrence of cardiovascular events by 25 to 45% [42, 43]. This has been supplemented by further reduction of lipids by the addition of niacin in the regression of carotid and coronary atherosclerosis and an increase of HDL [21].<sup>10</sup>

In addition, the suppression of lipid deposition may safely and effectively decrease subsequent vascular events. Statins also have proven to be very effective in prevention of stroke [44], and early adenosine sestamibi nuclear scanning [45] may identify a group at low risk for future coronary events—those with a small (20% or less) perfusion deficit. Such patients can safely be treated with OMT and discharged early from the hospital, thereby avoiding an expensive intervention.

The increasing evidence of the non-lipid-lowering but pleiotropic effects of statins includes directly increased endothelial vascular activity, benefits in non-ischemic strokes, and congestive heart failure [42–44]. This information has increased the importance of statins as a primary part of OMT for coronary artery disease and stroke prevention.

In the past, conventional wisdom did not call for the use of statins without the presence of coronary disease symptoms or a coronary event. However, the findings of the Jupiter Study [46] suggest the benefits of prescribing a statin for anyone with risk factors but no clinical acute coronary syndrome (ACS). This study involved 17,802 healthy individuals in 26 countries. The patients, whose mean age was 66, had normal LDL cholesterol values but elevated levels of C-reactive protein (CRP). A newer statin drug, rosuvastatin (in 20 mg doses), or a placebo, was given to each patient. The relative risk for subsequent coronary events was decreased by 44% in those who received rosuvastatin, as compared with those who received the placebo. In those with a family history or existing history of coronary artery disease, the risk reduction was 65% for those who received the medication rather than the placebo.<sup>11</sup>

<sup>&</sup>lt;sup>8</sup> Now it has been reported that makers of brand name drugs have paid generic drug makers to delay the marketing of cheaper, alternative generic drugs. However, new health care legislation may curtail such agreements, which could save health consumers several billion dollars a year on prescription drugs (Singer, *New York Times*, 13 January 2010, pp. B1, B4).

<sup>&</sup>lt;sup>9</sup> In addition, red wines have been found to decrease tooth decay, as reported by Hubbard in *Newsmax* (January 8, 2010).

<sup>&</sup>lt;sup>10</sup> Elevation of HDL levels tend to lower LDL levels reciprocally.

<sup>&</sup>lt;sup>11</sup> Although arteriosclerosis was known for a long time to cause death in patients with coronary disease, no successful therapeutic treatment was available until the advent of statins. The accumulation of lipids and inflammatory cells in the walls of arteries is not newly discovered. Marchand in 1904, Ignatawsky and Neudauss in 1905,

Similar results were obtained in a 5-year study of lovastatin [49] that examined the reduction in coronary events in patients with normal lipid profiles but elevated levels of CRP. The combination of lifestyle change and lipid-lowering therapy reduced myocardial events more effectively than lipid-lowering therapy alone.

Periprocedural acute myocardial infarctions have been reported to occur in 5 to 15% of patients undergoing PCI. This is associated with an increase in long-term mortality. However, a single large dose of a potent statin given one day prior to PCI has resulted in a 40% reduction in periprocedural heart attacks (the pleiotropic statin effect) and a huge reduction in subsequent heart attacks [50].

In a study of 1,475 elderly patients (over age 65), trends in health management, which include increased use of coronary disease guideline therapy, resulted in a decline of 42% in mortality within 30 days after a heart attack [51]. The increased use of OMT in the elderly, previously ignored, has demonstrated effectiveness in all age groups. However, interventional coronary artery procedures are now more often provided to 70- and 80-year-old patients.

Moreover, as reported in the Optimize HF Study, the aggressive treatment of congestive heart failure has now progressed beyond low salt diets, digitalis, and diuretics, with resulting improvements in the quality and length of life. Teo et al. [52] have demonstrated the clinical effectiveness of appropriate use of beta blockers in patients with heart failure and left ventricular systolic dysfunction, thereby reducing associated costs. Additionally, researchers have identified two specific biomarkers for patients with chronic heart failure. Using these markers, it has been demonstrated that patients with both markers elevated had a 71% mortality, patients with one measure elevated had a 34% mortality, and patients with low values for both markers had only a 4% mortality [53].<sup>12</sup> In addition, a continuous-flow left ventricular assist device is proving beneficial for patients with severe congestive heart failure [54].

