

Health and Medical Economics: Applications to Integrative Medicine

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The responsibility for the content of this paper rests with the authors and does not necessarily represent the views or endorsement of the Institute of Medicine or its committees and convening bodies. The paper is one of several commissioned by the Institute of Medicine. Reflective of the varied range of issues and interpretations related to integrative medicine, the papers developed represent a broad range of perspectives.

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ABSTRACT *Cost-benefit analyses (CBA) of every aspect of health and medical care are a necessity to address both the clinical effectiveness and cost-effectiveness of health and medical care for the purpose of allocating limited practitioner, organizational, governmental, and monetary resources while maintaining the highest quality outcomes. In response, there are an array of approaches that emphasize the full continuum of prevention, restructuring primary care, involvement of the workplace and communities, and adoption of innovative strategies and interventions ranging from genomic assessments to complementary and alternative medicine (CAM). Among these approaches is an Integrative Medicine (IM) model that is consistent with these national objectives, and which uniquely and explicitly includes “evidence-based global medical strategies” in its definition. All of these strategies require rigorous, appropriate, state of the art medical economic analyses. Among the objectives of this paper are: 1) Briefly consider the broad array of such innovative approaches to evaluating the possible economic implications of health care options; 2) Introduce the concepts and models most frequently applied in the medical economic evaluations of health interventions; 3) Present a systematic review of the current scope and quality of the medical economic evaluations of CAM to provide an economic context for assessing specific practices that might productively be included in an IM model; 4) Explore what is known about worksites and corporate settings as models where clinical and cost effectiveness outcomes have been, and are most frequently undertaken; 5) Identify issues relevant to diagnostic and billing coding protocols; and 6) Provide actionable recommendations. Since few if any IM models have been rigorously evaluated in terms of CBA, it is possible to draw upon the cost effectiveness research focused on a limited number of CAM modalities as well as from the worksite/corporate clinical and cost outcomes research to suggest the evidence-based foundation from which a true health care system will evolve.*

ANATOMY OF A GLOBAL MEDICAL CRISIS

According to the Institute of Medicine (IOM) Roundtable on Evidence-Based Medicine, “Health care in the United States currently underperforms on many dimensions. From the global perspective, with per capita expenditures more than 20 percent higher than any other country in the world and more than twice the average expenditure for European countries, the nation ranks well below at least two dozen others on key health indices such as infant survival and life expectancy” (2008). This crisis is underscored in the IOM Integrative Medicine Summit Background paper which states, “With the United States spending twice

as much per capita as the average for most other developed countries—and 50 percent more than the second largest spending nation in the world—yet achieving poorer results than nearly two dozen other countries, the resources currently devoted to health are clearly sufficient to obtain much better outcomes.” (2009). For over 50 years, this dire circumstance has been driven by the growing burden of risk factors underlying both acute and chronic diseases. These trends translate into the current, global economic crisis in medical care. More than a matter of semantics, in reality these are the costs associated with the provision of “medical” care and it is a misnomer at best to attribute these costs to “health” care since less than 3 percent of the annual U.S. medical expenditures (Thorpe, 2008), which is in excess of \$2.2 trillion in 2008, are attributable to eliciting, sustaining, or enhancing population health.

Clearly, the need for economic evaluations has been growing exponentially in every aspect of conventional health and medical care. An increasing number of health plans and hospitals have moved from a simple budgetary focus such as formulary decisions to requiring detailed evidence on the economic value of covered therapies relative to more cost-effective options (Goetzel et al., 2008; Serxner, 2006). Beyond their use in decisions concerning health insurance coverage, economic outcomes of both conventional and Complementary and Alternative Medicine (CAM) therapies also influence health policy, justify licensure of practitioners, provide a rationale for emerging medical technologies, inform industry investment decisions, provide general evidence to consumers about potential economic benefits, and can guide future research efforts by identifying the essential parameters of future research (Claxton et al., 2001; Claxton and Posnett, 1996). Both clinical effectiveness and cost-effectiveness outcomes are required to formulate evidence-based policy.

Although this white paper focuses on medical economics with an emphasis on Integrative Medicine (IM)—which we consider to be the evidence-based integration of conventional and CAM—it needs to be emphasized that the present crisis is not inherently one of not enough money, *per se*. Clearly, the global crisis is due to a perfect storm where potentially adequate funding is misdirected, expenditures are excessive in many domains while inadequate in others, expended on fragmented clinical services, overreliance on excessive technology and pharmaceuticals, lack of a continuity of care, fragmentation of services and appropriate medical records, with inadequate funding of basic prevention services that have been documented to be cost-effective.

Currently in the United States, there are over 133 million people with one or more chronic conditions. As a result, 70 percent of all deaths and 75 percent of the current \$2 trillion plus spent annually in medical care expenditures is related to chronic conditions (RWJF, 2004; Loeppke, 2008). One study cited the fact that more than 80 percent of medical spending is consumed in the care of chronic

conditions. In fact, chronic conditions drive 96 percent of the costs in the Medicare system and 83 percent of the costs of the Medicaid system as well as being responsible for two thirds of the rise in overall medical care costs in the United States since 1980 (Thorpe, 2006). On a global scale, chronic medical conditions that are largely preventable are responsible for more than half of all deaths in the world and are projected to account for over two-thirds of all deaths in the next 25 years (World Economic Forum, 2008). Given such dire, long standing predictions, it is indeed urgent to operationalize both prevention and intervention practices that are demonstrably effective in terms of both clinical and cost outcomes.

According to the consensus statements of the “Workforce Health and Productivity Summit,” medical expenditures are rising dramatically just at the time when the “silver tsunami” is arriving in the form of millions of aging baby boomers who are exiting the workforce, no longer helping fund Medicare and Social Security, and beginning to utilize the medical care system with a growing burden of illness and medical conditions (ACOEM, 2008). Employers ranging from Fortune 500 companies to the federal government currently provide funding for the majority of this financial burden and the impact upon all employers is central to any successful solution to the current global medical crisis (Loeppke, 2008). Chronic conditions are on the rise across all age groups, and it is expected that in the near future, conditions such as diabetes, heart disease, and cancer will tax employers more heavily as they provide medical benefits for employees and absorb the costs of absence, short term disability (STD) and long term disability (LTD) costs (Thorpe, 2006).

Another important issue is the link between poor health and reduced performance and productivity. Research has demonstrated that on average, for every one dollar that employers spend on worker medical/pharmacy costs, the employers lose two to three dollars of health-related productivity costs. These costs are manifested largely in the form of *presenteeism*, which is a condition where employees are on the job but not fully productive, resulting in increased absence, and escalating STD and LTD. Research has also documented that in addition to common chronic conditions such as cancer, heart disease, and diabetes, there are a host of other readily identifiable chronic conditions—ranging from musculoskeletal/pain, depression, fatigue, anxiety, and obesity—that are driving total medical costs in the workplace. Such excessive expenditures add to the cost of every product and service and therefore affect the ability of all U.S. corporations to compete in the increasingly global markets.

Increasingly there is the recognition that greater emphasis on the full continuum of prevention and a profound restructuring of basic primary care is necessary to address the overwhelming challenges posed by increasing rates of chronic disease. Writing in *JAMA*, Baron and Cassel (2008) have noted: “Primary

care is in search of redefinition. Prevalent payment modes have undermined traditional models ... At a time where advances in understanding systems of care point to new models in which physicians' roles might be redefined to contribute more value to patients and to the delivery system, financing models have not yet caught up. Many of the most important aspects of primary care services, including care coordination and intervisit care, remain unsupported. The fee for service payment model influences how society thinks about medical care, reducing it to visits or hospitalizations or procedures—the component 'widgets' of fee for service economic production—and overshadowing a patient-centered, longitudinal, multidimensional practice that primary care physicians aspire to give and patients to receive." This later, preferred approach, is consistent with the "chronic care model" articulated by Bodenheimer, Wagner, and Grumbach. "The primary care model" is a guide to higher quality illness management within primary care. The model predicts that improvement in its six interrelated components – self management, clinical information systems, delivery system redesign, decision support, health care organization, and community resources – can produce system reform in which informed, activated patients interact with prepared, proactive practice teams" (2008). However, even with a limited focus on the chronic care management" (CCM) model, the issue of the cost-effectiveness of such an approach remains unanswered. According to Thomas Bodenheimer (2009), "The problem is that CCM is such a mixed bunch components that there is no easy answer to that question (of cost-effectiveness). There may be one answer for diabetes, one for asthma, one for CHF, and one for high-cost patients with multiple diagnoses. How do you plan to deal with that complexity?" Clearly this same thorny issue applies to all other innovations in primary care, the continuum of prevention, and Integrative Medicine as an evolving model (Coleman et al., 2009). It is within and consistent with these challenges and possible solutions that the newly evolving area of Integrative Medicine needs to be considered and evaluated in terms of both clinical and cost outcomes.

INTEGRATIVE MEDICINE

There are a number of different definitions of integrative health and Integrative Medicine in widespread usage. According to the Bravewell Collaborative (2008), integrative medicine has the following characteristics:

- 1) Patient-centered care and focuses on healing the whole person—mind, body, and spirit in the context of community;

- 2) Educates and empowers people to be active participants in their own care, and to take responsibility for their own health and wellness;
- 3) Integrates the best of Western scientific medicine with a broader understanding of the nature of illness, healing, and wellness;
- 4) Makes use of all appropriate therapeutic approaches and evidence-based global medical modalities to achieve optimal health and healing;
- 5) Encourages partnerships between the provider and patient, supports the individualization of care; and
- 6) Creates a culture of wellness.

In 2005, the Consortium of Academic Health Centers for Integrative Medicine (CAHCIM), a consortium of 42 medical schools, developed the following definition: “Integrative medicine is the practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, health care professionals and disciplines to achieve optimal health and healing.” For the purposes of this white paper, integrative medicine will be used to describe a prevention oriented approach to health and medicine that adheres to the above definitions. It is important to note that neither of these definitions explicitly includes CAM as a part of these previous definitions. By contrast, several other definitions do explicitly include CAM, such as the definition provided on the National Institutes of Health-National Center for Complementary and Alternative Medicine’s (NCCAM) website which states, “Integrative medicine combines treatments from conventional medicine and CAM for which there is some high-quality evidence of safety and effectiveness” (NCCAM, 2009). CAM is also explicitly included in the definitions of Integrative Medicine adhered to by the UCSF Osher Center for Integrative Medicine (Osher Center, 2009), and the University of Arizona School of Medicine’s Center for Integrative Medicine (Maizes et al., 2009). Overall, CAM is a term that is used to describe a group of diverse medical and health care systems, practices, products, and services that are not considered to be part of conventional medicine. CAM is practiced by a vast array of disciplines including nurses, chiropractic physicians, nutritionists, clinical psychologists, naturopathic physicians, physical therapists, traditional Chinese medicine practitioners, allopathic physicians, osteopaths, meditation teachers, and health coaches, to cite but a few disciplines. By definition, Integrative Medicine is neither synonymous with nor reducible to CAM practices. However, elements of evidence-based CAM practices are likely to be included in an IM model.

Clearly the objective of IM is not to apply all such disciplines to a given condition or patient but to broaden the array of evidence-based interventions that are selectively available through an integrated, collaborative network of providers. A number of these definitions suggest that the only distinction between conventional medicine, which is highly fragmented and not at all integrated, and IM is the inclusion of CAM interventions. With so many competing definitions, what is and is not IM is in flux at best, if not in complete disarray. What is certain is that IM is consistent with many other evolving models of primary care and the continuum of prevention which emphasizes an approach that is patient-, more accurately, *person*-centered, evidence-based, proactive, continuous in nature, as well as one that promotes health and well being. For purposes of this white paper, we are focusing on a limited number of clinically and cost-effective CAM interventions which are consistent with the emphasis on “all appropriate therapeutic approaches and evidence-based global medical modalities to achieve optimal health and healing” (Bravewell Collaboration, 2008). What appears to be the unique element of an IM model, as compared to the growing array philosophically compatible primary care models, is the explicit possible inclusion of evidence-based CAM modalities.

Within the current medical/economic crisis resides the potential of transforming the current disease management industry into a truly proactive health care system. From the outset, it is important to acknowledge that there is an existing and rapidly growing body of basic and clinical research that supports the clinical efficacy of an array of potential IM practices. However, assessment of the body of evidence for adequacy, quality, dose-response issues, positive versus negative outcomes, or the long term outcomes is beyond the scope of this paper. Suffice it to note, that the *evidence-based* approach to conventional medicine is inadequate as well. For example, numerous publications have documented this lack of adequate evidence by indicating that, based on ratings by the American College of Chest Physicians, the evidence from large randomized clinical trials (RCTs) and positive results in cardiology was rated at 44 percent in 1998 (Dalen, 1998). Another study that reviewed the conventional medicine assessments by the Cochrane Collaboration concluded that only 38.4 percent of 153 reviews indicated *evidence of positive effect* (20.8 percent) or *possibly positive effect* (17.6 percent) with all others ranging from *no evidence of effect* (24.5 percent) to *evidence of negative effect* at an alarming 6.9 percent (Ezzo et al., 1999). Added to the issue of the quality of evidence-based conventional medicine is the persistent double standard regarding the economic value of prevention versus intervention. Most recently Steven H. Woolf succinctly addressed this issue by stating: “Throughout health care, the spending crisis requires a comprehensive search for ways to shift spending from services of dubious economic value to those with high cost-effectiveness or net savings. Whether those services are

preventive or otherwise is not the point; what matters is prioritizing services that produce the greatest health benefits for the dollars spent... As a matter of economic security and ethics, it is inappropriate to debate the economic value of prevention while excusing the rest of medical care from such scrutiny” (Woolf, 2009). This is not to diminish the rigor by which integrative medicine can and should be evaluated but that all evidence-based standards need to be equally and more vigorously applied to all of medicine and health care. For now, the focus is upon the potential receptor sites and settings for developing an IM model ranging from schools, worksites, competing vendors, health insurance plans, health spas, entire communities, the global internet, and the evolving sophistication of telemedicine technologies.

At the present time, there is a growing body of basic and clinical research focused on IM. However, there is a virtual absence of cost-effectiveness or return on investment (ROI) analyses of such approaches to health and medical care. Despite this lack of current cost-effectiveness data in IM, this also holds as well for the vast majority of conventional medicine practices, innovations such as the Patient-Centered Primary Care Collaborative (PCPCC) with its emphasis on the *patient-centered medical home* (Grundy, 2008), and the innovative IOM roundtable that focuses on the expertise and technology to create a “learning healthcare system” (McGinnis, 2008). Despite this lack of adequate CBAs in primary care, there are positive models from the corporate sector that have a clear vested interest in the health and productivity of employees (Pelletier, 2008), emphasis on “health and productivity” in the most recent ACOEM white paper (Loeppke, 2008), introduction of a U.S. Senate Bill by Senator Tom Harkin (Harkin, 2008), as well as ongoing, federally funded demonstration projects. Collectively these initiatives focus on integrated population health enhancement approaches. Such clinical and policy innovations are designed to elicit and sustain health while ensuring the cost-effectiveness of both risk reduction and disease management. Eliciting and sustaining health, reducing health risks, lowering the prevalence of illness, and improving the quality of care management for those with illness does lower total cost for patients (Loeppke, 2008; Burton et al., 2004, 2006; Goetzel and Ozminkowski, 2008). However, such measures necessitate an investment at the outset. Integrated programs and services throughout the continuum of care with total population health management require effective identification of interventions and coordination of care for the whole person and the entire population. It is a sobering note that none of the previously cited major, public health policy documents explicitly refer to IM and/or CAM, *per se*. Additionally, total population health management requires total population health measurement in terms of both clinical effectiveness and cost-effectiveness. Again, integrative medicine is rarely acknowledged in the cost-effectiveness literature.

Medical economics, which is often considered only in the context of disease care, is inherently linked to the health, performance, and productivity of individuals, populations, corporations, and the nation. At the present time, the costs of managing preventable conditions are resulting in an unsustainable economic burden both domestically and internationally. On a more positive note, a new, global value proposition is emerging that recognizes and monetizes the economic and business value of health and healthy employees as “human capital” assets. There is a growing recognition that there is a business case for health, as the key to improving the health of the nation in order to moderate or even reduce medical costs resides in investing in individual health or human capital as a national economic value which can reshape the focus of the U.S. health care system. It is within this context that IM needs to be considered and evaluated as an integral part of the solution in terms of both clinical and cost outcomes.

MEDICAL ECONOMICS TERMINOLOGY AND APPLICATIONS

Overall economic evaluations provide information to decision makers on both the inputs and outcomes of a health or medical intervention or approach compared to its alternatives. These types of analyses build upon the results of clinical effectiveness studies, but go beyond them to include both a broader view of outcomes, and the costs of resources involved in implementation and delivery. Such outcomes can be economic, clinical, or humanistic as in the Economic, Clinical, and Humanistic Outcomes (ECHO) model (Gunter, 1999). Economic outcomes represent the consumption and production of resources and their monetary value from the perspective of a decision maker. Clinical outcomes are medical events that are professionally meaningful. Humanistic outcomes include a broad category of intangible personal attributes, typically collected through self-report, such as quality of life and even spiritual well-being. Conventionally, clinical and humanistic outcomes are considered health outcomes.

Not all studies that measure costs or resource use are full economic evaluations. To be considered a full economic evaluation a study must provide: 1) A comparison of one or more interventions/approaches of interest (e.g., integrative medicine) to a defined standard of care; and 2) A comparison of the costs of each intervention/approach to the effects (or benefits or returns) of each (Drummond, O'Brien et al., 1997). Partial economic evaluations are studies that inform future full evaluations and usually only compare investment costs between interventions or approaches.