Aspirin and clopidogrel are a mainstay of anti-platelet therapy for coronary disease. However, patient resistance to aspirin and clopidogrel suppression of platelets as clotting prevention is not often recognized or tested by doctors. Aspirin resistance may be overcome by a larger dose of aspirin or by the addition of omega-3 fatty acids. It has been estimated that this involves 10 to 20% of the population in the United States—these studies have identified genetic linkages and markers [55, 56]. Tests to evaluate aspirin resistance should be pursued with aspirin doses of 81, 125, and 325 mg. An investigative drug, prasugrel [57], promises to be more safely effective than other commonly prescribed preventive medications, coumadin and clopidogrel, but has increased bleeding consequences.

Regular aspirin users also have been shown to have less colon cancer—an effect believed to be due to aspirin's action as a Cox-2 inhibitor of inflammation. This is one inexpensive method of helping to prevent cancer [58].

Diabetes, latent or overt, is a high risk factor for vascular disease in coronary, cerebral, peripheral, and renal arteries. Patients with a family history of diabetes or elevated blood sugar or hemoglobin A1C, a marker for identifying diabetes control, are prime suspects for the presence of diabetes. Diet and medical management may prevent this worsening of vascular disease in any or all areas [59]. It is cheaper and more effective to recognize and treat diabetes early as a critical contribution to preventive and cost effective medical care. Similarly, awareness of the dangers of hypoglycemia by overmedication is also a paramount concern.

The control of blood pressure is also a factor in preventing coronary and cerebral events. More widespread and accurate monitoring of blood pressure—especially in the early morning, before arising—yields a specific diagnostic observation that merits monitoring and treatment. Weight loss, salt restriction, and reduction of stress often are neglected as salient steps for blood pressure reduction and control. As noted by Kostis and others [15, 60], in the long-term, statins and anti-hypertensives also have been used to treat high blood pressure safely and successfully.<sup>13</sup>

Depression has been inadequately addressed as a risk factor for heart attack [61]. Similarly, the consequent increase in mortality via the combination of heart attack with depression has not been adequately examined. Depression affects blood coagulation, blood vessel endothelium activity, heart rate variability, patient compliance with medication, diet, and other risk factors. In addition, patients with depression and heart attacks have longer hospital stays and, thus, their expenses are 11 to 41% higher than other patients, on average. However, it is not known whether or not more effective antidepressant medications would shorten hospital stays and decrease costs for heart attack patients.

Footnote 11 continued

and Anitchvov in his classic paper in 1913 all connected the relation of cholesterol to obstructive atherosclerotic vascular disease. An editorial in 1958, by William Dock, published in the *Annals of Internal Medicine* likened Anitchvov's discovery to that of the tubercle bacillus by Koch and Harvey [47, 48].

<sup>&</sup>lt;sup>12</sup> Biomarkers here are interleukin-1 receptor (ST2) and N-terminal pro-B type naturetic peptide (N-pro-BNP).

<sup>&</sup>lt;sup>13</sup> The use of diuretics as an essential medication for treatment of hypertension requires close and careful monitoring for electrolyte imbalance and dehydration.

#### Cost Savings via Lifestyle Changes that May Reduce Disease and Associated Costs

There are also promising steps that individuals can take without any need for medical advice. A prime example is the adoption of a Mediterranean diet (increased consumption of vegetables, nuts, and fresh whole grains). In a National Institutes of Health study of more than 200,000 men and 160,000 women, participants who adhered to a Mediterranean diet showed a decrease in mortality from all causes, including cardiovascular disease and cancer, as well as preservation of cognitive functions [62, 63]. The cost-saving implications of such a diet are obvious.

A report by Devol et al. [64] also suggests that the promulgation and acceptance of guidelines for healthy living could save more than two trillion dollars in health costs by the year 2023. In addition, the Partnership for Prevention, created by the Robert Wood Johnson Foundation [31], has determined that regular flu shots and cancer screening could save 100,000 lives annually. They also postulate that there would be 45,000 fewer acute coronary events if 90% of people took daily aspirin, and they assert that general cessation of smoking could save 42,000 lives annually.

Cigarette smoking is known to increase lung cancer and coronary artery disease [65]. Although there has been a downturn in the number of smokers in the United States, according to the Centers for Disease Control [66], smoking bans and high federal taxes have not yet decreased smoking significantly, and it remains an unacceptably high health hazard. According to the Centers for Disease Control, some 20.8% of Americans (age 18+) were smokers in 2008 only a slight reduction from 1997, when 24.7% of American adults were smokers. One study found that patients on continual statins after a first heart attack, who quit smoking, had greater long-term survival and significantly negated effects of smoking [67]. But much still needs to be done. Smoking cessation remains a prime means of reducing the costs of health care via disease prevention.

In addition, decreased death and recurrence of breast cancer was reported in women who consume high soy protein diets [68]. A similar report of decreased prostate cancer in men is reported from the use of soy products [69].