There are several forms of economic evaluation that can be performed and each differs based on the selection and measurement of health outcomes. Although the term “cost-effectiveness” is frequently applied as a rubric for all

medical economic analyses, cost-effectiveness analysis is only one type of assessment. Actually, the most basic form of economic evaluation is a matrix or table that lists the individual economic and health outcomes of alternative interventions. This table is known as a cost-consequence study. Cost-identification studies and cost-minimization analyses only address economic outcomes. Cost-identification studies only measure the investment cost of interventions and are used to inform full economic evaluations. That is, they provide the data needed to better design future studies that consider both the economic and health outcomes of two or more alternative therapies. A cost-minimization analysis (CMA) explicitly assumes equivalence in health outcomes among alternative therapies and examines only economic outcomes. In practice, it can appear to be the same as a cost-identification study, but under the assumption of equivalence, a CMA is a full economic evaluation. All of the remaining forms of economic evaluations summarize economic and health outcomes into a single result.

Full Economic Evaluations

There are three forms of full economic evaluations, which include: cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), and cost-utility analysis (CUA). These evaluations are summarized in Table 1 noted below.

Among the advantages of performing a CBA and a CUA is that multiple outcomes are summarized into a single unit, either monetary units such as dollars (as in the CBA) or quality-adjusted life-years or QALYs (as in the CUA). Using such approaches, therapies with different sets of health outcomes can be compared based on the differences in the summary measures. CBA has the additional benefits of directly indicating whether the therapy pays for itself or not, and of allowing for a ROI to be calculated.

TABLE 1 Three Types of Full Economic Evaluations

	Cost-benefit Analysis	Cost-effectiveness Analysis	Cost-utility Analysis
Number of Health Outcomes	Multiple outcomes	One outcome	Multiple outcomes

	Cost-benefit Analysis	Cost-effectiveness Analysis	Cost-utility Analysis
Unit of Health Outcomes	Summary measure in monetary units (eg, US dollars)	Natural units (eg, reduction in number of hot flashes)	Summary measure in quality of life units (eg, quality adjusted life years, QALY)
Results	Net benefits* $(B_1 - B_2) - (C_1 - C_2)$	Cost-effectiveness ratio** $\frac{(C_1 - C_2)}{(E_1 - E_2)}$	Cost-utility ratio** $\frac{(C_1 - C_2)}{(QALY_1 - QALY_2)}$

*The results of a CBA can also be used to calculate a ROI. The ROI for alternative 1 is generally calculated as $(B_1 - B_2 - C_1 + C_2) / C_1$.

**These ratios are calculated when both the costs and the effects (health outcomes) of one therapy are higher than those of another. When the costs are lower and the effects are higher for one therapy, it is said to dominate the alternative (and the alternative is said to be dominated) and no ratio is presented.

C_1 = total costs of alternative 1; C_2 = total costs of alternative 2; B_1 = monetary value of health outcomes of alternative 1; B_2 = monetary value of health outcomes of alternative 2; E_1 = health effects of alternative 1; E_2 = health effects of alternative 2; $QALY_1$ = quality-adjusted life-years of alternative 1; $QALY_2$ = quality-adjusted life-years of alternative 2.

There are also disadvantages of both CBA and CUA, which derive from the techniques required to produce a summary measure. CBA can require putting a monetary value on health outcomes, including life, and CUA assign value to health outcomes based on their contribution to quality of life under the presumption of population-based preferences. CBA often assess the monetary value of health outcomes based on willingness-to-pay using a technique called conjoint analysis (Johannesson, Aberg et al., 1991; Drummond, O'Brien et al., 1997; Ratcliffe, van Haselen et al., 2002). Willingness-to-pay inherently places a lower value of life on individuals with low income, because they cannot pay what they do not have. On the other hand, CUAs have multiple methods to place quality of life values on health outcomes. CUA from the societal perspective has been designated by the Panel on Cost-Effectiveness in Health and Medicine, convened in 1993 by the US Public Health Service as the "Reference Case" to be used by policy makers for the broad allocation of health resources (Gold et al., 1996). In these analyses, all costs are considered, no matter to whom they occur. Summary measures of quality of life may not be sensitive enough to pick up short-term changes such as for acute conditions and will not pick up specific clinical outcomes like blood pressure control (Chapman, Berger et al., 2004). Examples of instruments used to capture these general health states include the EuroQoL (EQ-5D) (Dolan, 1997) and the Health Utilities Index (Coons, Rao et

al., 2000). Each of these disadvantages indicates that CBA analyses are highly variable both in their applications and limitations.

CEA is the current standard in the literature, and has the most straight forward interpretation. Under CEA, therapies useful for a specific disease or condition can be directly compared using a metric of effectiveness relevant to that condition, such as blood pressure control. Although these types of analyses do not allow a summary measure of multiple outcomes, they do tend to respond well to the most urgent questions, such as how much would it cost to reduce the number of acute myocardial infarctions by 10 percent. Clearly, a reduction in heart attacks has measurable implications in quality of life and economic units, but the creation of a summary measure is not necessary to address the decision maker's question.

No matter the approach taken for economic evaluations, it is recommended that the estimated outcomes (economic, clinical, and humanistic) of health care alternatives used in the evaluation be estimated whenever possible in pragmatic clinical trials that directly and realistically compare the therapies of interest (Eisenberg, 1994; Drummond, O'Brien et al., 1997). Models based on the best available evidence, such as previous pragmatic trials, are often used when time is short or a full trial—especially one of sufficient duration—is not feasible (Sheldon, 1996; Meltzer, 2001). Rarely are the results of placebo-controlled trials used in these analyses as direct inputs to economic evaluation (White, Resch et al., 1996; Drummond, O'Brien et al., 1997). Also, since chronic disease treatment and prevention are major issues in health care, it is important that the study period be long enough to capture the full benefits and costs of each intervention, and that future costs and benefits be discounted to the present for comparison. Finally, all economic evaluations should include some type of sensitivity analysis to test the robustness of results to the various assumptions made (Briggs, Sculpher et al., 1994; Drummond, Jefferson et al., 1996; Meltzer, 2001). When these elements are in place, then it is possible to undertake a sound medical economic analysis.

Studies that only measure the investment cost of interventions are known as cost-identification studies. These studies inform full economic evaluations. That is, they provide the data needed to better design future studies that consider both the economic and health outcomes of two or more alternative therapies. A cost-minimization analysis (CMA) explicitly assumes equivalence in health outcome among alternative therapies, and examines only economic outcomes. In practice, it can appear to be the same as a cost-identification study, but under the assumption of equivalence, a CMA is a full economic evaluation.

Economic Outcomes

Economic outcomes are the net bundle of resources forgone due to an intervention, valued at the opportunity cost of those resources (the value of their next best use or “opportunity”). Different stakeholders (i.e., different decision makers) have different points of view as to the economic outcomes (the costs) of any health care intervention or approach, because each is only concerned with the impact of the intervention on resources under their own control. Thus, the cost of IM will be different depending on the perspective of the stakeholder—i.e., different from the perspective of a patient than they are from the perspective of a hospital (or clinic, or health care system, or other provider), a third party payer (private or public), an employer, or a local, state, or national policy maker societal perspective).

Noted below is Table 2, which presents a partial list of the types of economic outcomes and the perspective of analysis where each outcome is considered. This table is a summary from a number of other studies (White, 1996; White et al., 1996; Naglak et al., 1998; Meltzer, 2001). These types of economic outcomes should be inclusive of both the full costs of the therapy and of any treatment for adverse effects, which can be expensive (Meltzer, 2001). In economic evaluations, the safety of a therapy is addressed through accounting for the cost of treating these adverse events, as well as through their impact on clinical and quality of life outcomes.

TABLE 2 Perspective and Costs to Include in Economic Evaluations

Type of Cost	Examples	Perspectives in Which This Cost is Included
Direct costs: Medical	Intervention costs: – Practitioner fees – Diagnostic costs – Therapy costs Service costs: – Facilities and equipment, including hospitalization or clinic/office costs – Ancillary staff	Only the portion paid by the health plan, employer, hospital/clinic, or patient is included in analyses from that perspective. All included in societal perspective
Direct costs: Non-medical	Transportation costs Time off work for	Only the portion paid by the employer or patient is included in

Type of Cost	Examples	Perspectives in Which This Cost is Included
	appointments/hospitalization	analyses from that perspective. All included in societal perspective
Indirect costs*	Work productivity lost during recuperation, or gained due to health improvements Leisure time lost or gained Child care or caregiver costs or cost savings	Only the portion paid by the employer or patient is included in analyses from that perspective. All included in societal perspective
Intangible costs	Pain Suffering Grief	Not usually included as costs; included in non-monetized outcome in cost-utility analysis

Summarized from similar tables in other references.

SOURCES: (White, 1996; White et al., 1996; Naglak et al., 1998; Meltzer, 2001)

*Although a health care alternative can sometimes reduce direct costs, it is more common that indirect “costs” include cost savings (the gain of resources that would have otherwise been used or lost) in addition to costs (the use or loss of resources). Indirect costs are usually the result of the intervention or approach and its health outcomes.

Any investment in integrative medicine is contained in the two direct cost categories (medical and non-medical). As can be seen, for all perspectives of analysis, other than the societal perspective, the investment cost of IM depends on who pays for it. Returns to this investment are also dependent on the perspective of the analysis. In this instance, returns are any costs avoided in the two direct cost categories because of no longer needing some or all aspects of the usual care approach being replaced, plus (for the patient, employer, and societal perspectives only) any savings over the usual care approach in the indirect costs category.

Given the above observations, it is important to underscore that the return on investment to any particular Integrative Medicine approach depends on who is paying and the perspective of the analysis. It is recommended that the economic outcome data are best collected prospectively as part of a pragmatic, effectiveness clinical trial (White et al., 1996; Drummond et al., 1997; White and Ernst, 2000). Inclusion and exclusion criteria for cost data should be established in the protocol, as for clinical outcome measurements, but provision must be made to add extra categories of costs, which only become apparent after the trial has commenced (Drummond, 1995; White et al., 1996). Many studies try to collect cost data retrospectively, often after a therapy has shown clinical effectiveness. This can be sufficient for preliminary analyses and for well understood costs. However,

retrospective data collection is seldom fertile, adapted, or exhaustive, and it is subject to bias (Drummond, 1995; White, 1996; Chaufferin, 2000). Building in CEA at the inception of a study does not add a great deal of cost, yet does provide the increasingly necessary economic outcome as a critical dimension.

Cost-effectiveness, cost-utility, and cost-benefit (including ROI) analyses are performed to provide information to make a decision. The decision here is whether or not to adopt the health care intervention or approach studied (i.e., integrative medicine) to replace the present standard of care. This decision depends on whether the incremental cost of a particular health care intervention or approach is worth its incremental benefits or effects. That being said, it is also understood that affirmative economic evidence is a necessary, but not sufficient, step toward coverage or payment for IM treatments or practice as a whole. Other factors such as historical demand, political expediency, consumer demand, practitioner enthusiasm, and equity may also be considered in the decision to incorporate IM into a health insurance policy (White and Ernst, 2000; Donaldson, Currie et al., 2002; Pelletier and Astin, 2002; IOM, 2006; Grosse, Teutsch et al., 2007). It should be noted that economic evaluation is used to determine the most *efficient* use of health care resources. It does not, however, determine the most *equitable* distribution of these resources. The evaluation of the impact of these programs on health disparities, for example, requires further analysis that notes the benefits and costs that accrue to various groups and not just to society as a whole or to particular decision makers.

Medical Offsets

A “medical offset” is defined as a reduction in utilization of a particular health care service that occurs after the addition of another type of health care service. Medical offsets can be beneficial to the system when the added service improves upon the outcome of the offset service and/or when added service provides the same outcome at a lower cost. When these medical savings exceed the cost of the added service, that service has effectively paid for itself through these offset savings.

There are two possible mechanisms by which medical offsets might occur. First, the additional service might alter the health outcomes or clinical trajectory of a patient such that some downstream health care services and costs are avoided. For example, the use of influenza vaccines is likely to reduce flu-related morbidity in a population as well as the related costs (Luce, 2008). The cost of the influenza vaccine is more than paid for by the downstream offsets. A second, more direct mechanism of offset savings is by simple substitution. That is, an added health care service might directly substitute for an existing health care

service or benefit. The net effect of the offset would therefore be a function of the relative costs of the added service versus the offset service.

This offset phenomenon has been extensively studied in the realm of mental health services (Mumford, 1997). Both mechanisms of offset are presumed to be in force. It has been well understood that many patients with mental health concerns are using their primary care physician for such concerns rather than mental health professionals (Brogquist, 1993). Thus the appropriate use of mental health professionals for this patient population would substitute for the primary care services. It is also known that the addition of mental health services may, in addition to addressing the specific psychological concerns, may produce downstream savings in the treatment of somatic disorders (Thompson, 1998). A model for how these offset effects can be optimized in a managed care/HMO setting has been proposed (Olfson, 1999) and is applicable to other clinical services environments as well.

Considering the issue of the term "CAM" usefully highlights the important economic question of whether those possible elements of integrative care might be used primarily as an adjunct (complementary) to conventional medical care or as a substitute (alternative) for conventional medical care. Another way to consider this is to ask whether the availability of a CAM service (enabled by the addition of a CAM insurance benefit) is the equivalent of adding, say, a dental benefit to an existing health plan, or if it is the equivalent of simply expanding the existing network of providers. To add a dental benefit where none is in force is, clearly, to add additional costs. There are few if any services provided by physicians that are likely to be offset by dental care. However, simply expanding the network of available providers is not the same as adding costs. When surveys indicate that in 1997 up to \$32.7 billion (Eisenberg, 1998) were spent on CAM professional services, we do not know whether that \$32.7 billion cost has been added to our health care system, or whether it is offsetting other medical costs.

If CAM is primarily a complementary health care service, the economic case in favor of integrative care becomes somewhat more challenging. The complementary care component of integrative services is likely adding costs to the system, at least in the short run. Unless the added CAM service results in improved clinical outcomes, the added cost of complementary services is unwarranted. Thus the burden that must be met, in order for complementary services to be considered as cost-effective, is that the additional costs are justified by the additional health benefits that result. As alternative care (substitution care), integrative services are being used in place of usual medical care and those offset medical costs may be greater than the integrative services that are being used in their place. In this scenario there is a very real possibility of cost savings to the system assuming the clinical benefits of the integrative care are equivalent or better than the medical care being replaced.

One example of this substitution phenomenon is demonstrated in a study of chiropractic services (Legoretta, et al., 2004). Taking advantage of a natural experiment, an analysis of utilization patterns of chiropractic and medical services in a managed health care plan has evaluated this phenomenon. In this particular health plan chiropractic services were offered as an optional benefit to employers. That is, employers, the purchasers of the health insurance, could choose to include a chiropractic benefit (at a slightly increased premium) or not. This health plan served a limited geographic area, southern California. As a result of this benefit structure and limited geographic coverage, two equivalent cohorts are created: one with the chiropractic benefit (over 700,000 members), and one without the benefit (over 1 million members). Both of these cohorts have an identical medical insurance benefit and access to essentially the same set of medical physicians, clinics, and hospitals, and thus, are likely to receive the same standard of medical care. These two cohorts also had very similar demographic and clinical profiles.

Four years of claims data were compared between these two cohorts. There were 38 percent fewer episodes of care for low back pain, neck pain, and related disorders in the cohort with the chiropractic benefit (Metz, et al., 2005). This in turn resulted in significant reductions in the rates of advanced imaging (low back pain: -20.3 percent; neck pain: -25.7 percent), in-patient episodes (low back pain: -24.8 percent; neck pain: -31.1 percent), and surgeries (low back pain: -13.7 percent; neck pain: -31.1 percent) related to these spinal complaints (Nelson, Metz, and La Brot, 2005). These offsets resulted in estimated savings of \$110 per episode of care for these complaints.

Medical offset effects of acupuncture have also been studied through a different methodology (Bonafede, 2008). Statistical models that compared health care utilization of actual users of acupuncture to non-users found that acupuncture use was negatively associated, or produced offsets, with outpatient primary care, emergency care, surgeries, digestive evaluative services, as well as medications. There are no equivalent offset data for other CAM professions. As noted above, massage therapists see a similar patient population, primarily with somatic pain complaints, as do chiropractors and acupuncturists, thus similar medical offsets might be expected (Cherkin et al., 2002). However, massage therapists do not practice as portal of entry providers with diagnostic responsibilities as do chiropractors. Conversely, medical gatekeepers are much more likely to be involved in massage therapy practices, and offsets may be more limited as a result. Naturopathic physicians do practice as portal of entry providers, but as their patient population may differ markedly from chiropractors. Whether the Legoretta or Bonafede studies are valid will depend on the extent to which their patient population can be considered to be similar to that of chiropractors and acupuncturists (Cherkin, et al., 2002). This gap in our understanding of medical offsets and CAM providers suggests an obvious research priority.

RETURN ON INVESTMENT AS THE GOLD STANDARD

A positive ROI is the gold standard in the corporate sector by which IM or any other prevention and/or medical intervention is ultimately judged, especially by employers and many health plans. However, when determining ROI, there are several major issues to be addressed:

- 1) Clinicians, researchers, and business do not share a common understanding or vocabulary regarding cost-effectiveness;
- 2) Even within the business environment, the Chief Medical Officers (CMOs) and the Chief Financial Officers (CFOs) do not share a common vocabulary and most often have little or no interaction with each other; and
- 3) Although ROI has the aura of monetary precision, there is virtually no agreement on what data points are entered into the cost and/or benefits sides of the equation.

With these caveats in mind, ROI remains the gold standard metric which IM must use to present its business case. ROI is a financial measure which can be determined prospectively or retrospectively. It is a measure of savings per dollar invested. It is expressed most frequently as a ratio, such as 2:1, a percent, or sometimes as a dollar return for every dollar invested. It is important to note that since chronic disease is so prevalent, the actual ROI for an intervention that lowers the medical costs of these conditions can be relatively low, but the dollar return can be quite substantial.

If cost-benefit analysis or ROI are calculated, it is fairly straightforward to determine if IM produces net benefits or a positive ROI. If a net benefit or a positive ROI is determined, then the decision to implement will depend on the size of the benefit compared to its risk, and sensitivity analyses are recommended. Also, if a cost-effectiveness or cost-utility analysis is performed and IM both reduces costs and improves health outcomes compared to an element of conventional medicine, the decision to implement is fairly straightforward. However, most effective health care interventions also increase costs. In this case whether that intervention is cost-effective depends on a judgment of whether the improvement in health is worth the additional cost. Because of this need for judgment and because of the high cost of health care at present, in this review we will highlight elements of IM, which may both improve health and lower costs.

One area where ROI analyses have been productively applied is in the area of Integrated Population Health (IPH) programs focused on primary prevention. Underlying all IPH programs is the hypothesis that certain modifiable risk factors such as diet, exercise habits, or tobacco use are known to cause or contribute to the development of certain disease states. IPH programs are designed to change behavior and impact those modifiable risk factors thereby reducing morbidity and ultimately reducing health care costs. There is an expectation, both among purchasers and vendors of IPH programs, that the health care cost savings will more than offset the cost of program implementation (Pelletier, 2006; Serxner, 2006). In other words, IPH programs are expected to produce a positive ROI. Indeed a positive ROI is not so much an expectation as it is a precondition for the implementation of IPH programs (Goetzel, 2007). If this condition cannot be satisfied there is very little demand in the market for IPH programs. If IPH programs do not deliver better health and consequent lowered medical costs and measurable productivity gains, their reason for existing is undermined. Those employers who purchase IPH programs do so with the expectation that the cost of the programs will be offset by reduced medical health care costs of the participants.

There is increasing demand in the purchaser community that reporting of financial outcomes of IPH programs be done using the actual medical claims experience of an employer's program participants. However, this preference is difficult to satisfy for a variety of reasons which have been documented by the Disease Management Association of America (DMAA),

- 1) Availability of Claims Data - In contrast to disease management (DM) programs, most IPH programs do not use or require claims data to implement the program itself and are thus not readily available. Where a DM program will use claims data to identify eligible participants—for example, persons with a diagnosis of diabetes—IPH programs will typically use a health risk assessment (HRA) to identify eligible members. Claims data can be obtained by IPH vendors, but only at additional cost and effort, and doing so will not contribute to program success;
- 2) Distribution and Variance of Claims Data - In those circumstances where there are claims data that are readily available to the IPH program vendor, then the necessary dataset for an effective CBA is usually available. However, even in cases such as these, the nature of claims data itself is problematic. Any real world set of claims data will resemble the following:

- The model value of medical claims costs is zero since there are very many individuals who in any one year will have no medical care cost incurred;
- There will be large numbers of individuals whose annual costs may range in the hundreds and thousands of dollars; and
- As a result, there will a long right “tail” representing individuals whose claims costs were in the tens-of-thousands or even hundreds-of-thousands of dollars.

There are of course appropriate statistical methods available to deal with this very non-normally distributed data, but in order to achieve an acceptable narrow confidence interval very large sample sizes are required. A recent analysis of the sample size problem produced the result described below (DMAA, 2007), Using a real-world claims database of several hundred thousand persons, samples of various sizes were randomly drawn and simulated cost/savings analyses were performed. For example, a sample representing a 10,000-person employee group of whom 600 participated in a DM/IPH program was drawn. This 6 percent participation rate is typical of such programs. A cost-reduction algorithm was applied to these 600 sets of claims data and a 95 percent confidence interval (CI) of those savings was calculated. The results, representing PMPM savings, were: (-\$2.88, \$13.26). That is, the 95 percent CI of the annual savings per member that might be achieved ranged from -\$34.56 (the program actually increased costs) to \$159.12. Of course larger sample sizes will diminish this variability but even with a sample size as large as 3000 program participants, the 95 percent CI still remains unacceptably wide: (\$2.53, \$8.09). The variability of this answer precludes making any exact estimates of the economic effects of IPH programs. It must be emphasized that this variability represents an absolute limit to the degree of precision that can be achieved through claims-based cost analyses;

- 3) Program Scope and Duration - IPH programs come in many different forms and levels of intensity of intervention. There are many worthy programs which have modest goals and costs such as company sponsored walking club. Whatever type of program is implemented, it cannot be expected to impact health care costs until it has been in place for an adequate period of time to allow for the changes in behavior to manifest itself as improved health and reduced medical costs. Medical claims data are not sensitive measures of such IPH program success or failure. In order to consider the possibility of using claims data as an outcome measure in IPH programs, the duration of the program must be sufficiently

long and the intensity of the program sufficiently robust such that claims costs are likely to reflect program effects;

- 4) Trending Assumptions - When using claims data as an outcome measure it is necessary to perform a “trend analysis.” In a trend analysis, one first estimates the underlying cost trend of health care services among the employee population of interest. This underlying cost trend would include core medical inflation, changes in population health, changes in benefit design, changes in the provider network, the effects of new technology, and new drugs. The trend would include all factors affecting health care costs *except* the effects of the IPH program. After establishing this medical cost trend (inevitably an upward trend), the actual medical claims costs of those in the IPH program are compared to this underlying cost profile after an index point where the population was exposed to the IPH intervention. The difference between these two sets of costs, if there is one, represents the savings that are attributable to the IPH program and the ROI can be easily calculated from that point. In reality, the process of establishing the underlying cost trend is not exact and can only be an estimate. The final ROI value that is calculated is extremely sensitive to the assumptions that make up the trend estimate; and
- 5) Program Costs Versus Evaluation Costs - The question of how best to evaluate the financial impact of programs must take into account the cost of evaluation versus the cost of the program itself. IPH program costs may vary widely but as a rule the unit cost of these programs tends to be relatively small. As such the cost of any evaluation must be commensurate with these low unit costs. An economic evaluation using claims data may be relatively costly when compared to program costs, particularly if the claims data are not directly available to the program vendor. Limited resources that are devoted to an IPH program should be spent predominantly on the program itself and not on the evaluation. Thus, we are faced with a dilemma—given claims data variance and distribution, the relatively low unit cost of IPH programs, and the uncertainties of trend analysis, ROI results may be more a function of trending methodology and chance, than a program’s success or failure. This is not a sound basis for making rational economic choices.

Econometric Modeling

One approach to resolving the dilemma described above is to model economic outcomes based on more readily measurable metrics such as health risk factors. This approach has been used by employers such as Dow Chemical (Goetzel,

2005), Motorola (Ozminkowski, 2004), and the Union Pacific Railroad/UPRR (Leutzinger, 2000). This method of evaluation is based on research done by the Health Enhancement Research Organization (HERO) (Goetzel, 1998). The HERO data represents a multi-employer database of 47,500 employees, all of whom completed a common health risk appraisal (HRA). These data were merged with medical claims data over a period of several years yielding 113,963 person years of experience. From this merged dataset, the relationship between specific modifiable risk factors and health care expenditures was measured. Eleven risk factors were identified from this merged database. They are: poor eating, poor exercise, former smoker, current smoker, high glucose, high blood pressure, high cholesterol, high stress, depression, high alcohol consumption, and obesity.

Regression models, based on the relationships between these risk factors and health care costs, were used to estimate the medical care cost of each risk factor. Most recently, this method was used in a study evaluating the ROI of an obesity management program (Baker, 2008). In this study, 890 employees enrolled in a health improvement and weight management program were followed for one year. This program provides support to individuals through telephonic coaching and a range of web-based and other informational resources addressing nutrition, exercise planning and support, stress management, and other factors that contribute to poor health. At the outset of the program, these 890 participants completed an HRA that evaluated the 11 risk factors identified in the HERO studies. After one year in the program, they completed a second HRA and changes in these risk factors were calculated. After one year, nine of the 11 HERO risk factors decreased in frequency. This decrease was statistically significant in seven of those nine factors. One factor, alcohol consumption increased slightly in frequency. There was also an average of a 5.8 percent weight loss. When these results are entered into the HERO risk model the resultant program ROI was—1.17:1. That is, for every \$1.00 spent on the program, there were savings of \$1.17.

This modeling method of calculating ROI has several strengths. It is predicated on publicly available, published scientific data and on known relationships between risk factors and costs. It is a transparent methodology which allows programs to be compared to one another and is not sensitive to assumptions about medical cost trends. It is inexpensive to perform and uses data that are routinely collected during the implementation of IPH programs. However, there are also limitations to the method. In the measurement of the risk factor changes that are the model inputs, there is not typically a control group against which to compare these changes. Thus a variety of possible threats to validity are introduced including regression to the mean and the selection bias. Most of the risk factors are self-reported by program participants and thus, may be less than accurate. Finally, there are the limitations of the model itself. It must always be

kept in mind that such mathematical models are not exact reflections of reality. These methodological difficulties described above suggest that precision and certainty in ROI calculations for IPH programs are always going to be an elusive goal. This measurement problem should not detract from the understanding that positive economic and health benefits are likely to result from effectively implemented IPH programs.

CHALLENGES OF ECONOMIC EVALUATIONS OF INTEGRATIVE MEDICINE

Most recently, the IOM commissioned a paper on research (Deng et al., 2009), which enumerates the issues involved in the determination of the effectiveness of integrative medicine in terms of health outcomes. Because integrative medicine is a multi-component approach that addresses the whole person, research methods will need to address it as a whole system of medicine providing individualized care, and documentation of the fidelity of the approach tested will be critical (Ritenbaugh, Verhoef et al., 2003; Herman, Sherman et al., 2006; Boon, MacPherson et al., 2007). Methods commonly used for the evaluation of single therapies will not be sufficient. However, in addition to the challenges of determining the impact of integrative medicine on health, an economic evaluation must also determine its impact on resource use and costs. Therefore, over and above the requirement for a detailed description of the health-producing components of the IM approach under study, the broader structure that delivers those components (e.g., the financial incentive structure faced by practitioners) must also be defined. It is the inherently complex nature of IM that limits the generalizability of studies of its effects. Additionally, the wide variation possible—in the resource mix used to deliver this approach and in the costs of these resources—imposes further limits (Ellwein and Drummond, 1996). That being said, these challenges are not insurmountable. However, they cannot be ignored if meaningful results on the economic returns of integrative medicine are desired. Results of an economic evaluation of IM will depend on the:

- 1) Intervention or approach to which IM interventions are being compared to. The appropriate comparator is whatever is considered to be usual care or status quo for that patient population and condition;
- 2) Payment structure. Different payment strategies, even for the same care, will generate different economic evaluation results depending on the parties responsible for various costs; and

- 3) Perspective of analysis. It is only a cost from that perspective (i.e., only included) if that decision maker is paying or would have paid for that resource.

Overall, the following stakeholders will use the following types of economic analyses in their decisions about IM:

- 1) Patients – Individuals do not tend to use formal economic evaluation. However, in deciding whether to use IM they will perform their own internal analyses comparing their out-of-pocket cost of IM to the effort involved in following the recommendations, the savings in other out-of-pocket medical costs, any change in travel costs and time, and their perceived changes in symptoms and overall well-being;
- 2) Hospitals, clinics, or other providers – CBA or ROI, where the cost of investment is any non-reimbursable cost of IM that cannot be passed on to patients, and the benefits/returns are any reductions in other non-reimbursable costs and any net increase in revenues from new patients being drawn by the services;
- 3) Private third party payers – CBA or ROI, where the cost of investment is what the payer reimburses for IM and the benefits/returns are any reductions in other reimbursable costs. If a payer is looking for an alternative for some particular class of care (e.g., treatment of high blood pressure), they may also be interested in CEA results to determine the lowest incremental cost of the intervention per incremental improvement in blood pressure;
- 4) Public third party payers – Some attention will be given to the same economic analyses results as private payers. However, if the payer has a mission to provide for the public good, their consideration of costs and benefits may also include direct costs to patients and worker productivity. They may also be interested in CUA results which would allow comparisons to be made across interventions for a number of different conditions;
- 5) Employers – CBA or ROI, where the cost of investment is what the employer pays for IM services and the benefits/returns are any savings in employer-funded health care costs (including disability) and improvements in employee productivity; and

- 6) Local, state, or national health policy maker – These policy makers may also consider other analyses, but ideally, decisions here will use CUA.

APPLYING MEDICAL ECONOMIC EVALUATIONS TO INTEGRATIVE MEDICINE AND COMPONENTS OF INTEGRATIVE MEDICINE

There is no general consensus as to the definition of IM and several definitions were considered in the introduction to this white paper. These proposed definitions do have features in common such as a whole person approach, an emphasis on the relationship or “partnership” between the practitioner and the patient, and the use of all appropriate and evidence-based therapeutic approaches. However, they also contain differences, and are all too general to enable even broad statements as to IM’s benefits. Bearing these caveats in mind, there are published economic evaluations of currently practiced health care elements of what might evolve into the components of a comprehensive IM approach. This section summarizes what can be gleaned from the literature with regard to the medical economics of these components of IM.

In this summary, we review the economic evaluations of a vast array of studies of appropriate therapeutic approaches and identify a number of promising components that could be included in an IM approach, which simply does not exist at the present time. Full economic evaluations require an assessment of effectiveness, so that these studies both include and inform the evidence base. A majority of these studies examine the economic impact of adding various therapies that have a whole person approach compared to what is now usual care. A combination of these approaches could be considered to address more of a whole person approach than conventional care alone. However, because these studies were not designed to specifically assess the relationship between the provider and the patient, or the benefits of a whole person approach, it is not possible to determine from the study’s documentation whether these were explicitly addressed. Therefore, we recommend interpreting these studies as providing some direction toward the future economic potential of IM, but not of IM itself.

As a caveat, the review of economic evaluations presented in this white paper should be considered indicative and suggestive but far from definitive. Since there are extensive literatures in a number of broad areas of potentially appropriate therapeutic approaches this current review relies heavily on other reviews for the stated results. There is also focus and emphasis on the subset studies of therapeutic approaches that both improve health outcomes *and* lower costs. These are the “low hanging fruit” (See Table in Appendix A) that may be considered first in new models of IM. Note that by design, the results of economic

evaluations are not as generalizable as the results of their underlying effectiveness studies. This is a result of differences across health care settings in the mix and costs of the resources used to deliver these therapeutic approaches, as well as the broader range of outcomes that are measured (Ellwein and Drummond, 1996). In practice, it is recommended that decision makers carry out their own pilot studies of promising approaches before full scale implementation. For relevance in terms of costs and approaches, this review is restricted to reporting of studies published in the past ten years of 1999 to 2009. Finally, this review includes economic evaluations that estimated resource utilization even if resources were not valued and which left out the cost of the intervention itself if the savings shown are likely large enough to cover that cost.

In this section, we review the studies available on the medical economics of disease management programs, the Patient-Centered Medical Home (PCMH), the CCM, intensive lifestyle interventions, clinical preventive services, CAM, as well as the IPH model, which was introduced above and will be discussed in more detail later in the worksite/corporate prototypes section of this white paper. Economic evaluations of all of these approaches face challenges similar to those expected for future evaluations of IM. CAM therapies, modalities, and medical systems are often included in IM, are part of its difference from other multi-component health care approaches, and bring with them their own research challenges (Hsiao, Ryan et al., 2006). It should be noted that although disease management programs, the patient-centered medical home (PCMH), and the chronic care model (CCM) are addressed separately in this white paper, there is considerable overlap in their definitions. In a very insightful publication, Kuraitis (2007) describes the elements that disease management and the medical home model have in common, and discusses the chronic care model as a component of the medical home concept.

There appears to be only one study of a therapeutic approach self-identified as IM and reporting cost savings. It is an analysis of claims data for the patients of an IM independent physician association consisting of chiropractic doctors, and medical doctors and doctors of osteopathy who practice as “natural medicine doctors” (Sarnat, Wintersteri et al., 2007). If the practice of these doctors can indeed be termed IM, these results bode well for its success.

Clinical Preventive Services

A recent review of clinical preventive services identified and ranked 25 effective services in terms of clinically preventable burden and cost-effectiveness (Maciosek, Coffield et al., 2006; Partnership for Prevention, 2008). These analyses, which considered the effectiveness, impact, and cost of preventive

interventions, led to recommendations for expanded access to services that would improve health outcomes for large population segments at a reasonable cost. Although designated CEA, these analyses used the Reference Case as defined by the Panel on Cost-Effectiveness in Health and Medicine (Gold et al., 1996). Therefore the results were actually CUA from the societal perspective. Economic outcomes included health care costs of providing the preventive services as well as savings in those costs from avoided, or less intensive, earlier stage treatments. The value of patients' time associated with receiving the service and needed follow-up were also included in the cost of each preventive service. However, no costs or cost savings were included for changes in worker productivity. Therefore, cost savings from the societal perspective, which should include productivity, and from the payer perspective, which should not include patient costs, are likely to be underestimated in these analyses.

Five of the 25 clinical preventive services reviewed were estimated to be cost-saving. The following services are included in the table of cost saving approaches in Appendix A: aspirin chemoprophylaxis to prevent cardiovascular events in men ≥ 40 and women ≥ 50 , childhood immunization, adult tobacco-use screening and brief intervention, one-time pneumococcal immunization for adults aged ≥ 65 , and routine vision screening for adults aged ≥ 65 . Because the reported cost savings are likely underestimated from a societal perspective (due to the absence of productivity cost savings), and from a payer perspective (due to the inclusion of patients' costs), the following lowest cost (all less than \$14,000 per QALY) clinical preventive services are also reported: routine colorectal cancer screening in adults aged ≥ 50 years, annual influenza immunization for adults aged ≥ 50 , screen adults for problem drinking and offer brief counseling, routine chlamydia screening in sexually active women aged ≥ 25 , and routine vision screening for children aged ≥ 5 years.