The minimal alcohol consumption of one to two drinks daily also has been shown to be beneficial. Moreover, the benefits of red wine [40], vitamin E, and omega-3 fatty acids for atherosclerosis have been reported widely. However, there appears to be a difference between the protective effects of alcohol in men and women. Here it is important to note that excessive alcohol may cause cardiomyopathy, a high cause of death among alcoholics. The drastic cardiotoxicity of alcohol is believed to be due to a metabolite of alcohol (acetaldehyde), which is eliminated by the enzyme aldehyde dehydrogenase [70]. In 2008, 31% of American adults were obese. It is estimated that, if current trends continue, 103 million Americans will be obese by 2018 and that the health care costs related to obesity will total \$344 billion in 2018 [71]. This has resulted in higher lifetime medical costs related to diabetes, heart disease, high cholesterol, hypertension, and stroke among the obese [72]. In addition, there are suspected relationships between cancer and obesity that may yet prove to be related to diet, lifestyle, or genetic susceptibility. As such, addressing the ongoing epidemic of childhood obesity presents an important opportunity to prevent disease later in life.

Another study, involving 1,169 non-diabetic patients in Stockholm, Sweden [73], who had experienced their first heart attacks between 1992 and 1994, followed patients for an average of 3,158 days (almost 9 years). The study found that patients who consumed chocolates at least twice weekly had a mortality rate of 6%; among non-chocolate consumers, the mortality rate was 14.5%. (This small, but sweet study goes to the heart of chocoholics.) In addition, cocoa has been reported to provide significant antioxidant effects [74].

# Cost Savings via Reform of the Medical Liability System

It is important to note that malpractice insurance and the practice of defensive medicine contribute significantly to the high cost of medical care in the United States [75].<sup>14,15</sup> Analysis of the issue emphasizes that there are few, if any, medical procedures that do not entail some risk to the patient, though these dangers often are remote and minimal. For those patients who do not seek medical consultation and care, the consequent delay may increase the cost of care and the possibility of a bad outcome, thereby resulting in malpractice litigation.

Given this, the need to provide witnessed patient informed consent, which acknowledges the possibility of unanticipated permanent injury or death, is medically and legally mandatory. Indeed, the actual or construed absence of a witnessed informed consent for a treatment or a procedure continues to be a significant basis for malpractice claims and losses.

Although much lip service has been devoted to the medical liability system and its relation to high medical

<sup>&</sup>lt;sup>14</sup> The cost of defensive medicine is commonly thought to account for no less than 25% of all medical care costs in the United States. However, it is impossible to quantify these costs.

<sup>&</sup>lt;sup>15</sup> Related to defensive medicine are patient demands for specific tests or treatments that may not be necessary, which also contribute significantly to the costs of unneeded medical care and can be dangerous.

care costs, little has been changed so far. The political strength of plaintiff attorneys has prohibited attempts to limit pain and suffering awards on a national basis, as was done in California and Texas, where malpractice insurance premiums have been reduced by almost one-half, as a result. Only national legal reform can significantly reduce pain and suffering awards and decrease the medical care costs related to defensive medicine practiced by physicians seeking to prevent unwarranted litigation awards. Still, it must be noted that there are legitimate instances of malpractice, which should be the only circumstances that merit financial and medical compensation.

# Cost Savings via Changes in Medical Education Practices

Current medical teaching and training methods also contribute indirectly to rising medical care costs. Part of the problem is that medical education currently relies predominantly upon teaching by specialists or subspecialists, rather than by broad-based internists (BBI) or family physicians (FP), who now account for only a small fraction of medical school teaching faculty. Modifications of the educational system that change the focus of pre-medical and medical training away from the current emphasis on specialization and subspecialization could provide appropriate medical care and reduce costs associated with overuse of special testing and unnecessary referrals to specialists or subspecialists. As Braunwald [76] has indicated, appropriate medical care requires an overseer-just as an orchestra requires a conductor. Specialists and subspecialists, however, are more like orchestral virtuosi. As an example, coronary artery disease is part of diffuse vascular disease that also may involve carotid and cerebral arteries to the brain, renal arteries to the kidneys, mesenteric arteries to the intestines, and peripheral arteries to the legs. While specialists or subspecialists-virtuosi-may be necessary for diagnostic and some therapeutic direction, the FP or BBI-like the conductor of an orchestra-is in the best position to recommend appropriate medical care for the whole patient.