Another more recent review also addressed the cost savings potential of prevention, and found that less than 20 percent of the 279 cost-effectiveness analyses of prevention measures reviewed were cost saving (Russell, 2009). However, it does seem that certain clinical preventive services are cost saving from several perspectives and should be incorporated into any model of IM.

Disease Management Programs

Disease management (DM) is defined by the Disease Management Association of America as "a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant" (http://www.dmaa.org/dm_definition.asp, January 31, 2009). The DMAA goes on to say that disease management:

- 1) Supports the physician or practitioner/patient relationship and plan of care;
- 2) Emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies; and
- 3) Evaluates clinical, humanistic, and economic outcomes on an on-going basis with the goal of improving overall health.

Actually, DM has a number of elements in common with IM; in particular support for the practitioner-patient relationship, the use of evidence-based practice, and an emphasis on patient empowerment. In support of the first and last of these, one systematic review of diabetes management programs found that only those interventions possessing a strong patient-oriented component resulted in noticeable improvements to patient outcomes (Renders, Wagner et al., 2001; Mattke, Bergamo et al., 2006).

DM started with pharmaceutical companies who used their dispensary databases to identify patients with chronic conditions and offered educational services to them. Later, health plans started to implement in-house DM programs, independent vendors appeared who offered DM services to health plans, and some provider organizations introduced their own smaller-scale programs (Bodenheimer 2000). Programs in DM, typically target chronic conditions such as diabetes, asthma, and congestive heart failure, and generally consist of a patient-centered approach with three main components (Mattke, Bergamo et al., 2006):

- 1) The provision of actionable data to patients and their providers;
- 2) Education, primarily of patients, but to some degree of their providers, about their disease and its treatment based on the latest medical evidence; and
- 3) The provision of social and emotional support to patients to enable them to act on the newly gained information.

A 2002 review of 118 DM programs found that patient education was the most commonly used intervention (92/118 programs), followed by education of health care providers (47/118), and provider feedback (32/118), and that most programs (70/118) used more than one intervention (Weingarten, Henning et al., 2002). It was also found that patient and provider education, provider feedback, both patient and provider reminders, and patient financial incentives were all associated with improved disease control. More recently, several additional

reviews have concluded that disease management improves quality of care and may improve health outcomes, but its effect on cost is uncertain (Weingarten, Henning et al., 2002; Short, Mays et al., 2003; Mattke, Bergamo et al., 2006; Levy, Nocerini et al., 2007; Mattke, Seid et al., 2007). However, there seem to be programs that both improve health and lower health care costs. A few of these are reviewed in Appendix A. In 2001, McAlister and colleagues found, through their review of DM programs for heart failure, that programs involving patient education, multidisciplinary teams, and specialized follow-up procedures resulted in improved prescribing practices or more use of drugs shown to be efficacious. Also, these DM programs were more likely to be cost saving, especially through reduced risk of hospitalization (McAlister, Lawson et al., 2001). It should be noted, however, that another review found that the savings in hospital costs are more than offset for some programs when the costs of the program, including increases in costs for outpatient visit and medications, are incorporated (Mattke, Seid et al., 2007). Discrepancies in findings often require a deeper disclosure of exactly what was included in both the cost and benefits of the analysis.

Another systematic review of DM programs calculated and reported average ROIs across the studies available for asthma, congestive heart failure (CHF), diabetes, depression, and multiple illnesses (Goetzel, Ozminkowski et al., 2005). Few program descriptions were presented. However, their analysis, which focused on high quality studies, found positive ROIs for programs directed at CHF (average ROI of \$2.78) and for three programs addressing multiple disease conditions (ROIs of \$4.37, \$6.65, and \$10.87). However, all programs directed at diabetes and depression returned ROIs less than \$1, and the results were mixed for asthma programs. It should be noted that these analyses did not include productivity cost savings. Further examples of cost saving DM programs are summarized in Appendix A.

It seems that some elements of DM programs should be considered for incorporation into future IM models, especially those targeting CHF and/or multiple risk factor conditions, and those containing the elements of patient education, multidisciplinary teams, and specialized follow-up procedures.

Chronic Care Model

Approximately 10 years ago, the CCM was developed through support from the Robert Wood Johnson Foundation's Improving Chronic Illness Care (ICIC) program (<http://www.improvingchroniccare.org/index.php?p=TheChronicCareModels&s=2>). Overall, the purpose of the CCM is to encourage high quality chronic disease care, and the model identifies six essential elements of a health care system for this purpose: the community, the health system, self-management

support, delivery system design, decision support, and clinical information systems. Each element is further defined as encompassing evidence-based change concepts, which “foster productive interactions between informed patients who take an active part in their care and providers with resources and expertise” (http://www.improvingchroniccare.org/index.php?p=The_Chronic_Care_Model&s=2).

A recent review found that redesigning practice according to the CCM model seemed to result in better care and better health outcomes, but that there was little evidence so far regarding its effect on costs (Coleman, Austin et al., 2009). The review cited three articles as cost saving, but only one even mentioned CCM. However, that study provides some rare insight into the components of the CCM that are potentially cost saving, at least in diabetes care (Gilmer, Whitebird et al., 2006). Gilmer and colleagues utilized a large health plan database, a survey of clinic medical directors and managers, and generalized linear models to determine the impact of a number of covariates on total medical costs (CBA – Payer perspective). They found that regular clinician meetings to discuss patient care problems, the use of diabetes registries to prioritize patients based on cardiovascular risk, and quality improvement strategies that provided feedback on resource use related to diabetes or heart disease care to physicians were associated with lower three-year costs. In contrast, the use of databases to monitor lab results and quality improvement strategies that emphasized pharmacy use for patients with heart disease or depression were associated with increased costs. These findings indicate that regular clinician meetings to discuss patient care, prioritization of patients based on risk, and feedback on resource use to physicians are elements of the chronic care model that should be considered for incorporation into future models of IM, especially for diabetes care.

Patient-Centered Medical Home

Historically, the medical home was originally described in the 1960s by the American Academy of Pediatrics (AAP) (Barr 2008). In 2007 the AAP, American College of Physicians (ACP), American Academy of Family Physicians (AAFP), and American Osteopathic Association (AOA) synthesized their respective viewpoints into the Joint Principles of the PCMH as a model of health care to test through demonstration projects. (Found at http://www.acponline.org/advocacy/where_we_stand/medical_home/approve_jp.pdf) These principles include:

- 1) An ongoing relationship between each patient and a trained personal physician;

- 2) Collective responsibility for the ongoing care of patients provided by the personal physician-led team;
- 3) Whole person orientation, including care for all stages of life; acute care, chronic care, preventive services, and end of life care;
- 4) Coordination of care across all elements of the complex health care system and the patient's community;
- 5) Quality and safety emphasized through advocating for patients, physician accountability, the use of evidence-based medicine and clinical decision-support tools, and patient participation in decision making;
- 6) Enhanced access to care through open scheduling, expanded hours, and new options for communication between patients, their personal physician, and practice staff; and
- 7) A payment structure that appropriately recognizes the added value provided to patients who have a patient-centered medical home.

As support for the medical home, Starfield and Shi (2004) reviewed the evidence for the benefits of having a regular primary care provider. The studies are in support of four characteristics of primary care, which are also part of the medical home concept: accessibility for first-contact care for each new problem or health need, long-term person-focused care, comprehensiveness of care (i.e., care is provided for all health needs except those specifically requiring a specialist), and coordination of care in instances in which patients do have to go elsewhere. The authors found that international and within-nation studies indicate that these four characteristics are associated with better individual and population health outcomes, lower overall costs of care, and reductions in health disparities (CEA, CBA – Payer perspective). Although no economic evaluations of PCMH itself could be found, a number of PCMH demonstration projects are now underway and their evaluations will be available soon (Barr, 2008).

Two studies provide some insight into the impact of patient-centered care. Dijkstra and colleagues (2006) directly compared patient-centered (education and diabetes “passports”) and professional-directed (feedback on baseline data, education, and reminders) implementation strategies for outpatient diabetes management and found that patient-centered implementation had better health outcomes, but also cost more in terms of medical costs both initially and over the patient's life (Dijkstra, Niessen et al., 2006). Another study looked at hospitals that are more or less patient-centered and found that patient-centeredness was

associated with better outcomes, but also with higher costs (Bechel, Myers et al., 2000). However, the authors noted that these costs could decrease in the long term given additional time and experience with this approach, and that costs might be smaller if the patient was followed through the entire episode of care.

Drawing upon the results to date, there is little actual data on the cost of the PCMH model. Two studies of “patient-centeredness” resulted in better care and health outcomes, but higher costs. In incorporating patient-centeredness into IM, care must be taken to minimize its cost impacts and to ensure that its care and health benefits are worth any resulting net increase in resource use and cost.

Intensive Lifestyle Interventions

Intensive lifestyle interventions focus exclusively on helping patients make healthy behavior changes. They differ from DM, CCM, and PCMH in that they do not address other aspects of care quality such as the coordination of care across providers. These programs tend to target secondary prevention of either heart disease or diabetes. Perhaps the two most well-known cardiac rehabilitation programs are the Ornish Lifestyle Heart Program and the Cardiac Wellness Program designed by Herbert Benson. In essence, the Ornish program consists of a heart-healthy, low-fat, whole food vegetarian diet, aerobic exercise, stress management training (including yoga and meditation), smoking cessation, and group psychosocial support. The Benson program consists of supervised exercise, individual nutritional counseling, and a comprehensive stress management program, including relaxation response training. One study exists of the actual costs of these programs to hospitals, and it compared those costs to Medicare allowed reimbursement rates (Lee and Shepard, In press, 2009). It found that hospitals incurred substantial non-reimbursable costs for both programs (costs of \$9,895 per patient and reimbursement of \$4,520 for the Ornish program, and costs of \$4,458 and reimbursement of \$3,840 for the Benson program). One early study compared the cost of the Ornish program to the estimated cost of percutaneous transluminal coronary angioplasties (PCTA) with cardiac catheterization and coronary artery bypass grafts (CABG) no longer needed by the experimental group (Ornish, 1998). Estimated savings were \$29,529 per patient compared to a cost of \$7,000 for the Ornish program. No study has been made on the impact of either program on long-term health care utilization and costs.

At the present time, the Diabetes Prevention Program (DPP) is the most well known and studied intensive lifestyle intervention for diabetes. The program is an individualized goal-based behavioral intervention—with a focus on weight loss, healthy diet (especially a reduction in fat intake), and physical activity—delivered by lifestyle coaches (DPP, 2002; Herman, Hoerger et al., 2005). In the main study

of this program, patients with impaired glucose tolerance were randomly assigned to the DPP lifestyle intervention, placebo, or metformin (DPP, 2003). Various analyses of the results have shown that the lifestyle intervention and metformin both improved health outcomes and increased costs compared to placebo, and that lifestyle intervention improved health outcomes and had lower costs when compared to metformin (DPP, 2003; Eddy, Schlessinger et al., 2005; Herman, Hoerger et al., 2005). However, since metformin is not considered usual care in this group (patients with impaired glucose tolerance) the lifestyle intervention cannot be said to be cost saving.

As models of IM are developed, the components of these programs should be examined for elements to help improve health outcomes and prevent disease. However, as with the incorporation of patient-centeredness discussed above, care must be taken to ensure that health care resources are being utilized wisely. Towards that goal, it seems that the Benson program should be carefully compared to the Ornish program to identify the elements that allow it to require substantially fewer resources, and those that are essential for optimal health outcomes.

Complementary and Alternative Medicine

According to the NCCAM, CAM is “a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine” (NCCAM, 2009). Therapies, modalities, and medical systems that make up CAM are diverse and, by definition, the list of what is included is constantly changing. However, there are some characteristics that most of CAM has in common: a focus on the whole person, patients as active participants in decisions and their care, an emphasis on health promotion and disease prevention, and a perception of being less invasive (Jonas and Levin, 1999; Swartzman, Harshman et al., 2002). CAM was explicitly included in the early definitions of IM and in NCCAM’s present definition (Rakel, 2002; NCCAM, 2009). It should also be noted that certain CAM practitioners (naturopathic physicians, chiropractic doctors, and acupuncturists) have been trained as—and are licensed to—practice in a number of states as primary care providers (Duenas, Carucci et al., 2003; American Association of Naturopathic Physicians, 2009; California Department of Consumer Affairs Acupuncture Board, 2009). Therefore, some of these practitioners are providers of a form of IM.

A number of systematic reviews of economic evaluations of CAM have been published (White and Ernst, 2000; Herman, Craig et al., 2005; Hulme and Long, 2005; Bornhoft, Wolf et al., 2006; Canter, Coon et al., 2006; Kennedy, Hart et al.,

2007). These reviews almost universally conclude that the economic outcomes of some CAM therapies are encouraging, but that more and better quality studies are needed.

Regarding the quality of CAM economic evaluations, the authors of one review used two new methods to analyze the quality of the studies (Herman, Craig et al., 2005). All full economic evaluations were subjected to a 35-item checklist developed by the BMJ Economic Evaluation Working Party to improve the quality of published economic evaluations (Drummond, Jefferson et al., 1996). The authors of this review found that although the reporting quality was poor for certain items, it was comparable to the quality found by systematic reviews of economic evaluations in conventional medicine. They also found that the number of full economic evaluations published, and the proportions of these evaluations that were randomized and that gathered data prospectively, had increased in the five years since an earlier systematic review (White and Ernst, 2000). There seems to be a trend toward more rigorous evaluations and more reliable results.

Addressing the need for more economic evaluations of CAM, a new comprehensive systematic review (Herman et al., Manuscript in preparation 2009) found 156 published economic evaluations of CAM, including 108 full evaluations and 48 partial evaluations. One hundred and twenty-one of these were published in the last 10 years with 88 full economic evaluations and 33 partial evaluations. These numbers seem to promise a surfeit of information on the economics of CAM. However, because the term CAM does not represent a single approach, but rather, a wide variety of therapies, modalities, and medical systems that each can be applied to a wide variety of health conditions, the actual numbers of studies available on any particular aspect of CAM—for even broad categories of health conditions—is still small. Therefore, for any category of CAM that is used for any broad group of conditions (e.g., chiropractic for back pain), there are at most 11 full economic evaluations and more frequently only one or two full economic evaluations. By contrast, a literature search on serotonin uptake inhibitors for depression, with one therapy used for one condition, returned 133 studies of which 40 were full economic evaluations published in the last 10 years. For this next section, the focus is on the most encouraging studies that demonstrate cost saving as reported in the economic reviews of CAM. Essentially all of these studies compared CAM to usual care or conventional medicine. In all cases, CAM can be considered to have been added to usual care since all subjects continued to see their conventional health care provider for the majority of their overall health care. In most cases, some aspect of conventional care was replaced or no longer needed when CAM was added. Since the focus here is on CAM that is cost saving, in terms of total medical costs, these CAM therapies, modalities, or

medical systems were net substitutes for conventional medicine for these conditions.

This review assessed over 100 studies of CAM that included economic evaluations. Studies providing evidence as to the CAM therapies, modalities, and systems of medicine whose combination with conventional medicine may be cost saving are summarized in Appendix A. These studies can be grouped into the following categories: acupuncture, chiropractic care and spinal manipulation, mind-body medicine (e.g., clinical biofeedback, meditation, and relaxation/stress management), homeopathy, outpatient oral supplementation, inpatient and surgical oral nutrition support, and hypnosis for surgical interventions. Findings within these categories will be summarized in general below.

Fifteen full economic evaluations of acupuncture published in the past ten years were reviewed. In these studies acupuncture was used for dyspepsia, dysmenorrhea, angina pectoris, and a variety of neuromusculoskeletal pain disorders, including low back pain, neck pain, knee and hip osteoarthritis, and headache. Of these 15 evaluations, six had results that showed both health improvements and cost savings (see Appendix A). The remaining nine evaluations generally showed improved health outcomes, but at a cost. Four of the six evaluations showed cost savings, and all of the nine that demonstrated increased costs were prospective randomized controlled studies. Therefore, it could be said that the higher quality studies, at least according to these criteria, were more likely to reveal acupuncture as increasing costs. However, given the multi-component aspect of IM and the new need to establish the fidelity of the treatment under study (as discussed in the challenges section of the primer on economic evaluations above) it is important to look a bit further into these studies to see what really was tested.

All of the information on what is termed “acupuncture” that was available in the published articles for the six cost saving studies is contained in the table in Appendix A. Of the nine studies that resulted in increased resource use, five were from Germany and used physicians with a German *A-diploma*, which is said to represent at least 140 hours of certified acupuncture training (Willich, Reinhold et al., 2006; Witt, Jena et al., 2006; Reinhold, Witt et al., 2008; Witt, Reinhold et al., 2008; Witt, Reinhold et al., 2008). Two others were from the UK and used physiotherapists who were *appropriately trained* in acupuncture (Vickers, Rees et al., 2004; Wonderling, Vickers et al., 2004). The final two used acupuncturists who treated patients *according to their usual custom* in one (Paterson, Ewings et al., 2003), and acupuncturists *trained in Traditional Chinese Medicine* in the other (Ratcliffe, Thomas et al., 2006). It could be that the differences across studies are at least in part due to the form of acupuncture used. In addition, as much of the work on optimal healing environments indicates, the setting in which the treatment takes place is also important (Samueli Institute, 2009). The studies

reviewed gave little information about the settings in which the treatment took place, other than an occasional one-word reference to the type of clinic. Therefore, strong statements as to the meaning of these studies with regard to the economics of an IM approach that would incorporate acupuncture are not possible. Instead we will say that there is enough evidence that acupuncture should be considered.

Eleven economic evaluations of chiropractic care and spinal manipulation were reviewed. Six resulted in cost savings, and improved—or at least used the implied assumption of equal (for most of the claims database studies)—health outcomes. Four of the five studies indicated an increase in resource use were prospective randomized controlled trials, as were two of the six that showed cost savings. All studies were of patients with back and/or neck pain. Again, all available information regarding the treatment provided and its setting is given in the table in Appendix A. As can be seen, some of these studies used what was called chiropractic care (including three of the studies showing increased resource use), but others used spinal manipulation (including two of the studies showing increased resource use) or manual therapy. Also, as demonstrated by the chiropractors providing IM in the independent physician association discussed above, the term chiropractic care can mean much more than spinal manipulation for back or neck pain, so the points made above under the discussion of acupuncture about study generalizability and synthesis hold true here also. Again, there is enough evidence regarding the economic benefits of chiropractic care and spinal manipulation to consider it in future models of IM.

Nine full economic evaluations of various types of mind-body medicine were reviewed and seven showed improved health outcomes and reduced resource use across a variety of conditions (See Appendix A for descriptions and references). Four of the seven showing cost savings and one of the two that resulted in increased resource use were randomized controlled trials that gathered data prospectively. Again, as discussed above, it is important to note the specific mind-body therapy tested and its setting before generalizing these results. However, it seems that therapies such as meditation, biofeedback, and relaxation training should be considered in future models of IM.

Four full economic evaluations of homeopathy were reviewed and three found both health improvements and cost savings. These three are shown in the table in Appendix A and none used randomization or a matched control design. The other study used randomization and collected data prospectively on the use of homeopathy for dyspepsia, but indicated a small increase in resource use, and had a small sample size (Paterson, Ewings et al., 2003). Therefore, there is some evidence of resource use reduction from homeopathy although further studies are clearly warranted.

Five full economic evaluations of outpatient oral supplementation were reviewed and two resulted in cost savings. Only one of these five studies used a randomized design. This was a study on cranberry concentrate or unsweetened cranberry juice to prevent urinary tract infections in women with a history of such. It demonstrated that the use of cranberry juice or concentrate reduced UTIs more than placebo but cost more than the antibiotic use they offset. However, it did not account for any cost savings that might accrue due to a reduction in future UTIs (Stothers, 2002). Three of the five evaluations used models and one of these used a simulation model to show savings from multiple vitamin use in older adults, as noted in Appendix A. In the second of the three studies, the researchers used a stochastic, agent-based model which showed increased costs from antioxidant and zinc supplementation for patients with age-related macular degeneration (Rein, Saaddine et al., 2007). A third study used a Bayesian modeling approach to examine the use of plant sterol esters for the prevention of cardiovascular disease through cholesterol lowering (Martikainen, Ottelin et al., 2007). The other study that showed cost savings used a control group that was not likely comparable. In considering outpatient oral supplementation, future models of IM should take into consideration the high cost of general supplementation for the prevention of disease. However, it seems that the broad nutrient support available from a multivitamin might make sense, especially in older populations.

Three full economic evaluations of hypnosis for surgery patients were reviewed, and all showed cost savings and improved health outcomes. Two were randomized and one used a matched control. Brief summaries of each are provided in Appendix A. In addition, four full economic evaluations of supplemental nutrition for hospitalized and surgical patients were reviewed and they also all showed a reduction in resource use. Three were randomized studies and one was a large modeling study. These studies are detailed in Appendix A. Hospital-based studies of hypnosis and/or supplemental nutrition resulting in decreased resource use should strongly be considered for any hospital-based IM models.

This review of published economic evaluations has highlighted a wide number of appropriate therapeutic approaches that might be included in an IM model. This review focused on the results of full economic evaluations of disease management programs, the patient-centered medical home, the chronic care model, intensive lifestyle interventions, clinical preventive services, and complementary and alternative medicine in order to identify therapeutic approaches that could be incorporated into future models of IM and improve health without further worsening our current crisis of sky-rocketing health care costs. Approaches that have been demonstrated, at least in other settings, to meet this challenge of better health at lower cost are listed in Appendix A.

Summarizing these evaluations highlights the need for future studies to better document the characteristics of the approach being tested, including the training of providers and the setting in which the care took place. In any case, even with the best documentation, as discussed above, economic evaluations are less generalizable than their underlying effectiveness studies. Therefore, although this review provides a list of therapeutic approaches deserving of further consideration, it is recommended that decision makers carry out their own pilot studies of promising approaches before full scale implementation. However, despite these challenges, the results of these studies show the potential for IM to be part of the solution in our present health care system.

INTEGRATIVE MEDICINE GOES TO WORK

Employers have an inherently vested interest in the health of their employees. Companies of all sizes, including those that are publicly traded, private, nonprofit, and governmental shoulder the largest economic burden of chronic disease and disability (Whitmer et al., 2003; Pelletier, 2009). Hospitals, clinics, and pharmaceutical companies appropriately focus on the diagnosis and treatment of disease and derive their *raison d'être* from providing appropriate disease care services. One setting where major innovation is taking place in operationalizing the entire continuum of prevention and innovations in primary care is in the workplace (ACOEM, 2008; 2009). For more than 30 years, researchers have documented the health and economic impacts of health promotion and disease management programs in a range of small, domestic companies to large, international employers (Goetzel and Ozminkowski, 2008). In the worksite/corporate research domain, the concept of *integrated population health and productivity enhancement* (Loeppke, 2008) is consistent with the objectives and definitions of IM. Furthermore, this integrated population health approach leverages the value of health and the power of prevention (Loeppke, 2008). Worksites and corporate research have linked clinical and cost-effectiveness outcomes for decades and can serve as prototypes for the further development and evaluation of IM systems.

Workplaces represent a microcosm of society since they contain concentrated groups of people who share a common purpose and culture. As a caveat, at the present time the majority of US employers do not provide comprehensive and research evidence-based programs considered best practices. However, such programs are thriving in a growing number of corporations ranging from small to major international corporations. Data supporting the success of these integrated population health initiatives have been reported in peer reviewed articles, compiled in literature reviews, available on websites, and through such national

organizations as the Academy of Occupational and Environmental Medicine (ACOEM), the Pacific Business Group on Health (PBGH), the National Business Group on Health (NBGH), and Partnership for Prevention (2001). There is a vital interface between worksites and IM since worksites/corporations can operationalize the full continuum and continuity of prevention. Employers, the ultimate purchasers of health and medical care for the majority of Americans, spend approximately \$13,000 per employee per year on total direct and indirect health-related costs (ACOEM, 2008; Loeppke et al., 2007; Loeppke, 2008). Applying the U.S. Department of Labor statistics, which document approximately 137 million non-farm employees in the United States, the overall annual cost to employers is an estimated \$1.7 trillion (Towers Perrin, 2008). Clearly, the employer perspective is critical to any discussion of both the medical and health care costs since the combined contributions of the employer and employee account for well over half of the funding for the entire American medical care system (KFF, 2007). Prevention and IM share the ultimate common goal of eliciting and sustaining health through population health management.

Employers have an inherently vested interest and incentive for eliciting, sustaining, and optimizing the health of their active employees, dependents, and retirees. If an employers' primary, secondary and tertiary prevention efforts are successful, workers use health and prevention care services more appropriately and use less unnecessary medical care (Loeppke, 2008). Employees also have lower absenteeism—disability rates decrease, worker safety improves, performance and productivity is improved—with a focus on retention and recruitment of key personnel. When such programs are appropriately implemented and evaluated, this constitutes a “win-win” for both employers and employees. (ACOEM, 2008).

Today, employers of all sizes and types are increasingly using strategies based on the relationship between health and productivity to lower health risks, reduce the burden of illness, improve wellness and performance, and enhance the quality of life for workers and their families, while reducing total health and medical related costs. Such programs help employers more accurately determine which health conditions have the greatest impact on overall productivity and then design strategies to help their employees prevent or better manage these conditions. Worksites offer unique resources and infrastructure for addressing these problems. In an environment in which health costs are escalating in an exponential manner, health promotion and health protection measures aimed at the nation's workforce could have significant long-term impact, potentially saving millions in costs. Furthermore, the positive impact of reaching large populations through the workplace extends beyond those currently employed. Families of the employed, retirees, and other beneficiaries could also benefit from integrated health and productivity strategies implemented by the nation's employers.

Underlying these efforts is a fundamental philosophy that indicates that health is not only of great value to individuals and populations, but also of great value to business and industry. Employers of all sizes need to look beyond health and medical care benefits as a cost to be managed. Employers need to grasp the benefits of good health as an investment to be leveraged. Ultimately, a healthier, more productive workforce can help drive greater profitability for employers as well as a healthier economy for our nation. With a healthy and productive workforce, the United States will thrive in an increasingly competitive global marketplace.

Comprehensive health promotion and disease management programs have evolved significantly in both large and small worksites over the last three decades. Historically, the first published worksite disease management intervention was conducted in 1974 at Gimbel's Department store in New York City. That early intervention focused on screening asymptomatic employees for hypertension. Based on that screening of 180 employees, there were 94 identified hypertensives who were retained in treatment for one year, with 81 percent achieving satisfactory blood pressure reduction (Alderman and Schoenbaum, 1975). An impressive prototype, especially since hypertension still remains one of the most poorly controlled risk factors for cardiovascular disease. Since 1974, large self-insured and self-administered corporate medical plans are placing more emphasis in their managed care plans upon comprehensive health promotion and disease management programs.

Inherent to managed care is an increased emphasis on both clinical and cost-effectiveness (Sherman, 2002). The current generation of worksite programs has a greater focus on disease management with high risk employees, combinations of public health and individualized behavioral risk management, utilization of telemedicine delivery technologies, and inclusion of performance and productivity measures in the economic analyses (Stokols et al., 1995; Heaney and Goetzel, 1997). Disease management programs may be more likely than general health promotion programs to generate ROI because they focus on high risk individuals who typically have a greater impact on medical or related costs such as near term absenteeism and productivity. However, that possibility has yet to be demonstrated by rigorous research. During the 2004-2008 interval., 7 of the 16 new studies (LoSasso, 2006; vanVonno, 2005; Chenoweth and Garrett, 2006; Pratt et al., 2007; Jordan et al., 2008; Ozminkowski et al., 2006; Naydeck, et al., 2008) reported positive ROI. All of these interventions focused on secondary prevention in an integrated population health model.

Increasingly, the research evidence supporting both the clinical and cost-effectiveness of such programs are becoming more compelling. Previous literature reviews of the clinical and cost outcomes of comprehensive, health promotion and disease management programs in the worksite have been published by Pelletier

(1991, 1993, 1995, 1999, 2001, 2005) and other researchers (Wright et al., 2002; Leutzinger et al., 2009). Based on these six reviews of overall, comprehensive health promotion and DM programs in worksites, 137 studies have been cited in the previous series of six reviews (Pelletier, 1991, 1993, 1995, 1999, 2001, 2005). Collectively these reviews clearly indicate evidence of clinical and/or cost-effectiveness for comprehensive interventions (Wasserman et al., 2000; Musich et al., 2001; Ramsey et al., 2002). Most recently, a review was conducted of this same clinical and cost outcomes research from 2004-2008 (Pelletier, 2009). During that time interval, the results from randomized clinical trials and quasi-experimental designs suggest that providing individualized, risk reduction for all employees, including high risk employees, within the context of comprehensive programming is the critical element of worksite interventions (Whitmer et al., 2003). Despite the acknowledged limitations of the current methodologies of the 16 new studies during 2004-2008, the vast majority of more than 153 research studies to date (including the current 16 studies) indicate positive clinical and cost outcomes.

There is one important caveat in this—not all research demonstrates statistically significant results, and those evaluations tend not to be published, which may result in a publication bias of positive outcomes. It is important to note that there has been a marked decline in both the quantity and quality of studies during 2004-2008. With an increasing demand for clinical and cost outcomes to justify corporate investments in health promotion and disease management, this is an ominous trend. Of the 16 additional studies published in 2004-2008, only one was a true experimental design (LoSasso, 2006). This decline, in both the number and quality of studies, is the lowest among the previous five reviews and may have a major, negative impact on the corporate health promotion and disease management field. Such studies and reviews cited in this white paper and in previous reviews are providing corporations, health insurance providers, managed care organizations, consulting firms, and government with the preliminary data to guide program design, implementation, with clinical and evaluations.

Worksites are ideal environments in which to implement and evaluate innovations in prevention and primary care including IM for numerous and unique reasons:

- 1) Employer populations of active employees, dependents, and retirees are representative of the entire U.S. population in terms of geographic distribution, gender representation, racial and ethnic composition, socioeconomic status, and therefore, results of interventions are generalizable to the entire U.S. population (Linna et al., 2004);

- 2) Among corporate medical directors there is no de facto philosophical resistance to IM since they are very pragmatic in fulfilling their mission of maintaining a healthy workforce (Loeppke, 2008);
- 3) There is an inherently vested interest in the health of their employees (Aldana, 2001; Aldana and Pronk, 2001);
- 4) Extensive infrastructures are already in place to facilitate communications, incentives for participation, and substantial in-kind contributions to worksite based demonstration projects (Heaney and Goetzel, 1998; Serxner et al., 2004);
- 5) Integrated databases which incorporate pharmacy, absenteeism, long- and short-term disability, and claims data by condition and cost already exist. Such integrated databases are excellent resources for evaluations and would cost hundreds of thousands, if not millions, of dollars to create de novo in order to conduct an ongoing clinical trial (O'Donnell et al., 1997);
- 6) Employee participation in research is facilitated with less attrition and enhanced compliance over multiple years;
- 7) Workplaces contain a concentrated group of people who usually live in relative proximity to one another and share a common purpose and common culture in a "virtual community" (Stokols, 1992; Goetzel et al., 2001);
- 8) Social and organizational supports are available when employees are attempting to change unhealthy behaviors;
- 9) Certain policies, procedures, and practices can be introduced into the workplace, and organizational norms can be established to promote certain behaviors and discourage others (French et al., 2001); and
- 10) Financial or other types of incentives can be offered to gain participation in programs.

Employers also tend to have long-term relationships with their employees. As a result, the duration of interventions can be longer, making it more probable that employees will attain benefits. Furthermore, workplace health promotion and disease management can be combined with existing efforts such as those related to health surveillance, workplace health and safety, and regulatory compliance

(Kreuter and Strecher, 1996). There is a large and growing body of evidence that shows interventions conducted in worksites span the entire array of prevention, are potential ideal sites for continuity of care, and already have demonstrable clinical and cost-effectiveness. Introducing IM interventions, demonstration projects, and clinical trials can build on these precedents and greatly accelerate the necessary effectiveness research to further IM and its promise to achieve optimal health for large populations.

Determining Return On Investment: Worksite/Corporate Prototypes For Integrative Medicine

It has been clearly demonstrated that worksite programs can influence the health behaviors of employees and subsequently reduce health and medical care costs. Over the past 30 years, numerous studies have addressed these issues and there is also growing evidence that worksite programs can yield significant financial returns to employers that invest in them. Several literature reviews that weigh the evidence from experimental and quasi-experimental studies suggest that programs grounded in behavior change theory and that utilize tailored communications and individualized counseling for high-risk individuals are likely to produce a positive return on the dollars invested in those programs (Goetzel et al., 1999; Aldana, 2001; HHS, 2003; Chapman, 2005; Pelletier, 2005). Overall, ROI research domain is largely based on evaluations of employer sponsored health and medical programs. One important caveat in assessing those evaluations is that they are most often funded by employers implementing the programs, and these employers may desire a positive assessment to justify their investment decisions. Studies often cited with the strongest research designs and large numbers of subjects include those performed at Johnson and Johnson (Bly et al., 1986; Breslow et al., 1990), Citibank (Ozminkowski et al., 1999), Dupont (Bertera, 1990), Bank of America (Leigh et al., 1992; Fries et al., 1993), Tenneco (Baun et al., 1986), Duke University (Knight et al., 1994), the California Public Retirees System – CALPERS (Fries et al., 1994), Procter and Gamble (Goetzel et al., 1998), and Chevron Corporation (Goetzel et al., 1998). Even accounting for inconsistencies in design and results, the majority of these worksite studies produced positive financial outcomes.

An early 1998 review of worksite studies, mostly conducted in the 1980s and early 1990s (Goetzel et al., 1999), estimated ROI savings ranging from \$1.40 to \$3.14 per dollar spent. There was a median ROI of \$3.00 saved per dollar spent on the program. That review acknowledged that negative results were not likely to be reported in the literature and that the quality of many of the studies was less than optimal (Benefits of Worksite Health Promotion, 2008). In a later review

(Aldana and Pronk, 2001), the researchers conducted a comprehensive literature review of the financial impact of health-promotion programming on health care costs in which they rated the rigor of the evaluations. In this analysis, only four of 32 studies reviewed reported no effects of health promotion on health and medical care costs. However, those four studies did not employ a randomized design, whereas several of the other studies that reported positive results applied experimental or rigorous quasi-experimental methods. Overall, the average ROI for seven studies reporting costs and benefits was \$3.48 for every dollar expended. In the same review, Aldana and Pronk (2001) also reported the impact of work site programs on absenteeism. All 14 studies reviewed that focused on absenteeism documented reductions in employee absenteeism, regardless of the research design used. However, only three of the seven studies reported ROI ratios which ranged from \$2.50 to \$10.10 saved for every dollar invested.