#### Cost Savings via Changes in Health Insurance Practices

Conventional wisdom holds [77–79] that veteran physicians/clinicians can more cost-effectively make diagnoses based on their knowledge and experience. It is also generally acknowledged that up to 70% of diagnoses can be made by taking a patient's comprehensive medical history and conducting a thorough physical exam. This process is more cost-effective, but it is also time-consuming and is not covered by most insurance plans. Instead, as a timesaving device, many patients commonly are asked to fill out long history forms. However, this practice is far less productive than a direct, face-to-face interview with a patient, where a hesitant answer or confusion may reveal evidence of disease. Abandoning these forms in favor of more thorough and focused questioning of patients by doctors may lead to more accurate, cost-effective work-ups and diagnoses. However, this would require changes in health insurance coverage in order to reimburse doctors for the time required in obtaining patients' complete medical histories and performing thorough physical exams. Currently, these activities are poorly reimbursed, if at all, by health insurance.

The National Institutes of Health recently published a treatise arguing that health care could be improved by having doctors obtain patients' complete family histories [80]. This approach is more likely to inspire and motivate patient lifestyle changes, improve individual decision-making by doctors in training and in practice, and promote clinical intervention that will improve outcomes in the treatment of disease. Another article in the same issue of the *Annals of Internal Medicine* [81] reiterates the value of a family history in assessing patients' risk for common diseases. But curiously, in only one of these articles is there a single sentence mentioning the fact that doctors' time spent in the acquisition of such complete medical histories currently is not reimbursed by health insurance.

Although it is an elusive goal, measurement of physicians' quality of care and performance [82] also may help to improve Americans' health. As part of this, the current "pay for performance" concept should be reconsidered. A chief concern about this is the documentation involved, which forces doctors to spend time that could be used for patient care completing forms and documenting procedures of care—hardly a cost effective process.

#### Conclusions

Announcements of new information about medical diseases and new methods of diagnosis and treatment arrive with increasingly rapid frequency. Indeed, as we wrote this article, we found it desirable almost every week to insert an addition about some medical innovation whose introduction had just been announced in the medical journals and the press. Some of these are indeed cost saving and some do promise benefits that justify their startling prices. All of them, however, indicate that rapid and impressive change is part of the evolving process of health care delivery and the costs this entails. As in so many fields, our knowledge of progress in the medical arena is extensive. Yet, as the saying goes, we are now capable of predicting everything except the future.

Amid this overwhelming influx of new knowledge, however, the effectiveness, safety, and cost of such new medical techniques are rarely considered. Over time, the value of many of these new techniques will be proven inadequate. As better approaches and procedures are recognized and utilized, doctors should be ready to abandon those that are no longer effective—that are sources of enhanced expense, with little or no benefit. Meanwhile, the cost of medical care will continue to rise rapidly and unnecessarily unless usable, acceptable, and affordable measures of the *appropriateness of care* are clearly defined by physicians and patients, and accepted by society [83].

There is no assurance that substantial containment of costs will be an easy matter, but as is evident from the information presented here, there are many opportunities to provide *appropriate and improved medical care* without directly increasing costs.

Prevention of disease is one primary means of reducing costs. One dazzling new example of this, the field of epigenetics—the study of how epigenomes alter gene activity without changing the genetic code, could lead to huge future cost savings via suppression of the genetic expression of cancer, diabetes, Alzheimer's disease, and other hereditary medical conditions.<sup>16</sup>

In addition, opportunities for cost savings and improved medical care urgently need to be emphasized in the curriculum of medical education. Elimination of waste in health care expenditure is another desirable goal, but it faces gigantic obstacles. An example pointed out by Fuchs [85] is the fact that magnetic resonance imaging (MRI) is performed three times as often per capita in the United States as it is in Canada. However, there is no evidence that better care and treatment results are attained in the United States, which suggests that such overutilization is a waste [86]. The evidence on all of these matters clearly requires further investigation and application.

Paradoxically, the most promising route to effective cost containment may *not* be through reduction of payment to doctors. Rather, as Uwe Reinhardt has observed, "Physicians are the central decision makers in health care. A superior strategy might be to pay them very well for helping us reduce unwarranted health spending" [87].

The art of medical practice urgently requires redirection, which, once achieved, will lead us—in the spirit of *Gaudeanus Igitur*—to rejoice in that accomplishment.

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<sup>&</sup>lt;sup>16</sup> Epigenomes, which sit on the outside top of each gene, promote or quiet the expression of that particular gene. Environmental forces, such as starvation or overeating, can cause epigenomes to enhance or suppress a particular gene in a mother or father's genetic material ova, sperm, and the embryo in utero, thereby passing on a new trait to the next generation. This could explain some genetic mysteries, such as why only one member of a set of identical twins may develop asthma or bipolar disorder. Furthermore, as has been shown in animals, the addition of a methyl group can change the expression of a gene by increasing or decreasing its activation [84].

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