In a later review of economic outcomes, Chapman et al. (2005) summarized the results from 56 qualifying financial impact studies conducted over the past two decades. That review concluded that participants in worksite programs have 25 to 30 percent lower medical and absenteeism costs compared with nonparticipants, over an average study period of 3.6 years. However, the Chapman et al. review included a mix of cross-sectional and prospective research studies and did not adjust for study design as rigorously as did Aldana and Pronk. As a consequence, Chapman's higher estimates of cost savings may be inflated. Some researchers point to selection bias as the likely reason for finding cost savings and high ROI estimates in worksite studies. In many studies, it is unclear whether program participants are healthier or more highly motivated than nonparticipants at the baseline. Such prior differences in health or motivation may explain why participants use fewer medical care or other services and may continue to do so even if a program was not available. Under this scenario, changes in medical expenditures or absenteeism may be due to underlying health and motivational factors that are independent of the program being evaluated, and these should not be counted in the program's favor. This type of selection bias can be minimized, however, if researchers are able to obtain data explaining why the decision to participate was made. Recent financial impact studies of worksite programs have attempted to control for such inherent differences between participants and nonparticipants at baseline (referred to as selection bias) and have used statistical methods such as propensity matching and weighting, to yield more accurate estimates of program savings and ROI (Ozminkowski and Goetzel, 2001). At the present time, it is quite clear that the more rigorous the research design, and the more sophisticated the medical economic analyses, then, the more likely the analysis will result in ROIs that are lower, but which remain in the 2:1 range.

Among the most recent studies is one conducted by Mercer, which assessed the ROI for components of 25 comprehensive health promotion and disease management programs in worksites. In this study, the researchers compared the average ROI for the impact on medical expenditures for a comprehensive versus a more focused disease management program (Serxner et al., 2006). In this instance the ROI for the comprehensive programs ranged from 1.5:1 to 3.0:1, as compared to the range for disease management programs at 1.2:1 to 1.8:1. When measures of productivity were added beyond the impact on medical costs, *per se*, the ROIs increased to a range of 3.0:1 to 5.0:1 for comprehensive programs and jumped to 2.5:1 to 3.5:1 for disease management programs. These savings and ROI estimates were based on programs in place for three to five years. Clearly the addition of variables other than medical costs to reflect the true impact of a worksite based intervention does increase the ROI for such programs.

One of the most significant new research models is the extension of ROI analyses to include other outcomes resulting from health interventions such as performance and productivity. Very few newly approved pharmaceuticals actually save money, but they can improve health at a reasonable expense. In the pharmacy literature, net increases in spending that are up to \$50,000 may be deemed acceptable or cost-effective, if these dollars will save at least one quality-adjusted year of life. However, this widely accepted methodology has rarely been used when considering the value of health improvement programs (Serxner et al., 2003). By contrast, the more demanding objective of realizing net savings has generally been required in evaluations of health and productivity management programs. As employers and payers realize that investments in health and productivity are long-term in nature and that there may be a significant lag between improvements in health and savings in medical expenditures or improvements in productivity, the significance of documenting ROI may become more sophisticated. This is more likely to occur if it can be demonstrated that investments that yield cost-effectiveness in the short run will subsequently lead to net cost savings in the intermediate and long run.

One often cited summary of the economic analyses of 10 years of economic outcomes from worksite studies concluded that the evidence is “very strong for average reductions in sick leave, health plan costs, worker’s compensation, and disability costs of slightly more than 25 percent” (Chapman et al., 2005). Whether or not the clinical and cost outcomes to date are this positive or not is clearly a matter of different interpretation of the research data to date. However, given the clear methodological flaws in the study designs and evaluations combined with the lack of standardization of the clinical and especially the cost outcomes, this issue remains to be resolved by the future and more rigorous, true experimental RCTs conducted in worksites over multiple years with adequate follow up times to determine both clinical effectiveness and cost-effectiveness.

In considering the area of best practices, it is important to note that not all workplace health promotion programs are created equal. There is a great deal of variation in program design and execution. In order to address what constitutes the best and most promising practices, the first step is to examine the outcomes of the most effective programs (O'Donnell et al., 1997; WELCOA, 1997; Goetzel et al., 2001; Goetzel et al., 2007;). By analyzing a series of benchmarking studies, it is possible to identify common themes. One such review (Goetzel, 1997) identified these six elements frequently found among best practices:

- 1) Organizational commitment;
- 2) Incentives for employees to participate;
- 3) Effective screening and triage;
- 4) State-of-the-art theory and evidence-based interventions;
- 5) Effective implementation; and
- 6) Ongoing program evaluation.

Similarly, another assessment of the best practices components (O'Donnell et al., 1997) identified the following characteristics of sustainable programs:

- 1) Linking of program to business objectives;
- 2) Executive management support;
- 3) Effective planning;
- 4) Employee input when developing goals and objectives;
- 5) Wide variety of program offerings;
- 6) Effective targeting of high-risk individuals;
- 7) Incentives to motivate employees to participate in the program, leading to high participation rates;
- 8) Program accessibility;

- 9) Effective communications; and
- 10) Evaluation of effectiveness.

Although this best practices checklist is derived from the worksite/corporate research literature, it provides a foundation template for the development and evaluation of IM interventions in worksites of all sizes.

Chief Financial Officers (CFOs) and CBAs

Although the health and medical research community focused on worksites does use ROI as the gold standard, it is sobering to note that such outcomes may or may not be convincing to CFOs or public health policy agencies. Within the corporate sector, the recent tsunami of financial mismanagement and malfeasance, coupled with the responsibilities of the Sarbanes-Oxley provisions, has placed increased focus on the corporate CFOs. Since these individuals are the conduit through which all major financial decisions must pass, it is essential to understand the metrics that CFOs use to make presumably cost-effective decisions regarding the health and medical benefits of tens-of-millions of active employees, dependents, and retirees. A landmark and ubiquitously cited survey was conducted in 2005 by the Integrated Benefits Institute (IBI) (2005). Among its major findings, the IBI survey includes the following:

- 1) Nearly all CFOs will focus on controlling health plan costs over the next two years. A majority, however, will also seek to manage all health related costs, including absenteeism and bottom-line effects as key impacts of employee ill health. A solid majority also agrees that the costs of ill health cannot be shifted away to employees or third parties.
- 2) Finance executives believe that work time lost to employee illness is reaching critical levels and is affecting business performance. Nearly half the CFOs in this survey estimate that their companies are *at* or *above* this critical point in lost work time from absence and presenteeism; that is, it is having a meaningful impact on their companies' business performance.
- 3) CFOs are ill-informed about health-related lost work time. Nearly half of survey respondents never receive reports about the incidence of absence, and less than a quarter receive reports on its financial impact. Far fewer know about presenteeism with nine in 10 never receiving reports on the incidence or impact of presenteeism in the organization.

- 4) “Flexible human-capital” responses are preferred to losing revenue as a strategy for managing lost work time. Almost nine in 10 CFOs prefer using overtime and six in 10 view temporary help as a way to manage potential productivity losses when employees are ill or injured. Still, almost four in 10 allow work to go undone and deadlines to be missed when employees lose work time—two strategies that may result in diminished revenue and loss of customer goodwill.
- 5) The financial effects of health-related lost productivity can be quantified based on the company’s response to lost work time. Eight in 10 CFOs would use overtime pay and the costs of temporary help to quantify the financial impact of absence, while seven in 10 would use wage-replacement costs. Six in 10 CFOs identify lost revenue and general “opportunity costs” as useful business measures.

This IBI survey of 343 senior finance executives also reported that CFOs have a quite different set of metrics than the ROI focus of health and medical researchers. Among the metrics of most importance to these CFOs are: overtime pay, temporary help costs, wage replacement, quality lapse, additional employees, absent worker wages, lost revenue, opportunity costs, and additional management effort. As the survey indicated, CFOs seldom receive information on the financial impact of absence or presenteeism, which is the effect of health conditions on performance at work. If such information was rendered into the business context that CFOs respect, then the survey indicated that such data would affect CFOs’ willingness to approve the funding necessary to support interventions in health-related productivity. Provided with the right information, two-thirds or more of the CFOs would consider absenteeism and presenteeism costs against the cost of health and medical care programs. Also, they would take steps to reduce absence and presenteeism and more closely manage all health and medical related costs. One of the conclusions drawn by IBI is that these survey results should encourage employers to track and monetize absence and presenteeism effects, engage the CFO as a strategic business partner in health and medical related productivity interventions, and identify the right internal and vendor partners who support health as a productivity investment and generate the relevant clinical and cost-effectiveness data necessary to inform CFO decisions.

In concluding their survey, the IBI report stated several “practical implications” of their research to render pragmatic recommendations for employers to consider. While these recommendations are geared to employers, they are directly relevant to the necessary CBA of IM, no matter what the context and perspective may be. Among these pragmatic recommendations are:

- 1) Find the right internal and external supplier partners whose interests are in improving your business results and not limited to risk and cost-shifting, and make data a key part of your relationship;
- 2) Link health status to outcomes that matter to the business. Clinical outcomes are important, but business outcomes are what resonate with CFOs;
- 3) Track absence and monetize your company's response. Absence is tangible, is readily observable by employers and has a demonstrable business impact;
- 4) Quantitatively evaluate presenteeism. Presenteeism is real and large, so employers would be well advised to take steps to get their arms around it and include its management in strategic corporate responses. There are a number of validated self-reporting tools available;
- 5) Pay attention to all health-related lost time. Avoid getting trapped into thinking that lost time for white-collar employees somehow doesn't matter because they can "make up the work." This response ignores the value of timely performance (e.g., missing deadlines, meetings, appointments, or engagements) and pretends that presenteeism isn't real, especially for chronic conditions; and
- 6) Benefits and risk managers should make the CFO their strategic partner in improving business success through health interventions and in evaluating their full impact. In this way, CFOs can analyze health-related investments as a value center and not a cost center. The full savings demonstrated to come from health-related investments will make their approval easier.

From this influential IBI survey, the overriding message is very clear that any clinical services provided within the worksite/corporate context need to include CBA. However, the metrics that are most meaningful to CFO's are often not included in such analyses. Clearly, the current ROI models for evaluating the clinical and cost-effectiveness of IM need to include such metrics if they are to have an impact on decisions made by CFOs, and therefore the domestic and global corporate community.

Employer Perceptions of the Potential Cost Savings of CAM

A series of surveys of health plans, employers, and employee benefits professionals between 1999 and 2001 captured some of the perceived economic value employers saw from CAM. While responsiveness to consumer or employee interest may affect a firm's global costs through potentially helping attract or maintain employees, more direct potential economic benefits were also motivators. Of employee benefits managers surveyed in 1999, 7 percent marked *potential fit with wellness programs* and 3 percent marked *potential for cost savings* as the chief motivator (IFEBCP, 1999). Typically the perception of possible value registered higher. An online survey through the American Compensation Association found anticipated cost advantages in a variety of areas:

- 1) Potential to contain rising costs of health and disability (14 percent);
- 2) Fits with existing wellness benefits (14 percent);
- 3) Potential long-term group health savings (11 percent);
- 4) Impact time off work (2 percent); and
- 5) Potential cost-effectiveness (14 percent).

Additionally, a survey of benefits professionals in Fortune 200 firms by PricewaterhouseCoopers found that for 31 percent of respondents, the top reason for inclusion of these services was out of expectation of *potential for more cost-effective services* (PricewaterhouseCoopers, 2000). Although employers may be more motivated by economics than altruism, corporations are fertile receptor sites for integrated population health, which is entirely consistent with an IM orientation.

In November of 2008, the American College of Occupational and Environmental Medicine (ACOEM) convened a "Health and Productivity Summit" (ACOEM, 2008) of public and private sectors employers and researchers to provide guidance for what kinds of clinical and research practices might make prevention, enhanced primary care, and, by inference, IM meaningful to employers. The resulting consensus document offers elements of what may constitute a more significant IM-employer relationship. In the ACOEM consensus document, Statement 8 speaks directly to research: "The concept of evidence-based medicine has grown more commonplace in U.S. health care. However, the evidence used to determine best practices needs to go beyond clinical outcomes and include functional impacts on health and productivity." Researchers should

“integrate health and productivity research and metrics into evidence-based outcomes.” Such integrated approaches are uniformly oriented around effectiveness. Overall, this consensus document recommends specific metrics that are currently a rare part of IM research and are consistent with the previously discussed IBI survey. Such metrics include “absenteeism, return-to-work, lost days, impaired work performance, presenteeism, total health-related costs, and patient satisfaction” (ACOEM, 2008). These ACOEM recommendations are entirely consistent with the patient-centered care approach characterized and defined as an integral aspect of IM.

Overall the ACOEM white paper recommends strategies that involve employees as active, incentivized participants (Statement 9 of the ACOEM white paper). Also, the recommended employee-centered approach is community-based and recognizes, as does integrative practice, that some of the determinants of health are global: “Broad social and environmental determinants—ranging from food and transportation systems to cultural practices—can influence health” (Statement 10). Among the other consensus statements within the document is a call for a transformation in the way employers approach health: “Continuing the *status quo* of current health care strategies in the workplace is not a sustainable option” (Statement 2 of the ACOEM white paper). Finally, the opportunity for integrative practices to fill a need is explicitly noted in a recommendation: “Expand the supply of health professionals that are educated and trained in how to implement and measure the impact of integrated health and productivity improvement strategies.” In considering the scope of these ACOEM recommendations, it is evident that there is both a philosophical and practical alignment of such worksite oriented interventions, extended models of primary care, and IM, as evolving innovations.

Turning briefly to the potential cost-effectiveness of IM interventions in worksite/corporate savings, the potential economic benefits to the corporate world, as well as to the United States as a whole, are major. In fact, a study conducted by the Milken Institute has calculated that seven chronic conditions result in the greatest economic impact on business. These include cancer, heart disease, hypertension, mental disorders, diabetes, pulmonary conditions, and stroke, which are costing the U.S. economy more than \$1 trillion per year alone. It is anticipated that the growth rates of the prevalence of these seven conditions will yield an illness burden of \$4 trillion per year by 2023. However, as compared to this business as usual scenario, plausible estimates of potential gains or avoided losses associated with reasonable improvements in prevention, detection and treatment of just those seven conditions would cut annual treatment costs in the United States by \$217 billion and reduce medically related productivity losses by \$905 billion by 2023 (Loeppke, 2008). Furthermore, just lowering obesity rates alone could lead to productivity gains of \$254 billion and the avoidance of \$60

billion in treatment expenditures (Devol et al., 2007). IM can play a vital role in primary, secondary, and tertiary care interventions conducted in worksites with both clinical and cost outcomes.

Employers clearly recognize the value of health and productivity enhancement. In 2008, the Staying@Work Report was published based on a survey of 355 large employers conducted by the Watson Wyatt and the National Business Group on Health. This study focused on the relationship between an organization's health and productivity programs and its business performance. Of greatest significance, this report documented findings that indicate employers with highly effective health and productivity programs experienced superior performance (Watson Wyatt, 2008):

- 1) Are more than two and a half times as likely to integrate health risk reduction, health management, disability management, health plan benefits and on-site clinics;
- 2) Were more than three times as likely to integrate health management programs through a single-access-point technology platform;
- 3) Yielded 20 percent more revenue per employee;
- 4) Have a 16.1 percent higher market value;
- 5) Delivered 57 percent higher shareholder returns; and
- 6) Have cost increases that are five times lower for sick leave, four and a half times lower for long-term disability (LTD), and four times lower for short-term disability (STD).

Clearly, good health is good business.

Corporate Health Improvement Program

Evaluating the clinical and cost outcomes and potential value of IM in employee health is presently the focus of one major research program undertaking a number of significant initiatives. At the present time, there are three ongoing research projects within major corporations that focus on IM approaches. These research projects are being undertaken by the Corporate Health Improvement Program (CHIP), which is a collaborative research program between the University of Arizona College of Medicine, the University of California, San Francisco (UCSF) School of Medicine, and Fortune 500 corporations including

Dow, Ford, IBM, Corning, and NASA as a federal employer (Pelletier, 2009). Each research project focuses on an IM intervention that is consistent with the integrated population health management approach that is increasingly evident in worksites. There are three ongoing studies:

- 1) An IM approach to back pain at Ford Motor Company (Berman, Pelletier, and Talamonti, 2009);
- 2) Implementation and assessment of an expanded disability management program to prevent conversion from STD to LTD at Prudential (Pelletier and Crighton, 2009); and
- 3) Development of a state of the art worksite stress assessment to identify subsequent interventions at NASA (Pelletier, Coons, and Davis, 2009).

Although none of these meet all the criteria in the definitions of IM, they are all structured as evidence-based approaches combining conventional and CAM therapies to be evaluated for both clinical and cost outcomes.

The Ford Motor Company: "Integrative Medicine for Acute Low Back Pain"

In the Ford Motor Company study, the focus of the Ford study is on the alleviation of back pain. Back pain is the leading cause of job related disability among U.S. employers. Numerous studies have demonstrated the limited impact of usual care to alleviate pain, restore an employee to active status, or to deliver care in a cost-effective manner (ACOEM, 2006). Given these limitations, this research project is to develop and implement an IM intervention, which when combined with current standard care, is hypothesized to produce more positive clinical and cost outcomes than the current standard of care alone. This intervention is currently being delivered in two Ford Motor Company Clinics to a total of 80 employees and compared to 80 employees receiving the usual care delivered in these same clinics. Overall, the IM intervention consists of an intensive four-week intervention involving four major components:

- 1) Traditional Chinese acupuncture;
- 2) A mind-body medicine intervention consisting of a self-care, audio, and workbook program emphasizing mindfulness meditation;
- 3) Patient educational materials dealing with acute back pain, supplemented by individualized patient education services delivered via a toll-free telephone number; and

- 4) Usual care provided in all Ford Clinics that is dedicated 24/7 to back pain care.

These enhanced IM services are coordinated onsite at the participating Ford Clinics by a case-manager working closely with physicians and researchers. This innovative intervention will be evaluated by an array of pain, functioning, productivity, medical utilization, and quality of life outcomes capable of being administered over the telephone in order to reduce experimental attrition. Overall, the primary hypothesis that will be tested is that an IM intervention delivered in addition to standard care will be more effective than standard care alone, in terms of both clinical and cost outcomes. With its implementation, this project will constitute the first research project to the feasibility of implementing an IM clinical model within a corporate workplace. As such, it constitutes a carefully controlled evaluation of an overall comprehensive, integrative approach that, if successful, would have important financial and policy implications for the Ford Motor Company. Given this objective, the study design itself will be tailored to the realities of the corporate workplace by emphasizing the maintenance of participant satisfaction and the minimization of participant burden.

Prudential: “Supporting Total Recovery In Valued Employees” (STRIVE)

For the second CHIP research project, the objective of a pilot study at Prudential is to demonstrate the empowerment of Prudential employees to more effectively utilize their health care resource needs when facing the prospect of work disability. This research project is the *Supporting Total Recovery In Valued Employees* (STRIVE). At the center of this intervention is an “advocacy” service offered through the Prudential Health & Wellness department, and available to all Prudential employees enrolled in the Integrated Health Care and Disability Management (IHCDM). Initially, telephone discussions are conducted by occupational health nurses in the role of health advocates. This telemedicine model ensures that all employees can benefit from the service regardless of their geographical location. As soon as the disability occurs, the health advocate assists employees to identify challenge(s), short- and long-term goals, as well as the action steps necessary to reach them. In addition feedback, support, and structure are provided to assist with maintaining focus. With the active participation of the employee, the health advocate works with the disability claim manager/team as well as other vendors to provide guidance to employees in areas that include:

- 1) Return to Work Accommodations;

- 2) Employee Assistance Needs;
- 3) Total Health Management;
- 4) Disease Management;
- 5) Work/Life-Return to Life Challenges; and
- 6) A nurse, case manager advocate.

Throughout the duration of the process, the health advocate is available to provide guidance, feedback, and further needs assessment, review available resources, and organize the available resources with the employee. Among the coordinated resources available to the employee are Prudential Health Solutions via WebMD, an ergonomics team, CIGNA Behavioral Health, an Employee Assistance Program and Work/Life resources through Prudential LifeSolutions. Together these coordinated services constitute a single comprehensive source that employees can use in managing life events inside and outside of work, whether emotional, social, psychological, or physical. This service assists employees and their families with productive responses to these various events using programs and services, both online and via telephone. Life coaching, eldercare, back up childcare, and legal services are additional services that are offered.

NASA/Johnson Space Center: "National Assessment of Stress Adaptation"
(NASA²)

A third study is being conducted at NASA under the rubric of the *National Assessment of Stress Adaptation* (NASA²). There are a number of stress management interventions that are well documented in the research literature to be effective. These can be used in various combinations to create a unique intervention for the particular circumstances of a specific worksite and employee population. Overall, there is clear evidence of a dose-response relationship where the more intensive intervention programs lead the best and most enduring outcomes. It is important to note that the most effective, worksite interventions focused on stress involve changes at the organizational/environmental level, as well the individual/behavioral level. Since NASA² will assess both levels of stress, it is anticipated that the subsequent intervention programs will focus on both levels also. Components of the intervention programs include:

- 1) Changes in worksite policy and/or procedures;

- 2) Alterations in lines of authority/reporting, communications, and/or performance incentives;
- 3) Environmental modifications including lighting, noise, ergonomics, and/or workplace privacy;
- 4) Stress management materials including books, specific workbooks focused on particular conditions ranging from anxiety management to reducing cardiovascular risks, audiotapes, CDs, DVDs, and computer software programs of varying sophistication;
- 5) All of the above to be utilized in conjunction with an online stress management program to be developed based on the NASA² assessment results;
- 6) All of the above plus a HealthLine/StressLine staffed by health educators to work one-on-one with employees to further focus the above materials through an (800) number and/or interactive, real time, online coaching; and
- 7) Links and appropriate triage to providers for employees determined to be at high risk.

Once this online assessment is developed, assessed, and standardized, it can be adapted to a wide range of worksites and types of employees. Perhaps more than any other sector, the corporate environment emphasizes the full continuum of prevention, an expanded model of primary care, and integrated population health management, which is consistent with the definition and goals of IM. Clinical and cost-effectiveness research within the corporate environment provides innovative prototypes of how such research can be productively conducted as IM evolves.

INTEGRATIVE MEDICINE AND CODING/PAYMENTS FOR ELEMENTS OF CAM

One last very pragmatic area which needs to be addressed regarding the economics of IM is that of diagnostic and billing coding issues associated with an IM model. It is essential for the evolution of IM to have a coding/billing system that accurately reflects the care being provided, as well as renders appropriate compensation to the providers of such IM services. All health care providers are required to utilize presently accepted coding systems, including Current

Procedural Terminology (CPT) (AMA, 2008) and International Classification of Diseases – 9th Edition (ICD-9) (AMA, 2008) for purposes of reimbursement and identification of services rendered. The AMA CPT code set forms the basis for clinical service description and billing for both traditional medicine and CAM practitioners, and with few exceptions is provider neutral. At the present time, the CPT system provides service codes that are common across various provider disciplines (e.g., Examination and Management codes) and others specific code sets used by distinct practitioners. Among the 2009 CPT code set are specific discipline examples that include: Chiropractic Manipulation (98940-98943); Acupuncture (97810-97814); Osteopathic Manipulation (98925-98929); Physical Therapy Evaluation (97001-97002); Occupation Therapy Evaluation (97003-97004); Athletic Training Evaluation (97005-97006); and, Medical Nutrition Therapy (97802-97804). While there are no unique reimbursement models, and no diagnostic and billing code set specific to an IM model, the presently accepted coding systems are appropriate for the IM health care delivery model. There are no standardized payment models for IM, *per se*, however, incorporation of the CPT and ICD-9 codes and implementation of the ICD-10 code set would provide the basis for payment in an integrative care model.

All licensed health care providers utilize the International Classification of Diseases – 9th Edition – Clinical Modification (ICD-9-CM) code set published by the World Health Organization. Also the ICD-10-CM (10th edition) is applicable to medical and CAM services providing an expanded set of common diagnostic descriptors that can be used to integrate conventional and CAM diagnostic code descriptors. Further, ICD-9 “E and V” Codes, used to define external causes and supplementary classification of factors influencing health, are also commonly used by both medical and CAM providers. Examples of ICD-9-CM codes that might be used in the Complementary System are: Chiropractic (847.2 Sprains and Strains, Lumbar); Acupuncture (787.02 Nausea); Athletic Training (845.01 Sprain Deltoid (ligament) Ankle); Dietetics (250.02 Diabetes Mellitus Type II); Massage Therapy (723.1 Cervicalgia (Neck Pain)); Naturopathy (477.8 Allergic Rhinitis Due to Other Allergen) (AMA, 2008).

Other code sets are defined by departments of workers’ compensation, and the federal or state governments. One such code set is the Healthcare Common Procedural Coding System (HCPCS) (AMA, 2008), as an example of an additional service description or coding method. The HCPCS also serves as the HIPAA standard code set used for reporting supplies, orthotics and prosthetics, and durable medical equipment.

A new, secondary coding system, specific to CAM and proposed application to IM was developed and identified as ABC Coding Solutions (ABC Coding Solution, 2009). These codes were specifically developed to supplement and extend the traditional code sets to describe services not clearly identified in the

traditional coding systems. These ABC codes define clinical services provided in nursing, behavioral health, alternative medicine, ethnic and minority care, midwifery, and spiritual care. However, to avoid a secondary coding system, and with the implementation of the ICD-10 system, the ABC code system has not been widely accepted or implemented. Preventive health services provided by complementary practitioners can be defined and coded using the traditional ICD-9 (and upon implementation, ICD-10) and CPT code sets.

These coding systems include diagnosis and service coding syntax that provides common language and a useful template to enable payment and research data management mechanisms within IM. As such, use of these standard coding elements could allow an IM model to facilitate and track referrals between traditional medical care providers and other CAM practitioners to ensure an understanding and shared use of common clinical descriptions of diagnoses and services rendered. Acceptance of coding systems and definition of terms within the coding system could support the continued development of understanding and common clinical descriptors across all practitioners within IM and the broader health care system. Applying the current payment and practice models, with the goal of highest quality patient-centered health care, would allow for systems of reimbursement to be implemented that provide for fiscal equity across integrative models. These payment systems would result in reimbursement rationales that value those practitioners who demonstrate the highest levels of competence for the given service, the appropriate choice of evidence-based or evidence-influenced practices, and the best outcomes in terms of quality of life, decreased complication rates, and costs. Common coding systems provide an infrastructure for systematizing communications within quality management systems that support the delivery of the health care service.

FEE SCHEDULE STRUCTURES APPLICABLE TO INTEGRATIVE MEDICINE

Within the current health care system, for integrative care benefits to reach a significant number of individuals, those benefits will have to be offered by the private, employer-based health insurance market. These insurers, whether for-profit or non-profit, will have to have good reasons to make such offerings and employers will need to see value above current, available products to consider purchasing insurance coverage. There are a number of incentives and disincentives that will influence the decision making. Among the incentives are:

- 1) Market differentiation - Health insurance may appear to many potential purchasers as merely a commodity where the only basis for comparison is

cost. The addition of one or more elements of integrative care, such as a CAM benefit or an IPH program, may break the commodity mold and allow an insurer to differentiate themselves in the market and thereby gain market share, which is always a corporate objective;

- 2) Offset/substitution savings - As described above, it is possible to add a health care benefit or service and pay for that addition by substituting or offsetting other health care services and costs. To the extent that it can be shown that lower cost CAM services are offsetting higher cost medical services the insurer is incentivized to offer the CAM benefits; and
- 3) Population health improvement - Insurers are always interested in attracting and insuring a healthier, rather than a sicker population. Insurers have traditionally attempted to achieve a healthy membership through various mechanisms that will cause more healthy people to select that insurer. A properly engineered and implemented IPH program offers the potential of creating, rather than simply attempting to select, a healthier (and less expensive to insure) population.

By way of countervailing forces, there are also disincentives for offering integrative care benefits, which include:

- 1) Premium increases - Unless proven otherwise, the addition of any particular benefit will be seen as an added cost that will require higher premiums. The health insurance market is extremely price sensitive and any increases in premium costs will tend to erode market share. If integrative care benefits are seen as cause for higher premiums, it will not survive in the market;
- 2) Member turnover - In any insured population there will always be a given number of individuals who change jobs and/or change insurers from year to year. If an insurer has made an investment in an IPH program with the expectation that total population health will improve and health care costs will be reduced, the benefit will not be accrued to the insurer that made the investment when members drop or switch coverage;
- 3) Inertia - For corporate managers there is always a certain deference given to the *status quo*. If an insurer has never offered integrative care benefits, and that insurer's position in the market is secure and is financially sound, change will be perceived as risky. There will always be uncertainty around the ROI effects of an IPH program or the offset effects of a CAM benefit.

The potential savings that might be derived from these programs may simply not be great enough to overcome the uncertainty and risk associated with making significant changes and additions to the benefit structure; and

- 4) Culture - The clinical managers of major health insurance companies are invariably medical physicians who are products of our medical educational system and culture. To varying degrees these physicians remain conflicted about the legitimacy of CAM services and practitioners. Medical sociologist Paul Starr has termed this legitimacy “the cultural authority of professionals to act in certain domains” (Starr, 1982). In the eyes of many in the medical community, the cultural authority of CAM practitioners to provide valid care for the population has not been established. These clinical managers will tend to have a veto over any potential integrative care benefits, and will exercise that veto if they are not confident of the legitimacy (including cost-effectiveness) of those benefits.

Complementary care services payment models are typically subsumed under one of three primary economic funding structures including: 1) Third party payer models; 2) Government-regulatory-defined payer models; and 3) Private fee for service models.

- 1) The third party payer reimbursement model reimburses CAM health care providers under either an insured fee-for-service model or managed care contract models. Indemnity fee-for-service coverage pays for almost any service, provided that the service is within the CAM practitioner’s licensure scope of practice. In some circumstances, coverage may be limited to a list of services that are narrower in breadth than allowed for by scope of practice. In those cases, similar to the traditional health care provider, the CAM provider may or may not (depending on insurance contract) be able to balance bill the member for the non-covered services. Managed care contracts typically pay a subset of services within a practitioner’s scope of practice-allowed services. These limitations are most typically influenced managed care contracts that may limit the services covered to the subset of a practitioner’s scope of licensure for which there is some reasonable level of scientific evidence of clinical utility and safety. For example, a managed care contract may cover chiropractic manual therapeutics for treatment of back pain, but not allow coverage for manual therapies applied in the treatment of irritable bowel syndrome. These evidence-based limitations are increasing as the

standards and market expectation for evidence-influenced and evidence-based practices increase. Alignment of evidence-influenced medical claims payment policies with specific coded procedures and health conditions has been found to be an effective way to control and influence the practice of medical care.

- 2) In terms of government reimbursement models, both state and federal systems maintain payment models that often use traditional code sets such as the ICD-9 and CPT. However, some states have found it more useful to implement state specific codes and code definitions to allow for payment and data management within defined regulatory parameters. Within government reimbursement systems, chiropractic health care is the most commonly reimbursed complementary health system. However, Centers for Medicare and Medicaid Services (CMS) limits coverage to chiropractic manipulative therapy services and for one diagnostic condition for Medicare reimbursement. Each state Medicaid program offers a different level of coverage for services by CAM providers, spanning the range from no coverage to broad coverage of CAM services. Combined, Medicare and Medicaid provide some level of recognition and payment for a limited set of services. Many states mandate coverage for complementary services within workers' compensation fee schedules. The Official Medical Fee Schedule system in California is an example of a state specific payment model that affords payment for various CAM providers, such as chiropractic and acupuncture, but utilizes its own coding system that loosely approximates the CPT system with additional codes added by the state.

The Relative Value Unit (RVU) system developed and maintained by the AMA provides a systematic method to calculate service value. This system is another example of a model that could be applied to the IM system. The RVU service value, or amount a service should be worth in the marketplace of health care services, is based on many drivers including work value, service complexity, length of training, malpractice costs, facility costs, and others. These units of measure have also been applied to some elements of CAM services such as chiropractic manipulation and acupuncture. Consistent with the traditional health care practitioner, the CMS uses a Resource Based Relative Value Scale (RBRVS) system (AMA, 2008) to calculate fee values for some CAM care practitioners.

- 3) The private payer, fee for service models remain the most common method of payment for many CAM services. It is not uncommon for nearly all services within a scope of a licensed CAM provider to be

covered in fee-for-service indemnity coverage. Personal Injury insurance may cover many CAM services but is likely to be limited by research evidence and/or medical policy limitations. Cash “out-of-pocket” comprises a large percentage of revenue for many complementary practitioners. Even when out-of-pocket payments are made, most CAM practitioners use ICD-9 / CPT coded invoices to document and define the services rendered. Capitated payment models (familiar to California, Minnesota, and other locations where strong-form managed care systems predominate) may or may not provide mechanisms for integrated payment beyond traditional medical management. Some capitated plans will cover any service referred for by the primary care physician (even if it is complementary) while others are limited to a fixed list of covered services. Payment for covered services within capitated systems provided by CAM practitioners are often the responsibility of the capitated medical group, and not easily tracked or managed in a way that enables effective data integration. Case-rate payments (e.g., fixed fee for normal uncomplicated live birth) common in medical reimbursement systems are less common in the CAM reimbursement models. In theory, case-rate systems provide incentives to integrated practitioner teams to provide the most clinically effective and cost efficient care. These systems arrange for care so that multiple medical and ancillary practitioners share in the treatment responsibility and reimbursement. This model could have application to IM as it has to integrated medical case-based reimbursements.

The management infrastructure to support IM will need electronic medical systems that use common syntax and coding systems to allow for connectivity and data sharing on common platforms. The use of current systems of coding services and conditions will continue to enable the proliferation of integrated data systems, which are a key component of efficient and effective IM.

Financial incentives within IM will align equitable reimbursement across all aspects of the integrative system based on expectations common to all practitioners within and adjunct to an integrative medical system. Those expectations should include use of common terms and coding, use of outcomes measures, choice of services with lowest complication rates, and appropriate referral decisions. All of these parameters require common syntax to assess whether or not a system or practitioner is meeting the expectations. A common language with consistent measurement systems allows for all practitioners across the system to receive parity compensation in accordance to RBRVS parameters as the integrative practices demonstrate better outcomes, lower complication rates, and lower costs to the system. This common language and consistent measurement system provides the necessary connection between the doctor-

patient relationship and the management infrastructure that provides support to that relationship. An evidence-based quality infrastructure (based on evidence derived from data warehouses of health encounters which are defined by these codes) will enable additional cost-benefits to the IM system through elimination of costs of poor quality. The current coding and syntax systems have certain key components in place to track and manage such a system upon development and implementation, based upon evidence-based practices and equitable reimbursement models. Integrative systems of “groups without walls” that align access, reimbursement, evidence-based practice expectations, and outcomes management enable effective and efficient use of resources which bring all of the appropriate and most competent practitioners to the bedside based on the explicit needs and expectations of the patient.

“Crossing the Quality Chasm” authored and published by the Institute of Medicine provides a compelling and accessible road map toward clearly defined and socially valuable goals (Committee, 2001). The construct and approach to systematic change proposed in these reports has resulted in changes in the system; not in totality, but in part. The movement and focus on Integrative Medicine can take its energy and focus from the core foundation of improvements in the quality infrastructure that supports the health care system. “Crossing the Quality Chasm” defines quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (Lohr, 1990). The Quality Chasm initiative was the second report of a comprehensive evaluation of the health care system with a focus on the health care delivery system. The first report of this committee, entitled “To Err is Human” (Kohn, 2000; Campenella, 1999), initiated the outcry for change and peaked societal awareness. The Quality Chasm report provides an organizational construct providing recommendations for new designs with a focus on sweeping recommendations that support change in the fundamental ways “the system meets the needs of the people it serves” (Kohn, 2000).

The same energy and expertise that goes into implementing comparative cost-benefit analysis of clinical outcomes must continue to be placed on the process of delivery and the management infrastructure that supports the health care system. Philip Crosby, a leader in Quality Management wrote, “Every penny you don’t spend on doing things wrong, or over, or instead, becomes half a penny right to the bottom line. If you concentrate on making quality certain, you can probably increase your profit by an amount equal to five to ten percent of your sales. That’s a lot of money for free” (Crosby, 1979).

The basic principles of product quality (the application of principles of evidence-based scientific investigation to meeting the needs, expectations, and specifications of customers at a price that is valued in the market) are often credited to the early work in the United States of leaders such as Deming, Juran,

Crosby, Feigenbaum, and others. Notably, the work of Avedis Donabedian, MD, MPH, a member of the Institute of Medicine, wrote extensively about the application of quality systems and quality outcomes management applied to health care. His work provided the foundation for quality-based health care management systems and practice applications (Donabedian, 1985). These authors, and many others, address key principles in quality systems management, including this “cost of quality principle” (Juran, 1999; Breyfogle, 2008; Evans; 2002; Steckler, 2002; AHRQ, 2002; Shalala; 2000). Quality systems research shows that 15-40 percent of business costs (e.g., rework, reduced service levels, complaints, lost revenue, liability losses) can be attributed to the cost of poor quality (Campenella, 1999).

If integrative medicine can bring with it both the best of (1 evidence-based health care; and (2 the best of quality-based health care management, a significant economic savings is possible while the system improves the outcomes of the care provided. Paul Schyve, MD, wrote about the work of Feigenbaum, “Total quality control is not a collection of technical projects and motivational initiatives, rather, it is a way of managing an organization, and the results of this management include high reliability and a reduction in operating costs” (Schyve, 2004; Feigenbaum, 1991). Quality managed systems produce improvements in cost and clinical outcomes; integrative medicine has an opportunity to demonstrate that effectively integrated integrative medicine produces both clinical and management cost-effectiveness without jeopardizing outcomes.

For this dichotomous quality movement to develop, total quality management must be engrained as a cultural phenomenon and integral component of the movement toward integrative medicine. The concepts within the “Cultural Phenomenon of Quality Management” are the collection of mutually compatible basic assumptions. If total quality management basic assumptions form such a structure, a culture of quality emerges. Organizational objectives, decision-making processes, and the nature of the organization must be compatible across all aspects of the organization for a quality structure to result (Kujala, 2004; Shein, 1992).

The cost of quality is the price paid by the system for nonconformance or the cost of poor quality (Campenella, 1999). The costs of quality are those costs to all parties in a system created by the provision of a poor quality product; one that is below customer expectations or specifications. Investments in quality improvement result in tangible returns to the system. Implementing effective evidence-based quality methods with evidence-based health care practices can enable rapid and influential system-wide change while saving costs by reducing waste.

FUTURE DIRECTIONS IN THE MEDICAL ECONOMIC ANALYSES OF IM

Cost-benefit analyses (CBA) of every aspect of health and medical care is necessary to address both the clinical and cost-effectiveness of health and medical care in order to allocate limited practitioner, organizational, governmental, and monetary resources. In response, there is an array of approaches that emphasize the full continuum of prevention, restructuring primary care, involvement of the workplace and communities, and adoption of innovative strategies and interventions ranging from genomic assessments to complementary and alternative medicine (CAM). Among these approaches is an IM model, which is consistent with these national objectives of improved health at sustainable cost with the unique and explicit inclusion of “evidence-based global medical strategies” in its definition. Although various forms of preliminary evidence are evolving, all of these strategies require rigorous, appropriate, state of the art medical economic analyses. This white paper discussed a number of key issues related to the economic evaluation of IM including:

- 1) An assessment of the broad array of such innovative prevention and primary care approaches to health and medical care;
- 2) A review of the essential concepts and models most frequently applied in the medical economic evaluations of health technologies or technology assessment;
- 3) A systematic review of the current scope and quality of the medical economic evaluations, including CAM, to link the cost-benefits analyses to specific practices that might productively be included in an IM model;
- 4) A description of worksites and corporate settings as models where clinical and cost-effectiveness outcomes have been and are most frequently undertaken;
- 5) A discussion of the fee structures under which IM might operate and brief consideration of the possible diagnostic and billing coding protocols; and
- 6) Development of actionable recommendations.

Since there are few if any IM models that have been rigorously evaluated in terms of CBA, it is possible to draw upon the cost-effectiveness research focused on a limited number of CAM modalities, as well as from the worksite/corporate clinical and cost outcomes research to suggest analyses necessary to develop the

evidence-based foundation from which an effective, efficient, and personalized health care system will evolve.

ACTIONABLE RECOMMENDATIONS

Based on this critical systematic review of the current available evidence, the authors propose the following recommendations for consideration by researchers, policy writers, researchers, clinicians, and decision makers within the health and medical care systems:

- 1) Incorporate CBA into all effectiveness trials throughout the continuum of prevention, in the innovative, evolving models of primary care, and in IM. It should be noted that quality CBA analyses are not limited to RCTs.
- 2) Match appropriate CBA methodology, perspective, and outcomes to the specific research hypothesis and implementation environment.
- 3) Engage worksite/corporate collaborators in *health*-oriented CBAs since employers have a vested interest in health, are fiscally responsible for the largest percentage of annual medical expenditures, and are accustomed to CBAs.
- 4) Extend CBA by monetizing such variables as pharmacy offsets, STD, LTD, patient/provider satisfaction, changes in HRA, absenteeism, presenteeism, performance, and productivity. Such inclusions appropriately increase the ROI.
- 5) With regard to a minimum set of standardized CBA metrics, develop an international, internet server-available, standardized foundation database of recommended clinical and cost outcome metrics.
- 6) Develop public-private partnerships between policy makers and third party payer organizations to build payment models and incentives that reward evidence-based best practices and eliminate interventions proven to be harmful and/or without reproducible health value.

Clearly, the future of IM should and will be defined by clinical and cost-effectiveness evidence, including but not limited to health, productivity, performance, and cost benefit outcomes and evidence.

APPENDIX A Interventions that Have Demonstrated Cost Savings

Study	Approach – Compared to usual care unless otherwise noted	Patient Population	Perspective to which cost savings accrue		
			Societal	Payer	Employer
Integrative medicine					
Sarnat et al, 2007	“Integrative medicine” independent physician association (IPA) – consisting of chiropractic doctors, and medical doctors and doctors of osteopathy who practice as “natural medicine doctors”	Members of a large HMO with access to the IPA (US)		Y	
Clinical preventive services					
Maciosek et al, 2006; Partnership for Prevention, 2008	Aspirin chemoprophylaxis – discuss the benefits/harms of daily aspirin in preventing cardiovascular events	Men ≥ 40 , women ≥ 50 , and others at increased risk for cardiovascular disease (US)	Y		Y
	Childhood immunization series - Immunize children: diphtheria, tetanus, pertussis, measles, mumps, rubella, inactivated polio virus, Haemophilus influenzae type b, hepatitis B, varicella, pneumococcal conjugate, influenza	Children (US)	Y		Y
	Tobacco-use screening and brief intervention - brief counseling and offer pharmacotherapy	Adults (US)	Y		Y
	Pneumococcal immunization - one dose for most in this population	Adults aged ≥ 65 (US)	Y		Y
	Vision screening - screen routinely for diminished visual acuity with Snellen visual acuity chart	Adults aged ≥ 65 (US)	Y		Y

Study	Approach – Compared to usual care unless otherwise noted	Patient Population	Perspective to which cost savings accrue		
			Societal	Payer	Employer
Disease management (examples)					
Naylor et al, 1999	Program of nurse-led patient education, coordination of home care, at least 2 home visits, use of a standardized protocol to optimize medications, and weekly telephone contact for 1 month	Patients ≥ 65 years admitted to a tertiary care hospital with either coronary disease or heart failure (US)		Y	
Stewart et al, 1999	Program of nurse-led patient education, counseling, an exercise regimen, a home visit 7 to 14 days after discharge, assessment regarding the patient's need for medication adjustments according to a protocol, and telephone contact at 3 and 6 months	Patients ≥ 55 years hospitalized with heart failure (Australia)		Y	
Wallack, 2002	Program used a multi-disciplinary team, including a nephrologist, a renal case manager, a renal dietician, a renal social worker, and a renal pharmacist. The protocol addressed kidney function maintenance, but also included co-morbid condition (e.g., hypertension and diabetes) management, the evaluation and management of vascular access (e.g., protecting the dominant arm from IV lines and blood drawing), and patient lifestyle/behavior modification, including weight control, smoking cessation, and exercise.	Patients with chronic renal insufficiency and end-stage renal disease (US)		Y	
Goetzel et al, 2005	Most programs	Patients with congestive heart failure (Many countries)		Y	
Coleman et al, 1999	Half-day Chronic Care Clinics held every 3 to 4 months. These clinics included an extended visit with the physician and nurse dedicated to planning chronic disease management; a pharmacist visit that emphasized reduction of polypharmacy and high-risk medications; and a patient self-management/support group.	Patients aged 65 and older in each practice with the highest risk for being hospitalized or experiencing functional decline (US)		Y	

Study	Approach – Compared to usual care unless otherwise noted	Patient Population	Perspective to which cost savings accrue		
			Societal	Payer	Employer
Lorig et al, 2001	Self-management program taught at community sites to groups with mixed diagnoses by trained peer leaders using a detailed teaching manual. The program covered exercise, nutrition, guided relaxation and distraction, emotion management, sleep management, medication use, community resources and health-problem problem-solving and communication was provided in 7 weekly sessions of 2 1/2-hours duration.	Patients 40 years and older with heart disease, lung disease, stroke, or arthritis		Y	
Complementary and alternative medicine					
Studies of Acupuncture					
Thomas et al, 2005	“Traditional acupuncture” – practiced by acupuncturists practicing in various acupuncture clinics with 5-18 years experience and identified for the study through the Foundation for Traditional Chinese Medicine	Patients with persistent non-specific low back pain	Y	Y	Y
Liguori et al, 2000	Acupuncture – no information on practitioners, but acupuncture was administer according to a protocol in a hospital pain clinic	Patients with migraine (Italy)	Y	Y	Y
Brown et al, 2001	Acupuncture – as one therapy offered among others including manual therapy, injections, and other pain management techniques by an orthopedic medicine physician as apposed to care by an orthopedic surgeon-led team	Patients with ‘non-surgical’ musculo-skeletal conditions – e.g., low back pain and soft tissue knee injuries (Scotland)	Y	Y	
Lindall, 1999	Acupuncture – ‘qualified medical acupuncturist’ who is a GP with 10 years experience	Patients with pain of musculoskeletal origin (UK)		Y	
Herman et al, 2008	Acupuncture – as part of a package of naturopathic care provided by a naturopathic physician that also included relaxation exercises, dietary and exercise advice offered in a worksite clinic	Patients with low back pain (Canada)	Y	N	Y

Study	Approach – Compared to usual care unless otherwise noted	Patient Population	Perspective to which cost savings accrue		
			Societal	Payer	Employer
Ballegaard et al, 2004	Acupuncture – as part of a combined treatment of acupuncture, lifestyle education, and self-administered Shiatsu (same practitioner provided all)	Patients with angina pectoris (Denmark)		Y	
Chiropractic care and spinal manipulation					
Brown et al, 2001	Manual therapy – as part of a package of pain management (see description above under acupuncture)				
Korthals-de Bos et al, 2003	Manual therapy – described as a range of interventions including hands-on techniques (muscular mobilization, specific articular mobilization, coordination or stabilization, but not low amplitude, high velocity spinal manipulation) provided by registered manual therapists trained in physiotherapy	Patients with neck pain (Netherlands)	Y	Y	Y
Burton et al, 2000	Spinal manipulation – consisting of ‘soft tissue stretching, low-amplitude passive articulatory manoeuvres of the lumbar spine and judicious use of high-velocity thrusts to one or more lumbar articulations’ provided by a ‘private osteopathic manipulator’ and compared to chemonucleolysis	Patients with lumbar disc herniation (UK)		Y	
Almog et al, 2004	Individualized chiropractic care – offered free in a chiropractic teaching clinic	Bus drivers with back pain (UK)			Y
Folsom and Holloway, 2002	Chiropractic doctors – whose services are covered by workers’ compensation	Florida workers’ compensation patients (US)		Y	Y
Legorreta et al, 2004	Chiropractic care - covered by a chiropractic benefit package	Insured patients with back pain (US)		Y	

Study	Approach – Compared to usual care unless otherwise noted	Patient Population	Perspective to which cost savings accrue		
			Societal	Payer	Employer
Nelson et al, 2005	Chiropractic care - covered by a chiropractic benefit package	Members of a managed care plan with low back or neck pain (US)		Y	
Mind-body medicine (biofeedback, meditation, relaxation/stress management)					
Stowell et al, 2007	A “biopsychosocial” intervention – cognitive behavioral therapy skills training and biofeedback	Patients with acute Temporomandibular disorder (TMD) (US)		Y	
Ryan and Gevirtz, 2004	Biofeedback-based psychophysiological treatment – administered by ‘biofeedback therapists’ who were health psychology graduate students	Patients with “functional” disorders (e.g., irritable bowel syndrome) (US)		Y	
Singh et al, 2008	Mindfulness meditation training – following <i>Meditation on the Soles of the Feet</i> mindfulness training (by Singh et al, 2007)	Adults in a forensic mental health facility for individuals with intellectual disability (US)			Y
Roth and Stanley, 2002	Mindfulness-based stress reduction (MBSR) training program – offered as an 8-week course; no other information available	Patients at an inner-city community health center (US)		Y*	
Herron and Hillis, 2000	Transcendental meditation – practiced for an average of 6.7 years and compared to individuals who did not identify as practitioners for this study	Individuals in the Quebec health care system (Canada)		Y	
Tusek et al, 1999	Guided imagery/relaxation - taught via audiotapes listened to pre- and post-surgery	Cardiac surgery patients (US)		Y	
van Dixhoorn and Duivenvoorden, 1999	Relaxation therapy – consisting of biofeedback and breathing regulation techniques offered in addition to exercise training and compared to exercise training alone	Patients with previous myocardial infarction (Netherlands)		Y	

Study	Approach – Compared to usual care unless otherwise noted	Patient Population	Perspective to which cost savings accrue		
			Societal	Payer	Employer
Homeopathy					
Frei and Thurnysen, 2001	Homeopathic care – individualized treatment provided by GPs at a pediatric practice	Children with acute otitis media (Switzerland)		Y	
Jain, 2003	Homeopathic treatment – provided by one GP	Patients with a variety of complaints (UK)		Y	
Trichard et al, 2005	“Homeopathic strategy” – homeopathic treatment provided by a GP compared to “antibiotic strategy” also provided by GPs	Children 18 months to 4 years of age with recurrent acute rhinopharyngitis (France)		Y	
Outpatient oral supplementation					
Chrubasik et al, 2001	Proprietary willow bark extract dosed at 120 mg salicin daily – two doses were tested (one with 120 mg salicin and the other with 240 mg), provided by GPs and compared to each other and to a control group of patients seen by an orthopedist	Patients with low back pain (Germany)			X
Dobson et al, 2004	Daily multivitamin	Adults aged 65 and older (US)			X
Inpatient and surgical oral nutrition support					
Braga et al, 2005; Braga and Gianotti, 2005	Pre-operative oral immuno-nutrition - omega 3 fatty acid and arginine supplementation given for 5 days pre-operatively	Well-nourished patients undergoing surgery for gastrointestinal cancer (Italy)		Y*	

Perspective to which cost savings accrue

Study	Approach – Compared to usual care unless otherwise noted	Patient Population	Societal	Payer	Employer
Smedley et al, 2004	Oral supplemental nutrition – protein drink containing vitamins and minerals provided as desired either pre-surgery, post-surgery, both, or neither	Patients undergoing lower gastrointestinal tract surgery (UK)		Y*	
Norris et al, 2004	Potassium-rich diet – patients selected from a menu of food options compared to a potassium chloride pill	Inpatient post-operative cardiac patients starting diuretics (US)		Y*	
Lassen et al, 2006	Nutritional care for inpatients according to recommended guidelines – compared to present nutritional care	All hospitalized patients (Denmark)		Y*	
Hypnosis for surgical interventions					
Defechereux et al, 1999; Meurisse et al, 1999	Hypnosis – consisting of hypnotic suggestions given by the anesthesiologist	Patients undergoing cervical endocrine surgery (Belgium)		Y*	
Lang and Rosen, 2002	Hypnosis – providers used a script to provide suggestions 5-10 minutes pre-operatively	Patients undergoing interventional radiological procedures (US)		Y*	
Montgomery et al, 2007	Hypnosis – delivered in a 15-minute session by PhD-level clinical psychologists with advanced training in the use of hypnosis in a medical setting	Women undergoing surgery for breast cancer (US)		Y*	

*The provider perspective was also reported.

Y = The therapy both lowered costs and improved health from this perspective. If reductions in resource use were reported, the study was included even if no monetary value was attached to the resource savings.

N = The therapy improved health, but increased costs from this perspective.

Blank = A full set of costs and benefits for this perspective were not calculated. This usually meant that productivity costs were not considered (societal and employer perspective) and/or that costs to the participant were not considered (societal perspective).

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